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PHARMACEUTICAL PATENTS AND THE RIGHT TO ACCESS TO MEDICINES IN CENTRAL AMERICA

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"It is my aspiration that health finally will be seen not as a blessing to be wished for, but as a human right to be fought for"

Former United Nations Secretary-General Kofi Annan

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INTRODUCTION

In recent decades the development of international law grounded on the regulation of specific, and supposedly, autonomous areas of knowledge and interest. Along such regulation, the international community established both judicial and quasi-judicial specialized bodies as well as regimes for cooperation in apparently dissimilar fields of law, such as economic, environmental, trade or human rights law. In order to give adequate impetus to their goals, States have entered into various treaties within each of these independent spheres of interest, without there having been any prior coordination or hierarchy among them that would allow harmonic coexistence of such complex *fragmentation* of international law. In this regard, scholars and legal practitioners have avidly debated over the challenges encountered in determining the obligations that States undertake when entering into a multiplicity of treaties which cover, apparently, independent areas of international law.

Under a broad perspective, this dissertation analyses the relationship between two of the aforementioned apparently independent areas of law, namely human rights and intellectual property protection (IPP). Certainly, many are the features of the aforesaid relationship that deserve time and attention for further inquiry, but the starting point of the argumentation is that such two legal frameworks are far from being independent. In particular, the overlapping between human rights and IPP finds its highest expression in the interaction between the right to access to medicines on the one hand and to patent protection for medicines on the other.

It does not take an expert in the field of international law to observe that multiple interests are at stake, ranging from protecting the right to health of patients to enhancing innovation in the pharmaceutical sector, as well as to safeguarding the interests of developing countries. The primary argument raised against IPP is that patent protection for medicines results in higher prices, which negatively impacts patients' access to medicines, especially in lower income countries. Simply stated, patent protection provides pharmaceutical companies with a monopoly position for a specified number of years, thus excluding competitors from the market.

On the contrary, the pharmaceutical industry argues that patents' rights are key in order to encourage the creation of new drugs, which certainly leads to an enhancement of the right to health protection worldwide. In fact, the latter industry claims that such monopoly is crucial in order to recoup the large research and development investments that pharmaceutical corporations incur. Accordingly, with no patent protection pharmaceutical companies would have no incentive to participate in innovation.

Nonetheless, almost two billion people, one-third of the world's population, lack regular access to essential medicines; and in poorest regions such as Africa, Central America and Asia, this lack of regular access concerns half of the population. This issue is even more noticeable when the treatment and confinement of pandemics and diseases such as HIV, tuberculosis and malaria are concerned. For example, the rational consumption of antiretroviral drugs (ARVs) can reduce morbidity and mortality rates and enhance quality of life of HIV patients, especially in countries in which the risk of infection is high. As a result, pharmaceuticals are no ordinary commodities, but are rather the cornerstones of human development.

Yet, for intellectual honesty, worth noting is that patent protection is not the only barrier nor the root cause of the problem to access to medicines, since socio-political issues are obviously involved. Accordingly, in addition to IP protection, corruption, inadequacy of the ruling class and natural disasters are just a few examples of causes for the lack of access to medicines.

The challenging interaction between access to medicines and pharmaceutical patents constitutes the hearth of the present analysis, leaving socio-political considerations as mere incidental remarks throughout the dissertation. In other words, the aforesaid gap in access to medicines is not only a moral-political challenge, but rather a legal dilemma: within the international human rights legal framework, access to essential medicines has been firmly interpreted as constituting a minimum core prerogative under the human right to the highest attainable standard of health (the right to health). This results in corresponding obligations and responsibilities on a wide spectrum of actors, whose aim should be to enable and ensure access to medicines to people in need of it.

After the establishment of the World Trade Organization (WTO) and the contextual adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in the mid-nineties, the debate over the alleged conflict between trade and human rights gained fuel. Because regulation plays an important role in any issue, when the issue at stake concerns public health, understanding the normative frameworks which regulates the patenting system becomes a mandatory step. The TRIPS agreement, which constitutes one of the most controversial as well as far-reaching multilateral agreements on intellectual of IP to date, recognized for the first-time minimum standards for the protection and enforcement of intellectual property rights among members of WTO.

The dissertation highlights that, since the adoption of the TRIPS, both developed as well as developing states have exposed their frustration for the manner in which the TRIPS agreement has been interpreted and executed. On the one hand, the developing world has argued that the TRIPS agreement does not suffice in fulfilling their social and economic needs while imposing greatly excessive burdens on their domestic legal systems. On the other hand, developed countries have called upon stricter protection for intellectual property rights.

The adoption and conclusion of such agreement was no easy task because of the numerous national interests involved. As the dissertation manifests, the primary intent of the TRIPS agreement was to internationally harmonize intellectual property laws by establishing minimum standards for protection of different types of intellectual property. The analysis provided in the present work, however, focuses merely of pharmaceutical patents and, thus, leaves the inquiries on other types of IP law, such as copyright and trademark, outside the scope of such study.

The TRIPS imposed upon signatory states, *inter alia,* the obligation to implement in their domestic legal systems provisions regarding the conferral of rights upon IP holders, dispute settlements mechanisms and available remedies for relevant infringements. The strong and effective WTO dispute settlement body monitors and assures that the undertakings agreed by States are adequately fulfilled. Such effectiveness is one of the key features of the TRIPS framework, in as much that non-

compliance with the agreement results in concrete sanctions on the responsible State. The conclusion may be reached that States are usually keener to address IP commitments, rather than their human rights obligations, since IP compliance can result in economic and financial sanctions, while human rights enforcement mechanisms are rarely binding upon States in practice.

The aforementioned scenario was further complicated and aggravated as a result of the adoption of regional free trade agreements (FTAs), which formed free-trade areas between the cooperating states. While FTAs mainly aim at eliminating trade barriers among members, they do provide detailed regulations in relation to intellectual property such as patents. These provisions, which were mainly demanded by developed countries, often establish higher levels of IP protection, thus, worsening access to medicines in the countries concerned. Such higher levels of protection norms are often referred to as TRIPs Plus, since they take IP provisions enshrined in the TRIPS agreement one step further, thus going beyond the minimum standards imposed by the latter agreement. Many developing countries, which have signed FTAs, are frequently under economic and political pressure to incorporate these tougher conditions in their domestic legal systems.

Hence, the present analysis cannot ignore the legal implications and challenges that such FTAs raise, since they are proof of the ways in which trade-related treaties are able to impact human rights, such as the right to health. This is the case of the Central America Trade Agreement (CAFTA), which in fact is the largest free trade agreement to date to include stronger IP provisions than those provided by the TRIPS Agreement. CAFTA offers an important case study to examine the broader dynamics of national and international regulations and their public health impacts. Comprehending the way CAFTA's IP provisions affect access to affordable medicines in Central America is imperative in order to strike a balance between pharmaceutical patents and the right to health.

In light of such premises, this work is structured in three main chapters which aim to analyze the aforesaid interplay between pharmaceutical patents and access to essential medicines. Worth noting is that in the last two decades many relevant scholars have

extensively researched and written on such interplay under numerous perspectives. Accordingly, there are several, and often divergent, understandings of the implications caused by IP provisions due to the fact that the discussion on this matter reaches beyond many ordinary arenas and disciplines.

Yet, this dissertation is distinct and novel in the sense that it analyses the issue at stake under a new multi-perspective approach, in light of which every chapter has been designed to both unravel a specific area of such complex tangle and to shed light on this fairly knotty legal issue. Accordingly, the outline of the dissertation will proceed as follows: the first chapter deals with the international legal framework related to the right to health. In particular, the chapter grounds on three main research questions:

1. *Is the right to access to medicines a fundamental part of the broader-in-scope right to health?*
2. *Do States have specific legally binding obligations concerning the right to access to medicines under international law?*
3. *Does the Inter-American Court of Human Rights provide a broader protection of the human rights at stake than international provisions?*

The Chapter, thus, begins with the analysis of the international framework and completes it with a focus on the Inter-American system. Such system constitutes one of the most internationally innovative legal frameworks with regard to human rights. Particular attention is devoted to the meticulous work of the related Court, since its jurisprudence has often represented a leading light in this sector, the one that has always been at the cutting edge, and also the one that has been able to attract the attention of the international scientific community.

A legal technicality makes the aforesaid human-rights system even more interesting. The American Convention on Human Rights does not enshrine any provisions for the direct protection of the right to health. In fact, its main focus is on civil and political rights, while social and economic rights are covered by a subsequent instrument, namely the San Salvador Protocol. This technicality provides valuable academic

materials for the study of the legal reasoning adopted by the judges of the Court, who, in fact, have usually protected the right to health indirectly as part of the civil right *par excellence,* namely the right to life. Remarkably, in the last few years, such approach has shifted towards a direct protection of the right at stake which, thus, offers interesting food for thought. The Chapter concludes with a section regarding specific legal obligations related to access to medicines in light of the United Nations Committee on Economic Social and Cultural Rights system (CESCR) as well as of the aforementioned regional Court.

The second chapter concerns the international legal framework related to intellectual property in general and pharmaceutical patents in particular. Diverse are the legal issues presented in this chapter; and its relevant research questions are:

1. *Is the conflict between IP-related treaties and human rights treaties genuine or only apparent?*
2. *Is it possible to avoid conflicts of norms throughout interpretative means?*
3. *Can human rights treaties be considered superior to trade-related treaties?*
4. *Did CAFTA worsen the access to affordable medicines in the Central American region?*

Accordingly, the chapter illustrates the main theories concerning normative antinomy between treaties and provides a comprehensive analysis of the TRIPS Agreement. The focus regards the so-called TRIPS' flexibilities as well as an overview of the subsequent Doha Declaration, both frameworks being of central importance for pharmaceutical companies. The chapter concludes with the analysis of the Central American region, which aims at demonstrating how the aforementioned CAFTA Agreement hindered the protection of the right to access to medicines for the parties concerned. Two case studies are, thus, provided in order to illustrate concrete instances in which the so-called TRIPS Plus provisions have impeded, even if to a different extent, both Guatemala and Costa Rica in properly fulfilling their human rights undertakings under international law. In order to answer the dilemma under discussion, the entire chapter will be based upon

the usage of a traditional legal dogmatic methodology, according to which the meaning of relevant provisions will be clarified proceeding from their own contents.

Lastly, the third and final chapter addresses an equally valuable aspect of the issue under examination, namely the human rights responsibilities of pharmaceutical corporations. Such economic actors play a crucial role in ensuring the protection of the right to access to medicines, since they are the holders, and principal defenders, of IP protection for drugs. This section illustrates the most acknowledged theories on the legal personality of such peculiar economic entities under a deductive approach. In fact, starting from a general analysis of multinational corporations, the chapter narrows it down in order to determine whether or not pharmaceutical corporations are burdened with human rights obligations. Accordingly, the chapter grounds, *inter alia,* on the following research questions:

1. *Are multinational corporations in general, and pharmaceutical corporations in particular, subject to international human rights law?*
2. *Is it possible to directly impose human rights obligations on such actors?*
3. *Do soft law instruments, such as Corporate Social Responsibility provisions, adequately influence the business conduct of pharmaceutical corporations?*

Methodology

In the field of human rights, some scholars have highlighted that research attention to methodology is often deficient, especially when it is conducted by lawyers[1]. In this regard, the indisputable theoretical and practical value of human rights has led scholars to imply that their research surely aims at enhancing the protection and respect of such particular sets of rights *a priori*. In light of this implied "wishful thinking"[2], while

[1] F. Coomans, F. Grünfeld and M. Kamminga, *Methods of Human Rights Research,* Intersentia, 2009, 11.
[2] A. Bastardi, E. Uhlmann and L. Ross, "Wishful Thinking: Belief, Desire, and the Motivated Evaluation of Scientific Evidence", *Psychological science* 22., 731-732.

scholars were passionately driven by the value of human rights, they rarely provided explicit methodological frameworks upon which their research was grounded.

There is no doubt that human rights are central to both the welfare of the human being as well as to the accomplishment of wider societal goals. Accordingly, enhancing the protection and respect for human rights is a goal worth fighting for. Nonetheless, in light of the indivisibility principle concerning human rights, each one of these rights should not be regarded as goal in itself, but it should be considered as an instrument to enhance the respect of the common denominator for all human rights, namely human dignity. The research has, thus, tried to be as unbiased as possible, leaving passionate and romantic considerations aside.

Certainly, personal beliefs, such as considering access to medicines, and at the very least access to *ARVs,* crucial for the respect of human dignity, have definitely influenced the tone and perspective under which the research was conducted. Putting aside economic and particular interests, an increasing number of people firmly consider that patients in need should receive the medical treatment they require, no matter their economic, social and cultural status. At the end of the day, academics, human rights activists, politicians or representatives of pharmaceutical corporations all agree on such issue. Hence, their conflicting views and positions ground on the way such goals should be achieved, rather than on the substance of the problem itself.

This is the reason the access to medicines dilemma has usually been depicted as a battle between good versus evil, in which the pharmaceutical industry definitely played the latter role, while health activists were portrayed as the heroes of the tale. Such approach, however, seems rather simplistic, since it would be unfair to ignore the outstanding work conducted by pharmaceutical corporations. Such actors certainly play a massive part in enhancing the protection of the right to health worldwide, and thus, of human dignity. Likewise, however, the reality demonstrates that the pharmaceutical industry is not a philanthropic institution whose main goal is the wellbeing of individuals worldwide, but rather an aggressively competitive and profitable industry which mainly aims at making profit for its shareholders.

Under such premises, methodology refers to the approach adopted in carrying out this

legal research. Better said, methodology refers to the manner in which relevant information has been found, how it has been gathered and the way in which the results have been processed. That is the reason competing arguments in favor and against patent's protection will be provided, while bearing in mind the fundamental aim, which is to maximize human rights protection.

In light of the multiple issues analyzed throughout the dissertation, different methods have been used in this study. The starting point was an extremely worthy liaison with the United Nations Economic Commission for Latin America and the Caribbean at Mexico City (Mexico), thanks to which official meetings and conferences with state's representatives and relevant experts were conducted. Important data and materials were then gathered in light of a theorical and practical approach. Likewise, chapter one was the result of a research period at the Inter-American Court of Human Rights in San José (Costa Rica), during which it was crucial both to attend relevant hearings as well as to interview judges and lawyers of such Court. Their comments and remarks were fundamental for understanding relevant procedural and substantial issues regarding the right to health, with a particular focus on the Central American region.

Parts of the dissertations are descriptive or expository in nature, and thus, expression of *lex lata*. This is to provide the content of what the law currently entails and to set out states' obligations under international law concerning medicines' access and patent protection for pharmaceuticals. Further, references to *lex ferenda* are provided especially in relation to human rights responsibilities of pharmaceutical corporations in order to present the emerging consent on such a delicate issue; and, I hope, in order to trigger change towards a more human-rights attentive regime.

CHAPTER I

The right to health and access to medicines in light of the international and Inter-American legal framework

1. The Evolution of the Right to Health as a Social Right

The notion of health does not have a clear definition and, therefore, it has often been used during different historical periods and in the laws of the States according to the political objectives of the moment. For this reason, instead of directly carrying out the task of elaborating its normative content, the approach adopted in this section is to begin with a narrative of the history and theory of this notion, finding the profound meaning that relevant actors intended to give to the aforementioned right and clarifying the debates as to its origins. The idea of the right to the highest attainable standard of health is, after all, a bold exhortation, and its inclusion in international instruments represents a clear willingness to focus on the protection of a right that directly influences the quality of life of all citizens of the world. A retrospective reading, therefore, allows us to discover how recently the reflection on the right to health has moved from a theoretical analysis of declarations of principles to a deepening of their concrete implications.

Currently the right to health is commonly recognized as a fundamental right in the general population, but professionals who practice international law often encounter situations in which the application of such right as fundamental is questioned. The right to health, as will be further examined in this chapter, has developed an inclusive nature which concerns an array of different components relating to the personal sphere of the individual, the community as a whole and international relations among States.

Indeed, finding an adequate definition of the right to health is not an easy task and much clarifications are required in order to define its scope and legal framework. In other words, the wording right to health can trigger multiple theoretical debates on its nature, which are surely controversial and which hide an incandescent background for

its practical application[3].

The first recognition of the right to health in the international order is found, as shown in the next section, in the Preamble to the Constitution of the World Health Organization (WHO), in which health is defined as *"a state of complete physical, mental and social well-being and not exclusively the absence of disease or infirmity. The enjoyment of the highest possible level of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition"*[4]. The affirmation of this fundamental right can also be traced back to art. 25 of the Universal Declaration of Human Rights and art. 12 of the International Covenant on Economic, Social and Cultural Rights, which requires governments to recognize the right of everyone to the highest level of physical and mental health (see next section).

Hence, in order to limit and identify the nature and scope of the right to health, several issues must be taken into account. Such issues include the intention when this right is invoked and a description of the defining elements that characterize the object of this right. In addition, the question also arises as to what an individual would be entitled to, whether to health care, a healthy environment, access to affordable medicines and/or one's own decisions about the health treatments to which one wishes to be, or not, subjected[5].

According to Ferrajoli, there are two main categories of rights, namely *primary and secondary rights.* The former refers to those rights that deal with needs or interests recognized as vital, and, that therefore belong to all human beings regardless of their ability to act, such as the social right to health and education. On the contrary *secondary rights,* depend on the ability of the individual to act in order to achieve goals concerning the private or political autonomy of their owners. In light of the latter distinction between these two categories of rights, Ferrajoli considers the right to health as a

[3]A. Santosuosso, "Gli sviluppi del diritto alla salute in Italia", *L'Arco di Giano* 4, 1994, 54-56.

[4]Preamble of the Constitution of the World Health Organization, New York, 22 July 1946, United Nations, *Treaty Series*, vol. 14, 185.

[5] Borsellino, "Alcune considerazioni preliminari in tema di "diritto" e di "salute"", in Borsellino , *Il diritto alla salute tra libertà e vincoli sociali,* Notizie di Politeia, 47/48, 1997, 3-4.

primary right of the person which has a dual structure: on the one hand, the right of the individual to be treated and to recover, if possible, a state of well-being lost[6], and on the other hand, that health is not put at risk in situations where the threat is avoidable[7]. In this perspective, the right to health is considered to be a key social right, understood as an individual fundamental right, which entails the existence of obligations on States (i.e. positive obligations to act) in favor of the holders of this right. These obligations aim at promoting minimum levels of substantial equality through the removal, or at least the reduction, of social inequalities related to economic and material conditions of life. Indeed, in the specific case related to health, these obligations to act can be examined under two perspectives: firstly, the obligation to ensure the right to care for individuals through the provision of services to ensure health care: secondly, the obligation to ensure the presence of hygienic, social and environmental conditions conducive to the maintenance of health promoted as a common good[8].

The right to health has been properly addressed and codified from the middle of the last century, but health has been a matter of interest for governments since the 19th century, when, with the establishment of public health departments, European states assumed the obligation of general prevention of infectious diseases and started to cooperate with one another in order to avoid international pandemics[9]. Since then, Governments have linked health to economic considerations and considered public hygiene crucial for economic development and growth of States. This attitude towards health did not rely on concerns for individual or collective health *per se,* but towards preventing illness as a limit to the performance of the services that every citizen was required to provide within the framework of a society inspired by the principle of *productivity*[10].

In those days, public intervention was mainly aimed at improving the hygienic

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[6]L. Ferrajoli, *Principia Iuris. Teoria del diritto e della democrazia*, Laterza, 2007, 733.

[7]V. Pocar, "Il diritto alla salute: un contributo d'analisi nella prospettiva sociologico-giuridica", in Borsellino , *Il diritto alla salute tra libertà e vincoli sociali,* Notizie di Politeia, 1997, 59.

[8]Ferrajoli, *Principia Iuris*, 742.

[9]Borsellino, *Alcune considerazioni preliminari*, 5-6.

[10]B. Poletti Di Teodoro, "Il diritto alla salute dallo Stato liberale alla riforma sanitaria", in F.D. Busnelli, U. Breccia, *Il diritto alla salute*, Il Mulino, 1978, 15-16.

conditions of specific areas of cities which lacked, for instance, an adequate sewer system or sanitation. Public policies were, hence, directed to increase life expectancy, and indirectly, to extend the life of the workforce. Health, under a functionalist perspective, focused on the instrumental role of people and place their productive capacity at the center of the public discourse. In this context, health was considered to be the requirement for the individual to be able to effectively contribute to the tasks and roles assigned to individual by society[11]. Better stated, until the first half of the 20th century, health was considered an instrument of social control, based on a concept of disease closely linked to the *functionality* of the individual, which had nothing to do with the treatment of diseases nor to biological considerations[12].

It is not surprising that social attention towards health was initially triggered by the problems that arose as a result of the emergence of salaried work, because in the absence of a social security system, the disease represented an economic loss not only for the community, but especially for the worker himself, whose only economic resources for him and his family derived from his work. As a result, health was then understood as a need for avoiding the consequences of illness and its effects on people's work abilities, rather than as a social interest towards the right to be healthy[13].

The establishment of hospitals, the introduction of hygienic standards in public spaces and the attention for the creation of healthy environments is understood to be a transitional stage to the active participation of State, typical of Welfare State, in which public authorities intervene in order to promote the health and well-being of the citizens. State's intervention relied on the well-known *social contract*, according to which the State assumed the role of guarantor of the welfare of citizens under considerations of substantive equality. In this sense, John Rawls, in *A Theory of Justice* of 1971, posed the problem of finding principles of justice that are the basis of society. He imagines a situation defined as the *original position* in which individuals have to choose the principles that will form the basis of the society that is about to be born. These

[11]Ibidem
[12]M. Marino, *Salute e malattia. Tra vecchi e nuovi paradigmi*, Franco Angeli, 2003, 45.
[13]Pocar, *Il diritto alla salute,* 60.

individuals know nothing about the personal characteristics they will have afterwards, such as their economic and social positions or their physical health. This condition is called *"Rawls' veil of ignorance"* and had the goal to achieve justice, unlike the contractualism of Hobbes, Locke, Kant or Rousseau, which aimed to justify the power of those who are in charge of governing a State[14].

The role of the State progressed, then, from the position of a simple observer, without powers of intervention in the private sphere of its population, to principal operator in providing health services with precise obligations. As a result, the recognition of social rights marked the transition from the liberal state to the welfare state that is characteristic of our times and that is attentive to the needs of the most vulnerable subjects of the population[15].

With the affirmation of the *welfaristic* principles, health became a fully enforceable right towards States, often provided for in domestic constitutions[16]. The concept of health, however, was still linked to a biological concept of well-being shaped on the absence of disease, thus limiting the object of protection to the treatment of diseases[17]. Only in modern times has the claim to health manifested itself in new dimensions and contexts, in which the emphasis has no longer been placed on the mere absence of disease, but on the notion of quality of life, understood not only in biological terms but also in social terms[18]. Chronologically speaking, this is the context in which first the WHO's Constitution Preamble and then the Universal declaration of Human Rights began to codify the right to health at the international level.

As a result, States and the international community began to consider social progress, the achievement of better standards of living, and individual well-being as a direct product of the protection of human rights[19]. From these facts, one may conclude, that

[14]J. Rawls, *A Theory of Justice*, Belknap Press of Harvard University Press, 1971, 56-60.
[15]J. Tobin, *The Right to Health in International Law,* Oxford University Press, 2012, 20.
[16]For example, the Political Constitution of Guatemala, Article 93: *"Derecho a la salud. El goce de la salud es un derecho fundamental del ser humano, sin discriminación alguna".*
[17]D. Neri, "Bisogno di salute e nuove frontiere della medicina*"*, in Borsellino , *Il diritto alla salute tra libertà e vincoli sociali,* Notizie di Politeia, 1997, 63-64.
[18]Pocar, *Il diritto alla salute,* 60.
[19] Santosuosso., *Gli sviluppi del diritto*, 35-36.

only at the end of the 1940s, the right to health acquired the status of subjective right which now constitutes a central piece of modern rule of law. As a subjective right, health-related norms provide not only for the guarantee of negative and positive obligations on the part of the State, but also for the provision of legitimate and directly enforceable rights before a court. In this way, any citizen who suffers a violation of the right in question may file a lawsuit before a competent court in order to obtain a concrete satisfaction of the individual's rights, which can never be overcome by public needs[20].

The process leading to the full recognition of the right to health as a subjective right has, however, been long and complex. Indeed, the international documents in which the right to health was first enshrined did not have binding legal force, such as to provide to individuals holding the right concrete instruments that could be immediately activated and used *vis-à-vis* States. Moreover, the idea that health was a matter for the subjective sphere of individuals was, and in many ways still is, difficult to accept. The affirmation of the right to self-determination in the field of health, even though enunciated in various supranational documents and reaffirmed in the Constitutional Charters of many States, has been forced to face much cultural and social resistance[21]. Almost ten years elapsed from the date of the *Universal Declaration of Human Rights* and the authorship of WHO Constitution for States to achieve full recognition of the right to health as an autonomous right in its internal legislation. This goal was reached in 1957, when the Supreme Court of the United States of America ruled that informed consent was required in order to provide medicines and medical treatments to persons in need of such medical attention[22]. In fact, in the *Salgo vs. Leland Stanford Jr. University Board of Trustees case,* the Supreme Court ruled in favor of patient, Martin Salgo, who was not informed of the risks of surgery to which he would be subjected and after which he became paraplegic. *Informed*, was added to the notion of consent

[20]Tobin, *The Right to health*, 54-55.
[21]S. Marks, "The emergence and scope of the human right to health", in *Advancing the Human Right to health,* Oxford University Press, 2013, 19-20.
[22]J. Katz, *The Silent World of Doctor and Patient*, Johns Hopkins University Press, 2002, 78-79.

for the first time[23]. The virtue of this judgment is to have placed the principle of individual self-determination as a key element of the equation. Patients have since that time become active subjects of treatments, in which they had the right to be properly informed about all aspects of the required cares and to *autonomously* decide whether or not to undergo surgery.

After the aforementioned judgment health became closely linked to individual freedom of human beings as a full enforceable subjective right, which for the first time departed from mere considerations of public health. Indeed, people now had freedom of choice in relation to their health in light of the principles formulated in the Constitution of the WHO and, in so doing, they regained powers over themselves and their choices[24]. The patriarchal doctor-patient relationship, in which only the physician was in charge over the situation and the decisions to be made, was finally abandoned[25].

In conclusion, the Content of the right to health cannot, therefore, be reduced to the right to an active intervention by the State, but also relies on the acknowledgment of the principle of self-determination of the people. Under this perspective the protection of health is achieved not only by state intervention, but also by supporting the autonomy of individuals in the same manner as in the case of rights of freedom[26].

As will be examined in the next sections, the international *corpus iuris* related to the right to health acknowledges both the obligation of State (immediate and progressive) in order to fully realize the right to health and the right of freedom for individuals. This means that, as a social right, the right to health entails the obligation of the State to create adequate conditions and to provide services to protect health; and as a right of freedom, it entails the abstention of the State from intervention in the individual sphere, ensuring protection for the self-determination of individuals in light of the principles

[23]For the sake of clarity, in 1914, in the *Schloendorff v. Society of N.Y. Hospital case*, the Supreme Court Judge Benjamin Cardozo expressed the need for consent stating: *"Every human being of adult years and sound mind has a right to determine what shall be done with his body, and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."*

[24]A. Santosuosso, "Volontà e autonomia: paradigmi giuridici della persona", in Bonacchi G., *Dialoghi di bioetica*, Annali della Fondazione Lelio e Lisli Basso, Carocci Editore, 2003, 64.

[25]A. Santosuosso, "Evoluzione del concetto di salute", in Bonacchi G., *Dialoghi di bioetica,* 111-112.

[26]P. Borsellino, *Bioetica tra 'morali' e diritto*, Raffaello Cortina Editore, 2009, 116.

of autonomy and freedom of individuals[27].

In light of the aforementioned principle of self-determination in relation to medical treatments, it is worth mentioning the European Convention on Human Rights and Biomedicine of 1997, often referred to as the *Oviedo Convention*. The Convention grounds on the principles of autonomy and freedom, and its second chapter confers legal status to the forms in which individuals express their will in relation to medical treatments. The Oviedo Convention, hence, provides for a legal recognition of the right to self-determination regarding medical cares.

In other words, the Convention confirms the departure from the classical tradition, which considered health as a tool for the economic and financial development of a State. The principles of autonomy and freedom finally prevail, making the individual the center of public policies and social considerations. Medical treatments must now be instrumental in order to achieve the complete well-being of the citizens under an individual perspective that is relative for each one and does not rely on objective and standardized economic and financial considerations.

[27]In this regard, it is worth mentioning the judgment of the Florence Court of Assizes during the *Carlo Massimo case* delivered in 1990. According to the Court, health is not a good that can be imposed coercively by the will of others, but must be based solely on the will of the person entitled, since it is a choice that concerns the quality of his/her life and that therefore only he/she can legitimately make. Judgment n. 13/90 of the Court of Assizes of I degree of Florence, par 57.

2. The International Protection of the Right to Health

As presented in the previous section, a clear and unique definition of the right to health is not an easy task, mainly due to its multi-facet nature. Today, the right to health has a normative content which is embodied at the international level in several treaties and declarations. In addition, numerous national constitutions and the consequent legislative development enshrine the right to health and provide concrete application at the domestic level. As a result, the right to health has been producing significant jurisprudence; and it is currently the social right which has greater enforceability and justiciability before national courts.

The issue of the protection of the right to health in international human rights law tends to generate debate on its legal nature in two related senses. On the one hand, the question arises as to whether it is a fundamental right in itself, or whether it is related to other rights, such as, the right to life. On the other hand, health as a right belongs to the well-known category of economic, social and cultural rights, which implies an active participation of States for protection and realization of these particular rights[28].

The theoretical distinction between economic and social rights on one hand and civil and political on the other was believed to rely on the grounds of their different natures[29]. As a result, civil and political rights, such as the right to life, prohibition of torture and the right of free expression, were argued to be *negative rights*, meaning rights granting protection to individuals from interference by the state[30]. On the contrary, economic, social and cultural rights, were considered *positive rights.* This meant that rights such as, the right to education, the right to food, and the right to health required states to actively intervene in order to safeguard the social position of the individual within

[28] L. Minkler, *The State of Economic and Social Human Rights: A Global Overview*, Cambridge Univerity Press, 2013, 62-63.

[29] Nonetheless, the Human Rights Council (HRC) jurisprudence has gone beyond this "anachronistic" theoretical approach between civil and political rights and economic, social, and cultural rights. Accordingly, the HRC has argued that all ICCPR rights impose negative duties of refraining as well as positive duties of performance upon States Parties. S. Joseph and M. Castan, *The International Covenant on Civil and Political Rights: Cases, Materials, and Commentary,* Oxford University Press, 2013, 41.

[30] A. Conte and R. Burchill, *Defining Civil and Political Rights: The Jurisprudence of the United Nations Human Rights Committee,* Ashgate, 2009.

society, according to economic and social equality[31]. These sets of rights depend on the financial resources of States; and this is the reason they are often referred to as *financially conditioned rights*[32]. However, this analysis is outdated and simplistic[33]. In fact, both categories of rights require States to act for their fulfillment and hence, they are considered interdependent for the concrete enjoyment of all human rights[34]. The right to a fair trial is the most frequent example used to prove that civil rights, as well as social and economic rights need an active intervention of the State. Indeed, there is no doubt that the right to a fair trial obliges state's authorities to establish an effective judicial system, which require a significant allocation of resources and implementation of costly domestic laws[35].

It is important to stress that the principle of indivisibility among human rights is generally accepted nowadays[36]. As a result, it is possible to understand the theory of the indivisibility of human rights as the doctrine that seeks to overcome all forms of division and hierarchy among the different categories of human rights, affirming that in order to fully enjoy a human right it is necessary to enjoy all human rights since the violation of some also entails the violation of others[37]. In other words, all human rights, whether civil, political, economic, social or cultural, are closely linked to each other in

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[31]T. Christian, *Human Rights. Between Idealism and Realism*, eds Philip Alston, Gráinne De Búrca, and Bruno De Witte, The Collected Courses of the Academy of European Law, Oxford University Press, 2003, 24.

[32]F. Merusi, "I servizi pubblici negli anni 80"*,* in *Servizi pubblici instabili,* 1990, 131-131.

[33]A. Rehman, *International Human Rights Law*, Pearson Education Ltd, 2010, 141-142.

[34]C. Courtis, *Courts and the Legal Enforcement of Economic, Social and Cultural Rights Comparative Experiences of Justiciability*, International Commission of Jurists, 2008, 10.

[35]Tomuschat, *Human Rights. Between Idealism and Realism*, 25.

[36]D. Hartley, *Social Rights and Human Welfare,* Routledge, 2015, 141. Another key reaffirmation of the equal nature between civil and political rights and economic, social and cultural rights is to be found in United Nations General Assembly *Resolution 32/130* of 16 December 1977, which states that*:"(a) all human rights and fundamental freedoms are indivisible and interdependent; equal attention and urgent consideration should be given to the implementation, promotion and protection of both civil and political, and economic, social and cultural rights; (b) the full realization of civil and political rights without the enjoyment of economic, social and cultural rights is impossible; (c) the achievement of lasting progress in the implementation of human rights is dependent upon sound and effective national and international policies of economic and social development"*.

[37] Inter-American Court of Human Rights, Advisory Opinion OC-23/17 of November 15, 2017. Series A No. 23, par. 2. The Environment and Human Rights (State obligations in relation to the environment in the context of the protection and guarantee of the rights to life and to personal integrity – interpretation and scope of Articles 4(1) and 5(1) of the American Convention on Human Rights).

such a way that it is not possible to sacrifice some rights for the benefit of others without harming the human being who is the holder of all rights[38].

In light of the above, the main focus of the present chapter is to highlight the key legal obligations related to the right to health that States must respect according to the existing international and regional legal framework. The study grounds on the most significant sources of the right at stake, *inter alia,* relevant declarations and treaties, and international, regional and domestic jurisprudence[39]. In addition to its recognition at the international and regional level, treaty bodies responsible for the interpretation and monitoring of the implementation of the right to health, triggered the development and shaped the key features of its content with the aim of clarifying the relevant legal framework[40]. This preliminary consideration is a logical requirement for the deeper analysis of the major issue of this thesis, which is the access to medicines as a key part of the right to health.

The development of the right to health is studied, in particular, on the grounds of the "jurisprudence" of the Committee on the United Nations Economic, Social and Cultural Rights and of the Inter-American Court of human rights. In this regard, the mentioned Committee provided great interpretative work of all the rights envisaged in the ICESCR, and, in specific, disclosed concrete attributes of the right to health for example, highlighting its minimum or essential content. On the other hand, the Inter-American Court provides a valuable example of how an international judicial body can create the conditions for an effective protection of the right object of the present analysis.

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[38]D. Vázquez and S. Serrano, "Los principios de universalidad, interdependencia, indivisibilidad y progresividad. Apuntes para su aplicación práctica", in Carbonell M. and Salazar , *La reforma constitucional de derechos humanos: un nuevo paradigma*, México, Instituto de Investigaciones Jurídicas-UNAM, 2011, 139; UN World Conference on Human Rights, *Vienna Declaration and Programme of Action* (UN Doc. A/CONF.157/23; 1993).

[39] Helena Alviar Garcia; Karl Klare; Lucy A. Williams, *Social and Economic Rights in Theory and Practice Critical Inquiries,* Routledge, 2015.

[40] M. Ssenyonjo, *Economic, Social and Cultural Rights in International Law*, Hart Publishing, 2009, 313-315.

2.1. International Declarations and Treaties related to the Right to Health

This section focuses on the description of the right to health according to International Human Rights Law. Firstly, it studies how the right to health has been progressively included as an autonomous human right in different international treaties, both at the universal and regional level. In addition, it examines briefly a series of specific conventions that enhance the acknowledgment of this right and tailor it to make it more inclusive for certain groups that are considered vulnerable or with specific needs. The last section studies the legal content of the right to health according to its tripartite nature and its basic components, namely the elements of availability, accessibility, quality and acceptability.

2.1.1 The United Nations System (UNS)

The first reference that internationally recognized the importance of health protection is to be found in the Charter of the United Nations of 1945. In fact, article 55 (b) mentioned health among the key elements for the establishment of the conditions of stability and well-being which are required for peaceful and friendly relations between nations[41]. A year later, in 1946, the World Health Organization (WHO) was created by the Economic and Social Council of the United Nations. The WHO, is the authority responsible for playing a leading role in global health affairs and of which 194 States are members. Its Constitution is particularly relevant, since for the first time it refers to health in terms of right, recognizing in its preamble that *"the enjoyment of the highest attainable standard of health is one of the fundamental*

[41]United Nations, *Charter of the United Nations*, 24 October 1945, 1 UNTS XVI, Art. 55(b).
The origins of this wording can be found into the preliminary work of the preamble and the aims and objectives of the WHO Constitution, which were drafted by sub-committees of the Technical Preparatory Committee for the International Health Conference held in March 1946.
WHO, Official Records of the World Health Organization No 1: Minutes of the Technical Preparatory Committee for the International Health Conference Held in Paris from 18 March to 5 April 1946 (UN WHO Interim Commission October 1947) annexes 10, 11.

rights of every human being without distinction of race, religion, political ideology or economic or social condition". According to the Constitution health is not simply defined as the *absence of disease or infirmity*, but as *'a state of complete physical, mental and social well-being"* which significantly broaden its scope and meaning[42].

In spite of the quite remarkable degree of consent among States when the WHO definition was drafted, the latter triggered an array of criticisms and was considered contentious soon after is adoption due to its vague and unclear nature[43]. It clearly departed from the so called biostatistical conception which considered health as the normal functioning of our physiological system measured by biomedical statistics[44]. The biostatistical definition has the asset of relying on objective biological definitions of a healthy organism, but excludes issues of equity or social variables, which are significant in the context of health policy and defining health[45]. This clarification is important for comprehending the significance of the right to health as the sum of different components that go beyond the mere absence of illnesses. In fact, although attempts to restrain the definition of health to a more objective conception, namely the biostatistical idea, can be valuable for some areas of public health practice, it definitely does not help the cause of promoting the human right to health[46]. The aim of the WHO definition was to overcome and extend the negative definition (absence of illness) to positive components in light of the recent attention on social issues of the late 1940s[47]. The programmatic nature of the mentioned norm left to national authorities the duty to design the related framework in order to achieve the required standard and determine which aspects of health should be understood as essential to this aim[48].

The incorporation of the social factor as a new component of health, alongside its

[42]Preamble of the Constitution of the World Health Organization, New York, 22 July 1946, United Nations, *Treaty Series*, vol. 14, 185.
[43]Tobin, *The Right to Health*, 28.
[44]N. Daniels, *Just Health. Meeting Health Needs Fairly*. Cambridge University Press, 2008, 56.
[45]Ibidem
[46]J. M. Zuniga, S. Marks and O. G. Lawrence, *Advancing the Human Right to Health,* Oxford University Press, 2013, 5.
[47]B.M. Meier, "Global health governance and the contentious politics of human rights: Mainstreaming the right to health for public health advancement", *Stanford Journal of International Law*, 2010, 46.
[48]Zuniga et al, *Advancing the Human Right to Health,* 6.

conventional "physical" and "mental" determinants, meant a substantial change, because health ceased to depend exclusively on the biostatistical conception and became part of a more complex realm. This promoted the consideration of health as a fundamental social right of all people, placing the State before the dilemma of how effectively exercising the protection of this right, since public policies and the cultural and ecological environment could harm the right a stake. Since then, the unquestionable connection that health had with other rights, such as, among others, the right to life and dignity of citizens was another key dilemma that States had to confront and deal with[49].

This broader conception of health, which was embodied in the WHO Constitution, is to be favored over the biostatistical notion on the grounds of two main considerations. Firstly, although the biostatistical definition is a useful tool in measuring individual's health, it does not add much in the design of human rights-inspired health policies for the population[50]. In fact, as the practice within the Committee on Economic, Social and Cultural Rights (CESCR) shows, there is no doubt that biostatistical considerations are key in order to identify possible interventions on the grounds of statistical data, such as *inter alia,* life expectancy and infant and maternal mortality[51]. Nevertheless, these markers are just a share of the whole picture since the way human rights monitoring bodies tackle public health issues relies on a broader analysis, namely on the study of health systems, inequalities, and other determinants of the right to health, as highlighted

[49]This concept of Health of the WHO was an important step forward, although only partial because it still had undoubted limitations. Thus, in the 70's, Million Terris, a famous North American public health expert, proposed a new definition: *"Health is a state of physical, mental and social well-being, with the capacity to function and not only the absence of discomfort or illness"*. Terris introduces a subjective aspect of feeling good and an objective aspect of functional ability. He eliminates the word "complete" by claiming that health is not an absolute - a heavenly happiness - but that there are different degrees of health. And separates the terms "disease" and "ill-ness", as it is possible to coexist with the term "disease". "feel good" and the disease. The conceptual advance implied by Milton Terris' proposal requires the exclusion of "feeling good" and disease. idea of "state", since it opposes the dynamic and changing vision of the flow of life (and health) while, on the contrary, it coincides with mechanistic vision and so characteristic with the hegemonic conception of traditional medicine. T. Milton, "La epidemiología y la Salud Pública: orígenes e impacto de la segunda revolución epidemiológica". *Rev. San. Hig. Pub.* 68*.,* 1994, 5-10.

[50]Zuniga et al, *Advancing the Human Right to Health,* 5.

[51] M. Ssenyonjo, *Economic, Social and Cultural Rights in International Law*, Hart Publishing, 2009, 315.

throughout the chapter. As a result, instruments adopted by the aforementioned monitoring body, such as CESCR's guidelines, are centered on policies aimed at guaranteeing and solving health related issues rather than on statistical information concerning those matters[52].

In the same way, a 2008 study carried out on 194 countries highlighted the need to depart from biostatistical considerations of health and showed the urge to employ a broader concept on the grounds of a variety of indicators. In sum, the study argued the necessity of assessing the right to health in light of a manageable set of indicators, with the aim of furthering the insight of health data and indicators in regard to the concrete implementation of the right to health. The vast majority of the selected 72 indicators relied on determinants which had little to do with biostatistical considerations and biological definitions of what has to be intended as a healthy organism. Indicators such as political decisions, non-discrimination, health information, participation, financing and social awareness constituted the starting point of the analysis. As a result, the purpose of both the CESCR and the 2008 study was to determine fulfillment of the right to health, not the health of the population or of an individual[53].

The second consideration which refutes a biostatistical conception of health is key in preventing a position that could be antithetical to human rights. Two examples help clarifying this view. First, if there were a norm which defined as healthy people only those whose sexual drive was solely directed towards reproduction, on the grounds of biological considerations, persons who faced fertility issues or those whose sexual interest was aimed towards same-sex relations, would be considered pathological, and hence *not healthy*. On the contrary, a human rights approach has nothing to do with simplistic biostatistical considerations; and individuals favoring same-sex relations and in general, individuals whose sexual drive is not directed to reproduction, would definitely be identified as healthy physically, mentally, and socially. Second, even if

[52]United Nations Committee on Economic, Social and Cultural Rights. *Guidelines on treaty-specific documents to be submitted by States parties under articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights.* UN Doc. E/C.12/2008/2, annex. 24 March. United Nations (UN): New York, NY, 2009.

[53]G. Backman, Hunt, C. Jaramillo-Strauss et al, "Health systems and the right to health: an assessment of 194 countries", *Lancet,* 372, 2008, 2048-2050.

persons with both physical and mental disabilities fall outside the biostatistical definition of being 'healthy', such as disabled people, in light of a human rights approach and taking into account the State's position towards their special needs, they are considered physically, mentally and socially healthy[54]. Consequently, health should be understood as a complex and dialectical process embodying social, cultural and economic determinants and not simply as a biological state. Similarly, illness, is part of the vital cycle of persons and is not the opposite of health[55].

Another aspect of the WHO Constitution which is worth mentioning is the alleged instrumental nature of the right to health embodied within as demonstrated in one of the first version of the Constitution's Preamble. Indeed, the Preparatory Committee stressed that health was a fundamental factor *achieving safety and well-being for individuals and nations*[56]. In addition, this approach has been confirmed in the final version of the preamble which reaffirmed the dependence of health on international cooperation and its instrumental character in relation to global security and peace[57]. In this way both the normative and instrumental sides of the right to health were formally accepted, with the consequent obligation on states to act individually and collectively with the aim at achieving not only the effective protection of the right to health of persons but also at fulfilling the key interests of states and of the community as a whole[58].

[54]Zuniga et al, *Advancing the Human Right to Health,* 6.
[55] M. Ssenyonjo, *Economic, Social and Cultural Rights in International Law*, Hart Publishing, 2009, 317.
[56] WHO, Official Records No1 (n 84), annex 10.
[57]Preamble of the WHO Constitution: *"The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States".*
[58]Tobin, *The Right to Health*, 29.

2.1.1.1. The Universal Declaration of Human Rights (UDHR)

In 1948, two years after the adoption of WHO Constitution, the United Nations General Assembly enacted the Universal Declaration of Human Rights (UDHR), which included the right to health in its article 25(1). Interestingly, the article did not provide a specific provision in regard with the right to health, instead it was referred to has a component of the broader concept of an adequate standard of living[59]. Article's 25 wording was proposed by the Latin American delegation, which play a crucial role during the drafting procedure within the respective Committee of the Commission on Human Rights. According to some scholars, Latin American tradition was key in including the right to health within the Declaration, since 13 national constitutions already contained the right to health as a specific right, in contrast to North Atlantic countries, which, at the time, did not provide any constitutional provisions recognizing the right at stake[60]. At the end the American proposal was adopted and after multiple editing, the final version established this right alongside the right to food, clothing, and housing in light of their close relationship with the practical achievement of healthcare and necessary social services[61].

Latin American participation in the drafting was not, however, without consequences. As the same scholars argue, this contribution in the wording of the right to health and of other economic and social rights within the Declaration was proof that the common belief that social and economic rights were a result of Soviet influence was not completely accurate. But even though this position is well grounded in the practice and within fundamental legal documents of the Latin American continent, reducing economic and social right to a sort of Latin American socialism is simplistic. Indeed,

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[59] *"Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control"*
UN General Assembly. (1948). *Universal Declaration of Human Rights, Doc 217A (III.* UN General Assembly: New York, NY.

[60] J. Morsin, *The Universal Declaration of Human Rights: Origins, Drafting and Intent.* University of Pennsylvania Press, 1998, 19.

[61] Ibidem.

other important factors must be taken into consideration.

Firstly, the development of the right to health has been profoundly linked to the necessity of implementing a concrete vision of how best addressing human suffering and inequality. Certainly, both communism and socialism have probably been the product, *inter alia*, of the idea that political and civil rights did not suffice and, hence, other tools were needed to protect the most vulnerable ones[62]. However, as Tobin points out, these movements, especially at their early stages, were more interested in addressing the collective sphere and less keen on using rights as a mechanism in order to tackle individual economic and social issues[63]. Marx himself was skeptical as he considers that any kind of rights were the expression of the egoistic and selfish positions of individuals that should always perish to the interest of the society as a whole[64]. It is worth noting that both communism and socialism did address, among others, two specific questions: on the one hand, whether another category of rights was needed alongside political and civil ones and, on the other, if personal rights, such as the right of private property could co-exist with the community's interest of improving the well-being of its most disadvantaged members[65]. The need to solve these two key issues triggered and shaped the discourse of a new approach to human rights within the Latin American continent as its nations reached their political independence in the 1900's. As authors such as Mary Ann Glendon highlighted in their works, the aforementioned new approach relied on a variety of components such as the different legal traditions between states, religion and the continent's historical development, and was not the outcome of Marxist or socialist ideology. In conclusion, the author demonstrated that this new vision towards human rights was mainly founded on Catholic beliefs in regard to human dignity and social justice with the aim of refuting positions of extreme individualism and collectivism[66].

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[62] L. Hunt, *Observing HumanRights:A History ,* WWNorton & Co, 2007, 197.
[63]Tobin, *The Right to Health*, 21.
[64] K. Baynes, "Rights as Critique and the Critique of Rights: Karl Marx, Wendy Brown and the Social Function of Rights", *Political Theory* 451, 2000, 451-454.
[65]L. Hunt, *Observing Human Rights: A History,* WW Norton & Co, 2007, 197.
[66] M. A. Glendon, "The Forgotten Crucible: The Latin American Influence on the Universal Human Rights Idea", *Harvard Human Rights Journal* 16, 2003, 27.

The political and sociological analysis of the link between Latin American socialism and economic and social rights is surely appealing and engaging: however, it departs from the main focus of this chapter, which is to highlight the development of the right to health at the international stage[67]. In line with the nature of this work, the following section deals with the study of the legal nature of the Universal Declaration of Human Rights, which indeed constitutes a milestone in international protection of human rights and which nature has a concrete impact on the tangible realization of the provisions within.

2.1.1.2. The Legal Nature of the Universal Declaration of Human Rights

Resolution 217 (III) of the General Assembly of the United Nations (UNGA) was adopted on December 10, 1948 with 48 votes in favor, 8 abstentions and no votes against, and embodied the Universal Declaration of Human Rights. As a resolution, the recently born document would not have legally binding character for member states. Indeed, in light of a literal interpretation of the articles regulating the functions and powers of the UNGA, namely Arts. 10 to 17 of the United Nations Charter, this scenario was explicitly provided for[68].

However, since the 1960s, many less developed countries have tried to give the UNGA the power to establish binding legal norms by means of its Resolutions, but these attempts were blocked by the opposition of Western States and the caution of Socialist States, that feared the creation of an international legislative assembly in which the most "powerful" countries would be a minority[69].

When the Declaration was drafted, all the opinions of United Nations Member States

[67]For further analysis see T. Campbell, *The Left and Rights: A Conceptual Analysis of the Idea of Socialist Rights,* Routledge, 1983; and P. Carozza, "From Conquest to Constitutions: Retrieving a Latin American Tradition of the Idea of Human Rights", 25 *Human Rights Quarterly* 281, 2003.

[68] At the San Francisco Conference of 1945, all proposals aimed at granting the UN General Assembly the competence to enact binding legal norms were rejected. Specifically, a proposal by the Philippines to that end was rejected by 26 votes against and 1 in favor.

[69]B. Conforti, *Le Nazioni Unite,* Cedam, 2010, 105.

coincided in pointing out its importance, but at the same time, they rejected the idea that the Declaration imposed conventional legal obligations in respect to the Human Rights and Fundamental Freedoms embodied within; in this sense, the great majority of the members who intervened in its drafting did not intend to create a compulsory document[70]. In other words, a Declaration rather than a treaty was adopted on the grounds that States would not accept being conventionally bound to implement those provisions in their legal systems[71].

If there is no doubt that the Declaration was merely a political document at the moment of its adoption, its legal nature has faced changes throughout the years. Indeed, considering the Declaration a simple Resolution with no legal effects, would mean underestimating its formal and substantial value as a fundamental piece of the international human rights law framework. The Declaration was in fact referred to as a source of legally binding obligations on States by international and national jurisprudence on multiple occasions. This section points out the most relevant theories on the legal nature of this instrument in light of the aforementioned jurisprudence and States' practice. There have been four main doctrinal assessments regarding the legal nature of the Declaration over the years: firstly, some scholars have denied its juridical obligatory nature; secondly, others, have not accepted its binding force, but have recognized its undeniable juridical relevance and great moral value; thirdly, others have considered that it endowed a juridical obligatory value as forming part of General International Law or being an expression of Fundamental Principles of the international order; and lastly, some have even considered the Declaration endowed with a cogent character. An examination of these trends is indicated.

According to one of the main reasoning excluding the binding nature of the Declaration, the UN Charter explicitly provides that the UNGA can adopt non-binding documents,

[70]Simirarly, Mrs. Roosevelt - Chairman of the Drafting Committee set up within the Human Rights Commission and US representative - pointed out that the UDHR was not a Treaty endowed with the force of law, but rather a Declaration of Principles on the Fundamental Rights and Freedoms of individuals. S. Tchirkovitch, "La Déclaration Universelle des Droits de l'Homme et sa portée international", *Revue Générale de Droit International Public* 3-4, 1949, 376.

[71]Szabo, "Fondements historiques et développement des droits de l'homme", in K. Vasak (Réd. gén.), *Les dimensions internationales des droits de l'homme*, UNESCO, Gand, 1978, 25.

namely, recommendations and resolutions, and no new customary norm has modified this framework over the years[72]. The best proof that UNGA instruments have not become binding is the fact that they have generally been followed by the adoption of treaties drawn up within the United Nations, treaties which contain provisions practically identical to those of the resolutions (in the case of the UDHR, it would be the two Covenants of 1966), so that if the resolutions were binding, it would not make sense for the United Nations to draw up a subsequent treaty with the same normative object[73]. In other words, the subsequent adoption of treaties with the specific objective of giving legal effectiveness to the Rights contained in the UDHR is a sufficient reason to deny its binding force[74].

Even the text of the Universal Declaration itself confirms that it has no binding character by affirming the Declaration *"as a common standard of achievement for all peoples and all nations*". In short, for this first aspect of the doctrine, the Universal Declaration of Human Rights would not be binding in function: firstly, the competence of the General Assembly limited exclusively to the adoption of resolutions and recommendations; secondly, the instrument denomination, which refers to a declaratory and non-binding document; thirdly, the history of its elaboration, in which it was expressly stated that it would not be mandatory; and lastly, from the text of the Declaration itself.

In line with the aforementioned position, other scholars refute the idea that the Declaration is either the expression of new customs, nor does it confirm or crystallize previously existent customary norms. In support of his argument, these scholars highlighted the conditions in which the Declaration was adopted. As stated above, the fact that Socialist States did not expressively accept the Declaration and abstained, is enough to determine that the instrument was not approved by the generality of the States of the International Community. Hence, one of the two main components of

[72]Charter of the United Nations, Articles 9 to 22.

[73] I. Seidl-Hohenveldern, "Propositions algeriennes pour un nouveau cadre de relations entre des entreprises des pays du tiers monde et des entreprises des pays developpes", in Mélanges F., *Les progés du Droit des Gens*, F. Nathan-París, Labor-Bruselas, 1979, 108.

[74] O. Schachter, *International Law in Theory and Practice*, Martinus Nijhoff, 1991, 337.

customary norms, namely *opinio iuris,* was missing[75].

In addition, according to these authors, Resolution 2625 (XXV) does constitute another ground on which confirm the political character of the Declaration. The resolution was adopted by consensus by the UNGA on 24 October 1970 and contained the *Declaration on Principles of International Law concerning Friendly Relations and Co-operation among States in accordance with the Charter of the United Nations.* Theses authors argue that the latter declaration, which in light of unanimous practice is considered declaratory of the fundamental principles of Public International Law[76], did not mention the principle of respecting Human Rights, nor the observance of the UDHR, establishing a decisive element for not granting customary value to the Declaration.[77] indeed, the Universal Declaration cannot be considered as a petrified normative text and must be interpreted and applied in light of current situations and not merely in light of the context of its adoption in 1948. Better said, this international instrument should be understood as a *living instrument,* whose legal nature, in its material aspect, may vary over time in accordance with the evolution of international relations and the commitment of States to international human rights law. In the same way as the European Court of Human Rights has qualified the European Convention for the Protection of Human Rights and Fundamental Freedoms, a text must therefore be interpreted in the light of the present conditions[78]. On these grounds, there is no such thing as a *socialist bloc nowadays*, and the States that formerly belonged to this orbit have, at least on paper, legally bound themselves to a variety of international instruments related to human rights and to the control mechanisms provided for therein.

The second group of scholars, the largest one, only recognize the undeniable legal relevance of the Declaration, in the same way as with other resolutions of the UNGA, but without accepting its legal obligatory nature or taking a stance on it[79]

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[75] F. Sudre, *Droit international et européen des droits de l'homme*, PUF, 1995, 106.

[76] International Court of Justice, Military and Paramilitary Activities (Nicaragua/United States of America) Merits. J. 27.6.1986, I.C.J. Reports 1986, 4.

[77] M. C. Ortega Carcelen, "Naturaleza y evoluciones de los Principios Fundamentales del Derecho Internacional", *Revista Española de Derecho Internacional,* 1998, 60;

[78] European Court of Human Rights, Judgment of 13 June 1979, *Marckx* v. *Belgium* case, par. 58.

[79] M. Giuliano, T. Scovazzi and T. Treves, *Diritto Internazionale. Parte Generale*, Giuffrè, 1991, 240.

A third group is composed of authors who confer binding legal value to the Declaration, understanding that all or some of the rights formulated therein are part of General International Law80; thus, they consider that UDHR is directly applicable to States whose legal frameworks have established a system of automatic incorporation of customary international law. These authors ground their position on the countless occasions in which the UDHR has been invoked as a universal standard and on the fact that a subsequent resolution of the U.N.G.A., *the Declaration on the grant of independence to colonial countries and peoples, of 1960*, clearly affirmed that *"all States must observe faithfully and strictly the provisions of the Charter and the UDHR"*[81].

Other scholars did recognize the Declaration legal obligatory nature, but did not derive it from a single source of International Law, since they consider the content of the UDHR either an international custom, expression of General or Fundamental Principles of the international order, or an authorized interpretation of the Charter to which the International Community conferred binding force[82].

This doctrine argues that the binding force of the Universal Declaration of Human Rights would derive from considering it as an authentic interpretation of the provisions of the UN Charter relating to Human Rights, a document that is binding on Member States. This was precisely the position taken by Judge Tanaka in the *South West Africa case* when he pointed out that even though the Declaration was not binding in itself, it constituted proof of the interpretation and application of the relevant provisions of the Charter[83]. In addition, the Judge Ammoun's opinion in the *Barcelona Traction case* concluded the same thing, when he pointed out that: "*Certain writers, for their part, see in this an interpretation based upon an argument drawn from the actual text of the*

[80]A. Mangas Martín, in M. Díez de Velasco, *Instituciones de Derecho Internacional Público*, Tecnos, 1999, 198.

[81]UNGA, *Declaration on the Granting of Independence to Colonial Countries and Peoples,* Resolution 1514 (XV) of 14 December 1960, par. 7.

[82]A. Carrillo Salcedo, "Algunas reflexiones sobre el valor jurídico de la Declaración Universal de Derechos Humanos", in *Hacia un nuevo orden internacional y europeo. Estudios en homenaje al Prof. D. Manuel Díez de Velasco*, Tecnos, 1993, 177-178.

[83]International Court of Justice, *South-West Africa Cases* (Ethiopia v. South Africa; Liberia v. South Africa)*; Second Phase*, 18 July 1966, par. 293.

Charter, strengthened by a teleological interpretation of that international constitutional instrument, which presupposes the existence of rights and liberties of man which "are not only moral ones, [but] . . . also have a legal character by the nature of the subject-matter ". They add that such an interpretation should take into account the functioning of the Charter in practice"[84].

One of the most interesting and well-founded theory on the binding nature of the Declaration was the one developed by Sieghart. The author grounds his thesis on three solid arguments, stating that the UDHR creates legal obligations on Member States of the United Nations, not because it embodied norms of customary international law, but because, there are evidences that States have expressly accepted such obligations[85].

The first argument relies on an attentive analysis of Articles 55 and 56 of the Charter. According to the author, the latter article creates a legal obligation for the Member States of the United Nations to adopt the necessary measures to achieve respect for human rights, even though the Charter does not list these rights, as does the Declaration. Hence, the author argued that the Declaration constitutes a text that complemented the Charter, in such a way that the Member States of the United Nations have retroactively incorporated this list into the Charter itself[86].

According to the second argument, the UDHR constitutes an interpretative guide to the wording *"human rights and fundamental freedoms"* embodied in Article 55(c) of the Charter. In fact, in accordance with the general rule of treaty interpretation established in Article 31(3)(b) of the *Vienna Convention on the Law of Treaties between States of 23 May 1969*, the context shall be to take into account together with "a*ny subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation"*[87]. There is a continuing practice by States, and by the United Nations itself, to cite the UDHR as the agreed catalogue of Human Rights and Fundamental Freedoms, often in the specific context of art. 55(c) of the Charter. This

[84]International Court of Justice, *Barcelona Traction, Light and Power Company, Limited, Judgment of 5 February 1970, I.C.J. Reports 1970*, 3; Separate Opinion Judge Ammoun, par. 302.
[85] *Sieghart, The International Law of Human Rights*, Clarendon Press, 1983, 53-55.
[86]Ibidem
[87]Vienna Convention on the Law of Treaties, Vienna, 23 May 1969, United Nations, *Treaty Series*, vol. 1155, 331, art. 31(3)(b).

was the case of the Tehran Proclamation of 13 May 1968, adopted at the First United Nations World Conference on Human Rights. Therefore, in the view of the author the wording *"human rights and fundamental freedoms"* proclaimed in the UN Charter must be interpreted in such a way as to refer to the rights and freedoms provided for in the UDHR[88].

The last view argued that in the aforementioned Tehran Proclamation, the representatives of 84 States agreed that the UDHR constituted an obligation for the members of the International Community, recognizing that if at the time, the UDHR did not constitute an obligation for the member States of the United Nations, it does since the cited Proclamation, which considers the UDHR *"obligatory for the International Community"*[89].

Subsequent State practice, however, did not confirm this view as shown by the Second World Conference on Human Rights held in Vienna in 1993, where States failed to reach the consensus required to confer legal character and reaffirmed the non-binding nature of the Declaration. The preamble of the Final Act of the Conference, which *inter alia* enshrined the concept of rights being indivisible, referred to the UDHR as *common goal* and *a source of inspiration,* in contrast to the binding definition provided for in the cited Proclamation of Teheran[90].

Although it is difficult to determine the concrete legal nature of the UDHR, it must be noted that it is not an ordinary UNGA Resolution, originally not obligatory but which has gradually become part of customary norm, by expressing a general legal conviction regarding the obligatory observance of most of the Rights and Freedoms listed therein[91]. In this sense, there is no doubt about the existence of an *opinio iuris* on the legal value

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[88] *Sieghart, The International Law of Human Rights*, Clarendon Press, Oxford, 1983, 53-55.

[89]Proclamation of Teheran, Final Act of the International Conference on Human Rights, Teheran, 22 April to 13 May 1968, U.N. Doc. A/CONF. 32/41 at 3 (1968), par. 2.

[90]*World Conference on Human Rights,* Vienna Declaration and Programme of Action*, June 1993*, NU, New York, 1995, 28.

[91]Nor should it be forgotten that in the past, in application of Article 73(e) of the Charter of the United Nations, the administering States of "Non-Self-Governing Territories" were requested to provide information on the means by which, and to what extent, the human rights law was applied in them. A. A. Cançado Trindade, "Co-existence and Co-ordination of Mechanisms of International Protection of Human Rights (at Global and Regional Levels)", *Recueil des Cours de l'Academie de Droit International de La Haya,* 1987-II, 202, 309.

of the Declaration, since all States recognized their obligation to protect human rights over the years. Furthermore, although in practice there are many cases of violations of this specific category of rights, the breach of a rule does not mean the denial of its existence, even though it does not have a coercive mechanism that sanctions its non-compliance. For example, as the frequent violations of criminal laws at the domestic level do not entail the non-existence of Criminal Law, the fact that many States still do not accept or do not observe the international obligations related to Human Rights does not undermine the validity of this group of norms.

The same view has been confirmed by the International Court of Justice in its Judgment of 27 June 1986, in the *Nicaragua vs. United States case*. The Court argued that, in order for a rule to be well established as custom, it is not necessary for the corresponding practice to have absolute conformity with that rule; since, what is needed is a general consistency with the rule and that in cases in which a State departs from the required conduct, *"should generally have been treated as breaches of that rule, not as indications of the recognition of a new rule".* Moreover, according to the Court, *"if a State acts in a way* prima facie *incompatible with a recognized rule, but defends its conduct by appealing to exceptions or justifications contained within the rule itself, then whether or not the State's conduct is in fact justifiable on that basis, the significance of that attitude is to confirm rather than to weaken the rule"*[92].

In the same way, the Advisory Opinion of the International Court of Justice on t*he Legality of the Threat or Use of Nuclear Weapons of 8 July 1996* stated: *"(...) General Assembly resolutions, although not binding, may sometimes have normative value. In certain circumstances, they may provide important evidence to determine the existence of a norm or the emergence of an* opinio iuris *(...)";* In order to do so, its content, the conditions under which it was adopted and the existence of a general legal conviction as to its normative character must be taken into account[93].

Finally, some authors even consider that the content of the UDHR has to be understood

[92] International Court of Justice, *Military and Paramilitary Activities in and against Nicaragua* (Nicaragua v. United States of America), Merits, Judgment*, I.C.J. Reports 1986,* 14. par. 186.

[93]International Court of Justice, *Legality of the Threat or Use of Nuclear Weapons*, Advisory Opinion*, I.C.J. Reports 1996,* 226, par. 255.

as endowed with *ius cogens* norms[94]. According to these scholars, the Universal Declaration of Human Rights is binding insofar as it is a positive legal expression of a generally accepted principle in contemporary international law, namely, the dignity of the human person. Furthermore, It understands that the Universal Declaration contains a set of general principles of law for which there is universal acceptance as shown *inter alia,* in the *Barcelona Traction case*, which considers the respect for human rights as an international obligation *erga omnes*: it is incumbent upon every State with respect to the International Community as a whole and every State has a legal interest in the protection of human rights. Similarly, the I.C.J. in its judgment of 24 May 1980 in the case of *Diplomatic and Consular Staff in Tehran*, concluded: *"Wrongfully to deprive human beings of their freedom and to subject them to physical constraint in conditions of hardship is in itself manifestly incompatible with the principles of the Charter of the United Nations, as well as with the fundamental principles enunciated in the Universal Declaration of Human Rights"*[95].

In conclusion, there is no doubt that a number of rights contained in the Universal Declaration of Human Rights have been addressed by the repeated and uniform practice of States and, in that sense, form part of customary law and, some other reached the status of *ius cogens.* In addition, it is not possible to deny the Declaration unquestionable legal relevance as an inspiring principle of international instruments of conventional character as shown by the practice within the United Nations, as well as in that of other United Nations agencies, and regional systems.

[94]A. Sanjosé Gil, *La protección de los derechos humanos en el ámbito del Derecho Internacional*, Tirant lo Blanch, 1992, 19- 20; F. S. Nariman, "Universalidad De Los Derechos Humanos", *Revista de la Comisión Internacional de Juristas* 50, 1993, 13.

[95]International Court of Justice, *United States Diplomatic and Consular Staff in Tehran* (United States of America v. Iran), Judgment of 24 May 1980, *I.C.J. Reports 1980*, 3. par. 91.

2.1.2. The United Nations International Covenant on Economic, Social and Cultural rights (ICESCR)

The International Covenant on Economic, Social and Cultural Rights (ICESCR) provides the most comprehensive article on the right to health in international human rights law[96]. The Covenant, counting 169 state parties[97], on Economic, protects a array of economic, social and cultural rights. For the purpose of the present analysis and considering information which will be further examined in Chapter II, it is important to mention that most of WTO members have ratified the ICESCR, although there is a notable exception. In fact, the United States of America signed the ICESCR in 1977, but has not ratified it[98]. Under article 18(a) of the Vienna Convention on the Law of the Treaties, the Covenant, however, does have legal effects on signatories' parties, indeed, the US and the others States with the same status, are obliged to abstain from any acts which would be against the object and purpose of the treaty[99].

In accordance with article 12.1 of the ICESCR, States Parties recognize *the right of everyone to the enjoyment of the highest attainable standard of physical and mental,* while article 12.2 presents a list of measures to be taken by States Parties to the Covenant in order to ensure the full effectiveness of the Covenant, almost all of which are directly or indirectly linked to the prevention and control of infectious diseases[100].

A quasi-judicial body, namely the Committee on Economic, Social and Cultural rights is in charge of monitoring the correct fulfillment of the rights envisaged by the Convention among States parties[101]. For the sake of clarity, the Convention, as opposed to the Convention on Civil and Political rights adopted in the same year (1966), did not establish the latter monitoring body. Indeed, the Committee was established by the

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[96]International Covenant on Economic, Social and Cultural Rights, New York, 16 December 1966, United Nations, *Treaty Series*, vol. 993, 3.

[97] That is at the time of writing, March 2019. See also http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en.

[98]Other States that have signed the Covenant but not ratified it are: Comoros (2008-09-25), Cuba (2008-02-28), Palau (2011-09-20).

[99] Vienna Convention on the Law of the Treaties, Article 18(a).

[100]Tobin, *The right to health,* 114.

[101]K. Arambulo, *Strengthening the Supervision of the International Covenant on Economic, Social, and Cultural Rights: Theoretical and Procedural Aspects,* Intersentia, 41-42.

Economic and Social Council (ECOSOC) following the adoption of Resolution 1985/17 of 28 May 1985[102]. Its purpose was to act on behalf of the United Nations Economic and Social Council ECOSOC in order to fulfill the oversight requirements as stated in Part IV of the Covenant[103].

The work of the Committee relies on a system of regular reports concerning the manner in which the rights are being implemented, which all States parties are obliged to submit. States must report initially within two years of accepting the Covenant and thereafter every five years. The Committee examines each report and addresses its concerns and recommendations to the State party in the form of "concluding observations"[104]. Furthermore, since the entering into force of the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights in May 2013, the Committee has the competence to receive and address communications from individuals claiming alleged violations of the rights provided for in the Covenant[105]. The publication of the interpretation of specific provisions of the Covenant in the form of *general comments* constitutes another key task performed by the Committee[106], which may also, assess inter-state complaints, and under particular conditions, initiate interrogations on grave or systematic breaching of any of the economic, social and cultural rights embodied in the Covenant[107].

[102]United Nations Economic and Social Council, *Resolution 1985/17*.
[103]M. Ssenyonjo, *Economic, Social and Cultural Rights in International Law*, Hart Publishing, 2009, 314-315.
[104]Ibidem
[105]The General Assembly adopted resolution *A/RES/63/117* on 10 December 2008, *Optional Protocol to the International Covenant on Economic, Social and Cultural Rights*, art. 2.
[106]For instance, the UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4.
[107]G. MacNaughton, *Economic and Social Rights in a Neoliberal World,* Cambridge University Press, 2018, 128

2.1.3. The Right to Health within the United Nations Committee on Economic Social and Cultural Rights System

As stressed from the beginning of this chapter, the right to health is deeply related to the economic and financial situations of States. Under this consideration the UN Committee on Economic, Social and Cultural rights is aware that *"for millions of people throughout the world, the full enjoyment of the right to health still remains a distant goal. Moreover, in many cases, especially for those living in poverty, this goal is becoming increasingly remote. The Committee recognizes the formidable structural and other obstacles resulting from international and other factors beyond the control of States that impede the full realization of article 12 in many States parties"*[108]. Therefore, determining specific and clear legal obligations is fundamental for the concrete protection and implementation of the right object of the current analysis. Starting from the consideration that it is now widely accepted that from the wording of article 12 ICESCR the right to health does not imply a right to be healthy[109]. The analysis further explores what article 12 of the Covenant entails. Article 12 of the Covenant goes as follow:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

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[108]UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4, par. 5.

[109]Ibidem, par. 8.

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The Third Committee of United Nations General Assembly, which was charge with drafting the article, decided to depart from the definition of health envisaged in the Preamble of the WHO Constitution, which conceives of health as *"a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity".* In addition, the Committee itself clarifies that the reference to article 12, paragraph 1, of the Covenant to the *"highest attainable standard of physical and mental health"* is not limited to the right to health care. On the contrary, the wording of article 12, paragraph 2 recognizes that the right to health encompasses a wide range of socio-economic factors that promote the conditions under which individuals can lead healthy lives and includes basic underlying determinants of health, such as the right to food and potable water[110].

As will be further detailed in section 6 of this chapter, access to medicines constitutes a key element of the right to health. Under this consideration, it is worthy reading the aforementioned article 12 in light of an *access to medicines approach.* On the one hand, there is doubt that medicines are vital and indispensable for the treatment of most diseases, and access to and the existence of such medicines is, hence, an essential component in permitting individuals to achieve their highest attainable standard of health[111]. On the other, on the grounds of paragraph 2 which lists *some of* the steps to be taken in order to fulfill the right, it goes without saying that medicines are particularly relevant in the event of preventing, treating and controlling epidemic, endemic, occupational and other diseases (article 12.2(c)) and in creating conditions which assure that everyone enjoys medical service and attention in the event of sickness

[110]Ibidem par. 4.

[111]H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines,* Oxford University Press, 2007, 104.

(article 12.2(d)). This interpretation is, therefore, consistent with both the wording of article 12 and the context, the object and purpose of the Covenant[112].

Even though General Comments of the CESCR do not have legally binding effects, they do constitute a key resource in determining State's obligations in light of the Covenant in general and on the right to health in particular. Based on the jurisprudence of the Committee on Economic, Social and Cultural Rights, in particular under General Comment 3 on the nature of States parties' obligations - paras. 1, 2, 9 and 10 and General Comment 14 on the right to the enjoyment of the highest attainable standard of health - paras. 12, 33, 43 and 44, the delimitation of the content of the right to health relies on three typologies of State obligations with respect to economic, social and cultural rights: firstly, obligations of availability, accessibility, acceptability and quality; secondly, obligations to respect, protect and fulfill; and thirdly, immediate and progressive obligations[113].

The Committee constructed and specified the right to health on the grounds of four interrelated and essential components, the implementation of which stems from the specific context within a state party. In summary, in accordance to the CESCR's analysis, *availability* implies the provision of "*[f]unctioning public health and health care facilities, goods and services, as well as programmes, which have to be available in sufficient quantity within the State Party"*[114]. Indeed, the Committee pointed out that level of development within each country must be always be taken into account; and, such facilities must be understood as comprising safe drinking water, adequate sanitation facilities, hospitals, clinics, trained medical and profession personnel, and *essential drugs* as defined by the WHO Action Programme on Essential Drugs[115].

According to the Committee, the second component of health is *accessibility,* which entails that *"health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State Party".* This second

[112]Vienna Convention on the Law of Treaties, Article 30.
[113]UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Par. 1, of the Covenant)*, 14 December 1990, E/1991/23; and UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14.*
[114]Ibidem, par. 12.
[115]Ibidem, par. 12(a).

component is then broken down to four overlapping dimensions: firstly, accessibility must be understood in accordance with the principle of non-discrimination; secondly, accessibility entails physical accessibility, understood as that health facilities, goods and services must be within safe physical reach, for rural areas as well as urban locations; thirdly, accessibility means economic accessibility, implying that health facilities, goods and services must be affordable for every individual; and, lastly, accessibility must be understood as the individual right of seeking, receiving and imparting information and ideas in relation to health issues[116].

Acceptability is the third component mentioned by the Committee, which entails that *"All health facilities, goods and services must be respectful of medical ethics and culturally* appropriate"[117]. Lastly, *q*uality means that, "health facilities, goods and services must also be scientifically and medically appropriate and of good quality"[118]. Since the interface between access to medicines and pharmaceutical patents protection constitutes the center of the present dissertation, it becomes clear that the analysis of the third dimension of accessibility, namely that health facilities, services and goods must be *affordable* is key in the present study. In fact, as will be presented in chapter 2, the international legal framework related to patents grants a 20-year monopoly for medicines, which usually result in higher prices. Higher prices lead to an impediment in accessing important medicines both for States, especially developing countries which generally deal with resource constraints, and private citizens who do not have the economic capacity to purchase them. In conclusion, under these considerations, in accordance with the interpretation delivered by the Committee and in light of the further analysis presented in section 6 of this chapter, access to essential medicines constitutes a crucial component of the right to health under article 12 ICESCR. As a result, essential medicines must be available and accessible in adequate manner, meaning that essential medicines must be affordable to all individuals of the population, culturally acceptable and of good quality, and not merely physically accessible. In light

[116]Ibidem, par. 12(b).
[117]Ibidem, par. 12(c)
[118]Ibidem, par. 12(d)

of the aforementioned analysis, it is instrumental to determine State's obligations in relation to the right to health on the basis of the Committee jurisprudence[119].

2.1.3.1. State's obligations concerning the Right to Health

General Comment 14 is precise in underlying that if it certain that States parties have an obligation to implement ICESCR's standards, they are, free in choosing the manner of implementation, which can differ from state to state. This means, that the ICESCR confer to state parties a margin of discretion in assessing which measures are most adequate in protecting the Covenant's rights at the national level. Indeed, even though states parties have a considerable margin of action in determining which are the most effective measures within their domestic level, the final evaluation on the appropriateness of such measures is left to the Committee[120].

2.1.3.2.The Tripartite Nature of the Right to Health

As with all human rights, the right to health grounds on a tripartite structure which is composed of three different kinds of obligations, namely the obligations to respect, protect and fulfill. In effect, this structure makes possible the delimitation of the state's conduct in such a way that its conduct concentrates on an abstention, on intervention in the conduct of third parties, and on the direct assumption of the commitment to realize the right. The Committee on Economic, Social and Cultural Rights (General Comment 14, para. 33) defines these obligations as follows[121]: firstly, in light of their obligations to respect, States must refrain from hindering, directly or indirectly, the enjoyment of the right to health, both for the individual and collective levels. Respect

[119]Tobin, *The right to health*, 47.
[120]CESCR, *General Comment No. 3,* par. 34.
[121]Ibidem, par. 33.

is directed towards freedom of action and the use of each individual's or collective's own resources. For example, the State must refrain from adopting discriminatory policies that prevent or limit the access of certain persons to health services which is an essential element of the right to health[122].

Secondly, obligations to protect require States to take measures to prevent third parties from interfering with or hindering the enjoyment of the Convention in the matter of right to health. The State must monitor and control the activities of individuals in the provision of health services, as well as of individuals whose activity is to provide such services. In addition, the State must ensure that certain types of family or community customs or practices are taken into account so that such customs and practice do not affect people's health[123].

Finally, obligations to fulfill entail that States must adopt legislative, administrative, budgetary, judicial or other measures in order to give full effect to the right to health. This includes the organization of the corresponding public service that makes the enjoyment of the right possible. Obligations to fulfil incorporate obligations to facilitate, provide and promote[124].

As has been previously stressed, the CESCR has determined the character of states parties' obligations on the grounds of article 2 ICESCR in its General Comment No. 3[125], which highlights that these obligations include both obligations of conduct and obligations of result[126]. According to the *Maastricht Guidelines on Violations of Economic, Social and Cultural Rights,* the former set of obligations requires States to adopt reasonably calculated actions in order to fulfill the enjoyment of a specific right, while the latter obligations require States to accomplish particular goals in order to realize a specific substantive standard[127].

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[122]Ibidem, par. 35.
[123]Ibidem, par. 36.
[124]Ibidem, par. 37; S. Fukuda-Parr, *Fulfilling social and economic rights,* Oxford University Press, 2015, 65-66.
[125]UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 3.*
[126]A. Nolan, *Economic and social rights after the global financial crisis,* Cambridge University Press, 2014, 73.
[127]V. Dankwa, C. Flinterman, and S. Leckie, "Commentary to the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights", *Human Rights Quarterly,* 20 (1998), 710.

Furthermore, the Committee highlights two kinds of obligations that States must confront in relation to ESCR under the Covenant, namely *immediate* and *progressive* obligations. States parties have two main *immediate* obligations under the Covenant. These obligations are the prohibition of discrimination (in light of Articles 2.2 and 3 ICESCR)[128] and the obligation to take steps in realizing the rights provided for in the Covenant. The prohibition of discrimination has already been examined throughout the section, on the contrary, the obligation to take steps require States to proceed towards realizing the right to health with deliberate, concrete and targeted steps[129]. Indeed, if States must achieve the standards provided for in the Covenant *progressively,* these *"steps towards that goal must be taken within a reasonably short time after the ICESCR's entry into force[130]".*

Secondly*,* states parties have the obligation *to progressively* realize the implementation of the Covenant's rights in general and of the right to health in particular. In consideration of this set of obligations, states parties are free to act, provided that they employ all appropriate means and to the maximum of their available resources. As a result of this margin of discretion, progressive obligations strictly depend on the specific context in light of States' level of development and, hence, are not uniform among them[131].

Interestingly, the Committee pointed out that if states parties are incapable respect the aforementioned obligations in relation to the right to health due to their specific economic and social context, such states have an obligation to seek international assistance. Actually, there is no doubt that the protection and fulfillment of ESCR has shifted from a territorial protection to more efficient forms of international cooperation, however, this is not sufficient to conclude that developed state parties are under an

[128]A. R. Chapman and S. Russell, *Core Obligations: Building a Framework for Economic, Social and Cultural Rights,* Intersentia, 2002, 5-6.
[129]CESCR, *General Comment No. 3*, par. 3.
[130]*The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights,* par. 21and CESCR, *General Comment No. 3*, par. 2.
[131] F. Coomans, "Application of the International Covenant on Economic, Social and Cultural Rights in the Framework of International Organisations", *Max Planck Yearbook of United Nations Law,* 11, 2007, 360.

obligation to provide assistance to less developed countries[132]. In this regard, the Committee claimed that *"core obligations give rise to national responsibilities for all States and international responsibilities for developed States, as well as others that are 'in a position to assist[133] "*. From the latter wording is ambiguous whether "responsibilities" is to be understood as enforceable obligations for States and how to determine if a State is in a position to assist[134]. As a result, it seems unlikely that States have an obligation to internationally cooperate in order to provide assistance to States which are unable to fulfill their obligations[135]. This, however, is not to be interpreted that the wording of article 2 is without meaning[136]. On the contrary, such international responsibilities on states should be considered as having a complementary tool[137].

The position taken by the Committee concerning other international agreements that States parties may conclude and States' conducts within international organizations is another issue which is of particular interest in relation to the object of the present work. Indeed the Committee stated that "*States parties should ensure that the right to health is given due attention in international agreements"*[138], and that *"States parties have an obligation to ensure that their actions as members of international organizations take due account of the right to health*.[139]" In the same way the *Maastricht Principle on Extraterritorial Obligations of States in the Area of ESC Rights* affirmed that *"States must elaborate, interpret and apply relevant international agreements and standards*

[132]*The Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights*, par. 8.
[133]CESCR, *Statement Adopted by the Committee on Economic, Social and Cultural Rights on 4 May 2001. Substantive Issues Arising in the Implementation of the ICESCR: Poverty and the ICESCR* (UN Doc. E/C.12/2001/10; 2001), par. 18.
[134]F. Coomans, "The Extraterritorial Scope of the International Covenant on Economic, Social and Cultural Rights in the Work of the United Nations Committee on Economic, Social and Cultural Rights", *Human Rights Law Review,* 11:1, 2011, 21.
[135]M. Sepúlveda Carmona, "The Obligations of 'International Assistance and Cooperation' under the International Covenant on Economic, Social and Cultural Rights. A Possible Entry Point to a Human Rights-Based Approach to Millennium Development Goal 8", *The International Journal of Human Rights,* 13:1, 2009, 93.
[136]M. Ssenyonjo, "Economic, Social and Cultural Rights: An Examination of State Obligations", in Joseph S. and Mcbeth A., *Research Handbook on International Human Rights Law,* Edward Elgar, 2010, 60-61.
[137]Coomans, *The Extraterritorial Scope*, 23.
[138]CESCR, *General Comment No. 14*, par. 39.
[139]Ibidem.

in a manner consistent with their human rights obligations. Such obligations include those pertaining to international trade, investment, finance, taxation, environmental protection, development cooperation, and security[140]*."* In light of this wording, state parties have the obligation to take into account the right to health both when concluding international agreements and in performing within international organizations. In other words, the ICESCR establishes an obligation on states parties to refrain from negotiating and ratifying agreements, such as international trade agreements (i.e. in relation to IPRs), which could eventually affect the State's capacity to fulfill the right to health, including access to medicines[141]. As will be examined throughout the present work, States often adopt agreements which require higher standards of protection for IPRs than those provided for by the TRIPS Agreement. These stricter treaties, usually referred to as TRIPS-plus Agreements, may and often do, hinder patients' access to essential medicines. Unfortunately, the practice has shown that assessing whether a State has complied with the obligation of due regard to the right to health in adopting an international agreement is quite challenging. For example, when negotiating a bilateral agreement which involves IPRs provisions, a state party could comply with the aforementioned obligation, by including clauses recognizing the so-called TRIPS flexibilities in order to balance IPRs and the right to health. In practice, however, these flexibilities rarely were properly implemented, and, thus were often ineffective[142].

[140]*Maastricht Principle on Extraterritorial Obligations of States in the Area of ESC Rights,* par. 17; *"As a member of an international organization, the State remains responsible for its own conduct in relation to its human rights obligations within its territory and extraterritorially. A State that transfers competences to, or participates in, an international organization must take all reasonable steps to ensure that the relevant organization acts consistently with the international human rights obligations of that State."* Ibidem, par. 15.

[141]Sepúlveda, *The Obligations of 'International Assistance and Cooperation*, 91.

[142] UN Commission on Human Rights, *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, Paul Hunt. Addendum. Mission to the WTO (UN Doc. E/CN.4/2004/49/add.1; 2004), par. 82.

3. The Inter-American Protection of the Right to Health

The Interamerican legal framework has three key legal standards related to economic social, and cultural (ESC) rights: the American Declaration of the Rights and Duties of Man (the Declaration), the American Convention on Human Rights (ACHR), and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, known as the 'Protocol of San Salvador' (the Protocol). The applicability and protection of human rights relies on its binary structure, which is composed of two main bodies, namely, the Inter-American Commission and the Court of Human Rights (hereinafter, "IACHR" or "the tribunal").

This section deals with the study of the evolution and definition of the right to health within the Inter-American System of Human Rights through the recent jurisprudence of the two aforementioned judicial and quasi-judicial organs. Among the obligations undertaken by States under the American Convention on Human Rights (hereinafter, "the ACHR" or "the Convention"), the right to health is included in its Article 26 and is specified in Article 10 of the Additional Protocol to the American Convention on Human Rights concerning Economic, Social and Cultural Rights (hereinafter, "ESCR Protocol" or "Protocol of San Salvador"). The combination of the latter articles constitutes a minimum standard of protection, which States that are parties to the Convention shall widen with greater degree of protection that may be afforded through other international instruments or through their own domestic legal systems.

The Inter-American system constitutes a valuable example of the way the enjoyment and justiciability of the right to health is weak in practice, in spite of its incorporation in the domestic law of States parties and in various international instruments. In fact, this section highlights that, in light of current practice and jurisprudence, the right to health is not a fully enforceable right, as is any civil or political right. This is the reason that some authors argue that rights, in order to become more than mere declarations, must be protected by judicial or quasi-judicial organs whose decisions are legally binding, concluding that the absence of such bodies equals the absence of rights[143]. In

[143]S. Holmes and C. R. Sustein R., *El costo de los derechos*, Siglo Veintiuno, 2011, 37-40.

other words, until some conceptual obstacles are overcome, the alleged injured party will not be able to claim the fulfillment of States' obligations before a judge or court[144]. Furthermore, because of their strict connection with the financial status of States, it is likely that social and economic rights are applied differently in different places. Due to the high cost of these public services that require an active role by the State, resource allocation plays a key role in determining the extent and quality of the rights provided[145].

As a result of the economic dependency of social right, the study of the concrete application of the right to health in the Inter-American framework is important. After all, cultures are not static, but are in continuous movement and, fortunately, are willing to advance in the field of human rights, as evidenced by the ratification of human rights treaties by the most diverse cultures. Indeed, the legal relevance of the right to health is reflected, to a large extent, by its enshrinement in the universal system and, mainly in the regional systems for the protection of human rights.

In order to understand the content and scope of the right to health in the Inter-American System, it is necessary to analyze the relevant legal provisions provided by regional instruments and emerging commitments of the American Court of Human Rights.

