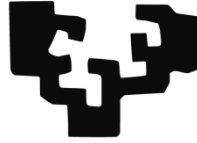


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THE GLOBAL REGIME OF INTELLECTUAL
PROPERTY RIGHTS. AN INTERPRETATION
GROUNDED IN THEIR SOCIAL FUNCTION.
THE CASE OF PHARMACEUTICAL
PATENTS.

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"Knowledge is like a candle. Even as it lights a new candle, the strength of the original flame is not diminished." - Thomas Jefferson

CHAPTER 1. INTRODUCTION. FRAMING A NEW METHODOLOGICAL APPROACH TO INTELLECTUAL PROPERTY.

Since the first synthesized drug chloral hydrate in 1869, our world has experienced a fast growing of drugs to prevent, cure and treat diseases. We live today in a world of drugs. Drugs for pain, drugs for disease, drugs for allergies, drugs for pleasure, drugs for mental health and even drugs for sex, sadness and unhappiness. In order to treat symptoms and diseases, conventional medicine is mostly based on radiation, surgery and sophisticated drugs that have been developed designed or synthesized in the laboratory or purified from nature.

Conventional medicine is also named allopathic medicine. This term was first coined by Dr. Samuel Hahnemann in the late 18th century. It derives from the Greek "allo" meaning "other" and is based on the theory that symptoms should be treated by substances that suppress symptoms. Other than drugs to combat, prevent or cure symptoms, pharmaceutical industry is also focused on developing diagnostic tools which can reveal the presence of a disease even before the patient experiences symptoms. These diagnostics tools can be lifesaving and thus have an extraordinary value.

Leaving apart the controversies between conventional medicine and the so-called *homeopathic* medicine, pharmaceutical drugs play an important role in the progress of human beings by increasing their life expectancy and health as long as improving their lives. Thanks to the development of new drugs, people are now free from many distresses and diseases affecting our ancestors in the recent past. In this sense, if we adopt the definition of health contained in the preamble to the Constitution of the World Health Organization (WHO), where health is conceptualized as "a state of

complete physical, mental and social well-being and not merely the absence of disease or infirmity”, we may conclude that the access to drugs becomes fundamental to enjoy healthy lives and it is at the heart of the right to the highest attainable standard of health ("the right to health").

The right to health first emerged as a social right in the World Health Organization (WHO) Constitution (1946) and in the Universal Declaration of Human Rights (1948). The binding International Covenant on Economic, Social, and Cultural Rights (ICESCR) of 1966 details the progressive realization of the right to health through four concrete steps, being the access to medicines (health facilities, goods and services) between them. Accessibility implies also economic accessibility (affordability) based on the principle of equity: health facilities, goods and services must be affordable for all (Authoritative General Comment 14 Committee of Economic, Social, and Cultural Rights 2000). Access to medicines is, therefore, indispensable for ensuring freedom of human beings in the sense of freedom as living a life in dignity.

The development of new and innovative drugs and the legal framework, under which this innovative process is carried out, has become a complex and expensive one. From the first pharmaceutical companies which were spin-offs from the textiles and synthetic dye industry and which owe much to the rich source of organic chemicals derived from the distillation of coal, we have passed to the current pharmaceutical companies. Current pharmaceutical companies have become important transnational companies interacting in a business market which is worth –US\$ 1 trillion a year, a figure expected to rise to US\$ 1,3 trillion by 2018. These companies stand for strong international monopoly rights (patents and other exclusive rights) in order to eventually recoup the costly investments on Research and Development (R&D) of new pharmaceuticals. Temporary monopoly rights are said to constitute a necessary incentive and a fair reward to pharmaceutical companies in exchange for the development of new drugs and processes which benefit society in what it is known as a social contract between society and innovators i.e., Intellectual Property Rights (IPRs) are instrumental rights aimed at pursuing certain social functions.

Notwithstanding this, pharmaceutical business dynamics and the current international market driven regime protecting their monopoly rights may hinder the access (affordability) to new drugs for millions of people, thus threatening their right to health. In accordance with the *Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health* (2011), one third of the world's population lacks such access; 100 million people fall into poverty actually because of high health-care costs and; only 5,2 of the 15 million persons living with HIV receive antiretroviral treatment. According to the recently published Report of the UN Secretary-General's High-Level Panel on Access to Medicines of September 2016, in spite of the fact that we are living in an era which has brought about impressive scientific and medical progress, many people and communities in need do not enjoy them; thus, availability, affordability and adaptation to specific settings and patient categories remain problematic.

The failures of this global regime has mainly three dimensions; first, medicines for diseases concentrated among the poor are neglected by pharmaceutical research and I&D efforts -this phenomenon has come to be known as the 10/90 gap, alluding to the claim that 'only 10 per cent of global health research is devoted to conditions that account for 90 per cent of the global disease burden; second, existing medicines are during their initial years on the market, priced vastly higher than their cost of production and; third, lack of adequate local health infrastructure as well as health professionals.

The global regime of IPRs and, in particular, of the pharmaceutical patents is anchored to a large extent in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) under the WTO which entailed a new and unprecedented era of global intellectual property norms. TRIPS Agreement provides developed countries' standards for the protection of IPRs and it encompasses an innovative and effective mechanism for the fulfilment and enforceability of its norms. This has had an important impact in many countries; especially if we take into account that before TRIPS more than 50 countries did not provide patent protection on pharmaceutical products. In this sense, TRIPS together with the growing income inequalities during the last decades –between countries and between individuals within the same

country-, and the reduction of national governments' room to implement public health policies¹ partly explain the lack of access to medicines by a significant volume of the world population. As it is observed in the above mentioned Special Rapporteur (2011); TRIPS and the so-called TRIPS-plus constitute an impediment to greater access to medicines the high standards of protection of Intellectual Property Rights (IPRs) implemented worldwide.

Furthermore, the creation of WTO and the enactment of the TRIPS Agreement is not an independent and autonomous reality which functions following its own founding principles and logic but it is part of a wider process aimed at restructuring the global economy under neoliberal parameters and where the accumulation of capital –by means between others of global and stronger protection of property and the weakening of distributive policies of nation states- takes precedence over any other concern. The recipe of privatization, commodification and liberalization has deepened social exclusion, increased inequality and unequal power relations, and it has eroded the state-sponsored commons² by giving rise to a new generation of enclosures as those related to knowledge and intangibles.

Interestingly, the implementation of this neoliberal agenda has run in parallel to the “evolution” of the individual’s psyche observed by the professor Byung-Chul Han³ towards a society composed of narcissistic and self-motivated individuals who under the promise of self-realization, seek the success within a *society of (productive) performance*. This psychological perception which is based on a fake belief of being free -not subject to anything- and being capable of succeeding, conceals the fact that the narcissistic individual, this homo *oeconomicus* exploits himself in a much more effective way than any other external authority could. Hence, each of us and our self-perception and the perception of others would permit the triumphant emergence of the neoliberal agenda which makes the rules of play without constraints.

¹ This gradual shrinking of maneuverability is mainly due to: the decline of their public revenues derived from reduced tariffs; its international commitments; and the international financial markets which dramatically constrain domestic policy space and make national governments unable to solve and compensate those “market failures” by putting in place public policies

² de Sousa Santos, B. (2005). Beyond neoliberal governance: The World Social Forum as subaltern cosmopolitan politics and legality. *Law and globalization from below: Towards a cosmopolitan legality*, 29, 29-63.

³ Han, B. C. (2014). *La agonía del Eros*. Herder Editorial.

The above analysis about the linkage of TRIPS -the creation of a global IPRs regime- with an economic restructuring of capitalism at global scale and thus, the economic and political reality affecting the configuration of international law -and even the psyche of individuals- is at odds with my legal education and -I suspect- with the education provided by most schools of law in Spain. Both the general courses leading to graduation and the specific post-graduate courses on Intellectual Property I have been lucky enough to be taught in order to have the opportunity of getting to the Promised Land in terms of becoming a prosperous and socially respected corporate lawyer, start from two conceptions of law and practice of law; first, an approach based mainly on a rather Kelsenian theory of law according to which, law is a set of hierarchical and complete set of autonomous norms whose application and evaluation are the subject of a new scientific discipline and; secondly and related to the first, that judges do not create law but they are neutral law adjudicators who apply law following simple syllogisms and interpretative codified techniques; law interpretation and application would be a logical quasi-automatic deductive system where legal rules are deducible from the facts of the case by a neutral and aseptic judge or law adjudicator. This approach to law purports to encapsulate law from any political or other discipline's interference -legal science is to be separated from legal politics, economics or morals-.

From the above standpoint it follows that law must be pure, law should get rid of all forms of moral, ethical, political, or religious impurities or bias. In this sense and despite the fact that Kelsenian approach remarkably contributed to protect law and legal practice from some undue interferences and unwanted interests at the time when this theory was proposed, it has also given rise to a formal legal interpretation where the *decontextualization* of law may have gone too far; in part due to this theoretical approach, law adjudication has often become a function of technically-minded legal experts unconnected from the social and political reality they intend to regulate; the denial of the factual nature of law has disconnected it from reality and has motivated important dysfunctions by undermining the substance, nature, scope and social functions of some legal institutions. As some critical theorists have argued, this "*depolitization*" is in fact a highly political option. Moreover, this "*depolitization*" of law -especially when interpreting law- silences and leaves out concepts and

principles which are counter-hegemonic to the hegemonic agenda of neoliberal globalization.

In this context, my experience with the study of Intellectual Property was reduced to the analysis of a special category of property (just like real property) but applied to intangibles. In a certainly natural, technical and unobjectionable manner, Intellectual Property rights (IPRs) were presented as the indispensable instrument in order to promote scientific progress (patents) and to protect defenseless and disadvantaged authors and poets who wandered worldwide (*droit d'auteur*) without any right. Hence, the expansion of IPRs to a global scale through TRIPS -among other instruments-, is seen as a natural step and a helpful instrument for the development of those countries which apparently were not capable of implementing and putting the basis for the flourishing and modernization of their societies.