3.1. The American Declaration of the Rights and Duties of Man

The American Declaration consists of 37 articles divided into two chapters: the first is devoted to the rights of the human person and the second to one's duties. The two peculiarities of the Declaration are: on one hand, the rights listed in the first chapter (Articles 1-28) include both civil and political rights, as well as economic, social and cultural rights, including property, culture, work, leisure and social security. The second chapter, unlike the Universal Declaration, also lists the duties of individuals towards

[144]M. Kaltenborn, *Social Rights and International Development Global Legal Standards for the Post-2015 Development Agenda*, Springer, 2015, 76.
[145]A. Neier, "Social and Economic Rights: A Critique", *Human Rights Brief* 13, no. 2, 2006, 4.

and within a society (articles 29-37). The duties of the individual include obligations to society, to children and relatives, the obligation to receive education, the obligation to vote, to obey the law, to serve the community and the nation, to cooperate for the respect of social security and welfare, to pay taxes, to work and to refrain from carrying out, in a foreign country, political activities that are by law limited to the citizens of that country.

The American Declaration of the Rights and Duties of Man (also known as the "Bogota Declaration") enshrines in Article XI that everyone has the right *"to have their health preserved by sanitary and social measures (...)".* The Declaration, adopted on May 2, 1948, is the first broad-spectrum international human rights instrument, preceding the Universal Declaration of Human Rights. In spite of its declaratory nature, the Declaration has, since its adoption, improved the development of the Inter-American legal framework for the protection and endorsement of human rights since its adoption. Furthermore, it constitutes, together with the American Convention on Human Rights, one of the two pillars within the OAS that establishes states' human rights obligations. The American Declaration was adopted as a *soft law* instrument, meaning as a merely declaratory and non-binding value. This instrument was to serve as a guideline for the development of the new inter-American system inaugurated with the establishment of the Organization of American States (OAS) and in line with its founding principles, including respect for the fundamental rights of the individual without distinction of race, nationality or gender[146]. In order to obtain the consent of the Member States, the Declaration was conceived as an initial form of protection of fundamental rights in connection with the social and legal conditions of the time, without excluding, however, that such a system could be strengthened under more favorable conditions[147].

Nevertheless, the inter-American system has championed the protection of human rights with the adoption of binding instruments over time. In this context, both the Commission and the American Court, as well as the General Assembly of the OAS, have acknowledged that the Declaration cannot be considered simply as *soft law,* but

[146]Organization of American States, *American Declaration of Rights and Duties of Man*, 1948, art. 1.
[147]Ibidem, Whereas IV.

constitutes a source of international obligations for OAS member states. In this regard, it is worth mentioning Resolution 314 (VII-O/77) of 22 June 1977, in which States instructed the Inter-American Commission to prepare a study in order to highlight their obligations under the American Declaration and Resolution 371 (VIII-O/78) of 1 July 1978, in which the General Assembly reaffirmed its commitment to promote compliance with the American Declaration[148]. In addition, Resolution 370 (VIII-O/78) of 1 July 1978, which, while addressing the crucial situation taking place in Paraguay, stressed the Member State's international commitments to respect the rights recognized in the American Declaration[149].

The stance taken by the quasi-judicial organ of the OAS, namely the Inter-American Commission of Human Rights, is even more strict. In fact, it is interesting to note that, according to the Commission, the Declaration is a source of legally binding obligations and not simply a political will[150]. This interpretation is clear in two specific instances: firstly, the Commission stated that the Declaration specifies all the rights that the Charter of the Organization of the American States envisaged in general terms. In fact, article 106 of the Charter authorizes the Commission to "promote the observance and protection of human rights", thus considering the American Declaration as a source of international obligations related to the Charter of the Organization[151].

Secondly, in a well-known Advisory Opinion, the Inter-American Court cites Article 1(2)(b) and Article 20 of the Statute of the American Commission, which articles refer to the Commission's obligation to adopt the human rights provisions of the American Declaration in two specific instances: firstly, to those OAS Member States which are not parties to the American Convention, and secondly, to those OAS members of the Convention that have not accepted the compulsory jurisdiction of the Court, thus

[148] Organization of American States, Ae/RES. 314 (VII-0/77), Means to promote respect for and protection of human rights, 1977, par.1; AG/RES. 371 (VIII-0/78), Promotion of Human Rights, 1978, par.4.

[149] Ibidem, AG/RES. 371 (VIII-0/78); Report of the Inter-American Commission on Human Rights on the situation of Human Rights in Paraguay, 1978, OEA/Ser.L/V/II.43Report.

[150] J. M. Pasqualucci, *The Practice and Procedure of the Inter-American Court of Human Rights,* Cambridge University Press, 2013, 26.

[151] Organization of American States, *Charter of the Organisation of American States*, 30 April 1948, art. 106.

proving the binding nature of the Declaration as an instrument applicable by the Commission[152].

The above stated interpretation had the noble objective of widening the protection of human rights within the system, and it has been defended in many final decisions of the Commission[153]. However, considering the American Declaration as a legally binding instrument contradicts basic principle of law, for instance the principle of expressing willingness to enter into a legally binding relationship[154]. In fact, without ratification or accession by all the OAS member States, the Declaration must be intended as a *soft law* instrument, namely a mere political document and not a treaty. In regard of the right to health, envisaged in Article XI of the Declaration, the legal nature of this *soft law* instrument has, however, practical purposes. In other words, the latter Article broadens the scope and concrete application of the right at stake, specifically to those States which are not members of the American Convention. The constant interpretative work of the Commission described above must be understood as an attempt designed to provide legal application to the Declaration in order to confer juridical meaning to its provisions and to provide the Commission with effective tools for the protection of human rights within States. It is important to highlight the dynamic nature of this legal source. Indeed, when *soft law* instruments do not envisage the existing law (*de lege lata*), they promote future law (*de lege ferenda*) understood in the sense of *"what the law should be"* on the grounds of moral and ethical considerations, mostly when the Declaration has been adopted by all OAS members[155]. A practical

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[152]Inter-American Court of Human Rights, *Interpretation of the American Declaration of the Rights and Duties of Man Within the Framework of Article 64 of the American Convention on Human Rights*, Advisory Opinion OC-10/89, July 14, 1989, par. 45. However, all Member States did not concur with this interpretation. In this regard Costa Rica expressed its opposition and stressed that the American Declaration must be considered as a political will, with no direct legal powers.

[153]Inter-American Commission on Human Rights, White and Potter, Resolution No. 23/81, Case No. 2141, U.S., March 6, 1981, OAS/Ser.L/V/II.54, Doc. 9 Rev. 1, October 16, 1981,

[154]C. Cerna, *"*Reflections on the Normative Status of the American Declaration of the Rights and Duties of Man Anniversary Contributions", *International Human Rights* 30 U, Pa. J. Int'l L. 1211, 2009, 2.

[155]The Commission highlights that: "*the American Declaration constitutes a source of international legal obligation for all member States of the Organization of American States, including The Bahamas". Moreover, the Commission is empowered under Article 20 of its Statute and Articles 49 and 50 of its Rules of Procedure to receive and examine any petition that contains a denunciation of alleged violations of the human rights set forth in the American Declaration in relation to OAS member States that are not parties to the American Convention/"* Inter-American Commission on Human Rights, *Prince Pinder the*

consequence is that national judges are not required to apply the Declaration as current international law, but they could take it into consideration in order to promote future law commensurate with universal justice and effective protection of human rights acknowledged by existing international non-binding instruments.

Many of the Universal Declaration's provisions, however, have become incorporated into customary international law, which instead is binding on all states. This development has been confirmed by States in intergovernmental and diplomatic settings, in arguments submitted to judicial tribunals, by the actions of intergovernmental organizations, and in the writings of legal scholars. Furthermore, the Court considered interpretation as an essential issue in its Advisory Opinions related to the American Declaration on the Rights and Duties of Man [156]. In addressing the question on the legal status of the Declaration, the Court stressed that the protection of human rights constitutes the grounds on which relies the evolution of the Interamerican system. The Court based its reasoning on the International Court of Justice's Namibia Advisory Opinion[157], and emphasized that international treaties, declarations and legal instruments in general should always be interpreted in view of the effective legal framework at the time the interpretation takes place[158].

The Declaration states that the essential rights of persons do not derive from the territorial principle, i.e. from the nationality of a person, but from his or her status as a human being. As a result, OAS members recognize that a State's legislation on fundamental rights does not create or grant rights, but only recognizes them on the grounds that such rights are applicable independently of the existence of a State.

Article 28, labeled *"Scope of the rights of man"*, includes a general limitation clause with respect to the provisions of the Declaration on Respect for Human Rights. The

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Bahamas Commonwealth of Human Rights, Report Nº 79/07, Case 12.513, October 15, 2007, par. 20.

[156]Inter-American Court of Human Rights, *Interpretation of the American Declaration of the Rights and Duties of Man within the Framework of Article 64 of the American Convention on Human Rights,* Advisory Opinion OC-10/89 of 14 July 1989, Series A No. 10, par. 37.

[157]International Court of Justice, *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) notwithstanding Security Council Resolution 276 (1970)*, Advisory Opinion, 1971, ICJ Rep 16.

[158]In doing so, the Court explicitly refused the so-called *historical interpretation*.

clause provides that: *"The rights of man are limited by the rights of others, by the security of all, and by the just demands of the general welfare and the advancement of democracy"*[159]. These reasons are, therefore, legitimate justifications for OAS members to derogate from human rights. The clause admits more cases than those provided within the United Nations' system. Accordingly, the Court had the opportunity to express itself more restrictively on the derogation of fundamental rights, for instance on the subject of *habeas corpus*. In this case the Court has made clear that the proceedings for *habeas corpus* are essential judicial guarantees for the protection of various rights and for the preservation of rule of law in a democratic society, hence declaring prohibited their derogation or suspension[160].

3.2. The American Convention on Human Rights

The American Convention on Human Rights, often referred to as the Pact of San José, was adopted in Costa Rica, on 22 November 1969, and came into force after the ratification of Grenada was deposited on 18 July 1978.

The Convention provided treaty-level protection to the rights previously contained in the Declaration, but did not provide a comprehensive legal framework related to economic and social rights. In fact, it condensed the entire area of ESC rights in a single provision, namely Article 26. The article provides a general provision requiring only the progressive development of the economic, social, educational, scientific, and cultural standards set out in the OAS Charter. This provision, must therefore be interpreted and applied depending on the specific case, even though it has been often put into effect in conjunction with other provisions[161].

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[159]Article 28 of the American Declaration on the rights and duties of man, 1948.

[160]Inter-American Court of Human Rights, Advisory Opinion, 8/87 of 30 January 1987 - Habeas corpus in state of emergency, par. 42.

[161]L. Lixinski, "Treaty Interpretation by the Inter-American Court of Human Rights: Expansionism at the Service of the Unity of International Law", *European Journal of International Law*, Volume 21, 2010, 588.

Article 26 states as follow: *"The States Parties undertake to adopt measures, both internally and through international cooperation, especially those of an economic and technical nature, with a view to achieving progressively, by legislation or other appropriate means, the full realization of the rights implicit in the economic, social, educational, scientific, and cultural standards set forth in the Charter of the Organization of American States as amended by the Protocol of Buenos Aires"*[162].

Article 26 does not provide any reference or definition of the right to health. It is therefore mandatory to study the progressive work of the ICHR, which designed the right to health in various decisions over time relying on an extensive interpretation of article 26. An important step taken by the Court was to link the principle of progressive development to the right to health as a social right.

In the case of *Acevedo Buendía and Others v. Peru* the Court determined that the commitment required by Article 26 consists of the adoption of measures, especially economic and technical to the extent of available resources, whether through legislation or other appropriate means to achieve progressively the full realization of certain economic, social and cultural rights, such as the right to health[163].

Article 26 of the ACHR establishes the scaffolding of the principle of progressive realization and prohibition of retrogression in the area of economic, social and cultural rights, as is the case with the right to health. Although this provision does not give rise to an interpretation that the American Convention expressly recognizes rights of this nature, it allows to affirm that it is the conventional obligation of States, even on the basis of the OAS Charter[164], to guarantee the securing of such rights, which, as already stated, are recognized in different instruments of the inter-American system. This means, as highlighted in a well-known Advisory Opinion, that the provisions within the Convention should be understood as taking into account the norms that are

[162]Organization of American States, *American Convention on Human Rights, "Pact of San Jose", Costa Rica*, 22 November 1969, Article 26.

[163]Inter-American Court of Human Rigths, *Acevedo Buendía and others case* v. *Perú*. Preliminary Exceptions, Merits, Remedies and Costs, Judgment of 1 July 2009, series C, n. 198, par. 105.

[164]Indeed, article 45 of the OAS Charter urges States to make every effort to develop an efficient social security policy.

envisaged in other treaties on the same subject matter. In particular, a regional treaty should be understood on the grounds of the doctrine and norms of international instruments[165]. The Court further explained that, in a case in which both the Convention and another treaty are relevant, the provision most favorable to the applicant must be considered[166]. Moreover, the obligation of non-regression constitutes an explicit limitation that human rights treaties impose on States and becomes a guarantee for citizens for the fulfillment of these rights[167].

3.3. The Optional Protocol to the American Convention on Economic, Social and Cultural Rights of 1988

It is worth noting that Article 10 of the Optional Protocol to the American Convention on Economic, Social and Cultural Rights of 1988 (also known as the Protocol of San Salvador) is the only precise and direct reference to the right to health within the Interamerican system. The protocol is an international treaty attached to the Convention, which provides a legal framework to ensure that the individuals, groups or communities may file complaints of violation of their economic, social and cultural rights. This mechanism can be triggered only to present cases in which the alleged victim has acknowledged as accountable one of the States Parties to the Convention that has also ratified the Optional Protocol.

Along with the right to health, enshrined in Article 10, the Protocol lists an array of ESC rights. However, this instrument provides for a peculiar system of protection, which relies on a specific procedural provision that limits the faculty of a victim to

[165] Inter-American Court of Human Rights, Advisory Opinion OC-5/85 of 13 November 1985, Compulsory Membership in an Association Prescribed by Law for the Practice of Journalism (arts. 13 and 29 of the American Convention on Human Rights), Series A, No. 5, par. 55.
[166] Ibidem, par. 52.
[167] V. Abramovich and L. Pautassi, *La medición de derechos en las políticas sociales*, CABA, Ed. del Puerto, 2010, 30.

activate the Commission or the Court. In fact, Article 19(6)[168] of the Protocol confer jurisdiction *ratione materiae* to the Commission and the Court explicitly over two ESC rights. Better stated, the article specifies that only the violation of the right to Trade Union (Article 8.1) and of the right to education (Article 13) may permit the triggering of the framework of individual petitions designed by the Convention[169]. This means that the Protocol itself provides for a sort of hierarchy between the rights provided and the possible breaching of obligations in violations of other than those rights expressively mentioned in Article 19.6 results in a procedural *impasse*[170].

Nevertheless, some scholars argue that the limitation set by Article 19(6) may be overcome by considering Article 26 of the American Convention directly applicable to any ESC rights violation[171]. The latter principle, often referred to as the "direct approach principle" faces an array of criticisms which rely on a literal interpretation of both Article 26 of the Convention and Article 19.6 of the Protocol. The former does not acknowledge individual, immediately actionable rights; and the latter Article, as described above, recognizes limited jurisdiction to trade union rights and the right to education. As a result, in the light of the mentioned literal interpretation, the intention of the American States preparing those two instruments was not to grant the Court powers to receive claims alleging ESC rights violations *via* the direct applicability of article 26[172].

The aforementioned *Acevedo Buendía and Others v. Peru* case constitutes a turning point in the interpretation of article 26, which departs from the literal approach towards

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[168]The article further urged, as is the case in the United Nations system, States to prepare and submit periodic reports on *"the progressive measures they have adopted to ensure due respect for the rights enshrined in the Protocol itself"*. The subsequent procedure also involves a review by the specialized agencies of the Inter-American System of the state of compliance or noncompliance with the obligations and corresponding recommendations.

[169]O. R. Ruiz-Chiriboga, "The American Convention and the Protocol of San Salvador: Two Intertwined treaties. Non-enforceability of Economic, Social and Cultural Rights in the Inter-American system", in *Netherlands Quarterly of Human Rights*, 2012, 161-162.

[170]J. L Cavallaro and E. Schaffer, "Less as More: Rethinking Supranational Litigation of Economic and Social Rights in the Americas", *Hastings Law Journal*, Vol. 56, 2005, 227.

[171] Inter-American Institute of Human Rights (IIHR}, La justiciabilidad directa de los derechos economicos, sociales y culturales ['The direct justiciability of Economic, Social, and Cultural Rights], *IIHR*, 2008, 26.

[172]Ruiz-Chiriboga, *The American Convention and the Protocol of San Salvador*, 163.

a more extensive application of the provision within the article at stake. Until the latter turning point, in no case, had any State Party objected the Court's jurisdiction *ratione materiae* concerning alleged ESC rights violations in accordance with Article 26. In fact, in the *Acevedo Buendía and Others v. Peru* case, the representatives of the government challenged the competence of the Court regarding the applicant's claim, stressing that the judicial organ lacked jurisdiction on matters related to the supposed breach of the right to social security. The State's position relied on the fact that neither had the Convention defined the right to social security, nor had the Protocol included it as one of the two rights that would be justiciable before the Interamerican framework in light of its Article 19(6)[173].

On the contrary, the judicial organ stated that in accordance with Article 62(1) of the Convention, which established the so called *compromissory clause*, the Court has full jurisdiction on "*all matters relating to the interpretation or application of this Convention"*[174]. Remarkably no reference to the Protocol was made, even if focusing on both treaties (the Convention and the Protocol) in the interpretation and application of ESC rights within the regional framework would have granted wider protection and have been in line with the State Parties' consent related to the legitimacy of the Interamerican judicial and quasi-judicial system[175].

According to Article 31.1 of the Vienna Convention on the Law of treaties of 1969, which comprises the general provisions of international law concerning treaties interpretation, *"a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose"*[176]. However, due to the special nature of human rights treaties, general norms on interpretation face some adjustments. In fact, unlike "normal" treaties, human rights instruments come into existence in order to provide specific rights to individual *vis-à-vis* States Parties and not to create mutual duties and rights

[173]Ibidem
[174]American Convention on Human Rights, Article 62.1.
[175] Ruiz-Chiriboga, *The American Convention and the Protocol of San Salvador,* 164.
[176]It is worth noting that Article 29 of the American Convention establishes hermeneutical rules in accordance to those provided in Article 31 of the Vienna Convention on the Law of Treaties (VCLT).

between States. The Inter-merican Court acknowledged and highlighted this distinctive nature of human rights treaties in the Advisory Opinion of 1982, known as *The effect of reservations in the entry into force of the American Convention on Human Rights*[177], according to which the object and purpose of these specific types of treaties play a key role in the application of general provisions of international law, above all, those related to the rules on interpretation. Article 33.4 of the Vienna Convention contains another important reference to the so-called *teleological criteria*, providing that in a case in which the literal interpretation of a provision is inconsistent with the object and purpose of the treaty, these must prevail.

This is the reason that, the Inter-American Court[178], *inter alia,* stressed that in the application of the American Convention and other instruments a *pro homine* interpretation should be used, hence interpreting the norms in the way which are most protective of the most vulnerable party in the dispute, namely the individual. According to the Court, the main reason that human rights treaties exist is to protect human beings from the authoritative power of the States, hence, limiting State's prerogatives by definition[179].

In so doing the Court explicitly dismissed the primary rule of interpretation according to general international law and emphasized that the teleological approach prevails over the literal interpretation of the legal framework, which relies on the ordinary meaning of the treaty wording. In the judgment of 1 September of 2001, on the preliminary exceptions in the *Hilaire v. Trinidad and Tobago case*[180], the Court applied the teleological approach to a declaration made by the State at the moment of accession to

[177]Advisory Opinion, 2/82 of 24 September 1982, par. 29.

[178]It must be noted that the European Court of Human Rights shares the same teleological approach in, *inter alia,* the *El-Masri v. The Former Yugoslav Republic of Macedonia* Case, 39630/09, Council of Europe: European Court of Human Rights, 13 December 2012, par.134. *"The Court reiterates that the Convention is an instrument for the protection of human rights and that it is of crucial importance that it is interpreted and applied in a manner that renders these rights practical and effective, not theoretical and illusory. This concerns not only the interpretation of substantive provisions of the Convention, but also procedural provisions".*

[179]Lixinski; *Treaty Interpretation by the Inter-American Court of Human Rights,* 590.

[180] Inter-American Court of Human Rights, *Constantine and Benjamin et al v Trinidad and Tobago, Hilaire and ors v Trinidad and Tobago*, Merits, reparations and costs, IACHR Series C no 9, IHRL 1477 (IACHR 2002), 21st June 2002.

the Convention, that had the same value as a reservation. The judges of San Jose concluded that it is for the Court to determine what a legal instrument means in light of hermeneutical rules of international law in general, and human rights law in particular, bearing in mind that the interpretation of human rights instruments has the main goal of championing the effective application (*effet utile*) of the norms, granting the highest degree of protection of individuals under its jurisdiction[181].

This approach has been confirmed in the *Mapiripán Massacre v. Colombia Case* of 2005. This, which constitutes one of the most significant cases of the Inter-American Court recent history, dealt with the attribution to the State of responsibility for human rights infringements carried out by non-state actors[182]. The Court departed from general rules of international law and stressed the special nature of human rights provisions which relies on the purposes of human rights treaties and obligations[183]. As a result the legal framework related to human rights constitutes an independent system from the general international legal structure, in which human rights treaties must be understood, *inter alia,* in light of current circumstances unlike an interpretation on the grounds of the *'original meaning'*[184].

Notwithstanding, Article 10 of the Protocol of San Salvador constitutes the only direct and precise reference to the right to health within the Interamerican system. According to the article:

1. *Everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being.*

2. In order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good and, particularly, to adopt the following measures to ensure that right:

a. Primary health care, that is, essential health care made available to all individuals and families in the community;

b. Extension of the benefits of health services to all individuals subject to the State's jurisdiction;

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[181]Ibidem, par.79.

[182]Interamerican Court of Human Rights, *Mapiripán Massacre v. Colombia Case*, Merits, Reparations, and Costs, Judgment of 15 Sept. 2005, Series C No. 134, paras. 104-108.

[183]Human rights then are considered as *lex specialis* to general international law.

[184]The reasoning of the Court was grounded on Article 29 of the American Convention, and indirectly on the rules of the Vienna Convention on the Law of Treaties.

c. Universal immunization against the principal infectious diseases;
d. Prevention and treatment of endemic, occupational and other diseases;
e. Education of the population on the prevention and treatment of health problems, and
f. Satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.

4. The Jurisprudence of the Inter-American Court of Human Rights (IACHR) referring to the Right to Health

The *Ximenes Lopes v. Brazil* case of 2006 constitutes the first case concerning the right to health before the Inter-American Court of Human Rights. The case provides a glimpse of some content of the right to health, remarkably not directly in an autonomous manner, but because of its connection with some other human rights envisaged in the Convention, such as the right to life and the right to a fair trial.
The lawsuit was filed by the Inter-American Commission on Human Rights before the IACHR for the alleged violation of the rights provided in articles 4 (right to life), (personal integrity), 8 (judicial guarantees) and 25 (judicial protection) of the ACHR, in light of the general obligation enshrined in article 1.1 (obligation to respect rights) of the same international treaty[185].

4.1. The *Ximenes Lopes v. Brazil* Case of 2006

The facts of the case concern the inhuman and degrading conditions in which the victim Ximenes Lopes, a person with mental disabilities, was hospitalized. He allegedly suffered beatings, as well as the violation of his personal integrity perpetrated by the staff members of the retirement home in which he was treated.
Ximenes Lopes was interned on October 1, 1999 in the "*Casa de Repouso Guararapes*",

[185]Inter-American Court of Human Rights, *Ximenes-Lopes v. Brazil case*, Judgment of July 4, 2006, (Merits, Reparations and Costs), par. 20.

a private psychiatric institution in Brazil, which provided health services within the framework of the Brazilian public health system, within the State of Ceará. The victim died on October 4, 1999, after three days in the hospital. In the lawsuit submitted to the IACHR, the Commission requested the Court to determine the international responsibility of the Brazilian State for the facts and for the particular condition of vulnerability of persons with mental disabilities in connection with the special obligation of the State to provide protection to persons under the healthcare centers that operate within the Brazilian Health System[186].

Under a legal perspective, the significance of the case lies mainly in the fact that it was the first opportunity for the Inter-American System for the Protection of Human Rights to formulate jurisprudence in relation to the rights of persons with mental disabilities and, for the sake of the current analysis, to shape the obligations of the State concerning the right to health in light of the management of healthcare centers which are, both under direct or indirect, control by national authorities.

In the case submitted before the Commission, the latter recalled the norms protecting the rights of detained persons as *analogia iuris*, in order to tackle the loophole in the legal system and offer an objective criterion of assessment, in relation to persons detained in institutions providing health services. It is worth noting that the Court itself addressed the issue of detained persons in several cases. In fact, the judicial body expressively proclaimed the right of whomever is detained to live in conditions of detention compatible with human dignity and, therefore the State has the obligation to guarantee anyone's right to life and personal integrity[187]. On the grounds of the aforesaid criterion, the Commission held that the State has a special position of guarantor because health authorities and their personnel have broader possibilities of establishing control over patients with mental disabilities who are in health centers under the care or protection of a trained staff, because of their vulnerable conditions.

[186]Ibidem, par. 2.

[187]Interamerican Court of Human Rights. *Instituto de Reeducación del Menor v. Paraguay*, 2 September 2004, Preliminary Objections, Merits, Reparations and Costs. Judgment of September 2, 2004. Series C, paras. 151-153; *Bulacio v. Argentina*, Merits, Reparations, and Costs. Judgment of September 18, 2003. Series C No. 100, paras. 126 and 138.

The latter status requires further measures, broader than in the case of persons housed in detention centers[188].

Finally, the Court, determined that Brazil had violated the right to life and personal integrity enshrined in Articles 4.1, 5.1 and 5.2 of the Convention, but no reference to any type of autonomous violation of the right to health was asserted. Furthermore, the Court declared the breach of the general obligation to respect and guarantee the rights established in Article1. The Court concluded ordering the State, *inter alia,* to develop a training program for medical staff on the principles that should govern the treatment of persons with mental disabilities, in accordance with relevant international standards and human rights law.

4.2. The *Albán Cornejo et al. v. Ecuador* Case of 2007

The *Albán Cornejo et al. v. Ecuador* case constitutes one of many cases that have been filed against Ecuador over the years regarding the State's failure to discipline the medical profession and properly prosecute cases of medical negligence.

On July 5, 2006, pursuant to Articles 50 and 61 of the American Convention, the Inter-American Commission on Human Rights submitted to the Court an application against the Republic of Ecuador, which originated in the complaint No. 12,406, forwarded to the Secretariat of the Commission on May 31, 2001[189].

The case dealt with the hospitalization of Laura Susana Albán Cornejo in a private health institution located in the city of Quito (the Metropolitano hospital), after she had been diagnosed with bacterial meningitis. During her stay in the institution, Mrs. Albán Cornejo had suffered severe pain. Because of these symptoms, a resident doctor had prescribed an injection of morphine to ease her discomfort. Unfortunately, the patient died, presumably due to the injection.

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[188]Interamerican Commission on Human Rights, Complaint before the Inter-American Court of Human Rights in the case of Damiao Ximenes Lopes, October 1, 2004, par. 143-144.

[189]Inter-American Court of Human Rights, *Albán-Cornejo et al. v. Ecuador,* Judgment of November 22, 2007, par. 1.

As a result, Mrs. Alban's parents requested access to her daughter's medical file pursuant a judicial action and subsequently filed a criminal complaint with the Ecuadorian judicial authorities to have their daughter's death investigated. This led to criminal lawsuits for medical malpractice against two doctors. However, one of them was dismissed because the criminal case was time-barred; and the other respondent had another legal situation pending before the national authorities at the time of the initiation of the process before the Inter-American System.

As a result of these circumstances, the Commission requested the IACHR to determine the international responsibility of the State of Ecuador for having violated rights enshrined in the Convention against Laura Albán and her parents, as indirect victims. Specifically, the Commission had alleged that the State of Ecuador had violated articles 8 (Judicial Guarantees) and 25 (Judicial Protection) in relation to articles 1.1 (Obligation to Respect Rights) and 2 (Duty to Adopt). Provisions of Domestic Law) of the ACHR (24)[190].

In conclusion, the Court held the State of Ecuador responsible without mentioning any reference to the right to health. In fact, the Court decided to hold the State internationally responsible for the violation of the right to personal integrity enshrined in article 5.1 of the Convention, in relation to article 1.1 of that treaty, and ordered Ecuador to carry out "*within a reasonable time, […] an education and training program for justice operators and health care professionals about the laws enacted by Ecuador in relation to patients' rights and"* to punish those responsible for non-compliance[191].

4.3. The *Suarez Peralta vs. Ecuador Case* of 2013

Another case related to the right to health was submitted to the contentious jurisdiction of the Inter-American Court of Human Rights, by means of a referral note from Fund

[190]Ibidem, par. 22.
[191]Ibidem, 164.

Report No. 75/11 of Case No. 12,683 of Melba del Carmen Suárez Peralta v. Republic of Ecuador[192]. This case related to the lack of judicial protection in the criminal process carried out against those allegedly responsible for the medical malpractice that affected the victim.

The facts concern the outcome of a surgery for Mrs. Suarez Peralta's appendicitis, in the private clinic called Minchala, which had provoked severe permanent damages to the patient. The criminal proceedings conducted for the clarification of the facts ended without result on the merits due to the time-barring of the case.

In light of these facts, the Commission submitted the case to the Court on the grounds of the failure to prosecute the health professionals who allegedly participated in medical malpractice, harming Ms. Suarez Peralta. The Commission requested the Court to hold the State of Ecuador internationally responsible for the violation of articles 8 and 25 (rights to judicial guarantees and judicial protection), in relation to the obligations arising from article 1.1 of the Convention.

In line with its previous pronouncements, the IACHR has held the State of Ecuador internationally responsible for the violation of the duty to guarantee the right to personal integrity, recognized in Article 5.1 of the Convention, in relation to Article 1.1 of that instrument, to Melba del Carmen Suárez Peralta, without declaring the specific violation of the right to health.

4.4. The Indirect Reference to the Right to Health by the Inter-American Court of Human Rights

In light of the aforementioned analysis, it is clear that the Court addressed and solved cases related to an alleged violation, *inter alia*, of the right to health by referring to a violation of the right to personal integrity; and the Court never based its reasoning on the direct violation of the right object of the present study.

From a legal perspective, it is not clear the reason why the Court did not apply the only

[192] Inter-American Court of Human Rights, *Suarez Peralta vs. Ecuador,* Judgement of May 21, 2013.

provision within the Convention which explicitly referred to economic, social and cultural rights, namely article 26. However, the three cases studied above have not closed the door to the enforceability of the right to health in the inter-American system[193]. Indeed, the possibility of achieving full judiciability of the right to health in light of the Convention legal framework of protection provided in the Convention remained latent until the Court's opposite approach of 2018.

This section deals with the study of the Court's jurisprudence on the indirect protection of the right to health through its connection with other civil rights envisaged in the Convention. On the contrary the next section focuses on the *Poblete Vilches and others v. Chile* Case of 2018, which constitutes a cornerstone that reversed the tide. In fact, the latter case is the first in which the Court mentioned a direct and autonomous violation of the right to health, as part of the repeatedly stressed article 26, hence, finally dissolving the bond with civil rights.

Remarkably, under the scheme of an alleged violation of the right to personal integrity ex Article 5.1 of the Convention, the Court has outlined some standards on the right to health, although, in a vague manner. For instance, the *Suárez Peralta v. Ecuador Case*, the Court has declared that lack of adequate medical care may lead to a violation of the normative content of Article 5.1 of the Convention[194].

At the same time, however, there is no question that over time the Court has built a solid system of protection, on the grounds of the various principles settled while adjudicating contentious issues. In the very first case submitted to the Court, the famous *Velásquez Rodríguez Case*, the Court has pointed out that International Human Rights law required the State to comply with a double set of peer obligations: firstly, the negative obligation of respecting the rights and freedoms recognized in the instruments for the protection of human rights; and secondly, the positive obligation relating to the

[193]It is worth noting that unlike the Court, the Committee on ESC Rights of the United Nations has pointed out that each State Party has a minimum obligation to ensure the satisfaction of at least essential levels of each of the rights. For example, a State Party is responsible under the Covenant for the deprivation of essential primary health care for a significant number of individuals.

[194]Inter-American Court of Human Rights, *Suárez Peralta v. Ecuador.* Preliminary Objections, Merits, Reparations and Costs. Judgment of 21 May 2013. Series C No. 261, par. 1/12 (operative part).

obligation to adopt all necessary measures to guarantee the envisaged rights[195]. Furthermore, the Court's jurisprudence, held that under Article 1.1 of the ACHR, States parties, such as Costa Rica and Guatemala, have an *erga omnes* international obligation to respect and guarantee the human rights established in the Convention and must ensure the concrete implementation of these rights[196].

As will be further outlined in the following sections, the obligation to actively guarantee the provisions within the Convention is not confined solely to the orbit of States and their State agents, since the obligation also includes the duty to prevent individuals or third parties from affecting protected human rights, in the private orbit, depending on the particular circumstances of each case[197].

In an array of cases, the judicial organ highlighted that the protection of the right to personal integrity relies, *inter alia,* on the regulation of health services in the internal sphere, as well as the implementation of a series of mechanisms aimed at protecting the concrete realization of the right at stake. In light of this reasoning, the Court determined that in order to comply with the obligation to guarantee the right to personal integrity in relation to the right to health, States must clearly regulate the establishment and functioning of health services[198]. These services shall bear in mind quality standards for public and private institutions in order to prevent any threat of violation of the right to personal integrity. Moreover, along with the obligation related to quality standards, the Court included that the State should provide mechanisms for monitoring and supervising health institutions, in addition to effective administrative and judicial

[195]Inter-American Court of Human Rights, *Velásquez Rodríguez v. Honduras*, Merits. Judgment of July 29, 1988, par. 165; *Santo Domingo Massacre v. Colombia*, Judgment on Preliminary Objections, Merits and Reparations of November 30, 2012. Series C No. 259, par. 188.

[196]Inter-American Court of Human Rights, *Mapiripán Massacre vs. Colombia*, Judgment of September 15, 2005. Series C No. 134, par. 111; *Ximenes Lopes v. Brazil*. Judgment of July 4, 2006, cited above, par. 85; Legal Status and Rights of Undocumented Migrants. Advisory Opinion OC-18/03 of 17 September 2003. Series A No. 18, par. 140.

[197]Case of the *Mapiripán Massacre*, par. 111; Inter-American Court of Human Rights, *Pueblo Bello Massacre v. Colombia*, Judgment of January 31, 2006. Series C No. 140, par. 123 *and Gonzalez et al ("Campo Algodonero") v. Mexico*, Preliminary Objection, Merits, Reparations and Costs. Judgment of November 16, 2009. Series C No. 205, par. 280.

[198]Inter-American Court of Human Rights. *Suárez Peralta v. Ecuador*, Preliminary Objections, Merits, Reparations and Costs. Judgment of 21 May 2013, cit. par. 134; Case of *Ximenes Lopes v. Brazil*, par. 99.

protection procedures for the victim[199]. The latter constitute the first set of obligations arising from the interconnection between the right to health and the right to personal integrity[200].It is remarkable that the source of the international responsibility of the State in cases involving the health of individuals has been determined without an autonomous consideration of the right to health, but through the normative content of the right to personal integrity[201]. In other words, the State has the obligation to adopt active measures in order to protect patients` integrity and lives. To this end, public authorities must guarantee quality of health services and regulate public and private medical professions[202].

According to the Court, the obligation to monitor and supervise constitutes the other side of the relationship between the right to health and personal integrity. Patients are under State's responsibility both when in public or private facilities. Indeed, there is no doubt that the State is directly responsible when it provides services first-hand to the population through public healthcare institutions such as hospitals or clinics. The State is further accountable when health services are provided by private institutions as a result of contracts with the State[203]. Thus, although States may delegate their functions, through so-called privatizations, they retain ownership of the obligation to provide

[199]The European Court of Human Rights adopted a similar reasoning in many cases brought before its jurisdiction. According to the judicial body, States are required under the European Convention to adopt the necessary measures in order to protect the life of persons in the sphere of public health. These measures entail positive obligations to regulate public or private health institutions in order to protect the life of its patients. European Court of Human Rigths, *Calvelli and Ciglio v. Italy* Case, nr. 32967/96. Judgment of 17 January 2002, paras. 09 and 49.

[200]Using the Court's wording: *"(...) States are responsible for regulating on an ongoing basis the provision of services and the implementation of national programmes relating to the achievement of quality public health service delivery in such a way as to discourage any threat to the right to life and physical integrity of persons undergoing health treatment. (...) They should, inter alia, create adequate mechanisms to inspect institutions, (...) present, investigate and resolve complaints and establish appropriate disciplinary or judicial procedures for cases of professional misconduct or violation of patients' rights"*. Inter-American Court of Human Rights, *Suárez Peralta v. Ecuador*, Preliminary Objections, Merits, Reparations, and Costs. Judgment of 21 May 2013, par. 136.

[201]Ibidem

[202]The UN Committee of ESC rights further detailed the obligations arising from the violations of third parties and stated that the State is responsible for the violation of the duty to protect the right to health when it does not adopt measures that explicitly regulate the conduct of non-state actors. UN, Committee on ESC Rights. *General Comment* 14, par. 40.

[203]Inter-American Court of Human Rights. *Suárez Peralta v. Ecuador,* Preliminary Objections, Merits, Reparations and Costs. Judgment of May 21, 2013, par. 145.

public services and to protect the respective public good[204]. As a result, the Court identifies a special obligation of safeguarding in accordance with its duty of providing an effective healthcare system. Better said, the formal delegation to private health entities by the State does not exempt it from its duty to guarantee the quality of private health care, as another aspect of the relationship between the right to personal integrity and health[205].

In summary, the State is responsible for omission if it does not comply with its duty to monitor the adequate enforcement of the provisions concerning healthcare services by both the private and public system. Instead, in regard to oversight the quality of health services, the IACHR has emphasized that "*(...) the State has the duty to regulate and supervise health benefits, ensuring, among other aspects, that health conditions and personnel are adequate, duly qualified, and remain fit to practice their profession"*[206].

[204]In light of reasons that are similar to those set forth by the IACHR, the Committee on ESC Rights of the International Covenant on Economic, Social and Cultural Rights has noted in its General Observation No. 14 that the right to life and the integrity of the patient are affected in the event of being treated in institutions, without proper authorization, without adequate infrastructure or hygiene to provide medical services, or by professionals who do not have the necessary qualifications for such activities.

[205]" The obligation of state control includes both services provided by the State, directly or indirectly, as well as those offered by private individuals". This duty extends to situations in which the service has been delegated, in which individuals provide it for the account and order of the State because it is a good of the highest social interest, the vigilance of which is also the responsibility of the public power". IACHR, *Albán Cornejo et al. v. Ecuador Case*. Reparations and Costs Fund. Judgment of November 22, 2007, par. 119.

[206]IACHR Court. Case of Suárez Peralta v. Ecuador. Preliminary Objections, Merits, Reparations, and Costs. Judgment of May 21, 2013, par. 153.

5. The turn in the Inter-American Court's approach on social rights

This section will focus much on the analysis of the change in perspective of the approach of the Inter-American Court of Human Rights in addressing the right to health. The turning point was marked by the adoption of the decision in *Poblete Vilches and others vs. Chile case* adopted in March of 2018. Indeed, this judgment was the first in which the Court considered the right to health in an autonomous manner and, enabling the right to health's being directly demanded before both the Commission and Court.

5.1. The *Poblete Vilches* Case of 2018

Briefly, the case concerned the malpractice in treating a senior Chilean citizen in a public hospital, where his special needs were not taken into consideration, which subsequently led to his death. Firstly, Mr Poblete was hospitalized, (following a diagnosis of diabetes), at which hospital he was not treated properly for his illness and in consideration of his advanced age. Due to his state of unconsciousness, he could not consent to surgery. His family was not consulted; indeed, investigations found consents documents were falsified by the medical personnel. Mr Poblete was then discharged from Hospital, after which his conditions became grave. Family members were not informed of this discharge, leaving him with no proper care. As a result of his increasing illness, he was returned to hospital by private ambulance, where the lack of care and adequate treatment was repeated. Mr Poblete was declared deceased on 7 February 2001[207].

In assessing the case, the Court specified that the right to social security was not analyzed because the right to health, life and integrity sufficed[208]. Furthermore, the Court cited its decision in *the Lago del Campo case* in which two key aspects were highlighted[209]: on the one hand, the Court's competence on Economic, Social and

[207]Inter-American Court of Human Rights, *Poblete Vilches and others vs. Chile*, 8 March 2018, par. 1.
[208]Ibidem, par. 99.
[209]L. Palladini, "Una nuova tappa nella giurisprudenza della Corte IDH: la giustiziabilità diretta del

Cultural rights in light of article 26 of the American Convention; on the other, the direct justiciability of this category of rights was substantiated[210].

The Court's competence was supported on the basis of the principle of interdependence of human rights, on the grounds of the Preamble of the Convention, which makes a direct reference to the Universal Declaration of Human Rights and to the Charter of the OAS[211]. In summary, the aforementioned principle states that all rights must be understood integrally and in a conjoint way as human rights, without hierarchy among themselves and as enforceable in all cases before the competent domestic and international authorities[212].

Additionally the Court, while recalling its decision in the aforementioned *Lago del Campo case,* included economic, social, cultural and environmental rights as part of the newly established international human rights law *corpus juris* on the grounds of an evolutionary and teleological interpretation of article 29 (d) of the American Convention, which completes the framework with the provisions enshrined in the OAS Charter and American Declaration on the Rights and Duties of Man[213].

According to the Court, progressive obligations refer to concrete and constant obligations in order to advance as expeditiously and effectively as possible towards the full protection and implementation of the ESCR. In other words, public authorities must design a plan of action at once and provide precise targeted policies, which must be implemented in accordance with the principle of due diligence and in a timely manner[214]. In the same way, the Court highlighted another key principle concerning ESCR, namely the obligation of non-regression. The latter states that if States have already adopted a defined set of norms for the protection of human rights, they must

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diritto al lavoro", *DPCE Online*, [S.l.], v. 33, n. 4, 2018.

[210]*Poblete Vilches and others vs. Chile*, par. 100.

[211]Ibidem, par. 102.

[212]N. Carrillo-Santarelli, "The Autonomous Justiciability of the Right to Health and Supervision of Immediate Obligations of States in the Inter-American Human Rights System", *DPCE Online* 37(4), 2018, 1208-1210.

[213]Article 29 (d): *"No provision of this Convention shall be interpreted as: excluding or limiting the effect that the American Declaration of the Rights and Duties of Man and other international acts of the same nature may have".*

[214]Ssenyonjo, *Economic, Social and Cultural Rights,* 58.

prohibit establishment of norms which could hinder and worsen the level of protection currently achieved[215]. Indeed, if a State does not comply with the principle of non-regression, it has to justify the reason it had adopted those measures *"with the most careful consideration"* and, only after a *"strict scrutiny",* the State can prove that it was forced to do so in light of its financial and economic situation[216]. These provisions must be understood in light of Article 1.1 of the American Convention, which requires States to adjust and implement, *inter alia,* legislative measures in order to respect the international human rights legal framework[217]. For the sake of clarity, the Court did not go further in analyzing the features of progressive obligations of States and did not determined a violation of the progressive element of the right to health by Chile, as the State had shown commitment in the enlargement of healthcare services in the country[218].

Instead, the Court declared a violation of the obligations under Article 26 ACHR and grounded its decision in light of the second category of legal obligations, namely immediate obligations concerning the right to health. Furthermore, the Court emphasized the need to take into account basic and concrete health services required in situations of urgency and medical emergency, such as, in the case object of this analysis, the age of the patient[219]. The judicial body nourished its reasoning on immediate obligations with the indications provided for by the Committee on ESCR in its *General Comment No. 14 on the Right to the Highest Attainable Standard of Health.* The Committee highlighted that the Covenant on ECSR imposes, also, obligations of legal effects on State parties, such as, among others, *"the guarantee that the right will be exercised without discrimination of any kind (art. 2.2) and the obligation to take steps (art. 2.1) towards the full realization of the article"*[220].

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[215]Inter-American Court of Human Rights, *Poblete Vilches and others vs. Chile*, 8 March 2018, par. 104.
[216] ICESCR, Arts 4–5; CESCR, *General Comment 3*, para 9.
[217]Inter-American Court of Human Rights, *Poblete Vilches and others vs. Chile*, 8 March 2018, par. 104.
[218]Ibidem, par. 134.
[219]Ibidem, paras. 116-134.
[220]CESCR, *General Comment 14,* paras. 30-31.

The Court stressed that the right to health entails a comprehensive *status* of full physical, mental and social welfare and must be understood as the sole absence of afflictions or illness. In this regard, States must guarantee access to essential health services that are efficient, have good quality and aim at improving the health of their populations. In addition, the Court further stated that the principle of non-discrimination must be considered thoroughly, in particular for persons who are involved in situations of risk or vulnerability and which require equal access to health services[221].

It must be noted that the Court provided that States must oversee that immediate obligations are respected by both public and private health providers, highlighting the need for a prompt implementation of National Health Programs which must ensure appropriate hygienic conditions, adequate facilities and qualified medical professionals[222]. At the same time, the Court analyzed and provided specific legal obligations in relation of the four basic standards of urgent health services already highlighted by the UN Committee in its General Observation n. 14, namely, quality, accessibility, availability and acceptability. Firstly, States must provide sufficient elements and medical staff in order to deliver basic and urgent treatments. Secondly, facilities, goods and services must be accessible for anyone in light of the principle of non-discrimination and informed consent. Thirdly, States must establish a system in which health institutions, with a sufficient number of providers and material elements, can be coordinated in order to provide urgent services in a timely manner to those in need. Lastly, medical ethics, adequate cultural criteria, gender perspectives, life conditions and proper information about diagnosis and treatment must be always taken into account[223].

Another aspect of the decision which is worth noting is the Court's analysis on whether deaths in medical contexts can trigger State responsibility in relation to article 4 of the American Convention, namely to the right to life. The Court began its analysis with the understanding that not every death, as a resulted of medical malpractice, can be

[221]Inter-American Court of Human Rights, *Poblete Vilches and others vs. Chile*, 8 March 2018, paras. 118-123.
[222]Ibidem, paras. 120-124.
[223]Ibidem, par. 121.

imputable to the State and specific circumstances of the case must be considered[224]. Indeed, the Court stated that in order to assess States' responsibilities, three basic requirements must be fulfilled: firstly, the predictability of risk as a consequence of the lack of indispensable medical services; secondly, evident and grave medical malpractice.; and lastly, a casual nexus between the medical conduct and the death must be identified. In other words, the Court emphasized that the aforementioned nexus does not entail solely a direct connection between medical treatment and death, but the State is responsible if satisfactory, timely and adequate treatments that were not given could have likely averted the deadly outcome[225].

Under this reasoning, the Court assessed that Chile was responsible for the conduct of the Hospital Rio Grande medical personnel, which did not provide prompt, urgent and basic services that were needed by Mr. Poblete[226]. In addition, the aforementioned personnel should have acknowledged the risk caused by the lack of treatment, in particular, taking into account the advanced age of the patient and that there was no justification for their denial[227]. Indeed, the Court concluded that there was a high probability that adequate health care might have at least prolonged the life of Mr Poblete Vilches; hence, the casual nexus existed and the omission of basic health treatments affected his right to life[228].

In conclusion, this case constitutes a fundamental building block in the protection of the ESCR in general and of the right to health in particular. In the proceedings described in the previous section, cases which involved health related issues were considered as *indirect* violations of other rights provided in the American conventions, namely the right to life (Article 4, ACHR), to personal integrity (Article 5.1, ACHR), and to a fair trial and effective judicial protection (Articles 8 and 25.1 ACHR). The ambiguity of Article 26 of the Convention and the limitations of the Court's jurisdiction established in Article 19.6 of the "San Salvador Protocol" undermined the protection of social

[224]Ibidem par. 147.
[225]Ibidem par. 148.
[226] Carrillo-Santarelli, *The Autonomous Justiciability of the Right to Health,* 1211.
[227]Inter-American Court of Human Rights, *Poblete Vilches and others vs. Chile*, 8 March 2018, paras. 149-150.
[228]Ibidem, par. 151.

rights until the shift asserted in 2017, in the ruling of the Lagos del Campo vs Peru case, in relation to the right to work, and in 2018, as described above, for the first time the Court made an express and direct reference to article 26 of the Convention in order to give effective protection to the right to health. In addition, the Judicial body delivered and presented a set of key provisions in relation to specific immediate obligations that States must comply in light of the American Convention - in doing so providing a pattern, certainly non inclusive, but with a practical use.

Interestingly, the aforementioned shift in the Court's jurisprudence regarding the direct justiciability of the right to health did not occur from dawn to dusk. In fact, until the *Albán Cornejo vs Ecuador case* of 2007, judges of the Court agreed on denying the direct justiciability of the right to health, as explicitly affirmed in then-judge Sergio García Ramírez separate opinion[229]. Later, in 2013, in the *Suárez Peralta vs Ecuador case,* the current president of the Inter-American Court Eduardo Ferrer MacGregor, expressed his perspective on providing insights in considering a direct violation of the right to health on the grounds of the interpretation of Article 26 of the American Convention[230]. The President argued that the absence of an explicit reference to the right to health in the case (and in the American Convention) does not impede the Court from referring directly to it in light of the general principle of law *iura novit curia*, "*which international case law has used repeatedly, (understanding it) in the sense that the judge has the power and even the obligation to apply the pertinent legal provisions in a litigation, even when the parties do not cite it expressly*"[231].

On the contrary, it is worth mentioning Judge Humberto Sierra Porto's concurring opinion in the *Poblete Vilches Case*, in which, he agreed with the final decision, but disagreed on the direct justiciability of the right to health in light of article 26 of the

[229] Separate opinion of judge Sergio García Ramírez regarding the Judgement rendered by the Inter-American Court of Human Rights in the *Albán Cornejo vs Ecuador* case of November, 2007, par. 8.
[230]Separate opinion of judge Eduardo Ferrer MacGregor regarding the Judgement rendered by the Inter-American Court of Human Rights in the *Suárez Peralta vs Ecuador case* of May, 2013, par. 91.
[231]Ibidem par. 92. See also, Case of *Cantos v. Argentina*. Merits, reparations and costs. Judgment of November 28, 2002, Series C No. 97, par. 58; Case of *S.S. "Lotus."* Series A No. 10. Judgment of 27 September 1927, 31; and ECHR. *Handyside v. United Kingdom*. No. 5493/72. Judgment of 7 December 1976, par. 41.

Convention. In fact, according to the judge the shift of perspective adopted by the Court could be destabilizing for the entire system. In summary, the Judge's opinion grounds on the assumption that the current Inter-American legal framework does not allow the Court to consider the right to health as an autonomously justiciable right. The Judge considered that the analysis on the *nexus* between the rights to life and integrity and health-related aspects would have sufficed in order to assess the present case. Furthermore, according to the Judge, the Court's decision is ambiguous in providing the specific impact of the right to health on the victim in this "individual" dimension and assumes a consequentialist position that fuses - and confuses - the effect on the integrity and life of Mr. Poblete Vilches with the violation of his right to health[232]. In other words, the Court primarily focuses on establishing the reasons that the State failed to comply with its obligations regarding health-related services, deriving from that, that his health was affected.

The right to health should be analyzed under two different perspectives: on the one hand, its individual dimension must be taken into account, which entails a connection with the right to personal integrity and/or to life; on the other hand, the progressive dimension, which relates to the adequacy of the health services provided by the State, must be considered as well. Under this reasoning the Court would be able to differentiate whether a State's conduct is in breach of the right to health and physical integrity in a specific case, or/and whether public policies adopted by a State are in breach of the general principle of progressiveness under article 26 of the Convention[233]. In other words, the Court is then able to make a distinction between individual-conjunctural violations on the one hand, and collective-structural ones on the other.

According to the Judge, the methodology adopted by the Court made the detection of the causal link between the actions and omissions of the State and the harm suffered in relation to Mr. Poblete Vilches' right to health difficult to detect[234]. Even though the Court listed a series of actions which determined a violation of the right to health by

[232] Concurring opinion of Judge Humberto Sierra Porto regarding the Judgement rendered by the Inter-American Court of Human Rights in the in the *Poblete Vilches Case* of March 2018, par. 9.
[233]Ibidem par. 12.
[234]Ibidem par. 14.

the State, in the Judge's view, the casual link between the conduct of the State and the violation of the right to health was not clear, mainly because of the performative nature of the latter right. Providing a clear definition of the features and of the performance required in order to respect the right to health would have turned the Court in a legislative assembly which in light of a specific violation could wrongly determine the violation of the entire health-care system of a State[235].

Another consideration which is worth mentioning concerns the principles of interdependence and indivisibility of human rights in light of an extensive interpretation of article 26. In the Judge's opinion, indeed, these principles entail that the enjoyment of a right depends on the realization of other rights, but this does not imply that ESCR must automatically be incorporated into the content of the Convention; and the jurisdiction of a court can be altered[236]. In other words, the aforementioned principles allow a broader understanding of the rights protected by the Convention, but do not mean an unlimited expansion of the Court's competences.

According to the Judge, the reading of Article 26 in light of the broader interpretation of article 29 of the Convention would expand the Court's jurisdiction extensively away from the competences formerly accepted by States. Following this maximalist logic, on the basis of article 29 of the Convention, the Court would have jurisdiction to declare the international responsibility of the State when it qualifies that it has violated a ESCR recognized in domestic or international law, turning article 26 in a permanent referral norm through which any kind of ESCR violation can assessed by the Inter-American Court[237]. It must, hence, bear in mind that the Inter-American Court is an international tribunal, not a constitutional tribunal, and that the American Convention is an international treaty, not a national constitution[238].

In the same way, article 29 of the Convention must be understood as an important tool in preventing States from limiting rights recognized at the national level or in other international instruments in light of Convention and in updating the normative content

[235]Ibidem
[236]Ibidem, par. 15.
[237]Ibidem, par. 17.
[238]Ibidem

of the Convention itself. On the contrary, using the latter article in order to assess a violation of rights which are not provided for in the Convention would determine an abuse of the *pro-person principle* and a violation of the principle of legal certainty that would not allow States to foresee the type of conduct in which they must engage in compliance with their international obligations[239].

Judge Humberto Sierra Porto concluded that the Court must be especially careful not to confuse the obligations that emanate for the States by virtue of conventional clauses, which recognize rights and obligations of immediate enforceability, and over which the Court has jurisdiction, of those norms or principles that serve for the interpretation of such conventional clauses, such as *soft law* instruments[240].

In conclusion, regardless of whether or not one shares Judge Sierra Porto's opinion, it cannot be denied that the Poblete case constitutes a milestone in the protection of ESCR and in assessing progressivity aspects, which are further examined in the analysis of the recent case against Guatemala presented in the next section. Furthermore, the direct approach adopted by the Court permits a deeper understanding of the different components and features of the right to health, which will allow national courts to have clear standards about access to, and quality of, healthcare services in accordance to General Comment No. 14 of the Committee on Economic, Social and Cultural Rights[241]. A more detailed analysis, is however required, if the Inter-American Court decides to deliver structural remedies relating to key issues of healthcare services, both from a domestic and an international view.

Interestingly, after the present case, ESC rights acquired autonomous strength in terms of access to justice; and they do not longer constitute an extension the civil and political counterparts. This shift in perspective must be understood as another step in getting over the obsolete distinction among human rights and in enhancing the principle of indivisibility among them.

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[239]Ibidem par. 20.
[240]Ibidem par. 21.
[241]Pedro Villarreal, "The Direct Justiciability of the Right to Health at the IACtHR – What is the Added Value?", *Völkerrechtsblog*, 22 October 2018.

Surely, the complex constitution of the right to health entails a further and instrumental examination of the wider economic and political context of each State involved in an alleged violation. As with other social rights, the establishment of a human-rights friendly healthcare sector depends on economic resources and political decisions which must always be taken into account. Nonetheless, the Inter-American Court's new approach towards ESCR may provide further guidance for national policy-makers in order to respect and implement their human rights obligations.

5.2. *The Cuscul Pivaral* Case of 2018

The Inter-American Court of Human Rights (IACHR) reached a decision in the case Cuscul Pivaral v. Guatemala on 23 August 2018. In the Judgment, the Court declared, for the first time in its more than 40 years as an international tribunal, the violation of the obligation of progressive realization (article 26 of the American Convention) which focused on the lack of treatments of 49 people living with HIV/AIDS.

The judgment in the case of *Cuscul Pivaral and others v. Guatemala* (hereinafter "the judgment" or "Cuscul Pivaral") constitutes a milestone in the shift of jurisprudence concerning the protection of ESCRs within the inter-american system. The Judgment fuels the approach followed by the Inter-American Court of Human Rights in recent cases with respect to the direct justiciability of the ESCR and the interpretative scope of Article 26 of the American Convention on Human Rights.[242]

The Judgment reaffirms that the right to health stems from the economic, social, educational, scientific, and cultural norms contained in the Charter of the Organization of American States; and, it further reaffirms that in light of an extensive interpretation

[242] Inter-American Court of Human Rights, *Acevedo Buendía y otros ("Cesantes y Jubilados de la Contraloría") Vs. Perú. Excepción Preliminar, Fondo, Reparaciones y Costas*. Sentencia de 1 de julio de 2009. Serie C No. 198. *Cfr. Caso Lagos del Campo Vs. Perú. Excepciones Preliminares, Fondo, Reparaciones y Costas.* Sentencia de 31 de agosto de 2017. Serie C No. 340 and *Cfr. Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359.

of Article 26 of the American Convention, the right at stake is autonomously justiciable before the Inter-American Court of Human Rights. In fact, as examined in the previous section on the *Poblete case*, the Court highlighted that the right to health can be identified through Article 26 of the ACHR in light of the norms contained in the OAS Charter which are binding for all States parties[243]. This new approach towards the right to health differs deeply from the aforementioned position of the Court, which protected the right indirectly in connection with civil and political rights, such as the right to life or personal integrity[244]. In addition, the Judgment addresses an important distinction that is both relevant to the present case and current analysis on ESCR: namely, the distinction between immediate and progressive obligations[245].

Interestingly, the Cuscul Pivaral case confirmed recent Court's Jurisprudence on direct juscticability of ESCR, but also introduced five important considerations that are relevant in the present section. The first of these considerations is that the present Judgment furthered the analysis and reasoning on the direct justiciability of the ESCRs in general and of the right to health in particular. Secondly, the Judgment identified precise health standards applicable to people living with HIV[246] in doing so extending what has already been stated in this regard in the cases of *Gonzáles Lluy v. Ecuador and Duque v. Colombia*[247]. Thirdly, the Court highlighted the obligations on State's

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[243]In this regard, the IACHR pointed out that: *"the Court considers that the consolidation of the right to health gives rise to various applicable standards [...] relating to basic and specific health benefits [...]". Case of Poblete Vilches et al. v. Chile*. Fund, Reparations and Costs. Judgment of 8 March 2018. Series C No. 349, par. 116.

[244]*Caso I.V. Vs. Bolivia. Excepciones Preliminares, Fondo, Reparaciones y Costas*. Sentencia de 30 de noviembre de 2016. Serie C No. 329; *Caso Chinchilla Sandoval y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas*. Sentencia de 29 de febrero de 2016. Serie C No. 312; *Caso Gonzales Lluy y otros Vs. Ecuador. Excepciones Preliminares, Fondo, Reparaciones y Costas.* Sentencia de 1 de septiembre de 2015. Serie C No. 298, y *Caso Suárez Peralta Vs. Ecuador. Excepciones Preliminares, Fondo, Reparaciones y Costas*. Sentencia de 21 de mayo de 2013. Serie C No. 261.

[245] E. Ferrer Mac-Gregor, "La Justiciabilidad de los Derechos Económicos, Sociales, Culturales y Ambientales en el Sistema Interamericano de Derechos Humanos", *Estándares del Sistema Interamericano de Derechos Humanos: miradas complementarias desde la academia,* Núm. 5, 2017, 54-57.

[246]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párrs. 42-45.

[247]*Caso Gonzales Lluy y otros Vs. Ecuador. Excepciones Preliminares, Fondo, Reparaciones y Costas.* Sentencia de 1 de septiembre de 2015. Serie C No. 298, párrs. 197 a 205.

Parties deriving from the principle of non-discrimination in relation to *vulnerable groups*, such as pregnant women living with HIV[248]. The fourth consideration, which makes the Judgment a milestone in the Jurisprudence of the Court, is that it is first time in the Court's history in which the latter determined State's responsibility for a violation of the obligation of progressive realization envisaged in Article 26 of the American Convention[249]. Moreover, in regard to progressive obligations, the Judges provided objective standards in order to identify State's efforts in taking steps towards the realization of the right to health. Finally, the Court established reparation measures that address both the victims of the case and aimed at improving the structural deficiencies of the State to provide comprehensive health care[250].

5.3. Progressive Obligations concerning the Right to Health in light of the Inter-American Court of Human Rights

Understanding the framework in relation to the progressive realization of the obligations related to ESCR in general and to the right to health in particular is the baseline in assessing State's responsibility in the present case. The judicial effort in establishing the boundaries of this kind of international obligations took its first steps in the *Acevedo Buendía and othes v. Peru case.* In the latter, the Court stressed that the fulfillment of ECSR cannot be achieved in a short period of time; and flexibility is required both in light of the global context in particular and in light of the specific situation of the country[251]. Despite the aforementioned flexibility, the State has an immediate obligation to act, meaning to adopt measures, usually legislative, in order to set the stage for the effectiveness of the rights involved. The economic and financial

[248]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párrs. 128-139.
[249]Ibidem, paras. 140-148.
[250]Ibidem, paras. 198-213 and 224- 230.
[251]L. O. Giupponi, "Assessing the evolution of the Inter-American Court of Human Rights in the protection of migrants' rights: past, present and future", *The International Journal of Human Rights* 21:9, 1485.

situation of the State, however, must always be taken into consideration[252]. Under these considerations the Court identified related obligations of non-regression which aimed at permitting restrictive measures only in exceptional circumstances, namely when States acted in light of their economic and financial constraints and proved that their conduct was adopted after careful consideration of all the provisions envisaged in the CESCR[253].

In this regard, it should be noted that the United Nations Committee on Economic, Social and Cultural Rights has presented criteria for the assessment of retrogressive measures. In order for regressive measures to be legitimate, States must demonstrate, *inter alia*, that such measures are (a) temporary, (b) necessary, (c) non-discriminatory or do not disproportionately affect disadvantaged and marginalized individuals and groups, and (d) that they at least respect the basic obligations of the social rights in question and are applicable to the specific population group in question[254].

In the present case the Court concluded that Guatemala violated the principle of progressive realization provided for under a joint-interpretation of Article 26 and 1.1 of the American Convention as a result of the State's inaction regarding the protection of the right to health for people living with HIV in Guatemala despite the existence of an international obligation and state regulation[255]. The Court grounded its decision on the assumption that the progressive dimension of the ESCR, while recognizing a certain degree of flexibility for their realization, also include an obligation of progress that requires an effective and continuous improvement of rights in such a way that social

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[252]Caso Acevedo Buendía y otros ("Cesantes y Jubilados de la Contraloría") Vs. Perú. Excepción Preliminar, Fondo, Reparaciones y Costas. Senten0cia de 1 de julio de 2009. Serie C No. 198, párr. 102.

[253]Committee on Economic, Social and Cultural Rights, General Comment No. 3.

[254]Committee on Economic, Social and Cultural Rights, General Comment No. 22 on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/GC/22, 2 May 2016, par. 38 and General Comment No. 23 on the right to just and favourable conditions of work (article 7 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/GC/23, 27 April 2016, par. 53.

[255]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 148.

inequalities are corrected and the inclusion of vulnerable groups is facilitated[256]. On these grounds the Court noted that Guatemala, despite having a series of laws and public policies for the treatment of people living with HIV in force prior to 2004, in practice, 48 of the 49 victims of this case did not have access to medical care[257].

In summary, the main argument delivered by the majority of the Judges in the *Cuscul Pivaral case* is that, despite the State's enjoyment of a margin of action for the fulfillment of its progressive obligations in realization to ECSR, this cannot be understood as free rein to not adopt any protective measures or to adopt measures which are not effective to their scope, especially in a situation in which vulnerable people are involved, such as people living with HIV[258]. The Court defined the vulnerability of this group of people in light of the nature of this chronic disease, of the high risk of suffering the so-called opportunistic diseases and of the high risk of being marginalized due to their condition. Chances that their right to life and personal integrity could be negatively affected are, hence, much higher in that condition of vulnerability.

Interestingly, the Court did not identify a violation of the principle of non-regression in the protection of people living with HIV in Guatemala, since the Judges recognized the provision of a series of laws, public policies and budget increases, especially after 2004, aimed at tackling the current issue. These measures, however, did not suffice in protecting the right to health of people living with HIV in practice[259].

Assessing whether a State is in compliance with its obligation of progressive realization of ESCR is not always an easy task, mainly in light of both its undefined nature and of the current economic and financial situation of the State involved. In this regard, along with the United Nations Committee on ESCR, the General Assembly of the Organization of American States (OAS) adopted a resolution with the aim at establishing a more confined set of standards in order to assess States' compliance with the principle of progressive realization. It is worth noting that the resolution, labeled

[256]Ibidem, par. 146.
[257]Ibidem, par. 119.
[258]Reasoned Vote of Judge E. Ferrer Mac-Gregor, par. 7.
[259]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 41-54.

Progress Indicators for measuring rights under the Protocol of San Salvador, is not a legally binding instrument, and *rationae materiae* has some kind of soft law legal effect merely for States' parties of the Protocol under the principle *pacta tertiis nec nocent nec prosunt*[260]. In other words, these criteria serve as the basis for States Parties to the Protocol to submit information on compliance with their obligations under the rights contained within. Furthermore, the jurisdiction of the Court to hear violations of the Protocol of San Salvador encounters the limits set for in Article 19(6) of that instrument already described in the Chapter. Notwithstanding, this does not mean that the Resolution is meaningless. The aforementioned criteria may still serve a practical function and be essential in assessing States' compliance with ESCR in relation to Article 26 of the Convention. Indeed, these criteria have a strong probative value before both the Court and the Commission, since they can be used by States as evidence in order to formulate solid legal arguments showing compliance with the effective realization of the rights in the terms of Article 26 of the American Convention.

Interestingly, national Constitutional Courts of the region seem to be in line with the system established by the Inter-American framework in relation to the progressive realization of ESCR. In this regard it worth mentioning two examples in which national Highest Courts addressed the issue object of the present analysis adopting a similar reasoning.

According to the Colombian Constitutional Court progressive obligations ground on three specific considerations on the judicial enforceability of social rights: primary, the existence of public policies oriented to the effective enjoyment of rights; secondly, these public policies must require a system of judicial protection for their implementation; finally, these policies must establish mechanism in order to limit the implementation of discretionary regressive measures[261]. Furthermore, the Court specified that regressive measures must be understood as measure which limit the

[260]O. Dörr and K. Schmalenbach, *Vienna Convention on the Law of Treaties- A Commentary,* Springer, 2018, 701.

[261]Corte Constitucional de Colombia. Sentencia T- 302/2017, Magistrado Ponente: Aquiles Arrieta Gómez, 8 de mayo del 2017, puntos 8.1.6., 8.1.7. y 8.1.8.

substantive scope of protection of the right involved and when the requirements for the enjoyment of such right substantially increased. In addition, a regressive measure is such if public authorities restricted or diverted the budget previously allocated for the protection of the right involved[262]. Under the aforementioned consideration, the Court stated that if a regressive measure is subject to constitutional control, the burden of proof on the State is to demonstrate, with sufficient and pertinent data that: i) that the measure seeks to satisfy an imperative constitutional purpose; ii) that, after a judicious evaluation, it is demonstrated that the measure is effectively conducive to achieving the desired purpose; iii) that after an analysis of the different alternatives, the measure appears necessary to achieve the proposed goal; iv) that it does not affect the unavailable minimum content of the committed social right; and v) that the benefit it achieves is clearly greater than the cost involved[263].

In the same way, the Guatemalan Constitutional Court has established whether or not a measure is regressive: (i) when it reduces or limits the substantive scope of protection of the respective benefit right; (ii) when it substantially increases the requirements for access to the right in question; and (iii) when it effectively and significantly reduces or diverts public resources allocated to the satisfaction of the right, before the fulfillment of such right. In addition, the Court stressed that regressive measure could be justified in a certain historical moment, provided that the principles of reasonableness and proportionality are observed[264].

In conclusion, the international responsibility of a State party to the American Convention for the violation of its obligation of progressive realization can be summarized in light of four key considerations: firstly, progressive obligations must be understood in light of a general prohibition of inaction by the State towards the effective realization of a right. Secondly, legislative measures and the establishment of public policies on social rights do not suffice for the correct implementation of the

[262] Corte Constitucional de Colombia, Sentencia C- 313/14, Magistrado Ponente Gabriel Eduardo Mendoza Martelo. Sentencia de 29 de mayo de 2014, págs. 7-8.
[263] Corte Constitucional de Colombia. Sentencia T-302/2017, Magistrado Ponente: Aquiles Arrieta Gómez, 8 de mayo de 2017, puntos 8.1.9., 8.1.10., 8.1.11. y 8.1.12.
[264] Corte de Constitucionalidad de Guatemala, Inconstitucionalidad general y parcial, Expedientes acumulados 3-2011, 4-2011 y 52-2011, pág. 25 y ss.

American Convention. In fact, the third consideration implies that, alongside with a normative progression, a *de facto* progression is indeed required, something that can be called as progression of result. Lastly, in order to assess compliance with the obligation of progressive realization, the maximum use of available resources, with a special attention to vulnerable or marginalized groups, must be taken into account.

Another aspect which makes the Cuscul Pivaral Case a leading judgment in the protection of the right to health is that the Inter-American Court set more detailed standards for the treatment of people living with HIV/AIDS. It went so far as to conceive that it should include access to quality goods, services and information for the prevention, treatment, care and support of infection. The Court highlighted the key role played by antiretroviral therapy and other medicines, diagnostic tests and safe and effective related technologies for the preventive, curative and palliative care of HIV, opportunistic diseases and related diseases, as well as social and psychological support, family and community care, and access to prevention technologies[265].

The last aspect of the current case which is worth examining in this section is the reparation measures ordered by the Court to Guatemala. These measures aimed at repairing the violations that occurred for the victims of the case and at preventing future violations on the same matter. In this regard, the Court ruled that the State must provide the victims with effective life-time medical care and psychological/ psychiatric treatment. This treatment should include crucial issues such as the free and lifelong provision of medicines needed to combat HIV (antiretroviral) or opportunistic diseases, diagnostic tests, social support including aspects such as nutritional or psychological assistance, and access to technologies for the prevention of infection. All of these aspects have a causal link with the type of treatment that the State failed to provide to victims, and which is necessary for the medical care of people living with HIV in accordance with the standards defined in the Judgment in light of the valuable reports of institutions such as UNAIDS or the World Health Organization[266]. In addition, the

[265]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 106-107.
[266]Ibidem, par. 210.

Judgment ordered certain guarantees of non-repetition that are aimed at improving the conditions of healthcare for people living with HIV in Guatemala, whether or not they were victims of the case. This is an aspect that is relevant to highlight for it seeks to promote structural changes in the country for the protection of all the population.

To conclude, the Judgment represents a point of maturity in a line of a jurisprudence that precisely addresses a crucial issue in Latina America: the need for States to comply with their obligations to respect and guarantee economic, social, cultural and environmental rights. Furthermore, the *Cuscul Pivaral* addresses specific question on the duty to guarantee the right to health for people living with HIV while considering for the first time the two features of ESCR - namely immediate and progressive obligations.

The approach adopted by the Court, despite the normative and methodological challenges it presented, might be key in addressing and tackling serious issues regarding the region such as inequality and social exclusion, especially for the most vulnerable groups. In the same way, the United Nations Economic Commission for Latin America and the Caribbean (ECLAC) has pointed out that the region remains the most unequal region in the world in terms of income distribution and that extreme poverty still constitute an issues that must be addressed soon affecting "more children, adolescents and young people" and highlighting the increase in the *"feminization of poverty"* in the young and adult population[267]. For all the aforementioned consideration, the Judgment constitute an important step forward in the effective protection and implementation of ESCR in Latin America with due regard of the fragile social situation and context of the countries of the region[268].

[267]CEPAL, *Panorama Social de América Latina* 2017, Naciones Unidas, (LC/PUB.2018/1-P), Santiago, 2018, págs. 14 y 47.

[268]Ibidem

5.4. Final remarks on the Inter-American Court of Human Rights Jurisprudence concerning the Right to Health

The shift in the Court's approach and jurisprudence in addressing the protection of health-related issues is both remarkable and surely relevant for the effective protection of human rights. The aforementioned analysis on the Inter-American system has presented the evolution of the Court's approach from those cases in which health related issues were assessed as violations of the right to life and personal integrity on the one hand, to the most recent cases in which the Court ruled on violations of the right to health, considered for the first time as an autonomous and directly enforceable right.
Furthermore, it is evident that this shift in the Court's perspective triggers an array of legal questions and fuels the debate on both the direct applicability of social rights in the international human rights framework and on the role of an international court established by a treaty in light of basic principles of international law. In this regards, Judge Humberto Antonio Sierra Porto's *partially* dissenting opinion on the *Cuscul Pivaral Case* constitutes a valuable source for the study of this updated Court's approach and for highlighting new perspectives that might be useful in order to tackle the aforesaid intellectually challenging legal reasoning. The Judge grounded his opinion on two main pillars: firstly, the study on the debate on the nature of the right to health; secondly, on the remedial measures adopted by the Court in relation to the guarantee of non-repetition and public health policies in Guatemala.
The analysis starts by presenting the Court's definition on the right to health, which must be understood as the right of everyone to the enjoyment of the highest attainable standard of physical, mental and social well-being. This right includes timely and appropriate health care in accordance with the principles of availability, accessibility, acceptability and quality[269]. In addition, the Court specified that the general obligation to protect health enshrines the State's duty to ensure people's access to essential health

[269]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 107.

services, guaranteeing quality and effective medical care, as well as to promote the improvement of the population's health conditions[270]. Under these considerations the Court highlighted Guatemala's non-compliance with the two aforementioned sets of international obligations concerning ESCR provided for in a article 26 of the American State namely immediate and progressive obligations[271].

In addition, the Court also concluded that the State was responsible for having violated the rights to life and personal integrity contained in Articles 4 and 5 of the American Convention. In this regard, the Court considered the existence of a causal link between the omissions of the State in the medical treatment and the cause of death of the alleged victims, especially when such death was caused by an opportunistic illness. The Court, therefore concluded that the State was responsible for the violation of the obligation to guarantee the right to life contained in Article 4(1) of the Convention[272]. In the same way, the Court assessed a violation of the right to personal integrity as defined by article 5 in light of the causal link between the lack of adequate medical treatment for the alleged victims and the physical and psychological harm suffered by the victims as people living with HIV[273].

On the grounds of this reasoning, a strong nexus between the violation of the right to health on the one hand, and of the right to life and personal integrity of the victims on the other, is quite evident. This is the reason Judge Sierra Porto highlighted that understanding article 26 in an autonomous manner is unnecessary, although the article has enormous relevance when considered in relation to the right to life and personal integrity. Indeed, according to the Judge, the conduct and omissions imputed to the State as violating the rights to health, life and personal integrity are, in essence, the same. In other words, the Judge stressed that the direct enforceability of the right to health in light of an extensive interpretation of Article 26 contravenes and illegitimately

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[270]*Caso Poblete Vilches y otros Vs. Chile. Fondo, Reparaciones y Costas.* Sentencia de 8 de marzo de 2018. Serie C No. 349, párr. 118, y *Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 105.

[271]*Caso Cuscul Pivaral y otros Vs. Guatemala. Excepción Preliminar, Fondo, Reparaciones y Costas.* Sentencia de 23 de agosto de 2018. Serie C No. 359, párr. 119.

[272]Ibidem, par. 159.

[273]Ibidem, par. 163.

expand the jurisdiction of the Court much further from the powers explicitly provided by the Convention. This could cause a situation of juridical uncertainty in which neither members States, nor alleged victims, would know how to act. As an international tribunal, the inter-american Court has a specific mandate which has to perform on the grounds of the legal settings agreed upon by the States at the moment of the adoption of the treaty.

This reasoning does not mean that ESCR are not protected in the Inter-American system. In fact, when the right to health was addressed indirectly, this did not prevent the Court from making important advances with respect to the requirements of availability, accessibility, acceptability and quality in the provision of health services, as well as the obligation to regulate, oversee and supervise the provision of services in private health centers. The Judge pointed out that this does not imply the creation of a new right. Instead it means to give content and scope to rights such as life and integrity that are contained in the Convention and, therefore, have been accepted by the States Parties[274].

In this regard, the Judge proposes a double-face construction of the right to health. According to this perspective, the right to health is both an individual, in relation to the related fundamental rights that may be affected, such as the right to personal integrity or to life; and a progressive right in relation to the complacency of health services provided by the State[275]. This reasoning would allow the Court to identify, on the one hand, when it is possible to link the actions of the State to the provision of health services in light of an alleged violations of the right to life and personal integrity, and on the other hand, to determine when the public policy on ESCR in the State is intrinsically in violation of the obligations of progressive realization established in Article 26 of the Convention. In doing so the Court could assess the case under a *micro perspective* in the first hypothesis on the basis of article 4 and/or 5 in relation to article 26 and 1.1 of the Convention; and, under a *macro perspective* in the second hypothesis,

[274] Voto Parcialmente Disidente Del Juez Humberto Sierra Porto, *Caso Cuscul Pivaral y otros vs. Guatemala,* par. 8.
[275] Ibidem, par. 6.

directly on the basis of article 26 in relation to article 1.1 of the mentioned instrument[276]. Furthermore, the Judge highlights that Guatemala was found in breach of its progressive obligations, despite not having adopted any regressive measures. In his view, if this reasoning were to be accepted as valid, the nature of progressive obligations would be changed into quite different ones, which would imply the obligation to comply with the implementation of ESCR, such as the right to health, in a reasonable period of time[277].

[276]Ibidem
[277]Ibidem, par. 10.

6. Access to Medicines as a key part of the Right to Health

In section 2 of this Chapter, the legal framework related to the right to health has been studied and developed, without explicitly mentioning a peculiar aspect of this right, i.e. access to medicines. According to official reports of the United Nations[278], almost 2,000 million people lack access to essential medicines (which causes considerable and avoidable suffering), directly influencing people's quality of life and causing situations such as ill health, pain, anxiety and loss of dignity and life[279]. Improving access to existing medicines could save 20 million lives each year, half of them in Africa and South-East Asia[280]. In addition to deprivation, severe inequality in access to medicines remains a major problem and the main feature of the global pharmaceutical situation.
Average per-capita expenditure on medicines in high-income countries is 100 times higher than in low-income countries; about $400 compared to $4 in the other country. In fact, the World Health Organization (hereinafter: "WHO") estimates that 15 per cent of the world's population consumes more than 90 per cent of the total production of pharmaceutical products and has clarified that the right to access to medicines is an integral part of the right to health. In addition, pharmaceuticals account for 60% of all health-related trade, yet 35% of the world's population, especially in developing countries, lacks regular access to essential medicines[281].
WHO defines essential medicines as *"those that meet the priority health care needs of the population"*[282]. Furthermore, according to WHO, access to essential medicines, as defined in the WHO Action Programme on Essential Medicines, should be guaranteed to all. WHO's health for all and primary health care strategies can inspire the core

[278]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health Note by the Secretary-General, 13 September 2006, A/61/338, 10.
[279]World Health Organization, Medicines Strategy: Countries at the Core, 2004-2007, WHO, 2004. According to WHO statistics presented at the XVI International AIDS Conference in Toronto in 2006, less than a quarter of all AIDS patients in Africa, and less than a tenth of children with AIDS, receive the antiretroviral drugs needed to save their lives.
[280]Department for International Development (DFID), *Increasing access to essential medicines in the developing world*, 2004.
[281] World Health Organization, "WHO Medicines Strategy: Countries at the Core, 2004-2007", http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf
[282]Definition provided in the OMS website http://www.who.int/medicines/services/essmedicines_def/en

content of the right to health: *"there is a health baseline below which no individual in any country should find himself"*[283]. In other words, there is a certain threshold below which States, regardless of the resources at their disposal, are not allowed to stop providing basic medicines to their populations.

Essential content includes the following services[284]:

(a) access to maternal and child health care, including family planning;
(b) immunization against major infectious diseases;
(c) adequate treatment of common diseases and injuries;
(d) Essential medicines;
(e) Adequate supply of safe drinking water and basic sanitation;
(f) absence of serious threats to environmental health.

It is clear that the right to access to medicines is a part of the core content of the right to health. Essential medicines, must therefore, be available to the public, at affordable prices and in adequate quantities. While there seems to be no doubt about the importance of the availability and affordability of life-saving medicines, in practice, millions of people are denied access to medicines and health-care services. This section examines the specific obligations of States under the right to health in relation to access to medicines.

[283] World Health Organization (WHO), Global Strategy for Health for All by the Year 2000 (Geneva, 1981), 31.
[284]UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant), 11 August 2000, E/C.12/2000/4, parr. 43-44.

6.1. Recognition of the Right to Access to Medicines as a Fundamental Right

The United Nations, with its various specialized agencies and committees, has played a determining role in establishing and recognizing access to medicines as an integral part of the right to health. Recalling the most relevant historical events, it should be noted that the debate related to access to medicines started after the adoption of the Declaration on the TRIPS Agreement and Public Health of 2001 (Doha Declaration)[285]. This Declaration was the product of formalized criticism by developing countries of the system that had been created in 1994 with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). These countries postulated that the framework established by the 1994 agreement strengthened intellectual property rights and left aside human rights, specifically the right to health. As a result, the Doha Declaration recommended that States reinterpret the TRIPS Agreement in order to guarantee the public health of their citizens and, especially, to promote the accessibility and availability of medicines for all. This instrument, while not legally binding for States, has a validity that is not simply political, but belongs to the so-called group of norms referred to as *soft law*.

It should be noted that about a year earlier (spring 2000) the Committee on Economic, Social and Cultural Rights (CESCR) adopted the already widely cited General Comment 14, in which access to medicines was formally recognized as an integral part of the right to health; and it is because of the interpretation delivered by the Committee and examined in this section that it is possible to determine and clarify the specific obligations with which States Parties must comply in relation to the right to the aforementioned right[286].

Chronologically speaking, four years after the Doha Declaration, the same CESCR adopted another General Comment in which it reaffirmed the importance of access to medicines, clarifying the obligation of States *"to prevent unreasonably high costs being*

[285]World Trade Organization *Doha Declaration on the TRIPS Agreement and Public Health Adopted at the Doha Ministerial Conference, Fourth Session* (WT/MIN(01)/DEC/2; 2001).
[286]CESCR, *General Comment 14*.

imposed for access to essential medicines (...)", and above all underlining the role of public authorities in prohibiting the patentability of inventions whose commercialization and use may have purposes contrary to dignity and other human rights, such as the rights to life, health and private life, in other words, endangering their full exercise[287].

Similarly, in 2013, the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, addressing the topic on access to medicines, highlighted and confirmed how the availability of essential medicines for all sectors of the population (especially the weakest strata) represents a fundamental part and is a crucial element for the enjoyment of the right to health at all levels[288]. The Special Rapporteur proposed:

a) Establish a regulatory framework on local drug production to ensure the accessibility and long-term affordability of medicines;
b) Strengthen the regulatory framework to increase the competitiveness of local industry and provide administrative and financial support, subsidies and guaranteed purchases;
c) Use flexibility factors under the TRIPS Agreement to promote regional collaboration to pool resources and facilitate the competitiveness of local production.

Furthermore, with regard to ensuring affordability of medicines, the Special Rapporteur recommends that States: (a) Take price control measures within the framework of pricing and reimbursement policies with a view to ensuring the population's access to affordable medicines, particularly in the case of vulnerable groups; (b) Select countries with a similar level of economic development to that of the State concerned as reference countries in order to ensure the lowest possible price of medicines through external

[287] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Par. 1 (c) of the Covenant)*, 12 January 2006, E/C.12/GC/17.
[288] A/HRC/23/42, par. 67.

pricing; (c) If necessary, monitor and regulate manufacturers' sales prices and distribution margins in the supply chain and ensure incentives for wholesalers and retailers for sustainable distribution; (d) Resist trade policies that undermine the ability of States to reimburse local pharmaceutical companies for the price of essential drugs; (e) Eliminate tariffs on the import of drugs, except where they are considered strategic for promoting local production of essential drugs; (f) Eliminate taxes on all medicines, especially essential medicines, and consider other revenue options in the area of health, such as excise taxes on socially harmful products such as tobacco, alcohol and junk foods which pharmaceutical companies to abuse anti-competitive practices and promote competitive pricing of medicines together with stringent enforcement measures[289].

Another significant step in the process for the recognition of access to medicines as a fundamental part of the right to health was the Human Rights Council resolution 32/15[290]. This resolution declared access to medicines one of the fundamental elements for progressively achieving the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. All countries were urged to take advantage of the flexibility clauses established by the TRIPS Agreement in light of the importance of intellectual property protection for the development of new medicines, as well as the concern caused by the price implications of such protection[291].

Interestingly, the General Assembly in 2015 adopted Resolution A/70/L.1, known as *"Transforming our world: Agenda 2030 for Sustainable Development"*, in which, among the 17 goals set, the right to health (Goal 3) is also included, and in particular *"Ensure a healthy life and promote the well-being of all at all ages"*. In the part in which the objective in question is explained in detail, the Assembly stresses that by

[289]Ibidem

[290]In addition to formal documents from various United Nations agencies, in accordance with Human Rights Council resolution 26/28, the Social Forum was held in Geneva from 18 to 20 February 2015 with the objective of underlining the importance of access to medicines in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including best practices in this regard.

[291]A/HRC/RES/32/15, 3.

2030, States must achieve access to safe, effective, affordable and quality medicines and vaccines for all, in accordance with the Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health and adopt the abovementioned limitations established by TRIPS[292].

In November 2015, former United Nations Secretary-General Ban Ki-Moon convened a High-Level Panel on Access to Medicines and asked them to propose solutions to boost research and development, as well as access to health technologies, through a high-level meeting on access to medicines[293]. To this end, the High-Level Group published a report in September 2016 entitled "Promoting innovation and access to health technology"[294].

The Report is composed of four parts, which address different aspects of the relationship between public health, trade and intellectual property and emphasize the importance of access to medicines as an essential element for the enjoyment of the highest attainable standard of health:

a) Technology, innovation and access to health: Reviews the current global situation and identifies multiple barriers to access to medicines. According to the Report, there are clear inconsistencies between the need to improve access and commercial and intellectual property incentives. In addition, the importance of the WHO Essential Medicines List (EML) for access is highlighted.

b) Intellectual property law and access to health technologies: Explains how intellectual property (IP) law, the World Trade Organization (WTO) and the regulatory provisions

[292] UN General Assembly, *Transforming our world: Agenda 2030 for Sustainable Development,* Resolution A/70/L.1, 18.

[293]In general, the report identifies ways to improve access to health technologies. Other proposals include greater transparency of costs (for pricing), results of clinical trials, governments taking responsibility for meeting the health needs of their populations, including increased spending on health-based research and development. In addition, it foresees new incentives for neglected areas, more transparent patent information, the need for publicly funded research and development to disseminate information obtained for the benefit of all.

[294]World Health Organization, Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines. Promoting innovation and access to health technologies. September 2016.

established by TRIPS work in relation to health technology. It also discusses public funding of pharmaceutical research and development.

c) New Incentives for Health Technology Research and Development: Shows possible new ways to promote research and development, for example, to cure less common antimicrobial resistant diseases. In fact, new technologies are rarely developed for health conditions that cannot deliver high yields, such as bacterial infections that require only antibiotics. As a result, rare diseases affecting comparatively small proportions of the population have not traditionally attracted investment.

d) Governance, accountability and transparency: Examines how rules governing trade and intellectual property may conflict with public health and human rights because of different mechanisms of regulation, accountability and transparency. To this end, it discusses the manner in which coordination and integration can help overcome inconsistencies and inequalities between countries.

6.2. The Obligation of Progressive Realization and the Prohibition of Regression in relation to the Right to Access to Medicines

The realization and concrete implementation of the right to health requires, by its very nature, the allocation of large amounts of resources by public authorities and depends on the economic and financial situation of the country analyzed. In fact, health represents the largest item of expenditure in public budgets; and the State, as mentioned above, has the positive obligation (to act) to deliver quality services in order to guarantee the social rights (health) of its citizens. In other words, the construction of hospitals, the training of specialized medical personnel, and the administration of vaccines and medicines involve the use of significant amounts of public capital.
It should be noted that two elements specifically influence the effective protection and implementation of the right to health: first, the aforementioned amount of available

resources; second, the economic and political decisions that the current government wants to implement. For example, in a situation of economic crisis, a government could adopt austerity measures and consequently reduce public spending; on the other hand, the same government could increase public spending in order to stimulate aggregate demand. It is evident that, under a qualitative perspective, the two political decisions mentioned (under equal economic conditions) have a different influence on the guarantee of the right to health and other social rights.

For this reason, the International Covenant on Economic, Social and Cultural Rights does not establish an obligation of immediate realization of the rights stipulated therein, but rather an obligation of progressive realization, with the objective of limiting the arbitrariness of States and especially of recognizing that these types of rights depend on the amount of available resources (economic-financial situation of a country). In addition, article 2, paragraph 1, provides: *"Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures"*[295].

Similarly, in its General Comment No. 3, the Committee on Economic, Social and Cultural Rights stated, with respect to this type of obligations, that *"The concept of progressive realization constitutes recognition of the fact that the full realization of all economic, social and cultural rights in general cannot be achieved in a short period of time"*[296]. This view is consistent with the design of the drafters of the International Covenant on Economic, Social and Cultural Rights who, despite concerns that some States might use this progressive obligation as an excuse for not fulfilling their obligations[297], recognize that the inclusion of this clarification was inevitable[298].

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[295]United Nations International Covenant on Economic, Social and Cultural Rights, Article 2, paragraph 1.

[296]CESCR, *General Comment 3*, par. 9.

[297] D. Hartley, *Social Rights and Human Welfare,* Routledge, 2015, 23.

[298]Indeed, the drafting history of the Covenant records that the use of the term progressively imposes on signatories the obligation to always achieve higher standards of compliance with rights. Ibidem.

The obligation of progressive realization, however, does not mean that States do not have specific obligations with which they have to comply, and for this reason, the same ESC Committee stressed that on the one hand, flexibility is called for to face the real situations of today's world and the challenges that each country faces in guaranteeing the full realization of economic, social and cultural rights. On the other hand, the obligation must be understood by considering *"the general objective, in reality the raison d'être, of the Covenant, which is to establish clear obligations for States parties with regard to the full realization of the rights in question"*[299].

Furthermore, the Committee underlines that progressively it means proceeding as expeditiously and efficiently as possible with a view to effectively implementing the established rights. Similarly, the Committee enunciates the corresponding prohibition of retrogression, that is, *"all measures of a deliberately retroactive nature in this regard shall require the most careful consideration and shall be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources"*[300].

Such a perspective seeks to understand the obligation of progressive realization as a mixture of practicality and sensitivity to the local context. Thus, in terms of implementation, it imposes an obligation on States to justify the measures they have taken to guarantee the right to health in the light of the resources at their disposal. In this regard, the Committee (CESCR) in its general comment on the right to health stated that, if the socio-economic context makes it impossible for a State party to comply fully with its obligations under the Covenant, it is the responsibility of public authorities to justify that, nevertheless, every effort has been made to use all the resources at their disposal to implement as a matter of priority the obligations imposed under the right to health1[301].

It is clear that the context and the economic situation of the country play a determining role, but they do not represent the only requirements to be analyzed. Similarly, in 2006,

[299]CESCR, *General Comment 3*, par. 9.
[300]Ibidem par. 10.
[301]CESCR, *General Comment 14*, par. 47.

CESCR further clarified that in order to assess the obligation of progressive realization, the following points must be taken into consideration[302]:

* the level of development of the country
* the gravity of the alleged infringement
* the current economic situation of the country
* the existence of other situations that negatively influenced resource management, such as those related to natural disasters or armed conflicts
* whether the state party has attempted to identify low-cost measures
* whether the state party sought the cooperation of the international community

The same Committee specified more precisely the requirements necessary to assess progress towards the fulfillment of the progressive realization obligation with respect to the communications procedure under the Optional Protocol to the International Covenant on Economic, Social and Cultural Rights[303].

The Committee on Economic, Social and Cultural Rights indicated that it would consider factors such as[304]:

* the extent to which the decisions taken were deliberate, concrete and specified towards the fulfillment of economic, social and cultural rights
* whether the Member State exercised its discretion in a non-discriminatory and non-arbitrary manner
* whether the State party's decision not to allocate available resources is in conformity with international human rights standards
* in cases where several options are available, if the State party has adopted the option

[302] CESCR, *An Assessment of the Obligation to Take Steps Towards the "Maximum of Available Resources" under an Optional Protocol to the Covenant*, UNDocE/C.12/2007/1, 10 May 2007, par. 10.
[303]Human Rights Council, *Optional Protocol to the International Covenant on Economic, Social and Cultural Rights,* UNDocA/63/435, 28 November 2008.
[304]CESCR, *An Assessment of the Obligation to Take Steps*, par. 8.

that least restricts Covenant rights

* the timeframe within which the measures were adopted

* whether the measures have taken into account the precarious situation of disadvantaged and marginalized individuals or groups, whether they were non-discriminatory and whether priority was given to serious or risky situations[305].

From the foregoing, it can be concluded that the obligation of progressive realization establishes clear limits to the arbitrariness of action on the part of public authorities, which have the responsibility to justify the taking of governmental decisions that negatively influenced the protection of the right to health. It should be noted that the general principle of international law, *pacta sunt servanda*, should guide States in adopting measures that could cause irreparable harm to the most vulnerable citizens. For this reason, public authorities must comply with the obligation in good faith and with the principle of effectiveness.

The Committee has, however, recognized that the application of this model will always respect the *"margin of appreciation"* of States to adopt the measures best suited to their specific circumstances, and only then will a careful analysis of the context assess the State's behavior in the broader context, i.e. in the light of international human rights in general and not simply the right to health[306].

[305]It is significant that this model has been used by the Committee on the Convention on the Rights of the Child, as an appropriate methodology to evaluate the fulfillment of the norms regarding the progressive realization of the obligation of States to ensure the right to health.

[306]Committee on Economic, Social and Cultural Rights An Assessment of the Obligation to Take Steps Towards the "Maximum of Available Resources" under an Optional Protocol to the Covenant, UNDocE/C.12/2007/1 (10 May 2007), par. 12.

6.3. Specific Legal Obligations related to Access to Medicines

The aforementioned General Comment 14 constitutes the key moment in defining the specific obligations related to access to medicines as a fundamental part of the right to health. In this document, the Committee on Economic, Social and Cultural Rights included the provision of essential medicines among the core obligations to be guaranteed by States parties[307]. In fact, while the International Covenant on Economic, Social and Cultural Rights recognizes the principle of progressive realization of these rights, this does not mean that States are free to postpone the fulfillment of their obligations with regard to the right to health[308].

Considering the above-mentioned tripartite structure[309] (respect, protect and fulfill) established for all economic, social and cultural rights by the Committee, specific legal obligations related to the right to access to medicines, understood as a fundamental part of the broader right to health, can be identified.

The obligation to respect the right to health with regard to medicines is described in paragraph 34 of general comment No. 14 as a duty of non-interference. In particular, States must *"refrain from denying or limiting equal access to preventive, curative and palliative health services for all persons, including prisoners or detainees, representatives of minorities, asylum-seekers or illegal immigrants "* [310] and refrain from marketing unsafe medicines or otherwise interfering with the acceptability, availability or accessibility of medicines. An example of denying equal access to medicines to all persons would be to limit access to available antibiotics because of the nature of the medicine or the patient's family status or because the State's medicines

[307]CESCR, *General Comment* 14, par. 43(d): *"To provide essential medicines, as defined periodically in the WHO Action Programme on Essential Medicines".*

[308]Even in cases of economic crisis or other emergency, these basic requirements must be guaranteed for all. States should use all available resources, including international cooperation, to ensure that everyone in their territory can enjoy a minimum level of protection of the economic, social and cultural rights set out in the Covenant.

[309]Previous section

[310] CESCR, General Comment 14, par. 34.

policy discriminates against women, ethnic minorities or other disadvantaged groups[311]. The obligation to protect the right to health with regard to medicines is elaborated in paragraph 35 of general comment No. 14 and provides for two precise obligations[312]:

* to ensure that the privatization of the health sector does not threaten the availability, accessibility, acceptability and quality of health facilities, goods and services;

* control the marketing of medical equipment and medicines by third parties.

This obligation includes the regulation of the production and sale of medicines in the national market. In other words, the obligation to protect is embodied in the task of States to take measures to safeguard the market against third party interventions that may harm the supply of medicines in relation to quality, price and quantity available. For example, the State must ensure that the privatization of the health sector promotes, rather than hinders, the realization of the right to health. Third-party interventions include pharmaceutical companies, which must be required by law to adhere to good manufacturing practices in order to produce medicines of guaranteed quality[313]. In addition, not only the production side, but also the supply side of medicines must be regulated. In fact, pharmacists and prescribers must be adequately trained to care for patients in the consumption of medicines in the proper manner, prescribing the appropriate medicine to the patient, in the appropriate dosage and for the correct duration[314]. The third obligation, to fulfill the right to health, is defined in paragraph 37 of general comment No. 14. According to this document, States have a duty to facilitate the right to health through the adoption of *"positive measures which enable and assist individuals and communities to enjoy the right"*[315]. Finally, States are obliged to promote the right to health through *"actions which create, maintain and restore the health of the population"*[316]. As a consequence, the obligation to fulfill requires States

[311]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 59.
[312]CESCR, *General Comment* 14, par. 35.
[313]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 59.
[314] CESCR, *General Comment* 14, par. 36.
[315]Ibidem, par. 37
[316]Ibidem

to take positive measures so that rights holders can enjoy their right to access to medicines[317]. In other words, States are responsible for developing and maintaining a health-care system through which medicines are available, accessible (affordable, physically accessible and without discrimination of any kind), approved and of guaranteed quality[318]. For example, while a State may contract the provision of health services to a private company, it does not delegate its right-to-health obligations by such an act. A State always retains residual responsibility for the proper regulation of its health systems and medicines, as well as for the welfare of the most disadvantaged in its jurisdiction[319]. Therefore, States also have a duty to provide medicines to the most vulnerable in society, such as the poor, the disabled146 and ethnic minorities[320]

In order to complete the legal framework related to access to medicines, it should be noted that the right in question *"in all its forms and at all levels encompasses the following essential and interrelated elements, the implementation of which will depend on the conditions prevailing in a given State "*[321], which are as already mentioned: availability, accessibility, acceptability and quality. These elements complement legal obligations in the sense that such a framework develops the multiple elements necessary to fully enjoy the respect, protection and fulfillment of rights related to medicines. It should be noted that the element of availability requires not only that health goods and services be available in sufficient quantity[322], but also requires another determinant aspect for the concrete realization/exercise of the right in question, namely the development and availability of new medicines, vaccines and diagnostic tools[323]. Indeed, States must use a variety of economic, financial and trade incentives to encourage research and development of specific medicines, primarily for diseases

[317]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 59.
[318]CESCR, *General Comment 14*, par. 30.
[319]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 60.
[320] CESCR, *General Comment 14*, paras. 26-27.
[321]Ibidem, par. 26.
[322]States must do all they reasonably can to ensure that existing medicines are available in sufficient quantities in their jurisdictions.
[323]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 47.

that create a particular challenge in developing countries. In other words, States have a duty to ensure that existing medicines are available within their borders, as well as a responsibility to take reasonable measures to ensure that new medicines, which are greatly needed are developed, and therefore available[324]. In addition to being available, medications must also be accessible. Accessibility has four dimensions1[325]:

* medicines must be accessible in all parts of the country (physical accessibility), especially in remote rural areas, far from urban centers.

* medicines must be affordable for all (economic accessibility), including people living in poverty. This dimension has a major impact on drug financing and pricing arrangements. In addition, it may mean that a State modifies import tariffs and other taxes on medicines in order to improve access for the most vulnerable strata[326].

*medicines must be accessible without discrimination on the basis of sex, race, ethnicity and socio-economic status. In this regard, a State must take measures to ensure equal access for all individuals and groups, particularly with disadvantaged minorities (non-discrimination).

* Patients and health professionals must have access to reliable information on medicines in order to be able to make informed decisions and use them safely (accessibility of information).

Together, health goods and services must also be culturally and generationally acceptable and respectful of medical ethics. For example, national measures should support the appropriate use of traditional medicine and its integration into health care systems, while clinical trials should ensure informed consent of patients. Medicines should be available in a form that is available to unconscious patients and incapacitated persons, as well as in doses appropriate for newborns[327]. In addition to being available,

[324]Ibidem, par. 48.
[325]Ibidem, par.49.
[326]States parties therefore have a duty to prevent excessively high costs of access to essential medicines, plant seeds or other means of food production, or textbooks and teaching materials from undermining the rights of broad sections of the population to health, food and education. CESCR, *General Comment 17,* par. 35.
[327]The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Note by the Secretary-General, A/61/338, par. 50.

accessible and acceptable, medicines and related issues should be of good quality. As underlined by Paul Hunt, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, if medicines are rejected in the North because they are beyond their expiry date and are unsafe, such medicines cannot be recycled in the South. Since medicines can be counterfeit or tampered with, States must establish a regulatory system to verify the safety and quality of medicines[328]. In conclusion, medical care in the event of illness, as well as the prevention, treatment and control of illness, are central features of the right to health that depend on access to medicines. Consequently, such features constitute an indispensable part of the right to the enjoyment of the highest attainable standard of health, as confirmed in various court cases [329], as well as in the aforementioned resolutions of the Commission on Human Rights, which furthermore reaffirm that access to essential medicines is closely related to other human rights, such as the right to life[330].

[328]Ibidem 51.
[329]Constitutional Court of Costa Rica, *Mr William García Álvarez vs Caja Costarricense de Seguro Social*, File 5778-V-97, 23 September 1997; Ombudsman for *Mrs Ledi Orellana Martínez vs Caja Costarricense de Seguro Social (CCSS)* Constitutional Court, File n°02-007871, 24 September 2002. Corte Constitucional de El Salvador, *Mr Jorge Odir Miranda Cortez vs la directora del Instituto Salvadoreño del Seguro Social* Constitutional Court, File n°348-99, 4 April 2004.
[330]Commission on Human Rights, Resolutions 2005/23, 2004/26 and 2003/29.

CHAPTER II

The impact of Intellectual Property protection on the right to access to medicines

1 Conflicts between Human Rights and Trade-related Treaties: Preliminary Considerations

The relationship between the norms regulating human rights protection and those regulating trade related issues constitutes a clear example of law fragmentation within international law. According to some authors, the term fragmentation, which has usually been employed in a pejorative manner, refers to three different features of the contemporary international legal framework[331]: firstly, the continuous growth of new and specific subfields of international law; secondly, the rise of new actors alongside states, such as international organizations, non-governmental organizations (NGOs), and corporations; and lastly, the rise of different types of international norms and judicial mechanisms related to multiple areas of law[332].

Such fragmentation of international law was further amplified by the collapse of the communist bloc in 1989, which resulted in the end of the bi-polar world order and in the emergence of an array of new States. This "new world order" was the stage for the adoption of multiple multilateral treaties[333] and the establishment of new organizations and other permanent international bodies, such as the World Trade Organization (WTO) in 1994[334].

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[331] M. Andenas and E. Bjorge, *A Farewell to Fragmentation: Reassertion and Convergence in International Law,* Cambridge University Press, 2015, 2.

[332] A. Peters, "The refinement of international law: From fragmentation to regime interaction and politicization", *I•CON* 3, 2017, 673.

[333] For example, the Rio Conventions and many hard and soft environmental instruments were adopted in 1992. Further, the membership of the International Convention on Settlement of Investment Disputes (ICSID Convention) and the number of bilateral investment treaties (BITs) increased exponentially.

[334] Moreover, new international courts and tribunals came into exitance such as the Yugoslavia and Rwanda criminal tribunals since 1992, the WTO dispute settlement body in 1994, the International Criminal Court Statute in 1998, the International Tribunal for the Law of the Sea (ITLOS) in 1996, and investment arbitration disputes increasing intensely. Further, it must be noted that already existing judicial bodies were changed into permanent courts with legal standing for individuals, such as the European Court of Human Rights (ECtHR) in 1998.

The transformation of the international legal system into an increasingly complex realm triggered concerns on possible damages to the coherence of the entire legal framework[335]. Simply stated, more actors and systems of law were involved, more likely scholars were to witness conflicts among norms belonging to such different areas of law. Accordingly, the International Law Commission (ILC) addressed the issue of fragmentation of international law extensively with the establishment of the Study Group on Fragmentation of International Law in 2002 (Fragmentation Study Group)[336]. The aim of the Study Group was to provide a toolbox that legal practitioners could adopt when dealing with cases concerning a collision of norms from different areas of international law, such is the case of human rights and trade law[337].

The aforementioned scenario constitutes the theoretical foundation of one of the legal challenges that the present dissertation wants to address, namely norms conflict between human rights provisions concerning the right to health and access to medicines on the one hand, and the norms related to intellectual property protection (IP) on the other. Accordingly, the first chapter presented the legal framework related to the right to health and demonstrated that the right to access to medicines is a fundamental part of such right on the grounds, *inter alia,* of judicial and quasi-judicial rulings. This Chapter will focus on the international and regional (Central America) legal framework concerning intellectual property, with a particular focus on the protection of the right to access to medicines.

A casual observer could perhaps argue that human rights and trade related treaties cover completely different subjects and, thus, debating on their relationship would be quite pretentious. On the contrary, the present chapter argues that such apparently unrelated areas of law actually collide, and a methodological legal approach is, thus, required in order to overcome such conflict among norms[338]. In line with this argumentation, in

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[335] Jonathan I. Charney, "Is International Law Threatened by Multiple International Tribunals?", *Collected Courses of the Hague Academy of International Law* 271, 1998, 347.

[336] International Law Commission (ILC), *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law,* UN Doc. A/CN.4/L.682 (Apr. 13, 2006).

[337] M. Milanovic, "Norm Conflict in International Law: Whither Human Rights", *Duke Journal of Comparative & International Law 20,* 2009, 70.

[338] M. Milanovic, *Extraterritorial Application of Human Rights Treaties: Law, Principles, and Policy,*

2015, participant within the UN Human Rights Council raised their concerns in joint and separate statements about the impacts that trade-related agreements have on the realization of human rights[339]. In specific, there is an evident collision among the provisions related to the right to access to health envisaged within the UN Covenant on Economic, Social and Cultural Rights (ICESCR) on the one hand, and the provisions related to patent's protection provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) on the other hand. Further, the Chapter argues that such collision concerns regional free trade agreements (FTAs) as well. For this aim, a particular focus is devoted to the Dominican Republic–Central America Free Trade Agreement (CAFTA), which actually increased IP provisions for pharmaceutical products and in so doing progressively hinder and worsen the protection of the right to health. In this regard, the following questions might be posed: should the rules of the World Trade Organization trump international human rights agreements? What are the rules that govern the issue of conflicts between treaty norms? Should international human rights treaties be considered hierarchically superior to trade related treaties? Are such legal conflicts among related norms envisaged by TRIPS and CAFTA on one side, and by ICESCR on the other, merely apparent or are they genuine?

The entire chapter, and the present section in particular, will try to find plausible solutions to these overwhelming and complex legal issues. Grounding on relevant legal provisions and literature concerning the relationship between contrasting norms and interpretation of treaties' provisions, the Chapter proposes legal tools in order to strike a balance between IP law and human rights, with the specific objective of enhancing access to medicines within the Central American Region.

Oxford University Press, 2011, 229.

[339] Office of the High Commissioner for Human Rights, 'UN experts voice concern over adverse impact of free trade and investment agreements on human rights' (2 June, 2015) available at <http://www.ohchr.org/FR/NewsEvents/Pages/DisplayNews.aspx?NewsID=16031&LangID=E>

1.1 Normative Antinomy between Treaties: An Introduction

What first needs to be defined, in order to properly address the aforesaid legal issues, is the very notion of norms conflicts or normative antinomy under international law. For the sake of clarity, the kind of antinomy addressed in this work concerns merely conflicts among treaties' norms. In particular, this section analyses conflicts between norms in the strict sense, namely *when a party to two treaties cannot simultaneously honor its obligations under both*[340].

Generally speaking, the issue of conflicts between treaty norms is a quite complex matter, since the overall practice has demonstrated that no all legal solutions are absolutely established[341]. Simply stated, it is problematic to derive general rules from such scattered practice. Further, it is not always easy to determine when a normative antinomy exists. Certainly, there are cases in which such normative collision is obvious, for example when two norms, applying to the same State and to the same number of facts, require two opposite conducts on such State. In other words, one norm imposes the State to do adopt a certain conduct, while the other norm excludes that very course, or one norm requires that State to act, while the other requires to abstain; no doubt arise that in such cases there is normative antinomy which is often referred to as a genuine conflict[342].

Nonetheless, other cases are not so easy to detect. In fact, it is common that normative conflicts are merely partial, that is, in relation to only a part of the norm. Under a wider perspective there are also apparent or potential normative antinomies. This is the case when the collision between two norms stems from the relevant interpretation given to that very norm and not from the substance of the norm itself. The solution of this type of conflict does not require the legal tools needed to solve normative conflicts, but rather can be avoided throughout the process of interpretation[343]. Accordingly, a further

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[340] C. J. Borgen, "Resolving Treaty Conflicts", *Faculty Publications*, 2005, 575.
[341] R. Kolb, *The Law of Treaties: An Introduction*, Edward Elgar, 2016, 182.
[342] J. Pauwelyn, *Conflict of Norms in Public International Law: How WTO law relates to other rules of international law,* Cambridge, 2003, 164.
[343] Milanovic, *Norm Conflict in International Law*, 73.

distinction can be made between conflict avoidance on one side, and conflict resolution on the other.

An apparent conflict can be avoided resorting to interpretation, as opposed to cases of genuine conflicts in which the incompatibility between two norms cannot be interpreted away. Such cases can be only resolved by determining which conflicting norm has to prevail or have priority over another. Further, the "complete" resolution of a genuine conflict not only requires determining which norm must prevail, but also *the wrongfulness on the part of the state for failing to abide by the displaced norm to be precluded as a matter of state responsibility*[344].

Notably, there is a general tendency in international law whereby the interpreter attempts to blunt or even avoid antinomies by means of "harmonizing"[345] toward the so-called systemic integration approach. Such approach aims at overcoming certain difficulties arising from the aforesaid fragmentation of public international law. The main argument concerns the postulation that *"when States wanted different rules to be applicable, they could not at the same time have wanted normative contradiction. If there were such a contradiction, this would lead at the end of the day to the sacrifice of one rule to the other. It is more reasonable to presume that the legislator wanted both rules to apply. Moreover, the presumption is nourished by the conception that international law should be put in a position of smooth functioning. This is all the more important since it is structurally weaker than municipal law, where State organs take care of enforcement*[346]*"*. The sake of the unity and coherence of the entire international legal framework constitutes, thus, the main objective followed by legal practitioners[347]. Indeed, international human rights courts are particularly inclined to apply presumptions against conflict and techniques of harmonious interpretation in an explicit or implicit manner[348]. As the present Chapter will demonstrate, both systemic

[344] Ibidem
[345] In fact, the general rule grounds on a presumption of non-conflict.
[346] Kolb, *The Law of Treaties,* 183.
[347] A. Rachovitsa, "The principle of systemic integration in human rights law", *International and Comparative Law Quarterly* 66(3), 558.
[348] For explicit examples see: Al-Jedda v UK case of the ECtHR (2011) in which the European Court of Human Rights grounded its ruling on the assumption that the Security Council could not impose on UN

integration and harmonization were the tools adopted by international judicial and quasi-judicial bodies in order to avoid conflict between human rights provisions related to the right to health on the one hand, and the TRIPS on the other. Such situation, thus, falls under the aforesaid apparent normative antinomy examples, in which interpretative means are employed to prevent conflicts between such two areas of law; and most importantly to guarantee that people in need are granted access to essential medicines. An extensive analysis follows throughout the Chapter.

The peculiar features of the international legal system make the study of normative antinomy even more arduous to address. Indeed, the international law system lacks the legal and structural characteristics of domestic legal frameworks, namely: a centralized system with a well-established hierarchy among different sources as well as judicial organs that can rule and determine which norm must prevail in a certain case[349]. In practice, hierarchy between norms in domestic legal systems is a matter of constitutional regulation, which provide detailed guidance to legal practitioners both about relevant interpretative means and provisions concerning solutions of conflicts among such norms[350].

On the contrary, international law has traditionally been considered as a horizontal system of legal norms which are legally binding only if states have expressed their consent to be bound by them. Further, the international framework lacks a centralized system of enforcement, thus, making the judiciary power much limited in comparison to the domestic level. "*Not only does this imply that the enforcement of international law remains a decentralized process, but also that the international legal order lacks a judicial mechanism for consistent interpretation and resolution of norm conflicts"*[351]. Simply stated, there is no hierarchy in international law, besides few exceptions[352], and

member States obligations incompatible with their human rights undertakings. Hence, any ambiguity in the solution of an apparent conflict must be interpreted in light of the compatibility between the obligations under the ECHR and those under the UN Security Council resolution.

[349] E. De Wet and J. Vidmar, *Hierarchy in International Law: The Place of Human Rights: a place for human rights law*, Oxford University Press, 2012, 46.

[350] Ibidem, 64.

[351] Ibidem

[352] See, *ius cogens norms.*

all sources of law are commonly considered equal[353].

International law, however, does provide methods in order to resolve treaty conflicts which stem both from the Vienna Convention of the Law of treaties as well as from relevant practice within the international and domestic realm. The case-by-case solutions provided by international law are a combination of three well established principles within international practice, namely: the *pacta sunt servanda* principle, *pacta tertiis nec nocent nec prosunt,* and lasty, *lex posterior derogate priori* principle. Other principles such as of *hierarchy* and of *lex specialis derogat generali,* which are basic principles employed in domestic legal system, play a minor role at the international level due to its peculiar structure and relevant practice. These methods and principles are described and illustrated in the following section.

1.2 Methods of Resolving Treaty Conflicts provided by International Law

In light of a combined reading of the principles *pacta sunt servanda* and of *good faith* there is a presumption against conflict among treaties. Nonetheless, when two norms are unreconcilable, the normative antinomy cannot be avoided by interpretative means, and, thus, the methods of resolving treaty conflicts provided by international law must be adopted[354].

This seems to be the case of the conflict between the health-related provisions of the ICESCR and the CAFTA agreement (to which a dedicated section is provided in this Chapter). At first sight, the aforesaid conflict between provisions cannot be avoided *via* interpretation and relevant international provisions must be taken into account in order to establish some kind of primacy among conflicting norms. Accordingly, the present

[353] J. Pauwelyn, *Conflict of Norms,* 94.
One of the few cases in which international law partially resembles domestic system regards law-making processes within international organizations, in which "legislative" bodies must comply with the provisions envisaged by the establishing treaty of the organization. The latter usually provide a sort of hierarchy among the sources and legal acts that can be adopted within the organization. In this regard, the United Nations Charter is often regarded as a sort of Constitution. Accordingly, a resolution adopted by the UN Security Council in breach of the UN Charter would be void because it was passed ultra vires.
[354] Milanovic, *Norm Conflict in International Law*, 70.

section provides the tools required to properly address the relationship between the two aforementioned treaties.

Under a formal perspective, all treaties appear as independent and autonomous entities with one another in light of the aforesaid *pacta sunt servanda* principle. Accordingly, some scholars describe a set of treaties as an accumulation of such agreements rather than a joint system[355]. Such thought is significant if we consider that the conflict settlement system envisaged by the international framework is laconic and provides guidance in just few detailed and confined situations.

Article 30 of the Vienna Convention constitutes the ultimate landmark for any scholar willing to address matters related to treaty conflicts. Unfortunately, such article, labelled *Application of successive treaties relating to the same subject matter*, already from its title has a quite limited scope. Such article is often regarded as an insufficient provision, since it does not provide solutions for all the problems which may arise in the case of a conflict of treaties[356]. For example, nothing in the article can be found in regard to treaties negotiated or concluded simultaneously.

Further, scholars highlighted that Article 30 is deficient in dealing with the complicated nature of many treaty conflicts, since, for example, it does not differentiate between different treaties, between the time of the treaty and the time of the treaty obligation, or between 'normal obligations' and *erga omnes* obligations[357]. Lastly, scholars raised concerns for the lack of provisions regarding situations in which treaties in question are compatible in relation to their substantive provisions but establish different dispute settlement procedures, thus resulting in to so-called 'forum shopping'[358].

In practice, the aforesaid article provides guidance for only two potential situations: on the one hand, in the case of successive treaties with identical parties; on the other, in

[355]P. Reuter, *Introducción al derecho de los tratados*, Fondo De Cultura Economica USA, 2004, 153.

[356]J. Finke, "Regime-Collisions: Tensions between Treaties (and How to Solve Them)" in Tams CJ, Tzanakopulos A, Zimmermann A, *Research Handbook on the Law of Treaties*, Edward Elgar, 2014, 415-416.

[357] M. Benzing, "US Bilateral Non-Surrender Agreements and Article 98 of the Statute of the International Criminal Court: An Exercise in the Law of Treaties", *MPYUNL 8*, 2004, 226.

[358] P. Zapatero, "Modern International Law and the Advent of Special Legal Systems", *ArizJICL* 23, 2005, 63-64.

the case of successive treaties with different parties[359]. Such limited scope of applicability, thus, merits closer scrutiny.

In specific, Article 30 allows States parties of a treaty to include so-called *compatibility clauses.* Accordingly, these clauses may make express provision for conflicts with other treaty norms, either by stipulating the primacy[360] or by admitting the subordination of either the latter of former treaty (Article 30.2). Further, paragraph 3 codifies the chronological principle (*lex posterior derogat priori*) under which in cases of identical parties between two conflicting treaties, the latter must prevail.

Problems arise when the parties of two conflicting treaties are not identical. Such scenario requires the combined application of the *pacta tertiis nec nocent nec prosunt* principle and of the aforesaid chronological principles. According to the latter principle, the later treaty will prevail *inter partes* for the States parties to the previous and the later agreement (article 30.4(a)).

In regard to the remaining parties, which are not identical, it is worth mentioning the two main theories on the effect of collision between treaty norms. Firstly, the objective theory grounds on the principle of legality; secondly, the subjective theory pivots upon the parties' will. According to the objective theory, in case of collision between two norms, the later provision must be considered void when contradicting an earlier one. This theory grounds on the argument that a party cannot unilaterally deprive a treaty partner of it rights by concluding a contradicting treaty with another State. *It must honour its existing obligations under the first treaty, which thus prevail over those of the later one*[361]. Such position was preferred by Lauterpacht during the drafting process of the Vienna Convention on the Law of Treaties (VCLT) of 1969. He argued that the *pacta sunt servanda* principle placed an implicit limit on the capacity of parties to adopt later conflicting treaties[362].

On the other hand, the subjective theory, which was the solution adopted in Article 30

[359]Dörr and Schmalenbach, *Vienna Convention on the Law of Treaties*, 539.
[360]The fact that clauses claiming priority over other treaties are not specifically included in para 2 does not restrain States from including such provisions within relevant treaty.
[361] Kolb, *The Law of Treaties,* 186.
[362] Ibidem

and relevant practice, holds that conflict between treaty norms triggers international responsibility for the obligation breached on the concerned State, notably to pay damages. In other words, such theory argues that while both treaties remain equally valid, the State bound by incompatible obligations will have discretion to respect one and sacrifice the other. The non-compliance, thus, involves State responsibility for breach, not nullity of the contrary provisions[363]. As far as Article 30 is concerned, the conflict between successive treaties does not lead to the invalidity of the former treaty. A joint reading of para 2 and 3 of such Article, solely provides the applicability of the prevailing treaty and the inapplicability of the previous treaty. The previous treaty still applies as far as it is compatible with the latter treaty[364]. It can be concluded that the choice of resorting to state's responsibility has a deterrent rather than repressive function. Accordingly, States which conclude a successive treaty that is incompatible with a previous treaty must be conscious of the fact that such action may not involve the invalidity of one of the treaties but instead their international responsibility.

As already stated, Article 30.2 provides the adoption of conflict-avoidance techniques, such as the possibility that the relationship between treaties is directly regulated by the will of the parties who establish which of the two treaties must prevail[365]. In such cases, the parties include specific *conflict clauses.* As a result, the will of the party must triumph and the aforementioned principles, such as the chronological one, are put aside and can only be adopted as subsidiary means when relevant conflicting norms are impossible to reconcile[366].

The inclusion of the aforesaid *conflict clauses* is desirable, since they both facilitate interpretation and shed light on how the parties want to address the international obligations envisaged in the new treaty. Unfortunately, neither the ICESCR, nor the CAFTA agreement provide explicit clauses, making the debate over their relationship difficult to address.

In light of the aforementioned considerations, Article 30 does not suffice in providing

[363]Dörr and Schmalenbach, *Vienna Convention on the Law of Treaties*, 539.
[364] Ibidem, 553.
[365]J. Pauwelyn, *Conflict of Norms,* 237-238.
[366] Dörr and Schmalenbach, *Vienna Convention on the Law of Treaties*, 539.

the proper tools for studying the specific relationship between human rights and trade-related treaties. Accordingly, in order to complete the analysis regarding norms of conflict between treaties, the principle *lex specialis derogat generali* (principle of speciality) cannot be ignored, even if it is not mentioned into the Vienna Convention.
In case of conflict between the chronological and specialty principle the general rule dictates that *lex posterior generalis non derogat prior specialis.* In other words, the special and more detailed nature of one of the treaties must be taken into consideration and suffices in granting precedence over more general provisions. Nonetheless, the ILC has recently questioned such approach, emphasizing that it is not always easy to determine the general and particular scope of a norm. Indeed, the substantive coverage of a provision or the number of legal subjects to whom it is directed may lead the observer to different conclusions. To this end, the ILC has argued the need to relativize the specialty principle with all to other methods of resolving treaty conflicts provided by international law[367].
Additional difficulties arise when one of the treaties in question concerns human rights protection. In fact, the requirement of effective protection which stems from every human rights treaty leads to a reduced application of both the specialty and chronological principles. Leaving aside more technical issues such as reservations, interpretations and successions of States in human rights treaties, which regulation significantly departs from general rule of international law[368], the application of the *traditional methods* of resolving treaty conflicts to human rights vs trade-related treaties poses the following problems. Firstly, to determine whether the two treaties cover the same subject matter; secondly, to solve the challenges arising from the different participation in the treaties; thirdly, to determine whether the *traditional methods* of resolving treaty conflicts can actually apply to human rights treaties. Before addressing such significant legal topics, at this point it is important to introduce the objective character of human rights obligations in order to properly contextualize the

[367] A/CN.4/L.682 13 April 2006, p 39-40.
[368] T. Scovazzi, *Corso di Diritto Internazionale: Parte III- La Tutela Internazionale dei Diritti Umani*, Giuffrè Editore, 2013, 39-41.

relationship of conflict when one of the two treaties has a human rights nature.

There is no doubt that international treaties cannot be considered standard treaties imposing merely synallagmatic obligations among States. Accordingly, both the Inter-American Court on Human Rights as well as its European counterpart held that differently from classical international treaties, human rights treaties include more than the typical mutual legal compromises among the parties. Such treaties create a net of bilateral compromises, namely objective obligations[369]. When States conclude such particular treaties, they do not merely *"accomplish the reciprocal exchange of rights for the mutual benefit of the contracting States. Such states can be deemed to submit themselves to a legal order within which they, for the common good, assume various obligations, not in relation to other States, but towards all within their jurisdiction"*[370]. The former president of the Inter-American Court, Cançado Trindade, argued that the main feature which distinguishes human right treaties from classic ones is the objective character of their human rights obligations[371]. Likewise, such different kinds of obligations imply that favorable interpretative means for the individual must be employed for human rights treaties. In fact, human rights treaties must be interpreted in accordance with the objective character of their obligations, which are ultimately aimed at the protection of individuals and not at synallagmatic concession of rights between states[372]. In this regard, the literal interpretation of particular treaty's provisions must surrender in light of the so-called *effet utile*. In particular, the Inter-American Court argued that *"the effective protection of human rights constitutes the object and purpose of the of the American Convention, so when interpreting it the Court shall do so in the sense that the human rights protection regime has all its proper effects*[373]*"*.

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[369] Inter-American Court of Human Rights, *The Effect of Reservations,* OC-2/82, 14-16; European Court of Human Rights, *Ireland* v. *the United Kingdom,* 18/01/1978.

[370] Inter-American Court of Human Rights, *The Effect of Reservations*, Advisory Opinion, OC-2/82 (IACtHR, 24 Se 1982), par. 29.

[371] L. Caflisch and A.A. Cançado Trindade, "Le conventions américaine et européenne des droits de l'homme et le droit international général", *RGDIP* 108, 2004, 12-18.

[372] Ibidem

[373] Inter-American Court of Human Rights, *The Right to Information on Consular Assistance. In the Framework of the Guarantees of the due Process of Law*, Advisory Opinion OC-16/99 of October 1,

The analysis regarding the objective character of human rights obligations would not be complete without the scrutiny of the *erga omnes* nature of such obligations. *Erga omnes* norms are not relevant for their particular hierarchy, but rather for their ability to determine both their recipients as well as which States have legal interest in ensuring compliance. The principle of obligations *erga omnes* was firstly introduce by the International Court of Justice (ICJ) in the Barcelona Traction case of 1970[374]. The case did not concern human rights obligations but rather an issue of diplomatic protection, in which the Belgian capacity to start proceedings against Spain depended on whether such a right existed[375]. Focusing merely on the ICJ understanding of *erga omnes* obligations, the Court held that they are *"owed to the international community as a whole, with the consequence that all States in the world have a legal interest in the compliance with the obligation*"[376]. For this reason, in a case of breach of such obligations, at least theoretically, any State can claim the international responsibility of the State which committed the violation.

The ICJ specifically mentioned aggression, genocide, slavery and racial discrimination as well as "*the principles and rules concerning the basic rights of the human person"* as illustrations of obligations *erga omnes*[377]. In addition, it must be noted that acts of aggression must be primarily regarded as triggering *erga omnes* obligations in relation to other States, as opposed to the other kinds of obligations trigger obligations *erga omnes* that apply predominantly to human beings. As a result, another distinction can be drawn "*between obligations* erga omnes *which seek to protect the interests of other States, and obligations* erga omnes *which seek to protect human beings directly"*[378]. For the sake of clarity, the present work focuses only on the type of obligations *erga omnes* which stem from the basic rights of the individual, and on those obligations,

1999, Serie A No. 16., par. 58.

[374] International Court of Justice, The Barcelona Traction Case, *ICJ Reports* 1970, p 33, 34, paras. 33-35.

[375] Ibidem

[376] *Report by ILC Special Rapporteur James Crawford* ACN.4/507, 2000, par. 106(a).

[377] *Barcelona Traction,* par. 34.

[378] H. Morten Haugen, "The Nature of Social Human Rights Treaties and Standard-Setting WTO Treaties: A Question of Hierarchy?", *Nordic Journal of International Law 76*, 2007, 446.

which aim to protect the interests of States.

Unfortunately, the practice of the ICJ or other international courts has not provided neither a defined list of *erga omnes* obligations nor guidance in relation to the seriousness of the breach of the obligations. Accordingly, it is not clear under which conditions the lack of observance and fulfilment of obligations by one State can trigger the legal interest of the international community to act. Some scholars, thus, argue that *"it is therefore reasonable to conclude that while the principle of obligations erga omnes is generally accepted, the principle is not sufficiently specified and clear"*[379]. In light of such unclear scenario, the present dissertation tries to shed light on the alleged *erga omnes* character of the right to access to medicines in its relationship with trade-related treaties such as the CAFTA agreement.

1.3 Legal challenges resulting from Article 30 of the Vienna Convention to Human Rights Treaties

The application of Article 30 of the Vienna Convention to the issue at stake, namely the relationship between article 12 of the ICESCR and the CAFTA agreement, requires a preliminary step to be taken. Indeed, such application depends on the fact that Article 30 regulates situations in which two conflicting treaties cover the *same subject matter.* Hence, what needs to be determined, in order for Article 30 to apply, is whether the ICESCR and the CAFTA agreement regulate identical matters.

The *travaux preparatoires* of the Vienna Convention do not provide any guidance in relation to the meaning that should be attributed to the wording *same subject manner.* Such an ambiguity triggered an array of different interpretations[380]. While some scholars adopted a restrictive approach, others grounded on more pragmatic methods. The latter scholars argued that a case-by-case test must be carried out in order to determine whether the application of two norms to the same facts leads to

[379] Ibidem

[380] Dörr and Schmalenbach, *Vienna Convention on the Law of Treaties*, 544.

incompatibles outcomes. In other words, the element that must be taken into account is whether the application of a treaty impacts the application of the other agreement[381]. Otherwise, a narrow interpretation would lift most of the important cases such as conflicts between environmental and trade treaties, or conflicts between human rights and humanitarian law treaties, outside the Article range of application[382].

The ILC followed the second pragmatic approach and held that "to limit the application of article 30 to treaties "dealing with the same subject" would allow States to deviate from their obligations simply by qualifying a novel treaty in terms of a novel "subject""[383]. Further, according to the ILC, the requirement established in Article 30 is met if two different norms are invoked for the regulation of the same subject and if the application of a treaty influences the proper fulfillment of another treaty's obligations[384].

In light of such considerations, it can be concluded that the requirement of covering *the same subject matter* is met, since what the ICESCR requires and what the CAFTA diminishes cover the same subject matter, namely access to medicines. The possibility of two treaties to regulate the same matter from different perspective must, thus, be admitted and that it is very likely to occur in light of the aforesaid fragmentation of international law[385]. Accordingly, "subject-matter" must refer to the object of the measure challenged[386]. This leads to the conclusion that the measure challenged refers to medicines under the perspective of both the ICESCR as well as the CAFTA agreement.

The second challenge relevant to the issue at stake concerns the diverse participation of the treaties involved. The parties of the ICESCR are not identical to the parties of

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[381] E. W. Vierdag, "The Time of the 'Conclusion' of a Multilateral Treaty: Article 30 of the Vienna Convention on the Law of Treaties and Related Provisions", *British Yearbook of International Law* 59, 1988, 109.

[382] C. J. Borgen, "Resolving Treaty Conflicts", *George Washington International Law Review* 37, 2005, 612-614.

[383]ILC, *Fragmentation of International Law,* 130.

[384] Ibidem, 21.

[385]M. Forrest, S. Schnably Stephen et al, *International Human Rights and Humanitarian Law: Treaties, Cases and Analysis*, Cambridge University Press, 2006.

[386] M. G. Zoe, "Conflicts of norms and conflicts of jurisdictions: the relationship between the WTO agreement and MEAs and other treaties", *Journal of World Trade* 35, 2001, 1090.

the CAFTA agreement, since, for example, the United States has not ratified the former human rights treaty. This scenario triggers an additional problem when the treaties in question do not provide mere synallagmatic obligations, but rather integral or *erga omnes* undertakings, such as human rights treaties. These treaties *"are held by states at the international level constitute, not a promise to one or more other states taken individually, but a promise to the collectivity or common conscience of all states involved. The objective of human rights obligations is essentially to prevent states mistreating their own nationals"*[387].

Putting aside the issue of *erga omnes* obligations, Article 41(b) of the Vienna Convention, named *Agreements to modify multilateral treaties between certain of the parties only*, seems to include the specific situation of human rights treaties and of the ICESCR in particular. Such article prohibits the conclusion of a successive treaty in two situations: on the one hand, if the latter negatively affects the enjoyment or the performance of the rights envisaged by the first treaty; and on the other, if the modification in question *is incompatible with the effective execution of the object and purpose of the treaty as a whole*[388].

In regard to integral obligations, the ILC argued that such obligations enjoy a sort of precedence over bilateral or conventional ones. While such consideration does not solve the general question of primacy, it does have practical effects, since according to the ILC the clauses of conflicts that the parties may include in a treaty cannot derogate such integral obligations[389]. In particular, the ILC emphasized that *inter se* agreements, which modify multilateral agreement including integral obligations, must be prohibited if they hinder the execution of the purpose and objective of the former multilateral treaty, as provided for by Article 41[390]. If that is the case, clauses of conflicts would not find application in relation to human rights treaties, such as the ICESCR.

Another issue the needs to be address is that while the US is not a party to the ICESCR,

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[387]Pauwelyn, *Conflict of Norms in Public International Law,* 65.
[388] Vienna Convention on the Law of Treaties, Article 41(b).
[389] H. Morten Haugen, "The Nature of Social Human Rights Treaties and Standard-Setting WTO Treaties: A Question of Hierarchy", *Nordic Journal of International Law 76*, 2007, 449.
[390] ILC, *Fragmentation of International Law*, 130.

since it has not ratified the agreement, it has signed the text of such convention. In light of the general principle *pacta tertiis nec nocent nec prosunt,* the US is not legally bound to the provisions envisaged in the ICESCR. This consideration seems to deprive the debate on conflicts among treaty of any relevance, since the US is not a party of one of the treaties under consideration. Signature, however, does provide *minoris generis* legal effects. In fact, according to Article 18 of the Vienna Convention, "a State is obliged to refrain from acts which would defeat the object and purpose of a treaty" if such state has signed the international instrument, thus, manifesting both its agreement of the treaty text and its will to be legally bound upon ratification.

In light of such reasoning, the provisions provided by the CAFTA agreement which impede the fulfillment and proper enjoyment of the right to health should be prohibited. In addition, under the considerations outlined in regard to the violations of the so-called *erga omnes* obligations, the legal consequences that must be admitted are their non-opposability and, as held by the ICJ, "*that States were under an obligation not to recognize the illegal situation resulting from the construction of the wall and not to render aid or assistance in maintaining the situation created by such construction"*[391].

1.4 Questions concerning the primacy of Human Rights vis-à-vis Trade-related Treaties

The previous section has incidentally highlighted various peculiar features of human rights treaties, which lead to the conclusions that they cannot (or should not) be considered standard treaties imposing merely synallagmatic obligations among States. Under this assumption, some scholars have argued that from the particular nature of these kinds of agreements should follow their primacy in a case of collision with other treaties[392].

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[391] Advisory Opinion Concerning Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory, International Court of Justice (ICJ), 9 July 2004, par. 159.

[392] X. Seuba, *La protección de la salud ante la regulación internacional de los productos farmacéuticos,* Marcial Pons, 2010, 329. Others have argued a sort of constitutional status for such rights: S. Gardbaum, "Human Rights as International Constitutional Rights", *European Journal of International Law*, 19, 4,

The joint reading of Articles 55 and 56 of the UN Charter mandates that States act towards the achievement of higher standards of living, progress in the economic, social and healthcare sector, and for the universal respect of human rights. Remarkably, the Charter constitutes one of the most significant examples concerning the aforesaid primacy clauses. Generally speaking, Article 103 provides that in case of collision between the obligations established by the Charter and other obligations contracted by any other international agreement, the former must always prevail. Such example is one of the few cases in which the international system overcome its horizontal character and establishes a clear hierarchy among norms.

The joint reading of the aforementioned Articles of the Charter has led some scholars to argue that in a case of norms conflict, international human rights law shall always prevail since the obligation to respect human rights is envisaged in the UN Charter, which prevalence is turn guaranteed by its Article 103[393]. According to some scholars, such argument applies to the issue at stake, namely the conflict between right to access to medicines provisions and intellectual property obligations[394].

Notwithstanding, other scholars argue that the human rights related provisions envisaged in the Charter are too broad in scope and, thus, cannot be regarded as sources of specific human rights obligations[395]. Although it is true that the inclusion of human rights provisions in the UN Charter constituted a significant progress in that area, such rights were neither properly listed nor were they adequately defined. In fact, the Charter does not mention any notions, such as protection or safeguard, but merely provides a general reference to human rights.

In support of such argument, it must be noted that also intellectual property right might

749; I. D. Seiderman, *Hierarchy in international law: the human rights dimension*, Intersentia, 2001, 67; S. Joseph, *Blame it on the WTO? A Human Rights Critique*, Oxford University Press, 2011. M. Scheinin, "How and Why to Assess the Relevance of Human Rights Norms in 'Other' International Courts", Chapter in *Human Rights Norms in 'Other' International Courts*, Studies on International Courts and Tribunals, Cambridge University Press, 2019

[393] E. Petersmann, "Human Rights and the Law of the World Trade Organization", *Journal of World Trade*, 2003, 247.

[394] P. Cullet, "Patents and medicines: the relationship between TRIPS and the human right to health", *International Affairs* 79(1), 2003, 158.

[395] M. Dixon, "The United Nations at Age Fifty: A Legal Perspective" in B. Tomuschat, *British Yearbook of International Law*, Kluwer Law International, 1996, 264.

fall under the protection granted by the Charter, since it is well-established that such private rights play a key role in boosting healthcare progress and economic progress. In addition, specific cases have demonstrated that human rights provisions yielded before decisions of the UN Security Council in light of Article 103 of the UN Charter[396]. Leaving aside such debates, it must be noted that the Charter has been the base line for later codification of human rights and for the adoption of specific treaties to this end.

Another argument, which is worth mentioning at this point of the analysis, is the understanding of human rights as *ius cogens* norms. Acknowledging the right to access to medicines as a *ius cogens* norm would completely reverse the perspective under which addressing the issue of conflicts between norms.

One of the first references to *ius cogens* dates back to the works of the Permanent Court of International Justice in the *Oscar Chinn case* and in particular to the words of Judge Schükingas, which has come to be understood as a precursor to modern debates about the *ius cogens* concept. The Judge argued that it would be impossible to commence the process of codification of international law without imagining a set of *ius cogens* norms, in a manner that a violation of such imperative obligations would be legally void[397]. Such universal, fundamental and imperative norms exist to fulfill the highest interest of the international community and not the particular needs of States. Remarkably, *ius cogens* norms have strict legal effects in practice, since their primacy refers to hierarchy and not only to precedence over a conflicting norm. As a result, in case of conflict not only the relevant provision, but the entire treaty, in which the conflicting norm is envisaged, is void in accordance with Article 53 of the Vienna Convention[398].

Such hierarchical nature triggered the hope of a number of scholars to include the entire category of human rights in the *ius cogens* box. Unfortunately, such argument lacks foundations in the relevant practice. In this regard, the ICJ has been extremely cautious when determining whether or not a specific had a *ius cogens* character. Similarly, the

[396] Joined Cases C-402 & C-415/05 P, Kadi v. Council of the European Union, and Al Barakaat Int'l Found. v. Council of the European Union, 2008 E.C.R. 299, par. 305 – 309.
[397] Permanent Court of International Justice, *Oscar Chinn (U.K. v. Belg.)*, 1934,(ser. A/B) No. 63 (Dec. 12), 150.
[398] Pauwelyn, *Conflict of Norms in Public International Law*, 276.

Human Rights Committee had only made express reference to few categories of human rights, such as *inter alia,* the right to life and the prohibition of torture. The Committee argued that the latter human rights have peremptory character meaning, for instance, that no one can be arbitrarily deprived of his life[399]. Likewise, the ILC has included under the *ius cogens* category norms related to the prohibition of aggression, slavery, torture, genocide, racial discrimination, *apartheid,* as well as fundamental norms of International Humanitarian Law and the right to self-determination[400].

Hence, the relevant practice shows that the human rights related norms are not regarded as *ius cogens* provisions *tout court,* but rather only few, well-established example of *gross violations* of human rights. In light of such considerations, it would be improper and incorrect to conclude that human rights norms enjoy superior hierarchical status in relation to trade provisions. Accordingly, if human rights norms are not considered *ius cogens,* even less the provisions related to the right to access to medicines can be regarded as such. Such provisions do not fulfill the requirements provided by Article 53 of the Vienna Convention since they are not norms "*accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character"*[401]. The practice has demonstrated that States have actually performed in the opposite direction, as showed by the conclusions of agreements such as the CAFTA. Notwithstanding, aligning the content and scope of the ICESCR to *ius cogens* would definitely provide stronger protection for this category of rights and would prevent trade-related treaties such as the CAFTA agreement to carry out its adverse effects.

[399] Human Rights Committee, E/CN.4/1983/9, par. 19.
[400] International Law Commission, Articles on Responsibility of States for Internationally Wrongful acts, Report of the International Law Commission on the work of its Fifty-third section, UN GAOR, 56th Sess. Sup Num. 10, UN Doc. A/56/10 (2001), 282-284.
[401] Dörr and Schmalenbach, *Vienna Convention on the Law of Treaties*, 965.

2. The evolution of the international legal framework related to Intellectual Property

In today's world, traditional resources such as raw materials, financial capitals and labour remain significant for the economic development of countries. The most advanced productive activities, however, cannot be achieved without the fruits of technical and scientific creativity, making research and innovation indispensable ingredients for economic progress. For this reason, in modern economy, the fruits of scientific and technological research activities are typically protected by international and domestic intellectual property (IP) regime. Indeed, just as raw materials and labor were key resources in the first and second industrial revolutions, intellectual property is a central asset in an economy based on information and knowledge.

The intellectual property legal framework allows inventors and creators to market their new products under monopoly conditions, albeit for a fixed and limited period, in order to achieve economic benefits that outweigh efforts to innovate. Intellectual capital is a form of knowledge to which societies have decided to grant specific property rights, which in fact have some similarity to property rights over movable and/or immovable assets. However, the protection of ingenuity products opens several debates about the interpretative challenges related to the typology of protected goods and the scope of the guaranteed protection, such as essential medicines[402].

This section examines the evolution of the legal framework related to intellectual property, with a particular focus on the most significant international treaties and organizations, as developed states, over the years, succeeded in establishing a binding international legal regime for most countries involved in international trade. In fact, the comparative panorama of rights over intellectual creations, although still marked by different regulations between countries, is increasingly characterized by two trends which, although different from each other, have a complementary effect: first, it is a

[402] L. R. Helfer and G.W. Austin, *Human Rights and Intellectual Property- Mapping the Global Interface,* Cambridge University Press, 2011, 16.

question of achieving the expansion of the scope of these rights of protection of human ingenuity and second, it is a question of universalizing and guaranteeing at a global level the protection related to the intellectual property regime. In short, intellectual property regimes seek to balance the moral and economic rights of creators and inventors with the broader interests and needs of society. An important justification for IP law in general and patents in particular is that incentives and rewards to inventors result in benefits to the global community[403].

2.1 The History of Intellectual Property Protection

The needs and efforts to protect intellectual property have a long history[404], which some analysts date back to the 4th century BC and others from 9th century China[405]. This section analyzes and highlights the main phases through which the system of recognition and protection of intellectual property rights has progressively developed at the international level. In the Middle Ages and especially in the first years of the modern age, the rights related to intellectual property had a concessionary character, understood as privileges or monopolies granted by the sovereign through administrative measures, which established a territorial limited protection. Moreover, some extra-territorial exceptions were provided in light of the principle of reciprocity or, as in the case of common law countries, on the grounds of international comity[406]. It is worth noting that the Venetians are credited with the creation of the first properly developed patent laws in 1474, which established that a formal approval of the sovereign, the Dux, would suffice to grant an inventor the privilege of exclusivity for a limited number of years over a new and original invention. This regime was extended

[403]A. Snodgrass Godoy, *Intellectual Property and Human Rights in the Free Trade Era,* Standford University Press, 2013, 15.
[404]In fact, the first traces of a form of protection for inventions were already found in the 5th century B.C. in *Magna Graecia,* in Sibari (Italy). An inscription dating back to that time has been found, which stated: *"All those who improve the well-being of society are encouraged, ensuring profits for the inventor for one year".*
[405]C. Heath, *Intellectual Property Law in China*, Kluwer Law International, 2015, 22.
[406]J. Davis, *Intellectual Property Law*, Oxford University Press, 2013, 6-7.

to other European states in the following 100 years[407].

In 1624, the Parliament of the Kingdom of England enacted *the Statute of Monopolies* which established for the first time the right to all of the temporary exclusivity of an invention, provided the latter met the requirements of novelty and originality. In particular, the modern copyright law began when the same Parliament adopted *Anne's Statute* in 1710[408].

In the United States of America, Article 1 of the 1787 Constitution empowered Congress to promote the progress of science and useful arts by assuring authors and inventors the exclusive right to their writings and discoveries[409]. Similarly, in 1790 the Act to Promote the Progress of Useful Arts was adopted, providing an early legal regime for patent protection; but only in 1836 did the Patent Act come into force, introducing a complex administrative procedure that has remained substantially unchanged to date[410].

Until the mid-fifties of the XIX century, intellectual property regimes, as the aforementioned analysis shows, were characterized by very limited territorial effect related to the specific context of the country taken into account. There was no real international legal framework related to intellectual property and no sign of cooperation between countries. This phase of territorial limitation of the intellectual property regime, however, began to decline mainly due to the economic and social changes occurred in the afterwards of the Industrial Revolution. In other words, the technological novelties implemented during this period and the transformation to a market economy made the protection of intellectual property not only a national issue,

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[407]In this regard, it is worth citing the case of the privilege granted in 1557 to Galileo Galilei for the construction of a hydraulic system that allowed water to be extracted from a well in sufficient quantity to power a fountain for mouths, known as *"The tool to raise the water"*. V. Marchis, *150 anni di invenzioni italiane,* Codice Edizioni, 2017, 25.

[408]P. Drahos, "The Universality of Intellectual Property Rights: Origins and Development", Intellectual Property and Human Rights, Geneva, World Intellectual Property Organization 1999, 15 (WIPO Publication No. 762 (E)). Number 8 Ann. c. 21 in *The Statutes of the Realm*.

[409]Art. 1, par. 8, Section 8, The Constitution of the United States, adopted 1787, Washington D.C., US Government Printing Office, 1985.

[410]C. M. Marenghi, *Il diritto alla salute e la proprietà intellettuale: una nuova strada?,* Lateran University Press, 2015, 21-22.

but also an issue to be addressed at a global level[411].

As a result of the aforementioned socio-economic changes, countries acknowledged the importance of providing a more extended protection of intellectual property beyond national borders. This led to the first forms of intergovernmental cooperation on the subject, at first through the conclusion of bilateral agreements between States. The second half of the XIX century is in fact by multiple bilateral agreements (precisely, in 1883 there were 69 agreements in force mostly dealing with trademark) which, however, made the system even more complex. In practice, these agreements created a fragmented system which could not satisfy the need of uniformity desired at the international level[412]. For example, contracting States parties were unable to properly guarantee the effectiveness of the *most favored nation* principle. In accordance with the latter, any State had the right to enjoy the more advantageous treatment granted by the recipient State to any other country. The intricate net of often overlapping bilateral agreements, hence, made the aforementioned principle inapplicable in practice and the entire system unable to ensure equal treatment among states.

In light of the above scenario, two multilateral acts, namely the Paris Convention (on the Protection of Industrial Property) of 1883 and the Bern Convention (on the Protection of Literary and Artistic Works) of 1886, were adopted. These conventions, which gathered the major trading powers of the time, constituted the first pillars of international cooperation related to intellectual property. Since then, there have been other multilateral agreements (such as the Madrid Convention of 1891 on trademarks and the Hague Convention of 1925 on designs), as well as numerous updates and revisions of these conventions. In 1893, the international offices established by these agreements were unified to create an international organization for the protection of intellectual property (better known by its French acronym, BIRPI)[413].

The Paris Convention, emended in 1967 for the last time, concerned, *inter alia,* the protection of inventions, trademarks, industrial designs, geographical indications and

[411]Ibidem
[412]S. Ricketson, *The law of intellectual property,* Law Book, 1984, 600.
[413]BIRPI: Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle.

the prosecution of unfair competition practices. The Convention surely did not provide a comprehensive and exhaustive legal framework in relation to the latter subjects. Notwithstanding, the Paris Convention constitutes an important achievement of the international diplomacy in the shift from national to international protection of intellectual property rights.

In summary, the Convention introduced at the global stage two main principles which would become the foundation of modern intellectual property law, namely, national treatment and priority. According to the first principle, when an application for a patent or a trademark is filed in another contracting State, the applicant benefits the same treatment as if he/she were a national of that particular State. In addition, the system granted applicants and right-holders with procedural protection. In fact, once the intellectual property right is conferred to the applicant, the latter can access the same legal remedy against any IP violation as if the right-holder was a national of that State[414].

The priority right principle constitutes a true update of the intellectual property regime and is often referred to as one of the cornerstones of the Paris Convention. In light of Article 4 of the Paris Convention, an applicant who firstly filed an application for a patent or trademark within one State party is entitled to use that first filing date in order to benefit protection in any other contracting State. The subsequent applications in other States parties must, however, be submitted within six months for trademarks and twelve months for patents from the first submission. In other words, the Convention conferred a preferential right to the first applicant, since subsequent applications are granted retroactive effect to the first filing date[415].

Nevertheless, the aforementioned regime presented multiple deficiencies in terms of substantive protection. For example, in accordance with the principle of national treatment, contracting States were required to apply their IP domestic legislation to foreigners, but were not compelled to harmonize related norms among them[416]. In

[414]G.H.C. Bodenhausen, Guide to the Application of the Paris Convention for the Protection of Industrial Property As Revised at Stockholm in 1967, *BIRPI, 1969, 12-13.*

[415]Ibidem

[416] U. Loewenheim, "The Principle of National Treatment in the International Conventions Protecting Intellectual Property". In: Pyrmont W.P..W.., Adelman M.J., Brauneis R., Drexl J., Nack R. (eds) *Patents and Technological Progress in a Globalized World*. MPI Studies on Intellectual Property, Competition

addition, the Paris Convention did not provide a punitive system in order to secure compliance and enforcement in case of infringement of the norms envisaged within, nor did the Convention established a mechanism for the settlement of interpretative and other disputes over its adequate implementation[417].

Interestingly, article 28 provided that in case of a possible dispute among contracting parties, the latter could initiate proceedings before the International Court of Justice of the United Nations. This specific provision, however, was not binding upon the parties, and this is the reason no proceeding was never brought before the Court[418]. The drafters of the Convention believed that regardless of the lack of uniformity among the different legal system, any kind of discrimination would have been avoided throughout the adoption of the national treatment principle. The principle, however, proved to be ineffective in practice, especially in developing countries which did not provide adequate legal frameworks for the protection of ip rights both under a substantive and procedural perspective[419].

In a changing world characterized by the liberalization of trade, in which the transfer of information and goods between States became every day much easier, developed countries soon realized that the former system was ineffective for the protection of their national IP rights abroad, and, indirectly, for the protection of their economies. For example, starting from the 1970s, phenomena such as counterfeiting and copyright-piracy developed exponentially, reaching 5 to 6 % of international trade[420]. The system was, hence, unable to address concrete violations of IP rights, which constituted a barrier to exportation, since the same goods were produced and sold locally in an unlawful manner. As a result, tensions arose between developed and developing countries. In most cases, the latter countries did not even ratifie the aforementioned

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and Tax Law, vol 6. Springer, 2009, 594-595.

[417]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 23.

[418]The same considerations and analysis can be made on the Bern Convention on the Protection of Literary and Artistic Works of 1886

[419]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 24.

[420] P. Picone and A. Ligustro, *Diritto dell'Organizzazione Mondiale del Commercio,* in Diritto Internazionale e Ordine Mondiale, 2002, 400.

Conventions and, thus, were not bound to the legal regime[421]. The situation did not change when the BIRPI was succeeded by the World Intellectual Property Organization (WIPO) established by the Stockholm Convention in 1967[422]. The new organization, which became a specialized agency under the auspices of the United Nations in 1974, was responsible for the development of the international system for the protection of intellectual property[423].

2.2. The shift of Intellectual Property protection from the World Intellectual Property Organization (WIPO) to the General Agreement on Tariffs and Trade (GATT) to the World Trade Organization (WTO)

It is important to note that until 1993, WIPO was the only organization competent in dealing with intellectual property and its institutional mandate was substantially limited to supporting and facilitating negotiations between governments for the adoption of international instruments in this field. The role played by this organization was to encourage negotiations and agreements mainly of a technical-specialist nature, which were largely limited to dealing with issues for industrialized countries with the mediation of professionals who mainly provided legal assistance[424].

It is worth noting that the legal regime established under the Stockholm Convention reflected the typical features of public international law, since it had relatively modest impact on the domestic legal systems of States parties, which, in fact depended on ratification and transposition at the national level of the acts adopted by the Organization[425]. As a result, competent national authorities (legislative, governmental and judicial) enjoyed broad discretion in the implementation of international standards,

[421]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 24.
[422]Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S. 3 [WIPO Convention].
[423]J. Davis, *Intellectual Property Law*, Oxford University Press, 2013, 10.
[424]C. May, *The World Intellectual Property Organization- Resurgence and the Development Agenda*, Routledge, 2007, 10-11.
[425]Ibidem, 14.

due to their ambiguous formulation, which, in addition established a weak and almost non-existent enforcement mechanism, as proved by the fact that the aforementioned referral clause to the International Court of Justice has never been used for the settlement of disputes in this matter.

The reiterated lack of coercive powers of the Organization led a group of countries, especially the United States (under the pressure of its multinational companies) with the support of other industrialized countries (such as, Europe, Japan and Canada) to start negotiations to establish a more effective system of intellectual property protection[426]. Therefore, in the mid-eighties of the last century, at the beginning of 1986 in Punta del Este, the negotiations of the so-called Uruguay Round were carried out with the purpose of satisfying the need to implement a more ambitious strategy of international regulation of intellectual property. Intellectual property regulation had come to the forefront in reference to the framework of international trade, due to the expansion of markets, globalization and the growing demand for integration of so-called developing countries[427]. The goal was, together with the harmonization of domestic systems in this area, to establish an organization with more binding powers and effective implementation mechanisms on a global scale, connecting intellectual property with international trade within the framework of the General Agreement of Tariffs and Trade of 1947 (GATT)[428]. In other words, developed countries highlighted that the failure in protecting intellectual property rights had massive adverse effects on international trade and, therefore, GATT was the competent *forum* in which to tackle possible infringements. On the contrary, developing countries disagreed with the aforementioned approach, claiming that the GATT framework lacked competence in addressing IP related issues and that WIPO was the empowered organization for those matters[429].

Actually, the developed countries' planned of action is quite clear in light of the strengths of the GATT system. The latter established an effective dispute settlement

[426]A. Krishen Koul, *Guide to the WTO and GATT: Economics, Law and Politics*, Springer, 2018, 9.
[427]Ibidem, 25.
[428]Ibidem
[429]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 26.

mechanism in which incisive sanctions could have been adopted in case of a breach of the agreement[430]. Relocating the international framework related to intellectual property under the protection of the GATT system, therefore, appeared as the most effective move in order to secure worldwide implementation of those norms.

Interestingly, the United States' strategy was double fold. On the one hand, at the international stage the US pressured States in order to transfer protection of ip law from the toothless WIPO to the more effective GATT system. On the other, at the domestic level, the American Government acted quickly and in 1984 added the so-called Section 301 in the Trade Act of 1974. This section, which was amended in 1988, provided a specific normative framework in relation to intellectual property law and in particular to infringements of IP rights occurred in foreign countries. In other words, according to this reform, the United States Trade Representative identified and monitored those countries in which their IP legal frameworks did not suffice in providing *equal and fair* access to their markets. Once the countries were found in breach of international IP law standards, the United States imposed upon them commercial retaliation in order to eliminate counterfeiting and copyright-piracy. Interestingly, the United States was not alone in adopting unilateral actions aimed at protecting their national interests. For example, in 1987 both Japan and the European Community withdrew trade facilitation granted to South Korea on the grounds of alleged violations of IP rights[431]. Another factor influencing the strategic shift towards the GATT system was the growing strength of developing countries in WIPO, causing proposals to be rejected or the agenda of developed countries to be frustrated. On the other hand, the permissiveness and variety of WIPO treaties allowed developing countries to choose, according to their development needs, to establish exceptions and to grant some freedom to adjust their domestic IP regimes[432]. It is no surprise that the request for a higher protection of IP rights worldwide came from sectors of industry, such as pharmaceutical companies, of those countries which presented a higher level of technological advancement and,

[430]Krishen Koul, *Guide to the WTO and GATT*, 26.
[431]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 26.
[432]May, *The World Intellectual Property Organization*, 32.

hence, feared IP infringements of their products[433].

As a result, in 1994, during the negotiations that established the World Trade Organization (WTO), the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was adopted, bringing the international system for the protection of intellectual property into a new phase of harmonization and global cooperation, under the umbrella of international trade. Many scholars argue that if the TRIPS agreement were not presented as one of the three "pillars" of the WTO (the other two being a revised GATT 1994 agreement and the trade in services agreement GATS) which had to be adopted as a *single undertaking, most of the States would not have accepted them. In fact, no state wanted to be left behind, or worse be economically isolated from the commercial advantages of the newly established WTO. Under a cost-benefit analysis, developing countries realized that bounding themselves to the recently designed TRIPS, which made* protection of intellectual property rights an integral part of the multilateral trading system, would also entail becoming important actors in international trade[434].

2.3 The Relationship between WIPO and WTO

In light of the aforementioned analysis, it stands out that intellectual property regime involves two different international legal frameworks, namely, on the one hand the World Intellectual Property Organization (WIPO), which should logically constitute the main forum, and on the other hand, the World Trade Organization (WTO), which has recently become the main organization in dealing with intellectual property disputes in light of TRIPS. This section highlights the institutional mandate of both organizations and the relationship between them in addressing intellectual property-related issues.

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[433]Krishen Koul, *Guide to the WTO and GATT*, 31.

[434]J. Malbon and C. Lawson, *Interpreting And Implementing The Trips Agreement: Is It Fair,*Edward Elgar Publishing, 2008, 32.

There is no doubt that the arrival of TRIPS created a significant strategic dilemma for WIPO[435]. The organization had presided over an intellectual property regime of great normative diversity and, since the establishment of WTO, the organization had to share its hitherto *'exclusive competence'* in intellectual property matters with another actor[436]. In an attempt to preserve its importance in this new scenario, WIPO adopted, in 1994, a resolution directing its International Bureau to provide technical assistance to WIPO members on matters related to the TRIPS Agreement. This was followed, in 1995, by a second resolution to sign a cooperation agreement with the WTO whereby WIPO would provide technical assistance to developing country WTO members whether or not they were members of WIPO[437].

As a result of the above 1995 resolution and in light of the TRIPS preamble, which explicitly sets out that the WTO desires a reciprocally supportive relationship with WIPO, both organizations concluded an agreement (WIPO-WTO Cooperation Agreement) which came into force on 1, 1996[438]. This Agreement specifically defined cooperation between WIPO and WTO on legal-technical assistance to contracting parties in three main areas: first, notification of, access to and translation of national laws and regulations; second, implementation of procedures for the protection of national emblems; third, technical cooperation on all matters related to ip law[439]. In other words, cooperation between the WIPO and the WTO has not turned into a mere *de facto* separation of roles and competences, but has established a system in which both organizations work together in order to administer the TRIPs agreement and the governance of IPRs in general[440]. Hence, it may be argued that the shift of intellectual property from WIPO to WTO should be referred to a as *forum proliferation* rather than

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[435] V. Hrbatá, "No International Organization is an Island . . . the WTO's Relationship with the WIPO: A Model for the Governance of Trade Linkage Areas?", *Journal of World Trade* 44, 2010, 2-4.
[436]P. Drahos, "Developing Countries and International Intellectual Property Standard Setting", *IPR Commission Study Paper* 8, 2002, 12.
[437]Wipo General Assembly Resolution WO/GA/24/5
[438]IP/C/6, 13 December 1995, and "Agreement between The World Intellectual Property Organization and The World Trade Organization", IP/C/6/Add.1, 17 January 1996.
[439]P. Stoll, J. Busche and K. Arend, "WTO – Trade-Related Aspects of Intellectual Property Rights", *Max Planck Commentaries on World Trade Law* 7, Martinus Nijhoff, 2009, 73.
[440]May, *The World Intellectual Property Organization,* 32.

a unilateral forum relocation[441].

These resolutions and the Cooperation agreement with WTO implied that WIPO had found a place in the TRIPS framework. WIPO also benefited from the fact that, while it was seen as lacking of enforcement mechanisms, the standards stipulated within, the treaties it oversaw and the technical expertise developed in the organization over the years were indispensable to ensure that the TRIPS Agreement was respected[442]. In fact, although since 1995 WIPO no longer has any enforcement obligations in relation to the various treaties it once monitored [443], the organization retains an essential administrative and support function in its three main areas of operation, namely, registration, technical support, and development of further governance measures. In addition, WIPO is turning into the preferred political forum for debating current issues relating to the global governance regime for intellectual property[444].

In conclusion, regardless of the aforementioned displacement of WIPO's competencies and control over IP-related issues in the aftermath of TRIPS adoption, it would be inaccurate to argue that the WIPO no longer plays a key role or it has been outcast in practice. On the contrary, the new regime led to a rearrangement of the modalities in which the organization perform the framework of global governance. The normative provision presented emphasizes an institutionalized system of intellectual property protection, with a secretariat whose main objective is to organize diplomatic conferences at which States can negotiate new multilateral intellectual property treaties, administer existing intellectual property agreements, and provide technical assistance and advice to national intellectual property offices, especially in developing countries. WIPO has, hence, turned into a much more technically oriented agency, focused on diplomatic conferences, norm-making procedures as well as being charged with enforcement and disputes settlement procedures[445].

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[441]Ibidem

[442]Frederick M Abbott, 'Distributed Governance at the WTO- WIPO: an evolving model for open-architecture integrated governance' (2000) *Journal of International Economic Law* 63, esp at 75ff

[443] This is because most of the treaties relating to IP law have been included into the TRIPs agreement.

[444]Christopher May, *The World Intellectual Property Organization- Resurgence and the Development Agenda*, Routledge, 2007, 36.

[445] Ibidem

3. The Trade-Related Aspects of Intellectual Property rights Agreement (TRIPS)

The Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), although considered one of the most essential treaties in the eyes of global governance of the protection of intellectual property law, is surely controversial within the multilateral trading system[446]. After the adoption of IP rights protection through the TRIPS Agreement, both developing countries and least developed countries faced new challenges in such different fields as health care and agriculture. There is no doubt that as a consequence of the Agreement, prices of life-saving medicines have exponentially increased, therefore creating impediments in the access to affordable drugs in developing and least developed countries[447]. This section deals with the legal analysis of the TRIPS Agreement, with a particular focus on its normative provisions related to patents and their impact on pharmaceutical products, such as medicines.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which, as already highlighted, constitutes one of the three pillars of the World Trade Organization, established minimum standards of protection of intellectual property rights worldwide. It entered into force on 1 January 1995 and has been referred to as the most complete multilateral treaty on intellectual property to date[448]. The adoption of TRIPS is the beginning of the global era of intellectual property protection, which resulted from the transfer of IP law enforcement under the WTO legal and political framework[449].

TRIPS covers copyright and related rights (including rights of performers, producers of sound recordings and broadcasting organizations), trademarks (as well as service marks), geographical indications (including appellations of origin), industrial designs,

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[446]A.B. Jaffe, J.Lerner, *Innovation and its Discontents. How our broken Patent System is endangering innovation and progress, and what to do about it*, Princeton University Press, 2004, 7.

[447]J. Sundaram, "Analysis of TRIPS Agreement and the justification of international IP rights protection in the WTO's multilateral trading system, with particular reference to pharmaceutical patents", *Information & Communications Technology Law* 24:2, 122.

[448]CM Ho, 'An Introduction to TRIPS' in CM Ho, Access to Medicine in Global Economy: International Agreement on Patents and Related Rights, Oxford, 2011, 57.

[449]D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, Sweet & Maxwell, 2008, 27.

patents (in addition to plant variety protection), layout-designs of integrated circuits, and undisclosed information (including trade secrets and protection against unfair competition). The agreement gathers virtually all the intellectual property issues whose norms were previously provided for in an array of unbundled international legal instruments and bodies[450]. In addition, the TRIPS Agreement obliged WTO contracting parties to adhere to the Berne and Paris Conventions in an effort to include most of the international community to the global protection of IP law[451].

The main objectives of TRIPS, as expressed in its preamble are: to reduce distortions of international trade, to promote effective and adequate protection of intellectual property rights and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade[452]. In regard to specific IP provisions, the Agreement envisaged three main obligations: firstly, it required WTO-member countries to protect minimum intellectual property rights standards in their domestic legislation; secondly, the agreement required parties to establish effective enforcement procedures for those rights; and lastly, States accepted to refer disputes to the WTO dispute settlement mechanism.

The principle of minimum standards is contained in Article 1.1 of the Agreement, and states that WTO Members may provide in their legislation for broader protection than that provided for in the Agreement, as long as such protection does not infringe any provision of the Agreement. This is not an obligation but a power that may or may not be exercised by recognizing the agreement as the framework in which to perform[453].

The principle of minimum intellectual property standards constitutes a significant conceptual and strategic basis for further negotiations at the bilateral and multilateral levels on intellectual property aimed at setting higher and broader standards[454]. Indeed,

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[450]M. Valbon, *The Politics of Intellectual Property Rights and Access to Medicines*, Palgrave McMillan, 2012, 64.

[451]Articles 1 to 4 of the TRIPS agreement.

[452]Preamble of the Trips Agreements.

[453]Article 1 TRIPS.

[454]P. Roffe, and M. Santa Cruz, "*Los Derechos de Propiedad Intelectual en los Acuerdos de Libre Comercio celebrados por países de América Latina con países desarrollados*. *Serie Comercio Internacional. Nº 70. División de Comercio Internacional e Integración*. CEPAL. Naciones Unidas. Santiago de Chile. Abril, 2006. 82.

since the adoption of the TRIPS, any rule adopted on intellectual property between WTO members, or between members and third parties, can only create higher standards. These stricter standards raise concerns in relation to the so-called TRIPS-PLUS provisions, which will be further examined in the chapter when addressing IP norms included in international trade treaties such as the Dominican Republic-Central America Free Trade Treaty (DR-CAFTA)[455].

The national treatment clause is a principle according to which WTO Members must accord to nationals of other Members a treatment no less than the one granted to their nationals in relation to the existence, acquisition, scope, maintenance, exercise and enforcement of IP rights. It differs from the Paris Convention which required States to recognize the same rights to nationals of another State. In light of this consideration some authors argue that rather than an equal treatment, the Agreement provides a more favourable status to foreigners, since nationals from other countries are entitled to at least the same treatment as nationals, which can, however, be even better[456].

The most-favoured-nation (MFN) principle has no precedent in intellectual property treaties, which by its nature is characteristic of trade treaties. The principle requires that any advantage, favor, privilege or immunity that a member grants to nationals of another country in relation to the existence, acquisition, scope, maintenance and enforcement of IPRs shall be accorded to nationals of all other WTO members. As shall be noted later in the chapter, this principle has affected deeply the conclusion of bilateral and regional agreements. In fact, the obligations envisaged in them and any legal consequences derived from them must be applied equally to all members of the WTO's multilateral trade system[457].

Notwithstanding, it is worth mentioning that the TRIPS Agreement does not merely impose the voluntary alignment of domestic legislation; in fact, the Agreement also requires the mutual acknowledgment of domestic laws that establish minimum

[455]C. Fink and P. Reichenmiller, *Tightening TRIPS: Intellectual Property Provisions of U.S. Free Trade Agreements, in Trade, Doha, and Development A Window into the Issues,* World Bank, 2005, 295.
[456]Roffe, *Los Derechos de Propiedad Intelectual*, 14.
[457]C. M. Correa, *Trade Related Aspects of Intellectual Property Rights,* Oxford University Press, 2007, 31.

standards of substantive IP protection[458].

Furthermore, the TRIPS Agreement was not meant to be a *harmonization agreement*, since States parties do not have to provide identical legal frameworks. In other words, contracting States have an obligation of result and are, hence, free to decide their own means of conformity with TRIPS Agreement obligations[459]. Indeed, the often-vague provisions of the Agreement in relation to minimum standards to be complied by Member States, result in variations in different implementation at national laws[460]. As a consequence, States are also free to provide more encompassing level of IP protection than those envisaged in the Agreement, bearing in mind, however, that in light of the most-favored nation principle, any privilege extended to a citizen of another country must be granted to all[461]. In case of an alleged violation of the TRIPS provisions, the dispute settlement mechanism permitted for cross-agreement retaliation, meaning that a party that was proved in breach of its obligations could face retaliatory trade sanctions on the grounds of another WTO agreement, normally the General Agreement on Tariffs and Trade (GATT)[462].

One of the key innovative features of the TRIPS Agreement concerned its enforcement provisions. Along with the dispute settlement mechanism established within the WTO system, the Agreement require States to ensure through their domestic legislation effective procedures and remedies for the protection of IP rights of both national and foreign-right holders[463]. In other words, enacting legislation in line with the provisions envisaged by the Agreement does not suffice. States must implement national laws and provide enforcement mechanisms to guarantee actual IP rights compliance[464].

In addition, TRIPS is the first multilateral treaty which imposes another burden on

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[458]Helfer, *Human Rights and Intellectual Property*, 28.
[459]Correa, *Trade Related Aspects of Intellectual Property Rights*, 32.
[460] J. Sundaram, "Brazil's Implementation of TRIPS Flexibilities: Ambitious Missions, Early Implementation, and the Plans for Reform", *I & CTL* 23(2), 2014, 86.
[461]J. Sundaram, "Analysis of TRIPS Agreement and the justification of international IP rights protection in the WTO's multilateral trading system, with particular reference to pharmaceutical patents", *Information & Communications Technology Law* 24:2, 2015, 123.
[462]R. Cardwell and P. L. Ghazalian, "The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights", *The International Trade Journal*, 26:1, 20.
[463]Helfer, *Human Rights and Intellectual Property*, 28.
[464]Ibidem

States in relation to protection of IP rights. States must enforce further laws and policies in order to avoid exportation of counterfeit goods. In fact, on the grounds of the Agreement, contracting parties must provide criminal sanctions for the confiscation, impounding and destruction of the counterfeit goods and of any tool used in the perpetration of the unlawful conduct[465].

As a result, many WTO parties had to significantly reform and adapt their respective legislation to the newly established framework. Not surprisingly, developing countries were those that endured the greatest modifications of their legal frameworks, since, among other reasons, most of these countries did not provide patents law protection for inventions prior to the adoption of the TRIPS Agreement and were not parties neither to the Paris nor to the Bern Convention. For example, India did not provide patents protection until the 1970s and totally exempted pharmaceutical products from the intellectual property rights[466]. Even some developed countries were not providing patent protection to pharmaceuticals before TRIPS did, such is the case of France, Germany and Switzerland, which have recognized patents on drugs since the1970s, while Portugal and Spain did so in the early 1990s[467]. In this regard, it is interesting to note that including the United States had to adopt its domestic legislation in order to meet some of the newly established TRIPS provisions, for instance implementing the domestic enforcement procedures provided by the Agreement[468].

In conclusion, the international standards of protection envisaged by the TRIPS Agreement had, and continue to have, crucial implications both for developing and developed countries. Indeed, the minimum level of protection required at the international level was key in creating a more reliable and uniform system, which in most cases eased international trade. At the same time, however, the aforementioned minimum levels of IP protection have been seen as insensitive to the diverse development of contracting parties, therefore, bearing a negative effect on some States'

[465]Ibidem
[466]Marenghi, *Il diritto alla salute e la proprietà intellettuale*, 24.
[467]Jaffe, *Innovation and its Discontents,* 6.
[468]Helfer, *Human Rights and Intellectual Property,* 29.

social welfare systems[469]. Lastly, the WTO dispute settlement mechanism moved the TRIPS provisions from theory to practice on the international stage, since the coercive powers of the WTO are able to terminate and cancel with *ex tunc effectiveness*, the outcomes of violations of IP rights.

3.1 Pharmaceutical Patents and Legal Obligations on States parties under the TRIPS Agreement

The *raison d'être* of intellectual property rights in general, and patents in particular is quite clear, as they are intended to encourage research and development, while ensuring economic gains protected by law. In other words, when it comes to pharmaceutical products, patent is an important incentive that gives the inventor an *ius excludendi*, designed to protect the inventor's investment in the development, production and marketing of new drugs.

The main concern in relation to the TRIPS patent frameworks is its detrimental effect on access to new medicines. Indeed, in accordance with Article 27.1 of the Agreement Member States are required to make available patents for products and processes without discrimination as to the field of technology if they are *"new, involve an inventive step and are capable of industrial application"*[470]. These provisions include patent protections to pharmaceutical products as well, going beyond to what was provided for in the Paris Convention for Protection of Industrial Property of 1883, under which member states were allowed to exclude patent protection in certain areas such as medicines[471]. Moreover, the wording of article 27.1 and the treaty's *travaux préparatoires* make obvious that patent protection concerns both pharmaceutical

[469] P. Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement- An Interpretation of the TRIPS Agreement in Relation to the Right to Health,* Martinus Nijhoff Publishers, 2012, 79.
[470] Article 27.1 of the TRIPS
[471] J. Sundaram, "Access to medicines and the TRIPS Agreement: what next for sub-Saharan Africa?", *Information & Communications Technology Law* 24, 2015, 243.

products and processes[472]. The latter consideration entails that product patent, as opposed to process patent, undermined the use generic drugs which are more affordable than patented/brand-name medicines developed by multinational pharmaceutical corporations[473]. In other words, if States are required to merely protect the process of making a new drug, but not the resulting product (so was the case of India), generic companies are allowed to develop the same drug with the same active substance, as long as they produce it undertaking different processes. As a result, requiring patents for both the final product and process constitute an evident obstacle to access to affordable medicines.

3.2 Patentability of Pharmaceutical products

Interestingly, the TRIPS agreement does not provide a definition of the term patent, but simply states that intellectual property refers to all the categories from section 1 to 7 of the Agreement, hence including patents as well[474]. Neither the Paris Convention set up a definition of patents, leaving contracting parties free to regulate what a patent might be, bearing in mind that is certainly an exclusive right to apply to an industrial invention[475]. Generally speaking, patent is intended as a legal instrument, usually a document, which proves compliance with the application requirements and grants the owner with the exclusive right to use the patent in conformity with the invention as presented in the application[476].