While my political conscience and my conception of justice and practice of law fit uneasily with what I perceived it was the “race of (narcissistic) rats” of corporate law firms, the idea of a virtuous world of norms hierarchically assembled and isolated from all the impurities of the external world was gradually fading. In this sense, application of law to specific facts reveals the shortcomings of law and its indeterminacy; law is inconclusive as it does not contemplate a specific solution for each and every given case, nor does it have a unique, clear and fixed meaning for indeterminate legal concepts and institutional categories such as democracy or public interest or market. Legal concepts in IPRs global regime such as property or public interest or even novelty are highly *under-determinate* (even containing internal antinomies), and therefore, their implementation/interpretation requires subsequent political-ethical choices to select which interpretation the law should enforce⁴.

Also, lawyers and other practitioners of law take for granted certain relations of cause and effect described by law or implicitly embodied in it without revising the casual

⁴ Fisher, W. W., & Syed, T. (2006). Global justice in healthcare: developing drugs for the developing world. *UC Davis L. Rev.*, 40, 581.

assumptions encompassed by legal institutions⁵; i.e. we all assume that IPRs are in the public interest since they promote and incentivize innovation and we often ignore that the conferred legal monopoly is grounded and enforceable on the assumption that IPRs actually foster innovation and provide social benefits. However, what about if those IPRs are not incentivizing innovation in a specific jurisdiction but on the contrary, it is deterring follow-on innovation? In this context, the underlying philosophical foundations of IPRs and patents are being challenged today and paradoxically, public interest is invoked not in favor of exclusive rights but in favor of affordable access by the public.

As a consequence of the above, if we accept the indeterminacy of law and the existence of indeterminate legal concepts and legal institutions, judges and adjudicators of law are no longer aseptic interpreters of law who apply the law following quasi-automatic deductive techniques and syllogisms between norms and facts but they have room to interpret law. While the process of law interpretation and application of law is anchored in the ideal premise or rather the illusion that decisions are the result of a scientific, dispassionate, neutral legal method, this configuration conceals first the inherent conflict and power struggles present in the judicial decision-making process and second, the ideological, political or other motivational constraints existing in the judge's interpretative process. In fact, legal practice and jurisprudence shows that legal institutions and interpretations of law fail to present a single and unequivocal version over time and space. On the contrary, legal institutions have proved to be shifting and contingent.

These considerations and concerns about the nature of law and law adjudication were intuitive and fragmented in my mind until the reading of some of the most prominent commentators within the so-called Critical Legal Studies (CLS)⁶. CLS shed light on different conceptual approaches to law and law adjudication and

⁵ As it is noted by Miaille, Michel. (1976) *Une introduction critique au droit*. Paris: Maspero: [...] une science qui, par autosatisfaction ou par crainte, se refuse directement ou indirectement à réfléchir sur sa propre démarche et a remettre en cause la nature de ses concepts n'est déjà plus une science : peut-être une nouvelle forme de métaphysique. [...]

⁶ Despite the fact that CLS has its origins in the US and in common law jurisdictions, legal traditions anchored in continental law like Spain or other Latin-American jurisdictions are incorporating CLS analysis as a result of the emergence of Constitutional Courts. See in this respect, Kennedy, D., Rodríguez, C., & López, D. E. (1999). *Libertad y restricción en la decisión judicial*. Bogota: Siglo del Hombre Editores.

interpretation and it help me to overcome certain conceptual paradigms. In particular, in *Critical Legal Studies Movement*⁷, Roberto Mangabeira Unger highlights the related critique of objectivism and the critique of formalism. Following Unger, objectivism would be the belief that the authoritative legal materials and sources applicable by judges and law adjudicators embody and integrate an intelligible moral order which go beyond the contingent power struggles and ideological disputes which characterize the lawmaking process; i.e., theoretically, law application is presented as a “noble” and “pure” exercise of application of a given moral or social order resulting from the system of statutes, cases and accepted legal ideas. CLS criticizes that this approach ignores the cause-effect premises and the different interests behind law and behind a given social order. On the other hand and directly linked to objectivism, the critique of formalism would be referred to the belief in the existence of a neutral and deductive method of legal justification and legal reasoning which is encapsulated from ideological, political or philosophical disputes.

This dissertation takes a CLS approach in the sense that our conception of law for the purposes of this study is based on some CLS premises: although our analysis does not hold the premise that all law is politics, we reject the idea that law, ideology and politics can be entirely separated from one another when it comes to law application. On the contrary, in our view, all those disciplines and realms are intertwined and they interact and influence each other. Neither do we hold that law serves *per se* the hegemonic neoliberal views or the oppression of the weeks and subalterns. In this sense, there is nothing intrinsic to the idea of law as a vehicle of social injustice and there is potential for thinking of law as a transformative tool. Finally, we consider that equality in the context of the application of law does not mean formal equality; judicial reasoning cannot ignore political, social or economic constraints that determine to a large extent the fate of societies, communities and individuals; application of law has to take into account the socioeconomic and cultural context of the society and individuals which are the object of regulation and it has to be applied accordingly in order to adequately fulfil its social function.

⁷ Unger, R. M. (1983). The critical legal studies movement. *Harvard Law Review*, 561-675.

Based on the foregoing, the purpose of this dissertation is to revise critically some of today's presumptions made about IPRs and IPRs application in the context of pharmaceutical patents and pharmaceutical exclusive rights and propose an alternative interpretation and implementation of IPRs. To this end and in line with our critical legal approach to law interpretation, it is imperative that the analysis of IPRs as a legal institution grounded in a set of presumptions, be accompanied by an adequate review of the economic, political, institutional and historic aspects and dimensions of IPRs and the structure and the world scenario where the new IPRs global regime is framed today. Only in this way, we will be capable and properly equipped to identify the root cause-effect relationships and the validity of the presumptions which justify the enforceability of IPRs and pharmaceutical patents. Also, from the review of the economic, political and institutional context –where IPRs are inserted- and of the reasons behind the current interpretation and implementation of IPRs, it is possible to formulate propositions addressed to change the current global regime.

In this sense, and for the proper understanding of today's hegemonic version on the application of IPRs and pharmaceutical patents, and to highlight the gaps and contradictions between the justification and founding principles of IPRs and their current formal and *naturalist* –as a natural right- application worldwide it becomes necessary to analyze two dimensions before presenting some conclusions as to the real motives leading to today's regime and state of facts and before formulating some propositive considerations; The first dimension is focused on the changes observed in the treatment of health and international architecture around health. In this sense, it is important to note and describe the transformation of public health and international health run by states towards a model which is rather a global market of health with the participation of a multiplicity of actors and where the performance of the pharmaceutical industry in terms of its entrepreneurial conduct is basically explained by its constant seeking of maximum profit. In this first dimension, it is also required to identify the legal framework under which these transformations operate and the official, hegemonic dialectic of the new global IPRs regime.

In the second dimension, it is analyzed the general perception of legitimacy deficit of today's international authorities responsible for the global architecture, in particular in the field of health. Also, it is noteworthy to explain the political and legal solutions proposed by hegemonic forces in order to countermeasure the failures and imbalances provoked by the neoliberal agenda in an attempt to legitimize and reconcile the maintenance of the regime with slight concessions to other political claims and democratic concerns. Finally, these two dimensions permit us to introduce our considerations and interpretation about the actual reasons and motives leading to the IPRs regime linked to the global capitalism. This analysis also enables us to challenge the hegemonic legal approach by proposing an alternative interpretation of law which ultimately becomes more congruent with the nature and founding principles of IPRs and which may contribute to generate a more legitimate and democratic political and legal order in this field. Therefore, we could say that the thesis encompasses three main blocks which are divided into six chapters.

The first two chapters -second and the third chapters- deal with the emergence of a new global regime in the field of health and the international legal framework in which the new regime operates. The new scenario reduces the states' maneuver and it has given rise to a constellation of new actors with an important impact on health and on medicines. The legal framework in the field of health and in particular, in the realm of medicines is substantially integrated by the agreements of WTO and TRIPS, i.e., health and access to medicines are mainly affected by an international regime whose concerns and purposes (free trade) are far from the dialectic of the right to health and the right to affordable medicines. In this sense, our analysis evaluates whether the global IPRs regime and the market oriented policies on health implied in it, guarantee an adequate access to medicines by world population. From this perspective, this dissertation analyses next the functioning of the pharmaceutical business, the contradictory interests at stake around health and development of medicines and profit seeking oriented activity and some ethical dilemmas faced by the pharmaceutical industry.

The fourth and the fifth chapters present a political and legal approximation to the deficit of legitimacy observed in WTO functioning and in the global IPRs regime. This

crisis of legitimacy not only affects WTO but it is having a multiplying effect in the sense of challenging some of the hegemonic settings of the neoliberal agenda for globalization. In this sense, the fourth chapter explores the nature and scope of the legitimacy crisis and it reviews some legal and conceptual constructions, measures and propositions of political and governance type developed by the system as a reaction to the disruptions and threats facing the consolidation of the new regime. These measures have been proposed to counteract or alleviate the failures, unbalances and pervasive effects of this global regime. In particular, it is important to analyze the utility and effectiveness of the proposed theories of the Global Public Goods to the international relations field as a means to cope with market failures and externalities by promoting a concerted collective action. Also, it deserves attention the eventual existence of a sort of Global Public Interest and its contours as an international legal concept to justify the implementation of public action internationally recognized in favor of the general interest.

Both approaches are anchored in the attempt to introduce “politics” and a political or humanistic view to compensate the negative impact of global capitalism which is however not questioned as it is considered inevitable and irreversible. Also, we cannot ignore the Human Rights regime as an eventual emancipatory dialectic to temper the severity of unrestricted capitalism. Notwithstanding this, it is necessary to wonder to which extent the lack of concreteness of Human Rights paradigm when it comes to descend to specific demands and problems and the different binding nature of other legal “self-contained” regimes –namely the one affecting free trade- make this paradigm an effective instrument for change. On the other hand, and despite the seemingly poor practical outcomes of confronting human rights versus other normative regimes, it is helpful to examine how human rights may play an important role to inspire, justify and inform the parameters to interpret and implement law in an alternative non hegemonic manner.