Patents constitute a really crucial area of intellectual property protection, to which the TRIPS Agreement devoted the section from Article 27 to Article 34. In particular,

[472]Gervais, *The TRIPS Agreement*, 218.
[473]Sundaram, *Access to medicines and the TRIPS Agreement: what next for sub-Saharan Africa?,* 244.
[474]Article 1.2 of the TRIPS Agreement
[475] G.H.C Bodenhausen, "Guide to the Application of the Paris Convention for the Protection of Industrial Property: As Revised at Stockholm in 1967", Geneva: *United International Bureaux for the Protection of Intellectual Property (BIRPI)*, 1968, 149–50.
[476]J. Malbon, C. Lawson and M. Davison, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights -A Commentary*, Elgar Commentaries series, 2015, 411.

Article 27, labeled *Patentable Subject Matter,* provides indications for the definition and application of patenting requirements. The three threshold requirements established by the aforementioned article set substantive positive obligations in making patents available for inventions that are new, include an inventive step and must be capable of industrial application. Understanding the scope of article 27 is, hence, decisive, since a wide interpretation of the patent regime with broad patentability criteria for innovations could result in unfair competitive practices that would potentially lead to more expensive drugs and, thus, have an adverse effect on access to medicines[477]. Article 27 constitutes a milestone in defining patentability, since for the first time an international agreement provided a general framework of eligibility criteria for patents[478]. The latter Article entails that any exclusion from patentability is considered as an exception, meaning that the normative content of the article shall be interpreted in a restrictive manner[479]. In other words, as highlighted above, patent protection has to be made available for any inventions whether product or process in any field of technology as long as the requirements for patentability are satisfied and unless their subject matter falls within a category as defined by Article 27.2, or specific class as stated in Article 27.3[480]. Notwithstanding, it remains unsettled whether or not the exceptions of patentability envisaged both in Articles 27.2 and 27.3 provide the only exclusions to Article 27.1[481].

Novelty is the first requirement for eligibility. In general term, novelty shall be referred to an invention that has not been publicly described or presented prior the submission of the application of the patent[482]. Notwithstanding, international law does not provide a generally accepted understanding of the term novelty and neither the TRIPS nor the

[477]C. M. Correa, "Integrating Public Health Concerns into Patent Legislation in Developing Countries", *South Centre*, Geneva, 2002, 37.
[478]Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement- An Interpretation of the TRIPS Agreement in Relation to the Right to Health,* Martinus Nijhoff Publishers, 2012, 160.
[479]Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 220.
[480]Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 160.
[481]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property,* 406.
[482]Ibidem

Paris Convention contain an explicit definition of novelty. The vague nature of the definition provides States with flexibility in implementing the requirement in their respective domestic law[483]. For example, in the United States an invention is considered disclosed and therefore lacking the requirement of novelty only if made in written form. This entails that knowledge of particular groups, such as indigenous communities, which knowledge has been likely used for centuries in an oral form, is considered new in light of the American legislation and, hence, can be protected through patents[484]. Furthermore, the proper understanding of what must be interpreted as new invention can have important implications in preventing the so called *evergreening of patents*[485]. In practice, if the definition of novelty is too broad, a pharmaceutical company could obtain a new patent on an already patented drug by making small alterations to it, by so doing delaying competition and extending its monopoly status[486]. This is the reason both India and the Philippines did not allow patents on *"new forms of known substances unless they were significantly more efficacious and new (or second) uses and combinations of new substances"*[487]. In particular, India refused to patent a new version of an already patented drug against cancer called *Glivec* by Novartis, leading to a unsuccessfully lawsuit brought before a local court by the latter pharmaceutical company[488].

The "inventive step" constitutes the second requirement of patentability. Similar to the term *novelty,* the TRIPS does not envisage a precise definition of what should be understood as "inventive step" nor provide the procedure that should be employed in order to assess if the criteria are satisfied[489]. Actually, different states provide different

[483] Correa, *Integrating Public Health Concerns into Patent Legislation,* 71.
[484]Ibidem
[485]This also concerns the so called second use patents, referring to newly discovered uses of existing medicines and new combinations of known substances that do not intensify the drug efficacy.
[486]Human Rights Council, 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover', UN doc. A/ HRC/11/12 (31 March 2009) para 34.
[487]Ibidem, para 35.
[488]*Novartis v India* W. Nos 24759 of 2006 and 24760 of 2006, High Court of Madras (India), 6 August 2007. See also Abbott and Reichmann, above n 20, 959.
[489]Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement- An Interpretation of the TRIPS Agreement in Relation to the Right to Health,* Martinus Nijhoff Publishers, 2012, 161.

variations, definitions and criteria for the inventive step requirement. In practice, the aim of this second requirement is to limit the robust *ius excludendi* awarded by patents merely to inventions which constitute a significant and concrete step forward in the art and to keep irrelevant change outside of such protection[490]. For example, in regard to chemicals and pharmaceuticals, known compounds, such as, among others, salts of acids, bases and isomers are often combined with allegedly new and inventive compounds. As the aforementioned analysis in relation to the first requirement, namely novelty, shows, a vague and broad understanding of the term *inventive step* could allow second use patents, leading into distortive competitive practices. As a result, only compounds which are proven to be new and inventive can be granted with patent protection[491].

In conclusion, the term in question allows discretion on its interpretation. Notwithstanding, the Agreement provides a further explanation as to what the term *"inventive steps"* entails. In fact, the Article 27 footnote states that contracting parties must refer to the latter term as a synonym of the term *"non-obvious"* with the aim, *inter alia*, at accommodating the several understandings of *"inventive step"* employed by different legal regimes[492]. Inventive step'/'non-obvious constitute a quality requirement needed in order to assess if the invention presented in the patent application deserves the rights conferred by a patent according to Article 28 of the TRIPS[493]. National Courts attempted to identify those required criteria so as to differentiate patent worthy inventions from other inventions which did simply provide workshop developments and therefore were ineligible for patent protection. In practice, the latter attempts by national courts led to the "person skilled in the art" criteria, which meant that an invention is patent worthy if involves an inventive step considered under the eyes of an expert in a particular field of knowledge[494]. Similarly, the US Patent Act,

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[490]K. Gamharter, *Access to Affordable Medicines: Developing Responses under TRIPS and EC Law,* Springer, 2004, 24.
[491]Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 161.
[492]Gamharter, *Access to Affordable Medicines,* 68–70;
Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights*, 421.
[494]Ibidem

35 (U.S.C. 35) states that *"A patent may not be obtained though the invention is [novel], if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains"*[495].

In conclusion, the aforementioned second requirement for patentability has been introduced to provide additional elements related to both the novelty of the invention in relation to the prior state of art on the one hand and to further provide an artificial criterion in light of the expertise of a person skilled in field of the invention on the other[496]. Due to their still subjective nature, these additional criteria have, however, been implemented differently among contracting parties[497]. In an attempt to overcome the challenge of implementing such vague criteria, the *travaux preparatoires* of the WIPO Substantive Patent Law Treaty has guided States towards the application of a similar standard: *"A claimed invention shall involve an inventive step. It shall be considered to involve an inventive step (be non-obvious) if, having regard to the differences and similarities between the claimed invention and the prior art as defined in Article 8(1), the claimed invention as a whole would not have been obvious to a person skilled in the art at the priority date of the claimed invention"*[498]. Despite both national courts and international organizations efforts for clarification, the interpretation of the required criteria of 'prior art' and of a 'person skilled in the art' is still controversial[499].

The last requirement provided for by Article 27 is that the invention must be capable of *"industrial application"*. As it was stated in the analysis for the second requirement, the footnote to the article adds further information, providing that industrial application

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[495]US Patent Act, 35 (U.S.C. 35), par. 104. See also: the European Patent Convention, Article 56 which states: *"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art"*.

[496]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,* 422.

[497]D. Burk and M. Lemley, "Is Patent Law Technology-Specific?", *Berkeley Technology Law Journal* 17 (4), 185-1186.

[498]WIPO Standing Committee on the Law of Patents (2003), Draft Substantive Patent Law Treaty , SCP/10/4, Article 12(3).

[499]WIPO Standing Committee on the Law of Patents (2004), Report , SCP/9/8, [102]–[109].

must be understood as a synonym of the term *"useful"*[500]. In practice, however, both terms "industrial applicability" and "useful" can have different interpretations in the numerous States' legal frameworks. In this regard, the negotiation of the WIPO Substantive Patent Law Treaty has reaffirmed the need of "industrially applicability (useful)" as requirement for patent, but has not shed light on the substance of the standard[501]. The proposed provision reads as follows[502]: *"A claimed invention shall be industrially applicable (useful). It shall be considered industrially applicable (useful) if it*

- *[Alternative A] can be made or used for exploitation in any field of [commercial] [economic] activity.*
- *[Alternative B] can be made or used in any kind of industry. 'Industry' shall be understood in its broadest sense, as in the Paris Convention.*
- *[Alternative C] has a specific, substantial and credible utility.*

The WIPO Substantive Patent Law Treaty negotiations have, hence, the aim to reassert that the TRIPS idea of *"capable of industrial application"* may be applied in light of an array of different approaches and considerations, taking into account the numerous fields of implementation. The Paris Convention of 1967 constitutes a valuable tool for limiting the scope of the term industrial applicability, since its article 1.3 provides a definition of: "*Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour"*[503]. In conclusion, TRIPS tries to gather consensus on the various interpretative approaches in order to standardize them in one text. In regard to pharmaceutical patent protection, the requirement of applicability/usefulness goes without saying, due to the particular

[500]Article 27.1 of the TRIPS Agreement.
[501] Standing Committee on the Law of Patents (2003), Report, SCP/8/9, [304]– [313]
[502] Standing Committee on the Law of Patents (2003), Draft Substantive Patent Law Treaty, SCP/10/4, Article 12(4).
[503] Paris Convention (1967), Article1(3).

nature of this sector which combines elements related to chemistry, genetics and bio-technology and typical elements of the chain of production. Moreover, a medicine is certainly useful if it is able to properly treat a condition[504]. Likewise, with the terms *novelty* and *inventive steps* criteria, the requirement *"industrial application"* is still subject to different interpretations, leaving room for contracting parties to regulate their own concept, definition, scope and tests. As a result, some scholars argue that the three requirements shall be understood as flexibilities for member States which are open for different modalities of implementation[505].

These particular provisions resulted in some major modifications in patent protection at the national level. Indeed, significant changes incorporated the stipulations that there be *no discrimination* among provisions of product or process patents and that patents shall be accessible in all fields of technology. Included also are the definition of the exclusive rights conferred by the product and process patents as provided for by article 28, the 20-year protection term counted from the filing date, and the burden of proof in Courts. Some of these changes, together with other provisions of TRIPS, have important implications for pharmaceutical patent protection, thus they may be relevant to the issue of access to medicines[506].

As a result of the ratification of TRIPS, States Parties are obliged to establish in national legislation procedures for the enforcement of intellectual property rights that allow for the adoption of effective measures against any action infringing intellectual property rights, including expeditious remedies to prevent violations and remedies that constitute an actual means of deterring further infringements[507].

These procedures, which have to be fair and equitable, shall be applied in such a way as to avoid the creation of obstacles to legitimate trade, and shall provide safeguards against their abuse. They shall not be unnecessarily complicated or burdensome, nor shall they result in unjustifiable time limits or unnecessary delays. In the case of final

[504]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,* 422.
[505] Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement,* 162.
[506]Ibidem
[507]Article 41 of the TRIPS Agreement

administrative decisions, which shall be taken in written form and should be reasoned, must provide for a review procedure by a competent judicial authority[508]. These include establishing criminal procedures and penalties for at least cases of unlawful trademark counterfeiting or copyright piracy on a commercial scale. The remedies available shall include imprisonment and/or the imposition of financial penalties sufficiently dissuasive to be consistent with the level of sanctions applied for offenses of a corresponding gravity. None of the above implies the creation of a different jurisdiction nor a commitment to direct new remedies for IPR enforcement purposes.

3.3.Test Data protection in the context of the TRIPS Agreement

Test data refers to the generation of information required to demonstrate to a health authority, in a given country, the safety and efficacy of a product whose marketing is regulated by the State for reasons of public health. The topic has had its main development in the agrochemical and pharmaceutical sectors, since they are areas in which the research and development industry had to invest surprisingly large amounts of economic and human resources over long periods of time in order. The aim is to obtain the information that finally allows accrediting the safety and efficacy required to guarantee that the product can be consumed directly or indirectly by human beings. The need to implement specific protection systems to prevent unfair commercial use of information has been particularly controversial in the pharmaceutical industry, given the implications that such use may have from the point of view of access to medicines[509].

In many countries of the world, the production and subsequent submission to the corresponding authorities of tests that certify the quality, safety and efficacy of the product are required before the commercialization of pharmaceutical and agrochemical products. The protection that different countries provided for these test data derived

[508]Gervais, *The TRIPS Agreement: Drafting History and Analysis,* 65-66.
[509]O. H. Shaikh, *Access to Medicine Versus Test Data Exclusivity, Safeguarding Flexibilities Under International Law*, Springer, 2016, 7.

from multiple stages of research, large investments and long evaluation periods prior to obtaining approval for entry into the market. In general, the provision of all types of undisclosed information was very unequal before the entry into force of TRIPS[510]. The lack of an international regime that installed common rules in the matter allowed to differentiate the models of protection in two basic forms[511].

The first model, mostly implemented by industrialized countries such as the United States and members of the European Union, confers exclusive rights to the person generating the data, and may prevent both governments and competition from relying on such data for approval of subsequent generic products[512]. To mitigate the extreme character of this system, compulsory licenses are sometimes granted in order to allow the use of the data in exchange for economic compensation for the originator of the information[513]. This model grounds on the fact that, in the Research and Development (R&D) of the pharmaceutical product manufacturers, invested large sums of money that they expect to recover. If companies' economic expectation is not protected, scholars argue that drugs producers would lose their incentives and stop technological progress by discouraging investment. In fact, originator companies argue that, ten to fifteen years and on average USD 1.2 billion are required in order to bring a drug to the market. Moreover, only one of every 5 to 10 thousand chemical compounds researched gets approved and sold, turning such high investments into a risky bargain, as the future gains are unsure [514]. In brief, it is considered unfair to allow competition (generic companies) to take commercial advantage and to rely on information which was produced by another subject (originator companies)[515]. Indeed, generic companies

[510]O. A. Owoeye, "Data Exclusivity and Public Health Under the TRIPS Agreement", Journal of Law, Information and Science", 2014, 107.
[511]G. L. Skillington and E. M. Solovy, "The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement", 24 Nw. J. Int'l L. & Bus. 1, 2004, 1-2.
[512] Ibidem, 2.
[513]See next section on TRIPS Flexibilities
[514]Christian R. Fackelmann, Clinical data, data exclusivity and private investment protection in Europe in Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective, in Josef Drexl & Nari Lee, *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Edward Elgar, 2013, 141.
[515]W. Armouti and M. F. A. Nsour, *"Test Data Protection: Different Approaches and Implementation in Pharmaceuticals"*, *Intellectual Property L. Rev. 267*, 2016, 271.

are merely required to demonstrate bioequivalence to already approved drugs in order to be authorized to sell[516]. In other words, generics companies usually are not required to submit preclinical (often performed on animals) and clinical (on human) tests to domestic regulatory agencies in order to prove safety and effectiveness of medicines. On the contrary, the latter companies must demonstrate scientifically that their drugs perform in the same manner as the originator one[517]. As a result, generics manufacturers do not face the same financial expenditure as originator companies are, hence, able to sell the same product at a lower price. Some scholars point out that generics always enter an already developed and studied market without assuming the risks of being pioneers in an undiscovered field of knowledge[518]. In this regard, originator and generic pharmaceutical companies do not carry a similar burden when it comes to achieving market approval. As a result, some literature highlighted that when national law does not prevent discriminating practice such as early price competition by generics manufacturers[519], the entire pharmaceutical market would be affected. Originator companies would not have any incentives in investing for the submission of safety and efficacy data[520].

A second approach, opposed to the aforementioned model, provides a very weak protection to test data. According to non-industrialized countries, the use of the information provided by the original manufacturer could be used to compare the chemical properties or bioequivalence of generic drugs. The adoption of this model was the result of the need to foster a more competitive market, which would lower the barriers to entry of generic products to the market, since many of the companies that manufacture generic pharmaceuticals would be unable to replicate them. The adoption of this model was the result of the need to promote a more competitive market, which would reduce the obstacles to the entry of generic products to the market, since many

[516]Ibidem
[517]Shaikh, *Access to Medicine Versus Test Data Exclusivity*, 8.
[518]B. N. Kuhlik, "The Assault on Pharmaceutical Intellectual Property", 71 *U. Chi. L. Rev. 93*, 94, 2004, 95.
[519]N. P. de Carvalho, *The TRIPS Regime of Patents and Test Data*, 5th Edition, Wolters Kluwer, 2017, 260.
[520]Owoeye, *Data Exclusivity and Public Health Under the TRIPS Agreement*, 110.

of the companies that manufacture generic pharmaceuticals would be unable to reproduce the approval data, due to its high cost, which would allow an exclusion of competitors beyond the 20 years guaranteed by a patent. The reasons that national authorities are not required to submit new test data are economic, practical and ethical. Firstly, replicating studies and trials requires a significant economic investment, which would have a negative impact on the economic affordability of medicines. Secondly, testing may take several years to complete and cause delay of the entry of cheaper generic medicines into the market. Finally, it has been argued that it is unethical to replicate some drug tests on humans when their efficacy has already been proven[521].

3.3.1 Legal obligations deriving from the TRIPS Agreement.

The issue of test data does not refer to a specific industrial property right. In practice, most of the pharmacological dossier of pharmaceutical products would rather constitute a collection of information protected by copyright seen as the result of a tedious scientific work. Notwithstanding, the generation of such information usually falls under the protection of two industrial property categories, namely patents for invention and trade secrets[522]: patents, because it is common that newly discovered active ingredients are protected by patents on both the molecule as such or on specific combinations of it; and, trade secrets, since in any case pharmacological dossier would be the product of information that has not been previously disclosed, and that in most cases is not even included in the dossier itself. This information referred to the patients on whom the corresponding tests were performed and that, ultimately, is the one that allows validating any conclusion on safety and efficacy proven in the study[523].
The protection of test data, however, cannot be assimilated to a patent or trade secret protection, since it involves a percentage of undisclosed information and since the

[521]Armouti, *Test Data Protection: Different Approaches and Implementation in Pharmaceuticals*, 273.
[522]O.H. Shaikh, *Test Data Exclusivity and Art 39(3) TRIPS. In: Access to Medicine Versus Test Data Exclusivity*, Springer, 2016, 35.
[523]Ibidem

protected good is the investment required to develop a new drug and not the invention itself. Nevertheless, test data does merit special and integral protection, since the indiscriminate use of the disclosed the information by third parties may have unfair competitive effects in a given market as demonstrated above. These considerations led to the inclusion of test data protection of new chemical entities within the Agreement on Trade-Related Aspects of Intellectual Property Rights of 1994[524].

This section examines the legal regime for test data protection under the TRIPS Agreement and the obligations deriving from it on Member States in relation to data exclusivity. Prior to the entry into force of the TRIPS Agreement, countries were free to determine whether to confer protection on test data. This Agreement introduced the first international legal provision on the related to test data as defined in its article 39[525]. The Agreement, however, does not provide for specific measures for the implementation a national level, thus granting broad discretion to the member countries of WTO to apply different models in relation to such protection[526].

It is interesting to note that Article 10bis of the *Paris Convention for the Protection of Industrial Property* provided for an indirect protection of test data, by forbidding conducts against unfair competition way before the legal regime established by the *TRIPS*[527]. Indeed, an extensive understanding of Article 10bis of the aforementioned convention may result in including the protection of test data within unfair competitive practices, but does not provide anything similar to data exclusivity[528]. On the contrary, the test data protection regime established by the *TRIPS* goes beyond the mere provision of protecting products against unfair competition and designed a data exclusivity discipline which confers an autonomous proprietary right to the natural or legal person entitled to such protection[529].

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[524]Owoeye, *Data Exclusivity and Public Health Under the TRIPS Agreement*, 108.
[525]C. M. Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford University Press, 2007, 367.
[526]Ibidem
[527]*Paris Convention for the Protection of Industrial Property*. adopted 20 March 1883,828 UNTS 305 (entered into force 7 July 1884), emended in 1967.
[528]Owoeye, *Data Exclusivity and Public Health Under the TRIPS Agreement*, 111.
[529]Ibidem

In detail, Article 39 of the TRIPS, which is composed of three different paragraphs, provides protection to confidential information submitted by a pharmaceutical company in order to obtaining market approval of a new drug. The aforementioned Article reads as follow:

1. *In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3*

2. *Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:*

a. is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

b. has commercial value because it is secret; and

c. has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. *Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected.*

As Article 39 shows, TRIPS protects confidential information as an extension of the discipline contained in article 10bis of the Paris Convention. The rights and obligations contained in section 7 of the TRIPS Agreement, therefore, develop in the context of the control of unfair competition. The fact that undisclosed information is considered by Art.1.2[530] as a category of intellectual property does not mean that it confers an

[530] Article 1.2: *"For the purposes of this Agreement, the term "intellectual property" refers to all*

exclusive exploitation right or a property right over the controlled information, since protection is strictly dispensed in cases of unfair competition, such as the breaking of a confidentiality contract to deliver information to the competition. If the information is obtained in good faith or by methods parallel to those used by the one who keeps it under his control, the TRIPS agreement does not oblige its protection[531]. The provision protects the holder of the information against unfair practices of competitors, not against third parties who do not act as such. The article, then, imposes a double basic obligation: firstly, to protect against unfair competition and secondly, to protect, undisclosed information[532].

Two main theories have arisen on the proper interpretation of Article 39, with the aim of identifying precise legal obligations with which member States are bound to comply. According to the first interpretation of the latter provision, the wording of Article 39.1 "*ensuring effective protection against unfair competition"* implies that the legal regime established grounds on the norms concerning unfair competition as stated in Article 10bis of the *Paris Convention*[533]. In line with this perspective, the latter provision would grant protection against unfair commercial practices and provide a *de facto* control to the right holder of the undisclosed information. Under this first theory of interpretation, Article 39.1 would not establish exclusive nor proprietary rights[534]. In the same way, scholars such as *Correa* and *Gervais* argue that Article 39 is sufficiently clear in indicating that its provisions do not go beyond the obligations of protection against unfair commercial use provided for by in the *Paris Convention*[535] and that the latter protection would suffice for the protection against non-disclosure[536]. In particular, according to *Correa* the wording of Article 39 is inadequate to recognize data exclusivity protection or the establishment of an autonomous proprietary right. Indeed,

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categories of intellectual property that are the subject of Sections 1 through 7 of Part II"
[531]Shaikh, *Access to Medicine Versus Test Data Exclusivity,* 39.
[532]C. M. Correa, "Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals", *Chicago Journal of International Law:* Vol. 3: No. 1, Article 8, 72.
[533]UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 522.
[534]Ibidem
[535]Correa, *Trade Related Aspects of Intellectual Property Rights,* 367.
[536]Gervais, *The TRIPS Agreement: Drafting History and* , 545.

Correa argues that understanding the meaning of the article differently would be departing from a literal interpretation of the such provisions resulting in a clear violation of Article 31 of the Vienna Convention on the Law of Treaties[537]. The Vienna Convention supports the so-called objective method which entails that the Treaty should be given the meaning that is made clear by its text, which results from the logical connection between the various terms of the treaty[538].

The aforementioned Article 31, which constitutes the main part of the norms for treaty interpretation, highlighted three elements for the interpretation of a treaty, namely the ordinary meaning of the terms, their context and the object-and-purpose of the treaty. Notwithstanding, establishing the ordinary meaning of the text is the primary method for interpretation since it is the starting point in order to identify the context and purpose of an international agreement[539]. The same position in relation to the fundamental value of the treaty-text has been acknowledged in different cases brought before the Appellate Body and dispute settlement panels of the WTO, such as in the *US vs Shrimp case.* The Appellate body stated that: *"A treaty interpreter must begin with, and focus upon, the text of the particular provision to be interpreted. It is in the words constituting that provision, read in their context, that the object and purpose of the states parties to the treaty must first be sought. Where the meaning imparted by the text itself is equivocal or inconclusive, or where confirmation of the correctness of the reading of the text itself is desired, light from the object and purpose of the treaty as a whole may usefully be sought"*[540]. It must be, however, taken into account that the same Appellate Body stressed that the three aforementioned elements outlined in Article 31 (text, context and purpose) have to be understood as "*one holistic rather than a sequence of separate tests to be applied in a hierarchical order*"[541].

[537]Article 31 of the Vienna Convention of 1969.
[538]Chang-fa Lo, *Treaty Interpretation Under the Vienna Convention on the Law of Treaties- A New Round of Codification*, Springer, 2017, 153.
[539]Ibidem
[540]Appellate Body Report, United States—Import Prohibition of Certain Shrimp and Shrimp Products, par. 114, WTO Doc. WT/DS58/AB/R (adopted 6 Nov 1998)
[541] Panel Report, United States—Sections 301–310 of the Trade Act 1974, par. 7.22, WTO Doc. WT/DS152/R (adopted 27 Jan 2000)

The theory that Article 39 does not go beyond the provisions to protect against unfair commercial use and do not provide an autonomous right relating to test data protection as outlined in the *Paris Convention* does sound appealing, but another reasoning can be made on the legal obligations stemming from the aforementioned article. Considering that a literal interpretation would solely lead to an understanding of Article 39 as a mere reproduction of Article 10bis of the Paris Convention it is not necessarily persuasive[542]. Indeed, it is noteworthy to remember that there is no doubt about the *Paris Convention* binding nature since its obligations are also part of the TRIPS Agreement as provided for by Article 2[543].

Under these considerations, the second theory related to the interpretation of Article 39 of the TRIPS Agreement, which will be further outlined in the following section, grounds on the idea that it would be redundant to solely restate the legal obligations under Article 10bis of the Paris Convention in the wording of Article 39. It, thus, seems likely to consider that the latter article contains obligations that go beyond and expand the scope of Article 10 bis[544].

As a matter of fact, scholars have commonly acknowledged that the first paragraph of Article 39 refers to the obligations of Members to protect undisclosed information. The main objective of this provision is to guarantee satisfactory protection against unfair competition in line with the Paris Convention. In the same manner, however, paragraphs 2 and 3 of Article 39 provide greater provisions than those required under the Paris Convention, in so doing going beyond the mere protection against unfair commercial practice and competition[545].

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[542]Owoeye, *Data Exclusivity and Public Health Under the TRIPS Agreement*, 112.

[543]Article 2 of the Paris Convention: *"In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).*
2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits."

[544]Owoeye, *Data Exclusivity and Public Health Under the TRIPS Agreement,* 112.

[545]N. P. de Carvalho, *The TRIPS Regime of Patent Rights*, Kluwer Law International, 2nded, 2004, 388.

3.3.2 The second theory on the interpretation of Article 39: test data protection as a data exclusivity regime?

A literal interpretation of Article 39, and in particular of its paragraph 3, does not clearly reveal the establishment of a data exclusivity IP regime[546]. In the same way some scholars, such as Correa, have stated that the wording of *TRIPS* in general, and Article 39 in particular, does not entail that the provided test data protection should be granted through the conferral of exclusive rights to entitled subjects[547]. In addition, the *travaux preparatoires* of *TRIPS* shows that the US negotiators proposal to include a ten year data exclusivity protection was entirely rejected by all other delegations[548]. Under these considerations, it seems fair to conclude that test data protection does not imply the establishment of a data exclusivity regime. Notwithstanding, scholars debate as to whether article 39 of the TRIPS Agreement imposes a test data exclusivity regime in light of the object and scope of the treaty, as countries with strong R&D pharmaceutical industry commonly argue[549]. Unfortunately, art 39(3) has not yet been interpreted by the WTO Dispute Settlement Body. Actually, in the year 2001, a WTO panel was preparing to interpret the scope and content of the minimum obligations of protection stemming by Art 39 (3) in a dispute between the US and Argentina[550], but the latter parties reached an agreement and the US withdrawn its demand[551]. This section attempts to clarify the ambiguity of Art 39(3) for WTO Members with regard to understanding whether or not the latter provision establishes a data protection regime autonomous from both trade secrets and unfair commercial use.

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[546]A. X. Fellmeth, "Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under the TRIPS Agreement", *Harvard International Law Journal 45,* 459.
[547]Correa, *Trade Related Aspects of Intellectual Property Rights*, 367.
[548]Gervais, *The TRIPS Agreement: Drafting History and Analysis,* 545.
[549]United States Trade Representative, The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3, cited in IFPMA (2000) at footnote 7.
[550]Argentina – Certain Measures on the Protection of Patents and Test Data: Request for Consultations by the United States, WT/DS196/1, IP/D/22 dated 6 June 2000 [hereinafter Request for Consultations by the US (2000)]
[551]Notification of Mutually Agreed Solution, Argentina – Certain Measures on the Protection of Patents and Test Data, WT/DS171/3 &WT/DS196/4 dated 20 June 2002.

Some scholars have argued that the main object and purpose of Article 39(3) is to prevent Member States from acting in a manner incompatible with the trade secret status of test data. As a result, the adequate reasoning to be drawn is that Article 39(3) is meant to establish a data exclusivity regime, and in so doing, conferring autonomous rights to the right-holders[552]. In the same way, subsequent state practice demonstrates that test data have been considerate as a new IP right[553]. In fact, scholars such as Lorna Dwyer have highlighted that test data went from a simple trade secret protection to an independent right similar to a patent, usually protected for five years[554]. Furthermore, test data were not merely confined to the protection of undisclosed test information, but also extended to the protection of publicly available information[555]. This led to creation of an insurmountable barrier for generic pharmaceutical manufacturers to enter the market, hence impeding access to necessary drugs to people in developing countries. Lorna Dwayer concluded that "*no credible justification for such protection has been offered. The research and development costs have already been recovered by the patent holders, having been included in the price of the medications for over twenty years"*[556].

In conclusion, it goes without saying that favoring a specific theory on the interpretation of article 39, and in particular of its paragraph 3, has a concrete impact on access to affordable medicines, especially in developing countries. Deriving a data exclusivity regime from Article 39 entails delaying the entry into the market of affordable drugs, thus affecting negatively human rights provisions related to the right to health. On the contrary, understanding Article 39 as a provision aimed at preventing unfair commercial practice would safeguard both the protection of human rights and the prerogatives of pharmaceutical companies. This is the reason that Articles 31 and 32 of the Vienna Convention on the Law of Treaties of 1969 play a key role in

[552]Fellmeth, *Secrecy, Monopoly, and Access to Pharmaceuticals,* 463.
[553]This is mainly the case of the so-called TRIPS-Plus provisions envisaged in multiple bilateral and multilateral trade agreements (see following sections on CAFTA).
[554]L. Dwyer, "Patent Protection and Access to Medicine: The Colombia and Peruvian Trade Promotion Agreements", *13 Law & Business Review of the Americas, 2007,* 825.
[555]Ibidem
[556]Ibidem

determining the legal framework stemming from article 39 paragraph 3 of the TRIPS Agreement, as will be outlined in the next section.

3.3.3 Treaty interpretation analysis of Article 39 (3) of TRIPS

According to Article 3(2) of the *"Understanding on rules and procedures governing the settlement of disputes",* the Dispute Settlement System of the WTO (DSS) constitutes a cardinal piece in providing stability and certainty in relation to the legal provisions established in the WTO Agreements. In light of the aforementioned article, the DSS should interpret WTO agreements according to the customary rules of interpretation of public international law [557], thus employing the elements of interpretation envisaged in Article 31 and 32 of the Vienna Convention. Indeed, it is now widely accepted that the latter convention has adequately codified the most relevant customary norms related to the interpretation of international treaties[558]. In the same manner, in 1991 the International Court of Justice (ICJ) highlighted that even though neither of the parties of the dispute had ratified the Vienna Convention, both countries, namely Botswana and Namibia, considered Article 31 of the latter Convention applicable to the controversy as a reflection of customary international law[559].

Under these considerations WTO dispute settlement panels and appellate bodies have fallen back on Arts 31 and 32 of the Vienna Convention in order to assess disputes relating to WTO agreements in general and the TRIPS in particular[560]. In summary and

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[557]Art 3(2) of the 'Understanding on rules and procedures governing the settlement of disputes', Annex 2 of the WTO Agreement, UNTS 401; 33 ILM 1226 (1994).

[558]International Court of Justice stated in the Judgment on the Arbitral Award of 31 July 1989 *(Guinea* v *Senegal)*: *"Articles 31 and 32 of the Vienna Convention on the Law of Treaties…may in many respects be considered as a codification of existing customary international law…"* (I.C.J. Reports 1991, p 69–70, par. 48).

[559]International Court of Justice, *Botswana v Namibia* of 1999, par. 18. Likewise the WTO Appellate Body in Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, DSR 1996:I, 9.

[560]For instance: WTO Appellate Body Report on United States – Section 211 Omnibus Appropriations Act of 1998, WT/DS176/AB/R

as briefly mentioned above, Art 31(1) provides that a treaty has to be interpreted in **good faith**, in line with its **ordinary meaning** bearing in mind the relevant **context** and on the grounds of the treaty **object** and **purpose**[561]. The WTO Appellate Body has often noted that the interpretation *must be based above all upon the text of the treaty*[562]. Paragraph 2 of article 31 requires that the context concerns the treaty's preamble and annexes as well as related agreements and other instruments linked with the the treaty at stake[563]. Paragraph 3 provides that *"there shall be taken into account, together with the context"* any related subsequent agreements, subsequent practice of the treaty parties and relevant rules of international law applicable in the relations between the party[564]. In addition, Paragraph 4 states the importance of any special meaning given to the terms of the treaty by the parties[565].

Furthermore, Article 32 provides the so-called supplementary means of interpretation and, in particular lists the *travaux preparatoires* and the circumstances of conclusion of the treaty. The latter may be employed in order to validate the interpretation derived from the process envisaged in Art 31 or where such interpretation leaves the meaning ambiguous or obscure or leads to a result that is manifestly absurd or unreasonable[566].

As to the **good faith** element of interpretation, the Appellate Body in the *US – Gasoline case* argued that the aforementioned element must be understood as a tool for assuring an effective interpretation of the treaty. In fact, according to the latter Body *"one of the corollaries of the general rule of interpretation in the Vienna Convention is that interpretation must give meaning and effect to all the terms of a treaty. An interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility* [567]. As a result, in the eye of the WTO Appellate body, the principle of effectiveness (*ut res magis valeat quam pereat*), which stems

[561]Article 31(1) of the Vienna Convention
[562] WTO Appellate Body Report on Japan – Taxes on Alcoholic Beverages, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, para. 12
[563]Article 31(2) of the Vienna Convention
[564]Article 31(3) of the Vienna Convention
[565]Article 31(4) of the Vienna Convention
[566]Article 32 of the Vienna Convention
[567]WTO Appellate Body Report on United States – Standards for Reformulated and Conventional Gasoline, WT/DS2/AB/R, para, 23.

from Article 31, is a fundamental tenet of treaty interpretation. According to the latter principle, if an agreement can be interpreted in two different manners and one of the two deprives the treaty of factual meaning, good faith and the objects and purpose of the treaty require the adoption of the interpretation that confers effectiveness to its provisions.[568]

With regard to the **ordinary meaning** element of interpretation, there is little doubt that the phrase 'unfair commercial use' must be understood as gaining possession of confidential test data for the approval of bioequivalent generic products through dishonest means[569].

As to **context**, the WTO Secretariat clarified that *"refers to the kinds of conclusions that can be drawn on the basis of, for example, the structure, content or terminology in other provisions belonging to the same agreement, particularly the ones preceding and following the rule subject to interpretation*"[570]. In line with the latter view expressed by the WTO Secretariat, some scholars have argued that the text, preamble and annexes and the terms of the treaty must be read in the context of the entire treaty, thus favoring the so-called holistic approach[571].

3.3.4 The object and purpose in light of Article 39(3)

As was presented in the previous section, according to the aforementioned article 31 of the Vienna Convention, the **object and purpose** of the treaty constitute a key element in determining the meaning of specific provisions of the agreement. Interestingly, in light of WTO jurisprudence, the main function of understanding the object and purpose of an agreement is to confirm and/or justify the literal interpretation of the text. In a dispute concerning the GATT Agreement, facing the European Communities as

[568]Yearbook of the International Law Commission 1966, Vol. II, 219.
[569] Shaikh, *Access to Medicine Versus Test Data Exclusivity*, 39.
[570]WTO Secretariat, *A Handbook on the WTO Dispute Settlement System*, A WTO Secretariat Publication 5 (2004).
[571]A. H. Qureshi, *Interpreting WTO Agreements: Problems and Perspectives*, Cambridge University Press, 2012, 19.

complainant and Japan as the respondent party, the Dispute Settlement body reaffirmed the view that the object and purpose method cannot be used as an autonomous basis for interpretation[572].

In the same manner, in another case still concerning the interpretation of the GATT Agreement, the WTO appellate body stressed that the object and purpose of a specific provision has to be understood in light of the object and purpose of the whole. This is the reason the interpreter has to assess the meaning of particular provisions, paragraphs or subparagraphs of WTO agreements in connection with its entirety[573].

In practice, the object and purpose of a treaty can be derived from its preamble, from the text of the treaty as a whole, and from specific provisions establishing the treaty's object and purpose[574]. In fact, specific WTO agreements, which are GATT, GATS and TRIPS, must also be interpreted in light of the Agreement establishing the WTO (often referred to as the Marrakesh Agreement) which, *inter alia,* stresses the importance of striking a balance between sustainable development and trade related goals. As described at the beginning of this chapter, the various treaties which formed the Marrakesh Agreement constitute an indivisible whole (a single undertaking), making impossible for a country to be part to one agreement without being bound to them all.

With particular reference to the object and purpose of the TRIPS Agreement as provided in its preamble, neither scholars, States, nor law practitioners agree on its content. Some scholars such as Correa believe that the wording of the preamble refers to the protectionist approach backed by developed countries, and by the US in particular, in relation to the international intellectual property regime[575]. On the contrary, other scholars believe that the TRIPS preamble allows a flexible interpretation in order to tackle all the different and clashing provisions and objectives contain

[572]Appellate Body Report, *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, DSR 1996:I, 97, footnote 20. (1966) Yearbook of the International Law Commission, Vol. II, 219.

[573]Appellate Body Report, *European Communities – Customs Classification of Frozen Boneless Chicken Cuts*, WT/DS269/AB/R, WT/DS286/AB/R, par. 238.

[574]Shaikh, *Access to Medicine Versus Test Data Exclusivity*, 52.

[575]Correa, *Trade Related Aspects of Intellectual Property Rights*, 2.

within[576]. The TRIPS agreement preamble, as these scholars highlighted, contains several provisions which reaffirm the necessity of finding an equilibrium between, *inter alia,* IP rights and free trade, developed and developing nations' interests and more generally in all the situations in which public needs are threatened by strict IP rules[577]. Furthermore, other scholars such as Xu Yi-Chong present a quite pessimistic perspective. According to the latter, the main object and purpose of the TRIPS agreement as a whole is to coerce developing and least developed countries in order to implement in their domestic law the limitless minimum standards related to IP as "*membership fee for the club WTO"*[578].

Important to remember is that the TRIPS articles are intended to be understood in concert with the aim of carrying out the objective of the WTO Agreement as a whole. Indeed, the TRIPS Agreement is a component of the entire WTO system similar to other instruments envisaged in the preamble of the WTO Agreement[579]. In regard to access to medicines, this consideration leads to interpreting TRIPS provisions in light of the principle of sustainable development of Nations even if the latter is not mentioned in the TRIPS preamble.

The aforementioned preamble refers to provisions related to the protection of IPRs in international trade, bearing in mind the different levels of normative development among parties, as well as providing special emphasis and waivers for least-developed countries[580]. The TRIPS Agreement differs from the WTO one because it has established specific provisions (in particular Articles 7 and 8) which state the object and purpose of the treaty. As a result, even though the preamble is vague in regard to IP rights protectionism or more liberal statements, the latter articles play a crucial role in understanding the object and purpose of the TRIPS agreement. Articles 7 and 8 have

[576] Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 81.
[577]Ibidem
[578]Xu Yi-Chong, 'Last Chance? Multilateralism, TRIPS and developing countries', in *Interpreting and Implementing the TRIPS Agreement: Is it Fair?*, 2008, 46.
[579]P. K. Yu, 'The Objectives and Principles of the TRIPS Agreement', in *Research Handbook on the Protection of Intellectual Property Under WTO Rules: Intellectual Property in the WTO,* 2010, 148.
[580]Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement, Oxford University Press, 2007, 3.

in fact a higher interpretative status since they are part of the treaty text and do not simply have a hortatory value as a treaty preamble[581]. Art 7 of the TRIPS labeled 'Objectives' states: *"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations"*[582].

In light of Art 7 the objectives of the TRIPS Agreement are promotion of technological innovation and transfer and dissemination of technology. Important to stress here is that this article highlighted four significant considerations about the protection and implementation of IP right. Firstly, they should trigger technological advancement and the dissemination of such innovation; secondly, IP rights should be both profitable for the producers and users; thirdly they should at the social and economic welfare of countries, and lastly, IP rights should balance the rights and obligations of producers and users. Therefore, it would seem that the reasonable inference to be drawn is that Art 7 works towards achieving the objective of *"sustainable development"* as provided for by the preamble of the WTO Agreement[583]. Indeed, the latter article in question makes clear that IPRs cannot be understood as an end in themselves, but provide a balancing regime which enhances and includes both dynamic and static competition[584]. Likewise, Art 8, labeled *"Principles"*, reflects the so-called principle of *integrated development* also envisaged in the WTO Agreement's preamble in introducing the public interest principle in order to protect socio-economic and technological development of members. Paragraph 1 states: *"Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures*

[581]Shaikh, *Access to Medicine Versus Test Data Exclusivity,* 54.
[582]Article 7 of the TRIPS Agreement.
[583]UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 126.
[584]Shaikh, *Access to Medicine Versus Test Data Exclusivity*, 55.

are consistent with the provisions of this Agreement"[585].

The incorporation of the public interest and health principle constitutes a key element in studying the relationship between access to medicines and IP rights since there is no doubt that providing affordable/accessible drugs falls under the latter category. Unfortunately, no authoritative interpretation is available since Article 8 has not been addressed in any WTO disputes to date. Notwithstanding, Article 8 provides two specific requirements, namely *necessity* and *TRIPS consistency,* that Members must satisfy in order to protect public health and public interest in general[586].

As to *necessity,* there is agreement in interpreting this requirement in a wide manner, in particular on the grounds of previous WTO Dispute Settlement Body decisions on akin provisions within GATS and GATT such as Article XX[587]. In particular, the Appellate Body provided a scheme of the so-called necessity test requirements in order to assess whether a measure adopted by a member can be considered necessary. According to this test, the States' measures must satisfy three *criteria*: firstly, they must contribute to the realization of the end desired; secondly, measures must be aim at protecting significant interests or values; and finally, measures cannot be harmful for international trade[588]. In accordance with this perspective from the WTO Appellate, some scholars have applied similar criteria in order to interpret the necessity requirement of Article 8 of TRIPS. In their opinion, measures have to be essential in the sense that one of the goals provided for in the aforementioned article, namely public health and public interest in sectors of vital importance, have to be in jeopardy. In this regard, the burden of proof in order to demonstrate this danger lies with the invoking State. Secondly, the measure has to be capable of achieving the goal pursued by the State. In this respect, the State relying on Article 8 must prove the measure ability to contribute to the advancement of the public interest at stake. Lastly, States should

[585]Article 8 of the TRIPS Agreement
[586]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property,* 212.
[587]WTO Appellate Body Report, Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef, 159–164, WT/DS161/AB/R, WT/DS169/AB/R or art. XX of GATT.
[588]I. C. Salinas Alcaraz, "The concept of necessity under the GATT and national regulatory autonomy", Vol. 10, N.° 2 / julio-diciembre 2015 / Bogotá, D. C. / Universidad Santo Tomás, 86.

enforce the least restrictive measure for international trade[589]. In other words, when States implement measures in light of Article 8, they must strike a balance between means and ends, thus proving that they have taken into consideration all the possible measures and have adopted the least detrimental measure for international trade[590].

Notwithstanding, the necessity requirement cannot be interpreted in isolation and has to be understood in concert with the second requirement, namely TRIPS consistency. Better said, all measures adopted by members related to public health and public interests should not be inconsistent with the framework provided for the TRIPS Agreement[591]. The latter Article establishes a compatibility clause which is not present within the wording of Article XX of GATT. In practice, the aforementioned clause deprives Article 8 of the power to function as an adequate exception to the obligations otherwise provided under the Agreement. As a result, exceptions to the protection granted by TRIPS are admissible only if they are provided by a specific provision of the TRIPS itself. On this ground, if an evident opposition emerges between a clear provision of the TRIPS and the Article 8 principles, the former prevails. An example will clarify the described scenario. Article 33 of TRIPS provides a 20 years patent protection counted from the filing date. If for instance, a State adopts a measure which shortens the unambiguous term of 20 years to 15 years aiming at protecting public health, such State is breaching both Articles 8 and 33 of TRIPS[592].

In relation of the specific analysis of this dissertation, Art 8 of TRIPS must be interpreted broadly with the aim at striking a balance between the rights and obligations and the social and economic welfare of its Members[593]. In line with this view, scholars such as Grosse Ruse-Khan highlighted that the WTO Doha Declaration of 2001 (which will be presented in the next section) stated that the specific provisions as well as the text of the Agreement as a whole should be interpreted and enforced in a way which is

[589]United States - Restrictions on Import of Tuna (No 1), Mexico v United States, GATT Panel Report, DS21/R, BISD/39S/155, (1991) 30 ILM 1594, ITL 041 (GATT 1991), 3rd September 1991, World Trade Organisation [WTO]; General Agreement on Tariffs and Trade (historical) [GATT], par. 5.28.
[590]Stoll, *Trade-Related Aspects of Intellectual Property Rights,* 197.
[591]Ibidem, 198.
[592]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property*, 212.
[593]Correa, *Trade Related Aspects of Intellectual Property Rights*, 104.

consistent to protect public health including guaranteeing access to inexpensive medicine[594].

3.3.5 Final remarks about article 39 of the TRIPS Agreement

In light of the aforementioned analysis, the interpretation of Article 39 of the TRIPS Agreement leads to the conclusion that the latter Article does not provide for a data exclusivity regime, but rather the protection of unfair commercial practices such as unfair competition. In summary, the *traveux preparatoires* demonstrated a clear intent by the parties to avoid the establishment of exclusive rights related to test data and the final text, in fact, only envisages protection for *'undisclosed test and other data'* presented as part of a marketing approval for new chemical entity pharmaceutical and agricultural chemical products, without mentioning any exclusivity regime nor a term of protection. In other words, regardless the status of IP right conferred by the provisions of the TRIPS agreement, undisclosed test data do not refer to an exclusive right such as a patent, copyright or trademark[595].

This is particularly true if the TRIPS provisions are understood in light of the *in dubiis benigniora praeferenda sunt* principle, which states that the imposition of onerous obligations should be deterred in cases in which the wording of a treaty is ambiguous thus allowing different interpretations[596]. Since the ordinary meaning of Article 39 TRIPS, as demonstrated, might lead to clashing perspectives, the interpretation that results in both a less onerous position for States and in a framework more consistent with human rights protection must prevail. As a result, the provisions of Article 39 should be understood as providing obligations on members in order to prevent unfair commercial use of test data and as granting drug safety and efficacy as a crucial part of the right to health and consumers' wellbeing.

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[594]Grosse, R., 'A Comparative Analysis of Policy Space in WTO Law', *Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper Series* No. 08-02, 2008, 40.
[595]Malbon, *The WTO Agreement on Trade-Related Aspects of Intellectual Property,* 578.
[596]Ibidem

It must be noted that Article 1.1 TRIPS provides that: '*Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice',* thus inferring that the Agreement does not establish an international harmonization of IP rights, but rather provides a minimum standard regime. In the latter, members are free to implement the envisaged provisions in the way that best suits their socioeconomic goals, bearing in mind other international obligations contracted in some other agreements such as human rights ones.

Under these considerations the establishment of data exclusivity regime is not the most convincing interpretation of article 39. In fact, as confirmed by the interpretative steps taken in accordance with articles 31 and 32 of the Vienna Convention, namely that a treaty has to be understood in good faith, according to the ordinary meaning and in light of the its context, object and purpose, States have the sole obligation of protecting test data from unfair commercial practice in the way they believe adequate.

4 Flexibilities provided by the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001

The previous parts of this Chapter have highlighted that the TRIPS agreement requires members to establish minimum standards of intellectual property protection within their domestic legal system in order to set up the so-called harmonization of IP laws. Accordingly, as a result of the ratification of the TRIPS agreement, patents extend to the protection of both processes and products of the pharmaceutical sector, thus creating a wide-ranging protection of originators' medicines. As discussed throughout the entire dissertation, such comprehensive protection resulted in social challenges for developing countries, which in light of the high price of patented drugs could not always provide essential medicines to millions of affected people.

Before TRIPS came into force, a large number of countries, which did not have sufficient productive capacity to manufacture locally the medicines required by their community, could depend with relative ease on imports from the countries that did have such infrastructure such as India, China or South Africa. At that time, the main producers of generics were free to supply the international market without any procedural barriers, since normally neither they nor the importing countries protected pharmaceutical products with patents.

Since 1995 the situation has drastically changed. Currently, only countries which are not part of the WTO system have the possibility to lawfully ignore the TRIPS framework and, thus, to freely import or export medicines. In addition, the TRIPS itself established a transitional period of ten years for least developed countries following the entry into force of the agreement, as provided for by its Article 66[597].

This situation is currently unlikely because almost all the countries in the world are members of the WTO, and most importantly, least-developed countries subject to the

[597] The transitional period has been extended three times for all least developed members as a result of a specific request by such countries within the organization. Firstly, throughout the 2005 Decision, the TRIPS Council extended the period until 1 July 2013, and on 11 June 2013, it extended this further until 1 July 2021. With a specific focus on pharmaceuticals, the 2001 Doha Ministerial Declaration on TRIPS and Public Health had already indicated the TRIPS Council to extend the period until 2016. Indication that was fulfilled in 2002, when the TRIPS Council formally adopted a decision implementing it. Lastly, in November 2015, TRIPS Council decided to further this transition period until 1 January 2033.

extension do not have productive capacity to take full advantage of such extension[598]. As a result, there is a strong need to analyze the flexibilities of the agreement, their practical application, and their ability to offer essential drugs at affordable prices.

Indeed, the TRIPS Agreement contains specific flexibility mechanisms that are available to all signatories' countries (although they were especially provided for developing countries) in light of the particular social and humanitarian needs that any country may encounter. Yet, the scope and meaning of some of the provisions regulating these *flexibilities* are still ambiguous. Some scholars have referred to a *constructive ambiguity* to explain the strategy behind the use of unclear language in many provisions of the WTO agreements. In fact, the wording of such provisions can be dynamically constructed in application and through interpretation depending on the particular circumstance and on the specific country involved[599]. Such ambiguity, which was successful for negotiations, however, resulted in harsh complications for developing countries wanting to implement such flexibilities, making their implementation contentious and ineffective[600].

Generally speaking, the first "flexibilities" pertinent to the right to health can be traced in the Preamble, in Articles 7 and 8 of TRIPS. The preamble, which established the background and tone of the agreement, addressed the desire for a reduction of distortions and impediments to international trade, the recognition of the public policy objectives of national laws and, most importantly, the requirement to consent determined flexibility for least developed countries[601]. The Preamble constitutes a crucial part of the Agreement when ambiguous provisions of the TRIPS need interpretation. Some scholars have highlighted that in comparison to the WIPO treaties, the TRIPS Preamble adopted a more economic and welfare-based approach, which,

[598]S. Olufemi and J. Wabwire, "The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional", *World Trade Review* 17: 1, 2018, 147.
[599]De Carvalho, *The TRIPS Regime of Patent Rights,* 27.
[600] J. Watal, "Implementing the TRIPS Agreement on Patents Optimal Legislative Strategies for Developing Countries" in Owen Lippert, ed., *Competitive Strategies for the Protection of Intellectual Property*, The Fraser Institute, 1999, 106.
[601]Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement,* 144.

thus, may require a more balanced understanding during interpretation[602].

The aforesaid Article 7, which concerns the objective of TRIPS, establishes that the protection and implementation of intellectual property protection is supposed to contribute to the dissemination of technology in a way that both users and producers can benefit from it, while taking into consideration both the social and economic welfare as well as the equilibrium of rights and obligations provided within. As a result, *the value of intellectual property protection and enforcement is located within a general context of social welfare*[603].

Likewise, Article 8 envisages some principles to reinforce TRIPS' balance with socio-economic provisions. Remarkably, Paragraph 1 explicitly relates to issues of public health and nutrition as well as vital areas of socio-economic and technological development, which members can take into consideration when implementing the Agreement in their domestic systems. In addition, Paragraph two aims to prevent owners abusing intellectual property in ways that might negatively distress trade or the international transfer of technology. Then, Paragraph 2 calls upon the desirability of technology transfer which is generally viewed as beneficial in economic and social development. These provisions suggest that policies adopted by Members to confront public health, nutrition and matters of significant socio-economic importance should be acknowledged to be consistent with TRIPS, and that any other Member wishing to question the exercise of discretion should accept the burden of proving inconsistency[604].

In this regard, some academic have highlighted that in light of a developmental understanding of Articles 7 and 8, that the TRIPS Agreement grants "considerable room" for national regulations to tackle two comprehensive topics. Firstly, the scope and boundaries of many legal concepts provided in Article 27 of the Agreement should be defined bearing in mind the principle envisaged in the latter two articles. For example, concepts such as invention, novelty, inventive step, and *ordre public* cannot be interpreted ignoring the developmental nature of the aforesaid provisions. Secondly,

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[602] Ibidem
[603] Ibidem
[604] UNCTAD-ICTSD, *Resource Book on Trips and Development,* Cambridge University Press, 2005, 127.

these scholars argue the need to understanding Article 6 (labeled *Exhaustion of rights*), which concerns the exceptions to the patentee's exclusive rights, as the theoretical foundation of one of the main flexibilities in the hands of developing countries, namely parallel importations[605].

At this point of the analysis, Article 30 of TRIPS deserves further inquiry. Such article envisages that signatory parties provide exception to the exclusive rights of patents' holders *provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*[606]. Nonetheless, the latter provision does not explicitly define the relevant exceptions, thus leaving a wide margin of discretion for domestic regulations, which can freely determine the scope and extent of such exceptions[607]. Remarkably, the WTO Dispute Settlement System (DSS) has highlighted that the conditions established by Article 30 must be met autonomously from the other in light of their cumulative nature[608]. This position taken by the DSS is the ground on which other flexibilities rely, as it will be illustrated in the present section.

The aforesaid flexibilities constitute general provisions which allow all countries to consider their health-related issues when implementing the agreement. Notwithstanding, such general flexibilities must be analyzed together with specific provisions of the agreement which offer practical tools at the disposal of developing countries. Accordingly, the focus of this section is on the TRIPS Agreement provisions on *compulsory licensing* and *parallel importation* and their implications for health in least developing countries in order to strike a balance between patents and access to medicines. This is because these two flexibilities are perhaps the most effective instruments for tackling the access to medicines dilemma. Remarkably, there is broad consensus on the acknowledgement of such flexibilities, but debates have arisen on

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[605] C. M. Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, Zed Books & Third World Network, 2010, 51-52.
[606] Article 30
[607] C. M. Correa, *Propiedad Intelectual y Salud Pública,* Buenos Aires, La Ley, 42.
[608] Canada - Patent Protection of Pharmaceutical Products (WT/DS114) Report of the Panel, March 2000, par. 7.20.

their scope and application.

In conclusion, the aim of this section is to determine whether or not TRIPS may be able to accommodate right to health-related norms in light of the broad language provided within the treaty and of the flexibilities of its open-textured provisions. Such flexibilities may strike a balance between the public and private sphere interpreting intellectual property protection and trade promotion which are envisaged in TRIPS, consistently with the protection of public health, as one of the main public goods concerned. The actual issue is, however, to understand whether such flexibilities are satisfactory to give effect to the right to health and access to medicines in TRIPS.

4.1 Compulsory licensing

The compulsory licensing system provided for by the TRIPS has been the subject of massive debates. Such debates mainly revolved around the various requirements needed in order to use compulsory licenses which often led to formal accusations of breaching the Agreement against the countries that tried to take advantage of the aforesaid flexibility[609]. As it is easy to understand, the adoption of compulsory licenses has always been followed by substantial disagreement of patents' holders, especially in the pharmaceutical sector. As a result, the circumstances and scope under which compulsory licenses may be granted are not well-defined, making the analysis on the relevance of compulsory licenses multifaceted and highly interesting[610]. This section provides an insight into the system established by TRIPS in relation to compulsory licensing.

In accordance with article 31 of the TRIPS Agreement, compulsory license does not stem from the autonomous and free will of the parties concerned, but rather from State

[609] J. Burton-Macleod, "Thai compulsory licenses redefine essential medicines debate" in T. Pogge et al (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines*, Cambridge University Press, 2010, 406.

[610] R. A. Epstein and F. S. Kieff, "The Licensing of Intellectual Property: Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents", 78 *University of Chicago Law Review,* 2011, 71.

intervention which compulsory establishes a new legal relationship[611]. Consequently, compulsory licensing can be defined as an authorization issued by the government or by a judicial authority to use patented products without the consent of the holder of the patent right[612]. Public authorities must first try to negotiate with the patent holder for a voluntary license, if such attempt does not succeed a member state can then waiver this prerequisite in the circumstance of a national emergency, such as for the protection public health.

The licensee can be a state, a company or any other interested party provided that adequate remuneration is paid. The right of the patent holder, thus, is converted from the enjoyment of the *ius excludendi alios* to receiving a royalty rate that is likely below what the patent owner would spontaneously negotiate[613]. In this regard, TRIPS does not provide any definition on what must be understood as "adequate compensation", thereby allowing the parties concerned to provide different interpretations in their domestic laws. Some scholars have argued that in order to determine the *quantum* required for compensation, elements such as the economic development and growth of the country concerned must be considered[614].

Nonetheless, the *quantum* is usually determined in light of the relevant domestic law and of the practice of judicial or administrative bodies of the state in which the compulsory license was issued.

Since the origin of the modern system of IP protection, compulsory licensing has been regarded as a tool of public policy as well as a fortunate mediation between the protection of inventions and the needs of the community[615]. In regard to pharmaceuticals products, compulsory licenses constitute a major tool since they act as

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[611]H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, Oxford University Press, 2007, 239.

[612]X. Seuba, *La protección de la salud ante la regulación internacional de los productos farmacéuticos,* Marcial Pons, 2010, 270.

[613]C. M. Ho, "Patent Breaking or Balancing?: Separating Strands of Fact from Fiction under TRIPS", 34 *North Carolina Journal of International Law & Commercial Regulation* 371, 2009, 373.

[614]D. R. Cahoy, "Confronting Myths and Myopia on the Road from Doha", 42 *Georgia Law Review* 131, 2007, 143.

[615]G. Segade, "Licencias obligatorias e invenciones farmacéuticas", in *La protección jurídica de las invenciones y la industria químico-farmacéutica*,1974, 348.

a defense against misuses that may arise from the monopoly rights conferred by patents in order to enhance competition and to make medicines economical especially in cases of public health emergencies[616]. Some scholars have argued that such flexibility is the most important public policy tool at States' disposal in light of the compulsory license capacity to limit the exercise of private rights in favor of the general interest[617]. In relation to medicines, economic or industrial considerations cannot be the only grounds for action, since social and humanitarian reasons must always be taken into account by public authorities[618].

Article 31 of the TRIPS Agreement establishes the regulatory framework for compulsory licensing. It must be noted that such provisions set out a more inclusive framework for the compulsory licensing of patented inventions than the one envisaged by the Paris Convention. Nonetheless, Article 31cannot be consider complete nor far-reaching since may rely on other grounds to invoke the use of compulsory licensing[619]. Naturally, the scope and duration of compulsory license is not unlimited as the very reason for the authorization of the waiver stems from unconventional circumstances. This means that the use is limited in time and scope to the objective authorized within a license, which must terminate if and when the conditions which triggered it cease to exist and are improbable to persist[620].

In light of the wording of article 31 of the TRIPS Agreement, countries are allowed to regulate several motives stated in their national laws for the use of compulsory licenses for pharmaceutical patents[621]. Yet, Article 31 of the TRIPS Agreement makes explicit reference to five grounds on which member countries may grant compulsory licenses, on the condition that they comply with the requirements envisaged therein and they are

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[616] W. Cornish D. Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks And Allied Rights,* Sweet & Maxwell, 2007, 295.

[617] David Fairman, Diana Chigas, Elizabeth McClintock and Nick Drager, *Negotiating Public Health in a Globalized World: Global Health Diplomacy in Action,* Springer, 2012, 171-172.

[618]Segade, *Licencias obligatorias e invenciones farmacéuticas*, 366.

[619] R. Elliot, "Trips and Rights: International Human Rights Law, Access to Medicines, and the interpretation of WTO Agreement on Trade Related Aspects of Intellectual Property Rights", *Canadian HIV/AIDS Legal Network,* 2001, 50.

[620] Article 31 (g)

[621] Correa, *Intellectual Property Rights, The WTO and Developing Countries. The TRIPS Agreement and Policy Options*, 7.

issued on a case by case approach. These grounds are:

1. Refusal to deal (article 31 (b))
2. Emergency and extreme urgency (article 31 (b))
3. Anti-competitive practices (article31(k))
4. Non-commercial use (article 31(b))
5. Dependent patents (article 31 (l))

These grounds leave room for wide interpretations, as it is not always easy to determine what a national emergency entail or the entire scope of anti-competitive practices. Nonetheless, in regard to the issue under consideration, namely access to essential medicines, the Doha Declaration of 2001, which will be further analyzed in the following sections, emphasized that the fight against HIV dissemination definitely falls under such category.

In sum, when granting a compulsory license, the aforesaid conditions must be met. Then, each case must be examined on its individual merits under a case-by-case evaluation and decision. The subject requesting the issue of a compulsory license must preliminarily request the patentee for a voluntary license, indicating the scope and duration of the license demanded. Thirdly, the license must be non-exclusive and preferably for the domestic market. This entails that that a compulsory license aimed at supplying a third market, would be in breach of TRIPS, unless local supply is central or it comprises anti-competitive matters[622]. Fourthly, as already mentioned, the patent holder must both receive adequate remuneration as well as be granted the possibility of demanding the revision of decisions and revocation of the relevant license[623].

Notwithstanding, not everything that looks valuable or accurate turns out to be so. In practice, even though compulsory licenses are important tools in endorsing actual price negotiations with pharmaceutical companies holding patens and, thus, for permitting local access of patented medicines at affordable prices, they do require certain pre

[622] TRIPS, Article 31(f)
[623] TRIPS, Article 31(h)

conditions that not all the counties are actually able to meet.

In order for a country to be able to appeal for compulsory licensing as a public policy tool to promote access to medications, such country must demonstrate that has the financial ability or technical capability to locally produce the relevant medicine. Secondly, when the party exploiting the patent is not a government (for example a generic company), an assessment of whether the relevant market has adequate purchasing power between the local population must be made in order to validate the investment made by the party. In countries such as Nicaragua or Belize, the population does not usually dispose of significant resources, which may guarantee returns for investment[624]. Likewise, if is the government the party requesting the compulsory license (usually for government –use- or acting as an agent on behalf of the population buying the patented medicines), there must be proof of both financial resources and technical capability for an adequate use of the drug licensed. In addition, the relevant legal and political structure must be capable of granting and monitoring the licenses issued[625]. The latter preconditions, which may appear as simple technical requirements, constitute an actual obstacle for the appropriate use of the aforesaid flexibility. In fact, only developed countries and few developing countries, such as India and Brazil are able to make use of this mechanism effectively. Even more, developed countries such as the United States have argued that compulsory license can authorize only local production of a patented drug, making, thus, impossible for least developed countries, which often lack significant pharmaceutical manufacturing capacity, to produce them within their boundaries. Such argument grounds on the requirement envisaged in Article 31 that products manufactured pursuant to a compulsory license shall be 'predominantly' for the supply of domestic markets. The Doha Declaration of 2001 put the foundation stone for the amendment of such provision in a way more consistent with public health emergencies which trouble countries al over the word. As the following section provides, parallel importation is a significant tool in order to

[624] F.M. Abbott, "WTO TRIPs Agreement and its implication for Access to Medicines in Developing Countries, a report prepared for the Intellectual Property Rights Commission", Washington DC, *Intellectual Property Rights Commission*, 2002, 13.
[625] Ibidem, 14.

overcome the difficulties stemming from the technicalities behind compulsory licenses. In conclusion, it worth mentioning one of the most important examples concerning compulsory licenses. Brazil, which is one of the main pillars of the so-called BRICS, paved the way for assuring that patents do not constitute an obstacle for the treatment of curable diseases. In particular, Brazil adopted new legislation in order to overcome patents monopoly and, thus, continuing to providing free ART for HIV-positive patients. Remarkably, such country has one of the most successful AIDS programs in the world, since relevant medicines are produced locally.

In 2001, the USA started proceedings before the WTO DSS against Brazil after the latter threatened to issue compulsory licenses for specific ARVs[626]. International pharmaceutical companies threatened to withdraw investments from Brazil and persuaded the USA to request a WTO dispute settlement. The US complaint grounded on the alleged incompatibility of the recently established article 68 of the Brazilian IP, which permitted compulsory licensing if the patent holder did not produce a product locally within three years of the granting of the patent. The Brazilian government decided face American accusations, arguing that Article 68 was compliant with the spirit of the TRIPS Agreement, and in particular with 5.4 of the Paris Convention, which consents for compulsory licensing if the patent is not worked locally[627]. AIDS militants and activities as well as NGOs from all around the world strongly supported the Latin American Country. Such support pressured the USA to withdrew its WTO proceedings against Brazil, which was able to grant access to ARVs to millions of people in need[628]. This illustrates the huge power that compulsory license embodies and encouraged governments worldwide to threaten compulsory licensing. The sole threatening sufficed in allowing governments to negotiate massive price discounts for ARVs from main pharmaceutical corporations.

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[626] WT/DSS199/1/G/L/385, IP/D23, 8 June 2000 and Request for the Establishment of a Panel by the United States, Brazil-measures affecting patent protection, WT/DS199/39, January 2001.

[627] M. Reto and Kung-Chung Liu, *Compulsory Licensing, Practical Experiences and Ways Forward,* Springer, 2015, 45.

[628] Joint Communication Brazil-United States, 25 June 2001. The US had by this time effectively been condemned by the UN Commission on Human Rights (Resolution 2001/33, Access to Medication in the Context of Pandemics such as HIV/AIDS, 57the Sess. April 2001)

4.2 Parallel importations

The previous section studied the significance of compulsory licensing in the access to medicines context, especially highlighting the challenges that such flexibilities provide for developing countries in practice. In this section, the highly debated issues of exhaustion of intellectual property rights and parallel importation are illustrated in relation to access to medicines in the developing world.

The exhaustion of rights, often referred to as "first sale" doctrine, constitutes one of the most significant principles relating to intellectual property (IP) law. This principle entails that once a patent holder puts, or authorizes others (an assignee or a licensee) to put on the market patented products, the patentee control over the sale and movement of goods is exhausted[629]. It must be noted that such principle merely concerns the rights of commercialization of the product and not its production or development. Accordingly, the control over the sale of the dispensed goods shifts from the patent holder to the buyer for reselling, lending and other third-party commercial uses[630].

The reasoning behind this principle are quite intuitive: by failing to apply the exhaustion of rights doctrine the patentee would exercise a perpetual over all the phases of production, distribution and use of the patented goods. In fact, once the patentee has placed the product on the market before any other competitors, the former has already gained an economic competitive advantage which is the foundation of intellectual property law. As a result, widening the control of patent holders beyond the point of the first sale implies authorizing measures detrimental to the free movement of goods and services, which, it is, thus, vital for preventing distortions in all market-based economies. Hence, the main goal of exhaustion regimes is to strike and preserve a balance between the public interest of assuring free movement of innovative goods on the one hand, and the private interest of patent holders, namely compensation for their innovative efforts on the other[631].

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[629] De Carvalho, *The TRIPS Regime of Patent Rights*, 103.
[630] UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 93.
[631] M. Slotboom, "The Exhaustion of Intellectual Property Rights - Different Approaches in EC and WTO Law", Vol. 6 Part 3 Journal of World Intellectual Property, 2003, 422.

While the exhaustion of IP rights appears a logical principle for limiting patentees' privileges, it was cause of multiple debates during the negotiations of the TRIPS Agreement[632]. Three were the main positions under discussion. Firstly, national exhaustion entails that once a product has been sold (lawfully), patent rights are exhausted only within the boundaries of a patent-granting member. The second is international exhaustion, which means that the patent rights are exhausted after the first authorized sale of patented products anywhere in the world[633]. The last doctrine, which constitutes an intermediate approach between the former two, is regional exhaustion. Accordingly, patent rights are exhausted after the first authorized sale of patented goods in any country part of a free trade or customs union agreement.

A renowned example is the exhaustion regime endorsed by the European Economic Area (EEA)[634].

During the TRIPS negotiations, developed countries such as the United States and Switzerland, were in favor of adopting a rule of national exhaustion, while developing countries supported either an international exhaustion regime or granting members with the discretion to decide which regime would better suit their national policies. Thus, these debates resulted in Article 6 of such Agreement, which ambiguously acknowledges the right of any member to freely determine the type of exhaustion regime that better accommodate their needs, pending compliance with the WTO non-discrimination principles (national treatment and most favored nation clause)[635].

It is now clear that the concepts of exhaustion of rights and parallel importation are strongly interconnected, since patented products can be imported only after the intellectual property rights enshrined within them have been exhausted. In other words, once such rights are exhausted, the importation of products from lower prices

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[632] C. Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules: Intellectual Property in the WTO*, Volume I, Edward Elgar, 2010, 220.

[633]E. Bonadio, 'Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?'. *European Intellectual Property Review*, 33(3), 2010, 155.

[634] The regional approach has been confirmed by the European Court of Justice (ECJ) since, among others, the *Centrafarm v Sterling Drug case* of 1974 (C-15/74). Subsequently, it was codified in numerous relevant directives and regulations, such as Article 7 of Directive 2009/95 and Article 13 of Regulation 207/2009.

[635] Article 6 of the TRIPS Agreement

jurisdictions allows to make the goods accessible at lower price in the importing jurisdiction. This scenario refers to parallel importation, which evidently constitutes a significant tool for the importation of cheaper drugs. In addition, the decision of whether to endorse an international, regional or national exhaustion regime does have a strong impact on international trade and disposal of affordable medicines[636]. For example, if a country adopts a national exhaustion regime, the sale of a patented medicine in another country has no impact on the former, since the patentee does not lose his rights to resale the good in the first country. Most importantly, in such case the patent holder is entitled to oppose patented medicines importation in the country adopting national exhaustion regime.

Parallel imports are a measure concerning the importation, without the consent of the patent holder, of a patented product which has a lower price in the exporting country[637]. Since there is a well-established differentiated policy concerning the costs of medicines in the different countries, the importation of drugs from third countries at prices more accessible to those of the domestic market, represents an economic advantage for the final consumer, who is, thus, able to choose between a greater number of alternatives[638]. Therefore, the parallel import of drugs or any other good becomes a suitable tool to increase competition in markets where the supply is controlled by one or very few companies[639].

Nonetheless, parallel importation should not be confused with neither *official importation* nor with illegal trade of pirated goods. The basic difference rests on the fact that while parallel imports were meant to be manufactured and sold in a specific market, the goods reached the final consumers in a different market without the authorization of the patentee. This scenario demonstrates that parallel imports can

[636] Bonadio, *Parallel Imports in a Global Market,* 156.
[637] S. Bartelt, "Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health", *Journal of World Intellectual Property* 284, 2003, 304.
[638] E. Siew-Kwan Ng, "The Impact of the Bilateral US – Singapore Free Trade Agreement on Singapore's Post –TRIPS Patent Regime in the Pharmaceutical Context", *International Trade Law and Regulation* 121, 2010, 125.
[639] T. K. Mirabile, "Aids, Africa and Access to Medicines", 11 *Michigan State University-DCL Journal of International Law* 175, 2002, 212.

expressively affect producers' revenues when the sales occur in low price markets instead of in high price markets[640]. This is due to the fact that companies, although they sell more quantities of products, do so in countries where the fixed price is lower. In addition, the importer can capitalize on the price difference by transferring and exporting the drugs for sale in a country with higher prices.

In particular, the patent protection mechanism allows originator companies to exploit their exclusive right through a price discrimination strategy by selling the same drug in different countries at different prices. For this reason, it is important to emphasize that the term parallel imports do not refer to the importation of low-cost generic products, but should be understood as the transfer of commercial quantities of the original drug in order to benefit from the price difference.

Many countries, such as the US and EU members, argue that importing a patented drug into another country constitutes a violation of the intellectual property rights of the originator pharmaceutical companies. On the other hand, developing countries argued that parallel imports are based on the aforesaid principle of exhaustion of rights. In other words, there is a prohibition related to the production and sale of the protected drug, unless the generic company explicitly notifies the sale of a patented product, conferring the buyer all the normal rights of an owner, including the right of resale.

It is important to stress that the marketing of medicines is usually carried out through private supply contracts, thus generating legal effects only between the contracting parties, and not against third parties. Secondly, parallel imports do not affect the overall sales volume of the pharmaceutical companies, but they reduce their total revenues and profits[641].

Furthermore, parallel importations may be passive or active[642]. Passive parallel imports, which are the most common method of parallel importation, take place when third parties purchase patented goods in a country and then resell them in its domestic

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[640]C. Stothers, "State of the Art: Parallel Trade and Free Trade Agreements", *Journal of Intellectual Property Law & Practice,* 2006*,* 578.

[641]Slotboom, *The Exhaustion of Intellectual Property Rights*, 425.

[642] It is worth noting that both these measures must comply with identical border standards pertinent to regular imports such as customs tariffs and quantitative restrictions.

market[643]. On the other hand, active parallel imports occur when an arbitrageur of the IPR holder sells the relevant goods in the patent holder's country, or in another licensee or distributor's country, thereby directly competing with the official local distributor in the importing country. In other words, the imported goods circulate outside the official distribution channels chosen by the authorized owner, turning active importations in a breach of contractual obligations committed by the arbitrageur. For this reason, international licensing and distribution agreements usually include *ad hoc* clauses aimed at both segregating international markets as well as establishing a prohibition on "invasions" of the patented products in parts of competence[644].

The concept of parallel importations triggered the opposition of the pharmaceutical industry, which claimed both that parallel importation of patented products is incompatible with Article 28 of TRIPS as well as that Article 6 only constitutes a procedural mechanisms in order to prevent members from starting proceedings actions against another member before the WTO dispute settlement system for infringement of the provisions envisaged in the latter article[645].

Such argument, however, cannot be accepted. Article 28, which does confer the patentee the right to forbid the importation of its goods without express consent, must be read together with Article 6, and thus, in light of the aforementioned exhaustion of rights principle. As a result, in cases in which a specific country adopts either the regional or international exhaustion principle, the patentee cannot resort to Article 28 to contain the parallel importation of a patented medicine precisely put on the market by himself or under its authorization. At the same time, it should not be ignored that the TRIPS agreement merely established a minimum standard for IP protection, thus, allowing Members states to impose most advanced provisions than those envisaged by the latter treaty.

In conclusion, an extensive interpretation of Article 6 becomes central for the protection of the right to access to medicines in the developing world, since it

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[643] Bonadio, *Parallel Imports in a Global Market,* 157.
[644] Ibidem
[645] H. E. Bale, "The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals", *Journal of International Economic Law* 637, 1999, 641.

constitutes another tool that countries can adopt in order to lower prices and thus enhance competition. Allowing parallel trade for patented medicines which have been put on the market by the IP owner seems to be effective to such end. Another option, which is relevant when countries adopt a national exhaustion of right approach, would be allowing pharmaceutical companies to use differential price strategy to provide accessible medicines in light of the particular situation of the country[646]. The solution that seems more adequate would be a combination of the latter two arguments, namely allowing parallel imports as well as promoting differential pricing for pharmaceutical corporations. In fact, depending solely on the benevolence of the private sector does not seem a viable path in order to satisfy the health needs that the developing world faces constantly. And more importantly, pharmaceutical companies could perhaps raise the prices of such medicines in developed world in order to recoup the potential loss that the differential pricing might entail. Nonetheless, as it will be illustrated in the next sections, the Doha Declaration has clarified the scope of Article 6 of TRIPS, clarifying that each country is *"free to establish its own regime for such exhaustion without challenge"*.

[646] J. Atik and H. H. Lidgard, "Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals", *University of Pennsylvania Journal of International Economic Law*, 2006, 1060.

4.3 Other flexibilities under the TRIPS Agreement

As outlined at the end of last section, apart from compulsory licensing and parallel imports, another mechanism to grant access to affordable drug is for pharmaceuticals companies to adopt a differential pricing strategy. This ensures that prices in the least developed countries are as low as possible, compared to most developed countries, where high prices are maintained and incentives for research and development. However, this strategy constitutes a free commercial choice for pharmaceutical companies and does not belong to the legal framework related to intellectual property. Similarly, even if large pharmaceutical companies agree to adopt this measure in the poorest countries, the price may remain unaffordable and inaccessible to them.

The object and extent of IP flexibilities may apply to non-commercial and commercial uses and, may differ substantially depending on the domestic regulations' taken into account. Accordingly, if on the one hand Article 30 of TRIPS provides States with the discretion to regulate the flexibilities at their disposal, on the other, such provision determines substantive requirements for their admissibility. These other flexibilities or exceptions refer to the use of the invention for teaching and research, commercial experimentation on the patented drug to try and make it more effective, and trials conducted with the aim at seeking regulatory approval for the selling of a drug after the expiration of a patent[647]. The latter exception, which is often referred as *early working* or *regulatory review exception*, functions automatically, which implies that the use of such exception does not require an *a priori* particular authorization from a governmental authority or judicial body, unlike, the aforementioned compulsory licenses under article 31 TRIPS. As a result, it is likely that such exceptions constitute the legal grounds for proceedings before the WTO dispute settlement body[648].

The *early working* or *regulatory review exception* is commonly known as the Bolar exception or provision. According to this provision, a patented drug can be used without authorization in order to facilitate regulatory approval of a generic drug before

[647] Correa, *Trade-Related Aspects of Intellectual Property Rights,* 303.
[648] UNCTAD-ICTSD, *Resource Book on TRIPS and Development*, 430.

the patent expires. In other words, the conduct of research and testing necessary for the approval of the marketing of the drug before the competent national authority does not constitute an infringement of IP rights[649]. This permits generic manufacturers to use the test data of the originator companies and, thus, to prepare generic drugs before the expiry of the patent in order to anticipate their sale in the market. Such anticipation would *de facto* limit the patentee's period of market exclusivity of the relevant medicine[650].

The origin of the Bolar exception can be traced in the case *Roche Products Inc v Bolar Pharm Co*, settled by the USA Court of Appeals for the Federal Circuit ('CAFC') in 1984[651]. Without going too far in the case, the latter resulted in the legitimization of clinical trials and other tests carried out on patented medicines with the object of proving the bio-equivalency of the generic drug under examination. Consequently, the case legitimized the submission of information for the drug regulator to secure approval.

At the WTO level, the case that constitutes a landmark in relation to the opportunity to adopt the Bolar exception is the *Canada – Patent Protection for Pharmaceutical Products* case of 2000[652]. This case concerned the allegedly unlawful reform of Canada's patent law, which introduced two provisions limiting the exclusive rights of patent holders: the first one provided that submitting information for regulatory approval before competent national authority (basically the Bolar exception) would not be an infringement of patent rights. The second provision established the stockpiling exception, which entails the lawfulness of manufacturing and storing generic products in the period immediately prior to the expiration of the 20-year related patent term (usually such period referred to six months before the patent's expiration)[653].

EU members lodged a complaint against Canada before the WTO system alleging that

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[649] E. Pfaff, ""Bolar" Exemptions – A Threat to the Research Tool Industry in the U.S. and the EU?", *International Review of Intellectual Property and Competition Law*, ILC, 2007, 260.

[650] C. Correa, "The International Dimension of the Research Exception", *Advancing Science, Serving Society*, 2005, 7.

[651] Roche Products v. Bolar Pharmaceuticals, 733F 2D 858 (Fed Cir. 1984)

[652] *Report of the Panel: Canada-Patent Protection of Pharmaceutical Products*, WTO Document No WT/DS114//R dated 17 March 2000.

[653] Subsections 55.2(1) and (2) of the Canadian patent Act.

the aforesaid limitations to patent rights were neither compliant to the nondiscrimination principle as enshrined in article 27.1 TRIPS, nor to "limited exceptions" as stated under Article 30. According to the EU such provisions would allow a detrimental treatment of pharmaceutical inventions in comparison to inventions in other fields of technology[654]. In addition, the claimant argued that the Bolar exception would infringe the 20-year minimum patent term as provided by article 33 TRIPS as well as the rights conferred to the patent holder under Article 30[655]. On the other hand, Canada responded that the newly reformed Patent Act was providing justifiable limited exceptions in compliance with article 30 of TRIPS. The WTO dispute panel upheld the adoption of the Bolar exception within the Canadian law as compatible with Article 30, while the stockpiling exception was rejected as was found to in breach of 28.1[656].

Accordingly, the Panel's ruling in the aforesaid case confirmed that in light of Article 30 TRIPS, three requirements must be satisfied so as to be considered a lawful exception under the TRIPS Agreement: firstly, the measure has to be "limited"; secondly, the measure must not "*unreasonably conflict with a normal exploitation of the patent*"; and lastly, the measure must not "*unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties"*[657]. The panel emphasized that "the three conditions are cumulative, each being a separate and independent requirement that must be satisfied" and that the *"three conditions must, of course, be interpreted in relation to each other. Each of the three must be presumed to mean something different from the other two, or else there would be redundancy"* [658].

In conclusion, the Bolar provision constitutes a significant flexibility in order to concretely protect the right to access to medicines in developing countries. As the aforementioned Panel highlighted the Bolar exception is sufficiently limited as it only

[654] *Canada – Patent Protection for Pharmaceutical Products*, par. 7.105.
[655] Ibidem, par. 7.84.
[656] Ibidem, par. 7.38.
[657] Article 30 of the TRIPS Agreement.
[658] *Canada – Patent Protection for Pharmaceutical,* par. 7.20–7.21

permitted to adopt specific measures in order to obtaining regulatory drug approval, thus being compliant with the spirit and scope of the IPs provisions envisaged by the TRIPS. If such exception was not permitted, a generic pharmaceutical producer must wait the expiration of the patent to manufacture the generic version which would result in a *de facto* extension of the monopoly for the patent holder, and, thus, in the inaccessibility of greatly needed medicines.

4.4 The Doha Declaration on the TRIPS Agreement and Public Health

On November 14th, 2001 the Fourth Ministerial Conference in Doha (Qatar) unanimously adopted the Doha Declaration on TRIPS Agreement and Public Health (Doha Declaration)[659]. The Declaration's aim was to amplify the scope of health considerations in regard to the TRIPS Agreement. In this regard, it is worth noting that the title of the Declaration was not narrowed to mere reference to pharmaceutical products or processes but rather to public health in general in order to include a far wider range of situations and matters[660].

The background of the Declaration is significant for determining the causes which led to the endorsement of the document. A number of events taking place few years before the Ministerial Conference in Doha emphasized the necessity to elucidate the flexibility within TRIPS in relation to public health[661].

The first case worth mentioning regards South Africa. At the end of the nineties, the latter country was facing a great growth in HIV infection rates, which further aggravated the scale of the public health problem. South Africa quickly converted into

[659] World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/1, 41 ILM 746 (2002).

[660] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreemen*t, 155.

[661] P. Vandoren, "Médicaments sans Frontières? Clarification of the Relationship between TRIPS and Public Health Resulting from the WTO Doha Ministerial Declaration", *5(1) Journal World Intellectual Property Rights*, 2002, 4.

the country with the greatest absolute number of people affected with HIV/AIDS[662]. Accordingly, in 1997, the South African Parliament adopted a new Section (15C) into the South African Medicines and Related Substances Control Act (MRSCA) allowing compulsory licensing, parallel importation and price regulation with the purpose of enhancing access to medicines and, thus, addressing the HIV/AIDS crisis. The new legislation triggered the reaction of the pharmaceutical industry, with both the support of the USA and EU, on the grounds of its alleged incompatibility with the TRIPS Agreement. Accordingly, the former U.S. Ambassador to South Africa, James Joseph, addressed the South African government, emphasizing the urgent need for South Africa to amend the aforesaid Section 15C[663]. As a result, South Africa was also put on US Trade *watch list* since the U.S. Trade Representative (USTR) determined that South Africa required adequate intellectual property protection to such a degree as motivating bilateral confrontations. an extent that merited bilateral attention[664]. Being on the watch list implied the highly chance of being subject to economic sanction by the US, such as the burden of unilateral trade sanctions which would be detrimental for South African economy. The US Government threatened to start proceedings before the WTO system, but strong international campaign in support of South Africa along with intense bilateral negations resulted in the US withdrawal in September 1999[665].

The second case leading up to the Doha Declaration concerned the aforementioned US vs Brazil controversy, which was examined in the previous sections.

Remarkably, public health related emergencies do not concern solely developing countries. For example, in 2001, soon after the 9/11 attacks, anonymous letters

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[662] W. W. Fisher III and C. Rigamonti, "The South Africa AIDS Controversy A Case Study in Patent Law and Policy", *Harvard Law School*, The Law and Business of Patents, 2005, 3.

[663] M. Azam, *Intellectual Property and Public Health in the Developing World,* Open Book Publisher, 2016. The Ambassador's letter stated: "[…] *My Government opposes the notion of parallel imports of patented products anywhere in the world*".

[664] 1999 USTR Special 301 Report, which also emphasized that *"South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights".*

[665] Fisher, *The South Africa AIDS Controversy*, 9. Likewise, the US confirmed its changed policy when in February 2001, the Bush Administration stated the United States would not oppose WTO Members taking steps to address major health crises "availed themselves of the flexibility" afforded by TRIPS. Statement by the U.S. Delegation, Minutes of the Council for TRIPS Special Discussions on Intellectual Property and Access to Medicines, IP/C/M/31 (July 10, 2001), p 33-34.

containing anthrax were found in the US.

Bayer Pharmaceuticals held patent rights on the only available treatment for anthrax named Cipro[666]. Accordingly, both the US and Canada did not doubt in threatening Bayer to limit its patent's rights, which, thus illustrates that public health emergencies can affect all countries and that in such cases patent protection should be restricted to the advantage of public health considerations[667]. Eventually, the US threaten to Bayer to acquire Cipro at more affordable prices, was kind of a paradox since the same strategy has been adopted by Brazil to obtain economical HIV/AIDS medicines. Nonetheless, as seen in this chapter, the US Government had criticized and prosecuted Brazil for the very same behavior adopted by the former country in response to the anthrax emergency.

At the same time, it cannot be ignored that the period in between the end and beginning of the last century was the climax of HIV/AIDS pandemic worldwide. The UN General Assembly addressed this emergency by calling upon UN Members to gather in a special session on HIV/AIDS. This resulted in the adoption of a Declaration of Commitment[668], which, then, led to the endorsement of the Abuja Declaration on HIV/AIDS and other related infectious diseases[669].