The sixth chapter reveals the nature of IPRs as a social construction resulting from different historical and political processes. We pay attention to nowadays’ “naturalization” process of patent rights, which are conceived as a natural proprietary right of its owner who is entitled to prevent no matter whom, and no matter under

which circumstances, from using her intangible asset irrespective of how much of her investment has been recoup or which social effects have the excludability from its use in a particular society.

In this sense, it is explored whether the proprietary approach in the application of IPRs today has been always the same, i.e., whether IPRs conception has varied or not in the different historic phases of nations. We will evaluate whether IPRs are actually no longer “instrumental” or intended for the benefit and welfare of society or at the service of national strategies to achieve social goals and the common good. As far as health is concerned, previous to TRIPS, patent law was adjusted to national needs in the field of public health. In this respect, it is important to review to which extent all this has changed with the global regime of IPRs, and to evaluate the impact of the *one size fit all* principle behind the TRIPS regime and the implementation worldwide of western standards of IPRs protection. Therefore, we would see to which extent TRIPS has constrained states’ room to regulate IPRs according to their necessities and to their stage of development. Finally, the chapter attempts to answer which is the logic followed by the adoption of TRIPS by states which apparently were contrary to its implementation; if many states (especially developing) held TRIPS as being detrimental to their interests, why they were unanimously adopted?

Finally, chapter seven elaborates upon the singular proprietary character of IPRs. The non-rivalrous and non-excludable characteristics of intangibles make that the social function of property is remarkably more pronounced when it comes to intellectual property and in particular to pharmaceutical patents. In this sense, chapter seven asks to which extent the instrumental character of IPRs makes this legal institution and its enforceability explicitly dependent on the fulfilment of their social function. In this sense, this dissertation proposes an alternative reading of IPRs by highlighting its instrumental nature and its inherent social function. Finally, the last chapter explores the potential of deliberative democracy to promote the reprogramming and redefinition of the interpretation of IPRs and giving the whole system a more legitimate and democratic character.

To conclude these introductory notes, it is important to highlight that this dissertation does not provide an explanation of previous ideas and conclusions living in my mind. Far from being an automatic embodiment of previously developed ideas, this thesis is rather the reflection of a learning process which was initiated from a suspicion about the fact that the global IPRs regime was not working out in the manner it was expected. Neither did this regime seem to bring about the announced benefits. In this sense and resorting to the CLS approach I felt the necessity to overcome the positivist view of law which isolated law as a parallel world and decontextualized law from social reality. Therefore, a political economic analysis of the reality where the global IPRs regime and pharmaceutical patents were inserted became a must. Hence, Chapter 2 and Chapter 3 focus on the study of the new international paradigm developed from a new phase of capitalism (global capitalism or supercapitalism) and on the study of the pharmaceutical industry, its performance and its evolution along time.

From Chapter 2 and Chapter 3 we got a factual basis to highlight the shadows and failures showed by certain market driven policy on health and on pharmaceutical innovation. Based on those finding of facts, Chapter 4 addresses the contestation of the current regime and its perceived lack of political legitimacy. Chapter 4 reveals the democratic deficit of the general regime whose flagrant example is precisely represented by the problems and challenges which pharmaceutical patents are generating around health by jeopardizing the access to medicines of a large number of world populations. Hence, it is not only that the global regime is not performing as it was announced or expected but it lacks legitimacy and political acceptance creating a very fragile regime which is constantly subject to contestation and questioning. Chapter 5 reviews some general legal and institutional tools presented as possible solutions to overcome the shortcomings of the global regime. Global public goods, public interest, public policy or *ordre public* have been considered as elements addressed to correct the defects and imbalances motivated by the global regime. An analysis of those legal and institutional approaches in the specific context of pharmaceutical patents does not seem very encouraging about their emancipatory capacity and effectiveness.

Despite the findings about the poor results of the global IPRs regime and the questionable use of pharmaceutical patents as instruments at the service of purposes other than innovation in health, this thesis does not embrace certain radical (even naively revolutionary) approach which intends to demolish or “demonize” the patent system. In this sense, the thesis uphold an approach which purports to overcome the too much simplistic debate about patents yes or patents but it tries to highlight the complexity of the issue.

Paradoxically, the thesis examines how much of the “blame” explaining the malfunctioning of the IPRs regime and the patents system has to do precisely with the process of “denaturalization” IPRs institution has been subjected to. This process of denaturalization has been forced with the dynamics and the needs of the voracious evolution of capitalism which may lead it to its own suicide. In particular, this “mutant” version of IPRs and pharmaceutical patents has forgot the basic foundation which justifies its existence and the ultimate meaning of the legally artificial scarcity over an unlimited and non-rivalrous good on which are based IPRs, i.e, its social function. The automatic application of IPRs deprived from their inherent and structurally defining element, i.e. of their social function is on the basis of the crisis of legitimacy of this legal institution. Hence, the thesis upholds a genealogic approach of this particular rights in order to recover their sense and meaning as well as ensuring the necessary balance among all the public and private interests. Finally, it is proposed a deliberative model of decision and law enforcing which may provide the concept of social function with the necessary legitimacy and flexibility to the enforcement of IPRs which by nature must be adjusted to the socioeconomic context where they operate.

CHAPTER 2. INTELLECTUAL PROPERTY GLOBAL REGIME AND ITS SHORTCOMINGS IN THE FIELD OF HEALTH.

2.1. Globalization and the imperatives of Global Health Governance.

The loss of innocence of the term Globalization.

Economist Theodore Levitt is widely credited with popularizing the term in the latter half of the 1980s since the publication of his article entitled "Globalization of Markets". Globalization is a misleading concept in its attempt to explain the new era we are living in today. Rather than describing objectively the reality, this concept responds to a dominant discourse which tries to mask the reasons and decisions – mostly of political character- leading to today's world. Also, it conceals the competing interests and inherent conflicts therein as well as the alternatives to create a different international order by resorting to an allegedly aseptic concept such as globalization. Globalization is presented as an exogenous phenomenon characterized by its presumed inevitability, a relentless event in the natural process of evolution of our societies. In this sense, the economist Joseph E. Stiglitz¹ describes Globalization as a phenomenon which generates the closer integration of the countries and peoples of the world which has been brought about by the enormous reduction of costs of transport and communication, and the breaking down of artificial barriers to the flows of goods, services, capital, knowledge and (to a lesser extent) people across borders². The assumed inevitability of globalization plays a firewall role against the legitimate questioning of decisions of political reach as well as the current status quo of international order.

The changes leading to today's world have sped up since mid of the 1970. In this period, from mid-1970 to present, international relations as long as social relations

¹ Stiglitz, J. E. (2002). *Globalization and its Discontents*. Norton: New York.

² Notwithstanding this, the concept of globalization as a closer integration of the countries and peoples cannot explain the causes leading to the deep world-wide transformations we are living in. It does not capture the reasons why our world has changed in this specific manner; it would be rather a post factual description of the features and characteristics of a new era. Thus, globalization neither does constitute a phenomenon in the sense of a singular happening causing a break with the immediate past, nor explains the reasons leading to today's transformations of our society.

Actually, most of the processes invoked by the allegedly novel paradigm of globalization have been happening

between the political and the economic and between the nation state and society have experienced profound transformations which cannot merely explained by the eventual strengthening of the world interdependence and an intensified interconnection but by a new era of capitalism, a new phase of development of capitalism eased by political decisions inspired by a particular hegemonic ideology – neoliberalism- and made possible by the new technological advances. In this sense, we could say that we have passed from democratic capitalism to supercapitalism, also known as neoliberal capitalism or financialization –finance-led capitalism-³.

Focusing on the developed world which has dominated the changes, the previous balance between capitalism and economic growth with increasing income equality and a perceived democratic political system characterized the western world since the Second World War and it made people have certain confidence in democracy and trust in government. Keynesian states intervened into the economy to induce growth and the liberal state changed into the welfare state recognizing a number of social rights which became universal. The result –*les 30 années glorieux*- was an expression of what was then understood as the common good.

All that changed since the mid 1970 –despite the causes leading to these changes were previous and latent-, as it has been profusely explained by some scholars⁴, the 30 glorious years of capitalism, a democratic capitalism or Fordist regime gave way to a finance-led capitalism or neoliberal capitalism. The main difference in relation to the precedent economic scenario was not a sudden globalization or massive exchange of trade or productive capital (capital stocks or productive investments abroad) but a financial globalization⁵ -deregulation and liberalization of financial markets and a major increase in financial flows around the world- and the expansion of capitalism. Under the Post-Fordism or neoliberal capitalism, there is first an enormous increase in the number and value of the financial assets circulating around the world as long as a multiplication of financial instruments; a decoupling of real wealth and fictitious or

³ Reich, R. (2008). *Supercapitalism. The transformation of business, democracy and everyday life*. New York: Vintage books.

⁴ Bresser-Pereira, L. C. (2010). The global financial crisis, neoclassical economics, and the neoliberal years of capitalism. *Revue de la régulation. Capitalisme, institutions, pouvoirs*, (7).

⁵ Navarro, V. (1998). *Neoliberalismo y Estado del bienestar*. Barcelona: Ariel.

speculative wealth –in the distinction highlighted by Adam Smith-; augmentation of the profit rate of financial institutions and financial rents to the benefit of capitalist rentiers.

This new scenario has provoked the creation of multiple trans-national corporations (TNCs) and the unprecedented concentration of wealth in few hands. For instance, between 1970 and 2000 the number of trans-national corporations (TNCs) grew from some 7000 to 55000 with the revenues of the largest 200 TNCs amounting to more than that of 182 of the world's nations, or 80 percent of the world's population⁶. As we will see, although economic power has always played a role in defining international, the role of economic or market driven logic is also prevalent in the current global health system⁷.

The emergence of this new capitalism has been backed by a concrete economic ideology; Neoclassical macroeconomics or neoliberalism. As Professor Navarro briefly describes⁸, neoliberal ideology posits the following three main characteristics: the state must reduce its shape and interventionism in economic and social activities –selective reduction of traditional state interventions but not quantitative reduction-; labor and financial markets need to be deregulated to liberate the creative energy of the markets and; commerce and investments need to be stimulated by eliminating borders and barriers. This economic mantra has inspired the political economy of state governments, international institutions –mainly World Bank and International Monetary Fund and an important number of economists, intellectuals and media which have so replaced the precedent hegemonic political economy orthodoxy based on Keynesian macroeconomics. As many observers note international economic and financial organizations (WTO, IMF, WB) are pushing a neoliberal agenda favoring capital and overriding the will of national democratic institutions⁹, this coming at the expense of equality.

⁶ Singh, K. (2001). *Global corporate power: emerging trends and issues*. Public Interest Research Centre.

⁷ Smith, R. (2010). The role of economic power in influencing the development of global health governance. *Global Health Governance*, 3(2).

⁸ Navarro, V. (2007). Neoliberalism as a class ideology; or, the political causes of the growth of inequalities. *International Journal of Health Services*, 37(1), 47-62.

⁹ Kohlmorgen, L. (2003). Globalisation, global health governance and national health politics in developing countries: an exploration into the dynamics of interfaces (No. 60). W. Hein (Ed.). GIGA-Hamburg.

The effects of these policies have brought about a substantial increase in financial instability -an increasing number of financial crisis-, a rampant inequality and disparities between and within countries¹⁰, a dramatic increase of the competition between companies, the end of the old system of large-scale production and the weakening of big labor unions and the permanent languishment of the middle class.

The decline of Democracy and political processes.

Also, this new architecture has given rise to important issues of legitimacy of the international regime, which are not perceived to be backed by democratic processes of decisions neither is subject to democratic control and supervision. In parallel to this crisis of legitimacy of international institutions, citizens have lost their confidence in national governments which are suspicious of being agents of interests other than those representing the general interest of citizens. Democracies seem unable to act upon the common good and its being installing a formal understanding of democratic systems which are threaten to be reduced to ex-post legitimizing processes of previously decisions taken somewhere else. National political systems start to be questioned as to their capacity to be a valid instrument of the political will of people. The social compromises under the Fordism years -the instruments to spread the wealth, stabilize jobs and communities and establish equitable rules of the game- have gradually vanished.

As pointed out by Ulrich Brand¹¹, Post-Fordist politics are characterized by the profound transformations occurred between the political and the economic and between the state and society. A permanent critique of the state together with a strong legitimization of the markets has enabled private interests to handle areas which were previously under public control. Furthermore, the significance of public and the role of the state as the safeguard of the general interest or common good are being gradually blurred into what the author calls a “national competition state”;

¹⁰ Progress, S. H. (2014). Human Development Report 2014. *Worldwide: IARC CancerBase No.*

¹¹ Brand, U. (2005). Order and regulation: Global Governance as a hegemonic discourse of international politics?. *Review of International Political Economy*, 12(1), 155-176.

national states have to be primarily concerned on ensuring international competitiveness, economic efficiency and the free development of market forces. Competition, efficiency and effectiveness are sacralized as objective, infallible and scientific standards which must be advanced by states and must prevail over other virtually wishful, naïve, “political” and non-objective considerations as equality or justice.

Furthermore, political margin or room for maneuver of national states have been drastically reduced and limited. These limitations in state power take place both in developing and developed countries and are mainly due to the “exit options” offered to the financial capital by the different national competition states and its higher mobility towards states which offer better suited regulative conditions to their interests and to some international commitments, -especially in the trade field- which sometimes reduce the sphere for democratic choice¹². Some countries are obliged to adjust their domestic public policies and public spending to the standards of what international private creditors consider appropriate and competitive without regard to what public spending cuts may affect to their national populations and thus, eroding the sovereignty of democratic elected governments as long as the confidence of people on politics and democracy. Apart from the exit-option of financial capitals which make developing countries hostage of their conditions to remain, conditions attached to loans from the World Bank and the IMF have become key elements of the economics of most developing countries over the past 30 years. As described extensively by some scholars¹³, the structural adjustment programs attached to credit granting ignored the social impact of the imposed macroeconomic policies which were exclusively aimed at reducing inflation, improving macroeconomic fundamentals and protecting the ability to repay external creditors. The same could be said to the today’s recipes imposed to Greece and other European countries in order for this European and “sovereign” country to have access to credit. These recipes based on public austerity, reduction of public services (mainly health and education) and pensions and a more flexible labor market are clearly inspired by the

¹² Sreenivasan, G. (2005). Does the GATS undermine democratic control over health?. *Current debates in global justice*, 269-281.

¹³ Woods, N. (2006). *The globalizers: the IMF, the World Bank, and their borrowers*. Ithaca: Cornell University Press.

neoliberal agenda -which already showed important shortcomings in the 90's in South America- and have been accurately qualified as "*politics of austericide*".

International architecture under the hegemonic discourse of Globalization.

In the international arena and despite considerations about the existence of different regimes (security, economic, environmental and human rights regimes¹⁴) eventually fragmented, unconnected and without a regime of regimes or superior system which makes sense to the whole picture, the truth is that, as we will see, it is emerging what some scholars call a "global constitutionalism". This new legal order ruling the international (global) society reserves a binding nature and a prior attention to property rights. Property rights are increasingly conceived as having the unobjectionable status of natural rights. International regime's main focus is therefore, to secure private property at the international level through international norm-settings which compel states to implement market and private interest friendly oriented policies overriding no matter which other consideration. This is possible thanks to some international organizations, namely IMF, WB and WTO which push the neoliberal agenda by means of financial power which constrain states maneuver – access to financial resources conditioned to the national implementation of tough macroeconomic measures- or by certain legal mechanisms which ensure compliance with international rules.

On the other hand, the internationalization of many social problems and processes which are the consequences of decisions adopted at a global scale and that eventually cannot be longer handled by national states has given rise to the hegemonic concept of Global Governance¹⁵. Despite the confusion that this concept generates around its meaning, it could be defined as the somehow political multilayered response by a diverse range of state, international institutions and non-state actors to the problems raised by the globalization process.

¹⁴ Hasenclever, A., Mayer, P., & Rittberger, V. (2000). Integrating theories of international regimes. *Review of International Studies*, 26(01), 3-33.

¹⁵ Dingwerth, K., & Pattberg, P. (2006). Global governance as a perspective on world politics. *Global governance: a review of multilateralism and international organizations*, 12(2), 185-203.

James Rosenau¹⁶ has also used "governance" to denote the regulation of interdependent relations in the absence of an overarching political authority, such as in the international system. Adil Najam has defined global governance simply as "the management of global processes in the absence of global government¹⁷." Thomas G. Weiss, refers to concrete cooperative problem-solving arrangements, many of which increasingly involve not only the United Nations of states but also 'other UNs,' namely international secretariats and other non-state actors."

These "cooperative problem-solving arrangements" may be formal, taking the shape of laws or formally constituted institutions for a variety of actors (such as state authorities, intergovernmental organizations (IGOs), non-governmental organizations (NGOs), private sector entities, other civil society actors, and individuals) to manage collective affairs.¹⁸ They may also be informal (as in the case of practices or guidelines) or ad hoc entities (as in the case of coalitions)¹⁹. Also, as it is noted by an important literature on the matter, the framework of governance for international economic transactions increasingly is created and maintained by the private sector and not by the state or interstate organization²⁰ in what has been called the "emergence of Private Authority in Global Governance".

This whole picture has been presented as the new economic reality of our world under the concepts of Globalization and Global Governance. Those two concepts take for granted the current situation without any critical or causal review of the current state of facts. These analyses tend to conceive the Post-Fordist economic processes as unavoidable and are somehow based on an economic determinism in the sense that economic processes which are taking place are a natural evolution in the development of humanity and their economic relations.

¹⁶ Rosenau, J. N. (1999). Toward an ontology for global governance. *Approaches to global governance theory*, 287-301.

¹⁷ Riazati, S. (2006). A Closer look: Professor seeks stronger UN. *The Daily Bruin*, 21.

¹⁸ Zaleski, P. (2006). *Global Non-governmental Administrative System: Geosociology of the Third Sector, Civil Society in the Making*. Warszawa: IFiS Publishers.

¹⁹ Momani, B., Karns, M. P., Mingst, K. A., Kirton, J. J., & Stefanova, R. N. (2006). *International Organizations: The Politics and Processes of Global Governance*, Boulder: Lynne Rienner.

²⁰ Cutler, A. C., Haufler, V., & Porter, T. (Eds.). (1999). *Private authority and international affairs*. Suny Press.

In this respect, as it is remarked by some above mentioned scholars²¹, by configuring them as unavoidable, the terms globalization and global governance themselves will be part of an hegemonic discourse to disguise the negative effects of discretionary decisions informed by the neoliberal economic agenda. All the terminology used to describe and refer to our reality would be aimed at disguising a specific ideological thinking which can be revealed by using deconstructive techniques²². In this sense, Global Governance is a hegemonic discourse because it is compatible with the dominant transformations of neoliberalism and it serves a legitimizing function as it does not question the current Post Fordist capitalism nor does formulate an alternative. On the contrary, it takes for granted this economic reality and it just proposes political cooperative answers to ensuing problems. Finally, behind the invocation of the technical character and complexity of some issues, it seems clear that decision making processes are less open to the scrutiny of civil society and citizenry, less transparent, less representative and finally less democratic.

Global Health and Global Health Governance.

Global Health and Global Health Governance (GHG) would be the translation of the concept of globalization to the kingdom of health. This concept intends to describe the changes in health and in health politics derived from both the new challenges posed by the globalization as long as the new international architecture in the field of health and the incapacity of national governments to effectively address health of their population. In this respect, it must be remarked that –as it happens with the term globalization- both concepts have been conceived and are commonly used in the context of a hegemonic discourse which assumes without any questioning, certain assumptions of the neoliberal agenda grounded -as it has been previously mentioned-, on a market driven globalization process.

Likewise, Global health Governance has been also defined in a variety of manners; there are those authors who define Global Health Governance as a means to a more

²¹ Dingwerth, K., & Pattberg, P. *Global governance... op. cit* footnote 21.