In conclusion, the adoption of the declaration triggered a significant change in the political and legal relations within the WTO. On the one hand, the close cooperation between the group of least developed and developing countries demonstrated their ability to organize and form joint strategies in defense of their common interests, unlike what happened 8 years earlier during the negotiation of the TRIPS agreement when sporadic and isolated niches of opposition, represented by Brazil and India, were the only focuses of action that underscored the implications that the agreement would have

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[666] D. A. Frenkel, *International Law, Conventions and Justice,* Athens Institute for Education and Research, 2011, 269.

[667] S.K. Verma, "The Doha Declaration and Access to Medicines by Countries without Manufacturing Capacity", in Carlos M. Correa (ed.), *Research Handbook on the Protection of Intellectual Property under WTO Rules. Intellectual Property in the WTO Volume 1,* Edward Elgar, 2010, 629.

[668] UN General Assembly, *Resolution S-26/2*, (UN Doc. A/RES/S-26/2).

[669] Organization of African Unity, *Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases. African Summit on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases in Abuja, Nigeria from 24–27 April 2001* (OAU/SPS/ABUJA/3;2001).

on public health. The attitude led by the African Group exhibits a new paradigm in participation, which illustrated the will of the South to be an active player in addressing health related concerns.

The same concerns were shared within the WTO system. In particular, special attention was delivered at least developed countries, which were the ones more affected by the actual ineffectiveness of the Article 31(f) provisions. The WTO, thus, emphasized: *"WTO members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement*[670]*"*.

In light of the aforementioned scenario, the circumstances were favorable for the adoption of a Declaration which clarified the extent and scope of members rights in order to adopt the aforesaid TRIPS flexibilities.

4.4.1 The content and scope of the Doha Declaration on the TRIPS Agreement and Public Health

The Doha Declaration, while confirming the obligations envisaged by the TRIPS Agreement, acknowledged the right of members to issue compulsory licenses and to regulate the grounds upon which such flexibilities can be adopted[671]. Accordingly, members have ample discretion in determining the grounds for what constitutes a national emergency or other conditions of extreme urgency, for example in cases concerning HIV/AIDS, tuberculosis, malaria and other epidemics. The Declaration also reaffirmed the right of each member to selectin the regime for exhaustion of intellectual property rights they find most suitable for their specific situation, pending compliance with the most favored nation's clause and national treatment principles of

[670] M. Reto Hilty and Kung-Chung Liu, *Compulsory Licensing: Practical Experiences and Ways Forward*, Springer, 2014, 53.

[671] *Doha Ministerial Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/Dec/2 (20 November 2001) (14 November 2001) para 5.

Articles 3 and 4 of TRIPS[672].

The complete Declaration is made of 7 paragraphs. The first three paragraphs illustrate the challenges to be considered and also recognized both the significant function that intellectual property rights play in favor of the development of new drugs as well as the topic of high prices as a result of intellectual property protection[673].

Paragraph 4 established the major objective of the Declaration: "W*e agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement,* ***we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member's right to protect public health and, in particular, to promote access to medicines for all****. In this connection, we re-affirm the right of WTO Members to use to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose*[674].

In light of the important function of the latter paragraph, many controversies arose on its interpretations. The legal analysis of the Declaration will be provided in the next section, but some considerations regarding the interpretation of Paragraph 4 are significant at this point of the study. On the one hand, some scholars have highlighted that a formal interpretation of TRIPS must rely on an official "recommendation" by the TRIPS Council in light of Article IX(2) of WTO Agreement[675].

On the other hand, the alleged severity of this provision may be softened by the way in which paragraph 4 begins, namely with "we agree". Such wording illustrates that the *Declaration is made in the form of an agreement and the function of the Declaration has already suggested its interpretive status*[676]. As a result, this paragraph has elucidated the purposes of members of TRIPS to interpret TRIPS provisions in a way

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[672] Ibidem, par. 5 (d)
[673] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) paras. 1–3.
[674] Ibidem, par. 4. (Emphasis added).
[675] Art IX(2) of the *Marrakesh Agreement* requires the Council of TRIPS to issue a recommendation upon which the Ministerial Conference and the General Council shall interpret a Multilateral Trade Agreement in Annex 1. Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 155.
[676] Ibidem.

favorable to public health-related concerns[677].

Paragraph 5 of the Declaration identified and confirmed the flexibilities provided by TRIPS, highlighting the need to interpret the TRIPS in light of its object and purpose in light of customary rules of interpretation of public international law. In addition, the paragraph clarified the scope of flexibilities such as compulsory licensing and exhaustion of rights[678].

Paragraph 6 stressed the worrying situation of members, mainly least developed countries, which lack adequate manufacturing capacities in the pharmaceutical sector and are, thus, incapable of taking advantage of TRIPS' flexibilities. For that reason, members urged *the Council for TRIPS to find an expeditious solution to this problem*[679]. This second part of the paragraph holds great legal values since it constitutes the grounds for future TRIPS amendment. Accordingly, in light of such provision, the WTO Council adopted a relevant decision in 2003[680] and a subsequent Decision in 2005[681], thereby amending the TRIPS Agreement for the first time. The Article 31bis was introduced into the agreement.

The last paragraph, Paragraph 7, focused on two main perspectives: first, the provision concerns the *"commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2"*[682]. Secondly, paragraph 7 addressed another significant flexibility for developing countries, namely the extension of transitional periods, which exempted least developing countries from complying with relevant provisions of TRIPS concerning pharmaceutical products[683]. The 2001 Doha Ministerial Declaration on TRIPS and Public Health had already urged the TRIPS Council to extend the period for compliance on pharmaceuticals until 2016. Such

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[677] F. M. Abbott, "The Doha Declaration on TRIPS and Public Health: Lighting a Dark Corner at the WTO", *Journal of International Economic Law* 469, 2002, 490.
[678] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) par. 4.
[679] Ibidem, par. 5.
[680] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540.
[681] *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641(8 December 2005).
[682] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) par. 7.
[683] Ibidem

instruction was promptly heard by the TRIPS Council, which formally adopted a decision implementing this extension. Remarkably, the TRIPS Council adopted another decision in November 2015, thereby further extending the transition period until 1 January 2033 or if a particular country no longer belong to the least developed category if that happens before 2033[684].

In conclusion, the Doha Declaration has actually performed as an important tool for the interpretation of TRIPS by the Ministerial Conference *and the recommendation for such an interpretation is approximately a formal "recommendation" by the TRIPS Council, examined with the draft text of the negotiation basis of the Doha Declaration*[685].

The next section focuses on the legal consequences that such amendment had on the interpretation and implementation of the TRIPS, while the last addresses the legal status of the Declaration.

4.4.2 The "Paragraph 6 Decision" and the 2017 TRIPS Amendment of 2017

On the 23 January 2017, the amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement entered into force. This date constitutes a milestone for the organization, as it marks the first time since the organization that WTO agreements have been amended. This significant goal, however, was not achieved in one day. As it was presented in the last section, the Doha Declaration constituted the first step in order to ease poor countries' access to affordable medicines.

In accordance with WTO law, a two-thirds threshold is required to formally bring an amendment to a WTO agreement into force. This happened at the beginning of 2017, when the WTO Secretariat received notifications from five additional members, which

[684] WTO; TRIPS Council, IP/C/73 of 6 November 2015.
[685] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 156.

have ratified the protocol amending the TRIPS Agreement[686].

The formal steps, which ended in the TRIPS amendment, can be summarized as follows. First, in 2001 the Doha Declaration shed light on the use of TRIPS flexibilities for least developed countries, with a particular focus on compulsory licensing. Secondly, on 30 August 2003, the General Council adopted a decision labelled *"the Implementation of paragraph 6 of the Doha Declaration on TRIPS and Public Health"* (2003 Decision) with the objective of elucidating technical aspects of the Doha declaration, mostly the acknowledgment of the "eligible importing members" and "eligible exporting members". The clarification related to eligible importing and exporting members has practical consequences both in relation to the use of compulsory licensing as well as parallel importation. Moreover, the 2003 Decision provided useful provisions aimed at clarifying the measures that States had to adopt in order to prevent alterations of medicines[687]. This Decision should be regarded as an official act of the WTO in order to confer a legitimate waiver of rights and obligations under TRIPS[688]. Both the Decision content and its legal source (WTO General Council) demonstrate that the aforesaid waiver was meant to be permanent unless a formal amendment was adopted to replace the related provisions[689].

From an interpretative perspective, these considerations hold very significant legal value. In fact, any interpretation of the TRIPS agreement needed to take the waiver of the rights and obligations into account until a formal amendment is made[690]. This shows continuity with the Doha Declaration of 2001, even though the 2003 Decision focused mainly of paragraph 6 of such Declaration.

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[686] The notification from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam helped reached the two-thirds threshold of the number of WTO members which have now ratified the amendment.

[687] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003).

[688] *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/L/540 and Corr.1 (1 September 2003), par. 11.

[689] D. Shanker, "Access to Medicines, Paragraph 6 of the Doha Declaration of Public Health, and Developing Countries in International Treaty Negotiations", *The Indian Journal of Law and Technology*, Volume 2, 2006, 51.

[690] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 158.

The last step before the TRIPS amendment was taken when the Council for the TRIPS Agreement submitted a proposal for an amendment to the TRIPS on 6 December 2005[691]. This amendment proposal was a further clarification of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6. The General Council adopted the Decision on the Amendment of TRIPS (2005 Decision) to adjust TRIPS, and Article 31bis constituted the main proposed amendment[692].

This Decision further illustrates the intent of the members to protect health rights related concerns as well as to the intent of the members to attend certain important complications faced by countries without sufficient manufacturing capacity. In sum, the decision secured a legal pathway to access affordable medicines under WTO for developing countries allowing the export of medicines by the conferral of compulsory licenses to manufacturers within their own jurisdictions[693].

In this regard, at this point of the analysis it is important to examine the new provisions introduced by Article 31-bis. Former Article 31allowed Members to grant compulsory licenses allowing the use of a patented invention, without the authorization of the patent holder, by the government or a third party.

Nonetheless, Article 31(f), provided the limit that "any such use shall be authorized *predominantly for the supply of the domestic market* of the Member authorizing such use". Such provision clearly discriminates between members that have the capacity to manufacture pharmaceutical products on the one hand, and least developed countries on the other, which could not grant compulsory licenses to their own generic companies authorizing the manufacture and sale of the patented drugs. For this reason, at the time of former Article 31, the country that lacked pharmaceutical manufacturing capacity was incapable of effectively using compulsory licensing to secure access of lower-cost generic versions of patented medicines: firstly, the country could not authorize a locally-situated manufacturer; secondly, hence the country had to depend on a

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[691] *Implementation of Paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of the Paragraph 6 of the Doha Declaration on TRIPS and Public Health: Proposal for a Decision on an Amendment to TRIPS*, WTO Doc IP/C/41 (6 December 2005)

[692] *Amendment of the TRIPS Agreement*, WTO Doc WT/L/641(8 December 2005).

[693] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 158.

compulsory license being granted in another country to approve the production of generics; and lastly, the aforesaid provision envisaging the predominant use to supply the domestic market of the country that already has the manufacturing capacity limited further importation to countries in need.

The new provisions introduced by Article 31-Bis, primarily refer to some procedural requirements which read as follows: firstly, both the importing and exporting country issue a compulsory license in order to authorize generic production; secondly, all importing countries, except least developed ones, must notify TRIPS of their desire and entitlement to adopt compulsory licensing. Lastly, members must specify in the aforesaid notifications all the details concerning the medicines produced and must provide special packaging to it in order to distinguish it from other medicines.

Once the aforementioned requirements are met, the member lacking manufacturing capacities has the right to ask another member to issue compulsory licensing for the production of the required medicine, without any other member being able to oppose such actions[694]. Such provisions established the legal basis for WTO members to issue special compulsory licenses exclusively for the production and export of accessible generic medicines to other members that could not domestically produce the required medicines in sufficient quantities for their population. The *domestic use* requirement of former Article 31 was, thus, overcome and a more health-friendly environment was established by the TRIPS amendment.

Notwithstanding, the WTO has been accused of failing to resolve some outstanding issues to ensure production and export of generic medicines to countries that do not produce, which some say is indicative of the fact that the optimism felt at Doha was premature. Some of these concerns raised will be discussed below.

[694] WTO General Council, WT/L/965, 2 December 2015

4.4.3 Legal Status of the Doha Declaration on the TRIPS Agreement and Public Health

It is widely accepted that the Doha Declaration on the TRIPS Agreement and Public Health cannot be regarded as a simple political commitment[695]. Nonetheless, the Declaration precise legal status is still ambiguous[696]. Some scholars have pointed out that its language imply that the Declaration must be intended as to interpret TRIPS, and, thus, should be regarded as an authoritative legal interpretation[697]. Such consideration, if accepted, leads to granting legal force to the Declaration, especially in a dispute settlement case.

The issue of what is the legal status of the Doha Declaration becomes particularly contentious as no official text specifies the binding power of the declarations emanating from the WTO ministerial conferences. In this regard, under article IX, para. 2, the Ministerial Conference and the General Council have the exclusive authority to adopt interpretations of the WTO, the General Agreement on Tariffs and Trade and the other Multilateral Trade Agreements[698]; it is, thus, generally accepted that interpretations rendered according to Article IX are "authoritative" and legally binding for all Members and the adjudicating bodies of the Organization[699]; in light of the latter article, depending on the subject matter under consideration, the Ministerial Conference and the General Council shall exercise such authority pursuant to a recommendation by the respective Council overseeing the agreement (for example, if the question regards the interpretation of the GATT, General Agreement on Trade in Services (GATS), or TRIPS Agreement, the respective council has to recommend the interpretation to the aforesaid

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[695] T. Pogge, *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, Cambridge, 2010, 84.

[696] D. Gervais, "The Relationship between Intellectual Property and Human Rights", in Paul L.C. Torremans, *Intellectual Property and Human Rights. Enhanced Edition of Copyright and Human Rights*, Kluwer Law International, 2008, 58.

[697] W. Benedek, K. De Feyter, and F. Marrella, *Economic Globalisation and Human Rights,* Cambridge University Press, 2007, 176.

[698] Marrakesh Agreement (n 5), art IX:2; T. Gazzini, "Can Authoritative Interpretation under Article IX:2 of the Agreement Establishing the WTO Modify the Rights and Obligations of Members?", *The International and Comparative Law Quarterly*, Vol. 57, No. 1 (Jan., 2008), 169.

[699] Ibidem

bodies). It is important to stress that the interpretative function, of which the highest WTO decision-making political bodies are vested in accordance with Article IX, exceeds the task played by the Dispute Settlement Body (DSB)[700]. In fact, the power of interpretation of the DSB to elucidate existing provisions of relevant agreements is limited by the restraints envisaged by Article 3.2 of the Dispute Settlement Understanding (DSU)[701]. On the contrary, the power of the Ministerial Conference and the General Council to interpret relevant povisions under Article IX is not bound to such restraints, with the only limitation concerning that such authoritative interpretation must not subvert the amendment provisions as laid down in Article X of the Marrakesh Agreement[702]. Accordingly, the aim of authoritative interpretations is to clarify and to refine the meaning and scope of existing obligations, *'not to modify their content'*[703]. Yet, the extent to which authoritative interpretations may or may not change the WTO law is still controversial[704]. Some scholars argue that if *authoritative interpretations were not able to modify the law, it could effectively clarify existing obligations only in accordance with the Vienna Convention interpretation rules*[705]. The same scholars emphasized that under a strict legal perspective *the application of the Vienna rules of interpretation does not make much sense for a decision emanating from a non-judicial, political organ that normally does not have the mandate, the habit and experience, nor the needed format (especially size) to interpret legal rules in the manner known from judicial bodies. Such an understanding would also excessively*

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[700] J. Chaisse and L. Tsai-Yu, *International Economic Law and Governance Essays in Honour of Mitsuo Matsushita*, Oxford University Press, 2016, 499.

[701] DSU art 3.2: "*The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of* ***the DSB cannot add to or diminish the rights and obligations*** *provided in the covered agreements".*

[702] S. Charnovitz, "The Legal Status of the Doha Declarations", 5 *J. of Int'l Econ. L.,* 2007, 208.

[703] Chaisse, *International Economic Law and Governance Essays*, 500.

[704] D. Murthy, "The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health", *American University International Law Review* 17, no. 6, 2002, 1327.

[705] C. D. Ehlermann, "The Authoritative Interpretation Under Article IX:2 of the Agreement Establishing the World Trade Organization: Current Law, Practice and Possible Improvements", Volume:8, *Journal of International Economic Law*, 2005, 808.

restrict the purpose for which an authoritative interpretation could be used[706].

In light of the aforesaid considerations, the present understanding regarding the power to interpret WTO provisions by the Ministerial Conference and the General Council *falls somewhere between 'clarification' and 'amendment'*[707]. Unfortunately, a proper analysis on the latter issue cannot depart from mere theoretical assumptions. indeed, WTO practice on Article IX:2 is insufficient, since no organ has adopted any authoritative interpretation to date[708].

In this regard, it is not clear if the Doha Declaration can be considered as an authoritative interpretation pursuant to Article IX[709]. Therefore, the alternatives for resolving this issue span a broad spectrum, ranging from depriving the document of any binding force to its concrete use in the interpretation of any agreement covered by the WTO Dispute Settlement Body, as occurred in the *Shrimp-Turtle decision*[710] with the Singapore Ministerial Declaration[711]. Whatever the result, it is certain that the declaration is not self-executing and it is therefore up to the Member States to make the necessary amendments to their legislation in order to introduce the changes for implementation.

Nonetheless, the U.S. government, through the report of its trade representative, has qualified the declaration as a political declaration, without any legally binding power[712].

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[706] Ibidem

[707] Chaisse, *International Economic Law and Governance*, 500.

[708] Ibidem

[709] T. Utomo, "Access to Essential Medicine Issues and the Doha Declaration: Contents, the Legal Status and the Problems with Implementation", *Indonesian Journal of International Law, vol. 5, no. 1*, 2007, 84-85.

[710] WTO Appellate Body Report, *United States–Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R at 50 (Oct. 12, 1998), par. 168: "Furthermore, we note that WTO members in the **Report of the CTE**, forming part of the Report of the General Council to Ministers on the occasion of the **Singapore Ministerial Conference**, endorsed and supported: *multilateral solutions based on international cooperation and consensus as the best and most effective way for governments to tackle environmental problems of a transboundary or global nature*. WTO Agreements and multilateral environmental agreements (MEAs) are representative of efforts of the international community to pursue *shared goals*, and in the development of a mutually supportive relationship between them, *due respect must be afforded to both"*.

[711] Committee on Trade and the Environment, Report (1996) of the Committee on Trade and Environment, WT/CTE/1 (November 12, 1996).

[712] USTR Fact Sheet Summarizing Results from WTO Doha Meeting, Nov. 15, 2001, *at* http://www.usembassy.it/file2001_11/alia/a1111516.htm.

To uphold this view is especially difficult after analyzing the circumstances, language, and level of participation and support surrounding the declaration. Indeed, the negotiation of the Doha text denotes the concern expressed by both developing as well as industrialized countries[713]. In fact, the USA was one of the states that most actively participated in the discussions, presenting various texts and drafts. Once the negotiating process was over, the declaration was adopted by consensus, without the abstention or dissent of any WTO member. These facts already shed light on the importance of the declaration, in which all members expressed their concern, something that proves a legal status that goes beyond a mere commitment of good intentions[714].

Likewise, the drafting process of the declaration, in which the most important organs of the WTO organization participated, could meet the requirements needed in order to consider such Declaration as the other extreme of what was postulated by the USA, namely that the declaration is an official decision or is an authoritative or authentic interpretation of TRIPS[715]. In this regard, the difference between an authoritative or authentic interpretation is quite slim but significant. On the one hand, an authoritative interpretation implies that such interpretation stems from an international organ specifically empowered to so by, for example, the treaty establishing an international organization[716]. In particular, in relation to the WTO system, such organ is the General Council. On the other hand, an act of interpretation is called authentic when is undertaken by the parties to that treaty themselves, namely States[717]. In both cases, however, the interpreted provisions are legally binding on all the parties of the organization.

If the Declaration is regarded as a Decision, the procedure established by the WTO establishing Treaty must be met. Accordingly, in order to adopt a decision, both the Ministerial Conference and the General Council of the WTO must follow the

[713] Gathi, James, The Legal Status of the Doha Declaration on TRIPS and Public Health Under The Vienna Convention on the Law of Treaties, Harvard Journal of Law Technology, 2002, Volume 15, Number 2, 315.
[714] Ibidem
[715] Martti Koskenniemi, Sources of International Law, Routledge, 2016,
[716] Ibidem.
[717] Ibidem

provisions of Art. IX (1) and Art. IX (2) of the agreement establishing the World Trade Organization of 1994[718]. It could be argued that in practice the declaration meets the requirements to be a decision because the agreement was discussed by all members in the TRIPS Council for a period of several months; once the discussions in that body were over, the obligation to reach a consensus was transferred to the WTO General Council, which forwarded its results to the ministerial conference in Doha that issued the agreed declaration by consensus, as required by Art. IX (1)[719]. Moreover, the language used in the declaration is the same as would be expected from a decision, since, for examples paragraph 4 of Declaration reads as follows: *"We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health"*[720].

Once it has been demonstrated that the mode of approval apparently followed the decision-making framework established in the WTO, that the participating bodies had the required competence and that the content of the declaration is of enormous importance and is expressed, at times, as an agreement, it could be concluded that the Doha Declaration is a decision. Nonetheless, some scholars have argued that such conclusion is erroneous, since an interpretation was never expressly requested by States, nor by a TRIPS Council recommendation. In addition, while the Declaration was adopted by unanimous consensus, it was endorsed by a three-fourths majority of members within the General Council as required by WTO law[721]. With that being said, it could still be claimed, that the Declaration can be regarded as in a ministerial decision in practice[722].

Nonetheless, to affirm that the Doha declaration is a ministerial conference decision would be to ignore its character as a declaration and in so doing to forcibly accommodate it in a category that does not correspond to it. Indeed, other acts of the

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[718] WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994), Article IX.
[719] Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 75-76.
[720] *Doha Declaration*, WTO Doc WT/MIN(01)/DEC/2 (20 November 2001) par. 4.
[721] C. M. Correa, Repercusiones de la Declaración de Doha relativa al Acuerdo sobre los ADPIC y la Salud Pública, Organización Mundial de la Salud, *WHO/E M/PAR/2002.3*, 2012, 45-46.
[722] Ibidem

WTO organs can also be source of WTO law, even though it is still ambiguous whether such other acts establish binding provisions on the WTO parties[723].

The aforementioned debates on the legal status of the Declaration have, perhaps, come to an end in June 2018. At that time, the *ad hoc* WTO panel established to address a dispute concerning Australia's legislation on plain packaging for tobacco products, reached the conclusion that 2001 Doha Declaration on the TRIPS Agreement and Public Health has to be considered an agreement on the interpretation of the TRIPS[724]. This ruling constitutes a landmark decision in order to provide legally binding status to the Declaration. Accordingly, the Panel has argued that the Declaration *"constitutes a "subsequent agreement" of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention. As the Appellate Body has clarified: Based on the text of Article 31(3)(a) of the Vienna Convention, we consider that a decision adopted by Members may qualify as a "subsequent agreement between the parties" regarding the interpretation of a covered agreement or the application of its provisions if: (i) the decision is, in a temporal sense, adopted subsequent to the relevant covered agreement; and (ii) the terms and content of the decision express an agreement between Members on the interpretation or application of a provision of WTO law"*[725].

The panel went on claiming that *"[i]n this instance, the instrument at issue is a "declaration", rather than a "decision". However, the Doha Declaration was adopted by a consensus decision of WTO Members, at the highest level, on 14 November 2001 on the occasion of the Fourth Ministerial Conference of the WTO, subsequent to the adoption of the WTO Agreement, Annex 1C of which comprises the TRIPS Agreement. The terms and contents of the decision adopting the Doha Declaration express, in our view, an agreement between Members on the approach to be followed in interpreting the provisions of the TRIPS Agreement. This agreement, rather than reflecting a*

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[723] P. Van Den Bossche and W. Zdouc, *The Law and Policy of the World Trade Organisation,* Cambridge University Press, 2013, 53.

[724] DS467: Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, 28 August 2018.

[725] DS441: Reports of Panels. Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging, WT/DS435/R, WT/DS441/R, WT/DS458/R, WT/DS467/R, 28 June 2018, par. 7.2409.

particular interpretation of a specific provision of the TRIPS Agreement, confirms the manner in which "each provision" of the Agreement must be interpreted, and thus "bears specifically" on the interpretation of each provision of the TRIPS Agreement"[726].

Under Art. 31 of the Vienna Convention on the Law of Treaties (VCLT), a treaty must be interpreted in good faith, according to the ordinary meaning of its words within the context of the treaty and taking into account its object and purpose. Art. 31.3 a) establishes any subsequent agreement between the parties as the primary means of interpretation, to be considered in conjunction with the context of the treaty, unlike supplementary means such as the *travaux preparatoires*. The declaration is, thus, an agreement between the parties to TRIPS which reflects their shared intention as to the interpretation of the latter treaty.

Firstly, the *ad hoc* Panel established for the aforesaid case concerning Australia, adopted *mutatis mutandis,* previous considerations that the Appellate Body made about a Ministerial Decision adopted in 2001. The related *US – Tuna II (Mexico)* case concerned the interpretation of a provision of a decision adopted by a technical committee (the TBT Committee) [727]. In this regard, the Appellate Body claimed that *"the TBT Committee Decision can be considered a 'subsequent agreement' within the meaning of article 31.3(a) of the Vienna Convention. The extent to which this Decision will inform the interpretation and application of a term or provision of the TBT Agreement in a specific case, however, will depend on the degree to which it 'bears specifically' on the interpretation and application of the respective term or provision"*[728].

In light of the aforesaid requirements, indeed the declaration was adopted subsequently

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[726] Ibidem, par. 7.2410. These two requirements were previously stated in the WTO Appellate Body Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, adopted 13 June 2012, WT/DS381/AB/R, par. 372.

[727] WTO Committee on Technical Barriers to Trade, *Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations with Relation to Articles 2, 5 and Annex 3 of the Agreement, in Decisions and Recommendations Adopted by the TBT Committee since 1 January 1995* (G/TBT/1/Rev.10;2011).

[728] WTO Appellate Body Report, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, adopted 13 June 2012, WT/DS381/AB/R, par. 372.

to the WTO Agreements, and in particular to the TRIPS. Secondly, the language of the Doha Declaration expresses an agreement between members *which bears specifically upon the interpretation of* the relevant agreement, namely the *TRIPS* one[729]. Some scholars even claimed that since Article 31(a) does not provide any formal requirement, it would allow the possibility for members to adopt an informal agreement. Such agreement may not be in treaty form but *must be such as to show that the parties intended their understanding to be the basis for an agreed interpretation. The proven fact, not the form, of an agreement is what counts* in light of Article 31(a)[730].

In this regard, as the International Law Commission has highlighted that: *"an agreement as to the interpretation of a provision reached after the conclusion of the treaty represents an* ***authentic interpretation*** *by the parties which must be read into the treaty for purposes of its interpretation*"[731]. As Article 3.2 of the DSU indicates, the DSB must resort to customary international law to interpret obscure or ambiguous provisions of any WTO agreement. Accordingly, dispute settlement panels, such as the appellate body, are referred back to the Vienna Convention for the purpose of following its rules of interpretation. These bodies would be forced to resort to the Doha Declaration to interpret TRIPS, as Art. 31.

In case there are objections about considering the declaration as an agreement, at least it is the written evidence of the practice agreed between the parties. The conduct of members, reflected in the declaration, is a consensual guide to the common understanding of the interpretation and application of the provisions of TRIPS. As expressed in paragraph 5 of the declaration, each TRIPS provision is read *"in the light of the object and purpose of the agreement"*, making it clear that it is a mandatory interpretation guide for the DSB and not just a complementary means. Therefore, for practical purposes, to consider that the declaration is a practice or a subsequent agreement is the same[732]; in both cases it is a means of interpretation which requires

[729] *United States – Measures Affecting the Production and Sale of Clove Cigarettes*, par. 265.
[730] Dörr, *Vienna Convention on the Law of Treaties*, 594.
[731] Reports of the International Law Commission to the General Assembly, Draft Articles on the Law of Treaties with commentaries, YILC II, 177, 221, par. 14.
[732] D. McGrogan, "On the Interpretation of Human Rights Treaties and Subsequent Practice", *Netherlands Quarterly of Human Rights 32*, 2014, 348.

good faith to be taken into account as well as conferring meaning to the terms of the treaty in their context and in light of its object and purpose[733].

5 Central America Free Trade Agreement (DR-CAFTA) and TRIPS-plus Provisions concerning Pharmaceutical Patents

When addressing the issue related to the interaction between pharmaceutical patents and access to medicines, another significant area of international law cannot be ignored. Such area refers to the growth in the negotiation and conclusion of bilateral and regional free trade agreements, especially under the impulse of developed world, such as the USA and Europe.

Remarkably, in light of article XXIV of GATT, the WTO system allows its members to enter into free trade agreements (FTAs) with the objective of enhancing free-trade by the establishment of closer bonds between the economies of countries that are parties to such treaties[734]. Trade does not entail only the regulation of goods and services, but also of intellectual property provisions which, thus, need to be protected and implemented. It must be highlighted that the lack of provisions similar to article XXIV of GATT in the TRIPS agreement has not precluded the aforesaid developed countries from including IP-related chapters when concluding FTAs. These chapters usually provide for higher and stricter IP provisions, which significantly depart from the minimum standard established by the TRIPS Agreement itself[735]. Such scenario is actually compliant with the latter agreement, since the TRIPS Agreement does not set a threshold for the degree of IP protection that WTO members are bound to enforce in their domestic legislations. The context is actually the opposite as the TRIPS allows individual members to determine whether or not to establish higher standards of IP protection than the minimum standards provided by TRIPS[736]. Accordingly, when the

[733]Dörr, *Vienna Convention on the Law of Treaties*, 595.
[734] A. Guzman and J. Pauwelyn, *International Trade Law*, 2nd edn (Wolter Kluwers/Aspen Law), 2012 337.
[735] S.K. Sell, "TRIPS-Plus Free Trade Agreements and Access to Medicines". *Liverpool Law Rev* 28, 44.
[736] Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules,* 53-54.

aforesaid category of agreements aims at enhancing IP protection, they have been labeled "TRIPS-plus" treaties or arrangements. As claimed by Anand Grover, former Special Rapporteur on the right to health of the United Nations Human Rights Council: *"[s]uch agreements have extensive implications for pharmaceutical patent protection, which can directly impact access to medicines"*[737].

FTAs agreements have been used as tools in order to avoid both the flexibility regime established by the TRIPS Agreement, as well as the spirit and scope of the Doha Declaration on TRIPS and Public Health. The strategy adopted by developed countries grounds on two main fronts: first, these countries pressure their counterparts to implement more extensive IP rights protection; second, they provide specific provisions that go beyond, or which render ineffective, TRIPS flexibilities[738]. In so doing, the already fragile balance between patents and access to medicines is further hindered and threatened by the proliferation of such peculiar agreements[739]. TRIPS-plus provisions, thus, place an additional burden to the current challenges that developing and particularly least-developed members face in order to balance their TRIPS obligations with their public needs.

For intellectual honesty, it must be emphasized that the stricter IP provisions are rarely fully accepted by developing countries. On the contrary, the inclusion of such provisions is usually realized through a single undertaking mechanism. Under this mechanism, developing countries that are willing to conclude FTAs with developed countries with the aim at enhancing their national economies, are put before a "single package choice", in which either they accept all the provisions envisaged within or no deal is reached[740]. The reasons behind such behavior by both developing and developed

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[737] UN Human Rights Council, *Report of the Special Rapporteur on the Right to Health*, (UN Doc. A/HRC/11/12), par. 68.

[738] For example, Article 15.1.1 of US-DR-CAFTA: *"Each Party shall, at a minimum, give effect to this Chapter. A Party may, but shall not be obliged to, implement in its domestic law more extensive protection and enforcement of intellectual property rights than is required under this Chapter, provided that such protection and enforcement does not contravene this Chapter".*

[739] P. Drahos, "Securing the Future of Intellectual Property: Intellectual Property Owners and Their Nodally Coordinated Enforcement Pyramid", 36 *Case W. Res. J. Int'l L.,* 2004, 53.

[740] M. K El Said, "Public health related TRIPS-plus provisions in bilateral trade agreements: A policy guide for negotiators and implementers in the WHO Eastern Mediterranean Region", *World Health Organization and International Centre for Trade and Sustainable Development*, 2010, 89.

countries are not object the present analysis. Surely, political and economic considerations are at stake, which are often address at a multilevel setting, including national, regional and international negotiations.

In particular, FTAs may go beyond TRIPS minimum standards related to patenting of pharmaceutical products throughout the adoption of different kinds of provisions, ranging from data protection to patentability criteria[741]. Accordingly, TRIPS-Plus agreements may provide for actual patent extensions. In fact, even though article 33 TRIPS establish patent terms of 20 years, everlasting administrative and regulatory approval procedures often limit the actual enjoyment of patent-holders' exclusive rights. Such delays justified patent term extensions in TRIPS-plus agreements beyond the aforesaid 20 years of protection.

When it comes to TRIPS flexibilities, both the use of compulsory licensing and parallel imports are usually limited by TRIPS-Plus provisions. In this regard, compulsory licensing has been generally allowed under TRIPS, especially in light of the Doha Declaration. On the contrary, TRIPS-plus provisions confine the adoption of such waivers to a restricted number of legal bases, such as, *inter alia,* anticompetitive practices, public non-commercial use and national emergencies[742].

In relation to parallel imports, the TRIPS Agreement, as reaffirmed by the Doha Declaration, allows member's discretion in regulating the issue of exhaustion of intellectual property rights, leaving such parties free to determine which national, regional or international exhaustion regime they want to adopt. *Some FTAs signed by the USA (Australia, Morocco and Singapore) expressly acknowledge the patent holder's right to prevent parallel imports,* such as Chapter 15, Article 15.9.4 of the

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[741]Lopert, *The High Price of "Free" Trade,* 203.

[742] For instance, Article 17.9(7) of the USA – Australia FTA : *"A Party shall not permit the use17-[22]of the subject matter of a patent without the authorisation of the right holder except in the following circumstances: (a) to remedy a practice determined after judicial or administrative process to be anti-competitive under the Party's laws relating to prevention of anti-competitive practices;17-[23]or (b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that: (i) the Party shall limit such use to use by the government or third persons authorised by the government; (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and (iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph".*

USA–Morocco FTA, and Chapter 17, Article 17.9.4 of the USA–Australia FTA[743].

In regard to patentability criteria, while the TRIPS Agreement confers discretion on members to determine whether or not to patent new uses or methods of already known products, most of the US FTAs permit the protection of already patented drugs if combined in a different way and for a different use. This leads to the so-called *evergreen patents*, which grant longer periods of protection than would normally be permissible under the law. Accordingly, whether the related IP provision of a specific treaty provides either a broad definition, such as of *new product,* or of *new chemical entity,* the difference is massive[744].

One of the areas of protection, which was object of most controversies, concerns data exclusivity regime. The related provisions under the TRIPS Agreement have been already analyzed in the previous sections. In sum, the latter agreement imposes upon members the duty to protect undisclosed information against unfair competition but leaves them free to determine whether such information should be protected under exclusive rights or under a system of unfair competition provisions. Likewise, the consequences of providing extended protection to clinical test data have already been addressed *supra.* Surely, test data protection constitutes an additional obstacle for market entrance of generic drugs, thus, hindering the protection of the right to health.

While an express provision for data exclusivity had originally been introduced by the US delegation during the Uruguay Round, these provisions were removed from the ultimate version of the Agreement[745]. On the contrary, an exclusive five-year protection of test data from the date of approval of the pharmaceutical product before competent national authority was included in FTAs such as, among others, the North Atlantic Free Trade Agreement (NAFTA)[746].

Specifically, the focus of this section is on the IP-related chapter of the FTA regarding Central America, namely the US-DR-CAFTA (hereinafter CAFTA-DR)[747]. This

[743] Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules*, 284.
[744] For example, Article 16.9.11 of the US–Peru FTA states or Article 15 of CAFTA-DR.
[745] UNCTAD- CTSD (2005), 525
[746] Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules*, 286.
[747] Dominican Repulic-Central America-United States Free Trade Agreement (CAFTA-DR), 2005.

agreement between the US and the Dominican Republic, Nicaragua, Guatemala, Costa Rica, El Salvador and Honduras which entered into force in 2006, offers interesting materials to be studied in regard to TRIPS-Plus provisions and access to medicines. The goal of CAFTA-DR is to establish a trade free-zone between the United States and Central America by eliminating tariffs and other trade barriers.

Chapter 15 of CAFTA is devoted to the establishment of intellectual property provision. In particular, article 15.1 provides a set of obligations that Members must respect in light of their status as parties to the CAFTA. Such agreement confirms the approach adopted by the TRIPS, since parties are obliged to implement the Chapter in their domestic legislation, while being free to adopt more extensive protection of IP[748]. Likewise, the national treatment principle as well as the most favored nation clause are here reaffirmed[749].

With the aim at assessing whether such provisions hinder the right to access to medicines, specific TRIPS-Plus provisions are here analyzed. As discussed in the previous section, significant efforts carried out by the international community resulted in the Doha Declaration and the subsequent TRIPS amendment. Such enhancement of human rights-related considerations left the developed world, especially the pharmaceutical sector there established, not particularly satisfied[750]. Accordingly, CAFTA is proof that the US, under the pressure of the pharmaceutical sector, wanted to duck the aforesaid system by clearly introducing adverse provisions on access to medicines.

In regard to patent extension, CAFTA prolonged patent protection by establishing an additional term adjustment to compensate for unreasonable delays of national competent authorities. Pharmaceuticals products must both acquire national approval for the selling in the domestic market as well as file an application for the grant of patent protection. These two procedures, which are usually autonomous from each other, are often lengthy and complex. Under these considerations, the pharmaceutical

[748] Article 15.1 (1).
[749] Ibidem, par. 7 & 8.
[750] F. Koehler-Geib, *Costa Rica Five Years after CAFTA-DR: Assessing Early Results*, World Bank Group, 2015, 89.

sector argues that the effective term of enjoyment of the patent, as well as the possibility of recouping research and development costs, are adversely affected by such occurrence in practice[751]. The wording of the CAFTA, however, does not require any particular number of years to comply with the agreement, leaving open possible interpretative gaps that could be positively used by state parties[752].

Another aspect of patent extension concerns the issue of new active ingredients. In fact, common practice shows that only a small number of patents applications regard new active ingredients. In the vast majority of cases, patents try to protect small chemical changes or different uses of the already patented product, with the objective of delaying generic competition[753].

In relation to test Data Exclusivity regime, as was repeatedly mentioned throughout the Chapter, Article 39(3) of the TRIPS Agreement does not impose on Members the granting of exclusive rights over test data. On the contrary, CAFTA provides specific provisions to this end. Indeed, Article 15.10 of the latter agreement grants five years of exclusive rights from the date of approval of the product, regardless of whether the product is already under patent protection in other states or whether data required for approval are undisclosed. Such exclusivity will apply irrespective of whether a Party requires the submission of the data (thus even to cases relying on approval given in a foreign country) and covers chemical entities that are not 'new', as they may have been previously approved in other territories. Moreover, CAFTA provides for a waiting period of five years[754]. Consequences of data exclusivity should be analyzed with much caution as medicines that do not yet enjoy patent rights might very well be protected by administrative procedures that extend monopoly rights on the originator company.

One of the innovations introduced by FTAs is the so-called *linkage* between drug

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[751] C. M Correa, "Implications of bilateral free trade agreements on access to medicines", *Bulletin of the World Health Organization* 84, 2006, 401-402.

[752] CAFTA, Article 15.9.6.(b): *"With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party".*

[753] Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules*, 285.

[754] Ibidem, 287.

approval and patent protection authorities. CAFTA is no exception as it provides for linkage-related provisions not provided for in the TRIPS Agreement. In sum, this procedure imposes upon a Party the duty to provide that its national competent authorities, for example the Food and Drug Administration (FDA) in the US, reject marketing approval of the generic version of a product if a patent is still effective and if the patent holder did not expressively authorize it. In such scenario, the *Bolar Exception,* provided and admitted under TRIPS, is considered lawful in very limited cases which entail the consent of the originator company and that the generic product must be sold outside the territory under consideration[755]. It is evident that the test-data protection regime envisaged by the CAFTA agreement places an additional burden on the generic companies.

In addition, a party wishing to apply for the approval of the generic medicines before national authorities is obliged to inform the patent owner about such applications. Some scholars have highlighted that linkage provision seem to ignore that patents are private rights, while the approval before health authorities are usually administrative procedures[756]. Such an obligation would actually transform the regulatory agencies into patent enforcement bodies, which would become overwhelmed with applications about which they lack sufficient competence. The task of the health authorities should focus only in ensuring compliance with standards of quality, safety and efficacy of medicines, without any interferences in the merit and enforcement of patent rights.

In conclusion, the actual consequences of these provisions seem to be in open contrast with the TRIPS Agreement as interpreted by the Doha Declaration as access to medicines at affordable prices find material obstacles, which are arduous to overcome by means of interpretation. In this regard, the interaction between human rights-related

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[755] CAFTA, Article 15.9.5: *"Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party".*

[756] Ibidem, 288.

treaties, such as the ICESCR, and CAFTA sounds like a case of pure conflict, which in light of the Vienna Convention should lead to the responsibility of the State for the adoption of the incompatible obligation.

Nevertheless, the theory of systemic integration might be the answer for the challenges posed by the interaction of the aforementioned treaties, with the goal of both enhancing access to medicines in Central America while avoiding the legal complexities that states incur if international responsibility is at stake.

In fact, similar considerations to those presented in relation to the TRIPS Agreement can be made in this regard; and the *apparent conflict* can be solved by interpretative means. Hence, CAFTA provisions may be interpreted in a manner to overcome the alleged incompatibility between the FTA under consideration and relevant human rights treaties.

For example, while chapter 15 of CAFTA (unlike relevant provisions of the TRIPS agreement) does not make any reference to the protection of health, it does so in relation to the protection of the public. Accordingly, the Agreement mentions one specific exception to test data protection, which entails that a Member State is entitled to derogate the related provisions in order to protect the public interest[757]. Such broad and vague wording definitely allows members to interpret the agreement in a way consistent with public health-related concerns, such as HIV pandemics in the region.

In line with this stream of thoughts, on 5 August 2004 the States concerned have signed an *"Understanding regarding certain Public Health measures"* in order to confirm that the obligations provided by Article 15 of CAFTA are not a barrier to implementing measures that are essential to protect public health and access to medicines[758]. Thus, *"the obligations of Chapter Fifteen do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other*

[757] Article 15.10(d): *"For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data".*

[758] R. Gader-Shafran, *The Patent Law Dictionary: United States Domestic Patent Law Terms & International Patent Law Terms*, iUniverse, 2013, 226-227.

epidemics as well as circumstances of extreme urgency or national emergency"[759].

It must be noted that Free Trade Agreements (FTAs) are usually concluded featuring side letters and understandings regarding specific aspects of the treaties themselves. These instruments are documents signed by the parties to the main agreement, with the object of clarifying the interpretation and scope of certain parts of the text. Theoretically, in light of Article 31.2 (b) they should be regarded as primary means of interpretation, since these instruments help in identifying the context of the main treaty itself[760]. Even though the legal status of such instruments has never been challenged in case of conflicts, some scholars argue that they should have the same legal status as the main agreement[761]. On the contrary other scholars compare the latter documents to a peculiar kind of agreement, namely to *Memorandum of Understanding* (MoU), thus, expressing doubt about their legally binding status[762].

What is important to highlight for the sake of the present analysis is that FTAs in general, and CAFTA in particular, use numerous mechanisms to preserve certain levels of flexibility, such as the use of open-textured terminology, the use of waivers, and the use of supplementary instruments such as side letters and contextual understandings. As stated by the *"Understanding regarding certain Public Health measures"* of 2004, the parties will have to interpret the provisions contained in CAFTA in accordance with TRIPS, including its object and purpose and its subsequent developments. Accordingly: *"In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement*

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[759]See the *Understanding Regarding Certain Public Health Measures between the US and CAFTA-DR* (August 5, 2004). Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement,* 307-308.

[760] Article 31.2(b) of the Vienna Convention on the Law of Treaties 1969: "*2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes: (b) any instrument which was made by one or more parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty".*

[761]Correa, *Research Handbook on the Protection of Intellectual Property under WTO Rules*, 282.

[762]P. Roffe, "A New Generation of Regional and Bilateral Trade Agreements: Lessons from the US-CAFTA- DR", in Blouin, Chantal, Heymann, Jody and Drager, Nick, *Trade and Health, Seeking Common Ground: Integrating Health Objectives and International Trade Policies*, McGill- Queen's University Press, 2007.

and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution. With respect to the aforementioned matters, if an amendment of a pertinent provision of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) enters into force with respect to the Parties and that amendment is incompatible with Chapter Fifteen, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment"[763]. This leads to the conclusion that all the subsequent development regarding the TRIPS agreement, including the Doha Declaration and the 2017 amendment, must be taken into account when interpreting and implementing health-related provisions of CAFTA. The CAFTA agreement itself makes numerous express references to TRIPS, thus, emphasizing the profound connection between the two treaties.

One last, but significant, consideration, that must be analyzed regards the aforementioned flexibilities. Chapter 15 of CAFTA lacks direct provisions similar to the ones provided by the TRIPS Agreement relating to compulsory licensing, parallel importation and other similar measures. Nonetheless, the abovementioned Understanding to the regional agreement makes specific reference to the Doha Declaration and the 2003 Decision and requires to take into account any subsequent amendment of TRIPS agreement[764]. Such express reference to the flexibilities envisaged by the TRIPS-framework in respect to pharmaceutical products seems to confirm the capability of members states to adopt compulsory licenses in order to address public health concerns[765]. This reasoning, which grounds on the direct reference to TRIPS provisions, constitutes the means for accomplishing a harmonization between TRIPS-plus and TRIPS through interpretative methods[766].

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[763] See the Understanding Regarding Certain Public Health Measures between the US and CAFTA-DR (August 5, 2004).

[764] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement*, 319.

[765] Abbott, *The Doha Round's Public Health Legacy*, 964.

[766] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS*

In addition, the compulsory licensing regime requires further analysis with regard to the principles of *lex specialis* and *lex posterior*. As the introductory section of this chapter has highlighted, in accordance with general rule of international law the *lex posterior* should prevail *over lex* priori and *lex Specialis* should prevail over *lex generali* in cases in which a successive treaty addresses the same subject-matter[767]. In light of such premises, the CAFTA provisions should prevail over WTO law agreement, since the former was concluded after the treaty establishing the WTO. Accordingly, the lack of an express reference to any TRIPS flexibilities should overrule the compulsory licensing clauses in TRIPS as a proof of the parties' will to depart from the former regulation.

Notwithstanding, the principle of *lex posterior derogat priori* requires further inquiry when multilateral treaties, such as the WTO Agreements, are under consideration. In the words of scholars such as Pauwelyn, these treaties have a *"continuing"* or *"living"* nature[768]. The norms stemming from such treaties are part of a legal framework that was created at a specific moment but which continues to produce their effects and advance over time[769]. These norms are constantly and progressively confirmed, applied, revised and extended, *for example, by means of judicial decisions, interpretations, new norms or the accession of new state parties (for which not only the consent of the new party is required, but also the reciprocal acceptance of all, or a majority of, existing parties)*[770]. In sum, the *living nature* of such multilateral treaties entails that the system under considerations evolves as a functional consequence of the international organization activities (such as the WTO). The crystallization of these norms in a precise moment of time (for example, when the relevant norms were created) would arguably be inconsistent with the evolving character of the norms themselves. These kinds of treaty norms derive *from what I term 'continuing'or 'living'treaties, not*

Agreement, 319.

[767] Pauwelyn, *Conflict of Norms in Public International Law*, 361.

[768] Ibidem, 378.

[769] McGrogan, *On the Interpretation of Human Rights Treaties,* 348.

[770] Ibidem. Other examples, besides the WTO Agreements, multilateral conventions such as the EU, UNCLOS and many human rights treaties and systems.

reflections of a 'one-shot-end-all'expression of state consent[771].

In light of such premises, in an event of a conflict between TRIPS and CAFTA, an evolutionary interpretation approach is required even though the latter agreement was concluded later than the TRIPS.

The Vienna Convention on the Law of Treaties does not make any express reference to the evolutionary interpretation of treaties, nor does its Article 31(3)(c), which omits any guidance to the challenges posed by *living-nature* treaties entailing inter-temporal rules[772]. Yet, the International Court of Justice has recognized the evolutionary method in different cases in which the judges have argued that such method is accepted on the grounds that the treaty under consideration contains evolutionary terms or its evolutionary nature is shown in the treaty itself[773].

In sum, as some scholars have highlighted, a treaty can be interpreted under an evolutionary approach when[774]:

1. *the terms used have or are acquiring an evolving meaning in general international law*
2. *the language used in expressing the object and purpose of a treaty to show a recognition or intention for the treaty to be able to have a progressive development*
3. *the description of obligations is expressed in broad terms*[775]

Both the TRIPS Agreement and CAFTA fulfil two out of the three aforementioned

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[771] Ibidem

[772] Campbell McLachlan, 'the Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention' (2005) 54 *ICLQ* 279, 316.

[773] ICJ, *Sea Continental Shelf Case* (*Greece v Turkey*) (1978) ICJ Rep 3, par. 77, and *Namibia (Legal Consequences) Advisory Opinion* (1971) ICJ Rep 3, par. 53: *"Mindful as it is of the primary necessity of interpreting an instrument in accordance with the intentions of the parties at the time of its conclusion, the Court is bound to take into account the fact that the concepts embodied in Article 22 of the Covenant-"the strenuous conditions of the modern world" and "the well-being and development" of the peoples concerned-were not static, but were by definition evolutionary, as also, therefore, was the concept of the "sacred trust". The parties to the Covenant must consequently be deemed to have accepted them as such. That is why, viewing the institutions of 1919, the Court must take into consideration the changes which have occurred in the supervening half-century, and its interpretation cannot remain unaffected by the subsequent development of law, through the Charter of the United Nations and by way of customary law"*.

[774] C. McLachlan, "The Principle of Systemic Integration and Art 31(3)(c) of the Vienna Convention", *54 ICLQ 279*, 2005, 317-318.

[775] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement,* 140.

conditions, since they have a *living nature* and provide open-textured provisions which allow different interpretations. Accordingly, expressions such as of "national emergency", "extreme urgency" and "public non-commercial use" envisaged by Article 31 permit an evolutionary way of interpretation of the agreement[776].

At this point of the inquiry, analyzing the CAFTA and TRIPS provisions in light of the *lex specialis* principle is important. According to some scholars such as Pauwelyn, the *lex specialis* principle is of little assistance in conferring meaning of terms in a treaty in light of arts 31 and 32 of the VCLT, since it is mainly employed as a means in order to solve genuine conflicts of norms[777]. Nonetheless, the question to be asked at this point is whether or not *lex specialis,* as a rule of treaty interpretation, can resolve (or avoid) the "conflict" between CAFTA and TRIPS. In addition, this principle can be regarded as a way to give full effect to more specific treaty provisions[778]. This argument grounds on the systemic integration presumption against conflict pursuant to the conflict-avoidance techniques outlined throughout this chapter[779].

At first stake, the CAFTA Agreement seems to be the special regime in light of its narrower membership than TRIPS and regional scope. Notwithstanding, this first impression overturns if we take into consideration specific health-related provisions such as compulsory licensing. Remarkably, even though CAFTA does not make any specific reference to compulsory licensing, subsequent developments in TRIPS have further clarified that scope and application of such important flexibility. In addition, as the Doha Declaration has emphasized, *"the concept of public health crises includes "those relating to HIV/ AIDS, tuberculosis, malaria and other epidemics", which are the specific narration of the grounds for issuing compulsory licensing. This specificity needs to be treated as* lex specialis*, and the interpretation of the compulsory licensing carve-outs in the FTAs,* such as CAFTA, *will need to refer to the specific language used in TRIPS in order to be given effect in the interpretation of the TRIPS-plus provisions. Through this kind of reference, the seeming conflict between TRIPS and TRIPS-plus*

[776] Ibidem
[777] Pauwelyn, *Conflict of Norms in Public International Law,* 414.
[778] Ibidem
[779] McGrogan, *On the Interpretation of Human Rights Treaties*, 349.

can be avoided"[780]. This leads to the conclusion that the framework developed and established by the TRIPS Agreement constitutes the special regime with reference to health-related flexibilities.

Some final remarks are, thus, required. As presented, CAFTA comprises many provisions that refer to TRIPS plus standards. The analysis has demonstrated that the application of TRIPS-plus provisions requires their interpretation in light of the broader TRIPS' regime. Stricter IP's provisions are surely included in the intellectual property chapters of CAFTA, but there should be a *"ceiling" upon the level of heightened patent protection that is consistent with the facilitation of trade and does not act as an impediment to trade*[781]. This leads to the argument that the interpretation of TRIPS-plus provisions contained in CAFTA not only needs to take the object and purpose of this Agreement itself, but also the ones of TRIPS into account.

Chapter 20 of CAFTA, which is labelled "Dispute settlement", provides the freedom of choice of forum in case no agreement is reached over the interpretation of a specific treaty's provision. In the event a panel is established pursuant to Chapter 20, the panelists resort to the rules of interpretation, as highlighted in this chapter, in light of which the interpretation of TRIPS-plus provisions needs to refer to the subsequent development of TRIPS and not only to its object and purpose. From this argument follows that the right to health-related flexibilities provided by TRIPS shall provide guidance for the interpretation of TRIPS-plus provisions contained in CAFTA[782]. It is, thus, through this method of interpretation that a main goal can be achieved: the harmonization between TRIPS and CAFTA leads to the subsequent harmonization between CAFTA and the International Covenant on Economic, Social and Cultural rights (ICESCR), hence making the right to access to medicines effective in the countries involved.

Moreover, the *lex posterior* and *the lex specialis* principles have to be understood in light of the principle of contractual freedom of states in order to determine what

[780] Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement,* 320.
[781] Ibidem
[782]McGrogan, *On the Interpretation of Human Rights Treaties*, 349.

coincides with current state consent. Accordingly, both the 2004 Understanding to CAFTA regarding public health-related concerns, as well as the subsequent practice within the WTO framework in relation to TRIPS-flexibilities[783], prove that States have acknowledged and recognized the imperative valued of such flexibilities. To assess whether TRIPS-plus provisions constitute an obstacle to international trade and to access to medicines, one has to study their implementation within national legislation[784]. The *conflict* between TRIPS and CAFTA (and consequently between intellectual property law and human rights) is, thus, only apparent, and systemic integration constitutes the means thorough which the patent's protection regime is compatible with the right to access to medicines.

6 Two case studies concerning the impact of IP provisions on access to medicines

6.1 A focus on Antiretroviral drugs for the fight against HIV

Antiretroviral drugs (ARVs) entered the market in 2000 and in 2015 the United Nations reported the start of actions to lower their prices[785]. These drugs hinder the reproduction of the virus and impede its spreading to avoid the progression of the HIV, which is why they are the most used and effective drugs in the treatment of the disease in the world. There are three main types of antiretroviral drugs: i) nucleoside reverse transcriptase inhibitors, which inhibit the enzyme that HIV-1 needs so that new replicas in the genetic structure do not occur; ii) non-nucleoside reverse transcriptase inhibitors, which produce a blocking action, and iii) protease inhibitors, the other substance that HIV-1 needs to replicate[786]. What this type of antiretroviral does is prevent HIV-1 from multiplying to the point of achieving an imbalance. The medication process begins with

[783] Which led to the 2017 TRIPS Amendment
[784] See the following section regarding the manner in which CAFTA was implemented respectively in Costa Rica and Guatemala.
[785] https://www.who.int/hiv/data/en/
[786] L. Benítez-Gutiérrez, V. Soriano, S. Requena and C. Mendoza, "Treatment and prevention of HIV infection with long-acting antiretrovirals", *Expert Review of Clinical Pharmacology*, 2018.

a combination of medications known as First-Line Therapy; then, after several years, the antiretroviral drugs stop acting against the virus, forcing a new action with other retroviral drugs, the so-called Second-Line Regimen; depending on the case, this may reach a Third-Line over time[787]. The recommendation made by WHO has been to apply three different medications in the same treatment. Since 2000 there has been a considerable increase in the number of patients treated with ARV medications[788]. This is reflected in the reduction of both infections and deaths; although the data varies widely by region and although many people still do not have access to these drugs, especially in low-income countries. The data and information that has been presented clearly shows the importance of access to antiretroviral drugs for the control and treatment of the disease[789]. On one hand, this shows that ARVs play a determining role not only in reducing new infections, but also in preventing AIDS-related deaths. On the other hand, there are deep inequalities in the supply and access to this therapy in countries with fewer resources, which are the countries with the highest number of people affected by the virus. These data underscore the unequal access to ARV therapy and the relevance of increasing access to it[790].

6.2 TRIPS-Plus provisions in Costa Rica: the impact of the antiretroviral drug Tenofovir

The latter section of this chapter has presented a general analysis of the legal framework related to pharmaceutical patents and their implementation after the entry into force of DR-CAFTA in the Central American region. Furthermore, significant information has been provided on the relevance of timely treatment of HIV/AIDS. This last section will examine two case studies that illustrate the impact of intellectual property rules on

[787] Ibidem
[788] P. H. Kilmarx, "Global epidemiology of HIV", *Curr Opin HIV AIDS* 4:240–246, Wolters Kluwer, 2009.
[789] European Aids Clinical Society, *Guidelines Version 8.2*, January 2017.
[790] Ibidem

access to generic and low-priced medicines for HIV / AIDS in Costa Rica and Guatemala in light of the relevant provisions in their laws: TRIPS and DR-CAFTA[791]. In 2004, the parties involved in DR-CAFTA signed *a Memorandum of Understanding regarding public health measures*, clarifying that the provisions established in article no. 15 of DR-CAFTA had to be interpreted effectively for the protection of the right to health.

6.2.1 Costa Rica, the Right to Health and Intellectual Property

This section analyses four important aspects related to access to medicines in Costa Rica[792]: first, the intellectual property provisions; second, the epidemiological relevance of HIV/AIDS in the country; third, the Government's response to it; and finally, the Tenofovir drug case analysis to illustrate the practical implications of the aforesaid points. Costa Rica recognizes the right to health indirectly in its political Constitution throughout its Articles 21[793] and 46[794]; and through the ratification of instruments such as the International Covenant on Economic, Social and Cultural Rights and its participation in international organizations such as the World Health Organization[795]. The Constitution protects people who are denied access to health and, indirectly, access to essential medicines, and provides them with the right to appeal to the Constitutional Court through a constitutional complaint (*recurso de amparo*) in

[791] For the sake of clarity, some footnotes will be presented in Spanish in order to preserve the substance and scope of the relative references and provisions.
[792] S. Walker, "The United States–Dominican Republic–Central American Free Trade Agreement and Access to Medicines in Costa Rica: A Human Rights Impact Assessment", *Journal of Human Rights Practice* 3, 2011, 188-190.
[793] "La vida humana es inviolable".
[794] "Los consumidores y usuarios tienen derecho a la protección de su salud, ambiente, seguridad e intereses económicos, a recibir información adecuada y veraz; a la libertad de elección, y a un trato equitativo. El Estado apoyará los organismos que ellos constituyan para la defensa de sus derechos. La ley regulará esas materias".
[795] Desde 1996, Costa Rica es miembro del Acuerdo de la Organización Mundial del Comercio sobre los Aspectos de los Derechos de Propiedad Intelectual (ADPIC), y en 2001, adoptó también la Declaración de Doha sobre el Acuerdo ADPIC y la Salud Pública, la cual estableció pautas interpretativas en materia de las flexibilidades contenidas en el tratado, como, por ejemplo, el derecho de brindar licencias obligatorias y exportaciones paralelas en circunstancias especiales.

order to uphold their rights. The nation also has a universal social insurance managed and executed by the Costa Rican Social Security Fund (CCSS)[796]. In the last 30 years, the CCSS has developed a policy of selection and supply of essential medicines that has guaranteed a considerable and free supply for the majority of the population, while allowing a sensible use of public spending on medicines. According to data shared by the Ministry of Health, the CCSS system is responsible for supplying 43% of pharmaceutical products in the country, while the private sector satisfies the rest of the demand[797]. A notable fact is that the resources allocated to the purchase and supply of drugs, which constituted almost 10% of the CCSS annual budget between 2007 and 2008, and was reduced as of 2009 around 7.5% of the total budget of the CCSS. Today, approximately 35% of that budget is for patent-protected drugs. The first patent law in Costa Rica was enacted in 1983 (Law No. 6867) and did not recognize any rights in relation to the patentability of pharmaceutical products. This law was amended in 2000 and 2008 [798] to shape the regulatory framework in accordance with TRIPS and subsequently to DR-CAFTA[799]. The most relevant developments after the entry into force of the DR-CAFTA refer to the term of the patents and the exclusivity of the test data[800]. This commercial agreement provides, in fact, that the protection period can be extended beyond 20 years if the applicant suffered unjustified delays in the granting of the patent license or for the analysis required for the approval for commercialization. Although the Patent Law indicates that the restoration cannot exceed a maximum period of 18 months[801], in case of delay both in the granting of the patent and in the

[796] Rocío Sáenz, María del, y Acosta, Mónica, y Muiser, Jorine, y Bermúdez, Juan Luis, y "Sistema de salud de Costa Rica", *Salud Pública de México 53,* no. 2, 2011, 157-158.
[797] G Hernández-González y M. Valverde, 'El CAFTA-DR y su impacto en la salud: el caso de Costa Rica', *International Centre for Trade and Sustainable Development*, 2009.

[798] En 2000 se aprobó una ley sobre la información no divulgada, (Ley 7975/2000), que fue modificada nuevamente en 2008 a la luz de las nuevas disposiciones contenidas en el tratado comercial.
[799] S. Ballar, Ricardo, "Costa Rica. Luchas contra las políticas de privatización Y el Tratado de Libre Comercio Centroamérica-EE.UU.", *Revista de Ciencias Sociales (Cr)* IV, 2004, 16-18.
[800] Koehler-Geib, Friederike, Sanchez, Susan, *Costa Rica Five Years after CAFTA-DR: Assessing Early Results*, World Bank Group, 2015.
[801] Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad N. 6867, Art. 17.3: "*Al recibir esta solicitud, el Registro de la Propiedad Industrial deberá compensar el plazo de la patente, en un día por cada día en que se excedan los períodos de tiempo referidos en el párrafo 2. Sin embargo, los períodos de tiempo imputables a acciones del solicitante no se incluirán en la*

approval of the commercialization, the extension may exceed 18 months up to a maximum of 3 years, which can pose problems of implementation and interpretation. The Ministry of Health is responsible for implementing appropriate measures to prevent third parties from marketing a patented product and information related to product marketing requests is displayed on the website of the Ministry of Health, so that each holder of the patent be properly informed[802]. As indicated in previous chapters, the new rules on intellectual property indicate that, in order to authorize the marketing of a new pharmaceutical product, the applicant must disclose undisclosed test data, including those related to safety and efficacy (test data). Such data will be protected for five years from the date of the initial marketing authorization against unfair commercial use and against any disclosure, except when its use is necessary to protect the public interest. Therefore, unless generic drug companies are willing to generate this data on their own, they are forced to postpone the sale of the drug for five years, since without these data it cannot be proven that the drugs are safe and effective[803]. On the other hand, exceptions to the protection of test data are scarce: competent authorities may preclude the use of test data to prevent practices that are likely to mislead consumers and may choose not to disclose this information in order to protect the life, health or safety of persons, or animal or plant life or the environment. Another innovation introduced by the DR-CAFTA, which forced the amendment of national law, refers to the definition of a new product, that is, one that does not contain any chemical entity that has been previously registered in the country[804]. Executive Decree no. 34927 states that: *"Those pharmaceutical products with new uses or indications, changes in the route of administration, in the dosage, in the pharmaceutical form or in the formulation of a chemical entity, or those products that have a combinations of chemical entities*

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determinación de los retrasos. No obstante lo anterior, la compensación total del plazo de la patente nunca podrá exceder de dieciocho meses".

[802] Chávez G, Blanca M., y Montoya B., Yonathan "Comparación de la reformas de los sistemas de salud en Colombia y Costa Rica en su dimensión política", *Revista Facultad Nacional de Salud Pública* 29, no. 1, 2011, 67-74.

[803] Correa, *Implications of bilateral free trade agreements*, 400-402.

[804] C. M. Correa, Carlos Maria, "Ownership of knowledge: The role of patents in pharmaceutical R&D", *Bulletin of the World Health Organization*, 82 (10), 2004, 785.

previously registered in the country shall not be considered new" [805] . The implementation rule could have a positive impact, because it excludes form the test data protection the products with a combination of chemical entities previously registered in the country, and therefore limits the number of drugs that may enjoy such protection, prohibiting the second use patents. However, the definition established by the aforementioned article 4 protects chemical entities not previously approved in Costa Rica even if they had already been approved in other countries[806]. This can lead to opportunistic behaviours in which the producer seeks the approval of a "new" product in Costa Rica after having enjoyed its protection in another country to the detriment of the production of generic medicines and the availability of more affordable products[807]. In order to reaffirm the flexibility aimed at protecting public health, the parties of the DR-CAFTA signed a Memorandum of Understanding in 2004 regarding certain public health measures. The agreement made it clear that the obligations established in Article 15 of the DR-CAFTA are not an impediment to adopt the necessary measures to protect public health and access to medicines. As a result of this Memorandum, Costa Rica is not obliged to give retroactive effect to patents, nor to grant patents whose exploitation may be contrary to public order or morality, among other things. This orientation seems reminiscent of the Doha Declaration agreements that reserve the exclusive right to states to determine their health system and the cases that constitute an emergency. Costa Rica also follows an international exhaustion regime, so it is possible to use parallel imports and issue compulsory licenses to protect the public interest.

[805] Decreto Ejecutivo Nº 34927-JCOMEX-S-MAG, Reglamento a la Ley de Información No Divulgada , artículo 4.
[806] A. Snodgrass Godoy, *Of Medicines and Markets Intellectual Property and Human Rights in the Free Trade Era,* Stanford University Press, 2013.
[807] Hernández-González G, "Evaluación del Impacto de las Disposiciones de ADPIC + en el Mercado Institucional de Medicamentos de Costa Rica", *Programa de ICTSD sobre Propiedad Intelectual y Desarrollo Sostenible*, 2009, 18-20,

6.2.2 HIV / AIDS in Costa Rica[808]

The first case of AIDS in Costa Rica was detected in 1983 and perinatal transmission was detected in 1990 with an increasing trend to 1995, when treatment with AZT was initiated for pregnant women with HIV[809]. As of 1998[810], antiretroviral therapy was introduced and currently the percentage prevalence of HIV in the general population is 1.6%; in the group of 15 to 24 years it is 0.11% and in the group of 15 to 49 years 0.4%[811]. There are currently 13,000 people living with HIV in Costa Rica, and the number has increased considerably over the past two decades. In addition, the impact of the introduction of antiretroviral treatment in reducing the rate of infection can be seen from 2000 to 2011[812]. Costa Rica has made great economic and institutional efforts to take on HIV / AIDS. These efforts have generated a multi-sectoral work where different actors of society are incorporated with the objective of strengthening capacities in a coordinated manner and developing strategic actions to build up relationships according to established needs and priorities[813]. This multi-sectoral work is generated by Public institutions, NGOs, members of the National Council for Comprehensive Care of HIV and AIDS (CONASIDA), international cooperation agencies and other support organizations. The National Council for Comprehensive Care of HIV and AIDS (CONASIDA) is the highest body responsible for recommending policies and programs of action on HIV/AIDS issues throughout the public sector. It has the function of advising the Minister of Health on policies and updating national plans for addressing HIV and AIDS. It should also coordinate with the different institutions on the issues related to the epidemic, promoting coordination

[808] All the data relative to the medicine *Tenofivir* provided in this section have been gathered as a result of interviews with states' officials in San José, Costa Rica.
[809] Ministerio de Salud Consejo Nacional de Atención Integral del VIH/SIDA Organización Panamericana de la Salud oficina regional de la Organización Mundial de la Salud Programa Conjunto de las Naciones Unidas sobre el VIH/SIDA, La situación del VIH/SIDA en Costa Rica, 2004.
[810] Programa Conjunto de las Naciones Unidas sobre el VIH/Sida (ONUSIDA), "Costa Rica: HIV and AIDS Estimates", 2018 [en línea] https://www.unaids.org/es/regionscountries/countries/costarica
[811] https://www.unaids.org/en/regionscountries/countries/costarica
[812] Ibidem
[813] Costa Rica, Plan Estrategíco Nacional 2016-2021.

and inter-institutional agreements and ensuring full observance and respect for the rights and guarantees of people with HIV/AIDS, their families and relatives. Seeking to control and eradicate this epidemic, Costa Rica has been implementing actions in terms of capacity building, training in strategic information, in representation spaces, in strategic planning and in participation in national dialogues and forums. Access to antiretroviral drugs is an important part of this strategy and the purchases of these medicines by the CCSS is a relevant indicator of their evolution and success[814]. Costa Rican social security currently allocates about 7.5% of its budget to the purchase of medicines. For any country, this represents an important economic effort but even more so for one in development and with universal health coverage. This effort is aligned with the conception of a welfare state that seeks universal access to health. As explained, Costa Rican social security acquires antiretroviral drugs and to provides them to a necessary extent since 1998 as part of the strategy against HIV/AIDS. In recent years, Costa Rican social security sought the purchase of *Tenofivir* through the Strategic Fund of the Pan American Health Organization (PAHO) to facilitate the purchase and reduce costs thanks to volumes and guaranteed access to certified suppliers. For the care of patients with HIV/AIDS, social insurance acquired the drug *Tenofivir* through the PAHO Strategic Fund at a price of 15.14 colones per one hundred (100 tablets), that is, 0.15 colones per tablet. The Strategic Fund purchased a product not registered in Costa Rica, which was imported under the Health Law (Article 117). It is established that the Ministry of Health, the CCSS and any other state entity, with functions of public health or social security, may acquire unregistered medicines, at any time or circumstance; In case of urgency or public necessity, the ministry can authorize the importation of unregistered medicines. The holder of the marketing authorization for the Tenofovir drug claimed before the Ministry of Health that the protection of test data was still in force, that is, a protection for five years in accordance with DR-CAFTA and Costa Rican legislation. Based on this legislation, the Ministry of Health suspended the authorization to import the medicine. From that moment, the price increased to 96.74

[814] Ibidem

colones per one hundred, that is, 0.96 *colones* per tablet. In 2016 the price was even higher, 125.62 *colones* per one hundred or 1.25 *colones* per tablet. Once the test data protection time expired, the drug could be acquired through the PAHO Strategic Fund, as of 2018, at a price of 13.96 *colones*, that is, 0.13 *colones* per tablet[815]. Costa Rican social security estimates that the purchase of medicines for the treatment of HIV/AIDS through the PAHO Strategic Fund has had a positive impact on their finances thanks to the inclusion of two medicines in combination at fixed doses48. Their inclusion was possible because they are available in the Strategic Fund, which resulted in savings of close to 1.5 million *colones* by implementing the use of these alternatives in the first-line treatment of patients with HIV infection. Acquiring these drugs at the market price in Costa Rica, where there is only one registered bidder for each combination, would have involved expenses close to 4.5 million *colones* more than what is currently invested.

6.3 TRIPS-Plus provisions in Guatemala: the situation concerning Abbott's antiretroviral drug *Kaletra*

Guatemala's Constitution recognizes the right to health in its Article 94, which is labelled "*Obligaciones del Estado, sobre salud y asistencia social".* The constitutional protection provided by the latter article states that: *"El Estado velará por la salud y la asistencia social de todos los habitantes. Desarrollará, a través de sus instituciones, acciones de prevención, promoción, recuperación, rehabilitación, coordinación y las complementarias pertinentes a fin de procurarles el más completo bienestar físico, mental y social*"[816]. At the same time, the Constitution grants protection to IP in light of Article 42, which provides that: "Según este artículo titulado Derecho de autor o inventor, *"Se reconoce el derecho de autor y el derecho de inventor; los titulares de los mismos gozarán de la propiedad exclusiva de su obra o invento, de conformidad*

[815] Elaboración propia sobre la base de información de la Caja Costarricense de Seguro Social.
[816]Constitución de Guatemala, art. 94.

con la ley y los tratados internacionales" [817]. Guatemala allows the patenting of products and processes for 20 years since 1999, when it passed the Industrial Property Law (Decree Number 57 200)[818]. In this way, more than 400 pharmaceutical products and processes are patented in Guatemala and 250 patent applications were filed in the first ten months of 2016 alone [819]. Most of the chemical substances for which applications have been submitted are not yet associated with drugs on the market and may incorporate patents on numerous and different molecules and processes. Despite the formal constitutional recognition of intellectual property, before the entry into force of TRIPS and DR-CAFTA, originating pharmaceutical companies generally did not seek recognition of patents on most of their medications in Guatemala. The reason given was that the little competition in that market and the reduced profits did not justify the implementation of complicated and long administrative processes. Guatemalan intellectual property regulations have been a controversial legislative issue in the country since the late 1990s. The main provisions of the Industrial Property Law of 1999 have been amended almost every year since their approval and the rules on the exclusivity of the test data has also been modified many times [820]. In 2000 the Guatemalan Parliament established the exclusivity of test data for a period of fifteen years for each patented drug. Although this exclusivity was revoked in 2002, after protests from civil society and generic companies, in 2003 a five-year protection was reintroduced, which was again repealed in 2004. Despite this, after the approval of DR-CAFTA in 2005, the exclusivity was established again for a period of five years. In order to prevent different and softer rules from being implemented in the legal frameworks, DR-CAFTA specifies its supremacy over the corresponding national laws in case of conflict. Guatemala established a period of five years for the exclusivity of the data and, as anticipated, that DR-CAFTA prevails over this law in case of conflict (Decree 30-2005 that repeals Decree 34-04). Finally, legal reforms were introduced for

[817]Constitución de Guatemala, art. 42.
[818] Godoy, *Of Medicines and Markets Intellectual Property,* 2013.
[819] Perfil Farmacéutico de la República de Guatemala, Publicado por el Ministerio de Salud Pública y Asistencia Social de Guatemala en colaboración con la Organización Panamericana de la Salud/Organización Mundial de la Salud (OPS/OMS), marzo 2016.
[820]Godoy, *Of Medicines and Markets Intellectual Property,* 2013.

the implementation of DR-CAFTA in Guatemala by means of Decree 11-2006[821]. The decree provides that if the companies are entitled to compensation if they suffered unjustified delays before the registration to obtain the patent, specifically, more than five years from the patent application, or more than three months from the request before the Department of Regulation and Control of Pharmaceutical Products to obtain the marketing permit[822]. The latter, despite the fact that no request for extension of the deadline has been made to date, in practice constitutes an extension of the *ius excludendi* from patent rights. This decree formalizes the aforementioned protection of test data. Through this rule, the protection obtains the duration of five years and a new type of "administrative monopoly" is established even when the patent has expired. In fact, as noted, this protection has an adverse effect on generic drugs, because they cannot be registered in the country since they cannot use the information on efficacy and safety that has been provided before the Department of Regulation and Control of Pharmaceutical products. To achieve the *ius excludendi* derived from patent rights companies must apply for the related claim before the Intellectual Property Registry (RPI), which a dependency of the Ministry of Economy[823]. The RPI is responsible for promoting the observance of the Rights of the Intellectual Property, as well as the enlisting and registration thereof, in the light of the intellectual property treaties to which the state of Guatemala is a party. In addition, to bring their medications to the market, pharmaceutical companies must demonstrate to the Department of Regulation and Control of Pharmaceutical Products that their medications are proven safe and effective through clinical studies and several trials. Instead, producers of generic drugs must demonstrate bioequivalence to brand names, that is, show that they work in the same way. Normally the manufacturers of generic medicines verify the safety and efficacy referring to the results of the clinical trials already produced by the equivalent brand name drugs. However, in Guatemala generic companies are prohibited from using or referring to the data of the clinical trials of the author of the drugs during the

[821] Decreto 11-2006, Artículo 61.
[822] Ibidem, Aartículos 66, 67, 68 y 69
[823] Acuerdo Gubernativo No. 182-2000 Reglamento Orgánico Interno del Ministerio de Economía.

period of time they are protected (5 years). Originating companies can select which medications they want to present to the Guatemalan drug regulatory agency - Department of Regulation and Control of Pharmaceutical and Related Products - to be included in the data protection list. The suspension of a request for registration (or sanitary license) as a precautionary measure under legal action to protect the intellectual property of a drug is another mechanism that negatively affects the competition of generics in practical terms. This may happen because a system has been established in which the patent office and the sanitary registration office work in direct contact (linkage) with each other and with the patent holders. This means that, if a company wants to request the registration of the generic version of a medicine, the national offices are obliged to inform the holders of a patent and the corresponding test data, about the process initiated. Finally, in Guatemala, other administrative protections are established that are not regulated by either TRIPS or DR-CAFTA, known as CAFTA-Plus, inter alia, border measures. These measures, which are common in Europe, regulate that customs authorities prevent the entry of a generic drug into the national market if the drug has legal protection in Guatemala. The regulatory provision is of interest even to drugs in transit, as national authorities can confiscate and even destroy those that not only have the Guatemalan market as their final destination but also another country where the drug is not patented. This creates administrative mechanisms applied by customs authorities that are an additional barrier to the marketing and circulation of generic medicines.

According to the United Nations and the World Bank (WB), Guatemala and Honduras are the two countries in Latin America with the highest presence of HIV and AIDS. In 2016, there were 46,000 people with HIV - it is necessary to bear in mind that underreporting is possible and therefore the data could be higher - of which 36% had access to antiretroviral therapy[824]. In 2017, 2,300 new HIV infections and 2,000 AIDS-related deaths occurred. Among pregnant women living with HIV, only 19% had access

[824] Banco Mundial - Programa Global del VIH/SIDA. América Latina y el Caribe. Reduciendo la Vulnerabilidad al VIH/SIDA en Centroamérica. Guatemala: Situación del VIH/SIDA y la respuesta a la epidemia.

to treatment or prophylaxis to prevent the transmission of HIV to their children. The United Nations estimates that more than 500 children were infected with HIV due to mother-to-child transmission. It is estimated that 25% of people living with HIV in Guatemala have suppressed viral loads thanks to antiretroviral therapies, which decreases the likelihood of virus transmission[825].

In 2000, the Guatemalan Parliament recognized the HIV/AIDS epidemic as a national emergency in Decree no. 27-2000-06-26[826]. This document highlighted that the state has an important role in the prevention and control of the virus, since in those days the pandemic was taking worrying dimensions in the country and throughout the region. Since 2000, the importance of physical and economic accessibility of antiretroviral drugs for HIV/AIDS treatment was also recognised through the Drug Accessibility Program[827]. It was established that the Ministry of Public Finance and Economy has to implement a program that allows access to quality antiretroviral drugs, at affordable prices for people affected by the virus. The country made an institutional effort to face the national emergency and established the National Program for the Prevention and Control of Sexually Transmitted Infections, Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (PNS), within the Ministry of Public Health and Social care. In addition, the law prompted the Ministry of Public Health to create the National Multi-sectoral Commission, consisting of organizations that work on the prevention of sexually transmitted infections, HIV and AIDS, with the aim of coordinating and supporting the ministry's policies at the national level. Eight years later, in 2008, the government launched the National Commission against AIDS (CONASIDA), to promote and implement plans, policies and programs that allowed the prevention of sexually transmitted infections and HIV/AIDS.

In 2011 the commission presented the National Strategic Plan for HIV and AIDS (PEN) 2011-2015. To address the epidemic, Guatemala updated its national response in a plan

[825] Joint United Nations Programme on HIV/AIDS (UNAIDS) https://www.unaids.org/en/regionscountries/countries/guatemala

[826] Ley General para el Combate del Virus de Inmunodeficiencia Humana (VIH) y del Síndrome de Inmunodeficiencia Adquirida (SIDA) y de la Promoción, Protección y Defensa de los Derechos Humanos ante el VIH/SIDA, Guatemala, 2000.

[827] Programa Nacional de Prevención y Control de ITS/ VIH y SIDA

now titled Institutional Strategic Plan (Plan Estratégico Institucional) 2016-2021 and established five strategic guidelines[828]: 1) Increase the availability of combined prevention programs. 2) Eliminate mother-to-child transmission of HIV. 3) Integrate health care and social support to individuals, families and communities. 4) Promote a legal and social environment that favours human rights and gender equality. 5) Strengthen the public health sector for the improvement and sustainability of the national response[829]. The accessibility and availability of the combined antiretroviral drug lopinavir + ritonavir in the Guatemalan health system and the implementation of the PNS is essential for the success of the aforementioned strategic plans. This program and the other government responses to the HIV/AIDS epidemic have a decisive impact on the health of the population living with the disease. The PNS reports highlight that the number of people receiving high intensity antiretroviral treatment has increased fivefold in the last eight years, even though only 60% of the almost 30,000 people who require treatment receive it.

Guatemalan law requires the Ministry of Health to opt for the most affordable option among a range of options presented during the bidding process in light of a transparent and impartial cost-benefit analysis. This framework should favour generic medicines to the extent that they are more affordable, can meet the treatment needs of a larger number of patients and are proven safe and effective. However, several organizations such as the Pan American Health Organization (PAHO) and the Office of the Human Rights Ombudsman of Guatemala have detected anomalies in the bidding processes and documented anti-competitive irregularities between 2003 and 2008[830].As a result of these anomalies, it has not always been possible to choose the most affordable solution[831]. Moreover, in most cases, tender processes were presented with unique

[828] Plan Estratégico Nacional para la Prevención, Atención y Control de ITS, VIH y Sida, Guatemala. 2016-2021.

[829] Godoy, *Of Medicines and Markets Intellectual Property,* 2013.

[830] Organizacion Panamericana de la Salud. 2005. *Opinion tecnica al evento DNCAE no. 08-2005 para la provision de productos medicinales y farmaceuticos paquete I, II, y III*. Organizacion Panamericana de la Salud, Expediente No. EIO.GUA 442-2004/DESC.

[831] En específico, los licitadores genéricos tienen que presentar una documentación adicional con el objetivo de probar la seguridad y eficacia de sus productos. Estos requerimientos van más allá de lo exigido por la ley marco de la contratación pública para el proceso de licitación, de tal forma que

offers by originating companies, being the only ones that could meet the additional administrative requirements. The case study of the *Kaletra* drug represents an example of what has just been mentioned and how intellectual property conditions hinders the access to the most economical medicines in the country. *Kaletra* is a multidrug compound consisting of two protease inhibitors, lopinavir and ritonavir, and is used for first- and second-line treatment of HIV/AIDS.

The history of this medicine in Guatemala begins in November 2000 when the pharmaceutical company Abbot obtained the certification of the Sanitary Registry PF-23619, after the presentation of the test data to the competent authority. In accordance with articles 165-167 of the Health Code, he was able to enjoy the right to market the product in Guatemala. The drug *Kaletra* enjoys protection of test data for 15 years, since the requesting company managed to obtain the authorization for sale before the legal changes from Decree 153-85 to Decree 57-2000 were pronounced. As noted, the data protection established in the DR-CAFTA constitutes a de facto limit for the use of compulsory licenses, since the latter are aimed at reducing the effect of a patent and do not produce any effect towards an administrative procedure, like the exclusivity of the test data[832]. The generic producer would still have to rely on clinical trial data from the original pharmaceutical company to produce the drug and since these are protected, the new company will not be able to manufacture the drug. In 2005, the Abbott representative in Guatemala was awarded the public contract at the price of 20,255 quetzales ($ 2.70) per capsule, surpassing the competence of three other applicant companies. The other participants, specifically the generic producers, presented a constitutional complaint in order to freeze the contracting process in light of the alleged anti-competitive practices. Although the lawsuits managed to stop the adjudication procedure, the Guatemalan government bought the medicine (*Kaletra*) directly from Abbott for the next three years. In addition, since the purchases were not made through a tender, the information on the prices obtained or the quantity purchased has not been published. Therefore, it is not easy to determine the total sum of resources spent;

constituye una carga excesiva para los licitadores genéricos por su costo y tiempo.

[832] Godoy, *Of Medicines and Markets Intellectual Property,* 2013.

however, in light of the available data it is possible to analyse the prices corresponding to 2009 and 2012. Due to several protests, Abbott lowered prices considerably, although they remained more expensive compared to generics and with the prices offered at public purchases made through the Strategic Fund of the Pan American Health Organization. According to information from the Intellectual Property Registry, on July 5, 2006, Abbott achieved the protection and exclusivity of the sale of the lopinavir/ritonavir compound until July 2026. In summary, before the Industrial Property Law, Abbott obtained an additional protection for nine years by filing a patent application for the drug from the date of admission of said application, even though the latter could have been granted several years later.

In 2005, the drug *Kaletra* became essential when a new version was introduced that included the same active ingredients in a slightly different proportion, with 200 mg of lopinavir and 33 mg of ritonavir, instead of the previous version with 133 mg and 33 mg respectively. With these changes, new therapeutic advantages were introduced since fewer pills could be taken per day and, not needing refrigeration, it became one of the few antiretroviral compounds suitable for the treatment of the disease in tropical countries (Snodgrass Godoy, 2013). Of the medications recommended by WHO for second-line therapy, this version of *Kaletra* is the only one available in a thermostable version. In 2005, the World Health Organization recognized *Kaletra* as an essential drug and since then several countries have shown interest in using compulsory licenses to guarantee the supply of this medicine[833]. Today, *Kaletra* continues to have a privileged position in Guatemala even when there are generic alternatives. However, intellectual property is not the only obstacle in accessing low-cost medicines. First of all, the mere presence of a generic alternative in the market does not guarantee greater access to the medicine, as happened in Guatemala where, despite the fact that a generic version of antiretroviral was available for years before the introduction of *Kaletra*, the State decided to buy only the patent version. Of course, when *Kaletra* achieved protection through intellectual property, the state bought only the patented drug in

[833] World Health Organization. 2005. WHO model list of essential medicines, 14th ed., in World Health Organization [database online]. Geneva: WHO. http://whqlibdoc.who.int/hq/2005/a87017_ eng.pdf.

accordance with the current legal framework[834]. Although trade agreements allow flexibility to guarantee public health, that is, parallel imports and compulsory licenses, none of these instruments have been used in Guatemala.

[834] El análisis demuestra que la Organización Panamericana de la Salud (OPS) puede comprar genéricos, en la medida en que sean para uso público, no comercial y por cuenta del Gobierno de Guatemala, como confirmado por el ADPIC, la Declaración de Doha. Sin embargo, hasta la fecha, el Ministerio de Salud Pública y Asistencia Social de Guatemala no ha usado las posibilidades que se otorgan a los miembros de la OMC en referencia a la implementación de las flexibilidades establecidas por la Declaración de Doha.