²² Balkin, J. M. (1987). Deconstructive practice and legal theory. *The Yale Law Journal*, 96(4), 743-786.

just world²³ or as a term encompassing the collective transnational actions to address public health concerns across borders²⁴. The existence of the term itself, constitutes an “optimistic view” –since it presupposes coordination and coherent operation- of the dynamics and interaction of the different agents and processes having an impact on global health issues. On its part, there are some critics about the use of this term as this is considered to support a neoliberal view of health and health public policy. From a more neutral perspective, GHG would encompass the institutions, processes, mechanisms, relationships and transnational actions to address global health concerns.

In this sense, Global Health and GHG could not be limited to address the policies to cope with the treatment of transnational diseases and plagues. On the contrary, health and health governance are deeply encapsulated within the problems and above mentioned discussions rose by the globalization, and cannot be separated from this. In fact, one of the most urgent tasks to do with this field of study is to reestablish the linkage between disease-oriented health care intervention and the broader socio-economic environment; inequality of access to health mirrors broader socioeconomic inequality²⁵. Because of that and in line with some scholars²⁶, it is not adequate to treat global health as a singular and separated field of analysis and study without resorting to the general socioeconomic context and circumstances around it. In this sense, global health is intrinsically linked to the wider landscape of globalization and global governance, of which health is a mere part, not even the most important. In this sense, many of the challenges and problems on nowadays health are thus, related to Post Fordist capitalism.

In effect, the increasing economic interdependence and the vast international movements of people and products which characterize our global era may provoke that infectious diseases originated in one remote country have important

²³ Meier, B. M. (2014). An Agenda for Normative Policy Analysis in the Study of Global Health Governance. *Law and Global Health, Current Legal Issues*, 16.

²⁴ Leon, J. K. (2015). *The Rise of Global Health: The Evolution of Effective Collective Action*. SUNY Press.

²⁵ Thomas, C., & Weber, M. (2004). The politics of global health governance: whatever happened to “health for all by the year 2000”? *Global Governance*, 10(2), 187-205.

²⁶ Williams, O., & Rushton, S. (2009, February). Global Health Governance as a contested space: competing discourses, interests and actors. 50th International Studies Association Annual Convention in New York. (Feb. 15-18, 2009), available at http://www.allacademic.com/meta/p311363_index.html (last visited Sept. 24, 2014).

repercussions everywhere (see the recent Ebola crisis). Needless to say that globalizing forces, including increasing interconnectivity in trade, finance, technology, communications, and population mobility have created impacts and challenges for public health that transcend national boundaries and which require transnational cooperation. Although this state of facts is invoked by some authors²⁷ to justify the necessity of addressing health on a global scale under the terms of Global Health and Global Health Governance, health outcomes of globalization go beyond the direct repercussions that transnational diseases can have in a more interrelated world. In this sense, it is important to highlight the effects derived from the new socioeconomic conditions brought by globalization and specially the increase in inequality (causes of the causes). In fact, and despite neoliberal assumptions in the sense that creating global markets will eventually “trickle down” and lead to better health²⁸, it seems clear that globalization is giving rise to new patterns of health and disease linked to the global restructuring of human societies and growing inequality. Poverty would thus be the most important cause of preventable death, disease, and disability²⁹.

According to the Final Report to the Commission on Social Determinants of Health³⁰ - one of the most serious and profusely cited studies on the field-, globalization does eventually affect health through different changes in social stratification, differential exposure or vulnerability, health system characteristics and differential consequences. Although recognizing that globalization holds considerable potential for improving human health (ease of the transfer of medical and public health knowledge and technology from one part of the globe to another), the study concludes that the past 25 years of intensified global market have seen a reversal on health improvements and growing health inequalities, between which; labor market “flexibility” and its inherent economic insecurity especially for most of unskilled workers and women; changes in diet habits towards industrial produced foods and

²⁷ Ng, N. Y., & Ruger, J. P. (2011). Global health governance at a crossroads. *Global health governance: the scholarly journal for the new health security paradigm*, 3(2), 1.

²⁸ Huynen, M. M., Martens, P., & Hilderink, H. B. (2005). The health impacts of globalisation: a conceptual framework. *Globalization and health*, 1(1), 14.

²⁹ Beaglehole, R., & Bonita, R. (1998). Public health at the crossroads: which way forward?. *The Lancet*, 351(9102), 590-592.

³⁰ Network, G. K. (2007). Towards health-equitable globalisation: rights, regulation and redistribution. Final Report of the Globalisation Knowledge Network of the Commission on Social Determinants of Health. Geneva: World Health Organization.

obesogenic food environments which increase the prevalence of chronic disease; increase of foreign debt and associated health policy reforms in low and middle income countries; migration of health professionals, this migration being asymmetrical –from poor countries to rich ones- and internal migration of health personnel from public to private health care systems; inequities in access to potable water; trade reforms in agriculture and food security and finally, the lack of access to medicines.

In spite of the clear linkage between health and socioeconomic equity, the modern GHG approach has departed from the spirit of “Health for All” strategy captured in the 1978 declaration of Alma Ata and it is being limited to specific interventions, diseases and goals such as Malaria, Global Alliance for Vaccines and Immunization (GAVI) or UNAIDS while abandoning any comprehensive view of the socioeconomic environment and social transformation. In this sense, it must be distinguished two different historic approaches of GHG; the one whose milestone was the Alma Ata Declaration in 1978. In this period of time in the 70’s, the UN was the forum for the articulation of the global governance, a sort of forum of political will formation which encompassed the call for a New International Economic Order which purported to integrate economic and social concerns and transformation. The second period of time from the 80’s onward the globalization process has been governed by global economic institutions such as the IMF, WB and WTO and neoliberal principles.

Whereas poverty was the cause of ill health in the previous period, the emphasis has shifted nowadays as ill health is one cause of poverty by causing low productivity. The business rhetoric of nowadays considers health as a business opportunity and a field of innovation of the potential of medicine to combat health problems instead of dealing with socioeconomic issues as the route to health. Also, production and distribution of health products and services are set apart from its social impact as mere goods and services within the market and economic logic and presented as functional and non-political. The global response at this new era is based on piecemeal investments from loans or donations while health policy is framed in terms of the rights of corporations and consumers rather than the human rights to health.

This approach has its reflection in the discursive framing of health. In this respect, between the contemporary discourses of global health, security and economism related discourses prevail over other conceptual framing. Security based discourses emphasize the necessity to cope with health crises, infectious disease and pandemic outbreaks which eventually may become risks to national security³¹, the role of the WHO is being reduced to ensure security of states by preventing the international expansion of diseases. This discourse narrows the global health agenda and public intervention and it is connected with the neoliberal agenda in the sense of reduce state role to deliver security to attain a free and secure market for private initiative.

Economism related discourses are a natural counterpart to those of security and frames health in the logic of the market. This view prioritizes the achievement of efficiency or the maximum benefit for a given expenditure. Also it attempts to quantify health ratios and the burden of disease in terms of the controversial Disability-Adjusted Life Years (DALYs). Finally, it embraces a customer market oriented approach to health, boosting liberalization, privatization and commodification of health systems, goods and services. Both economism and security related discourses tend to sidestep the social dimension of health, its social determinants and contribute to deal with health issues from a superficial formal and abstract perspective which is keen on using “prefabricated” recipes or “neoliberal templates” while ignoring the structural causes and grounds of people’s health.

This new approach to the globalization and its impact on health has created a new scenario which can be described by the following features; the incapacity of nation states to cope with the totality of health problems of their populations; the fact that decision making centers with an important impact in Health do not have health as one of their main concerns; the emergence of new international actors in the health outlook; the lack of a global and integral strategy to address health in a systematic pro general interest manner.

³¹ Williams, O., & Rushton, S. (2009, February). Global Health Governance as a contested space: competing discourses, interests and actors. 50th International Studies Association Annual Convention in New York. available at http://www.allacademic.com/meta/p311363_index.html (last visited Sept. 24, 2014).

As to the lesser capacity of nation states to handle health issues, we can observe that national governments maneuver has been significantly reduced. National governments (especially those of developing countries) find difficulties to deal with health problems of their population. On the one hand, financial liberalization and the ease with which money can shift around the world make national governments adapt their public policies and public spending to what international creditors and financial markets deem more appropriate for their investments to be profitable. In this sense, even governments with strong commitments to egalitarian domestic policies have to temper them in order to maintain certain credibility with international financial markets³².

On the other hand, there is an important decline in public revenues from tariffs reduction in many low-income countries which are not able to develop alternative methods of revenue collection; out of 96 countries, import tariffs and other taxes on trade accounted for more than five percent of total revenues in 58 countries; in 16 of these, trade taxes contributed more than 25 percent of total revenues³³. This reduction has its effect on public spending and public services like health.

Furthermore, as we will see, trade agreements limit the range of policy instruments available to governments; the expansion and harmonization of Intellectual Property Rights (IPRs), especially TRIPS and “TRIPS-plus” endanger equitable access to patented medicines. Also, while IPRs are believed to foster Research and Development (R&D) by Pharmaceutical companies to develop new medicines, these efforts go primarily to combat mainly health problems and illnesses of high-income countries without low-income consumers substantially benefiting of the prices of patented medicines. Although the developing world suffers 90 percent of the global disease burden, only 10 percent of research expenditures target that burden. This is due to the poor economic incentives to make investments on innovative research to

³² It is very illustrative of what we are saying, some financial media comments and opinions about Syriza and their purposes of ending up with austerity measures (<http://blogs.ft.com/the-world/2015/01/syriza-and-vooodoo-economics/>)

³³ Center, W. (2006). Summary of Proceeding of a Conference on the “Impact of Trade Liberalization on Poverty”, organized on 15 April 2006. *USAID and Woodrow Wilson International Center for Scholars, Washington, DC* (www.wilsoncenter.org/tradeandpoverty).

cope with developing world diseases and because developing countries have not the necessary means and infrastructures to conduct that kind of research³⁴.

Finally, the fact that health services were included in the WTO treaty (after an insistent and powerful US corporate lobbying³⁵) and in spite of the exemption regime established in the Annex 1 B (General Agreement on trade services), these trade rules favor markets and privatization into areas traditionally seen as essential to public welfare (health care) and have the undoubted potential to further constrain the ability of governments to regulate committed services in the public interest.

Global Health and economic determinism.

The second remarkable characteristic of the new order is that global health “governance” is more and more determined by economic organizations whose principle concern is not health but other objectives such as that of market liberalization³⁶. This trend begun in the 1980s where the neo-liberal approaches to social policy, and widespread promotion of structural adjustment policies carried out by the World Bank replaced the goal of providing universal comprehensive primary care (enunciated in the Alma-Ata declaration) with the health care systems reform as part of a privatization agenda. The World Bank became the arbiter of health development norms³⁷. Health is one of the elements of the agenda and program of the World Bank. The Bank is often the world’s largest external funder of health having committed in 2005 more than 1 billion USD annually in new projects and lending³⁸.

The adverse effects of these market oriented health policies have come under severe criticism by health activists. Criticism to both the World Bank and the IMF are

³⁴ Pakenham-Walsh, N., & Priestley, C. (2002). Towards equity in global health knowledge. *Qjm*, 95(7), 469-473.

³⁵ Hoekman, B. M., & Kostecki, M. M. (2009). *The political economy of the world trading system: the WTO and beyond*. Oxford: Oxford University Press.

³⁶ Smith, R. The role of economic power in influencing the development of global health governance. See supranote 13.

³⁷ Kickbusch, I. (2000). The development of international health policies—accountability intact?. *Social Science & Medicine*, 51(6), 979-989.

³⁸ Ruger, J. P. (2005). The changing role of the World Bank in global health. *American journal of public health*, 95(1), 60-70.

generally focused on the approaches adopted by the World Bank and the IMF in formulating their policies, and the way they are governed. This includes the social and economic impact these policies have on the population of countries who avail themselves of financial assistance from these two institutions, and the lack of accountability for these impacts.

Critics to the World Bank and the IMF are centered on the 'conditionalities' and structural adjustments imposed on borrower countries. The World Bank and the IMF often attach loan conditionalities based on what is termed the 'Washington Consensus', by emphasizing economic management, macroeconomic stability, privatization of nationalized industries, liberalization and deregulation of trade, investment and financial sector, and public sector contraction. Often the conditionalities are attached without due regard for the borrower countries' individual circumstances and the prescriptive recommendations by the World Bank and IMF fail to resolve the economic problems within the countries. These conditionalities and structural adjustments have been linked with negative social outcomes such as reduced investment in public health. Critics argue that such programs reduce health care spending and have deleterious health effects³⁹. UNICEF already in the eighties estimated that structural adjustment programs may have been associated with 500.000 deaths of young children in a 12-month period⁴⁰.

Also, a number of critics were made on the World Bank's health sector policies with regard to user fees (disproportionately affecting poor and sick people), use of DALYs⁴¹ (a health indicator criticized for ignoring equity), and privatization (some research shows that a strong government is necessary to address market failures that occur in financing, consuming, and providing both personal and public health services)⁴².

³⁹ Rao, M. (Ed.). (1999). *Disinvesting in health: the World Bank's prescriptions for health*. New Delhi: Sage Publications India.

⁴⁰ UNICEF (1989). *The State of the World's Children*. Oxford University Press 16–7

⁴¹ Anand, S., & Hanson, K. (1997). Disability-adjusted life years: a critical review. *Journal of health economics*, 16(6), 685-702.

⁴² Turshen, M. (1999). *Privatizing health services in Africa*. Rutgers University Press.

On the other hand, as expressly recognized by the WTO itself in the joint study by the World Trade Organization and the World Health Organization on trade and public health in August 2012, the rules of multilateral free trade have important implications for health⁴³. The WTO role has expanded as its rules address fundamental issues to health such as access to drugs and health services. Because of this and according to some scholars, WTO has become the most important international institution in the architecture of global health governance⁴⁴. WTO and TRIPS agreements main concern is not related to health but to trade liberalization. Needless to say that health holds the weaker position in the health-trade nexus.

Part of the strength of this international institution lies in its power to enforce compliance of the countries with WTO rules and thus limiting national choices in public health policies. This is possible through the celebrated Dispute Settlement Understanding (DSU) which envisages ultimately a right of retaliation through the suspension of trade concessions or obligations as well as countermeasures. Many criticisms have been raised regarding the asymmetries created by this system between developing and developed countries⁴⁵. In effect, while such "retaliatory measures" are a strong mechanism when applied by economically powerful countries like the United States or the European Union, when applied by economically weak countries against stronger ones, they can often be ignored. The critique of these retaliation rules, from a developing-country perspective, is that developing countries with small domestic markets are not able to impose sufficient economic or political losses within the larger WTO Members to generate the requisite pressure to induce compliance. In fact, the suspension of trade concessions may be more detrimental to the developing country than the non-complying Member. Consequently, there is a common perception that shortcomings in the WTO retaliation rules undermine the utility of WTO dispute settlement for developing countries.

⁴³ Agreements, W. T. O. (2002). Public health—A Joint STUDY BY THE WHO AND THE WTO SECRETARIAT. *World Trade Organization & World Health Organization*.

⁴⁴ Williams, O. (2005). *The WTO, Trade Rules and Global Health Security*. Health, Foreign Policy and Security: Towards a Conceptual Framework for Research and Policy, 73-87.

⁴⁵ Aginam, O. (2007). Food Safety, South-North Asymmetries, and the Clash of Regulatory Regimes. *Vand. J. Transnat'l L.*, 40, 1099.

In any case, the DSU mechanism is one of the unique features of the WTO which permits this international regulation to be profusely complied –especially in favor of the commercial interests of the developed countries-. The former WTO Director-General Mr. Supachai Panitchpakdi characterized the WTO dispute settlement system as "the most active international adjudicative mechanism in the world today".

In contrast, WHO is no longer the “coordinating authority for health” which should be according with its constitutional mandate, its budget is insignificant within the general investments in global health and it does not enjoy with the binding powers of other international institutions as the before mentioned WTO⁴⁶. Thus, trade’s formalized governance with its important impact on health has not its counterpart on the health governance instruments. WHO lacks enforcement power and it bases its authority mainly on technical expertise⁴⁷.

As we will see, the WHO’s role has raised a number of critics about its weakness as the “global health conscience” and supreme coordinator which is supposed to be and which constitutes its foundational mandate. It is vulnerable to bilateral influence and political pressure, it has no enforcement powers and it does not hold the capacity to apply the international law⁴⁸. Also, critics claim that it is too focused on technical matters and vertical programs, too bureaucratic and insufficiently engaged with civil society⁴⁹. Its conflicting roles as advocate, advisor and evaluator further limit its effectiveness and its partnership with the private sector might undermine its ability and legitimacy to set norms and standards. All this may explain the reasons why the record of member state compliance with WHO binding rules and non-binding recommendations is poor⁵⁰.

The role and the increasing importance of institutions such as the World Bank, the IMF and the WTO in the field of health are not irrelevant for health-related outcomes.

⁴⁶ Hashemian, F., & Yach, D. Global Health Functions In The 21st Century. mimeo.

⁴⁷ Ng, N. Y., & Ruger, J. P. *Global health governance at a crossroads*. See supranote 33.

⁴⁸ Gostin, L. O. (2007). Meeting the survival needs of the world's least healthy people: a proposed model for global health governance. *Jama*, 298(2), 225-228.

⁴⁹ Murray, C. J., Lopez, A. D., & Wibulpolprasert, S. (2004). Monitoring global health: time for new solutions. *BMJ: British Medical Journal*, 1096-1100.

⁵⁰ Ruger, J. P. (2008). Normative foundations of global health law. *The Georgetown law journal*, 96(2), 423.

In effect, these market-liberalization oriented institutions are proving to be detrimental to advance and achieve the international standards and aims to improve global health as economic liberalization does not necessarily support poverty-oriented health care, nor does public health necessarily improve under the devolution of health responsibilities to the individual level when health's determinants are also national and global⁵¹.

New actors in the international scene and Global Health. Public-Private Partnerships.

The third feature of the new regime of global health is the emergence of new actors in the health field. The new scenario in the field of health politics began at the end of last century. Until then, nation states and multilateral organizations with state members governed international health⁵². National governments had the capacity and sovereignty to organize and regulate their health systems according to their national priorities (public/private health systems; universal/partial coverage; drug pricing and patent protection...). International health governance –also referred to as the multilateral health regime- was simple with a few actors and clearer lines of responsibility. Health funding was mainly bilateral and the World Health Organization (WHO) coordinated worldwide efforts addressed to specific targets and provided International Health Regulations (IHRs) for international reporting and handling of disease outbreaks and developing a knowledge base for country information and technical expertise on global health issues. The underlying premise for national and international health governance is that states possess responsibility for health⁵³.

Nowadays, however things have ostensibly changed as to the relevant actors in the domain of health. There is a new plethora of players and agencies financing and affecting global health issues and activities giving rise to “pluralism in international

⁵¹ Kohlmorgen, L. Globalisation, global health governance and national health politics in developing countries... supranote 15.

⁵² Ng, N. Y., & Ruger, J. P. See supranote 33.

⁵³ Brown, S. (2008). Global public-private partnerships for pharmaceuticals: operational and normative features, challenges, and prospects. *Canadian Public Administration Journal*.

health”⁵⁴. In this sense, to nation states and WHO we should add first other multilateral organizations, namely UNICEF, UNFPA, UNDP and UNAIDS (within the UN organizations), the above mentioned WTO, World Bank and IMF; regional development banks, G8/G20, European Commission and the Global Fund; secondly, Non-Governmental Organizations (NGOs) and Civil Society Organizations (CSOs) such as Medecins Sans Frontiers, Partners in Health, Red Cross or Rotaly International and last but not least the important private sector composed of philanthropic foundations (Bill and Melinda Gates Foundation, the Rockefeller Foundation), the pharmaceutical transnational companies whose 10 top companies account for 50 percent of the world market and Public-Private Partnerships (PPPs).