CHAPTER III

Human Rights Responsibilities of Pharmaceutical Corporations

1. Globalization, Pharmaceuticals and Transnational Corporations: definition and development in international law

Over the last few decades, the phenomenon of economic globalization and the liberalization of trade have triggered the emergence and expansion on the world stage of new actors capable of playing decisive roles in both the economic and political spheres. In addition to the international financial institutions, often referred to as the Bretton Woods organizations[835], the players that dominate the new era of global trade are undoubtedly transnational corporations which have gradually and progressively increased their economic might over the years[836]. In fact, a document presented by UN Sub-commission on Human Rights has shown that transnational companies are often able to gain more economic power than the host states themselves, as demonstrated by the fact that of the 100 largest concentrations of wealth in the world, 51% are owned by multinational companies and 49% are owned by States[837].

1.1.The definition of Transnational Corporations in international law

Multinationals are certainly a completely new model for the organizational structure and functioning of economic enterprises that originated after the Second World War (WWII). Previously, the expansion of the activities of large companies abroad had mainly taken place through commercial operations. Indeed, companies purchased raw

[835] S. Skogly, *The human rights obligations of the World Bank and the International Monetary Fund*, Cavendish Publishing Limited, 2003, 9.
[836] Picone, *Diritto internazionale dell'economia*, 699.
[837] UN Subcommission on Human Rights, *The Realization of Economic, Social and Cultural Rights: The Question of Transnational Corporations, Working Document on the impact of activities of transnational corporations on the realization of economic, social and cultural rights*, E/CN.4/1998/6, 10 June 1998, 2.

materials abroad, but the production processes were carried out entirely within the country of origin. Occasionally, the expansion abroad took the form of granting independent foreign companies the production and/or marketing of the product. The phases of production, however, took place in the same country and no real delocalization occurred[838].

In the aftermath of WWII, the gradual improvement of information technology combined with the perfection of telecommunications and transports, has, on the one hand, made possible the connection and control of business centers located thousands of miles away, and on the other, has favored the development of an international market in which consumers demanded similar categories of goods[839]. As a result, these economic opportunities have led to a real race to conquer new markets, which has accentuated competition between companies.

The grounds of the aforementioned changes at the global economic stage have been spotted in a variety of factors such as, among others, the speed and reduction of production costs of long-distance transports on the one hand and the technological progress on the other. The easier and faster exchange of goods, services and information across the world has improved the international integration among nations and private actors. As a result, companies could reconsider the logistics of their production systems internationally with the aim at decreasing costs and enhancing efficiency, which actions have led to the formation of large business groups characterized by a fragmentation of production and/or distribution activities in many countries, especially in developing countries. In these countries, in fact, large Western companies have found extremely favorable conditions for production facilities, obtaining strong competitive advantages based on the containment of operating costs. The phenomenon of *delocalization* constitutes the key element of the economic, productive, and legal framework of transnational corporations and explains the relevance of such analysis[840].

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[838] Picone, *Diritto internazionale dell'economia*, 700.
[839] Ibidem
[840] A. Bonfanti, *Imprese multinazionali, diritti umani e ambiente: Profili di Diritto Internazionale Pubblico e Privato,* Giuffrè Editore, 2012, 2.

In general terms, transnational corporations have multiple stages of production which are located in different countries, but which are directed centrally from the companies' headquarters. Interestingly, the international delocalization of production and processing of goods can be implemented in different ways by the company. For example, such delocalization can be carried out by creating subsidiaries or by acquiring control over companies established in foreign states (usually referred to as *host States*) in respect to the country in which the *parent company* is located (*home States*). Furthermore, the *parent company* can conclude contractual relationships of agency, cooperation, franchising or license with private entities located abroad[841]. Nonetheless, the *parent company* always enjoys autonomous legal personality in respect to all the other legal subjects located abroad.

Before proceeding to a full analysis of the main issue of the present work, assessing what transnational corporations are and how their complex structure can be studied under international law is necessary. Indeed, the ability of such corporations to operate across national borders and outside the effective supervision of national and international law makes them the object of further investigation under international law[842]. Specifically, their nebulous structure often produces a sort of legal immunity to the control of particular States, posing doubts over desirable regulation and protection at the international level.

For all of the above, there is no doubt about the impact and reach that transnational corporations have and have had in the world. Notwithstanding, there is no agreed definition among the different countries, much less among the different international actors, regarding an adequate definition of such corporations. Even today, there is no terminological consensus on how to refer to them; and suffixes such as, "multi", "supra" and "supra" are often used and exchanged in the same manner[843]. Such entities can be defined and classified differently depending on the perspective taken into account.

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[841] Ibidem

[842] M. Y. Kamminga and S. Zia-Sarifi, *Liability of Multinational Corporations under International Law*. The Hague, Kluwer Law International, 2001, 5-6.

[843] F. Francioni, *Imprese multinazionali, protezione diplomatica e responsabilità internazionale,* Giuffrè editore, Milano, 1986, 13.

Scholars worldwide noted that the notion of transnational corporations does not have a precise legal connotation and could not provide an exhaustive definition in international law. In their views, the studies and intergovernmental negotiations aimed at regulating international corporations provided a clarification of the concept, but did not offer a proper definition[844].

This nominative discrepancy reflects the complexity of their legal nature, the constant mutability and the difficulty of adapting conceptual instruments to these new business realities. Consequently, in the absence of a universally accepted delimitation of its concept, various public institutions, international organizations and academic fora have outlined what they believe would be a definition of transnational corporations.

The first reference to the term multinational company appears in the early 1960s, specifically in a paper presented by David E. Lilienthal, in which he defines these kinds of entities as those companies that are based in one country but operate and function according to the laws of other countries[845].

Subsequently, the term multinational developed in such a way as to feature three main specifications: firstly, they had to present some form of direct investment in at least one foreign country; secondly, the management of the undertaking had to take full responsibility for the company's activities abroad; and lastly, that decisions would be made on grounds of the alternatives envisaged anywhere in the world and be not limited to a single country.

1.2. Examples of judicial understanding of Corporations

Interestingly, the Court of Justice of the European Communities (in the case 270/83 of 1986), defined a transnational company as an entity constituted by a parent company, created in accordance with the law of a given country. The Court added that the latter

[844] Bonfanti, *Imprese multinazionali,* 2.

[845] S. J. Kobrin, "Sovereignty@Bay: Globalization, Multinational Enterprise, and the International Political System", *The Oxford Handbook of International Business (2 ed.)*, 2009; D. Lilienthal, "The Multinational Corporation" in Melvin, Ashen and G.L. Bach, *Management and Corporations*, McGraw-Hill, 1985.

company has to be established in other countries through direct investments, either without creating local companies or through subsidiaries which are constituted in accordance with the law of the host country[846]. Important to note is that since the 1970s national Courts have highlighted the peculiar situation in which multinational corporations have acted. Indeed, in 1973, the Argentine Supreme Court stressed that, in those cases in which the legal status of subsidiaries companies turned them into independent entities, it was necessary to *"lift the veil"* of such legal fiction and let the factual and economic reality prevail. According to the Court, the parent company may shirk its responsibilities thanks to the special legal status these companies enjoy[847]. In practice, however, on several occasions the jurisprudence of national Courts has considered parent companies as completely different entities from the subsidiaries they control, granting legal immunities to the latter. For the same reason, it is not surprising that scholars argue that the refined corporate structure such corporations have, as well as their global reach, is what allows them to benefit from an extraordinary lack of responsibility for all but their shareholders. In other words, transnational corporations, although they have the legal appearance of a plurality of corporations, constitute, in essence, an economic unit with a single center of decision-making power[848]. A clear and precise definition of a multinational corporation is, hence, a difficult task to achieve. Notwithstanding, the identification of the features that distinguish such companies from other entities on the one hand, and makes them fascinating from a legal perspective on the other, is propaedeutic for the present analysis. Detecting accurate international legal obligations upon transnational corporations without having outlined a set of key qualities and notions would be, thus, unfeasible. As a result, it is appropriate to build a desirable legal framework on the grounds of the definitions provided by international organizations, which in different time and occasions have attempted to regulate the activities performed by multinational corporations and have highlighted

[846] Judgment of the Court of 28 January 1986. Commission of the European Communities v French Republic. Freedom of establishment in regard to insurance - Corporation tax and shareholders' tax credits. Case 270/83. European Court Reports 1986 -00273

[847] Corte Suprema Argentina, Judgment of 31/7/73 "Parke Davis Case".

[848] P. Ireland, "Limited Liability, shareholder rights and the problem of corporate irresponsibility", *Cambridge Journal of Economics* 34(5), 2010, 848.

their distinguishing features and characteristics[849].

1.3. Multilateral approach to corporations

The United Nations Norms on the Responsibilities of Transnational Corporations and other Business Enterprises with Regard to Human Rights (UN Norms) addressed the term "transnational corporation" as *"an economic entity operating in more than one country or a cluster of economic entities operating in two or more countries - whatever their legal form, whether in their home country or country of activity, and whether taken individually or collectively"*[850]. This definition enhanced some key aspects, such as that these corporations are single economic units or a group of entities which operate in different countries under different juridical statuses[851].

Another document that constitutes a pillar for the identification of a definition of such corporations is the OECD Declaration and Decisions on International Investment and Multinational Enterprises and in particular its Annex 1 labelled OECD Guidelines for Multinational Enterprises (OECD Guidelines)[852]. In paragraph I.4 of the latter, multinational corporations are referred to as *"companies or other entities established in more than one country and so linked that they may coordinate their operations in various ways. While one or more of these entities may be able to exercise a significant influence over the activities of others, their degree of autonomy within the enterprise may vary widely from one multinational enterprise to another. Ownership may be private, State or mixed"*[853]. Interestingly, the Guidelines themselves provide a broad notion which intentionally avoid delivering an accurate definition. In fact, the latter paragraph aimed at stressing that a fundamental element of these corporations is the

[849]Bonfanti, *Imprese multinazionali*, 2-3.
[850] Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights, U.N. Doc. E/CN.4/Sub.2/2003/12/Rev.2 (2003), par. 20.
[851] S. Tully, *Corporations and International Lawmaking*, Martinus Nijhoff Publishers, 2007, 132.
[852] OECD, The OECD Declaration and Decisions on International Investment and Multinational Enterprises, 2011.
[853] OECD, OECD Guidelines for Multinational Enterprises. Recommendations for responsible business conduct in a global context, 9, adopted in June 21 1976 and amended in May 25 2011.

tight link among the multiple companies that constitute multinational undertakings. Such link can be carried out in numerous ways[854]. According to the aforementioned Guidelines the latter link does not depend on the majority of share ownership by the parent company. Furthermore, such Guidelines exclude that the share of *know-how* and resources among the parent company and its subsidiaries suffice in determining the liaison among them[855].

In the same manner, paragraph 6 of the OIL Tripartite Declaration of 1977 provides important requirements of multinational corporations, without even attempting to deliver a definition of such entities[856]. The broad wording of paragraph 6 is intended to simplify the comprehension of the Declaration and not to offer such a definition. Notwithstanding, the latter paragraph highlights three important elements of multinational enterprises: firstly, their delocalized structure; secondly, their international nature and establishment in different countries outside the State of origin; and thirdly, *"The degree of autonomy of entities within multinational enterprises in relation to each other varies widely from one such enterprise to another, depending on the nature of the links between such entities and their fields of activity and having regard to the great diversity in the form of ownership, in the size, in the nature and location of the operations of the enterprises concerned"*[857].

Another definition, proposed within the United Nations and in specific within the Commission on Transnational Corporations in 1990, stressed the importance of the link among the entities and companies that constitutes the enterprise and the existence of a common decision making-center. This definition was included in the draft code of conduct on transnational corporations submitted to the UN Economic and Social Council on 31 May 1990. Regrettably, this proposal has never been formalized in an official document due to the unsolvable disagreement among the members of the

[854] Bonfanti, *Imprese multinazionali*, 3.
[855] Ibidem
[856] Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy, adopted by the Governing Body of the International Labour Office at its 204th Session (Geneva, November 1977) and amended at its 279th (November 2000), 295th (March 2006) and 329th (March 2017) Sessions.
[857] Ibidem, paragraph 6.

aforementioned Commission which works finally stopped in 1992[858].

Lastly, the UN Conference on Trade and Development focused on other aspects related to multinational corporations, which aspects were presented in the *World Investment Report* of 2007. The report emphasized three requirements as elements important in order to identify the multinational status of the company: firstly, the intensity of commercial transactions with foreign countries; secondly, the membership of the management; and, lastly, the composition of its shareholders[859].

Another definition worth noting was presented outside the UN system by the *Institut de Droit International* in the resolution labeled *Les enterprises multinationals* adopted in Oslo in 1977. According to the resolution "*enterprises which consist of a decision-making center located in one country and of operating centers, with or without legal personality, situated in one or more other countries should, in law, be considered as multinational enterprises[860]".*

In light of the aforementioned definitions and understandings of to what a multinational corporation refers, the following conclusions and considerations may be drawn. What really differentiate a multinational company from a national counterpart are: the company's size, the magnitude of its *know-how*, the international delocalization of its productive structure, the multitude companies that make part of it and the pursuit of common economic objectives by every unit that composes the multinational corporation[861]. Some scholars argue that the latter two aspects are the most relevant under a legal perspective, claiming that the most qualifying elements of multinational corporations are the dichotomy between economic unity and the fragmentated structure in multiple entities with different legal personalities[862]. As a result, each of the

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[858] UN Commission on Transnational Corporations, Proposed text of the draft code of conduct on transnational corporations, UN Doc. E/1990/94. In light of its Article 1: *"[multinational corporations] operate under a system of decision-making centers, in which the entities are so linked, by ownership or otherwise, that one or more of them may be able to exercise a significant influence over the activities of others and, in particular, to share knowledge, resources and responsibilities with others".*

[859] UNCTAD, *World Investment Report 2007. Transnational Corporations. Extractive Industries and Development,* 26 ss.

[860] The Institute of International Law, *Multinational Enterprises,* (Second Commission, Rapporteur: Mr Berthold Goldman), Oslo, 1977, paragraph I.

[861]Bonfanti, *Imprese multinazionali,* 5.

[862]Galgano, *Diritto del Commercio Internazionale,* 894.

companies/subsidiaries is an autonomous legal subject that has to comply with the law of the country of registration and incorporation. Simply stated, under a legal perspective the group of companies itself is not a corporation. Consequently, domestic law for can only regulate the conduct of the distinct legal entities, not of the single economic group. On the contrary, the enterprise acts as a unitary entity in light of an economic and strategic perspective under the monitoring and guidance of a single decision-making center[863]. Other scholars, such as Cassese, added that the power of such companies to conclude agreements not only with private actors, but specifically with States and international organizations constitutes an additional key requirement in the process of identifying a multinational corporation[864].

Worth noting at this point is that the legal status acquired by a company within a specific nation is not relevant in detecting the requirements that a multinational company must present. In fact, the notion of company at the domestic level is broad and differs depending on the particular national legal system taken into account. As a result, the subsidiaries of a company can be registered in the host State with different legal statuses. The aforementioned legal autonomy of the different entities of a multinational corporation is, however, a double-edged sword. On the one hand, the parent company can allow each of its subsidiaries to enjoy limited responsibility; but on the other, the structural fragmentation entails the formal compliance with a variety of different legal systems which regulate the conduct of companies within their jurisdictions[865].

Notwithstanding, the benefits go beyond the drawbacks. In practice, the different legal systems provide opportunities for multinational corporations, which can benefit from the grey areas and lack of coordination among such legal frameworks. These situations

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[863]T. Muchlinski, *Human rights, social responsibility and the regulation of international business: The development of international standards by intergovernmental organisations*, *Non-State Actors and International Law*, Kluwer Law International, 2003, 123.

[864] J. G. Ruggie, "Multinationals as global institution: Power, authority and relative autonomy". *Regulation & Governance* 12, 320.

[865] M. M. Winkler, *Imprese multinazionali e ordinamento internazionale nell'era della globalizzazione,* Giuffrè Editore, 2009, 170.

are often referred to as *forum shopping* and/or *jurisdiction shopping*[866]. Nowadays, companies enjoy having the choice among distinctive conveniences under legal and economic perspectives. For example, a company could pick a State in which tax laws are particularly beneficial or a State with a weak environmental, social or trade union law[867].

In detail, the control of the *parent company* over its subsidiaries can take place through a formal legal control, such as the ownership of the majority of the shareholding, or the control can be a *de facto* through, *inter alia,* the direction of production, composition of the executive board and financial dependency[868].

In practice, detecting the link between the headquarters and subsidiaries is often complicated. It is common for multinational corporation to hide their real internal structure throughout an array of different mechanisms. These mechanisms make up the so-called *corporate veil,* which entails the implementation of layers of intermediaries to distance the parent company legally from the host State subsidiary in order to become legally autonomous and benefit from favorable normative systems[869].

From such legal autonomy derives the power of the subsidiaries, at least theoretically, to independently manage their assets and assume contractual and/or non-contractual obligations. As result, the real decision center (the parent company) remains outside the legally binding agreements concluded by its subsidiaries, especially in connection with unlawful conducts by the latter and the consequent obligation to pay compensation for infractions of laws.

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[866] Joseph, *Corporations and Transnational Human Rights Litigation*, 150.
[867] Bonfanti, *Imprese multinazionali, diritti umani e ambiente,* 7.
[868] Ibidem
[869] V. Yilmaz and R. Chambers, "Overcoming the corporate veil challenge: could investment law inspire the proposed business and human rights treaty?", *International and Comparative Law Quarterly*, 67, 2, 2018, 389-390.

2. Legal Status of Transnational Corporations in International Law

The first sections of this chapter have highlighted the unquestionable and constant progression of multinational corporations on the international stage. Their economic and political might has overcome the power and influence of multiple States. Therefore, international law cannot ignore the rise of such new actors and changes that these kinds of corporations have brought worldwide. In this regard, some scholars point out that while economists, political scientists and sociologists widely recognize multinational corporations as global economic actors with a relevant role in international politics and society, practitioners and academics of international law have lagged behind in the legal status of companies despite the ***de facto*** influence of such enterprises in this area[870].

According to traditional theories on international legal personality, however, States and International Organizations remain the sole actors, leaving to multinational corporations the role of mere object of the international legal system[871]. Furthermore, as part of the doctrine has argued over the years, the issue of legal personality constitutes one of the most difficult problem of all international law[872], negatively impacting the proper respect of human rights globally[873].

In practice, international law has great potential to create a comprehensive legal framework that articulates direct obligations on multinational corporations to respect human rights, especially in those States that lack an adequate and efficient domestic judicial system. In such cases, international law could provide satisfactory means in order to stop human rights violations and to bring justice to the victims. So far, however, the international legal framework's role has been more focused on regulating the inter-state structure that sustains the international community; and the regulation of non-state actors has rarely been put at the top of the agenda.

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[870] A. de Jong, *Transnational corporations and international law. Accountability in the global business environment*, Cheltenham-Northampton: Edward Elgar, 2011, 147-148.

[871] N. M. C. Jaegers, "The Legal Status of the Multinational Corporation Under International Law", in *Human Rights Standards and Responsibility of Transnational Corporations*, 262.

[872] R. Monaco, *Manuale di diritto internazionale pubblico*, II edizione, UTET, Torino, 1971, 238.

[873] D. Kinley, and J. Tadaki, "The Emergence of Human Rights Responsibilities for Corporations at International Law", *Virginia Journal of International Law*, 2004, vol.44, no.4, 937-93; Carbone, Luzzatto, Santa Maria, *Istituzioni di diritto internazionale*, Giappichelli editore, 2002, 33-34.

This section studies the legal status of multinational corporations within the international framework. The question related to the international legal personality of these companies requires a brief analysis of the notion of international legal personality in light of the prominent theories on such matter, with the aim at understanding whether or not the current framework allows the inclusion of these powerful actors as new subjects of international law.

Having identified an acceptable definition of such companies in the previous section, traditional and recent theories on legal personality will be here presented in order to demonstrate the urgency for renovation and improvement of the international framework. Indeed, an innovative doctrine on international legal personality which could satisfactorily mirror the current global context in relation to business and human rights would be, hence, desirable[874].

2.1 An introduction to International Legal Personality

Generally speaking, the concept of legal personality refers to the capability of a certain actor to be entitled of rights and duties within a specific legal system. Any legal system has to establish whom it provides with the rights and duties enshrined in it and *"whose actions it takes account of by attaching legal consequences to them"*[875]. Legal personality is a key concept of domestic legal frameworks as well as of the International one. Still, two characteristics, which make the international legal framework peculiar and unique, differentiate personality in international law from that in domestic law.

The first feature of the international legal system is that international personality is not limited to the quality of having rights and duties, as well as particular powers according to the law, but that it also comprises the capability to create the law[876].

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[874] *"When convictions have been accepted for a long time in doctrine it is easy to lose sight of their derivation from certain assumptions; they therefore continue to be regarded as truths, even when these assumptions have been discarded*". Roberto Ago, Positive Law and International Law, 1957

[875] R. Portmann, *Legal personality in International Law, Cambridge University Press*, 2010, 7.

[876] Malcolm N, Shaw., International Law, 6th edition (Cambridge University Press, 2008), p 195–200;

Law-creation, as a key requirement of international personality, is the result of another peculiar feature of the international system: the absence of a centralized legislator. In fact, as opposed to domestic legal systems in which the formation of the law relies within the powers of centralized State organs, such as national parliaments and governments, at the international stage *States enact international law themselves through different modes of explicit and implicit coordination*[877]. Stated differently, the creation of international law derives directly from the will of States, which are the addressees of that very law.

There is no doubt in considering States as typical international subjects to the extent that often the terms statehood and international personality were treated as synonymous. In the same manner, no question exists that at least international personality of States embraces the power to create law while being subject to this very law[878]. In practice, the focal issue to be addressed is whether the competence to create law is a fundamental requirement of an international person, or, on the contrary, whether there also can be international subjects lacking such competence. This issue will be tackled in this section, putting traditional and innovative approaches to legal personality in perspective, in light of international jurisprudence and main doctrine.

The second characteristic that distinguishes personality in international law from that in domestic law is the absence of an *ad hoc* treaty or established norms of customary international law that properly addresses matters of personality. In the words of some scholars, there is no *centralized law of persons* in the international legal framework[879]. For example, in contrast to the attitude towards Article 38 of the ICJ Statute, which is commonly seen as the authoritative provision on the sources of international law, the same cannot be said about Article 34 of such Statute, which gives standing only to States but does not provide a statement on international legal personality more generally. Additionally, not even the International Law Commission has ever chosen the law of persons for codification regardless of a suggestion forwarded in 1949, as

[877]Typically, States act through the formation of customs and the conclusion of treaties. Roland Portmann, Legal personality in International Law, Cambridge University Press, 2010, 9.
[878] Ibidem
[879] Ibidem

opposed to the law of treaties or international responsibility to which the ILC has devoted much of its attention[880].

In this respect, the International Court of Justice's relevant comment on this matter was delivered in the *Reparation for Injuries* Advisory Opinion of 1949, which constitutes the first step for anyone attempting to comprehend theories related to the concept of international legal *subjectivity*[881]. The definition provided in the latter Opinion constitutes the closest international law gets to an authoritative pronunciation on international personality, since, as mentioned above, there is neither a relevant treaty nor are there consolidated customary norms that address such issues[882].

Without analyzing the merits of the issue presented before the Court, the latter had to determine whether the United Nations, as an international organization, was entitled to bring an international claim for damages against a State for the injuries suffered by a UN agent during an official mission in that very State[883]. Another peculiarity of this Advisory Opinion was that the State concerned, Israel, was not a member of the UN at the time, an aspect which further complicated the task of the Court.

The Court concluded that the United Nations enjoyed international personality, which meant that in the words of the Court: *"it is a subject of international law and capable of possessing international rights and duties, and that it has the capacity to maintain its rights by bringing international claims"*[884].

The aforementioned conclusion grounded on a reasoning by the Court, which is quite flexible and surely permits for a different conception of what is an international subject[885]. According to the Court, international subjects are not necessarily alike, and

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[880] Survey of International Law in Relation to the Work of Codification of the International Law Commission: Preparatory work within the purview of article 18, paragraph 1, of the Statute of the International Law Commission, Memorandum submitted by the Secretary-General, UN Doc. A/CN.4/1/Rev.1, at 19–22.

[881] Reparation for Injuries Suffered in the Service of the United Nations (Advisory Opinion), in ICJ Reports 1949, 174 ss.

[882] Portmann, *Legal personality in International Law*, 9.

[883] The case is often referred to as the Count Bernadotte case, who was killed while serving as the UN Chief negotiator for Palestine.

[884] Reparation for Injuries Suffered in the Service of the United Nations (Advisory Opinion), 1949 ICJ Reports 174, 179.

[885] A. Clapham, *Human Rights Obligations of Non-State Actors*, Oxford University Press, 2006, 64.

the extension of their rights and duties depends on the needs of the community and the requirements of international life[886]. In light of this assumption, if international personality varies in its scope and content depending on the needs of the community, the number and kinds of international subjects could progressively increase over the course of the development of international law[887]. As a result, this reasoning could allow the inclusion of multinational corporations as subject of international law, in view of the important economic and social changes occurring globally over time.

Notwithstanding, not all that glitters is gold. In fact, some scholars have emphasized the absence of a legal provision in accordance to which entities actually are international persons or pursuant to which requirements personality is attributed[888]. In addition, other authors have highlighted the tautological nature of the definition of international personality presented by the Court[889]. In their views, *"International law recognizes the capacity to act at the international level of an entity that is already capable of acting at the international level"*[890]. In other words, it can be inferred that international personality, as well as the capacity to act at the international stage, constitutes essential requirements for the exercise of functions and rights. The Court, however, addressed international personality as the capacity to have rights and to exercise them. In the words of the former President of the International Court of Justice, Judge Higgins, the Court itself created a sort of "*intellectual prison"* over the understanding of international personality[891]. To break out of this *prison,* the Judge argued the need to adopt a functional approach to international personality and to leave behind the dichotomy *subject-object* of law which has *"no credible reality"*[892].

In this context, the progressive recognition of international law of the legal personality to entities which have different features from States, such as international organization,

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[886] Reparation for Injuries Suffered in the Service of the United Nations (Advisory Opinion), 1949 ICJ Reports 174, 179.
[887] Bonfanti, *Imprese multinazionali,* 34.
[888] Portmann*, Legal personality in International Law*, 10.
[889] I. Brownlie, *Principles of Public International Law*, Oxford University Press, 6th edn, 2003, 57.
[890] Ibidem
[891] R. Higgins, *Problem and Process. International Law and how we use it*, Clarendon Press, 1994, 49-50.
[892] Ibidem

individuals and rebels, demonstrates how the notion and concept of legal subjectivity must essentially present functional ends. Accordingly, the traditional division of the international legal system into *subjects* and *objects* seems outdated and a more dynamic and realistic approach would be desirable. To this end, acknowledging the role played by all the different actors at the international level by referring to them as *participants* rather than subjects/objects would undoubtedly bring international law more in line with the current situation[893].

As has been presented throughout this dissertation, the progressive development of human rights law and international economic law has enhanced the role played by non-state actors and their scope for participation in international law. Studying the extent to which international law recognizes the presence of diverse classes of participants in the international legal context would thus be a more beneficial method in order to update theories on international personality[894].

In conclusion, if international law reflects the needs and requirements of the international community, understanding multinationals corporations as *participants* of international system offers a much more accurate description of the role played by private entities globally. As a result, the definition provided by Brownlie, according to which *"a subject of International law is an entity possessing international rights and obligations and having the power to maintain its rights by bringing international claims and be responsible for its breaches of obligation by being subjected to such claims"* seems only partially adequate[895].

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[893] J.A. Zerk, *Multinationals and Corporate Social Responsibility, Limitations and Opportunities in International Law*, Cambridge University Press, 2007, 74.
[894] Ibidem
[895] Brownlie, *Principles of International Law,* 47.

2.2 Theories on International Legal Personality

In light of the preliminary considerations presented on the concept of international personality, this section undertakes a literature review in order to determine to which extent multinational corporations can be considered legal persons under international law. The supporting structure and guiding line of the next section are the five conceptions that Portmann presents in relation to international legal personality, which are namely: *States-only, Recognition, Individualistic, Formal* and *Actor conception*[896].

2.2.1 The States-Only Conception

The states-only conception acknowledged by Portmann summarized traditional conceptions related to international personality which hold the State as the exclusive subject of international law[897]. Accordingly, individuals and other entities only fully exist as nationals of a State and are therefore not directly relevant for international law[898]. Such approach grounded on philosophers such as Hegel, the German socio-political and legal context in the aftermath of its unification of 1971, as well as on the work of authors such as Heinrich Triepel[899], Lassa Oppenheim[900] and Dionisio Anzilotti[901]. In this understanding, statehood and international personality are considered as synonymous[902].

In the aftermath of the German and Italian unification, scholars needed to find

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[896] Portmann, *Legal personality in International Law*, Cambridge University Press, 2010

[897] Some of the most significant displays of the states-only conception in legal practice are *the Mavrommatis Palestine Concessions*, the Serbian Loans statement regarding state contracts, the Jurisdiction of Courts of Danzig Advisory Opinion, as well as the well-known *Lotus* pronouncement on international law regulating relations among independent States.

[898] Ibidem, 42.

[899] H. Triepel,"Les Rapports entre le Droit Interne et le Droit International", *RCADI* 1, 1923, 81.

[900] L. Oppenheim, *International Law: A Treatise, 1st edition,* Green, and Co, 1905, 99.

[901] D. Anzilotti, *Corso di Diritto Internazionale' in Società Italiana per l'Organizzazione Internazionale,* Cedam, 1955, 112-113.

[902] J. Crawford, *The Creation of States in International Law*, Oxford University Press, 2007.

theoretical assumptions in order to legitimize these recently born States[903]. In this regard, Hegel's view of the State was taken into consideration and used to develop the States-only conception. The philosopher refuted the idea of the State as the product of a social-contract among free individuals with the aim of protecting their specific interests. On the contrary, Hegel argued that the State was the result of an historical process which started from the social institutions of the family and the civil society and which finally terminated in modern statehood[904]. Accordingly, the State was conceived as an entity resembling the human body, with the capability of organizing itself in order to preserve and to develop in light of mutating social needs during the course of time[905]. The state was therefore considered as a factual organism, rather than an abstract entity created by a formal contract of individuals. In this scenario, international law, merely took reality into account while transforming social reality into legal prescriptions. As a result, some scholars argued that the State precedes the law and "*becomes a 'natural', 'original' or 'absolute' international person existing* a priori"[906].

The backbone principle of the international system is sovereign equality among States, as entities *superiorem non recognoscentes*, which are the only one that can create, consent and modify international law[907]. In other words, States are bound to the international provisions upon which they have *explicitly* or *tacitly* agreed[908], bearing in mind the principle of sovereign equality among States, also codified in the United Nations Charter, which *inter alia* codified the equal and horizontal nature of the international community[909].

According to this conception, individuals are conceived as component parts of the State in which the nationality resides. As a result, the consideration of the relationship

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[903] A. P. Sereni, *The Italian Conception of International Law*, Columbia University Press, 1943, 202.
[904] G. Hegel, "Grundlinien der Philosophie des Rechts, 'Georg Friedrich Wilhelm Hegel: Sämtliche Werke", Felix Meiner, 1930, 207.
[905] Ibidem, 97.
[906] Portmann, *Legal personality in International Law*, 248.
[907] Separate Opinion of Judge Guillaume on the Advisory Opinion on Legality of Threat or Use of Nuclear Weapons, 1966 I.C.J. 226, at 291, para 10.
[908] Ibidem, 258.
[909] R. Anand, *Sovereign Equality of States in International Law,* International Studies, Sage Publications, 1966, 216.

between international and domestic law as *dualistic* may be considered adequate. In fact, the latter and former frameworks feature different sources and different subjects, allowing the drawing of a sharp line between the two. In the words of Triepel, the aforementioned legal systems are *two circles touching each other but never overlapping*[910].

In light of this *dualistic* conception, international law derives from the collective will of a number of States, as opposed to domestic law which is the result of the will of one State. Accordingly, *"international law is not a mere external public law (and thus part of national law) that one state can lawfully create and change according to its own will. There must be a common will of several states to establish or to change international rules"*[911].

Under the aforementioned considerations, the inference is that domestic law regulates both the relations among individuals on the one hand and between the State and individuals on the other. On the contrary, international law applies to the relations among those States that have formed the international norms under discussion.

In conclusion, if we were to apply the theoretical elements of the State-only conception described above to the reality of multinational corporations, which in fact is the aim of this section, the following remarks can be drawn. Firstly, international law cannot be applied to corporations since international norms are only relevant for those States that have concurred with them. Secondly, if a particular State has participated in the formation of a specific international norm which envisage provisions relating corporations, such provisions are not considered as being directly applicable to those corporations. The latter are not in fact subjects of the international community, rather only constitutive members of the State such corporations are incorporated to in accordance to the respective domestic law[912].

This leads to the conclusion that corporations enjoy no rights or obligations under international law and that even treaties providing norms affecting corporations have to

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[910] Triepel, *Les Rapports entre le Droit Interne*, 82.
[911] Portmann, *Legal personality in International Law*, 44.
[912] J. Slawotsky, "The Global Corporation as International law Actor", *Virginia Journal of International law* 52, 2012, 80.

be interpreted as obligations only on the member State to such treaty[913].

In regard to human rights, only States are bound to abide to the respect, protect and fulfil framework, which they have agreed upon either under international treaty law or under customary international law. According to the State-only conception, the only way corporations can be bound to human rights law is for the State to provide specific norms in its national law[914], making international law ineffective without State's action[915]. This traditional view of international personality, thus concludes that corporations cannot be considered subjects of law and are relevant to international law in general and human rights law in particular, solely indirectly through the intervention of States[916]. The main legal displays of the aforementioned conception on international personality can be found in the well-know *Mavrommatis* case and in the *Jurisdiction of the Courts of Danzig* advisory opinion.

2.2.2 Legal manifestations of the State-Only Conception (A) – the *Mavrommatis Case*

The relevant part to the present section concerns the so-called *Mavrommatis formula,* through which the Judges of the Permanent Court of International Justice (PCIJ) emphasized that the individual has no direct rights in the international legal system, but that a state can call upon its own international rights in order to safeguard interests of its nationals[917]. This resembles the states-only conception of international legal subjectivity: the individual is not an independent entity and becomes significant under international law as a national of a State, since States are the only international right

[913] Ibidem
[914] Brief of Amicus Curiae Professor James Crawford in support of conditional cross-petitioner, Presbyterian Church of Sudan v Talisman Energy Inc., 582 F.3d 244 (2009) (no.091418), 16.
[915] J.A. Zerk, *Multinationals and corporate social responsibility: limitations and opportunities in International law*, Cambridge University Press, 2006, 73.
[916] J. I. Charney, *Transnational Corporations and Developing Public International law*, Duke Law Journal, 1983, 750-753.
[917] The Mavrommatis Palestine Concessions (Greece v. UK), Jurisdiction, 1924 PCIJ Series A No. 2, at 12.

holders[918]. Such understanding of international personality has been acknowledged in numerous leading cases and, to some degree, is currently affirmed in the ILC's work on diplomatic protection today[919].

The Mavrommatis case concerned the dispute between a Greek national named Mr Mavrommatis and the British government. Before de commencement of World War I, Mr Mavrommatis was awarded concession to begin public works in Palestine by the then presiding Ottoman government. When the British mandate over Palestine[920] came into existence, as a result of a mandate from the League of Nations in June 1922[921], the government had allegedly failed to protect Mr Mavrommatis concessionary rights. The Greek national claimed a violation of Article 9 of Protocol XII of the *Lausanne Peace Treaty* between Turkey and the Allied Powers, as well as Greece and Great Britain. Mavrommatis's claim was then taken on by Greece, which brought the case before the PCIJ. The British government questioned the jurisdiction of the Court, since in light of Article 26 of the Mandate for Palestine, the requirements for jurisdiction were not met. The first issue to be addressed by the Court was thus to determine whether the dispute was related to the interpretation or the application of the provisions of the Mandate when applying the Article 26.

In this regard, the Court replied with the aforementioned Mavrommatis Formula which reads as follows: *"In the case of the Mavrommatis Concessions it is true that the dispute was at first between a private person and a State – i.e. between M. Mavrommatis and Great Britain. Subsequently, the Greek Government took up the case. The dispute then entered upon a new phase; it entered the domain of international law, and became a dispute between two States. . . . By taking up the case of one of its subjects and by resorting to diplomatic action or international juridical proceedings on his behalf, a State is in reality asserting its own rights. . . . The question, therefore, whether the*

[918] Portmann, *Legal personality in International Law*, 65.
[919] Report of the International Law Commission, Official Records of the General Assembly, Sixty-first Session, Supplement No. 10 (A/61/10), Chapter IV.
[920] As provided for by the Sykes–Picot Agreement of 1916, a secret treaty between France and the United Kingdom in order to determine the future of the Ottoman Empire.
[921] Such mandate for Palestine was a Class A League of Nations mandate for British administration of the territories of Palestine and Transjordan.

present dispute originates in an injury to a private interest, which in point of fact is the case in many international disputes, is irrelevant from this standpoint. Once a State has taken up a case on behalf of one of its subjects before an international tribunal, in the eyes of the latter the State is sole claimant"[922].

The argument presented by the Court constitutes the typical understanding of diplomatic protection under international law, according to which the mistreatment of a foreign national's interests undermines the international rights of the national's home state, not the rights of the individual[923]. International law is thus concerned only when the home state of a private party becomes involved in a case related to a private interest and calls upon its own international rights against other states. Hence, in the *Mavrommatis case* the supposed inadequacy of the British government to protect Mavrommatis's concessionary rights concerned the international rights of Greece, not the rights of Mr Mavrommatis[924].

Despite the fact that the *Mavrommatis-formula* has been, and is, frequently challenged in doctrine, clearly it is still applied in current international legal practice related to diplomatic protection. There is no doubt that such continuous use of the formula demonstrates that the basic assumptions of the states-only conception of international subjectivity are implicitly accepted, in specific the view that the individual has no independent existence in the international realm except as being a national of a state[925].

[922] Mavrommatis Palestine Concessions (Greece v. U.K.), 1924 C.I.J. (ser. B) No. 3 (Aug. 30), par. 12.
[923] Portmann, *Legal personality in International Law*, 66.
[924] Ibidem
[925] Ibidem

2.2.3. Legal manifestations of the State-Only Conception (B) – The Jurisdiction of the Courts of Danzig Advisory Opinion

The *Jurisdiction of the Courts of Danzig* opinion has raised criticism over its interpretation. Some scholars, such as Anzilotti[926], consider the opinion as a firm testimony of the states-only conception of international subjectivity. On the contrary, another part of academia perceives such opinion as a manifestation of the direct applicability of international law to individuals (if the parties have so envisaged) and thus they regard it as a valuable tool in order to broaden the notion of international personality. In this respect, Portmann argues that the Jurisdiction of the Courts of Danzig opinion is a useful evidence of the states-only conception, *but applied it in such a way as to partly open the (back) door for involving the individual in international law*[927].

The Advisory Opinion concerned whether specific agreements concluded between the Free City of Danzig and Poland were applicable to individuals. The case stemmed from the special settings related to the city of Danzig during the interval between the two great wars. In fact, in 1919 the Treaty of Versailles established Danzig as a Free City with the aim of granting Poland's access to the sea while safeguarding the city's German-speaking population.

Danzig had the requirements of statehood provided by international law [928], and thus could enter into two agreements with Poland, one establishing that the Danzig railways were to be managed by Polish authorities[929] and the other, namely the *Definitive Agreement Regarding Officials* (*Beamtenabkommen*), regulating the entry of the Danzig railway workers into Polish employment[930].

Several cases were brought before the courts of Danzig by Danzig railway officials against the Polish Railway Administration, claiming monetary compensations for

[926] Judge Anzilotti was the then president of the Court and one of the drafters of the opinion.
[927] Portmann, *Legal personality in International Law*, 70.
[928] Crawford, *The Creation of States in International Law*, 240-241.
[929] Convention between Poland and the Free City of Danzig, 9 November 1920, 6 LNTS 160, Article 21.
[930] Endgültiges Beamtenabkommen, 22 October 1921, reproduced in 1928 PCIJ Series B No. 15, at 37–43.

alleged violations of the aforementioned *Definitive Agreement Regarding Officials.* Once these cases were brought to the consideration of the High Commissioner of the League of Nations at Danzig, the latter concluded that the proceedings could not be grounded on the *Definitive Agreement Regarding Officials*[931]. The Free City of Danzig confronted this conclusion before the Council of the League of Nations, which requested an advisory opinion to the PCIJ on this matter. The issue was, hence, to determine whether an international agreement, namely *Definitive Agreement Regarding Officials,* was directly applicable to individual railway workers or, on the contrary, only to the parties to the treaty as claimed by the Polish government[932]. The Court replied that: *"It may be readily admitted that, according to a well-established principle of international law, the* Beamtenabkommen*, being an international agreement, cannot, as such, create direct rights and obligations for private individuals. But it cannot be disputed that the very object of an international agreement, according to the intention of the contracting Parties, may be the adoption by the Parties of some definite rules creating individual rights and obligations and enforceable by the national courts. That there is such an intention in the present case can be established by reference to the terms of the* Beamtenabkommen*"*[933].

The pronouncement of the Court on the issue at stake was controversial, since some authors have interpreted it as a recognition by the Court that treaties can create individual rights if the parties so have established[934]. Notwithstanding, such position appears to be extreme, especially in light of the reasoning delivered by Anzilotti, who argued that a treaty could not be directly applicable to individuals, but at most could compel the parties to implement into their domestic law the provisions provided by the treaty[935]. Only in such a way, could treaties be directly relevant to individuals.

In conclusion, the theoretical approach adopted by the Court in the Danzig opinion is a demonstration of the state-only conception on international personality. Accordingly,

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[931] Portmann*, Legal personality in International Law*, 69.
[932] Ibidem
[933] Jurisdiction of the Courts of Danzig (Advisory Opinion), 1928 PCIJ Series B No. 15, par. 18.
[934] Crawford, James R., The ILC's Articles on Responsibility of States for Internationally Wrongful Acts: A Retrospect', AJIL, 96 (2002), 874–90 ['The ILC's Articles on Responsibility of States'], 887.
[935] Anzilotti, *Corso di Diritto Internazionale*, 340.

an international treaty cannot create rights directly applicable for individuals, but only States are the right holders. Individuals can, however, be objects but never subjects of international agreements. In fact, pursuant to the second part of the Court's reasoning, international agreements can regulate matters concerning individuals, but the relevant norms cannot bestow direct rights on them. Such provisions merely establish an obligation of the parties to adopt appropriate norms into their domestic law in order to thus be enforceable before national courts.

2.3. The Recognition Conception

The recognition conception constitutes the evolution and adjustment of the states-only conception. The primacy of the state in international law remains a basic assumption of this legal theory, but States are no longer the only international subjects. States can in fact recognize other entities as non-state actors.

The recognition approach grounds on the work and studies of scholars such as Karl Strupp, Arrigo Cavaglieri and Georg Schwarzenberger, who developed this theory in light of what they identified as state practice regarding international subjectivity[936]. This conception, which some authors consider the leading theory on international subjectivity today, developed as a result of social, economic and political changes which occurred over time and which weakened the 'States-only' approach's basic assumptions [937] . In particular, this *corrective* conception towards international personality emerged in response of the increasing importance within the international framework of the United Nations and of international organizations in general. Such approach grounded on the assumption that if legal analysis distanced itself too far from

[936] Strupp, Karl, *Das völkerrechtliche Delikt*, 'Handbuch des Völkerrechts' Fritz Stier-Somlo, ed , Berlin et al.: W. Kohlhammer, 1920; Cavaglieri, Arrigo, *I soggetti del diritto internazionale*, Rdi, 1925; Schwarzenberger, Georg, *A Manual of International Law*, 1st edition, London: Stevens & Sons, 1947. *"The original subjects of international law are sovereign States. . . .Nonetheless, it is a mistake to deduce from this state of affairs that sovereign States alone are eligible to be subjects of international law. This is a matter within the discretion of each of the existing subjects of international law".*

[937] Portmann*, Legal personality in International Law,* 80.

social reality, a corrective measure is, hence, needed[938].

The recognition conception, while relying on the basic analytical structure of the 'States-only' conception, accepts other international subjects alongside States. Indeed, States remain the main legal persons granted with full subjectivity and are the only authorities competent to confer and consent to *limited* international legal personality to other entities[939]. In other words, this conception argues that the emergence and scope of a new subject of law in the international realm stems completely from the will and recognition of States, which, thus, have the power both to establish and exclude which entities can be part of the international legal framework[940]. According to some scholars, State's recognition to non-States actors has to be carried out by at least two States as well as being explicit and unequivocal. This scrupulous degree of recognition in reference to such entities is required due to the presumption that non-state actors (such as individuals) belong to the domestic framework and not to the international one. State's will, thus, has to be unquestionable in order to grant limited personality which exists pursuant to the limitations provided in the act of recognition [941].

Apparently, the aforesaid conception leaves room for the hypothesis that multinational corporations are granted with limited international legal personality separated from that of States[942], certainly, if the latter have recognized such corporations as subjects of international law[943]. Accordingly, corporations' existence and scope of action at the international stage are the result of states' recognition and will.

Regrettably, the practice differs greatly from the theory. In fact, certain kinds of international subjects have widely been accepted at the international level as separate and autonomous international legal persons, such is the case of international organizations and individuals [944]. The same can be said in reference to another

[938] Ibidem, 85.
[939] M. Goldman, "We Need to Cut Off the Head of the King: Past, Present, and Future Approaches to International Soft Law", 25 *Leiden Journal of International law*, 2012, 341.
[940] Ibidem, 85.
[941] Cavaglieri, *I soggetti del diritto internazionale*, 183.
[942] Goldman, *We Need to Cut Off the Head of the King,* 68.
[943] Portmann*, Legal personality in International Law*, 84.
[944] M. N. Shaw, *International law*, Cambridge University Press, 2017, 257-260.

categories of actors deemed to have State-like qualities as well as to entities in the process of becoming States. Among the aforementioned category are insurgents recognized as belligerents, national liberation movements ('NLMs') which act on behalf of peoples campaigning for self-determination, *de facto* regimes, the Holy See, and including the Sovereign Military Order of Malta[945].

Notwithstanding, the same observations cannot be made in relation to multinational corporations since in practice, States have never explicitly agreed to recognize legal status to such enterprises, nor have they concluded a treaty providing specific norms on this matter[946].

The relevant legal practice related to the recognition conception is identified, *inter alia,* in two specific cases, namely the aforementioned ICJ Advisory Opinion of 1949 and in the case concerning the international legal status of the International Committee of the Red Cross (ICRC).

The main features of the 1949 ICJ *Reparations for Injuries* Advisory Opinion have already be presented in the introduction of this section in order to set the theoretical framework in relation to international legal personality. The Court's definition regarding the UN legal status *"a subject of international law and capable of possessing international rights and duties, and it has capacity to maintain its rights by bringing international claims"* has already been mentioned and discussed[947].

However, the key assumptions of such Advisory Opinion, are here further studied and presented in order to highlight the foundations of the recognition conception.

Briefly stated, the Court concluded that the UN, as an international organization, was a peculiar subject of international law, since even entities that were not States could be granted with international legal personality. Such personality does not inevitably require that the same rights and obligations that apply to States also extend to international organizationd. This leads to the conclusion that statehood and international personality have different theoretical and practical implications, since the

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[945] A. Clapham, *Human Rights Obligations of Non-State Actors,* Oxford University Press, 2006, 59.
[946] J. Crawford, *Brownly's Principles of Public International law*, Oxford University Press, 2012, 122.
[947] ICJ, *Reparations for Injuries Suffiered in the Service of the United Nations*, Advisory Opinion, 1949 I.C.J. 174, 179.

legal status of international organizations can vary in scope and content from the legal status that States or other recognized actors have. The flexibility of the international system[948] entails that such organizations may have different degrees of legal personality, which may differ over time, depending on the international capacities States have provided for in their respective founding treaties[949].

The ICJ emphasized the developing nature of the international arena and accordingly the fact that *"subjects of law in any legal system depend on the needs of the community"*[950]. This means that the recognition of new legal subjects is needed since the international legal framework is dynamic and may considerably change over time[951]. As already described above, the Court pointed out the functional nature of the UN legal personality. In fact, the personality attributed by States to the organization serves a precise purpose, namely allowing the UN to carry out its objectives and goals[952]. In this regard, some scholars have argued that the personality of an international organization is limited by its respective constitution which explicitly provides the scope and extent of the legal status such organization enjoys, such as the capacity to conclude treaties and to start international proceedings[953]. Another important consideration made by the Court concerns the fact that UN personality is objective and valid even for non-member States although such organizations are usually the product of a specific treaty that is only binding on the parties[954].

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[948] A. McBeth, *Every Organ of Society: The Responsibility of Non-State Actors for the Realization of Human Rights* 30 Journal of Public Law and Policy 33, 2008-2009, 64.

[949] Andrew Clapham, *Human Rights Obligations of Non-State Actors,* Oxford University Press, 2006, 70.

[950] *Reparations for Injuries Suffiered in the Service of the United Nations*, Advisory Opinion, 1949 I.C.J. 174, 178.

[951] Malcolm N. Shaw, *International law*, 8th Edition, Cambridge University Press, 2017, 261.

[952] The Court argued that the UN`s Member States conferred international personality to the UN by "*entrusting certain functions to it, with the attendant duties and responsibilities"*. Such conferral was required in order for the UN to perform its purposes and principles as provided for in the UN Charter. *Reparations for Injuries,* 178-179.

[953] M. Dixon and R. McCorquodale, *Cases & Materials on International Law*, Oxford University Press, 2016, 151.

[954] I. Brownlie, *Principles of Public International Law*, Oxford University Press, 2003, 57.

2.3.1. The Recognition Conception and Transnational Corporations

The ICJ's understanding of international personality is flexible enough to recognize multinational corporations as subjects of international law. The latter personality does however, depend on State action. In fact, as some scholars have highlighted, State's conduct is necessary in order to assess whether a specific entity has legal personality and to what extent such personality can be exercised by a non-state actor[955]. As a result, multinational corporations upon States will are granted with legal rights and obligations that are not relevant to other categories of international legal persons and which depend on *"needs of the international community"*[956].

It is worth noting that a specific area of international law, namely the international investment regime, provides a valuable practical example of the aforesaid theoretical assumptions. In light of the ICJ reasoning in the *Reparation Case*, international enterprises and other investors under Bilateral Investment Treaties (BITs) and Free Trade Agreements (FTAs) enjoy international legal status to the same extent the UN was understood as a subject of International law by the Court[957]. Indeed, investment treaties provide precise rights to corporations different than those envisaged for the States parties to such treaties, resulting in a limited personality of these enterprises, likewise the UN Charter tacitly acknowledges distinct legal status to the organization than to its member States[958].

In addition, in the same manner the U.N. Charter provides the faculty of the organization to conclude certain agreements and treaties under international law, *"many BITs' and FTAs' umbrella clauses explicitly 'internationalize' investor-State contracts, thereby elevating such contractual assurances to the level of inter-State*

[955] D. Kinley and R. Chambers, "The UN Human Rights Norms for Corporations: The Private Implications of Public International law", *Human Rights Law Review*, 2006, 33.
[956] J.A. Zerk, *Multinationals and corporate social responsibility: limitations and opportunities in International law*, Cambridge University Press, 2006, 73-74.
[957] J. Alvarez, "Are Corporations "Subjects" of International law?", *9 Santa Clara Journal of International law*, 2011, 3.
[958] McBeth, *Every Organ of Society*, 64-65.

pacts"[959]. Furthermore, the majority of BITs and FTAs, as opposed to the UN Charter, envisage explicit clauses providing investors with the right to institute proceedings against States before international tribunals (usually arbitral tribunal) in order to pursue their claims. To state it in the words of Alvarez: *"to the extent the ICJ concluded in the Reparation Case that the ability to act as a person is the principal determinant of personhood status, the same conclusion can even more readily be drawn with respect to corporations and other investors under the international investment regime"*[960].

The recognition conception, thus, theoretically allows States to recognize multinational corporations as subjects of international law and the study of *de lex lata* demonstrates that such corporations enjoy specific rights under international investment treaties. Many scholars, however, argue that such rights seem unsatisfactory to conclude that States have conferred legal status to such corporations[961]. Emerging from the practice is States' unwillingness to properly attribute international legal personality to multinational corporations *via* any formal act expressing consent. On the contrary, States' practice proves that the creation of corporation takes place through domestic law. In this regard Cassese concludes that States have never upgraded these entities to international subjects and thus, the author pointed out that multinational corporations enjoy no international rights and nor are bound to international obligations. *"They are only subjects of municipal and 'transnational' law"*[962]. In this regard, in the words of the SRSG "*nothing prevents States from imposing international legal responsibility for human rights directly on corporations. But the evidence we reviewed does not indicate that they have already done so to any appreciable extent"*[963].

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[959] J. Alvarez, *Are Corporations "Subjects" of International law?*, 9 Santa Clara Journal of International law, 2011, 3.
[960] Ibidem
[961] Kamminga, MT 2004, Corporate Obligations under International Law. in Report of the 71st Conference of the International Law Association. International Law Association, Berlin, 422.
[962] Antonio Cassese, *International Law in a Divided World*, 1986, 103.
[963] J. Ruggie, *Business and Human Rights: The Evolving International Agenda,* 20 (John F. Kennedy School of Government, Corporate Social Responsibility Initiative Working Paper No. 31, 2007).

2.4. The Individualistic Conception

The third conception acknowledged by Portmann is the individualistic conception. According to the latter, as a general rule, the human being is placed at the center of the international system and, as such, is an international subject enjoying certain basic international rights and duties[964]. This conception emerged from the work of Hersch Lauterpacht who, over the course of and in the aftermath of the atrocities of WWII, attempted to put the individual back at the center of the international debate[965] .

The main assumption is that the human being is a *priori* international subject and such legal status does not derive from the explicit or implicit recognition nor consent of States. In this regard, in light of sociological, philosophical and natural law remarks, some scholars have drawn the ultimate conclusion that individuals and not States are the only subjects at the international level[966]. Hersch Lauterpacht, however, mitigated such extreme approaches and elaborated a theory which influenced following legal practice mostly related to international criminal law and human rights law[967]. Nowadays, this approach towards legal personality has been championed by prominent figures such as Antônio Augusto Cançado Trindade and, with less strength, by Antonio Cassese[968].

The individualistic conception grounds on two main theoretical pillars, which combined result in considering the human being as a *priori* subject of international law. The first pillar concerns the understanding of the State as a functional entity governed by human beings *who are subject to the rule of law in the interest of those being governed*[969]; the second pillar relies on understating international law as consisting of fundamental principles of law being superior to expressions of state will (constitutional

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[964] Portmann*, Legal personality in International Law*, 126.
[965] H. Lauterpacht, "The Subjects of the Law of Nations' in Elihu Lauterpacht ", *International Law: Being the Collected Papers of Hersch Lauterpacht,* Cambridge University Press, 1975, 520-526.
[966] G. Scelle, *Précis de Droit des Gens,* Recueil Sirey, 1932, 42.
[967] Portmann*, Legal personality in International Law*, 127.
[968] A. A. Cançado Trindade, "International Law for Humankind: Towards a New Jus Gentium: General Course on Public International Law", *RCADI*, 2005, 316-318 and 252-284; A. Cassese, *International Law*, Oxford University Press, 2001, 165.
[969] Portmann*, Legal personality in International Law*, 127.

principles of *ius cogens* character)[970].

As a result, the principal goal of the international legal system is to protect the freedom and well-being of all individuals, making, thus, necessary for international law and ultimately States, to directly represent the interests of all human beings. Accordingly, the individualistic approach understands public and private spheres as a single entity in which all the provisions adopted are aimed at enhancing the wellbeing of individuals[971].

In brief, the individualistic conception addresses three specific aspects of the international legal framework. Firstly, the conception challenges and rejects the aforesaid Hegelian understanding of the State. The State is in fact understood as a corporate entity created by individuals for fulfilling their own interests and not merely as a mystical entity resulting from an historical process. In principle there is no distinction between State and individual interests[972]. This leads to the assumption that international law can confer rights upon individuals (both if acting on behalf of the State or privately) and requires obligations of the individual[973].

Secondly, the individualistic conception criticizes the system of the sources of law outlined in the *state-only* conception and proposes a new regime. Accordingly, sources of law do not merely originate from the will of State, and natural law principles are placed at the center of the legal framework independently of the positive law of a certain political order, community or State. This understanding of the international legal system relies on Article 38(3) of the ICJ, which allows the Court to apply *general principles of law recognized by civilized nations*. The latter provision is understood to support the idea, also often found in international arbitration practice, that natural law is an acknowledged source of international law supplementing treaties and custom[974].

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[970] Ibidem

[971] Ibidem 133.

[972] Ibidem

[973] According to Lauterpacht, in theory the international responsibility regime can be applied both to individuals acting on behalf of the state and to States. Lauterpacht, Hersch, 'The Subjects of the Law of Nations' in Elihu Lauterpacht (ed.), International Law: Being the Collected Papers of Hersch Lauterpacht (Cambridge University Press, 1975) (originally published 1947), 487–533, 520.

[974] H. Lauterpacht, *The Function of Law in the International Community* (Oxford: The Clarendon Press, 1933), 67.

In this scenario, there are general rules that bind and concern all States, namely fundamental legal principles and international peremptory norms (often referred to as *ius cogens* norms)[975]. Without going into further details, *ius cogens* refers to a specific group of dominant norms which do not derive from customs nor treaties and which are hierarchically superior to them[976]. Consequently, *ius cogens* norms can be modified only by subsequent norms of the same status and, in addition, may function to invalidate a treaty or agreement between states to the extent of the incompatibility with any such principles or norms[977].

The latter kinds of norms ground on the existence of an *opinion iuris* which acceptance is broader than ordinary international customs and which aim is to protect fundamental values of the international community and the human being. This is the reason *ius cogens* norms refer to the safeguarding of peace, and *inter alia* the prohibition against crimes against humanity, genocide and *gross violations* of human rights[978]. The violation of such norms *shocks the conscience of humankind* and *ius cogens* is thus binding regardless of protests, acknowledgment and acquiescence by States[979].

Lastly, the individualistic conception challenges the view that international personality of non-state actors depends upon State's recognition as presented in the *recognition conception.* Indeed, the international personality of the individual is not the result of the expressions of State will, since the individual is understood as a *priori subject* on the grounds of general principles establishing individuals to be the ultimate recipients of the law. Individuals, thus, *have certain fundamental rights a State and other individuals cannot interfere with*[980].

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[975] Lauterpacht, *International Law-The General Part*, 31.
[976] Ibidem 131.
[977] Vienna Convention on the Law of Treaties 1969, Article 53.
[978] Portmann*, Legal personality in International Law*, 262-263.
[979] C. Focarelli, *Diritto Internazionale,* Terza Edizione, CEDAM, 2016, 204.
[980] Portmann*, Legal personality in International Law*, 131.

2.4.1. Legal manifestations of the Individualistic Conception – (A) The Nuremberg judgment

The main manifestations of the individualistic conception in legal practice are identified in the Nuremberg judgment and in much of the human rights practice OF the ECHR[981]. In October 1946, the International Military Tribunal (IMT) applied the individualistic conception of international personality since twelve Nazi defendants were sentenced to death and seven to jail for committing international crimes under international law and not under municipal penal law[982].

The IMT was established as a result of the London Agreement signed by the Allied Powers (including France) for the Prosecution and Punishment of the Major War Criminals of the European Axis. In detail, the Charter of the International Military Tribunal, which was attached to the aforesaid agreement, defined the international crimes for which individuals could be brought before the Tribunal, namely crimes against peace (war of aggression), war crimes, and crimes against humanity[983].

The tribunal, however, faced a procedural and theoretical impasse. According to the principle of non-retroactivity, also referred to as *nullum crimen nulla poena sine lege*, no one can face criminal punishment except for a conduct that was specifically criminalized by predetermined law before such conduct took place[984]. The latter Latin maxim, which is the legal foundation of all domestic criminal systems and is enshrined in human rights instruments such as the ICCPR and ECHR[985], poses a prohibition against *ex post facto* criminal laws and its subsequent rule of non-retroactive application of penal laws and sanctions

The issue at stake was to determine whether the establishment of the IMT conferred

[981] As well as, in the Jurisprudence related to the Alien Tort Claims Act (ATCA).
[982] In re Goering and Others (International Military Tribunal at Nuremberg, Judgment), 41 AJIL 1947, 172–333, at 217). See also 13 Annual Digest and Reports of Public International Law Cases (ILR) 203, 208.
[983] Article 1 London Agreement of 8 August 1945. The Agreement is reproduced in AJIL Sup, 39 (1945), 257–58.
[984] A. Mokhtar, *Nullum Crimen, Nulla Poena Sine Lege: Aspects and Prospects,* Oxford University Press, 2005, 41.
[985] Respectively articles 15(2) and 7(2).

jurisdiction to try individuals for international crimes considered as such according to the Tribunal's Charter or whether such crimes were part of international law before the creation of the Tribunal. The former scenario entailed a violation of the non-retroactivity principle and an *ex post facto* criminal procedure, as opposed to the latter scenario which would comply with such principle since the crimes were already enshrined within the international legal framework at the time the offences occurred[986]. The question was mostly relevant in relation to the crime of aggressive war, for which the Tribunal considered mandatory to prove that international law had already envisaged individual responsibility for aggressive war at the time Nazis' unlawful conducts took place. In practice the Tribunal had to assess whether aggressive war had previously been banned in 1939 and whether such banning concerned individuals acting on behalf of States[987].

To this end, the Tribunal found that the Kellogg-Briand Pact of 1928, to which Germany was a party, had already established a prohibition of aggressive war not merely in terms of a *normal* international delict, but specifically in terms of an international crime. This understanding, however, did not derive directly from the Pact but was extracted from "*general principles of justice",* since in accordance with the Tribunal, aggressive war could lead only to *"inevitable and terrible consequences for the international community as a whole"*[988].

Once having identified the criminal provision prohibiting aggressive war, the Tribunal highlighted that its violation led to individual rather than to state responsibility[989]. Indeed, when the defendants presented the argument that international law prescribed obligations only upon states and not upon individuals, the Tribunal remarkably responded: *"That international law imposes duties and liabilities upon individuals as well as upon States has long been recognized […]. Crimes against international law are committed by men, not by abstract entities, and only by punishing individuals who*

[986] Mokhtar, *Nullum Crimen, Nulla Poena Sine Lege*, 52-53.
[987] In re Goering and Others (International Military Tribunal at Nuremberg, Judgment), 41 AJIL 1947, 172–333, at 217). See also 13 Annual Digest and Reports of Public International Law Cases (ILR) 203, 208.
[988] Ibidem 219.
[989] Ibidem

commit such crimes can the provisions of international law be enforced"[990]. Hence, in the eyes of the Tribunal, the crime of aggression was well established within the international framework and implied international responsibility of individuals and not of States. The arguments presented by the Tribunal concerning individual responsibility for the crime of aggression reflects the main features of the individualistic conception of international subjectivity. Indeed, the Tribunal referred to States as not being *"abstract entities"* in accordance with the individualistic conception understanding of the State as a corporate entity created by individuals[991].

Interestingly, the Tribunal did not tackle the issue of whether States had displayed their intention to confer international legal status to individuals with regard to international crimes, nor had the magistrates researched whether existed a customary norm to that end. Instead, the reasoning of the Tribunal grounded on the assumption that there must be individual responsibility for international crimes in order to make international law an effective legal system[992]. *This is in accordance with the individualistic view that there are fundamental international rights and duties binding upon every individual* (be they gouvernants or gouverne´s) *in the interest of individual freedom. Finally, the fact that the tribunal had recourse to general principles of justice in order to declare aggressive war an international crime reveals the same view on sources of international law as in the individualistic conception*[993].

In conclusion, the Nuremberg case demonstrates that in a specific branch of international law, namely criminal law, there is the assumption of the individual being an international subject; accordingly, international criminal law subsists because the

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[990] Ibidem 220.

[991] Portmann, *Legal personality in International Law*, 158.

[992] The International Law Commission was asked to formulate the principle related to individual responsibility. This task was first accomplished in 1950 and later codified in 1996 in the *Draft Code of Crimes against the Peace and Security of Mankind,* which article 2 states: *"The principle of individual responsibility and punishment for crimes under international law recognized at Nürnberg is the cornerstone of international criminal law. This principle is the enduring legacy of the Charter and the Judgment of the Nürnberg Tribunal which gives meaning to the prohibition of crimes under international law by ensuring that the individuals who commit such crimes incur responsibility and are liable to punishment".* Draft Code of Crimes against the Peace and Security of Mankind, UN Doc. A/51/10, YILC 1996-II(2), 19.

[993] Ibidem

individual is understood as the recipient of fundamental international norms in accordance with the individualistic conception of international subjectivity.

2.4.2. (B) The Human Rights practice within the European Court of Human Rights framework

International human rights law is often considered a direct manifestation of the individualistic conception of international personality, mainly in light of its scope and aim which places human beings at the center of the legal framework[994]. This consideration is in fact illustrated in the case law of multiple judicial and quasi-judicial systems such as, among others, the UN Human Rights Committee and the Inter-American Court of Human Rights[995]. This section, however, focuses purely on the jurisprudence of the European Court of Human Rights, since the reasoning behind the work of the Strasbourg Judges is a valuable example of how the theoretical implications of the individualistic conception have come into existence.

As a preliminary reflection, it is worth noting that it is not common for regional human rights tribunals to directly address matters of international personality. It is hence problematic to identify the features of the international legal status of individuals at first hand from the case law. Therefore, the key qualifications of the individualistic conception are here inferred from the broad reasoning behind the *Loizidou v. Turkey* case[996] and its following applications in the "European" jurisprudence.

Indeed, what can be deduced from the Court's argument in the *Loizidou v. Turkey* case is that the individual must be deemed an international subject in the European human rights framework due to the very nature of human rights representing constitutional

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[994] C. M. Vazquez, "Direct vs. Indirect Obligations of Corporations Under International Law", *Columbia Journal of Transnational Law* 43, 2005, 944.

[995] L. Caflisch and A. A. Cançado Trindade, "Les Conventions Américaine et Européenne des Droits de l'Homme et le Droit International Général", *RGDIP*, CVIII, 2004, 9-10.

[996] Loizidou v. Turkey I (Grand Chamber, Preliminary Objections, 1995), ECHR Series A No 310; Loizidou v. Turkey II (Grand Chamber, Merits), ECHR Reports 1996-VI.

norms of the international legal system[997].

The case of *Loizidou v. Turkey* concerned the alleged violations of different rights envisaged in the European Convention perpetrated by Turkey in the aftermath of the Turkish occupation of Northern Cyprus in 1974. In particular the case involved a Cypriot national named Ms Titina Loizidou who lived in Southern Cyprus and who was prohibited by Turkish authorities to have access to her property situated in the northern part of the island. On 19 March 1989, Ms Titina Loizidou was arrested by Turkish forces after having participated in a demonstration during which she crossed the border to Northern Cyprus. On 22 July after her release, Ms Loizidou and the government of Cyprus started proceedings against Turkey claiming that Turkey had violated Article 1 of Protocol No. 1 and numerous other norms of the European Convention on Human Rights[998].

On its side, Turkey preliminary objected the lack of jurisdiction of the ECHR to assess facts that that occurred outside Turkish boundaries. In fact, Turkey pointed out that in light of former article 25 (1) of the Convention, Turkey accepted the competence of the human rights system of protection of the Council of Europe only "*to allegations concerning acts or omissions of public authorities in Turkey performed within the boundaries of the territory to which the Constitution of the Republic of Turkey"*[999]. In this regard, the respondent State stressed that the facts occurred in the Northern Republic of Cyprus were not imputable to Turkey referring to a reservation presented on 28 January 1987 with the aim of excluding Northern Cyprus from the jurisdiction of the Court. The reservation was undoubtably still in force given that it had been renewed numerous times afterwards its submission[1000]. The legal issue that the Court had to tackle was whether the reservation filed by Turkey was permissible under specific provisions enshrined within the Convention, namely articles 25 and 46 of the latter. According to the Court the Convention could not be regarded as a typical

[997] Portmann, *Legal personality in International Law*, 172.
[998] Convention for the Protection of Human Rights and Fundamental Freedoms, 4 November 1950, 213 UNTS 222.
[999] Loizidou v. Turkey I (Grand Chamber, Preliminary Objections, 1995), ECHR Series A No 310; Loizidou v. Turkey II (Grand Chamber, Merits), ECHR Reports 1996-VI, par. 15.
[1000] Portmann, *Legal personality in International Law*, 168.

international agreement. Indeed, recalling an already presented statement, the Judges highlighted the special character of the Convention which *"unlike international treaties of the classic kind, the Convention comprises more than mere reciprocal engagements between Contracting States. It creates, over and above a network of mutual, bilateral undertakings, objective obligations which, in the words of the Preamble benefit from a* collective enforcement*"*[1001].

From this argument it follows that Articles 25 and 46 of the Convention are essential in conferring effectiveness to the entire human rights-protective system *since they delineate the responsibility of the Commission and Court to ensure the observance of the engagements undertaken by the High Contracting Parties*, bearing in mind *the special character of the Convention as a treaty for the collective enforcement of human rights and fundamental freedoms*[1002].

In the eyes of the Court, the object and purpose of the Convention is the protection of individual human beings. This means that its provisions have to be interpreted and applied in a such a manner to make its safeguards practical and effective. It follows that a reservation which hinders the proper application of the aforementioned two articles could render the entire system ineffective since the European Convention on Human Rights did not embody mere bilateral obligations, but rather represented *a constitutional instrument of European public order (ordre public)* intended for the protection of the human being[1003].

Accordingly, the reservation filed by Turkey in order to restrict the Court's jurisdiction, even if admissible under general international law, could not be considered acceptable in light of the special character of the European Convention on Human Rights, which required special considerations with respect to treaty interpretation[1004]. Thus, the Court, stressed the constitutional character of international human rights law, which is situated in the ov\\erall international legal system. As a result, according to the Judges human

[1001] Ireland v. United Kingdom (Judgment, 1976), ECHR Series A No 25, par. 239.
[1002] Loizidou v. Turkey I, par. 70 In addition, the rights envisaged in the Convention should so far as possible be interpreted in harmony with other rules of international law of which they form part.
[1003] Ibidem par. 75.
[1004] Ibidem para 89.

rights norms do not create a self-contained legal system nor a new legal order, rather such norms have to be regarded as constitutional norms protecting the individual within the framework of existing general international law.

In conclusion, though not addressing matters relating to international personality, the Court adopted the individualistic conception of international subjectivity mainly in light of both the style of the Courts' reasoning and the reference to certain expressions such as *constitutional norms*, *fundamental freedoms*. Furthermore, the unambiguous placement of the human being as the pivot of the entire European human rights system reflects the individualistic understanding of the individual as *a priori* subject of the international framework. As the Court pointed out in the *Al-Adsani* and *Bankovic* judgments, such international framework is thus perceived as able to provide the overall legal framework in which these constitutional norms for the protection of the individual are positioned[1005]. Accordingly, it can be inferred that the individual must be considered an international person in the European human rights system, mainly due to very nature of human rights which represent constitutional norms of the international legal framework[1006].

[1005] Al-Adsani v. The United Kingdom, 35763/97, Council of Europe: European Court of Human Rights, 21 November 2001, par. 55. Bankovic v. Belgium and others, par. 80

[1006] Wildhaber, Luzius, 'The European Convention on Human Rights and International Law', ICLQ, 56 (2007), 217–31, at 227

2.4.3. Individualistic Conception and Multinational companies

In light of the aforementioned arguments on the individualistic conception, it can be inferred that such conception on international personality provides scope for multinational corporations created under national law to be regarded as international legal subjects. Indeed, as international legal rights and obligations are conferred directly on human beings, *mutatis mutandis,* they can be applicable to corporations, as there are no logical reasons precluding analogy with individuals[1007].

Grounding on the theoretical assumptions of the individualistic conception, corporations are in fact associations of individuals and as such are conceptually equal to individuals. As some scholars have pointed out, national courts have treated corporations as mere groups of persons under the consideration that "*what is illegal for one individual to do should be equally illegal for a group of them, even when this group is formed to make a profit*"[1008]. The same was inferred by the US Supreme Court which in the *Citizens United v Federal Election Commission* case held that freedom of speech provisions extend to corporations in the same manner as the First amendment protects individuals, even though such corporations are not natural persons[1009].

There are a number of considerations upon which the academia supported the view that multinational corporations can be directly bound by norms of international human rights law, which, in fact ground on the reasoning behind the individualistic conception. The point of departure of such considerations is the opinion that the Universal Declaration of Human Rights (UDHR), as provided for within its preamble, targets "*all organs of society"*, thus addressing companies as well. Accordingly, human rights obligations envisaged in the UDHR are legally binding for companies as are binding for any other *organ* in *society*[1010]. Undoubted, the UDHR is the most commonly

[1007] Portmann*, Legal personality in International Law*, 274.
[1008] J. Alvarez, "Are Corporations "Subjects" of International law?", *Santa Clara Journal of International law*, 2011, 4.
[1009] Citizens United v Federal Election Commission, 558 US 310 (Su Ct, 2010).
[1010] Universal Declaration of Human Rights, G.A. Res. 217(III) A, U.N. Doc. A/Res/217(III) (Dec. 10, 1948).

recognized benchmark in order to identify relevant human rights norms [1011]. Nonetheless, as some scholars have highlighted, both the Declaration peculiar legal status as a *soft law* instrument and the fact that the preambles of international agreements are not binding on the parties have the effect that the source of such norms as well as the conditions for their application are embodied elsewhere, beyond and outside the Declaration [1012]. Under human rights law the view that multinational corporations have legal personality equivalent to that of individuals is, in fact, desirable [1013]. There is a great number of scholars who welcome the argument of acknowledging corporate rights under international Human Rights law[1014]. One logical implication of recognizing such corporate rights would be beneficial, mainly in terms of enhancing the commitment and acceptance of human rights and subsequent responsibilities for multinational companies[1015]. Such recognition would result in the effective use of existing mechanisms with the aim of bolstering companies' responsibility and accountability for human rights, without the need of creating new legal mechanisms [1016]. Accordingly, some scholars have noted that the option of establishing direct obligations on corporations is desirable, since monitoring procedures such as that of the Human Rights Council might be applicable to such entities. In the same manner, the jurisdiction of the Rome Statute could theoretically be extended in order to recognize companies as legal persons next to individuals. Similarly, domestic norms, such as the *Alien Tort Claim Act*, could be used by alleged victims in order to assess corporate conducts, in cases in which a corporation has perpetrated *direct* violations of customary international human rights law[1017].

[1011] T. Wood, "Reinforcing Participatory Governance Through International Human Rights Obligations of Political Parties", 28 *Harvard Human Rights Journal*, 2015, 160.
[1012] Adam McBeth, *Every Organ of Society: The Responsibility of Non-State Actors for the Realization of Human Rights* 30 Journal of Public Law and Policy 33, 64 (2008-2009), 53.
[1013] Wood, *Reinforcing Participatory Governance Through International Human*, 161.
[1014] Alvarez, *Are Corporations "Subjects" of International law?*, 7.
[1015] G. Ku. Julian, "The Limits of Corporate Rights Under International law", 12 *Chicago Journal of International law*, 2012, 737-738.
[1016] J.H. Knox, *The Ruggie Rules: Applying Human Rights Law to Corporations, The UN Guiding Principles on Business and Human Rights*, Radu Mares ed, Wake Forest Univ. Legal Studies, 2012, 12.
[1017] Ibidem

2.5.The Formal Conception

Hans Kelsen is the founder of the formal conception which was developed as part of his pure theory of law[1018]. Other scholars such as Julio A. Barberis and D.P. O' Connell have embraced, with some minor addenda, such conception in their works[1019]. The core legal displays of this conception are, among others, the *LaGrand* and *Avena* pronouncements of the ICJ, mixed cases under Bilateral Investment Treaties and human rights treaties in general.

In light of the formal conception, there is no presumption related to the international status of a particular entity, given that both international personality as well as the international legal system are understood a completely open concept. Accordingly, there are no pre-established suppositions related to which entities have international legal subjectivity in international law. International personality is thus an *a posteriori* concept: in practice, any entity which is the recipient of an international norm (right or duty) is, thus, an international subject. As a result, legal persons are simple legal creations established as a consequence of an international norm creating and targeting them.

In this regard, Portmann added that, in theory, there are no direct legal implications connected with holding the status of international persons since *inter alia,* according to the formal conception, the ability to create international law does not stem from enjoying the status of international subject[1020].

Under the aforementioned conception there are no restrictions as to which entities can be international subjects. In this respect, scholars such as Kelsen emphasized that: *"in considering the scope of international law, it is necessary to ask for which subjects this order is valid for, to whom it is addressed, i.e. which subjects it regulates the conduct, rights and duties of. We will have to show that in this respect the validity of*

[1018] H. Kelsen, "Théorie Générale du Droit International Public", *RCADI*, 42 (1932-IV), 121-351.
[1019] J. A. Barberis, 'Nouvelles Questions Conçernant la Personnalité Juridique Internationale', *RCADI*, 179 (1983-I), 145-304 and O'Connell, D., 'La Personnalité en Droit International', RGDIP, 34 (1963), 5-43.
[1020] Portmann, *Legal personality in International Law*, 173.

international law knows no limits"[1021].

Therefore, the formal conception refutes that legal subjectivity is an *a priori* concept and on the contrary, regards it as *a posteriori* legal construction. Such subjectivity is in fact not deemed as a notion belonging to positive law. Conversely, being considered an international subject is regarded as the result of a descriptive process belonging to the realm of legal theory and, as such, is without tangible legal effects[1022]: being an international subject thus merely mirrors the sum of legal norms addressing a certain entity[1023].

International norms determine their recipients and, as such, their legal persons lead to the conclusion that provided that the interpretation of a norm results in addressing the conduct of a particular entity, this entity is an international person[1024]. Interestingly, Kelsen emphasized that international norms, in the same manner as all legal rules, are basically aimed at addressing the conduct of human beings. That is the reason that all international norms are ultimately targeted at individuals and *the only social reality to which legal norms can refer are he relations between human beings. Hence, a legal obligation as well as a legal right cannon have for its contents anything but the behavior of human beings. If, then, international law should not obligate and authorize individuals, the obligations and rights stipulated by international law would have no contents at all and international law would not oblige or authorize anybody to do anything*[1025]. According to Kelsen, the traditional idea that only States are subjects of international law and that the latter law is incapable of regulating the conduct of individuals is, thus, inaccurate[1026]. This allows to the deduction that such conception discards traditional notions of Statehood and the hierarchical superiority of States to law. States are perceived as *juristic persons,* which are a combination of individuals acting as organs on behalf of them.

Notwithstanding, the latter assumption does not entail that, under the formal conception,

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[1021] Kelsen, *Théorie Générale du Droit International Public*, 141.
[1022] Portmann*, Legal personality in International Law*, 174.
[1023] Barberis, *Nouvelles Questions Conçernant la Personnalité Juridique*, 169.
[1024] Portmann*, Legal personality in International Law*, 174.
[1025] H. Kelsen*, General Theory of Law and State*, Harvard University Press, 1945, 343.
[1026] Ibidem

only individuals are international subjects. Indeed, it is evident that international norms are often referred to individuals indirectly as organs of collective organizations, namely States and not as private entities. In such a scenario, states and other corporate bodies such as international organizations do become international subjects, since the relevant international norm is oriented to an individual who acts on behalf of the corporate body of which is an organ and not to the individual itself[1027]. Remarkably, every domestic system determine which individual has the power to act on behalf of the State and accordingly who is the ultimate addressee of the international norm[1028].

Furthermore, under the formal conception individuals can also be direct recipients of international norms and not merely indirect addressee as organs of collective organizations. *This is the case when their conduct is regulated by international norms in matters not attributable to a corporate entity according to the national legal system*[1029].

In addition, in light of the aforementioned conception, being an international subject does not have any auxiliary legal implications outside those specifically provided within the relevant norms. This entails that fundamental rights and duties or certain capacities do not depend on the concept of legal personality in the abstract. On the contrary all these powers and competences stem from particular international norms which specifically address the relevant subject[1030]. In sum, an entity is an international person because it is a subject of international rights and duties[1031].

In the same manner, international norms are those that confer upon social entities the power to create international law. Law creation is, thus, not a consequence of being an international person, but it is only by means of customary international norms that individuals, as organs of states, acquired the competence to create such law[1032]. As a

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[1027] Ibidem
[1028] Ibidem
[1029] Portmann, *Legal personality in International Law*, 175.
[1030] Barberis, *Nouvelles Questions Conçernant la Personnalité Juridique Internationale*, 170.
[1031] Kelsen, *General Theory of Law and State,* 250.
[1032] It is worth noting that the formal conception regards intenational custom *as law emerging from general use among competent organs* and as such generally pertinent in international relations and does not regard it as a tacit treaty. Accordingly, general customary law provides norms which establish that states have the power to create law by adopting international treaties. Customary law is thus intended to

result, law-creation merely regards the application of a hierarchically higher norm allowing a particular entity to create law, making the distinction between law-creation and law-application basically inoperative under the formal conception[1033].

2.5.1. Legal manifestations of the Formal Conception in practice – the *LaGrand Case*

In legal practice the formal conception of international personality is mainly relevant when the direct effect of treaties on individuals, and corporations within the international investment law framework, is at stake. Such conception has been the theoretical foundation of the LaGrand and Avena case and, in general when individual treaty rights had to be applied. The present section focuses only on the analysis of the LaGrand Judgment in light of the aforesaid theoretical considerations regarding the formal conception.

Certainly, the *LaGrand case* constitutes the steering contemporary case regarding the direct effect of treaties on individuals[1034]. As opposed to the aforesaid Courts of Danzig advisory opinion, in *LaGrand* the ICJ explicitly embraced the argument that an international treaty norm can create individual rights[1035]. Some scholars have interpreted the case reasoning as the conceptual foundation to confer the individual the status of international person[1036], although the decision entirely referred to Article 36(1)(b) of the Vienna Convention on Consular Relations (VCCR) and did not hold any assumption with respect to international personality[1037]. The case was brought to the attention of the ICJ under rather uncommon situations toward the end of numerous sets of judicial proceedings in the United States. Without going into the merits, the case

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be effective regardless of who participated in its creation.

[1033] Ibidem

[1034] LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466.

[1035] In the case, the ICJ referred to Article 36(1)(b) of the Vienna Convention on Consular Relations (VCCR). LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466, par. 77.

[1036] Gaja, Giorgio (Special Rapporteur), First Report on responsibility of international organizations, ILC 2003, UN Doc. A/CN.4/532, par. 17

[1037] Portmann, *Legal personality in International Law*, 197.

before the American Courts concerned the sentence to death of two German nationals, namely the LaGrand brothers. In that case, the ICJ found that the United States had violated Article 36 of the Vienna Convention of 24 April 1963 on Consular Relations in light of two main reasons[1038]: firstly, the US did not inform the two German citizens about their right to consular assistance under the aforesaid conventional text; secondly, the US did not allow the review and revision of the verdict delivered against the LaGrand brothers, once the violation of the previous obligation had been acknowledged[1039]. As a result, the Court explicitly recognized that the 1963 Vienna Convention, pursuant its Article 36, created rights not only for the State but for individuals who benefited from consular assistance as well. Therefore, the violations that had taken place were not only against the German State but also against the LaGrand brothers[1040]. This means that under modern international law individual rights do not solely derive from human rights treaties, but are a universal phenomenon that can concern any kind of international agreement. The same argument was proposed by the Inter-American Court of Human Rights (IACHR) in its Advisory Opinion of 1999 on the right to consular assistance[1041]. Remarkably, the IACHR took the reasoning on the right at stake one step ahead by emphasizing the human right status of the individual right to consular assistance, which according to the Court cannot be subject by the protests of the sending State nor hindered by the State's will to exercise such right[1042]. Nevertheless, the ICJ avoided to tackle the issue of whether Article 36 of the VCCR was also to be considered a human right, therby cautiously dodging a tricky politicization of the decision[1043].The Court in fact merely focused on the text of Article

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[1038] Tams, Christian J., *Consular Assistance: Rights, Remedies, and Responsibility Comments on the ICJ's Judgment in the LaGrand Case*. European Journal of International Law, Vol. 13, 2002, 1257.
[1039] In addition, it is worth noting that the ICJ affirms for the first time the value of the ordinances indicating provisional measures, which resulted in the responsibility of the United States for non-compliance with the Court's Ruling of March 3, 1999. *"The Court will now consider the Order of 3 March 1999. This Order was not a mere exhortation. It had been adopted pursuant to Article 41 of the Statute. This Order was consequently binding in character and created a legal obligation for the United States"*. LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466, par. 110.
[1040] LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466, par. 85.
[1041] Inter-American Court of Human Rigths, Advisory Opinion OC-16/99
[1042] Ibidem, 65.
[1043] Tams, *Consular Assistance,* 1257.

36(1)(b) VCCR in light of the interpretative framework provided for by Article 31 of the Vienna Convention on the Law of Treaties in order to assess whether Article 36 could apply to individuals. According to the Court, the text of the aforesaid Article itself was sufficiently explicit in recognizing specific individual rights, resulting in a self-winding application of the provisions *"as they stand"*[1044]. Yet, it is noteworthy to highlight that the Judgment at stake did not address the issue of direct effects of treaties on individuals, but of treaty interpretation in general[1045]. On the grounds of such reasoning, the Court concluded that the direct effect of treaties on individuals depended on the treaty provisions itself and in particular on the clarity of such provisions[1046].

In conclusion, the reasoning of the ICJ in the LaGrand case is a clear demonstration of the formal conception of international personality. In light of the aforementioned considerations on such conception, the Court "complied" with the formal approach by solely focusing on the treaty norm in question in order to assessing both the identity of the real recipient of such norm and whether the treaty attributed direct international rights to individuals. "*Without even mentioning the concept of international personality, the Court stated that Article 36(1)(b) VCCR directly applies to individuals. International personality is then only a device of legal doctrine to conceptualize the fact that the individual holds a direct international right, but no legal concept stating any material presumptions or consequences. This clearly is in conformity with the formal conception of international personality"*[1047].

[1044] LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466, par. 92.
[1045] Portmann, *Legal personality in International Law*, 200.
[1046] *"Based on the text of these provisions, the Court concludes that Article 36, paragraph 1, creates individual rights, which, by virtue of Article 1 of the Optional Protocol, may be invoked in this Court by the national State of the detained person. These rights were violated in the present case"*. LaGrand Case (Germany v. United States), Judgment, 2001 ICJ Reports 466, para 77.
[1047] Portmann, *Legal personality in International Law*, 203.

2.5.2. The Formal Conception and Transnational Corporations

Having presented the key assumptions of the formal conception, it is now interesting to observe whether such considerations allow the view that multinational corporations can be regarded as international persons under such conception and, thus, be the ultimate addressees of rights and duties.

The formal conception grounds on the assumption that international personality is an open concept. This consideration allows, at least theoretically, that multinational corporations can be treated as international legal subjects. The reasoning behind international personality in the formal conception depends on the existence of a norm the specifically address an entity. This means that the legal personality of multinational corporations can be determined on the basis of the assessment of the rights, duties or capacities that international norms have attributed to such entities. In such a scenario, international personality is attained *a posteriori* to the international legal framework making legal subjectivity nothing more than a descriptive tool[1048].