As other actors will deserve special attention in other chapters of this dissertation, it is necessary to stop at this point at the figure of Public-Private Partnerships (PPPs). Some authors argue that the rationale for global PPPs in health is that they are a response to both market failure⁵⁵ and institutional failure or lethargy to provide health care goods and services, particularly in developing countries. Others argue that the emergence and growth of PPPs are due to the neo-liberalism agenda and neo-liberal international regime addressed to the retrenchment of the public sector in social policy and the increase of opportunities and invigoration of the private sector⁵⁶. Finally, and from the “globalization discourse” perspective, PPPs would be an “unavoidable necessity” in harnessing the necessary resources to address increasingly complex, inter-related, global health issues⁵⁷.

From this third perspective, PPPs promise private sector managerial skills, expansive financial and in-kind resources, innovation and the always mentioned efficiency. Global public-private partnerships (GPPPs) in health would have been created, purportedly, as a response to both market and government failure to provide health

⁵⁴ Ruger, J. P., & Yach, D. (2005). Global functions at the World Health Organization: WHO must reassert its role in integrating, coordinating, and advancing the worldwide agenda on health. *BMJ: British Medical Journal*, 330(7500), 1099.

⁵⁵ Evans, T., & Chen, L. (2005). Public-Private Partnerships in Global Health. *Washington DC, Rockefeller Foundation*.

⁵⁶ Holm, K. (2001, September). Public-private partnerships for health and guaranteeing drug delivery through health systems: Issues needing further analysis. In *Report of a Meeting Hosted by the London School of Hygiene and Tropical Medicine*. September (pp. 27-28).

⁵⁷ Brundtland, G. H. (2002). Address by Dr. Gro Harlem Brundtland. Director-General, to the Fifty-Fifth World Health Assembly. Geneva, World Health Organization.

care goods and services, particularly in developing countries. They are said to have been created to address issues of product development (vaccines or pharmaceuticals), improve access to healthcare products, assist with global coordination mechanisms, strengthen health care services, provide public advocacy and education, and for regulatory and quality assurance purposes⁵⁸. Some celebrate this figure as an extraordinary instrument to overcome public institutional and market shortcomings and deficiencies⁵⁹ particularly in developing countries.

From a formal legal view a PPP is a collaborative relationship formed between at least three parties: 1) a corporation or industry association, 2) intergovernmental organizations, and 3) national authorities⁶⁰. It covers a wide variety of ventures involving a diversity of arrangements, varying with regard to participants, legal status, governance, management, policy-setting prerogatives, contributions and operational roles. They range from small, single-product collaborations with industry to large entities hosted in United Nations agencies or private not-for-profit organizations⁶¹

Despite the enthusiasm and tolerance of PPPs in health by the UN and international community, there are no global norms or guidelines on the matter. They operate in a highly unregulated environment and fashion and there has not been a serious evaluation on PPPs impact and outcomes for health.

PPPs operate under the premise of 'mutual benefit'. In this sense, PPPs afford a number of benefits to private partners including direct financial returns, payment for services or products or tax deductions, entering new markets and promotion of their image and brand, corporate legitimacy and authority with UN and other institutions⁶² etc. Meanwhile, recipient countries get resources to cope with national needs in the form of drugs, supplies, services, or funds. Partnerships also provide skills, expertise,

⁵⁸ Nishtar, S. (2004). Public-private 'partnerships' in health—a global call to action. *Health Research Policy and Systems*, 2(1), 5.

⁵⁹ Reinicke, W. H., Deng, F., Witte, J. M., Benner, T., & Whitaker, B. (2000). *Critical choices: The United Nations, networks, and the future of global governance*. IDRC, Ottawa, ON, CA.

⁶⁰ Buse, K., & Walt, G. (2000). Global public-private partnerships: part II—what are the health issues for global governance?. *Bulletin of the World Health Organization*, 78(5), 699-709.

⁶¹ WHO Glossary at <http://www.who.int/trade/glossary/story077/en/>

⁶² Buse, K., & G. Walt. Global Public-Private Partnerships (see footnote 66)

and management to health interventions. For example, the African Comprehensive HIV/AIDS partnership (ACHAP), a partnership between the Bill and Melinda Gates Foundation and Merck Foundation, has provided training to over 500 Government, NGO and other actors in project development, monitoring, evaluation, proposal development, media training, and computer skills, as well as training for over 1200 health care workers.

Notwithstanding this, PPPs are the subject of increasing criticism focusing on the structure and governance arrangements under which these PPPs perform and on their impact on health and healthcare delivery in developing countries. From the critical school, it is contended that PPPs would be part of a broader hegemonic shift, primarily discursive, which acts as a continuation of the neoliberal dominance of development theory and practice. The depoliticized language in much of the policy research and official documentation on partnerships, these critics attest, falsely suggests that power relations within partnerships are equitable and benign – a kind of ‘win-win-win’ scenario in which all agents are party to an absolute gain⁶³. As Buse and Harmer state, the concept of partnership is constructed through a dominant discourse as ‘natural’, inevitable, and as ‘win to win.’ Partnerships are, therefore, considered desirable solutions to global health crises. Similarly, any negative impacts or consequences are regarded as regrettable but unavoidable: for example, the challenges of coordinating a proliferation of initiatives, or the burden placed on recipient administrations in terms of applications, monitoring and reporting. The discursive construction of ‘partnership’ has been so effective that criticism of partnership per se is almost unthinkable⁶⁴. However, things are not always what they look.

Firstly, and regarding the arrangements through which they are governed; there are concerns with PPPs in terms of real and potential conflict of interest situations, interfaces between institutions and structures of national health governance and the partnerships accountability, transparency, decision-making structures and

⁶³ MacLean, S., Brown, S., & Fourie, P. (Eds.). (2009). *Health for some: the political economy of global health governance*. Berlin: Springer.

⁶⁴ Buse, K., & Harmer, A. (2004). Power to the Partners?: The politics of public-private health partnerships. *Development*, 47(2), 49-56.

participation, sustainability, and outcome orientations. The governing boards of various PPPs are mostly integrated by representatives of major pharmaceutical companies, having WHO a marginal role. Also, it is remarkable the lack of representation of affected communities and NGOs on partnership governing boards⁶⁵. An eloquent example of this is represented by the Global Alliance on Vaccines and Immunization (GAVI) whose Board of Directors is made up of two representatives of the pharmaceutical industry versus one member representing the WHO.

Some scholars⁶⁶ note that there is not an adequate scrutiny of corporate partners by international public bodies for potential conflicts of interest. Buse's study notes that only four (4) out of the nineteen (19) partnerships in his study undertook formal assessments of the background of their commercial partners⁶⁷. Furthermore, this study also notes that there is a "gross under representation of southern stakeholders" in the governing arrangements of PPPs. In this sense, most of PPPs secretariats are located in western countries (particularly, USA and Switzerland). Thus, it seems difficult to see a meaningful involvement in decision-making process in favor of developing countries when the loci of those processes are mainly located in western countries.

On the other hand, it is argued that decision-making processes are increasingly inaccessible to the public, this exacerbating the problems of transparency⁶⁸. For instance, the access to the Global PPPs eventually accessible in the web page of the Initiative for Public-Private Partnership in Health (IPPPH) is not available at the time of writing this dissertation. Many of the materials on PPPs rather resemble public relations or promotional materials than rigorous information with valuable and verifiable data. It is difficult to find PPPs information on their annual budgets or program evaluation/impact documentation. In the above mentioned study carried by

⁶⁵ Buse, K., & Harmer, A. M. (2007). Seven habits of highly effective global public-private health partnerships: practice and potential. *Social science & medicine*, 64(2), 259-271.

⁶⁶ Richter, J. (2004). Public-private Partnerships for Health: A trend with no alternatives?. *Development*, 47(2), 43-48.

⁶⁷ Buse, K. (2004). Governing public-private infectious disease partnerships. *The Brown Journal of World Affairs*, 10(2), 225-242.

⁶⁸ Kickbusch, I. (1997). New players for a new era: responding to the global public health challenges. *Journal of Public health*, 19(2), 171-178.

Buse (2004), he found that none of the partnerships with independent legal status make available the minutes of their deliberations.

Despite the fact that PPPs often report on quantitative data (number of drug units distributed, the number of personnel trained, the total funds distributed, and so on). There is little information on whether the PPPs actually contribute to improvements in the quality and efficiency of their pharmaceutical donations, product development and in general, about their performance in specific countries. Neither is there reliable information on the potential problems or unintended side-effects of PPPs. Also, it is stated that there is poor baseline data upon which to conduct research on the effectiveness of partnerships in their specific contributions to health or health outcomes⁶⁹.

Furthermore, there is considerable debate on the issue of accountability of PPPs in the literature. Scholars have found various shadows to the accountability of PPPs which impairs their legitimacy as global actors in the governance of health.⁷⁰ Questions are raised as to whom the partners are actually accountable to (stakeholders, general public, national states or international agencies); the availability and employment of reporting mechanisms; eventual sanctions; instruments of evaluation of their performance; criteria upon which partners are judged on measures of accountability and many other questions with uncertain answer which make numerous scholars conclude that many PPPs do not ensure that all players are held accountable for the delivery of efficient, effective and equitable healthcare services⁷¹.

As to the second type of criticism received by PPPs, there are serious concerns on the impact of PPPs on the social determinants of health⁷² since PPPs are not just influencing how health priorities are financed but also what is financed. In this sense,

⁶⁹ Holm, K. Public-Private Partnerships for Health and Guaranteeing Drug Delivery Through Health Systems: Issues Needing Further Analysis. See suprenote 62.

⁷⁰ Bartsch, S. (2007). Global Public-Private Partnerships in Health: A Question of Accountability and Legitimacy. *Wall Summer Institute for Research*, 25-28.

⁷¹ Nishtar, S. Public-private 'partnerships' in health—a global call to action. See supranote 64.

⁷² Smith, R. See supranote 13.

it is noted that efforts are specific communicable disease oriented rather than focused on social determinants of health, national health systems or preventive services⁷³.

Also, some observers questions whether drug donations are sustainable models for the provision of essential medicines⁷⁴. In effect, these partnerships operates based on charity standards of health rather than being a model of health based on rights of citizens and the result of a political collective action for health. Populations depend on the donor, who may or may not continue their programs upon expiration. In this respect, some of the partnerships do not even have stated timelines. Also, there is no such thing as accountability or binding undertakings of PPPs to be claimed by their beneficiaries. All this make these entities unstable instruments in order to guarantee the provision of health services to the people.