Even though individuals are the original recipients of the norm, such norm can be ascribed to corporations on the basis that those individuals are addressed in their role and function of organs of the latter corporation. As a result, the scope and extent of legal personality cannot be determined *a priori*, but rather under a case by case analysis of the relevant norms imputed to corporations.

Clapham is a one of the scholars who seemed to have accepted the basic assumptions of the formal conception. Remarkably, he endeavored to divert the discussion towards issues related to capacity and discrete obligations[1049] with the aim at going one step ahead the quarrels on whether multinational corporations are primary or secondary subjects of international law[1050]. According to Clapham, an adequate manner to tackle

[1048] Ibidem

[1049] Clapham*, Human Rights Obligations of Non-State Actors,* 78.

[1050] A. Cassese, *International Law in a Divided World*, Oxford Univ Press, 1986, 103. Many scholars and Cassese in particular have presented the demarcation between States as primary subjects of international law on the one hand and all other non-state actors as secondary subjects on the other. According to Cassese when it comes to multinational corporations: *"Socialist countries are politically opposed to them and the majority of developing countries are suspicious of their power; both groups*

the issue at stake is to put aside the concerns on primary and secondary subjects of law and simply emphasizes that corporations have limited international legal personality[1051]. *"As long as we admit that individuals have rights and duties under customary international law and international humanitarian law, we have to admit that legal persons may also possess the international legal personality necessary to enjoy some of these rights, and conversely to be prosecuted or held accountable for violations of the relevant duties"*[1052]. The scholar argued that international rights and duties are subject to the capacity of the entity to enjoy such rights and abide those obligations as provided by the relevant international norm and not on the riddle of international personality[1053]. In this regard, there is no doubt about the existence of specific norms that address directly non-State actors, even when such actors have no state-like characteristics or pretensions[1054].

Accordingly, Clapham suggests a two-question model, as presented in the *Reparation for Injuries Advisory Opinion* of 1949, in order to assess whether or not a non-State actor enjoys the status of international personality. Firstly, the author asks whether the entity has the necessary legal capacity to directly acquire rights and obligations under international law. Secondly, Clapham questions whether the entity has the capacity to be party to a claim (either as a claimant or as a defendant) at the international level [1055]. If the answer to both the aforesaid questions is positive, the entity can be regarded as an international subject.

In practice the aforementioned two-question model constitutes the tool used by many scholars in order to assess the international legal personality of multinational

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will never allow them to play an autonomous role in international affairs. Even Western countries are reluctant to grant them international standing; they prefer to keep them under their control—of course, to the extent that this is possible. It follows that multinational corporations possess no international rights and duties: they are only subjects of municipal and 'transnational law'".

In this regard, Clapham argues the opportunity to challenge this reasoning and thus change the focus of the debate outside the aforementioned distinction in order to tackle new issues concerning the current global situation.

[1051] Clapham, *Human Rights Obligations of Non-State Actors*, 77-80.

[1052] Ibidem 79.

[1053] Ibidem 71.

[1054] Ibidem 80.

[1055] Ibidem 71.

corporations[1056]. Accordingly, if such corporations are the addressee of international rights and obligations norms and/or have a capacity to start international proceeding, then they are international persons[1057]. This is the case in the realm of two specific areas of international law: human rights law, under specific treaty provisions, such as the case of the European Convention on Human Rights[1058]; and international investment law, under those detailed provisions provided by relevant investment treaties[1059]. Hence, corporations enjoy limited international personality pursuant to specific treaties and conventions, and not automatically through customary international law. In the view of Ku, such corporations are the recipients of a *specific textual authorization in a particular treaty or convention,* turning the reasoning to conclude that corporations can be acknowledged subjects of international customary norms unsatisfactory[1060].

In conclusion, Clapham suggests that since multinational corporations have limited, but still acceptable international personality in order to enjoy rights and bring claims under international human rights law, they can also be acknowledged as to have adequate faculty to abide international human rights obligations. As highlighted by the author, if entity such as the Sunday Times[1061] has sufficient capacity to enjoy rights and start international proceedings in light of the European Convention on Human Rights[1062], *it might surely have enough personality and capacity to be subject to duties under International Human Rights law*[1063].

[1056] See counter argument by Gatto, according to which corporations are in fact an *anomaly* since as opposed to other new subjects of international law, *their progressive acquisition of rights has not been matched by a similar acquisition of duties*. Gatto Alexandra, *Multinational enterprises and human rights obligations under EU law and international law*, Edward Elgar, 2011, 53.

[1057] Wouters, Jan and Chané, Anna-Luise, *Multinational Corporations in International Law* (December 1, 2013). KU Leuven Working Paper No. 129, 3. Reparation for Injuries Suffered in the Service of the United Nations (Advisory Opinion) [1949] ICJ Rep 174.

[1058] For example, Right to a fair trial Article 6 and Freedom of Expression Article 10.

[1059] For example, the Amco v. Indonesia under the Convention on the Settlement of Investment Disputes (ICSID) and numerous bilateral investment treaties.

[1060] Julian G. Ku, *The Limits of Corporate Rights Under International law*, 12 Chicago Journal of International law, 2012, 730.

[1061] Sunday Times v United Kingdom, Judgment, App No 6538/74, A/30, [1979] ECHR 1, (1979-80) 2 EHRR 245, (1979) 76 LSG 328, IHRL 21 (ECHR 1979), 26th April 1979, European Court of Human Rights [ECHR]

[1062] Clapham, *Human Rights Obligations of Non-State Actors*, 81.

[1063] Ibidem, 82.

Differently stated, the faculty of multinational corporations to be the recipients, and thus the holders, of international rights seems to infer that such corporations have international legal subjectivity, and accordingly that they can also abide international obligations. This reasoning leads to the conclusion that since corporations already enjoy international, albeit limited, personality nothing stands in the way for ascribing international human rights obligations on multinationals.

2.6. The Actor Conception

Some of the basic features of the *actor conception* have been presented previously in the introductory part of this section concerning the theories on international personality. Briefly stated, this conception perceives as international subjects all the entities which exercise effective power within the international decision-making process[1064].

Remarkably, in light of the factual nature of such conception, the concept and notion of international personality are not taken into account; and the terms *actor* or *participant* are indeed favored. Basically, the concept of participant has the same practical usage of the concept of international personality; and in fact it is often used in this very manner. References to the status of specific participants as subjects of international law are frequently employed, mainly in order to identify and describe which social entities are relevant to international law[1065].

The genesis of the actor conception has to be inferred from the joint efforts of McDougal and Lasswell[1066], who had originally posited the theoretical grounds of such conception, and its further development by former ICJ president Ms. Higgins[1067]. It is worth noting that Lasswell was a sociologist, thus explaining the functional nature of

[1064] Portmann, *Legal personality in International Law*, 208.
[1065] Ibidem
[1066] McDougal, Myers S., 'International Law, Power, and Policy: A Contemporary Conception', RCADI, 82 (1953-I), 133–259 and 160-162.
[1067] R. Higgins, "Conceptual Thinking about the Individual in International Law" in Richard Falk, Friedrich Kratochwil and S. H. Mendlovitz, *International Law: A Contemporary Perspective* ,Westview Press, 1985, 479.

this policy-oriented approach to international personality which considers the dichotomy between subjects and mere objects of international law as basically fallacious[1068]. *Subjects* are perceived as carriers of the elements of personhood and as having been acknowledged as such by a norm of international law. On the contrary, *objects* of international law are defined by elimination: any entity which is not a *subject,* is hence an *object*[1069]. The aforesaid dichotomy surely eases in providing the entire international legal system with both simplicity and structural clarity. Nonetheless, according to some scholars, this distinction between subjects and objects seems simplistic rather than simple and clear. Indeed, such view fails to represent the current international situation and does not take into account the legally relevant detail that non-State actors are fully present within the international scene, as opposed to what the term *object* of international law refers. In order to move ahead from such outdated and non-realistic view of personhood, the actor conception departs from the common understanding of international law as a set of rules[1070] and proposes the view that such law should be considered as an authoritative *decision-making process*[1071]. This dynamic view of the international system, as a process, allows the consideration and inclusion of *a variety of participants, making claims across State lines, with the object of maximizing various values*. *Determinations will be made on those claims by various authoritative decision-makers – Foreign Office Legal Advisers, arbitral tribunals, courts. Now, in this model, there are no 'subjects' or 'objects', but only participants. Individuals are participants along with States, international organizations (such as the United Nations, or the IMF, or the ILO), multinational corporations, and indeed private*

[1068] Portmann*, Legal personality in International Law*, 210.
[1069] R. Higgins, *Problems and process: International law and how we use it,* Clarendon Press, 1994, 49.
[1070] Such view of the international legal system relies on pragmatic assumptions which take into account mainly practical aspects of specific problems, leaving formal considerations aside. In this scenario, policy rationales as the outcome of this decision-making process are promptly preferred over norms. To this end, Portmann, highlights that such view clashes with the acceptance in international practice and doctrine of general and indeed peremptory norms. In fact, peremptory norms, as stated above, are not open for negotiation and most importantly they may not be derogated from, regardless of whether there are policies standing against them.
[1071] McDougal, Myers S., Harold D. Lasswell and Lung-chu Chen, *Human Rights and World Public Order: The Basic Policies of an International Law of Human Dignity*, Yale University Press, 1980, 162.

nongovernmental groups[1072]. Simply stated, under this conception all participants in the international legal system are international subjects. This approach seems consistent with Morgenthau's functional understanding on international law, which was based entirely on psychological and sociological elements and according to which a norm was significant only if had effect in practice. Accordingly, the observation of the actual international realm was a mandatory step in order to determine the normative content of the international order[1073].

The entire conception grounds on the idea that there is no norm providing the legal capacity to an entity in order to engage in this process. This implies that the participation in such *decision-making process* depends only on factual power and all of the actors actually involved are participants of the international legal order regardless of the cause for participation[1074]. Accordingly, international legal practitioners and scholars do not have to identify particular rules or formal acts of recognition by States in order to assess the legal status of a particular entity, but rather they have to detect which actors participated in the *decision-making process* in practice[1075]. Stated differently, neither the lack of legal rules conferring legal personality nor the absence of an act of recognition by States has any noteworthiness in conferring legal personality to non-States actors in international law. In conclusion, the actor conception can be summarized as follows: international law is not a set of rules, but an authoritative decision-making process to which participation does not rely on legal rules or specific acts of recognition, but on the effective power and ability to participate.

[1072] R. Higgins, *International Law and the Avoidance, Containment and Resolution of Disputes: General Course on Public International Law*, RCADI, 230, 1991-V, 81.

[1073] Such understanding of international law is often referred to as international realism. Morgenthau, Hans J., *La Réalité des Normes, en Particulier des Normes du Droit International: Fondements d'une The´orie des Normes*, Librairie Felix Alcan, 1934, 8.

[1074] Roland Portmann*, Legal personality in International Law*, Cambridge University Press, 2010, 212.

[1075] R. Higgins, *International Law and the Avoidance, Containment and Resolution of Disputes: General Course on Public International Law*, RCADI, 230 (1991-V), 80.

2.6.1 The Actor Conception and Transnational Corporations

The literature review, assumptions that have been presented throughout the section, and the current global situation propose that, under the actor conception, multinational corporations have all the requirements to be *participants* of the international community like any other actor.

It is certain that multinationals actively participate to the aforesaid authoritative *decision-making process*, along with States, international organizations and private actors. This implies that observation is required in order to assess the legal status of multinationals, their concrete participation in such decision-making processes and thus their *de facto power* to influence the international agenda.

In the same manner, in order to determine the exact content of a norm that enshrines duties and responsibilities of corporations, under the actor conception assessment is needed in order to determine whether the core of such norm deploys full effects in practice and has the ability to condition actual behavior.

The traditional positivists distinction between subjects and objects of international law seems anachronistic and, thus, unable to properly address the needs of modern society. In fact, the subject/object dichotomy fails to recognize three main factual considerations: firstly, multinational corporations actively participate in international conferences and *fora,* such as the multiple diplomatic meetings that led to the adoption of the TRIPS agreement[1076]. Secondly, lobbying by such corporations has become a typical practice especially when enormous economic and political interests are involved. Their economic might impacts and significantly influences the international agenda in such a manner as to orient international policies and objectives, even at the United Nations. Lastly, corporations have taken over central provision of services which were previously of State competence, such as, among others, the supply of running water and the establishment of healthcare structures.

For all the above, the role that corporations have come to exercise in the international

[1076] R. Smith, C. Correa and C. Oh, *Trade, TRIPS, and pharmaceuticals*, Lancet, 2008, 685.

community over the last few decades is evident and massive[1077]. Accordingly, the identification of corporations as mere *objects* of international law seems, to say the least, static, inadequate and insensitive to changes in international legal sphere [1078]. In this regard, Higgins argues that corporations should be considered *at minimum participants in the international legal system, with the capacity to bear some rights and duties under international law*[1079].

According to Higgins, business enterprises can be considered participants in international law 'making claims across State lines, with the object of maximizing various values'[1080].

Other scholars such as Ruggie shared this argument, highlighting that both the international framework and contemporary international law have become much more intricate[1081]. Indeed, the acknowledgement of corporations as participants rather than subjects mirrors the current state of affairs as corporations are further and further involved in the making of international law. In particular, as has been briefly mentioned above, their participation is key in the establishment of international investment law as a result of investor-State adjudications[1082].

Other scholars have supported the view that considering the degree to which international law distinguishes the existence of diverse kinds of participants in the international legal framework constitutes a much more useful method than that of adopting the subject/object approach[1083].

In light of current events, referring to a *corporate entity as "subject" or "object" of international law confuses more than enlightens* and debating on whether business enterprises are subject or legal persons is *at best a distraction and that affirmative*

[1077]Zerk, *Multinationals and corporate social responsibility,* 74.
[1078]Higgins, *Problems and process*, 50.
[1079] J. Ruggie, *Business and Human Rights: The Evolving International Agenda,* 20 (John F. Kennedy School of Government, Corporate Social Responsibility Initiative Working Paper No. 31, 2007), 32.
[1080] Higgins, *Problem and Process,* 51.
[1081] Ibidem
[1082] J. Alvarez, *Are Corporations "Subjects" of International law,* 9.
[1083] *"The idea of multinationals as 'participants' in the international system provides a much more realistic picture of the role of private commercial organizations within the international system than the traditional 'subject--object' dichotomy".* Zerk, *Multinationals and Corporate Social Responsibility*, 74.

decisions to this effect may be a very bad idea[1084]. Accordingly, some scholars propose, in line with the actor conception, that norms should be meaningful under existing realities in order to actually impact and influence behavior. This is the reason such scholars challenge the so called top-down approach to human rights[1085], especially when determining which obligations apply to corporations. According to this part of the literature: *"In any case, such a top down approach to finding international corporate obligations is precisely the wrong way to figure out what obligations make sense or reflect what the principal makers of international law, namely states, actually want. Most importantly, such a top down approach loses sight of the ways that corporations are distinct from states or natural persons. It makes it more difficult to contextualize corporate obligations in light of these realities"*[1086].

A case by case approach ought to be adopted when determining specific obligations on corporations and their role and capacities vis-à-vis States as *profit-creating actors* cannot be ignored[1087]. In practice, corporations greatly differ from both States and individuals, which implies that the theoretical implications of both the state-only and the individualistic conception are thus superfluous and ineffective in determining the accountability and responsibilities of corporations[1088].

Remarkably, under the actor conception there are not real legal consequences on corporations as a result of their acknowledgment as legal persons, since such status has been considered a mere social construct with slight practical effect. Theoretically, such status can provide the legal grounds for stemming human rights and obligations, but no real legal outcome must automatically derive from such conferral. No matter how judicial organisms such as the International Court of Justice and the International Tribunal for the former Yugoslavia have tackled the issue of subject and personality in

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[1084] Ibidem, 3.

[1085] According to the top-down approach, human rights and respective obligations depend on the principle or principle from which they are said to be derivable and their social use is not taken into account. J. Griffin, *On Human Rights,* Oxford University Press, 2008, 29.

[1086] Alvarez, *Are Corporations "Subjects" of International law,* 25.

[1087] M. Pentikäinen, "Changing International 'Subjectivity' and Rights and Obligations under International law – Status of Corporations", *8 Utrecht Law Review* 145, 2012, 153.

[1088] Alvarez, *Are Corporations "Subjects" of International law*, 26.

their decisions, *this can only represent an ad hoc declaration of the situation rather than a constitutive act creating personality*[1089]. To report the words of Klabbers: *"After all is said and done, personality in international law, like "subjectivity", is but a descriptive notion: useful to describe a state of affairs, but normatively empty, as neither rights nor obligations flow automatically from a grant of personality*[1090]*"*.

In conclusion, the actor conception presents valuable assumptions which mirror the current state of affairs of the international realm. Firstly, in light of the peculiar status of multinational corporations considering them as participants rather than subjects/objects reflects their international relevance and factual power to take part in authoritative decision-making processes. Secondly, even though the acts of recognition of international personality are vain for corporations to exist as international legal subjects, such recognition, however, reinforces the status of multinationals as participants in the international decision-making process. Thirdly, even in light of the classical approach to personality[1091], some scholars have pointed out that there is more and more acknowledgement of considering corporations as subjects under international law, since they do hold rights under international law, some of which may be enforced directly, for example pursuant to treaty-based dispute resolution procedures; secondly, they do participate in law making mechanisms such as diplomatic conferences; thirdly, they to possess *locus standi* before international tribunals. For all of the above, a case by case approach seems beneficial in order to assess the factual participation of corporations to the international *lige* and, thus, to this direction it can be concluded that they surely hold some degree of international legal personality.

[1089] L. Boisson De Chazournes and M. Gustavo Kohen, *International Law and the Quest for Its Implementation*, Martinus Nijhoff Publishers, 2010, 48.

[1090] J. Klabbers*, An Introduction to International Institutional Law,* Cambridge University Press, 2002, 57.

[1091] According to which a legal person is the entity which holds *"the ability to participate in the development of international law through custom, the capacity to enter into international treaties, the prospect of direct legal responsibility for breaches of obligations and the ability to bring legal claims".*

3. Corporate Social Responsibility (CSR) under International Law

The difficulties in providing an adequate understanding of what multinational corporations are and their status under international law resulted in decades of debates over which legal standards might apply to multinationals and on their relevance to human rights norms. In addition, concerns arose on the consideration that such actors are actually capable of operating outside State's control and regulations, and thus are able to act in so-called "grey zones". Accordingly, the most important task is to ensure that the desire for profit from corporations does not allow corporate human rights abuses as well as to find effective mechanisms to impose norms bearing duties upon these peculiar and powerful actors.

The preceding sections have followed two lines of argumentation. The first part of this chapter emphasized the role played by multinational corporations in the present-day world, mostly focusing on the consequences of social, political and economic globalization. A legal definition of such corporations was provided, taking into account the most relevant literature and approach adopted in international organizations and *fora*.

The second part of the chapter focused on the analysis of traditional as well as unorthodox approaches on international legal personality of non-state actors in general and on corporations in particular. It was demonstrated that recent developments of the theoretical conceptions regarding legal personality are shifting the discourse about human rights protection towards the inclusion of non-State actors' responsibility and, thus, of corporations.

In light of the aforementioned considerations, the next logical step in the reasoning would be allowing a legal framework for the direct application of international human rights law to multinational corporations. Notwithstanding, the theoretical likelihood of this deduction needs now to be assessed on the grounds of the relevant practice within the international realm. Definitely, due to the peculiar nature of the international system, in which practice is decisive in both law-making processes as well as in understanding relations among states, simply ascertaining the theoretical direct applicability of

international human rights norms on corporations does not suffice[1092].

For this reason, the study and examination of relevant elements of practice of international actors become central in determining whether the theory has actually become reality. Simply stated, once displayed that there is a changing attitude towards holding corporations legally accountable for violations of international human rights, it is now time to analyze the practice from the main subjects of international law in order to be able, or not, to posit the emergence of a new custom of direct applicability of international human rights norms on corporations on the grounds of the existence of a *uniform pattern of thought and behavior*[1093].

In particular, three issues need to be addressed at this point: firstly, attempts towards the adoption of a binding instruments for corporations, such as *inter alia,* the *United Nations Code of Conduct on Transnational Corporations,* have been unsuccessful since the 1960s. Secondly, concerns arose regarding the unprecedented economic and political might of corporations and the perceived negative impact of their activities worldwide. Lastly, national legal frameworks, especially those of developing countries, proved their inability in monitoring multinationals which could then operate in a *de facto* regulatory *vacuum*. For all of the above, civil society raised awareness on this *regulatory vacuum* and called on corporations to assume greater governance responsibilities[1094]. These debates led to the so-called *corporate social responsibility* (CSR) of business enterprises, which refers to the voluntary commitment of such entities in order to address social and environmental issues in parallel to their natural goal of maximizing shareholders value and to make profits[1095]. Since the 1990s, the topic of corporate social responsibility (CSR) has gained momentum in both national

[1092] E. De Brabandere, "Human Rights and Transnational Corporations: The Limits of Direct Corporate Responsibility", 4 *Human Rights and International Legal Discourse*, 2010, 69.

[1093] S. Danailov, "The Accountability of Non-State Actors for Human Rights Violations: The Special Case of Transnational Corporations, 1998",
Available at: http://www.humanrights.ch/upload/pdf/000303_danailov_studie.pdf

[1094] K. Sauvant, "The Negotiations of the United Nations Code of Conduct on Transnational Corporations Experience and Lessons Learned"*, The journal of world investment & trade*, Brill Nijhoff, 2015, 22.

[1095] T. Gossling, *Corporate Social Responsibility and Business Performance*, Edward Elgar Publishing, 2011, 2-3.

and international policy programs and CSR is now employed in a wide range of social challenges, ranging from environmental sustainability to human rights and labor market issues[1096]. Nowadays, CSR constitutes an important item in the global corporate agenda and has increased its importance as an area of business practice and academic research.

3.1 Defining Corporate Social Responsibility in light of the relevant literature

Many scholars and practitioners have highlighted that CSR, as a notion, is unclear and frequently vaguely defined[1097]. This is mainly because since the 1950s, when the actual term was firstly employed as a management idea[1098], definitions of CSR often have varied depending on the various industry sectors and agenda taken into account. Such definitions, however, all grounded on the *voluntary* aspect of CSR which has seemed to distinguish between *"legislative standards and that additional activity which many businesses undertake anyway to add value to the business and build their reputation"*[1099].

According to current literature, CSR refers only to the aforementioned *additional activity* over and beyond legal requirements which also demonstrates the non-juridical link between corporations and sustainable development objectives[1100]. Generally speaking, CRS concerns the way corporations take into consideration their economic, social and environmental impacts with the aim at maximizing the benefits and minimizing the downsides[1101]. In other words, CSR refers to voluntary actions that corporations can carry out beyond compliance with minimum legal requirements in

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[1096] Jeanette Brejning, *Corporate Social Responsibility and the Welfare State- The Historical and Contemporary Role of CSR in the Mixed Economy of Welfare,* Ashgate, 2012, 1.
[1097] Zerk, *Multinationals and Corporate Social Responsibility,* 29.
[1098] R. Kasturi, *Business Solutions for the Global Poor: Creating Social and Economic Value*, Jossey-Bass, 2007, 209.
[1099] Zerk, *Multinationals and Corporate Social Responsibility,* 30.
[1100] M. Kerr, R. Janda and C. Pitts, *Corporate Social Responsibility: A Legal Analysis*, LexisNexis, 2009, 12-14.
[1101] Ibidem

order to address both their own economic competitive interests as well as the interests of the community[1102]. In this regard, CSR is often addressed as the result of the so-called PPP framework (*profit, people, planet)* which has the purpose of generating economic (profit), social (people), and environmental (planet) value while considering the whole set of issues and processes that companies shall voluntarily take into account in order to reduce any damage resulting from their actions[1103]. The PPP framework led to a general expectation from corporations to be profitable as well as socially and environmentally responsible in light of a more transparent, ethical and humane way of carrying out their businesses[1104]. This comprises being explicit about the corporation's goal while bearing in mind the needs of all the parties involved, such as shareholders, clients, personnel, business partners, governments, local societies, and the public in general[1105].

Likewise, the European Commission appears to understand CSR mainly as a voluntary activity. Nonetheless, the Commission's view includes compliance with the law as a key determinant of being socially responsible. In fact, in the words of the European body: *"Being socially responsible means not only fulfilling legal expectations, but also going beyond compliance and investing more into human capital, the environment and relations with stakeholders"* [1106]. On the contrary, other global entities such as NGOs tend to belittle the view that CSR is grounded on voluntary commitments, emphasizing instead the ethical requirements for companies to behave as *good corporate citizens*[1107]. In this regard, *corporate citizenship* is a term often used as a synonym of CSR; and the World Economic Forum (WEF) has defined it as: "*the contribution that a company*

[1102] S. Vertigans and S.O. Idowu, *Corporate Social Responsibility Academic Insights and Impacts,* Springer, 2017, 224.

[1103] E. M.J. Schouten, "Defining the corporate social responsibility of business from international law", *Emerald Managerial Law*, Vol. 49 No. 1/2, 2007, 21.

[1104] A.S. Queiruz and D. Wood,"In search of theory: global standards of business", *Proceedings of the Annual Conference of the International Association of Business and Society*, 2003, 170.

[1105] Esther M.J. Schouten, *Defining the corporate social responsibility of business from international law,* Emerald, Managerial Law, Vol. 49 No. 1/2, 2007, 21.

[1106] European Commission, 'Communication from the Commission concerning Corporate Social Responsibility: a Business Contribution to Sustainable Development', COM (2002) 347, final, Brussels, 2 July 2002, 5.

[1107]Zerk, *Multinationals and Corporate Social Responsibility*, 31.

makes in society through its core business activities, its social investment and philanthropy programmes, and its engagement in public policy. That contribution is determined by the manner in which a company manages its economic, social and environmental impacts and manages its relationships with different stakeholders, in particular, shareholders, employees, customers, business partners, governments, communities and future generations"[1108]. As this description displays, CSR can be likely referred to both in terms of decision-making procedures and in terms of social and environmental results. In addition, this definition, such as other more neutral understandings of CSR, evades mentioning legal standards and instead supposes that there is a group of ethical principles to which all corporations should adhere. In fact, drawing a line between law and CSR is misleading and obstructive[1109]. Furthermore, other aspects of CSR remain unclear, such as what its results should be or which actor should do what to make CSR work, mainly because CSR involves different meanings to different observers[1110]. Most importantly, while there is consensus that CSR concerns social and ethical *obligations* on corporations, there is little agreement about what these obligations might comprise[1111].

Understanding the meaning of CSR is thus a complex task; and the emergence of new terms such as corporate citizenship and corporate sustainability, which are commonly used in the same manner, turned providing a definition of CSR to be a real challenge[1112]. The recent practice of corporations to use the term *corporate responsibility,* excluding

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[1108] World Economic Forum, 'Follow-up Questionnaire on the World Economic Forum CEO Statement: Global Corporate Citizenship: the Leadership Challenge for CEOs and Boards', 2002.

[1109] Zerk, *Multinationals and Corporate Social Responsibility*, 30.

[1110] The issue becomes even more complex as corporations too have given their own definitions of CSR: for instance, according to Mc Donald's: *"corporate responsibility is about living our values each and every day. It's about taking action, achieving results and always maintaining open lines of communication with our customers and other key stakeholders. We're determined to continuously improve our social and environmental performance. We work hard, together with our suppliers and independent restaurant franchisees, to strive toward a sustainable future – for our company and the communities in which we operate"*. (McDonalds, 2009).

[1111] C. Smith and W. Halina, "Business as usual is not the answer to society's problems" in Smith, C. N. & Lenssen, *Mainstreaming corporate responsibility,* John Wiley & Sons, 8-9.

[1112] Corporate citizenship usually refers to corporate philanthropy which is a limited aspect of the social commitment of a corporation. On the other hand, sustainability is a term frequently used to address environmental issues, as well as sustainable development challenges such as economic and social policies aimed at maximizing the long-term well-being of the individual corporation and community

the word *social,* is evidence of a dangerous approach by politicians and companies. Such actors can easily deflect attention from away from social and environmental matters, *towards more business-centred concerns like corporate governance and financial reporting*[1113].

In light of the aforementioned consideration, the term corporate *social* responsibility is chosen for the goals of this dissertation and must be understood as *the notion that each business enterprise, as a member of society, has a responsibility to operate ethically and in accordance with its legal obligations and to strive to minimize any adverse effects of its operations and activities on the environment, society and human health*[1114]. In order to avoid losing track of the focus of this chapter, namely addressing human rights responsibilities of pharmaceutical companies, such definition can be theoretically applied to a broad range of management-related topics, such as corporate governance, trade practices and other business ethics topics, including political pressure on governments in order to adopt stricter IP regulations and bribery.

In conclusion, the advent of CSR as a phenomenon, characterized by the voluntary nature of corporations' will to self-regulate their activities, has been molded by specific socio-political changes that have occurred since the early 1980s. Such changes can be summarized in four factors that the relevant literature has identified as the reasons the international community has resorted to voluntary practices such as CSR. The first factor concerns the political change towards *economic liberalism* policies which promoted market autonomy instead of governmental intervention. Corporations were thus released from any "chains" mandated by States, and market deregulation was adopted as the most suitable route to economic growth and social wealth[1115]. In a context in which markets constituted the engine of global economy, CSR self-regulatory standards were vastly endorsed as operative tools of controlling business activities.

[1113] M. Hopkins, *The Planetary Bargain: Corporate Social Responsibility Matters*, Earthscan Publications, 2003, 11.

[1114]Zerk, *Multinationals and Corporate Social Responsibility,* 32.

[1115]F. Wilkinson, "Neo-liberalism and new labour policy: Economic performance, historical comparisons and future prospects", *Cambridge Journal of Economics*, 31(6), 2009, 820.

Secondly, socio-political globalization reduced the role of the state as mere spectators. Accordingly, pseudo-regulatory practices, such as voluntariness, unilateralism, self-regulation and legal unenforceability become central elements in the delimitation of corporate social responsibility in light of a drastic change in the relationship between companies and workers. Briefly put, CSR nourished of the understanding of globalization as an unalterable and inevitable socio-political model in which neoliberal management theories took over class struggle as well as debates on social inequality[1116]. In this scenario, the normative control of transnational corporations by States and the international community is considered unfeasible, due to both the decline of States sovereignty as well as the fragility of international institutions. In fact, these institutions have opted for the logic of voluntarism, since the relevant practice has proven their inability to regulate corporations via legally binding instruments. On the other hand, the crisis of sovereignty can be briefly explained as the result of economic and political globalization, which has had stronger effects on developing countries, since corporations are often more powerful than governments and States must be ready to give up some sovereignty to global institutions if the international system is to function[1117]. Indeed, the farther States are from decision-making centers, the deeper and more severe the crisis expresses itself[1118].

Thirdly, in order to fill the void left by the retreat of the state as a result of globalization, NGOs together with corporations, have started to address issues and tackle challenges that were once within the domain of the government[1119]. As a result, new institutional measures involving various non-governmental actors became more frequent and civil society organizations pressured corporations in order to alter their agendas. In addition,

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[1116] R. Jáuregui, "La RSE y la izquierda", en La Responsabilidad Social de las Empresas. Miradas desde la izquierda", *Secretaría Federal de Política Económica y Empleo del PSOE*, fundación Jaime Vera, Madrid, 2007.

[1117] For example, the international trade sector demonstrates that States accept decisions of the World Trade Organization because of the benefits stemming from the international trading order, even if a specific ruling requires governments to modify practices that constitute their sovereign right to undertake. M. Marsonet, "National Sovereignty Vs. Globalization", *Academicus International Scientific Journal*, 2017, 48.

[1118] Ibidem, 52.

[1119] L. Albareda, "Corporate responsibility, governance and accountability: From selfregulation to co-regulation", *Corporate Governance*, 8(4), 2008, 435.

while exercising pressure through confrontational activism, such non-governmental actors cooperated with corporations, business associations and international organizations through various forms of participations[1120].

Lastly, numerous corporate accidents and exposures of business misbehavior have drawn corporations to the center of public blame, enhancing the need for more responsible business processes and activities. For instance, many are the cases which involved environmental disasters caused by corporations, such as the BP's Deepwater Horizon Oil Spill of 2010 or the Exxon Valdez Oil Spill of 1989. Furthermore, many reports revealed illegal practices perpetrated by leading corporations such as NIKE and Shell which undermined fundamental human rights, including the prohibition of child labor or the protection of decent working conditions[1121]. In this context, the normative asymmetry between the protection of rights and the fulfilment of obligations by transnational corporations fully displays its consequences. As a result, within the aforesaid framework, in which the unviability of alternatives to capitalism becomes an immovable principle, CSR constitutes a required, yet partial, step in order to limit the socio-economic might of corporations.

3.2 Corporate Social Responsibility and Human Rights

The general perception concerning corporations has shifted from expecting such actors to simply generate economic wealth towards a more inclusive social role. Such role should, in fact, ground on shared responsibilities for human rights and related ethical responsibilities in a manner more in line with the vision envisaged by the Universal Declaration of Human Rights. This led to a call for corporations to conduct their business in a more human rights friendly manner, bearing in mind the legal challenges that such statement encompasses[1122].

[1120] Ibidem

[1121] Organización Internacional del Trabajo (OIT), *Estimaciones mundiales sobre el trabajo infantil: Resultados y tendencias 2012-2016*, ISBN 978-92-2-331046-2 (print); ISBN 978-92-2-331047-9 (web pdf), ILO, Geneva, 2017, 32.

[1122] W. Cragg, ‘‘Human rights and business ethics: fashioning a new social contract’’, *Journal of Business*

Creating a link between corporations having responsibilities towards human rights and CSR is a logical step in order to identify human rights commitments in practice.

Indeed, human rights are frequently perceived as the social pillar of CSR, mainly due to their status as inalienable rights of individuals and, thus, they must always be taken into consideration[1123]. Likewise, in 2001 the European Commission presented a Green Paper entitled *Promoting a European framework for corporate social responsibility,* which emphasized the *strong human rights dimension* of CSR, especially in realtion to international operations and global supply chains[1124]. Yet, such CSR approach to human rights departs significantly from the positivist conception which grounds on the understanding of human rights as moral and legal prerogatives resulting in equivalent legally binding obligations. This CRS's human rights dimension perceives such particular rights as a portion of a wider CSR schema that includes substantive issues such as transparency, management and community investment[1125].

In practice, the human rights dimension of CSR resulted in a proliferation of multiple CSR regulatory initiatives such as codes of conduct, guidelines and framework conventions. In specific, codes of conduct constitute the favorite means through which corporations usually identify their human rights responsibilities. Such codes usually establish provisions related to working conditions, human rights and environmental aspects, with particular attention to those of their subcontractors and suppliers[1126]. Nonetheless, these valuable attempts to recognize the human rights dimension of CSR are not purely driven by philanthropic impulses. Indeed, codes of conduct are precious marketing strategies aim at enhancing corporate's image and, thus, reduce the risk of negative consumer reaction. Accordingly, Robert Reich, Minister of Labour under former President Clinton, considers that a *supercapitalism* is currently being

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Ethics, Vol. 27 No. 27, 206.

[1123] E. M.J. Schouten, "Defining the corporate social responsibility of business from international law", *Emerald Managerial Law,* Vol. 49 No. 1/2, 2007, 22.

[1124] European Commission, DOC 01/09, Brussels, 18 July 2001.

[1125] F. Wettstein, "From side show to main act: can business and human rights save corporate responsibility", in *Business and Human Rights: From Principles to Practise*, Dorothe Baumann-Pauly & Justine Nolan, 2016, 81.

[1126] European Commission, DOC 01/09, Brussels, 18 July 2001., par. 55.

consolidated, empty of democratic principles, where CSR is a farce that is used to win in the economic field at the expense of social and environmental principles. He understands that voluntary actions do not work and that the best guarantee is legally binding control and inspection over the company[1127].

As a result, codes of conduct should not be an alternative to national and international laws and binding rules, since binding regulations guarantee minimum standards of protection, while codes of conduct and other voluntary initiatives can round out these and endorse higher standards. The *mandatory versus voluntary* debate is, thus, key in understanding the scope of the relationship between CRS and human rights, bearing in mind that not governments but corporations (and respective stakeholders) are the driving force and executers of CSR initiatives[1128].

Such stimulating debate is helpful in order to address challenging inquiries, such as how to determine where corporations responsibilities lie as distinct from those of governments, *how to monitor whether their business partners are complying with their core values, how to approach countries with broad human rights violations,* and *how to operate in countries where human rights principles are not fully respected*[1129].

There is no consensus on the role that hard law should play concerning CRS in future. On one side representatives of corporations and industry organizations claim that CSR should not be legally binding, since in their view such regulation would suffocate innovation and hinder national *competitiveness* [1130]. According to these actors, corporations are capable to elaborate effective solutions to CSR related challenges and peer pressure is sufficient in order to raise the standards of the entire sector[1131]. New regulations would be, thus, counter-productive and unnecessary as corporations already know that monetary gains are to be made in acting socially responsible. On the other side, public opinion and many NGOs argue that the voluntaristic approach to CSR does

[1127] R. Reich, *Supercapitalism: The Transnformation of Business, Democracy, and Everyday Life,* Knopf, 2007.
[1128] Zerk, *Multinationals and Corporate Social Responsibility,* 32.
[1129] European Commission, DOC 01/09, Brussels, 18 July 2001., par. 55.
[1130] Zerk, *Multinationals and Corporate Social Responsibility,* 33.
[1131] See, for example. the aforementioned CSR Europe, 'Response to the European Commission Green Paper "For a European Framework on CSR", December 2001.

not suffice in itself as an assurance of responsible corporate behavior, and only legally binding instruments would enhance human rights protection.

Without going too further into the debate, some scholars argued that paying too much attention to the mandatory versus voluntary discussion is misleading and irrelevant for three main reasons[1132]. Firstly, such debate ignores that numerous CSR-related issues are already carefully regulated. Indeed, many States have already provided detailed regulatory frameworks for corporations in relation to issues such as workplace health and safety consumer protection and environmental issues. Corporations which do not comply with the aforesaid regulations are, at least theoretically, subjected to liability for their victims under civil law as well as to criminal law proceedings.

Secondly, *voluntary versus mandatory* debate grounds on an excessively simplistic perception of what law is and how it can steer human conduct. In light of the above, CSR refers to an *obligation* for corporations to act ethically and to consider social and environmental issues as well as include legal compliance. This is especially significant in countries in which institutions and legal provisions are blurred or vague or are not properly imposed. Yet, no legal framework is perfect; and grey areas in which corporations could act within the boundaries of the law, while still adopting socially irresponsible conducts can exist[1133]. Corporations are, in fact, frequently criticized for the tactics they adopt in approaching legal claims, since they understand that no regulatory regime is bullet-proof and what the law is does not often match what the law should be.

Lastly, the *voluntary versus mandatory* tends to overlook the fact that binding legal requirements will not automatically result in more advanced standards of corporate behavior and transparency. *In reality, the law, as important as it is, is only one of a range of factors that influence corporate behaviour. In many cases – especially where the legal standards are flexible or unclear or are unlikely to be enforced -- other factors, such as corporate culture or pressure from consumer groups, will be just as important,*

[1132] Zerk, *Multinationals and Corporate Social Responsibility*, 34.

[1133] B. Dinham and S. Sarangi, "The Bhopal Gas Tragedy 1984 to the Evasion of Corporate Responsibility", 14(1) *Environment and Urbanisation*, 2002, 90.

if not more so. Simply put, the fact that something is required by law does not necessarily mean it will be done well[1134].

In conclusion, focusing too much on the legal status of CSR and human rights seems to confuse rather than simplify the debate on the scope of CRS regulations. Codes of conduct and other voluntary instruments adopted by corporations are not legally binding and simply constitute a sort of gentleman agreement among the parties involved, with no concrete legal consequences. The crucial issue to address is thus not if CSR should be 'voluntary' or 'mandatory', but rather, what is the most effective regulatory option in order to enhance human rights protection worldwide.

This section has provided a definition and explanations regarding CSR in general and on specific voluntary corporations' regulations. The internal sphere of CSR has, thus, been the focus of the discourse. The next section will focus of the external sphere of CRS in light of the relevant soft law instruments adopted at the international level by the United Nations and other international organizations.

4. The Human Rights Responsibilities of Corporations under the UN System

The previous section concerns the *internal* sphere of CSR. Multinational corporations had voluntarily adopted internal codes of conduct as a response to the numerous criticisms regarding their approach to protecting the environment, human rights and the social sphere more broadly. On the contrary, the present section focuses on the so-called *external* sphere of CSR, which refers to voluntary instruments adopted at the intergovernmental level aimed towards corporations which provide a set of values and principles promoting ethical behavior and human rights. The most relevant examples of such external sphere were firstly endorsed in the 1970s, both within the UN system (i.e. the ILO *Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy* of 1977) as well as by the Organization for Economic Co-operation and Development (i.e. the Guidelines for Multinational Enterprises of 1976).

[1134] Zerk, *Multinationals and Corporate Social Responsibility,* 35.

The goal of the *ILO Tripartite Declaration* is to boost the positive influence, which corporations can make to economic and social progress with a particular focus on the realization of decent work conditions while minimizing the negative impact of such corporations in the community. "*This aim will be furthered by appropriate laws and policies, measures and actions adopted by the governments, including in the fields of labour administration and public labour inspection, and by cooperation among the governments and the employers' and workers' organizations of all countries"*[1135].

On the other hand, the OECD Guidelines for Multinational Enterprises, which were amended in 2011, bind 42 countries to new, tougher criterion of corporate behavior. These, which constitute the first inter-governmental arrangement in the field of company responsibility for supply chains, provide new recommendations on human rights misapplication. In specific, the Guidelines establish that corporations should respect human rights and environmental and labor standards in every country in which they carry out their activities, throughout having suitable due diligence procedures in place to ensure such compliance[1136]. Both the OECD Guidelines and the ILO Tripartite Declaration comprise a comprehensive, non-binding code of conduct that member countries and others have agreed to advocate among the business sector. The *soft law* nature of such instruments makes their legal analysis challenging and interesting under human rights law.

After having briefly mentioned these two relevant instruments related to the external sphere of CSR, the present section will focus only on the legal analysis of the major soft law regulations adopted by the United Nations since the late 1990s onwards. The reasons for narrowing down the analysis to such a precise timeframe and to just one international organization is based on a qualitative approach. In fact, the particular nature of the UN, which is the largest, most internationally represented and most influential intergovernmental organization in the world, makes the study of its attempts regarding regulating corporations crucial and decisive. Secondly, the UN is the only

[1135] ILO, *Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy*, ILO (2006), par. 2.

[1136] For example, paying decent wages, fighting bribe solicitation and extortion, and the advocacy for sustainable consumption.

organizations that has expressively tackled the issue of determining detailed responsibilities for pharmaceutical companies. As a result, the main objective of this chapter is to identify key responsibilities of such companies in relation to access to essential medicines in light of a deductive approach, which departs from corporations in general and concludes with the drug sector in particular.

4.1. The United Nations Global Compact

In 1974, the Economic and Social Council (ECOSOC) established the Commission on Multinational Enterprises (UNCTC) with the mandate to gather information on the activities and impact of multinationals in terms of development and to draw up a Code of Conduct as a universal regulatory instrument[1137]. The Commission presented the first draft to the General Assembly in 1982. Despite ten years of negotiations, however, the project sank definitively in 1992. The main reason for the lack of success of the negotiations was the disagreement on the binding or non-mandatory nature of the Code as well as other details regarding the protection of multinational companies. In 1993 the Commission was removed from office and transferred to the Conference on Trade and Development (UNCTAD) [1138]. The fiasco in establishing a universal code of conduct for multinational companies marked a new UN approach to corporate social responsibility, which basically consisted of focusing on non-binding regulations.

In this scenario, on 31 January 1999 the former UN Secretary General Kofi Annan presented at the World Economic Forum in Davos a new proposal for business and the UN to work together in order to create a compact of shared values and principles. As a result, the *UN Global Compact* was adopted in 2000 as a voluntary instrument for multinational corporations with the aim at promoting ethical behavior and human rights[1139]. Such instrument does not provide any active part for States or any other

[1137] K. Weilert, "Taming the Untamable? Transnational Corporations in United Nations Law and Practice", *Max Planck Yearbook of United Nations Law*, Volume 14, 2010, 462.
[1138] Sauvant, *The Negotiations of the United Nations Code of Conduct,* 19.
[1139] The international document was published in 2000 and updated in June 2010 during the Leaders'

regulative bodies, but it rather constitutes a network-model organization to which companies can directly adhere in order promote constructive engagement between them and civil society[1140]. Each of the OECD Guidelines, the ILO Tripartite Declaration and the UN's Global Compact principles includes an explicit provision to the effect that no legal obligations are proposed[1141]. Currently, there are almost 14,000 participating companies from more than 170 countries. While this data may appear to be a fairly large number, facts prove the contrary, as there are over 80,000 multinational corporations operating worldwide which did not take part in the initiative[1142].

The procedure establishes that corporations who are willing to take part in the initiative are required to pledge to honor and to sign the ten principles set out in the Global Compact. The Global Compact's ten principles concern human rights, labor, the environment and anti-corruption standards[1143]. Interestingly, the such principles extend their effect in relation to all of corporations' strategies and operations from the supply chain, including the exclusion to claim a lack of competence in monitoring subcontractors[1144]. This leads to an internalization of human rights protection within the companies' *sphere of influence*, strategies and activities, which consequently steer the overall company's activities.

The first two principles include explicit provisions regarding human rights which provide to support and respect *internationally proclaimed human rights*[1145] and to *assure that* corporations *are not complicit in human rights abuses*[1146]. The principles

summit *"Building a new era of sustainability"*. United Nations Global Compact Annual Review – Anniversary Edition June 2010.

[1140] Weilert*, Taming the Untamable?,* 470.

[1141] OECD Guidelines, (2001) 40 ILM 237, Part I (Concepts and Principles), para. 1.

[1142] Information available at: https://www.unglobalcompact.org

[1143] The ten principles grounds on various international treaties and declarations, such as the Declaration of Human rights, the International Labor Organization's Declaration on Fundamental Principles and Rights at Work, the Rio Declaration on Environment and Development and the United Nations Convention Against Corruption.

[1144] UN Global Compact Office and the Office of the UN High Commissioner for Human Rights a joint publication from the Business Leaders Initiative on Human Rights, 'A Guide for Integrating Human Rights into Business Management' (2007);

[1145] The United Nations Global Compact, the Ten Principles of the UN Global Compact, Principles 1 and 2.

[1146] Remarkably, the Global Compact provides three types of complicity, namely: direct complicity, beneficial complicity and silent complicity. General complicity refers to the facilitation or participation

aim at giving actual application rather than offering legal definitions of the provisions envisaged within. Such task is transferred onto corporations which are free to regulate their activities on the grounds of the Global Compact human rights standards of protection[1147].

One of the most significant features of the Global Compact was the inclusion of the term *sphere of influence*, which is understood to refer to the various individuals and groups to whom the company has a certain political, contractual, economic or geographic proximity[1148]. Such *sphere* can be represented as a series of concentric circles in which influence weakens as the observers move farther from the center and the circles become greater[1149]. The closest to the core circle the strongest business activities are directly linked to the corporation's activities. An example of this sphere can be presented as follows: the first circle includes the corporation's employees; the second one, includes the supply chain; the third circle encompasses a corporation's community interaction, social investment and philanthropy activities. And the last one refers corporation's 'engagement in public policy dialogue and advocacy activities[1150]. Even if the corporation's control becomes weaker as the operations move away from the decision-making center, companies are still under a *duty* of supervision. Notwithstanding, the Global Compact recognizes that the primary responsibility to protect human rights falls on states and governments; but it acknowledges that individuals and organizations must play a decisive role in supporting and respecting such rights[1151].

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of a company in human rights abuses committed by others whether it is a state, a rebel group, another company or an individual. That means that the company does not directly put in place the unlawful conduct, rather it benefits, encourages and tolerates it. On the other hand, silent complicity concerns the company's conduct as a witness to the abuses while remaining silent on their occurrence. Lastly, beneficial complicity refers to the situation in which the company directly benefits from the abuse. *OHCHR Briefing Paper on The Global Compact and Human Rights: Understanding Sphere of Influence and Complicity*, 2004, p. 20, in Embedding Human Rights into Business Practice, A joint publication of the United Nations Global Compact and the Office of the High Commissioner of Human Rights.

[1147] U. A. Wynhoven, "The Protect-Respect-Remedy Framework and the United Nations Global Compact", 9 *Santa Clara Journal of International Law* 81, 2001, 87-88.

[1148] United Nations Global Compact, *Embedding Human Rights into Business Practice I*, 17-18.

[1149] Ibidem, p. 14.

[1150] Ibidem, p. 13.

[1151] UN Global Compact Principle One, http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/principle1.html

At this point, studying the procedure envisaged by the Global Compact is key to comprehending its legal significance and strength. Accordingly, a written statement, which has to be adopted by their board of directors or corresponding body, constitutes the first step that corporations must take in order to become part of the initiative[1152]. An annual follow-up process is established, according to which corporations must report on their progress to stakeholders while also indicating their efforts in enforcing the Global Compact principles and in assisting the UN partnership projects[1153]. In addition, the companies' compromise requires annual renewal to prove that such entity is still willing and able to observe the principles envisaged in the Global Compact[1154]. Regrettably, such procedure relies on the corporation's own will to share its progress with the community. In practice, no mechanisms for compliance or sanctions exist to assure that corporations actually submit their annual reports, nor is there a way to ensure that the facts presented are true. The real consequence of not complying with such duty is the publication of the non-cooperative corporations' names on the database's website. The success of the procedures thus depends on the will of all companies to project a good image of themselves in the community, mainly for economic and financial gains.

In this regard, it must be noted that the Compact is often not even included in the category of *soft law*, since under a legal analysis it is not a declaration, a recommendation, nor a resolution of an international organization. The Global Compact could be labeled more precisely as a platform for dialogue in order to support existing international standards by a direct communication with TNCs. *The distinctiveness does not lie in any new standards, but in the approach to address TNCs not only via the nation states but via different stakeholders*[1155].

The Global Compact has triggered mixed reactions among non-governmental organizations and the business world. The initiative has in fact received a very positive

[1152] Wynhoven, *The Protect-Respect-Remedy Framework,* 85.
[1153] *Embedding Human Rights into Business Practice,* 19.
[1154] J. R. Wetzel, *Human Rights in Transnational Business Translating Human Rights Obligations into Compliance Procedures,* Springer, 2016, 150.
[1155] Weilert, *Taming the Untamable?,* 472.

response among big multinational corporations, but such optimistic view was far from being shared by the majority relevant NGOs. Their main fear was that a partnership with companies could seriously compromise the role of the United Nations, as the only supranational body able to control corporations' activities. Moreover, in their opinion, the Global Compact was only a vague declaration of principles that did not provide, among other provisions, for an independent monitoring system capable of concretely assessing companies' compliance with the principles [1156]. Such situation was highlighted in a letter by a large number of academics, economists and NGOs representatives sent to Kofi Annan in July 2000. The letter emphasized allegations and doubts on the role of the Global Compact, which in fact functioned as a shield behind which companies could refuge under the United Nations flag in order to purify their public image while preventing any real change in their conduct [1157]. Many pharmaceutical companies, such as *Johnson&Johnson*, are in fact part of the initiative, but their practice is distant from a human rights-friendly approach.

In order to tackle and respond to such criticism, in 2004 the United Nations introduced a formal complaint which charged the Global Compact Office with the function of assessing any reports of non-compliance or abuse of the general principles perpetrated by corporations. Unfortunately, these initiatives have also proved to be unsatisfactory. In the event of a complaint, the Global Compact Office could use its means to encourage the resolution of the dispute. Such means included reporting the existence of the matter to one or more United Nations competent agencies, asking for their support, assistance or intervention. Or, the office could ask the relevant local/regional Global Compact Network or other organizations participating in the initiative to assist the company in resolving the dispute. The only sanction, however, remained the removal of the *delinquent* companies from the list of participants and the publication of their names on the database's website.

In conclusion, the mechanisms envisaged by the Global Compact do not seem to be

[1156] S. Prakash Sethi, *Setting Global Standards, guidelines for creating codes of conduct in multinational corporations*, Jhon Wiley & Sons Inc, 2003, 127.
[1157] Ibidem

effective or reliable[1158]. Corporations have proven to participate to the initiative merely under economic and financial drives with the intent of boosting their public image among consumers. Nonetheless, the authority of the Global Compact is in its political rather than legal value. Its emphasis is more on corporations learning the significance of the various principles than on instant compliance[1159]. Moreover, the initiative confers upon corporations the competence to differentiate themselves apart from their competitors and, in so doing, are able to determine a baseline for ethical behavior. Corporations' accountability is obtained through the so-called *blame & shame* approach, since their activities are increasingly under public scrutiny. Further, the legal value of the initiative can be traced as the Global compact constitutes an important step in acknowledging human rights responsibilities of corporations and in making them aware that their operations are constantly under attention and causing stakeholders to be increasingly more conscious about their rights.

4.2 The United Nations Norms on the Responsibility of Transnational Corporations and other Business Enterprises with Regard to Human Rights (UN Norms)

The critiques concerning the alleged ineffectiveness of the UN Global Compact boosted interest in codifying legally binding international human rights norms for corporations. As a result, an *ad hoc* Working Group of the Sub-Commission on the Promotion and Protection of Human Rights [1160] was officially tasked to collect information and to assist in drafting related human rights norms. In particular, the Working Group was given the mandate to *"analyze the possibility of establishing a monitoring mechanism in order to apply sanctions and obtain compensation for infringements committed and damage caused by transnational corporations, and contribute to the drafting of binding norms for that purpose"*[1161].

[1158] E.F. Carasco and J. B Singh, "Towards Holding Transnational Corporations Responsible for Human Rights", 22 *European Business Review 432*, 438.
[1159] N. Seppälä, "Business and the International Human Rights Regime: A Comparison of UN Initiatives", *87 Journal of Business Ethics*, 2008, 408.
[1160] A subsidiary body of the former Commission on Human Rights
[1161] U.N. Sub-Commission on the Promotion and Protection of Human Rights Res. 2001/3, The effects

The task was accomplished in August 2003 when the Sub-Commission adopted the draft Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights (from here UN Norms) in its Resolution 2003/16 and forwarded the text to the former Commission on Human Rights for "its consideration and adoption" [1162].

The UN Norms and their Commentary, which are acknowledged by the Norms itself as a valuable interpretation and elaboration of the standards, constitute a general guide to ethical business conduct concerning human rights. The object of the UN Norms and their essence considerably differ from the other initiatives that have been mentioned so far. Accordingly, the UN Norms aimed at mandatory regulations and thus attempted to discontinue the practice of adopting ineffective voluntary regulative measures by the UN. A consistent number of insiders pointed out that the UN Norms were not supposed to automatically and immediately become binding, but rather were to progress from *soft law* towards *hard law* after building consensus among States and stakeholders in general[1163]. The UN Norms were intended to be an instrument in the middle between the voluntary Global Compact and a completely compulsory instrument as hoped for many NGOs[1164]. Similarly, the UN Norms were expected to go beyond the voluntary guidelines offered in the Global Compact, the ILO Tripartite Declaration and the OECD Guidelines for Multinational Corporations, since they were *the first non-voluntary initiative accepted at the international level*[1165]

Regrettably, such hopes of becoming binding regulations were crushed by the objections of the international community that confirmed that the UN Norms would not secure such legal status. In fact, *via* Resolution 116 of April 2004 of the UN Human Rights Commission, the UN Norms were destined to merely exist as a draft

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of the working methods and activities of transnational corporations on the enjoyment of human rights, U.N. Doc E/CN.4/Sub.2/2001/40 (2001).

[1162] Ibidem, U.N. Doc. E/CN.4/Sub.2/2003/L.11 (Apr.13, 2003).

[1163] D. Weissbrodt and M. Kruger, "Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights", 97 *The American Journal of International Law*, 2003, 914.

[1164] T. Rule, "Using "Norms" to Change International Law: UN Human Rights Laws Sneaking in through the Back Door?", 5 *Chicago Journal of International Law*, 2005, 328.

[1165] Weissbrodt, *Norms on the Responsibilities of Transnational Corporations*, 913.

proposal[1166].The UN Norms were finally laid aside in 2005, as the High Commissioner observed that similar norms already existed among other initiatives for corporations and human rights[1167].

4.2.1 The Content and Legal Status of the UN Norms

The Norms were intended to create a 'non-voluntary', comprehensive framework, providing direct obligations for corporations and enhanced by a rigid enforcement mechanism which included the monitoring by non-state actors (NGOs and corporations themselves). Notwithstanding, the UN Commission on Human Rights expressively pointed out that the aforementioned UN Norms, while containing useful "*elements and ideas"*, were not being requested by such Commission and were not given any legal standing[1168]. This outcome was quite expected for the UN Norms to be divisive and ineffective in obtaining the backing from the Members of the former UN Commission, since many states, multinational corporations and UN organs had criticized such Norms from the very beginning.

For examples, both developing and developed states objected that the UN Norms could *de facto* transfer the responsibility for the implementation of human rights standards from States to companies[1169]. Backer viewed the Norms as going even further, arguing that a change was needed in the foundations of corporate regulation which altered the way in which human rights were to be implemented at national level and their relationship with international law. In this regard, "*human rights under the Norms*

[1166] Human Rights Commission, Resolution 2004/116, E/CN.4/DEC/2004/116 (2004).
[1167] United Nations High Commissioner on Human Rights on the Responsibilities of Transnational Corporations and Related Business Enterprises With Regards to Human Rights, 'Report of the United Nations High Commissioner on Human Rights on the Responsibilities of Transnational Corporations and Related Business Enterprises With Regards to Human Rights, U.N. Doc. E/CN.4/2005/91' (2005) 52(d).
[1168] Human Rights Council, Resolution 2004/116, E/CN.4/DEC/2004/116 (2004).
[1169] P. P. Miretski and S. Bachmann, "The UN 'Norms on the responsibility of transnational corporations and other business enterprises with regard to human rights': a requiem", *Deakin Law Review Volume*, 2012, 16.

would enter municipal legal systems and international law not from above as part of prescribed international treaty law, but rather from below through private law governing business relations, which would then establish binding rules which in turn would become new customary international law"[1170]. Most states articulated robust doubts and emphasized their will not to leave the traditional framework of international law, *which stresses the central and pivotal role of the state as a legal subject of public international law*[1171].

In practice, the *Norms* were innovative, and perhaps mainly controversial, due to the fact that such norms imposed human rights obligations directly on corporations, rather than requiring States to implement legislation within their jurisdiction in order to regulate the operations of these commercial entities[1172].

The Norms were, in several respects, establishing new legal standards concerning corporate human rights responsibilities. They mirrored and nourished from already existing human rights obligations, but boldly incorporated concepts of progressive development and novel notions of human rights protection. The Norms attempted to establish an explicit duty for corporations to promote human rights from the "bottom", even with regard to corporations incorporated in non-state parties[1173].

Unusually, the UN Norms did not provide so called *negative* duties, under which corporations were merely bound to refrain from violating human rights, but rather enshrined a *positive* duty upon such entities to promote and ensure respect for those rights[1174]. The attempt was, thus, to create a *quasi*-horizontal structure of human rights protection. On the contrary, countries highlighted the State's role as the main legal actor responsible for the implementation of human rights standards throughout the regulation of corporations' conduct under domestic law. Further, some states, while mentioning

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[1170] L. Catá Backer, "Multinational Corporations, Transnational Law: The United Nation's Norms on the Responsibilities of Transnational Corporations as Harbinger of Corporate Responsibility in International Law", 37 *Columbia Human Rights Law Review* 287, 2006, 357-358.

[1171] Miretski, *The UN 'Norms on the responsibility of transnational corporations*, 9.

[1172] Ibidem, 10.

[1173] Ibidem, 18.

[1174] S. Deva, "UN's Human Rights Norms for Transnational Corporations and Other Business Enterprises: An Imperfect Step in the Right Direction", 10 *ILSA Journal of International & Comparative Law*, 2004, 498.

the OECD Guidelines and the ILO Tripartite Declaration as positive cases in this respect, complained to the fact that the UN Norms could bound corporations to observe treaties that either did not apply nor were enforced in the countries where they carried out their activities[1175].

The business community raised similar concerns and doubts about the UN Norms. According to them, the main issue regarded the likely risk of the so-called "privatization of human rights"[1176]. This notion concerned the distinction between the private operations of corporations and the public duties of States, which according to the business community were the ultimate and only human rights duty holders[1177]. In fact, if the UN Norms were to be treated as binding legal instruments, such scholars argued, corporations would replace states in public functions and be burdened with tasks incumbent on States. In this scenario, States could escape and avoid their responsibilities and, thus, create a situation characterized by misperception on who was supposed to do what[1178]. The same complexity would involve cases in which corporations were faced with the difficult task determining the scope of the imprecisely formulated obligations of conduct, which instead is a state duty[1179].

With respect to the content, the UN Norms did not limit corporations' obligations to only civil and political rights. In fact, the norms also incorporated both collective social, economic and cultural rights of the second and third generations of human rights. In addition to such a variety of different kinds of human rights envisaged by the Norms, its Preamble basically restated the fundamental feature of Corporate Social Responsibility as a way to promote and protect human rights. In light of such preamble,

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[1175] *Comments by Australia in Respect of the Report Requested from the Office of the High Commissioner for Human Rights by the commission on Human Rights in its Decision 2004/116 of 20 April 2004 on Existing Initiatives and Standards Relating to the Responsibility of Transnational Corporations and Related Business Enterprises With Regard to Human Rights* (Sept. 8, 2004).

[1176] As a matter of fact, the UN Norms themselves provided that: *"Nothing in these Norms shall be construed as diminishing, restricting, or adversely affecting the human rights obligations of States"*. UN Draft Norms (n 315)

[1177] IOE & ICC, *Joint views of the IOE and ICC on the draft 'Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights'*, (2003), http://www.reports-andmaterials.
org/sites/default/files/reports-and-materials/IOE-ICC-views-UN-norms-March-2004.doc.

[1178] Ibidem, para. 4.

[1179] Ibidem, para. 22.

many scholars grounded the legal foundations of the duty of corporations to promote and protect human rights directly from the Universal Declaration of Human Rights[1180]. Interestingly, the provisions contained within the Preamble of the Norms created an open, non-exhaustive list of the international treaties and conventions which determined the legal basis for human rights obligations of corporations. This was a clear attempt to *"characterise the Norms as a mere codification of already established principles of customary international law, rather than a progressive development of such legal principles"*[1181]. Nonetheless, the legitimization of human rights standards upon corporations becomes challenging if the legal documents that are referenced are not built to embrace other actors than state entities, such was the case concerning the UN Norms.

At this point of the scrutiny, the legal analysis on the legal basis of the UN Norms is grounded on the commentaries to it provided by Prof. Ruggie, who would be later appointed (in 2005) as the Special Representative to the UN Secretary General on this delicate matter.

Ruggie's main complaint regarded the dual statement that the UN Norms restated international law while providing that international law imposes direct human rights obligations on corporation on the one hand; and that the UN Norms were non-voluntary and thus binding on such economic actors on the other[1182].

The drafters of the UN Norms derived such assumptions from the language of the UDHR Preamble, which stated that the provisions contained in the UNHR should apply to "all organs of society"; thus, including that human rights apply to corporations like any other 'organ' in society[1183]. On the contrary, Ruggie objected to considering the pre-ambular language of the UDHR as an authoritative legal basis for conferring

[1180] J. Campagna, "United Nations Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights: The International Community Asserts Binding Law on the Global Rule Makers", 37 *John Marshall Law Review,* 2004, 1208.
[1181] Miretski, *The UN 'Norms on the responsibility of transnational corporations,* 18.
[1182] Weissbrodt, *Norms on the responsibilities of transnational corporations,* 912.
[1183] L. van den Herik and J. Letnar Černič, "Regulating Corporations under International Law: From Human Rights to International Criminal Law and Back Again", *Journal of International Criminal Justice*, 2010, 734.

human rights obligations to corporations. As broadly presented in the first chapter of this dissertation, the UDHR was envisioned to be non-binding at its inception. Further, Ruggie emphasized that *"preambles, even to binding international instruments are not themselves legally binding"*[1184].

These considerations led to the conclusion that moral claims and aspirational language envisaged in the UDHR could only turn into *hard law* indirectly, after their codification in international human rights treaties or their crystallization as norms of customary international law[1185].

In light of the above, it would be inadequate to impose human rights obligations which were provided to states *mutatis mutandis* to international corporations[1186]. Such economic actors cannot be functionally treated as States, since their goals and conducts largely differ from public functions. As a result, features and scope of the corporate responsibilities for human rights must, thus, reflect these special natures and function[1187].

In light of the above, Ruggie added that: "*while corporations may be considered "organs of society", they are specialized economic organs, not democratic public interest institutions. As such, their responsibilities cannot and should not simply mirror the duties of States. Accordingly, the Special Representative has focused on identifying the distinctive responsibilities of companies in relation to human rights"*[1188].

In conclusion, while the Norms may have been a bold attempt in order to present a good vision of de *lege ferenda*, or the law to which the community may aspire, they

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[1184] John Gerard Ruggie, Just Business Multinational Corporations and Human Rights, 40 (W.W. Norton & Company, 2013).

[1185] Ibidem; Such is the case of numerous provisions of the UDHR that became legally binding through their elaboration in the ICCPR and the ICESCR. Notably, these provisions did not include the wording "all organs of society".

[1186] Commission on Human Rights, Interim Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, E/CN.4/2006/97 (2006), p. 2.

[1187] *Interim Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises*, ¶ 54 U.N. Doc. E/CN.4/2006/97 (Feb. 2006), p. 6.

[1188] Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, *Protect, Respect and Remedy: A Framework for Business and Human Rights*, ¶ 53, U.N. doc. A/HRC/8/5 (April 7, 2008)

did not reproduce *lex lata*, or positive existing law. Accordingly, this section highlighted the reasons and arguments, which led to the actual abandoning of the draft *Norms* by the international community which can be summarized as follows: firstly, the fact that a large part of the provisioned contained within the *Norms* did not constitute a mere codification of existing international law but rather represented a further development of existing international norms. This contrasted with the positivist approach to international law. Secondly, the fact that the *Norms* assigned a significant legal role to corporations rather than to the traditional recipients of international law, namely the states. This construction shook the entire international realm and destabilized the central role of states as international law subjects, since it blurred the distinction between international public and private legal frameworks. Third, both developing and developed countries objected to the lack of transparency in the adoption of the Norms. In particular, such states pointed out that the actual mandate to draft such norms was never given to the Sub-Commission on Human Rights. Lastly, as opposed to other human rights instruments, the Norms focused mainly on the duty-bearers, to which the different provisions apply, rather than establishing a single set of rights (i.e. civil, political, and economic) or rights holders (i.e. women, children, indigenous people). This resulted in vagueness regarding their overall nature and applicability and the exact scope of the specific rights which led to raising criticism on their actual applicability to corporations[1189].

[1189] Miretski, *The UN 'Norms on the responsibility of transnational corporations*, 25.

4.3 Professor Ruggie's contribution to the issue regarding Business and Human Rights

As the controversies on the UN Norms had not been resolved, in April 2005 the Commission on Human Rights adopted a resolution for the nomination of a Special Representative on the issue of Human Rights and Business Enterprises (from here Special Representative)[1190]. In light of the Commission, such expert was to be given the task to determine and clarify standards of corporate responsibility and accountability for transnational corporations and other business enterprises with regard to human rights, including clarifying notions such as "complicity" and "sphere of influence"[1191].

On 25 July 2005, former UN Secretary General Kofi Annan appointed Harvard Professor John Ruggie to the position with the aim at moving *"beyond what had been a long-standing and deeply divisive debate over the human rights responsibilities of companies"*[1192]. The initial mandate was supposed to last for a period of 2 years, but the term of the Special Representative was extended for one more year and in June 2008, the Human Rights Council[1193] prolonged the mandate further for another 3 years[1194]. Ruggie's mandate resulted in two key accomplishments related to the subject at stake, namely the *Protect, Respect and Remedy Framework* and its outcome, the *Guiding Principles on Business and Human Rights* of 2011.

The setbacks of the aforementioned Global Compact and UN Norms fueled, instead of appease, the discussion over the voluntary or mandatory nature of the regulative measures regarding business and human rights. On the one hand, the Global Compact, while gathering a fair amount of consensus from the international community, proved

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[1190] Commission on Human Rights, Resolution 2005/69.
[1191] Commission on Human Rights, Human Rights and Transnational Corporations and Other Business Enterprises, E/CN.4/2005/L.87 (2005).
[1192] UN Office of the High Commissioner of Human Rights, Press Release; New Guiding Principles on Business and Human Rights Endorsed by the U.N. Human Rights Council (2011).
[1193] The Human Rights Council replaced the former Human Rights Commission in 2006.
[1194] Human Rights Council, 'Mandate of the Special Representative of the Secretary General on the issue of Human Rights and Transnational Corporations and Other Business Enterprises', Resolution 8/7 (18 June 2008), para 4.

to be quite ineffective. On the other hand, the intent of the UN Norms of becoming a mandatory instrument had found the objections of the majority of the actors involved, ranging from States to corporations[1195]. The Special Representative himself labelled the UN Norms *a train wreck,* while delivering a speech in Geneva[1196]. In this scenario, the UN acknowledged the need for a completely new approach in order to address the thorny issue regarding corporations and human rights.

Since the beginning of his mandate, Ruggie distanced himself from previous attempts carried out within the UN, which showed in a number of important documents presented to the Human Rights Commission[1197]. In fact, in Ruggie's first *interim report* of 2006, the representative pointed out that international human rights had been acknowledged by states for states; and his mission was to comprehend which of these standards, if any, could be transferred onto transnational corporations[1198]. Remarkably, he emphasized the valuable role of the Global Compact as an important complementary instrument. In practice Ruggie, together with his team of researchers and advisors, embarked on consultations with the most significant actors in this matter and has led extensive academic research in this field.

4.3.1 The Protect, Respect and Remedy Framework

The focus of this section will be on the so-colled "Protect, Respect and Remedy framework" (hereinafter the Framework) which was presented in a report released in 2008 and unanimously approved by the Human Rights Council. Such framework

[1195] K. Buhmann, L. Roseberry and M. Morsing, *Corporate Social and Human Rights Responsibilities, Global Legal and Management Perspectives,* Palgrave Macmillan, 2011, 110.

[1196] Special Representative to the Secretary-General, 'Remarks by John Ruggie: Delivered at a Forum on Corporate Social Responisibility, Co-Sponsored by the Fair Labor Association and the German Network of Business Ethichs, Bamberg, Germany' (14 June 2006)

[1197] Ruggie, J. 2007. Business and Human Rights: The Evolving International Agenda. American Journal of International Law, v. 101, 822.

[1198] Human Rights Council, Business and Human Rights: Mapping International Standards of Responsibility and Accountability for Corporate Acts - Report of the Special Representative of the Secretary-General (SRSG) on the Issue of Human Rights and Transnational Corporations and Other, A/HRC/4/035 (9 February 2007).

contains a proposed a *"conceptual and policy framework, a foundation on which thinking and action can build"*[1199] with aim at closing the normative gaps caused by globalization[1200]. To this end, the Framework creates simple steps for governments, companies and society to address the various duties and responsibilities which have not been properly defined in the past.

The framework grounds on "differentiated but complementary responsibilities", which are interconnected and includes three main pillars[1201]. First, the report established the state's duty to protect human rights against non-state actors' abuse[1202]. For this purpose, states are encouraged to adopt regulatory measures to reinforce the legal framework governing human rights and corporations, as well as to establish mechanisms for the implementation of such obligations[1203]. Such duty on states is well established and documented in international law[1204]. Generally speaking, human rights duties upon states rests on the often referred to tripartite structure, which identifies the States obligations to *protect, respect and fulfil*[1205].

The obligation to "protect" concerns the protection by the state against human rights violation by third parties and, thus, by private actors. Much of the early understanding about third parties' detection revolved around armed rebel groups. Nonetheless, by definition third parties comprise corporations. Thus, the state duty to protect against business-related human rights abuse became the point of departure for the Framework. Ruggie's first challenge was, thus, to make the meaning of such duty clear, and consequently to detect ways for states to carry out this duty more successfully.

[1199] Wynhoven, *The Protect-Respect-Remedy,* 89.
[1200] A/HRC/8/5, 5, par. 11.
[1201] Special Representative to the Secretary-General on Business and Human Rights. Protect, Respect and Remedy: A Framework for Business and Human Rights, UN Doc A/HRC/8/5 (2008), par. 9.
[1202] One of numerous examples concerning the violation of the state duty to protect regards a situation in which the government of Nigeria, besides from actively violating human rights, permitted oil companies to pollute the environment. As a result, human rights such as the right to health and the right to food of the Ogoni people in that area were violated. Nigeria was, thus, recognized to be in breach of multiple provisions envisaged under the African Charter in Social and Economic Rights Action Centre and Centre for Economic and Social Rights v Nigeria.
[1203] Special Representative to the Secretary-General on Business and Human Rights. Protect, Respect and Remedy: A Framework for Business and Human Rights, UN Doc A/HRC/8/5 (2008), par. 18.
[1204] Ruggie, J, *Just Business: multinational corporations and human rights,* Wwnorton, 2013, 54.
[1205] The tripartite structure, which was outlined in the first chapter in relation to both the right to health and the right to access to medicines, regards all kinds of human rights.

Governments are, *inter alia,* required to create a corporate culture recognizing that respect for human rights is an integral part of all businesses[1206].

The international community agrees that the state duty to protect is a criterion of conduct, not of result. This entails that states are not *per se* to blame when corporations commit a human rights violation. On the contrary, states may find themselves in breach of their international human rights obligations when they overlook to taking proper steps to avoid such violation, as well as to investigate, punish, and compensate the violation when it occurs; or in such a case in which the conduct of a corporation may be directly attributable to the state, as the former economic entity simply served as the state's agent[1207]. In this respect, states themselves are logically more likely to bear some responsibility when the acts are carried out by a state-owned enterprise. Within this legal framework, international law provides states with wide-ranging discretion as to how to fulfill their duty to protect.

The second pillar concerns the corporate responsibility to respect human rights in light of a basic expectation society has on businesses to that extent. Corporations know they must comply with all applicable laws to gain their legal license to operate within a particular country[1208]. Besides compliance with domestic law, the framework claims that corporate responsibility ranges to all internationally recognized human rights. Ruggie highlighted that the responsibility of corporations to respect human rights already existed as deep-rooted social norm. In this regard, the professor used the term responsibility in order to emphasized that it differs from legal obligations[1209]. Interestingly, he argues: "*social norms exist over and above compliance with laws and regulations. And of course, some social norms become law over time; in many countries there were social norms against racial bias in employment, for example, or against smoking in restaurants, long before laws prohibited the practice. Social norms exist independently of states' abilities or willingness to fulfill their own duties"*[1210].

[1206] Wetzel, *Human Rights in Transnational Business*, 170.
[1207] Ruggie, *Just Business,* 54.
[1208] Ibidem, 56.
[1209] Ibidem
[1210] Ibidem

As a result, Ruggie emphasized the need to focus on the detailed responsibilities of corporations in relation to fundamental rights and to differentiate these from the duties of states. In the words of the relative provision envisaged in the Framework, "*to respect rights essentially means not to infringe on the rights of others – put simply to do no harm"*[1211]. In this respect, the report provided a "due diligence" approach in which corporations are expected to guarantee that the effects and impacts of their operations does not cause adverse human rights consequences. Corporate responsibility to respect human rights is autonomous from the obligations of States, thus eliminating the primary and secondary responsibility dispute initiated by the Draft Norms[1212].

Finally, the third pillar provides that there must be access to remedies if disputes arise regarding the confirmed adverse effects of corporations upon fundamental rights [1213] .This comprises guaranteeing that investigative processes occur where violations are detected, as well as establishing provisions for compensation and punishment where needed. The framework outlines a range of judicial and non-judicial mechanisms aimed at fostering and strengthening enforcement.

The aforementioned Framework constitutes the backbone of the later endorsed Guiding Principles on Business and Human Rights, which will be widely analyzed in the next section. At this point, it is important to stress the main reasons the Framework was welcomed by the international community as a significant step forward in determining human rights responsibilities on corporations. Such reasons revolve around three main considerations: firstly, the Framework was perceived by all the relevant stakeholders as the product of a *democratic* process in which States and corporations were allowed to be heard and shared their comments and proposals. Secondly, the Framework expressively discerned between the primary duty-holders, namely the States and the complementary subjects, namely corporations. In this regard, it was the first time in which the different nature and scope of the actors involved were actually acknowledged

[1211] Special Representative to the Secretary-General on Business and Human Rights. Protect, Respect and Remedy: A Framework for Business and Human Rights, UN Doc A/HRC/8/5 (2008), par. 24.
[1212] A/HRC/8/5, 17.
[1213] Special Representative to the Secretary-General on Business and Human Rights. Protect, Respect and Remedy: A Framework for Business and Human Rights, UN Doc A/HRC/8/5 (2008), para 26.

and that different obligations stemmed from such considerations. In other words, the economic functional nature of corporations was taken into account. Lastly, the document expressively presented itself as a non-binding instruments, which constituted a huge factor for its adoption. The legal analysis of the Framework will be provided in the next section, since, as was mentioned above, it constitutes the grounds on which the Guiding principles developed and were adopted.

4.3.2. The Guiding Principles on Business and Human Rights

The Guiding Principles on Business and Human Rights (hereinafter the Guiding Principles) were adopted by the Human Rights Council on 16 June 2011[1214]. The Guiding Principles provide thirty-one principles built around and in light of the aforementioned *Protect, Respect and Remedy Framework.*

The Guiding Principles are provided with a detailed Commentary. Their aim is to deliver a cohesive set of standards applicable to all corporations in all states *"regardless of their size, sector, operational context, ownership and structure"*[1215].

A significant aspect of the Guiding Principles is the provision of specified guidance on how to incorporate the Framework and due diligence into the corporation's activities. According to Ruggie, three autonomous but deeply related systems are at stake in relation to business and human rights, namely: the domestic law system, the international system and the social-norm system[1216]. The Guiding Principles attempt to find *inter-systemic harmonization* among the latter systems and to create the right

[1214] Human Rights Council, Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie - Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework, A/HRC/17/31 (2011).

[1215] The UN Guiding Principles on Business and Human Rights (2011) 14

[1216] L. Catá Backer, "From Institutional Misalignments to Socially Sustainable Governance: The Guiding Principles for the Implementation of the United Nations: Protect, Respect and Remedy and the Construction of Inter-Systemic Global Governance", *Pacific McGeorge Global Business & Development Law Journal 69*, 2012, 87.

conditions for corporations to develop a form of responsibility alongside national law. Remarkably, Ruggie emphasized the fact that the Principles do not wish to create binding international obligations or to alter the existing state of international law. Further, they do not create law or generate new legal responsibilities for corporations. In fact, "*nothing in these Guiding Principles should be read as creating new international obligations, or as limiting or undermining any legal obligations a State may have undertaken or be subject to under international law with regard to human rights"*[1217]. These merely voluntary principles aim at steering away from possible theoretical difficulties surrounding corporate obligations.

In the words of Ruggie himself: *"the Guiding Principles' normative contribution lies not in the creation of new international law obligations but in elaborating the implications of existing standards and practices for States and businesses; integrating them within a single, logically coherent and comprehensive template; and identifying where the current regime falls short and how it should be improved"*[1218].

In light of the above, the Framework endorsed in 2008 by the Human Rights Council constitutes the theoretical foundation of the Guiding Principles, which has thus become the operational instrument of the framework itself. In the words of Ruggie: *"if the Framework addresses the 'what' then the Guiding Principles address the 'how'"*[1219].

The voluntary nature of the provisions envisaged within these instruments highlights the distinction between state obligations and corporate responsibilities and provide practical recommendations that assist in defining existing international rules[1220]. The role of corporations, which is described as a critical element of this framework, is hierarchically inferior to the role of States, which are acknowledged as the principal actors responsible for the fulfillment of human rights and fundamental freedoms[1221].

[1217] Backer, *From Institutional Misalignments to Socially Sustainable Governance,* 106.

[1218] Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework (n 373) Introduction; 14.

[1219] J. Ruggie, "The Construction of the UN "Protect, Respect and Remedy" Framework: The True Confession of a Principled Pragmatist", *European Human Rights Law Review*, 2011, 129.

[1220] C. Lopez, 'The "Ruggie Process": from Legal Obligations to Corporate Social Responsibility?' in Surya Deva and David Bilchitz (eds), *Human Rights Obligations of Business - Beyond the Corporate Responsibility to Protect* (Cambridge University Press 2013), 59.

[1221] L. Catá Backer, "From Institutional Misalignments to Socially Sustainable Governance: The Guiding

In fact, the social role of corporations is distinguished from public functions carried out by States. This reflects the different sources and extent of the relevant obligations upon these actors. On the one hand, State's obligations are set by International Human Rights treaties, to which states are parties, and customary law. On the other hand, the responsibilities of corporations reflect their nature as economic-specialized organs of society and are of a dual character. Firstly, corporations must comply with all applicable law; and secondly, they must respect human rights.

The following sections will provide further analysis on the Guiding Principles in order to properly outline and describe the content and scope of the specific obligations and objectives established in such instrument. Both the Framework and the Guiding Principles provide to a large extent the same structure and obligations. For this reason, the previous section had merely presented the Framework's structure and briefly illustrated its content. The focus of the following sections will be on the tripartite nature of the *Protect, Respect and Remedy Framework* with particular emphasis on the role of corporations and on social expectations as the foundation for corporate responsibilities.

4.3.2.1 The State Duty to Protect Human Rights

The first ten principles of the aforesaid instrument regard the State duty to protect human rights. This grounds on the traditional responsibility of States in relation to such rights in light of International Human Rights Law and State commitments to human rights that the international community has generally acknowledged. The role of States as primary bearers of human rights obligations within their territories and/or jurisdictions is here reaffirmed[1222].

Principles for the Implementation of the United Nations Protect, Respect and Remedy and the Construction of Inter-Systemic Global Governance", 25 *Global Business & Development Law Journal* 69, 2012, 86.

[1222] Working Group on the issue of human rights and transnational corporations and other business enterprises, *Report of the Working Group on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises in Accordance with Human Rights Council resolution 17/4, transmitted*

The State duty to protect human rights requires States to protect against human rights violations committed by third parties, as is, *inter alia,* the case of corporations[1223]. Further, such duty includes that States must take proper measures to prevent, investigate, punish and compensate corporate breaches within the States' territories or jurisdictions[1224]. The Guiding Principles establish an obligation upon states to impose human rights on corporations as well as to provide within their domestic legal framework and territory that such corporations conduct their activities accordingly.

Under a broader human rights analysis, the State duty to protect is intrinsic to the State duty to "ensure" human rights, as established in numerous human rights treaties, such as the ICCPR[1225] and the ICESCR. In regard to violations committed by non-state actors, the UN Human Rights Committee further explained the general obligation on State parties in its General Comment 31. According to the Committee, the duty to respect entails that the rights envisaged by the Covenant are protected *not only against violations by the State's agents of their rights, but also against acts committed by private persons or entities that would impair the enjoyment of Covenant rights in so far as they are amenable to application between private persons or entities"*[1226]. In other words, in light of the Committee's view, State's obligations under the Covenant are fulfilled if individuals are protected by the State against violations of their rights also committed by non-state actors[1227].

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by note of the Secretary General, ¶ 6, U.N. doc. A/68/279 (Aug. 6, 2013).

[1223] As mentioned above, the obligations of states and the responsibilities of corporations are separated and do not depend on one another. Such a distinction is to designate that an autonomously existing corporate responsibility is not an obligation provided by the existing international human rights law.

[1224] Report of the Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, *Protect, Respect and Remedy: A Framework for Business and Human Rights*, ¶ 3, U.N. doc. A/HRC/8/5 (April 7, 2008)

[1225] According to Article 2 of such instrument: *"Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant"*. Paragraph 2 states as follows: *"Each State Party to the present Covenant undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such laws or other measures as may be necessary to give effect to the rights recognized in the present Covenant"*. International Covenant on Civil and Political Rights, art.2.2, *opened for signature* 16 December 1966.

[1226] UN Human Rights Committee, General Comment 31, Nature of the General Legal Obligation on States Parties to the Covenant, UN Doc. CCPR/C/21/Rev.1/Add.13, 80th Sess., 2187th meeting (Mar. 29, 2004). General Assembly resolution 2200A (XXI).

[1227] Ibidme, par. 8.

Further, the duty of States to ensure the human rights of all individuals within their territory and jurisdiction implies that States have an obligation in relation to individuals situated under *their power and effective control*, including if an individual is not within the territory of the State party[1228]. This is often referred to as to the *extraterritorial effects* of human rights.

4.3.2.1.1. Hints on extraterritorial effects regarding Human Rights and Corporations

The enforceability of human rights is deeply connected with sovereignty, which for its part closely depends on territoriality. In this context, the sovereign authority of a State is able to exercise its power within its jurisdiction [1229]. Jurisdiction basically refers to the power of the State to regulate and enforce persons and events within its boundaries in light of the territoriality principle. In other words, jurisdiction refers to the scope of each state's right *"to regulate conduct or the consequences of events"*[1230].

Territoriality is in fact the general rule[1231], but such principle is not absolute. In fact, the complexity of the international realm results in several circumstances in which doubts arise on jurisdiction. Such are the cases of conducts and activities with transnational quality, which, thus, either take place or produce their effects outside domestic borders[1232]. The aim is clearly to prevent human rights violations abroad, especially when such abuses occur in countries with a permissive or inadequate domestic legal system.

Defining extraterritoriality is, hence, a multifaceted task in which there are no

[1228] Such provision also extends to individuals within the power or effective control of the milirary forces of a State conducting its activities outside the territory and in situations of armed conflict in which the rules of International Humanitarian Law apply. Ibidem, par. 10.

[1229] J. Scott, "Territorial Sovereignty and Territorial Extension in an Inter-Connected World", in R. Rawlings, P. Leyland, and A. Young (ed.), *Sovereignty and the Law: Domestic, European and International Perspectives*, Oxford University Press, 2013, 270.

[1230] R. Jennings and A. Watts (eds), *Oppenheim's International Law,* Longman 1992, 456.

[1231] N. Bernaz, "Enhancing Corporate Accountability for Human Rights Violations: Is Extraterritoriality the Magic Potion?", *Journal of Business Ethics*, 2013, 495.

[1232] Brownlie, *Principles of Public International Law*, 163.

unambiguous guiding principle or norms in force, especially regarding international human rights law[1233]. Extraterritoriality raises procedural questions about finding a justification for the exercise of a State's sovereignty outside its jurisdiction. Accordingly, the international legal framework provides guidance in cases in which there is a connection between the state and the relevant conduct object of the regulation[1234]. In such cases there are not many problems on the application of the extraterritoriality principle[1235]. For instance, nationality, in both its active and passive dimension, constitutes a valid element of connection which allows State's jurisdiction in cases in which either the offender or the victim is its national.

On the contrary, the universal jurisdiction principle grounds only on the nature of the conduct and does not depend upon the aforesaid requirement of connection[1236]. The international community attributes a faculty on States to act, even though such State is not directly concerned with the relevant conduct. Such universality rests on the fact that other states cannot or are unwilling to exercise jurisdiction pursuant with the aforementioned rules. This risky impasse can be overcome in light of the interest of the international community as a whole, to which the State acts as a surrogate, with the aim at protecting against the breach of a *erga omnes* violation[1237]. Nonetheless, as confirmed by judge Van den Wyngaert in the *Arrest Warrant case* of 2000, there is no generally accepted definition of universal jurisdiction, which surely causes difficulties concerning its applicability[1238].

In practice, treaties such as the Geneva Conventions explicitly permit extraterritorial prosecution for war crimes. Universal jurisdiction, *inter alia,* regards the so-called

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[1233] A. J Colangelo, "An Unified Approach to Extraterritoriality", *Virginia Law Review* 97, 2011, 1021.
[1234] W. O'Neill, "(Re)Building the Rule of Law after Identity-Based Conflict: What Responsibility to Protect Practitioners Will Confront", 1 Global Responsibility to Protect, 2009, 353.
[1235] In addition, according to the protective principle States have jurisdiction in any case in which their vital interests are at stake. F. A Gevurtz, "Determining Extraterritoriality", 56 *William & Mary Law Review*, 2014, 352.
[1236] A. J Colangelo, "The Legal Limits of Universal Jurisdiction", 47 *Virginia Journal of International Law*, 2007, 150.
[1237] M. C. Bassiouni, "Universal Jurisdiction for International Crimes: Historical Perspectives and Contemporary Practice", 42 *Virginia Journal of International Law*, 2001, 96.
[1238] International Court of Justice, *Arrest Warrant of 11 April 2000, Democratic Republic of the Congo v. Belgium*, dissenting opinion Van den Wyngaert (14 February 2002), par. 46.

gross violations of human rights such as genocide. Accordingly, some scholars have argued the applicability of universal jurisdiction to the entire *ius cogens* category, which is surely desirable, but unlikely in practice, due to the lack of consensus on the scope and definition of such peculiar rights[1239].

In respect to the issue at stake, the second Principle of the Guiding Principles enunciates the obligation of States to openly articulate their expectation that all corporations registered under their jurisdiction respect human rights in carrying out their activities. In relation to these premises, Ruggie approached the issue regarding the obligations of States to regulate the extraterritorial operations of corporations.

The Commentary to Principle 2 helps to clarify the view regarding extraterritoriality envisaged in the Guiding Principles. Such commentary states that: *"At present States* ***are not generally required*** *under international human rights law to regulate the extraterritorial activities of businesses domiciled in their territory and/or jurisdiction. Nor are they generally prohibited from doing so, provided there is a recognized jurisdictional basis. Within these parameters some human rights treaty bodies recommend that home States take steps to prevent abuse abroad by business enterprises within their jurisdiction"*[1240].

The wording of the Commentary suggests that present international human rights law does not impose extraterritorial obligations on States, but either does it prohibit its exercise. In fact, in light of the Commentary, human rights law acknowledges that States are permitted to regulate extraterritorially if this does not lead to a violation of international law.

Regardless of the view outlined in the commentary, a large number of scholars embrace the idea that States have at the minimum some extraterritorial obligations, even if the extent and implications of such obligations are still unclear[1241]. The Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and

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[1239] Clapham, *Human Rights Obligations,* 94.

[1240] UN Office of the High Commissioner for Human Rights: *"Guiding Principles on Business and Human Rights: Implementing the United Nations 'Protect, Respect and Remedy' Framework",* 2011, 3.

[1241] O. De Schutter, *Commentary to the Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights, Human Rights Quarterly*, The Johns Hopkins University Press, 2012, 1094.

Cultural Rights (Maastricht Principles) seems to confirm this perspective. Despite their non-binding character, the Maastricht principles constitute a valuable tool in order to determine the scope of States' obligations. According to Principle 3 of such instrument, *all States have obligations to respect, protect and fulfil human rights, including civil, cultural, economic, political and social rights, both within their territories and extraterritorially*[1242].

Principle 8, which is labeled *"Definition of extraterritorial obligations"*, provides two situations in which such obligations occur:

For the purposes of these Principles, extraterritorial obligations encompass: a) obligations relating to the acts and omissions of a State, within or beyond its territory, that have effects on the enjoyment of human rights outside of that State's territory; and b) obligations of a global character that are set out in the Charter of the United Nations and human rights instruments to take action, separately, and jointly through international cooperation, to realize human rights universally[1243].

The Commentary itself offers an example in which a corporate-related activity may trigger extraterritorial obligations for the State where the two aforesaid grounds combines. A State has an obligation to ensure *that a corporation domiciled within its jurisdiction does not provide loans to projects leading to forced evictions* for two reasons. Firstly, *because the state has the legal and factual power to regulate the corporation's conduct*, and secondly, the State has the obligation *to take separate and joint action to realize human rights internationally*[1244].

Scholars, such as De Schutter, argue that from the authoritative ruling of several UN human rights bodies stems the obligation of States to control the conduct of corporations that are incorporated in a State's territory/jurisdiction, when such conduct may cause human rights abuses abroad[1245].

[1242] Maastricht Principles on Extraterritorial Obligations of States in the Area of Economic, Social and Cultural Rights. (2011). *Netherlands Quarterly of Human Rights*, *29*(4), 9. 581.
[1243] Ibidem, 1101.
[1244] Ibidem, 1102.
[1245] In its capacity as the United Nations Special Rapporteur on the right to food, De Schutter emphasized such situation with regard to food related issues. De Schutter, Regulating Transnational Corporations: A Duty under International Human Rights Law,

In conclusion, in relation to extraterritorial obligations, recent literature endorsed the perspective that the Guiding Principles do not replicate contemporary advances in the developing body of International Human Rights Law. These progresses have identified a regular consolidation of the extraterritorial duties of States to regulate the conduct of companies[1246].

Despite the non-binding character of the interpretations and observations delivered by the UN, the academia has acknowledged them as authoritative pronunciations. The same scholars argue that to not recognize extraterritorial obligations on State by default seems based on an inaccurate regressive approach in light of relevant practice[1247]. As a result, the approach proposed concerned the characterization of such obligations as "disputed or unsettled", instead of completely rejecting the scheme of the extraterritorial State duty to protect.

4.3.2.1.2. Horizontal effects regarding Human Rights and Corporations

Generally, the duties of States concerning human rights can be divided in negative and positive obligations. While the former obligations bind States to abstain from directly violating human rights provisions, the latter oblige States to actively intervene or adopt measures for the protection of such rights. As a result, non-compliance by the State in regard to its negative obligations turns into an unlawful commissive act. On the contrary, from the violation of positive obligations stems the omissive unlawful act of the State.

In respect to the object of the present study, here provided will be an analysis of the positive obligations, which in fact are the kinds of duties that most characterize the conduct of the state in relation to corporations' activities. Usually, human rights abuses

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Contribution of the Special Rapporteur on the right to food, Mr. Olivier de Schutter, to the workshop 'Human Rights and Transnational corporations: Paving the way for a legally binding instrument' convened by Ecuador; 11-12 March 2014, during the 25th session of the Human Rights Council (2014).

[1246] Ibidem

[1247] J. H.Knox, "The Ruggie Rules: Applying Human Rights Law to Corporations", in *The UN Guiding Principles on Business and Human Rights: Foundations and Implementation,* R. Mares ed., 2012, 81.

committed by corporations take place when states fail to comply with their positive obligations concerning the adoption of preventive and repressive measures between private actors. In practice, states have three obligations in relation to the private realm, namely: *"to prevent violations of human rights in the private sphere"; "to regulate and control private actors";* and *"to investigate violations, punish perpetrators and provide effective remedies to victims"*[1248]

In such circumstances, violations of human rights result from the actions put in place by private actors (individuals), rather than by the States. In order to prevent such violations occurring, scholars have debated on the horizontal application of human rights, which concerns the ability of this category of rights to have effect in relations between private actors[1249]. This is surely the case of multinational corporations, which throughout their activities can deeply impact the adequate enjoyment of human rights of private actors, such as individuals and communities.

In accordance with the dynamic interpretation of human rights treaties and with the *Drittwirkung* theory[1250], States are bound to adopt relevant positive measures in order to prevent that *inter-privatistic* abuses occcorur committed by individuals under their jurisdiction[1251]. Remarkably, some scholars have argued that, in specific cases, corporations act as *catalyseur* of State's responsibility, bearing in mind that acts of private actors are not attributable to a state[1252]. Notwithstanding, the responsibility of the state may stem from the unlawful activities of a non-state actor, if such activities are attributed to the state in light of international law provisions[1253] and if the State has not taken adequate *due diligence* steps to prevent the respective violation[1254].

[1248] D. M. Chirwa, "The Doctrine of State Responsibility as a Potential Means of Holding Private Actors Accountable for Human Rights", *4 Melbourne Journal of International Law*, 2004, 40.

[1249] E. Pariotti, "International Soft Law, Human Rights and Non-State Actors: Towards the Accountability of Transnational Corporations?", 10 *Human Rights Review*, 2009, 142.

[1250] Horizontal effects of human rights

[1251] Bonfanti, *Imprese multinazionali, diritti umani e ambiente*, 49.

[1252] L. Condorelli, *L'Imputation à l'Etat d'un fait internationalement illicite: solutions classiques et nouvelles tendances,* M. Nijhoff, 1988, 96.

[1253] K. Creutz, "Transnational Privatised Security and the International Protection of Human Rights", *Erik Castren Institute of Itnernational Law and Human Rights*, University of Helsinki, 2006, 72.

[1254] Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework.* U.N.Doc. A/HRC/17/31, General Principles

The considerations provided by the ICJ Judges in the *United States Diplomatic and Consular Staff in Tehran* case of 1979 concerning the Iranian students[1255], *mutatis mutandis* can be applied to corporations. The State, thus, does not respond internationally for the unlawful conduct perpetrated by corporations, but does so only in light of an omissive conduct by the State for not having complied with its positive duties to prevention and repression.

At this point, it is important to inquire whether the State's duty to protect human rights is an obligation of conduct or an obligation of result. Such inquiry is significant in light of both the attribution of the burden of proof on the claimant as well as its use as a possible justification that the State can raise in order to be considered unaccountable.

In light of Ruggie, the duties at stake must be considered obligation of conduct or of *due diligence,* under which States are bound to adopt reasonable measures in order to safeguard the enjoyment of specific rights. In other words, *due diligence* concerns *s'efforcer* obligations[1256], which violation occur if the State does not adopt the required diligence in the adoption or implementation of the relevant measure concerning prevention mechanisms and remedies for all victims of human rights violation[1257].

The scope of such obligations is clarified by a number of international and regional human rights bodies such as the Commission of Human Rights[1258] and the Committee on Economic Social and Cultural Rights[1259], as well as by the Inter-American Court on Human Rights.

The latter regional Court addressed the issue of *due diligence* in two cases concerning Honduras namely, the *Velasquez Rodrigues Case* of 1988 and the *Godínez-Cruz Case*

(March 21, 2011). Commentary to Principle 1.

[1255] Case Concerning United States Diplomatic and Consular Staff in Tehran (United States of America v. Iran); Order, 12 V 81, International Court of Justice (ICJ), 12 May 1981, par. 58.

[1256] R. Pisillo Mazzeschi, "Responsabilité de l'État pour violation des obligations positives relatives aux droits de l'homme", *Recueil des Cours 333*, 2009, 224-225.

[1257] J. Kulesza, *Due Diligence in International Law,* Brill Nijhoff, 2016, 29.

[1258] See the aforementioned General Comment 31; UN Human Rights Committee (HRC), *General comment no. 31 [80], The nature of the general legal obligation imposed on States Parties to the Covenant*, 26 May 2004, CCPR/C/21/Rev.1/Add.13

[1259] U.N. Comm. on Economic, Social and Cultural Rights, General Comment No. 15 The right to water (arts. 11 and 12 of the International Covenant on Economic, Social and Cultural Rights), ¶ 23-24, U.N. doc. E/C.12/2002/11, 29th Sess. (Nov. 11-29, 2004).

of 1989[1260]. The Court stated that to comply with the duty 'to ensure' human rights enshrined in Article 1 of the American Convention [1261], States must "*prevent, investigate and punish any violation of the rights recognized by the Convention and, moreover, if possible attempt to restore the right violated and provide compensation as warranted for damages resulting from the violation"*[1262].

The Court confirmed that private actors that abuse human rights may not trigger State responsibility, unless it is proven "*the lack of due diligence to prevent the violation or to respond to it as required by the Convention"* upon States[1263]. The Court took the task of clarifying the obligations of states one step further; and concerning due diligence, the State has *to take reasonable steps to prevent human rights violations and to use the means at its disposal to carry out a serious investigation of violations committed within its jurisdiction, to identify those responsible, to impose the appropriate punishment and to ensure the victim adequate compensation*[1264].

Without attempting to provide a comprehensive list regarding the duty to prevent, the Court emphasized that such duty *includes all those means of a legal, political, administrative and cultural nature that promote the protection of human rights and ensure that any violations are considered and treated as illegal acts, which, as such, may lead to the punishment of those responsible and the obligation to indemnify the victims for damages*[1265]. In addition, this means that states are obligated to investigate every situation involving a violation of the rights protected by the Convention and punish private actors if violations occur[1266].

In conclusion, using the words provided by the Commentary to Principle one of the Ruggie's Guidelines: *"The State duty to protect is a standard of conduct. Therefore,*

[1260] Inter-American Court of Human Rights, Velásquez Rodríguez v. Honduras, (29 July 1988), para 174; Inter-American Court of Human Rights, *Godínez-Cruz v. Honduras*, (20 January 1989), par. 184.
[1261] Article 1: "The States Parties to this Convention undertake to respect the rights and freedoms recognized herein and to ensure to all persons subject to their jurisdiction the free and full exercise of those rights and freedoms, without any discrimination for reasons of race, color, sex, language, religion, political or other opinion, national or social origin, economic status, birth, or any other social condition".
[1262] Inter-American Court of Human Rights, *Velásquez Rodríguez v. Honduras*, (29 July 1988), para 66.
[1263] Ibidem, par. 172.
[1264] Ibidem 174.
[1265] Ibidem 175.
[1266] Ibidem 176.

States are not per se responsible for human rights abuse by private actors. However, States may breach their international human rights law obligations where such abuse can be attributed to them, or where they fail to take appropriate steps to prevent, investigate, punish and redress private actors' abuse. While States generally have discretion in deciding upon these steps, they should consider the full range of permissible preventative and remedial measures, including policies, legislation, regulations and adjudication. States also have the duty to protect and promote the rule of law, including by taking measures to ensure equality before the law, fairness in its application, and by providing for adequate accountability, legal certainty, and procedural and legal transparency".

4.3.2.2 The Corporate Responsibility to respect Human Rights.

The second pillar of the Guiding Principles concerns the corporate responsibility to respect human rights. It does not take an extremely attentive reader to realize that the wording itself implies a key different approach from the aforesaid state duty. The legal approach for corporations deliberately revolves around the use of the notion responsibility as opposed to the term duty. Such terminological choice is aimed at stressing that international law does not provide legal obligations for multinational corporations[1267]. In the same manner, as a consequence of corporate activities, terms such as impact and risk are favored to the notion of violation, which is merely attributed for states.

The goal is quite clear. Corporate responsibilities must be distinguished from the obligations of the state on the one hand, and they cannot be considered legally binding and enforceable standards under International Human Rights Law on the other[1268]. In fact, the notion of responsibility places a much lighter burden on its holder, since such

[1267] S. Wheeler, "Global Production, Csr and Human Rights: The Courts of Public Opinion and the Social Licence to Operate", 19 *International Journal of Human Rights*, 2015, 761.
[1268] N. Jägers, "Will transnational private regulation close the governance gap?" in *Human Rights Obligations of Business: Beyond the Corporate Responsibility to Respect?*, 2013, 298.

notion can be understood as a much ductile term than duty. In this respect, scholars have emphasized that the state duty grounds on the language of law and policy while corporate responsibility to respect is sets on the language of *due diligence*[1269]. Hence, corporate responsibilities are non-binding standards of expected conduct that ground on international social expectations rather than on international legal obligations and that do not lessen any of the obligations contracted internationally by a state[1270].

In specific, the corporate responsibility to respect is built as a negative responsibility, with entails two detailed expected conducts. Firstly, corporations must not harm and thus should *"avoid infringing on the human rights of others"*. Secondly, corporations should *"address adverse human rights impacts with which they are involved"*.

Notwithstanding, corporate responsibility comprises also the necessity of active steps, in specific human rights due diligence requirements[1271]. While these requirements 'apply to all enterprises regardless of their size, sector, operational context, ownership and structure', their scope and complexity may vary depending on the size and capacity of the corporations and on the potential human rights impacts [1272]. In practice, corporations have to carry out policy self-commitments and processes to identify and prevent (possible) human rights infringements. This applies to the entire spectrum of internationally recognized human rights that corporations are capable of harming, such as civil and political, as well as social, economic and cultural rights[1273].

Corporate due diligence as opposed to State due diligence is delimited to the areas in which corporations might have adverse human rights impacts. Nonetheless, analogous to States, such corporate responsibility is a standard of conduct, rather than a standard of result, which, thus, must be process-oriented rather than performance oriented[1274].

[1269] Backer, *From Institutional Misalignments to Socially Sustainable Governance*, 124..

[1270] N. Jägers, *Will transnational private regulation close the governance gap*? in *Human Rights Obligations of Business: Beyond the Corporate Responsibility to Respect?*, 2013, 299.

[1271] C. Glinski, "The Ruggie Framework, tort law and business human rights self-regulation: Increasing standards through mutual impact and learning"*, CEVIA Working Paper Series*, Issue 1/2017, No. 4., 5.

[1272] Principle 14.

[1273] Ibidem, 15.

[1274] C. Parker and J. Howe, "Ruggie's diplomatic project and its missing regulatory infrastructure" in R. Mares, *The UN Guiding Principles on Business and Human Rights: Foundations and Implementation,* Martinus Nijhoff Publishers, 2013, 273 - 301.

In specific, such due diligence process must comprise at least these four foundations: firstly, it must assess actual and potential human rights impacts; secondly, the process must integrate and act upon the findings; thirdly, it must track responses; and lastly, the process has to provide communications on how impacts are addressed[1275].

The Guiding Principles go further, and along with requiring compliance with domestic legislation, they demand companies to comply with all applicable law, respect human rights and honor internationally accepted human rights. As is the case of this dissertation, pharmaceutical companies often conduct their activities in countries in which the state is incapable or unwilling to regulate and enforce human rights provisions. In these peculiar situations, pharmaceuticals must consider issues such as the countries in which they operate, the risks their operations carry and the relationships they have with third parties[1276]. In addition, under the Guiding Principles, these factors do not depend on the place where corporations operate and, thus, corporations must endorse the responsibility regardless of geographical location or territorial boundaries.

In conclusion, as was previously presented, neither the Reggie's framework nor the Guiding Principles are intended to provide a comprehensive list of human rights relevant to multinational corporations. Both instruments were written to tackle the entire subject of human rights providing general scope responsibilities for corporations in a manner more realistic and practical than they had been in the past. The extent of corporate activities is much too broad and multifaceted for the adoption of a specific set of rules for such economic entities. The creation of a *due diligence* framework, which in practice can be applied to all kinds of rights and situations, seems a valuable means for monitoring and diminishing the chances of corporate harmful conduct.

[1275] Commentary GP 17.
[1276] The UN Guiding Principles, 57.

4.3.2.3. Access to remedy for victims of business-related abuses

The last pillar of the Guiding Principles concerns the access to remedy for victims of business-related abuses. The State remains at the center of the framework in light of the traditional understanding of state power supremacy. Notwithstanding, the integrated set of redress methods envisaged in the Guiding Principles apply to both States and corporations in order to guarantee that victims of human rights violations have access to remedies. Such remedies cover national judicial and quasi-judicial structures as well as private complaint mechanisms provided by companies and international mechanisms. "One category of non-State-based grievance mechanisms encompasses those administered by a business enterprise alone or with stakeholders, by an industry association or a multi-stakeholder group. They are non-judicial, but may use adjudicative, dialogue-based or other culturally appropriate and rights-compatible processes. These mechanisms may offer particular benefits such as speed of access and remediation, reduced costs and/or transnational reach"[1277].

Such State duty to provide effective remedy, which specifically entails the duty to investigate, punish and redress, in case a human rights violation has taken place[1278], confirms a general principle founded in International Human Rights Law.

States must ensure that the formal judicial mechanism as well as complementary administrative, legislative and other State-based non-judicial grievance mechanisms are effective. Such effectiveness relies on their "impartiality, integrity and ability to accord due process"[1279].

Remarkably, States must ensure that where judicial remedy is not compulsory or preferred, non-judicial complaint procedures assume a complementary and supplementary role. In addition, no practical or procedural obstacles may avert human rights abuses from being brought before courts[1280]. To this end, States must raise public awareness of, and simplify access to State-based complaint mechanisms.

[1277] Guiding Principles Commentary 28.
[1278] Principle 26.
[1279] Ibidem
[1280] Commentary to GP 27.

Likewise, States must provide favorable conditions in relation to non–State-based complaint mechanisms tackling business-related human rights abuses to the extent that such remedies should be incorporated into the broader State-based system.

The UN Guiding Principles provide different classes of non–State-based complaint mechanisms such as: firstly, operative complaint mechanisms that are managed by corporations alone, or featuring stakeholders; secondly, mechanisms administered by industry association, multi-stakeholder. Lastly, the Guiding Principles provide international or regional human rights mechanisms.

Even though non-State-based mechanisms are non-judicial, in practice they can be more effective since they provide access and remediation promptly, at a lower cost and at better transnational reach[1281].

The approach envisaged by the Guiding principles is dualist in both scope and jurisdictional extent. In fact, they establish stipulations for ensuring the effectiveness of both state-based and non-state-based entities, such as legitimacy, accessibility, predictability, equitability, transparency and rights-compatibility[1282].

As mentioned above, States are the primary actors in ensuring access to remedies with the expectation of the incorporation of international human rights in the domestic court system and the autonomy of every state to regulate them within their jurisdiction.

4.3.3. The legal status of the UN Guiding Principles

The UN Guiding Principles have demonstrated that the challenge in addressing corporate-human rights issues stems mainly from the institutional misalignments resulting in governance gaps. Such gaps allow corporations to shield their actions behind their corporate veils, which often result in human rights violations without neither having to face consequences nor provide victims with access to effective remedies.

[1281] Commentary to GP 28.
[1282] Ibidem 31

The Ruggie's framework was, thus, established in order to provide a manifesto of guidance to which relevant actors could resort in order to fill the aforesaid governance gaps. Since the Guiding Principles adoption, the prospect has been that once this guidance reached adequate endorsement, it may lead into a *systemic revolution* and finally result in the institutionalization of a new coordinated global business and human rights framework.

In light of such premises, it is important to assess whether the Guiding Principles are actually capable of achieving the aforementioned goals. Accordingly, one of the key perspectives that must be studied is the legal status of the Principles in order to determine the legal strength and bite that such framework is able to emanate.

The text of the Guiding Principles does not provide any assistance in accomplishing such task and does not present any reference to its legal status whatsoever. That is why an evaluation of the legal character of the Principles will be here provided in light of both the sources of international law as envisaged by Article 38(1) of the Statute of the ICJ and relevant definitions of *soft law* provided by leading scholars.

To be fair, the Special Representative himself was clear about the non-legally binding character of the framework since its inception. Further, Ruggie emphasized that "*nothing in these Guiding Principles should be read as creating new international law obligations, or as limiting or undermining any legal obligations a State may have undertaken or be subject to under international law with regard to human rights"*[1283]. Likewise, State parties of the Human Rights Council have expressed their anonymous endorsement of the Guiding Principles on the premises of the non-binding nature of the instrument as evinced by the oral statements delivered at the time[1284].

Hence, it would inadequate to perceive the Principles as constitutive evidence of State practice or *opinion iuris sive necessitates* which lead to the creation of new customary norms nor can they be perceived as a binding treaty among the parties under Article

[1283] Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework.* U.N.Doc. A/HRC/17/31, General Principles (March 21, 2011)

[1284] Noteworthy is that Ruggie was carrying out his activities in light of a special procedure of the HRC. This leads to the conclusion that he did not have the legal mandate to develop this kind of legal provisions.

38(1)(a) and (b) of the Statute of the ICJ.

On the contrary, the study of the Guiding Principles text mirrors a common perception of existing and emerging standards that regulate the responsibility and accountability of corporations and human rights law as codified in international treaties and customary international law. Such standards do not stem solely from the State positive legal sources, but include, among others, non-State based social and moral rules.

In light of the aforesaid considerations, the Principles solely reinforce already existing obligations, especially in regard to the State duty to protect human right under a *lege lata* approach. To this end, such instrument has direct legal effect on States and at the most can produce a sort of *"pro-memoria and declaratory effect"*[1285]. In addition, in regard to States' obligations, the Guiding Principles could possibly be viewed as auxiliary evidence of international human rights serving the function of clarifying the findings of the most highly qualified scholars worldwide[1286].

As a result of the aforesaid analysis, the Guiding Principles fall outside the typical sources of international law envisaged by Article 38(1) of the Statute of the ICJ, which merely refer to treaties, customs and general principles of law as recognized by "civilized nations", the decisions of national and lower courts, and juristic writings. The aim of this section, however, is not to provide a comprehensive analysis of the sources of international law, but rather to determine on which legal grounds the Guiding Principles can be regarded as a *soft law* instrument.

In a quickly changing and developing world order, scholars regarded soft law as both a significant intermediate phase towards a more severely binding system as well as a tool allowing experiments and speedy adjustments[1287]. Unfortunately, consensus cannot be found on a common understanding to what the notion soft-law refers. Scholars have dated the usage of such terminology to the aftermath of the second World

[1285] Ian Brownlie, "Legal Effects of Codes of Conduct for MNEs: Commentary" in *Legal Problems of Codes of Conduct for Multinational Enterprises*, Deventer, 1983, 41.

[1286] D. Kinley and R. Chambers, "The UN Human Rights Norms for Corporations: The Private Implications of Public International Law", *6 Human Rights Law Review*, 2006, 36.

[1287] M. E. O'Connell, "The Role of Soft law in a Global Order", in D. Shelton, *Commitment and Compliance: The Role of Non-Binding Norms in the International Legal System*, Oxford University Press, 2000, 100.

War. At that time the term *soft-law* was announced to label *legally relevant pronouncements formulated in international organizations and amongst States*[1288]. Nonetheless, consensus arose on the understanding of *soft law* instruments as instruments in which their binding quality is somehow missing or attenuated[1289].

Thirlway provides a definition of *soft law* which properly reflects the aim and scope of the Guiding Principles. In fact, he argued that such peculiar law *"is a system of international commitments or obligations that are not regarded by those concerned as binding in the sense that can be enforced in the same way as those imposed by international law proper, but yet are considered as something more than mere political gestures, so that there is an expectation of compliance even if there is no legal duty"*[1290].

Sources such as resolutions and declarations of international organizations, quasi-legislative activities adopted within the UN, and non-legally binding but influential codes of conduct from States and State declarations of intentions are generally recognized as *soft law* instruments[1291]. They arose and stem from States' authority and were usually adopted within Inter-Governmental organizations. No doubts, thus, arose on their solid international and public nature.

According to Thirlway, two kinds of *soft law* categories can be listed, namely, *soft negotium* and *soft instrumentum.* Briefly stated, the former mainly focus on the intention of the stakeholders rather than the instrument of adoption. In other words, specific provisions of a treaty, which constitutes the archetypical source of international law, could establish *soft law* provisions if the parties so intended. In the case of the Guiding Principles, States never agreed to confer legal effects to them; instead they endorsed such instrument bearing in mind their non-legal character.

On the contrary, the category referred to as *soft instrumentum* pays attention to the means of creation of such instrument, rather than to the intention of the parties concerned. The aforesaid Guiding Principles fall under such category of soft law, since

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[1288] E. Riedel, "Standards and Sources. Farewell to the Exclusivity of the Sources Triad in International Law?"*, European Journal of International Law*, 2013, 63.
[1289] Thirlway, *The Sources of International Law,* 186.
[1290] Ibidem, 187.
[1291] Riedel, *Standards and Sources,* 59.

resolutions adopted within the Human Rights Council are, *per se,* non-binding source of law. Such is the case of "*legislative action by bodies lacking the authority, under international 'hard' law to impose binding obligations"*[1292]. This means that, even if the adopting States manifested ardent wishes that the Principle were to create hard law, the result could be a *soft law* instrument at most.

Notwithstanding, *soft-law* instruments do create certain effects. For example, failure to observe such provisions could theoretically result in ostracism from other States within the UN. Regardless of the political rather than juridical consequences, these provisions were recognized as having a noticeable influence in the behavior of States[1293].

At this point, it is important to determine and discuss whether *soft law* has different impacts in relation to human rights law rather than to the public international law. In fact, human rights law is characterized by specific features, which will be only partially outlined in this section, since debates on the fragmentation of international law and on the specific nature of human rights law are not the objects of the present analysis.

Nonetheless, two main properties are traditionally regarded as relevant to international human rights law. Firstly, generally speaking, traditional international treaties bind the parties and only the parties under the *pacta tertiis nec nocent nec prosunt* principle. On the contrary, human rights instruments bind states to protect the rights of third parties to the treaty, namely individuals. The human rights obligations that states commit to fulfill have been regarded as *erga omnes,* since it is commonly recognized that human rights treaties shield the common interest of all states parties, autonomously from particular self-interests[1294]. Such peculiar feature produces its consequences on the relevant reservation's regime as well as the interpretive rules of human rights treaties, which, in fact, follow a completely different pattern. For instance, reservations are not admitted unless they do not hinder the object and scope of the treaties and interpretation must always lead to a concrete application of the treaty's provisions[1295].

[1292] Thirlway, *The Sources of International Law, Second Edition,* 191.
[1293] Riedel, *Standards and Sources*, 62.
[1294] This perception has been presented in several occasions by both the ICJ and European Court of Human Rights. For example, see ICJ Advisory Opinion concerning *Reservations to the Genocide Convention*, 1951, ICJ Re at 15 and ECtHR Judgment *Ireland v.UK*, 18 Jan. 1978, A.25, at 239
[1295] T. Scovazzi, *Corso di Diritto Internazionale*, Parte III, Giuffrè Editore, 2013, 39-54.

The second property of international human rights law concerns the establishment of independent and autonomous supranatural judicial and quasi-judicial monitoring bodies. Accordingly, alleged victims (individuals) have the right to start different kinds of supranational proceedings against Sates, whose activities are constantly monitored. In this scenario, supranational bodies and domestic courts engage regular dialogues with each other, creating synergies and confrontations in the enforcement of human rights obligations. As a result, these interactions endorse the shaping and development of international human rights law and in such context, *soft law* does not provide individuals the same legal protection.

In light of the aforesaid observations, in traditional international law *soft law* only reduces the value and power of the commitments that states made to each other; on the contrary, in the human rights realm, non-binding provisions reduce the legal quality of the protection accorded to individuals. This is the reason debates over the legal nature of the Guiding Principles are not merely theoretical but rather practical.

Following the definition provided by Shelton, the Guiding Principles are acknowledged as *secondary soft law*, since they are non- binding standards produced by intergovernmental bodies and institutions. On the other hand, *primary soft law* refers to normative texts not adopted in treaty form, such as Declarations, which provide new norms, elaborate or reaffirm formerly accepted binding and non- binding provisions[1296].

In practice, most scholars argue that the legal effects of *soft law* provisions need to be explained in light of *dynamic* perspective concerning sources of international law. When such instruments do not reproduce existing international law, they promote *lege ferenda,* namely future law that the international community regards as more appropriate for the regulation of a certain conduct. A concrete consequence is represented by the fact that domestic courts cannot apply such non-binding provisions in order to directly address pending cases before them. These national courts may, however, use *lege ferenda* provisions with the aim at innovating existing international

[1296] D. Shelton, "International Law and "Relative Normativity", in M. D. Evans, *International Law*, Oxford University Press, 2010, 169.

law in light of universal justice[1297]. Further, *soft law* provisions can turn into binding obligations following to different situations: firstly, if States reproduce their contents in legally binding instruments such as treaties. Secondly, if States' practice (*diuturnitas*) as well as States' understanding of such provisions as binding upon them (*opinio juris*), transform *soft law* into customary international law[1298].

In conclusion, the UN Guiding Principles can be considered a *soft law* instrument. Better said, they are a typical case of *expert- driven* soft law, under two considerations. Firstly, even though they have not been negotiated directly by States, the Guiding Principles were the result of the anonymous "endorsement" by the Human Rights Council, which is a proof of the State backing and acceptance of such instrument. Nonetheless, controversies arose on the exact legal consequences of *endorsement* as divergent from *acceptance*, which is far from obvious. Further, their international character is demonstrated by the fact that they were adopted within the United Nations. Secondly, the content of the Guiding Principles clearly testifies their character as soft law instrument, since in the words of their creator, they provide non-binding provisions that mostly reflect *lex lata "that prescribes minimum standards of conduct for all states and all business enterprises in relation to all human rights"*[1299].

In addition, as a final remark, Ruggie embarked on a *soft law* journey as opposed to starting negotiations for a predominant international treaty placing binding obligations on business enterprises under international law for three main reasons. "*Firstly, treaty-making can be painfully slow, while the challenges of business and human rights are immediate and urgent. Second, and worse, a treaty-making process now risks undermining effective shorter-term measures to raise business standards on human rights. And third, even if treaty obligations were imposed on companies, serious questions remain about how they would be enforced"*[1300].

[1297] S. Lagoutt and T. Gammeltoft-Hansen, *Tracing the Roles of Soft Law in Human Rights*, Oxford University Press, 2016, 19.
[1298] Ibidem, 23.
[1299] Ruggie, *Regulating Multinationals: The UN Guiding Principles*, 6..
[1300] J. Ruggie, *Business and Human Rights: Treaty road not travelled*, Ethical Corporation, 2008.

5. The 2011 Statement by the Committee on Economic, Social and Cultural Rights and the General Comment No. 16 of the Committee on the Rights of the Child

The analysis here provided concerning the United Nations realm would not be adequate without mentioning two documents adopted respectively by the Economic Social and Cultural Rights Committee (ESCRC) and by the Committee on the Rights of the Child (CRC). Both instruments aim at clarifying corporate activities in relation to their corresponding "jurisdiction". The analysis here presented stems from the study of the texts of the two instruments.

The ESCRS adopted a document labelled *Draft Statement on the obligations of States Parties regarding the corporate sector and economic, social and cultural rights* in May 2011[1301]. The Statement confirms that the main obligation of States under Article 2(1) of the ICESCR is to respect, protect and fulfill the rights of all persons under their jurisdiction in the context of corporate-related activities undertaken by state-owned or private enterprises[1302].

Firstly, the Committee regards the State duty to respect as imposing a duty on States to assure that laws and policies concerning corporate activities adopted within their jurisdiction comply with the rights envisaged by ICESCR. States must ensure that companies *"demonstrate due diligence to make certain that they do not impede the enjoyment of the Covenant rights by those who depend on or are negatively affected by their activities"*[1303]. Such interpretation grounds on the societal expectation provided in the aforesaid Ruggie's framework. In other words, the community has an expectation upon corporations that they will conduct their activities under a *due diligence* approach. Such approach serves a dual purpose: it is necessary in order to regulate corporation's negative impacts on human rights on the one hand; and it helps determining the obligation of States to respect human rights as States place the burden of proof on

[1301] U.N. Comm. on Economic, Social and Cultural Rights, *Statement on the obligations of States parties regarding the corporate sector and economic, social and cultural rights,* U.N. doc. E/C.12/2011/1, 46th Sess. (July 12, 2011).
[1302] Ibidem, par. 3.
[1303] Ibidem, par. 4.

corporations in order for them to manifest their compliance with the societal expectation of conduct.

Moreover, the statement poses a *due diligence* duty on States which binds States' action to ensure that rights holders are effectively protected against violations of their ESCR rights by corporate actors. In this regard, States must provide regulatory measures, such as *"establishing appropriate laws, regulations, as well as monitoring, investigation and accountability procedures to set and enforce standards for the performance of corporations"*[1304]. Further, the Committee emphasized the importance for States to establish mechanisms "*to ensure access to effective remedies to victims of corporate abuses of economic, social and cultural rights, through judicial, administrative, legislative or other appropriate means"*[1305].

Interestingly, recalling its General Comment 15 on the Rights to water, the Committee stressed that the State duties extend to extraterritorial activities and impose States to "*take steps to prevent human rights contraventions abroad by corporations which have their main seat under their jurisdiction, without infringing the sovereignty or diminishing the obligations of the host States under the Covenant"*.

The statements went even further and placed a duty on States their capacity to influence corporations *to respect the right, through legal or political means, such steps should be taken in accordance with the Charter of the United Nations and applicable international law*. In addition, the statement recalls the social duty provide by corporations which *"have a particular role to play in job creation, hiring policies and non-discriminatory access to work. They should conduct their activities on the basis of legislation, administrative measures, codes of conduct and other appropriate measures promoting respect for the right to work, agreed between the government and civil society"*[1306].

In conclusion, the Statement recognized the framework provided by the Guiding Principles and respective framework. Its legal value revolves around the consideration

[1304] Ibidem, par. 5.
[1305] Ibidem
[1306] E/C.12/GC/18.

that another UN organ accepted and reaffirmed the structure provided by Ruggie, however it does not add much either from a qualitative nor does so from substantive approach. In fact, the committee does not even attempt to define the functional content of the responsibility to respect human rights, and actually recognizes that such responsibility should be interpreted in light of the hopes envisaged by the Guiding Principle. As a result, *"the Committee calls on States Parties to include in their initial and periodic reports information on challenges faced and measures taken in relation to the role and impact of the corporate sector on the realization of economic, social and cultural rights. Other stakeholders are also encouraged to include relevant information into their presentations to the Committee, as appropriate"*[1307].

5.1. General Comment No. 16 of the UN Committee on the Rights of the Child

In February 2013, the Committee on the Rights of the Child adopted General Comment No. 16 which concerns the state obligations in relation to the impact of businesses on children's rights. The Comment is one of the most recent and significant instruments of international law available on the issue of business and children's rights. Briefly stated, such Comment grounds on three main pillars: firstly, it provides guidance on the measures that States must implement in order to prevent and remedy violations of child rights committed by business actors in light of the Convention on the Rights of the Child (CRC) and the Operational Protocols thereto; secondly, the Comment confirms the responsibilities that the business sector to shall fulfil for the realization of the rights of children; and lastly, it encourages and urges business to positively contribute for the actual the implementation of these rights. Further, the General Comment sets on principles envisaged by the CRC such as, the best interests of the child (article 3(1)) ; the right to non-discrimination (article 2); the right of the child to be heard (article 12) and the right to life, survival and development (article 6)[1308].

[1307] Ibidem, par. 7.
[1308] UN General Assembly,*Convention on the Rights of the Child*, 20 November 1989,United Nations,

In particular, the Committee acknowledged that in light of the peculiar and vulnerable character of the subjects protected by the CRC, namely children, States are obliged "*to have adequate legal and institutional frameworks to respect, protect and fulfil children's rights, and to provide remedies in case of violations in the context of business activities and operations"*[1309].

Likewise, the Committee provides guidance to in order to[1310]:

- ensure that the activities and operations of business enterprises do not adversely impact on children's rights;
- Create an enabling and supportive environment for business enterprises to respect children's rights, including across any business relationships linked to their operations, products or services and across their global operations;
- Ensure access to effective remedy for children whose rights have been infringed by a business enterprise acting as a private party or as a State agent.

The Comment recognizes that currently no international legally binding instrument concerning the business sector's responsibilities vis-à-vis human rights exists. Notwithstanding, the Committee emphasized that all corporations must comply with their responsibilities concerning children's rights and States must ensure they do so. Accordingly, "*duties and responsibilities to respect the rights of children extend in practice beyond the State and State-controlled services and institutions and apply to private actors and business enterprises. Therefore, all In addition, business enterprises should not undermine the State's ability to meet their obligations towards children under the CRC and its protocols"*[1311].

In relation to States' obligations the General Comment sets on the typical tripartite structure of human rights, namely *respect, protect* and fulfil. The obligation to respect imposes that States do not directly or indirectly facilitate, aid and support any violations

Treaty Series, vol. 1577, 3.

[1309] U.N. Comm. on the Rights of the Child, General Comment No. 16 on State obligations regarding the impact of business sector on children`s rights, U.N. doc. CRC/C/GC/16, 62nd Sess. (Jan. 14-Febr.1, 2013).

[1310] Ibidem, par. 5.

[1311] Ibidem, par. 6.

of children's rights. Unfortunately, plenty were the cases in which States have been found guilty of participating in unlawful practices which concerned child labor especially in developing countries[1312]. As a result, a State should *"not engage in, support or condone abuses of children's rights when it has a business role itself or conducts business with private enterprises"*[1313].

The obligation to protect envisages that *States must take all necessary, appropriate and reasonable measures to prevent business enterprises from causing or contributing to abuses of children's rights.* In relation to pharmaceutical companies, such include the adoption of laws and regulations, their monitoring and enforcement, and policy adoption that frame how such corporations are able to have an impact on children's rights. *States must investigate, adjudicate and redress violations of children's rights caused or contributed to by a business enterprise*[1314]. This means *"having in place child-sensitive mechanisms – criminal, civil and administrative – that are known by children and their representatives, that are prompt, genuinely available and accessible and that provide adequate reparation for harm suffered"*[1315].

Lastly, "*the obligation to fulfil requires States to take positive action to facilitate, promote and provide for the enjoyment of children's rights. This means that States must implement legislative, administrative, budgetary, judicial, promotional and other measures in conformity with article 4 relating to business activities that impact on children's rights"*[1316]. In light of such statement, it seems clear that the adoption of a trade agreement which hinders and infringes the proper enjoyment of the right to access to medicines, constitutes a clear violation of the aforesaid obligation.

In this regard, home States should accurately and comprehensively inform businesses, that are willing to or are already operating in a certain State's jurisdiction, about the

[1312] For example, multinational corporations such as Nike, Nestlé and Walmart were caught in various scandals concerning the employment of child labor in India, Vietnam and Myanmar.
[1313] U.N. Comm. on the Rights of the Child, General Comment No. 16 on State obligations regarding the impact of business sector on children`s rights, U.N. doc. CRC/C/GC/16, 62nd Sess. (Jan. 14-Febr.1, 2013), par. 26.
[1314] Ibidem, par. 27.
[1315] Ibidem, par. 30.
[1316] Ibidem, par. 28.

local children's rights situation bearing in mind that corporations have *"identical responsibilities to respect children's rights in such setting as they do elsewhere"*[1317]. Remarkably, the General Comment directly mentions the Ruggie's Framework and the UNGPs, as well as the ILO Tripartite Declaration of Principles, the OECD Guidelines for Multinational Enterprises and the Children's Rights and Business Principles. Notwithstanding, as opposed to the Ruggie's understanding of the extraterritorial effect of human rights, the Committee argues the State duty to protect children's rights extends beyond states' borders to all children subject to the State's jurisdiction. In particular, home States have extraterritorial obligations to assure that realization children's rights in the field of corporations' *"extra-territorial activities and operations provided that there is a reasonable link between the State and the conduct concerned. A reasonable link exists when a business enterprise has its centre of activity, is registered or domiciled or has its main place of business or substantial business activities in the State concerned"*[1318].

In conclusion, the General Comment provided detailed content concerning States' obligation in relation to business-related activities in a comprehensive and coherent way. Some scholars attach particular normative significance to General Comments of quasi-judicial bodies, which strongly calls for a brief discussion on their legal status as under international law.

Generally speaking, such comments are usually regarded as non-binding instruments, but their legal values should not be underestimated. Some scholars consider them as valuable tool for interpreting relevant treaties as well as advantageous signposts since they provide indications of the content of rights and the steps that states parties are required to take in order to ensure adequate compliance[1319]. On the contrary, other commentators argue that General Comments have "practical authority" because they reflect the legal perspective and argumentation of important body of experience in light

[1317] Ibidem, par. 51.
[1318] Ibidem, par. 43.
[1319] K. Mechlem, "Treaty Bodies and the Interpretation of Human Rights", *Vanderbilt Journal of Transnational Law 42*, 2009, 929.

of the distinguished personalities who compose such committees[1320]. In this regard, it must be taken into account that UN Committees are composed of prominent legal scholars globally recognized for their outstanding contributions to international law.

Accordingly, some scholars acknowledge that General Comments have significant legal strength and they argue that a committee *is the most authoritative interpreter of the treaty it monitors*[1321]. States parties are, thus, not free to ignore a committee's understanding of the relevant treaty's provisions, even if such parties do not agree with the committee's work and even in light of their nonbinding nature.

The treaty's interpretation provided by a committee is accordingly regarded as more than a simple recommendation and some scholars even supported the "authoritative interpretative" character of the committee's views[1322]. This understanding stems from the fact that General Comments also participate in the formation of customary international norms by assisting in framing *opinio iuris* and state practice. Given their normative authority and role, the Committee on the Right of the Child here complied with a specific responsibility to adopt a comprehensive legal methodology when legal questions concerning States' obligations in relation to children's' rights were at stake. It that was not the case, no other body was entitled to provide useful interpretations on the subject concerning one of the most vulnerable *participants* at the global stage, namely children.

[1320] Ibidem
[1321] Ibidem, 930.
[1322] Ibidem

6. The Responsibilities of Pharmaceutical Corporations

The whole chapter adopted a deductive approach in order to illustrate the legal role that pharmaceutical corporations play in granting access to essential medicines. In fact, the analysis commenced with an introduction on of globalization and with an attempt at providing a suitable definition of multinational corporations. The task was not easy, and even harder was the understanding of the particular legal status that such economic actors currently enjoy under international law. The third section illustrated the main theories on legal personality of non-state actors with a particular focus on multinational corporations.

Regardless of a desirable change of such theories, relevant State's practice and international instruments have proven that States remain the primary duty bearers in relation to human rights obligations. This argumentation led to the analysis of the so called Social Corporate Responsibility, which as presented, grounds on the social expectation that corporations should not only be profit-driven, but rather take also into consideration social issues while operating. Accordingly, international organizations, such as the United Nations, have, in fact, embarked on a tortuous journey with the aim at addressing human rights impacts of multinational corporations' activities, since there is now wide consensus on the adverse consequences that such powerful private actors can have on the proper enjoyment of human rights of individuals.

In this regard, the chapter provided an analysis of the relevant instruments adopted, such as the Guiding Principles on Business and Human Rights, in order to determine, if possible, the legal responsibilities of corporations. Hence, at this point of the study, the present section focuses on the responsibilities of a particular kind of corporations, namely pharmaceuticals as well as on a specific activity carried out by such actors, namely granting access to medicines. In other words, this section aims at narrowing down the human rights responsibilities that society places upon pharmaceutical companies with regard to access to essential medicines[1323] in developing countries. The

[1323] Essential Medicines refer to *"Those that satisfy the priority health care needs of the population.... selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness…[and] intended to be available within the context of functioning health systems at all*

methodological approach of the section sets on the work of Paul Hunt, who was appointed by the Human Rights Council in 2002 as the first UN Special Rapporteur on the right to health.

6.1 The Human Rights Guidelines for Pharmaceutical Corporations on Access to Medicines

In 2002, the Commission on Human Rights appointed Paul Hunt as the first United Nations Special Rapporteur on the right to health for three years; and in 2005, the mandate was extended for three more years. Interestingly, Hunts' mandate (2005-2008) overlapped with that of Ruggie (2005-2011). Such overlapping makes the comparative analysis of the works of the two experts both theoretically challenging as well as relevant in practice.

The product of Hunts' mandate, which constitute the normative baseline for the attribution of responsibilities for pharmaceuticals, was the *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.* Hunt presented the aforesaid Guidelines in August 2008 before the UN General Assembly, after having received comments and observations from relevant stakeholders, including states, NGOs and pharmaceuticals[1324].

The 2008 United Nations Human Rights Guidelines provide for 47 guidelines covering a wide range of areas, including transparency, management, lobbying, research, patents and licensing, and pricing. The Guidelines ground on the consideration that the pharmaceutical sector plays an indispensable role in relation to the right to health and access to medicines. Notwithstanding, the nature and scope of pharmaceutical companies' human rights responsibilities concerning the access to medicines are not

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times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford". World Health Organization, "Essential Medicines." Available at http://www.who.int/topics/essential_ medicines/en/.

[1324] Special Rapporteur on the Right to the Highest Attainable Standard of Health, UN Doc. A/63/263, August 11, 2008.

easy to determine. Further, such responsibility is to be understood as a shared responsibility among numerous private and public actors, such as governments, NGOs and the business sector, since it would not be feasible to place such a huge burden merely on pharmaceuticals. Others relevant documents, such as the Millennium Development Goals, confirms and recognizes that pharmaceutical companies are among the key players sharing this responsibility.

Notwithstanding, the absence of a "detailed guidance" for pharmaceutical companies and human rights led to a paradox in which even if these actors wished to respect and fulfill their right-to-health responsibilities, they simply did not know what they were[1325]. As a result, there is a crucial need to move from general and abstracts provisions to specific and operational responsibilities for the pharmaceutical sector[1326].

According to the Special Representative, States remain the main duty bearers, but pharmaceutical companies hold corporate responsibilities to respect the right to access to medicines (and implicitly the right to health) which derive from "social expectations". As Ruggie emphasizes in its framework, corporate social responsibility stems from the so-called *social license*, and thus requires human rights *"due diligence"*[1327]. Accordingly, both experts suggested that the corporate responsibility to respect is not source of legally binding provisions under international law, unless States provide corresponding binding obligations under their respective domestic law[1328].

Remarkably, the complexity of the pharmaceutical sectors makes the task of determining the scope and terms of the social license to operate even more complex. In fact, such sector encompasses a range of different companies both from a qualitative

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[1325] L. Joo-Young, and Paul Hunt. "Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines", *The Journal of Law, Medicine & Ethics* 40, 2012, 221.

[1326] For instance, as it was presented in the first chapter, the UN Committee on Economic, Social and Cultural Rights, emphasizes that the private business sector has responsibilities in relation to the realization of the right to health, but the Committee has not provided further guidance in order to specify these responsibilities. Committee on Economic, Social and Cultural Rights, General Comment 14: The Right to the Highest Attainable Standard of
Physical and Mental Health, UN Doc. E/C.12/2000/4, par. 42.

[1327] Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, "Protect, Respect and Remedy: A Framework for Business and Human Rights," A/ HRC/8/5, April 7, 2008, par. 25.

[1328] Joo-Young, *Human Rights Responsibilities of Pharmaceutical Companies,* 221.

as well as quantitative perspective. Social expectations, thus, vary in light of specific sectoral area taken into account such as, among others, innovator, generic and biotechnology companies. For example, a company holding *ius excludendi* rights on a life-saving medicine is different from a company that struggles for the production of the relevant generic version.

Accordingly, Ruggie and Hunt recognized that when corporations perform certain public functions, *"additional corporate responsibilities may arise as a result of the specific functions the company is performing"*[1329]. Even thought, it remains unclear what the full range of public functions might be, Hunt places additional responsibilities on the grounds of the peculiar and delicate activities they perform.

6.1.1. Social license to operate of Pharmaceutical Corporations which do not hold Patents Rights

There is a particular element which distinguishes the methodological approach employed by Ruggie as opposed to the one adopted by Hunt. In fact, as outlined in the previous sections, Ruggie clearly distinguished the duties imposed on States from the responsibilities of corporations concerning business and human rights. Likewise, Hunt shared the perspective that human rights responsibilities of companies cannot be identical to the human rights duties of States. For example, typical duties of States, such as enacting appropriate legislation and provide enforceability of such rights, cannot be imposed upon private businesses. Notwithstanding, Hunt took the reasoning a step forward and found in the overanalyzed UN General Comment 14 (concerning the Right to health) the legal basis for grasping detailed responsibilities for pharmaceuticals. Accordingly, *mutatis mutandis,* Hunt adopted on pharmaceutical corporations the *Availability, Accessibility, Acceptability* and *Quality* framework established for States in relation to their right-to-health obligations.

[1329] Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, Business and human rights: Towards operationalizing the "protect, respect and remedy" framework, UN Doc. A/HRC/11/13, April 22, 2009, par. 64.

The Guidelines provide a general responsibility on pharmaceuticals to consistently integrate the right to health and endorse impact assessment across all relevant policies and programs, such as pricing, intellectual property, research and development, clinical trials, and marketing[1330].

With respect to *Availability,* the Guidelines prescribe that pharmaceutical companies do all they reasonably can to assure that drugs are available in sufficient quantities in the regions where they are required. Such responsibility is key in underdeveloped regions in which pharmaceutical companies have an additional "burden" to take adequate steps since they have not properly addressed the priority health needs of such countries[1331]. A suitable example concerns the so-called "diseases of the developing world", which affect the poorest populations of the poorest countries. Development departments of pharmaceuticals often ignore furthering research for the production of relevant medicines, such as drugs against tuberculosis or malaria, due to the scarce revenues that come from them[1332].

With respect to *Accessibility,* the Guidelines provide that in addition to being available, medicines must also be accessible. Accessibility can be understood in light of different perspectives: firstly, medicines must be accessible everywhere within a country, from big cities to remote rural areas. Obviously, pharmaceutical companies are not the exclusive holder of such overwhelming responsibility, but they must do everything they reasonably can. In this regard, such companies should provide medicines with adequate packaging in relation to different local climates[1333].

Moreover, medicines must be financially accessible to all segments of society, especially for those living in poverty. As the present work has demonstrated throughout,

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[1330] Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, "Protect, Respect and Remedy: A Framework for Business and Human Rights," A/ HRC/8/5, April 7, 2008, paras. 60-62.

[1331] S. Moon, "Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the pharmaceutical industry", *Health and human rights volume 15*, 2013, 37.

[1332] S. Ahmadiani and S. Nikfar, "Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective", Ahmadiani and Nikfar, *DARU Journal of Pharmaceutical Sciences*, 2016, 24:13, 3.

[1333] Joo-Young, *Human Rights Responsibilities of Pharmaceutical Companies*, 225.

high prices often constitute the main obstacles for accessing to medicines, which are often too costly for poor peoples in developing countries.

It is worth noting that also financial accessibility falls under the category of shared responsibilities, since the final price of a particular drug includes the price charged by the manufacturer as well as tariffs, shipping costs, VAT, and the mark-up added by retailers. Accordingly, pharmaceutical companies must take into account the introduction of a differential policy in relation to prices, which does not only concern different countries as well as providing market segmentation in the same country[1334].

In addition, *Accessibility* refers to information about medicines in relation to their safety and possible side effects, so as to ensure that individuals can make informed decisions about their use[1335].

In addition to being available and accessible, drugs and corresponding developing procedures such as clinical trials, must be *acceptable*, understood as they must be *respectful of medical ethics, culturally appropriate and sensitive to gender and life cycle issues*[1336]. In this regard, pharmaceutical companies must ensure that clinical trials are based on informed consent and comply with the highest ethical and human rights standards. Further, with respect to *quality*, pharmaceutical companies must guarantee that their drugs are of good quality, safe and effective in light of national and international manufacturing standards[1337].

Having outlined the Framework provided by the Human Rights Guidelines for Pharmaceutical Companies on Access to Medicines of 2008, it is now important to address the issue of accountability and the consequences of non-compliance. According to legal philosophers, such as Hobbes and Austin, rules must be enforced by an autonomous power in order to be law. In particular, the latter argues that, since international rules are not usually enforced, they cannot be considered as law, by definition[1338]. Also, Kelsen considered sanctions a decisive feature of a legal system,

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[1334] Ibidem
[1335] Ibidem, 226.
[1336] Ibidem
[1337] Guideline 20.
[1338] S. Raponi, "Is Coercion Necessary for Law? The Role of Coercion in International and Domestic Law", *8 Wash. U. Jur. Rev. 35*, 2015, 39.

since law can be the source of coercive orders only if it is backed by sanctions[1339]. This brief premises are significant in order to comprehend the perspective that Hunt adopted while drafting his guidelines regarding pharmaceuticals.

Human rights place both obligations (either duties or responsibilities) on different actors as well as positive legal entitlements for individuals and communities. Such rights and obligations, however, remain mere aspirational language, practically devoid of content, unless effective systems of accountability are established. Hunt, thus, argues that a right to-health approach must emphasize that all duty-holders must be held accountable for their behavior[1340].

In many cases, however, *accountability* is used as a synonym of sanctioning, but such limited interpretation of the notion is much too narrow. In practice, due to the peculiar legal nature of both pharmaceutical corporations and their quasi-legal responsibilities, accountability comes in many formulae. An accountability mechanism for the right-to-health must determine which health policies and practices are effective with the aim at improving the actual realization of the right to health. This means that the objective is not necessarily to blame and punish, but rather ensuring the no one is a victim of human rights violations.

Unfortunately, in this context, practice is much too far from theoretical considerations. Monitoring and accountability mechanisms are rarely accessible, effective, transparent, and independent in relation to corporate social responsibility of pharmaceutical companies. In fact, such companies usually report on access to medicines-related issues thought out self-reporting mechanisms, which obviously are far from unbiased[1341].

Accordingly, Hunt urges for the establishment of monitoring and accountability by an independent body to determine whether or not a pharmaceutical company is complying with its duties and to ensure the right to access to medicines is protected[1342]. A system featuring both internal and external monitoring and accountability mechanisms is, thus,

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[1339] H. Kelsen, "Sanctions in International Law Under the Charter of the United Nations", *31 Iowa Law Review*, 1946, 499.
[1340] Joo-Young, *Human Rights Responsibilities of Pharmaceutical Companies*, 227.
[1341] Ibidem
[1342] Ibidem

required. Actually, pharmaceutical companies are already exposed to the scrutiny of internal and external mechanisms. Nonetheless, such mechanisms are rarely effective in holding a company accountable for its human rights responsibilities to improve access to medicines. To this end, Hunt proposed the establishment of a specific Ombudsman for pharmaceuticals, with the function of oversighting the company's human rights responsibilities, particularly those relating to access to medicines.

6.1.2. Responsibilities of Patent-Holding Pharmaceutical Corporations

This last section tackles one of the main topics of the present work, which concerns the responsibilities of patent-holding pharmaceutical companies. It does not take an expert to understand that such companies play a delicate and decisive role in the realization of the right to health, as the two relevant case studies have demonstrated in Chapter 2. Originator companies have been capable of finding cures and treatments for the deadliest diseases, and in so doing they were able to enhance the quality of life not only of individuals, but of entire regions and communities. These companies, thus, perform a critically important public function, which is legally protected by the monopoly rights over the relevant medicine (*ius excludendi*) established by patents. Chapter 2 provided broad analysis of the legal consequences of patents. Such chapter demonstrated that patent-holding companies often negatively impact the affordability of relevant drugs, which then results in an obstruction for enjoyment of the rights to life and health.

The relationship between society and patent- holder has been differently described by relevant experts, which often found the legal basis of the privileges and responsibilities arising from a patent in terms such as, "social contract" [1343] or "social license to operate"[1344]. Others acknowledge such relationship as fiduciary, emphasizing the

[1343] Pharmaceutical Shareowners Group, The Public Health Crisis in Emerging Markets, London, 2004, 1.

[1344] Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, "Protect, Respect and Remedy: A Framework for Business and Human Rights," A/HRC/8/5, April 7, 2008, par. 54.

limited period of the *ius excludendi* as the result of a trust for society. No matter what terms is employed to refer to the aforesaid relationship, society has legitimate hopes on a corporation granted with a patent on a life-saving medicine, in light of its critical social function. This results in important right-to-health responsibilities on the patent holder, which are strengthened when the patent was the result of publicly funded research and development processes[1345].

Since patent-holding pharmaceutical companies mainly affect the right to access to medicines because of the high prices they impose, such companies must to whatever they can *"to avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved[1346]".* As already mentioned, the UN Guiding Principles require al companies, thus, pharmaceuticals as well, to establish policies and processes on the basis of human rights due diligence approach, which includes "remediation" of any adverse human rights impacts they cause. For example, a patent-holding company should "*assess the [potential and actual] impact of the company's strategies, policies, programs, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations"[1347]*

In a case in which an impact assessment proves that a company's policy, such as on patenting, licensing and pricing, results in an adverse impact on access to medicines, such company should take the necessary steps in order to dodge this effect. "*In order to prevent or address the potential and actual adverse impacts on access to affordable medicines, the company must use all the arrangements at its disposal, including non-exclusive commercial voluntary licenses, non-commercial voluntary licenses, donation programs, public-private partnerships, and so on*"[1348].

The company holding a patent on a life-saving medicine has a supplementary human rights responsibility to take all reasonable steps to make the medicine as accessible as

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[1345] Joo-Young, *Human Rights Responsibilities of Pharmaceutical Companies*, 228.
[1346] The Guiding Principles on Business and Human Rights are annexed to the Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie, UN Doc. A/HRC/17/31, March 21, 2011. par. 11.
[1347] Guideline 14.
[1348] Joo-Young, *Human Rights Responsibilities of Pharmaceutical Companies*, 228.

possible to all those who need it at the earliest opportunity [1349].

Remarkably, such responsibility does not entirely fall on corporations which in fact are responsible for compliance along with States. In addition, as such responsibility is not immediate for States, so it is for corporations which can progressively fulfill their responsibilities *expeditiously and effectively, by way of deliberate, concrete, and targeted measures, to make the medicine as accessible as possible*[1350].

Akin to State's responsibility to take steps *"to the maximum of its available resources"*[1351], pharmaceuticals activities depend on their capacity. Hence, more is required from powerful transnational company with global networks than of from local businesses. It must always be taken into account the economic and financial nature of such entities which are conditioned by market realities and economic cycles. Accordingly, companies must be permitted to adopt a viable business model with the objective of making a reasonable profit and enhancing shareholder value [1352]. Nonetheless, particular situations may require for a pharmaceutical company to operate on a not-for-profit basis, such as in relation to rural poor areas. Naturally, the State remains the key actor and may provide subsidies so that the companies recover their costs such as shipping and administrative procedures[1353].

In conclusion, pharmaceuticals holding patents are expected to provide mechanism such as differential pricing between and within countries, to improve access for those who cannot afford the high prices resulting by patents. Besides the few cases outlined in Chapter 2, pharmaceuticals holding patents are the only one authorized to take these steps. The aforesaid relationship between society and patent holder, thus, imply that if the patent is worked without such steps being taken, then the pharmaceutical company is in breach of its right-to-health responsibilities. *Of course, the success of the patent*

[1349] Ibidem
[1350] Ibidem
[1351] Article 2 of the Covenant
[1352] L. Forman and J. Clare Kohler, *Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility,* Toronto University Press, 2012, 5.
[1353] J. Mesquita, P. Hunt, and R. Khosla, "The Human Rights Responsibility of International Assistance and Cooperation in Health," in M. Gibney and S. Skogly, *Universal Human Rights and Extraterritorial Obligations*, University of Pennsylvania Press, 2010, 114.

holder's actions will sometimes depend upon States, donors, and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it reasonably can. In sum, the Human Rights Guidelines for Pharmaceutical Companies on Access to Medicines provide that these companies recognize the importance of human rights in their corporate mission, provide board level responsibility and accountability for their access strategy, publicly commit to contributing to the research and development of less common diseases and respect the right of countries to use TRIPS flexibilities.

Unfortunately, as highlighted in this section, international law does not impose direct obligations on pharmaceutical companies, nor do the above-mentioned guidelines establish a binding legal framework for them. This is because it is only states that are responsible under international human rights law. Therefore, although there may be a moral and political justification for such obligations, there is no legal basis for transposing into multinational corporations the obligations assumed by States under international law. Thus, in examining the obligations of non-State actors under international law, it is necessary to distinguish between what is law (lex lata) and what should be law (lex ferenda).

However, this does not mean that non-state actors are immune from the consequences of actions necessary to ensure that a state can progressively realize the right to health. On the contrary, States, in light of their obligations to protect and implement, and not just respect, must inevitably adopt measures to guarantee the right to health that impose obligations on non-state actors. Furthermore, the central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other stakeholders, including those who wish to monitor and hold companies accountable, with the aim of realizing the most prominent enjoyment of the right to access to medicines. Currently, the remedies for holding a corporation accountable and obtaining reparations for eventual human rights breaches are[1354]:

[1354] UN Doc. No. A/63/263.

a) Sue pharmaceutical companies before the national authorities, or the State of origin or the host State.

b) Suing the State of origin or the host State before national courts for failure to comply with the obligation to protect or for failure to carry out due diligence in controlling pharmaceutical companies.

c) Suing before international tribunals the States on behalf of which the companies have acted.

d) Organizing media awareness campaigns of naming and shaming by public opinion and non-governmental organizations (NGOs) to tarnish the reputation of the responsible companies, with the aim of losing market share and diminishing profits.

FINAL REMARKS

Patent protection for medicines does interfere with patients' access to essential medicines. The research has demonstrated that patients worldwide, especially in developing countries, still encounter obstacles in relation to access to medicines, mainly due to scarcity and high prices. The argument often made that patents negatively impact patients' access to medicines was found throughout the dissertation, mainly due to the higher prices resulting from IP protection.

Access in the context of this research must be understood in the sense that medicines are available, physically accessible and affordable on a non-discriminatory basis (as well as being culturally acceptable and of good quality). Certainly, the interplay between medicines and patents shifts the focus of the analysis primarily to the element of financial accessibility of essential medicines. Such situation most directly affects developing countries, in which policy makers are in a constant struggle to gather and allocate the resources required to adequately administer their public healthcare systems. The two case studies provided have illustrated the crucial need for developing countries to ensure that medicines' prices are as low as is realistically possible, so as to monitor, and it is hoped, to defeat the widespread of diseases, such as the HIV dissemination. On the contrary, the pharmaceutical industry argues that such higher prices are justified due to the fact that patents are indispensable for innovation, since otherwise there would be no incentive to invest. Pharmaceutical corporations can, thus, recoup their substantial research and development costs.

The innovation argument is not contested here, since it seems a quite understandable position in light of the non-philanthropic nature of pharmaceutical companies. Notwithstanding, it must be noted that many are the cases in which the private sectors receives public funding by national governments, thus surely making weaker the argument of large resources involved. If the research is primarily founded and sponsored with public resources, patents would hence result in a disproportionate advantage for such economic actors, which would make huge profit at the expenses of both patients and governments. Furthermore, extensive relevant literature has shown

that innovation is not always a direct consequence of higher and stricter IP provisions. For example, *evergreen* patents on the one hand and *neglected diseases* on the other are concrete examples of how the pharmaceutical industry and health research are mainly economically driven, as they focus primarily on the diseases of the developed world. Evergreen patents refer to the *de facto* extension of the protection granted to an already patented drug on the grounds of minor modification. On the other hand, neglected diseases are illnesses that concern the vast majority of the world population but that receive little to zero attention since their treatment is not considered profitable. Such diseases (for example, malaria and tuberculosis) occur most often in developing and least developed countries which feature a general population with limited financial power. In light of these considerations, the argument regarding the importance of patent protection for innovation seems to be true only in regard to diseases to which the use of medicines is lucrative and not for the majority of affected individuals worldwide.

Once the dissertation has presented the negative impact of patents on the right to access to medicines, the next logical step is to determine whether or not such right is protected under international human rights law. The work grounded on the assumption that the leading task of human rights is to protect the dignity of any individual. Many are the criticisms concerning the work of the United Nations, but human rights protection definitely constitutes an area of success for the organization which adopted many treaties, declarations and instruments on human rights since the adoption of the Universal Declaration of Human Rights in 1948.

Chapter I addressed the question on whether (and in which manner) the international human rights framework protects a "subcategory of the right to health", namely access to (essential) medicines. The dilemma was answered positively, since there is an array of sources which protect access to medicines, and even more significantly to essential medicines, to different extents.

The analysis departs from the most noticeable and rational baseline, which is article 12 ICESCR. Such article implies a right to access to essential medicines as part of the minimum core content of the right to health. This conclusion grounds on the UN Committee on Economic, Social and Cultural Rights (CESCR) interpretation of the

scope of the right to health, which, thus, includes the availability, accessibility and affordability of essential medicines on a non-discriminatory basis (General Comment 14). Alongside the latter General Comment, other international human rights treaties containing health rights, such as the Inter-American Human Rights framework, have also included access to medicines as a key component of the right to health. Accordingly, the present dissertation has highlighted the precious work for the protection of such peculiar right conducted by the Inter-American Court. This judicial body played a fundamental role in determining specific obligations upon States and emphasized the value of interpretation for the effective protection of the rights at stake. The effect utile principle, according to which the effects of conventional provisions must be ensured in practice (*ut res magit valeat quam pereat*), constitutes a founding pillar of the approach adopted by the Court towards the right to health. To summarize, the provisions of a certain treaty must be interpreted in a manner that ensures practical application of such provisions.

The two case studies provided illustrated different degrees of protection of the right of access to medicines. While both Guatemala and Costa Rica have the obligation to progressively realize the right to health and a core obligation to provide essential medicines, such countries adopted a margin of discretion when complying with the Covenant's obligations. As such States parties are free to determine the exact manner in which to implement the right to health, as long as they take all appropriate measures to the maximum of their available resources in order to ensure that the right to health and access to medicines is respected, protected and fulfilled. In specific, both Guatemala and Costa Rica are parties to the ICESCR and the American Convention on Human Rights on the one hand, as well as to the TRIPS and CAFTA Agreement to the other. The membership to the latter treaty required these countries to adopt the so-called TRIPS Plus provisions, thereby moving away from their right to health undertakings. In this regard, bearing in mind the General Comment No. 14 (CESCR), one must differentiate between a state party's inability and its unwillingness to comply with its obligations under the ICESCR in order to assess whether or not a state has violated the right to health. For example, Guatemala's protection of test data for a period of 10 years

constitutes an example of unwillingness, since it has proven to have prevented HIV-infected patients from accessing ARVs. On the contrary, Costa Rican's fairly successful HIV/AIDS policy agenda demonstrated willingness of complying with health-related obligations. Regardless of economic and financial constraints, States are under the obligations to respect, protect and fulfill health-related *core obligations* as well as to take steps through all appropriate means in order to progressively recognize and institute the right to access to medicines. The CESCR has stressed that the obligation of progressive realization cannot be regarded as an excuse for noncompliance. Accordingly, *progressive realization* must be considered in conjunction with the prohibition of *regressive measures,* entailing that *"all measures of a deliberately retroactive nature in this regard shall require the most careful consideration and shall be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources".* Such a perspective seeks to understand the obligation of progressive realization as a mixture of practicality and sensitivity to the local context. Thus, in terms of implementation, progressive realization imposes an obligation on States to justify the measures they have taken to guarantee the right to access to medicines in light of the resources at their disposal. In this respect, the CESCR has presented criteria for the assessment of retrogressive measures. In order for regressive measures to be legitimate, States must demonstrate, *inter alia*, that such measures are (a) temporary, (b) necessary, (c) non-discriminatory or do not disproportionately affect disadvantaged and marginalized individuals and groups, and (d) that they at least respect the basic obligations of the social rights in question and are applicable to the specific population group in question[1356]

In a similar fashion to the CESCR, but to a greater extent, the Inter-American Court of Human Rights played a key role in both shaping the content of the right to health amd

[1356]Committee on Economic, Social and Cultural Rights, General Comment No. 22 on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/GC/22, 2 May 2016, para. 38 and General Comment No. 23 on the right to just and favourable conditions of work (article 7 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/GC/23, 27 April 2016, para. 53.

in identifying specific obligations of members states in relation to ARVs. As presented in the first Chapter, the shift in the Court's approach and jurisprudence in addressing the protection of health-related issues is both remarkable and surely relevant for the effective protection of human rights. The aforementioned analysis on the Inter-American system has presented the evolution of the Court's approach from those cases in which health related issues were assessed as violations of the right to life and personal integrity on the one hand to the most recent cases in which the Court ruled on violations of the right to health, considered for the first time as an autonomous and directly enforceable right. In this regard, the *Cuscul Pivaral* Judgment constitutes a milestone in the Court's jurisprudence, since in light of an extensive interpretation of Article 26 of the American Convention, the right at stake becomes autonomously justiciable before the Inter-American Court of Human Rights. This new approach towards the right to health has important practical implications, for it broadens and enhance the effective protection of economic and social rights in general and access to medicine in particular.

The analysis presented in the first chapter, thus, allows the reader to answer in the affirmative all three of the research questions outlined in the introduction of this dissertation. Firstly, it can be concluded that the right to access to medicines constitutes a key part of the broader right to health. Secondly, the chapter presented that States do have specific legally binding obligations concerning the right to access to medicines under international law. Lastly, the Inter-American Court of Human Rights provides broad and extensive protection of the human rights at stake in light of a comprehensive interpretation of the relevant provisions of the American Convention on Human Rights.

Another relevant issue addressed in the thesis concerns the interface between access to medicines and patents. Accordingly, Chapter II revolved around the TRIPS Agreement as one of the most relevant and far-reaching international agreements within the field of intellectual property protection. Even more interesting is the fact that such agreement was concluded within the framework of the World Trade Organization (WTO), thus extending the jurisdiction of the WTO dispute settlement mechanism to the agreement, as well. The transfer of intellectual property from the World Intellectual Property

Organization (WIPO) to the competence of the WTO should not be underestimated. As highlighted throughout the thesis, the stronger enforcement mechanisms within the WTO provided a more effective international regulation of IP compared to the weak and ineffective monitoring system within the UN human rights system.

Notwithstanding, developing countries have raised concerns over the dispute settlement mechanism under the WTO. These countries argued that such mechanism has been allegedly used by developed countries as a tool to prevent developing nations from fully adopting the so-called TRIPS' flexibilities. These flexibilities were in fact a key issue addressed in the dissertation.

Under Article 27 TRIPS, patent's protection has now been extended to all fields of technology, thus making mandatory that members incorporate patent protection for pharmaceuticals into their domestic law. Further, Articles 28 and 33 of TRIPS require that members grant patent holders a set protection for a minimum period of 20 years. Under a superficial reading of the latter provisions, the TRIPS Agreement appears as an insurmountable barrier to access to medicines.

Nonetheless, as the second chapter illustrates, the objective and purpose of the TRIPS Agreement (under both its preamble, articles 7 and 8 and as established by the Doha Declaration) do not hinder the protection of intellectual property rights in itself. In fact, the TRIPS agreement does acknowledge the need to strike a balance between free trade and IP protection on the one hand and public health necessities on the other, between the needs of highly developed and developing and least-developed countries, and between the private rights of the right holders and public policy objectives, including technological and developmental objectives of national systems of IP protection.

In addition, both the TRIPS system does take into consideration the different needs of developing and least-developed countries by establishing transitional periods. For example, pre-TRIPS Guatemala did not impose product patents for pharmaceuticals; a situation that did not change until the end of the aforesaid transnational period. Further, TRIPS provides flexibilities which go beyond a favorable access to medicines interpretative approach. Articles 30 and 31 establish a set of concrete possibilities for developing members to balance patent protection with the right of access to medicines.

Accordingly, developing members such as Guatemala and Costa Rica can implement a number of effective instruments to protect their public health needs, such as compulsory licensing, parallel importation and the highly debated Bolar exception. Unfortunately, the actual effectiveness of these flexibilities mainly depends on political and economic considerations, rather than on legal opportunities.

Another important issue that Chapter II has taken under consideration regarded the two distinct conceptual approaches in relation to collision among treaty norms, namely genuine and apparent conflict. In the case of access to medicines and trade-related treaties, genuine conflict refers to the fact that collisions among norms cannot be avoided using interpretative means. On the contrary, apparent collision refers to actual coexistence between human rights and intellectual property rights, since they are essentially compatible. Under appropriate interpretative means is, thus, possible to assess how a fair balance between patents and access should be determined as well as to avoid opening the Pandoras' box of state responsibility.

The issue of access to medicines concerns both the human rights and trade-related systems and, thus, constitutes a valuable example of how these two systems overlap in practice. As a result, the chapter highlighted two different scenarios: firstly, the relationship between TRIPS provisions dealing with protection of patents and international human rights law. And secondly, the interplay between the CAFTA Agreement and human rights.

In regard to the first scenario, the findings demonstrated that the alleged conflict is merely apparent. In fact, a genuine conflict between TRIPS and ICESCR can be avoided by interpreting the TRIPS Agreement in a manner favorable to promoting and protecting human rights, in particular public health and the right to access to medicines. In fact, both the TRIPS agreement as well as the Doha Declaration provide all the tools needed in order to avoid conflicts among norms. Such understanding must be confirmed in light of the recent WTO dispute regarding Australia and plain packaging of tobacco products, in which the panel reached two conclusions: firstly, the Doha Declaration has the status of an a 'subsequent agreement' of WTO Members within the meaning of Article 31(3)(a) of the Vienna Convention, and secondly, that such

Declaration applies broadly to health-related issues.

On the other hand, the second scenario, namely the one concerning the CAFTA Agreement, poses additional legal challenges. The TRIPS-Plus provisions envisaged therein seem to constitute an example of genuine conflict among international norms at first sight. For instance, test data protection provided in the CAFTA is an obstacle that appears to be insurmountable throughout interpretations. As was illustrated in the chapter, a combination of methods for resolving treaty conflicts was presented: the principles *of pacta tertiis nec nocent nec prosunt, lex specialis derogat generali* and *pacta sunt servanda* provide the tools in order to determine which norm must prevail. Notwithstanding, the horizontal nature of the international system further complicates the analysis, since it is impossible to assess hierarchical superiority among its norms. Questions were posed, however, on the peculiar nature of human rights, under which some scholars have proposed a sort of constitutional nature of such special group of norms. Unfortunately, neither international practice of states nor the rulings of relevant judicial and quasi-judicial human rights bodies has demonstrated that the right to health and/or access to medicines has achieved a position of superiority in international law. In practice, besides few *ius cogens norms* examples, such as *inter alia* the prohibition of genocide, slavery and torture, human rights provisions do not enjoy a particular status at the moment. A genuine conflict leads to the conclusion that the State which breaches a human rights provision, while complying with CAFTA provisions, must incur international state responsibility and provide appropriate remedies for the affected party. Legally speaking, when States conclude trade-related treaties which directly or indirectly hinder human rights obligations assumed in other treaties, such States must be held accountable in the appropriate fora. Nonetheless, competent human rights bodies often lack any sort of effective enforcement system, which grant a *de facto* hierarchy in favor of the WTO framework.

The relevant issue is, thus, to determine whether or not the CAFTA Agreement constitute a genuine conflict which cannot be overcome by interpretative means. The analysis conducted, however, led to the opposite conclusion. According to the examination presented in the second Chapter, the CAFTA incompatibility with health

related-provisions is merely apparent. Such assumption grounds on, *inter alia,* three main considerations: firstly, on the vague and blurred nature of the provisions envisaged by CAFTA; secondly, on the *2004 Understanding to CAFTA regarding public health-related concerns*; and thirdly, on the subsequent practice within the WTO framework in relation to TRIPS-flexibilities. The broad wording of the Free Trade Agreement under consideration allows the interpreter to tailor related provisions in a manner compatible with the right to health. Furthermore, the *2004 Understanding to CAFTA regarding public health-related concern* demonstrated State's acknowledgement and consent to the health-related provisions envisaged by TRIPS and by the Doha Declaration, such as the recognition of compulsory licensing as well as parallel imports as means to grant disposal of the required medicines. Lastly, worth mentioning is the so-called *continuing* or *living* theory regarding multilateral treaties, which was outlined at the end of Chapter II in relation to the TRIPS Agreement. These kinds of multilateral treaties are meant to produce their effects over time, thus allowing an evolutionary approach which reflects the intention of the parties to apply a dynamic interpretation of the treaty itself. Stated differently, the will of the parties concerned cannot be crystallized at the moment in which the treaty entered into force, since the goals and purposes can change over time. For example, even though CAFTA does not make any specific reference to access to medicines-related flexibilities, the conclusion does not follow that the parties concerned have decided to ignore them. On the contrary, subsequent developments in TRIPS, in which the relevant parties participated, have further clarified the scope and application of such important tools. To this end, the CAFTA opens to the waivers and flexibilities under consideration. Accordingly, in order to assess the compatibility between CAFTA and the right to health, a sort of transitive property test might need to be adopted. The *conflict* between TRIPS and CAFTA (and consequently between intellectual property law and human rights) is, thus, only apparent, since systemic integration constitutes the means thorough which the patent's protection regime is compatible with the right to access to medicines. Now, since CAFTA is compatible with TRIPS, which in turn is compatible with the human right to access to medicines in light of the aforesaid principle of *systemic integration,*

we conclude that that CAFTA can be interpreted in a manner consistent with the right to access to medicines. In accordance with this principle, both treaties should be interpreted simultaneously taking into consideration the larger normative environment within international law, so as to reach a harmonious interpretation in which a balance is determined between patents and access to medicines.

The third, and final chapter, completed the analysis by addressing another perspective of the issue under consideration, namely whether or not pharmaceutical companies have human rights responsibilities under international law. The study began with the presentation of the main theories regarding international personality of non-state actors, with a particular focus on pharmaceutical corporations. Regardless of the fact that some scholars have suggested granting international personality to multinational corporations, such economic actors cannot be considered subject of international law in light of relevant practice. Accordingly, no direct legal obligations can be imposed on pharmaceutical companies.

In this regard, the "Recognition conception" seems to be the theory that most mirrors the current international realm. This conception arose as a result of the changes that have been occurring internationally and which destabilized the theoretical foundations of the "States-only' conception". For example, the greater role played by international organizations and by other non-states questioned the unique role of States as exclusive international actors. The Recognition conception took such consideration into account and proposed a corrective doctrine in order to reconcile the primary role of States with the emergence of new actors. In brief, in light of such conception, while States remain the main subjects of international law and have full personality, other entities can obtain limited international legal personality if States recognize them as such. Accordingly, the limited legal personality of a non-State actor depends completely on the will of States, which are the only competent authorities in determining which entities can take part in the international system. States have not granted the status of international subject to pharmaceutical companies, as opposed to the formal recognition delivered to international organizations and other non-state actors, such as insurgents.

In line with this reasoning, the chapter has demonstrated that international human rights

obligations cannot be imposed directly upon corporations. Nonetheless, this does not mean that pharmaceutical companies are exempt from complying with international human rights law. The practice has shown that multinational corporations are very much capable of negatively impacting the adequate enjoyment of human rights of private actors, such as individuals and communities. In such circumstances, violations of human rights result from the actions put in place by private actors (corporations), rather than by the States. In order to prevent such violations from occurring, scholars have debated on the horizontal application of human rights, which concerns the ability of this category of rights to have effect in relations between private actors. Although a direct horizontal effect is commonly declined, the international community agrees on the indirect horizontal effect of human rights. Accordingly, those whose rights have been negatively affected by corporations are not able to hold them directly accountable, for example through a legal complaint against the corporations for not complying with human rights standards. On the contrary, while it is generally true that the States do not respond internationally for the unlawful conduct perpetrated by corporations, they do so only in light of an omissive conduct by the State for not having complied with its positive duties to prevention and repression. This grounds on the consideration that States' international obligation to protect human rights compels national authorities to provide direct obligations (or at least standards of conduct) for corporations at the domestic level.

As a response to what is commonly perceived as corporate unaccountability, an entire new area of law emerged in order to limit and monitor the human rights responsibilities of these actors, namely Corporate Social Responsibility (CSR). This refers to the voluntary commitment of such entities to address social and environmental issues in parallel to their natural goal of maximizing shareholders value and to make profits. The emergence of such movement, which cover both internal and external soft law instruments, testifies the importance of the issue under consideration. The Chapter highlighted the development and legal status of such peculiar framework, which mainly grounds on the work of Ruggie and Hunt. The Guiding Principles on Business and Human Rights and the Human Rights Guidelines for Pharmaceutical Corporations on

Access to Medicines constitute the departing point for any study on this topic. Accordingly, while States remain the main duty bearers, pharmaceutical companies hold corporate responsibilities to respect the right to access to medicines (and implicitly the right to health) which derive from "social expectations". As Ruggie emphasizes in its framework, corporate social responsibility stems from the so-called *social license*, and thus requires human rights *"due diligence"*[1357]. Both experts, however, highlighted that the corporate responsibility to respect is not source of legally binding provisions under international law, unless States provide corresponding binding obligations under their respective domestic law[1358]. Nonetheless, the latter scholars recognized that while social corporate responsibility grounds mainly on *soft law* instruments, corporation do have to tailor their activities in a human rights-attentive manner.

The lack of legally binding power of such instruments should not be underestimated. These provisions are considered as something more than mere political commitments, so that there is an expectation of compliance even if no legal duty has been prescribed on corporations. In this regard, CSR can serve as an important pathway from *lex lata* to *lex ferenda.* It has been persuasively argued that in a rapidly changing and developing world order, CSR is an essential intermediate stage towards a more rigorously binding system on corporations, permitting experiment and rapid modification.

Possibly, human rights law has reached a deadlock with the issue of holding international corporations accountable for the harm they cause to human rights. The solution to such dilemma may not be within international human rights law as it currently stands. Much progress remains to be made, however, especially in light of the overwhelming number of cases in which corporations did not face the legal consequences due to their effective supremacy and transnational legal structure. This leads to two main paths for moving forward: extending the scope of international

[1357] Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and other Business Enterprises, John Ruggie, "Protect, Respect and Remedy: A Framework for Business and Human Rights," A/ HRC/8/5, April 7, 2008, para. 25.

[1358] L. Joo-Young, and P. Hunt. "Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines", *The Journal of Law, Medicine & Ethics* 40, 2012, 221.

human rights law in order to directly apply to pharmaceutical corporations, or seek elsewhere beyond the international legal framework to enhance the conduct of such corporations for what concerns the right to access to medicines. The dissertation has demonstrated that non-legal measures such as the so-called *blaming and shaming* approach proved to be very effective in the easing of difficult cases as the ones of Brazil and South Africa.

In conclusion, the main question to be answered at this point is whether or not recognizing legal status to corporations improves the efficacy of the human rights framework, or on the contrary, whether the protection of human rights can be better achieved under the State's guardianship. Accordingly, doubts arose on the assumption which considers a legally binding treaty on corporations to be the most adequate answer to the challenge under consideration. These interesting topics surely deserve further analysis and examination in light of current practice and *lex lata* on the one hand, but mostly in light of *lex ferenda* which must serve as a lighthouse for championing the effective application (*effet utile*) of relevant human rights provisions with the aim at granting the highest degree of protection for the individuals involved.

How TRIPS law relates to human rights provisions, and whether one prevails over the other in the event of conflict, still remains a quite controversial and debated topic. Nonetheless, *lex ferenda* should provide guidance for the establishment of a certain international legal system in which human rights take precedence over trade-related rules. This reasoning grounds on at least four considerations: firstly, international trade is mainly a means to advance socioeconomic objectives, most of which are already acknowledged as human rights by the international community. Accordingly, in a case of conflict between the two systems, the purposes should always prevail over the means. Secondly, while at least certain human rights norms have *ius cogens* character, WTO law is merely made of ordinary treaties of reciprocal character. Thirdly, the primary status enjoyed by the U.N. Charter, which is commonly regarded as the cornerstone of modern human rights law, should confer upon human rights a greater status compared to ordinary treaties. Finally, the peculiar purpose and features of human rights law should always be taken into account. The primary function of human rights is to limit

the power of the State in its interactions with the individual, which, thus, extend beyond reciprocal commitments between States. To this end, human rights norms are different from conventional commitments among trading countries, for they are inalienable, inherent, indivisible and universal for all human beings. Therefore, one should be very careful of confusing the interests of the pharmaceutical industry with the interest of the millions of patients affected with treatable diseases worldwide. The fact that medicines are not ordinary commodities is a part of the reasoning that cannot be ignored. As such, bearing in mind that the fundamental function of medicines is the comprehensive development of the human being, pure economic considerations must yield to human rights ends.

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