Moreover, it is not fully considered the obstacles and unintended side-effects of implementation, integration, and management of partnerships with existing health governance structures and institutions. Partnerships are said to have the potential to overwhelm the capacity of the national health system⁷⁵. There is a risk of skewing national priorities by PPPs. For example, although HIV/AIDS only accounts for 5% of global burden of disease (and overall 20% burden in Africa), approximately half of the total aid flows for health are spent on HIV/AIDS. In this respect, malaria (and it disproportionate effect on the poor) gets only one-twenty fifth of that provided for HIV/AIDS, being obviously underfunded confronted with HIV/AIDS⁷⁶.

Thus, partnerships, particularly those in developing countries, are likely to confront inadequate health infrastructure, and have the potential to overwhelm already overextended health personnel and infrastructure. Furthermore, because very few partnerships actually address more than one aspect of health (product development, access to products, health systems and services, research, public information and

⁷³ Buse, K. (2004). *Global health partnerships: Mapping a shifting terrain*. London: DFID Health Resource Center.

⁷⁴ Gardiner, E. (2003). *The Price of Access: Making Drugs Available in Africa* (Doctoral dissertation, Masters Thesis, Sloan Fellowship Masters Program, London Business School).

⁷⁵ Holm, K. Public-Private Partnerships for Health and Guaranteeing Drug Delivery Through Health Systems: Issues Needing Further Analysis. See suprenote 62.

⁷⁶ Hashemian, F., & Yach, D. Global Health Functions. Supranote 52.

advocacy, and coordination), PPPs are, for the most part, vertical programs that require integration into existing health infrastructures and strategies, and could possibly contribute to the fragmentation of health systems⁷⁷. In this sense, it is argued that PPPs have the potential to alter public priorities, redirect national policies, and shift public responsibility for health to the private sector. Also, PPPs may contribute to the further commercialization and privatization of health governance by weakening the role of the public sector in providing essential health services and treatments and by transferring this responsibility to private sectors partners.

In this sense, questions are raised on whether PPPs are not eroding the national state's capacity and autonomy to deliver health services. PPPs may be just a new form of developing country dependency on developed countries. Given that very few of the partnerships involve real transfers in knowledge, or building of new infrastructure, and that the intellectual property generated by these partnerships (i.e. in vaccine development) will be largely retained by researchers in the north, some authors wonder how these partnerships, beyond the value-added component, contribute to the building of equitable, sustainable health systems in developing countries.⁷⁸

Other "collateral" disadvantage of these PPP funds are their capacity to whet the industry's appetite for otherwise "unpatented" countries. In this sense, funds such as the Global Fund have created new markets for the pharmaceutical industry. Where previously there might have been no incentives to apply for AIDS patents in countries with poor purchasing power, fresh funding of those affluent donors has awoken companies' interest in seeking patents in those countries.

Last but not least, there are reasonable concerns over excessive corporate influence in setting the global health. It is noted that partnerships have increased corporate influence in policy making at global and national levels⁷⁹. In this sense, it is argued that PPPs pose a risk to the "integrity, independence, and reputation" of the United

⁷⁷ Nishtar, S. Public-private 'partnerships' in health—a global call to action. See supranote 64.

⁷⁸ Brown, S. (2008). Global public-private partnerships for pharmaceuticals: operational and normative features, challenges, and prospects. *Canadian Public Administration Journal*.

⁷⁹ Richter, J. . Public-private Partnerships for Health: A trend with no alternatives?. See supranote 72.

Nations. Also, some authors⁸⁰ question the appropriateness of using public money (in the partnership arrangements) to support corporate legitimacy. These partnerships open up considerable space for private sector influence in global health decision-making, and could potentially undermine traditional support for the UN. Finally, some authors⁸¹ claim that there is a need for “consensus about the underlying moral and ethical principles that guide global health cooperation”.

Therefore, we should conclude that there are yet many questions on the advantages and virtues of the PPPs in order to consider them as a valid instrument to provide people with more, better and affordable health.

Together with the emergence of new actors, the last feature of the new institutional architecture of global health would be the lack of coordination between the different actors this leading to an increasingly fragmented, uncoordinated and disparate global health agenda creating a leadership gap. The large plethora of actors in the field of health are operating within multiple more uncoordinated frameworks affecting health at both national and global levels without sharing a common aim, discourse or inner coherence for resource mobilization and priority setting purposes. A lack of clear structure and the blurring of responsibility are therefore characteristics of the new scenario. There is no a clear architecture of global health⁸², there is no an integrated and systematic approach to global health. Neither is there formalized governance regulating it. As we have mentioned before, the WHO is no longer the major source of knowledge neither is the supreme coordinating body of health. This state of facts which has been called by some authors as “pluralism in international health”⁸³ could rather reveal a state of anarchy or at least of a sort of unstructured plurality.

As the Dean of the Harvard School of Public Health argued when speaking on the influx of new actors and approaches into global health, “there’s one missing piece.

⁸⁰ Buse, K., & Walt, G. Global Public-Private Partnerships (see footnote 66)

⁸¹ Dodgson, R., Lee, K., & Drager, N. (2002). Global health governance. *A Conceptual Review, London/Geneva.*

⁸² Carter, J., Clinton, B., Blair, & Kofi, U. (2006). The new world of global health. *Science*, 311(5758), 162-162.

⁸³ Ruger, J. P., & Yach, D. Global functions at the World Health Organization: WHO must reassert its role in integrating, coordinating, and advancing the worldwide agenda on health. Supranote 60.

There's no architecture of global health"⁸⁴. Some authors claim that it is wrong to use the term architecture to describe a situation which does not have to do with the "old school anarchy" used by international relations academia to refer the difficulties for the states to create and maintain collective action⁸⁵. According to these authors, it is more appropriate to use the term of "open source anarchy" which better describe the different anarchy problem governance in international relations nowadays. Open-source anarchy describes anarchy, as a governance space, as accessible to, and shaped by states but also by non-state actors.

The objective of this new paradigm "open source" anarchy is said to go beyond highly structured architecture towards a purposeful plurality. It is argued that thinking of global health governance in terms of applying a source code as opposed to building architecture better reflects the opportunities and constraints created for global health by open-source anarchy. Notwithstanding this, it is difficult to see the utility of this conceptual framework except in the case we want to legitimize the established order which -as the author recognizes-, prioritizes approaches grounded in security and economic policy rather than rights-based or humanitarian thinking, this all resulting in an uncoordinated, suboptimal and even regressive governance.

Some authors claim that the new global health regime, its decentralization, and non-hierarchical character is actually promoting efficiency and a high level of specialization of the different actors, this reducing the overlapping tasks associated with regime complexity⁸⁶. However, this does not seem to be the case in the field of health. According to a study carried out by the University of Oxford⁸⁷, *the pluralism of global health institutions and the informal alliances on which power in global health rests make a unified and fully coordinated health system highly unlikely*. Contributions made by the four largest donors in the field of health, i.e., the World Bank, Bill & Melinda Gates Foundation (BMGF), the US Government, and the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, are considered to be far from achieving an

⁸⁴ Quoted in Cohen, J. (2006). The new world of global health. *Science*, 311(5758), 162-167.

⁸⁵ Fidler, D. (2007). Architecture amidst anarchy: global health's quest for governance. *1 Global Health Governance* (2007).

⁸⁶ Leon, J. K. The Rise of Global Health... supranote 30.

⁸⁷ Sridhar, D., & Batniji, R. (2008). Misfinancing global health: a case for transparency in disbursements and decision making. *The Lancet*, 372(9644), 1185-1191.

optimal allocation of resources. Also, the study interestingly notes that this inefficiency is due to lack of transparency as to what and how is financed and, specially that these donations or loans do not comply with the concept of ownership as defined in the Paris Declaration of 2005, i.e., they do not explicitly incorporate the demands of the governments or citizens of the developing country where the aids are assigned. On the contrary, these money flows could even unduly distort national plans.

As the mentioned research notes, the inclination of donors to repeatedly create new initiatives, like the parallel priorities and delivery of care by donors, weakens national strategies. This difficulty was exacerbated by the absence of transparency among donors, and restricted awareness by health ministries about what donors were directing funds to. As one minister said about donors, “they like to monitor activities, but they do not like to be monitored and evaluated”. Similar conclusions were reached by another research analyzing international health financing in India, Brazil and Russia.⁸⁸

The UN Sustainable Development Goals (SDGs) which supersedes the Millennium Development Goals (MDGs) is not either very encouraging in this respect. SDGs embrace somehow the principles and values of the market oriented, pro corporation globalization process. SDGs lack consistency in distinguishing between health delivery and policies in other sectors to realize health outcomes, specially poverty and equality -between countries and within countries-. In this sense, it keeps the framing of health policies as a sum or fragmented, piecemeal patches and interventions addressed to deal with specific technical issues and diseases without having the general picture of health and its diverse manifestations in other fields. On the other hand, it does not ensure accountability for the new actors while also promoting country ownership. Finally, there is no articulation of a rights-based approach in the health goal⁸⁹.

⁸⁸ Sridhar, D., & Gómez, E. J. (2011). Health financing in Brazil, Russia and India: what role does the international community play?. *Health Policy and Planning*, 26(1), 12-24.

⁸⁹ Buse, K., & Hawkes, S. (2015). Health in the sustainable development goals: ready for a paradigm shift?. *Globalization and health*, 11(1), 13.

In summary, Global Health is deepening inequalities between states and within states; the loss of sovereignty and maneuver of states is deteriorating public health as long as other public policies aimed at reaching equality goals; the approach of health made by the market-oriented forces running the globalization process is focused on considering health as a commodity and a business opportunity to innovate and find new market niches. Health products and services have been deprived of their social dimension for public health. There is a current tendency of ignoring the clear linkage between health and socioeconomic equity. Ill health is now viewed as a cause of poverty due to the low productivity that generates. Trying to improve health without taking into account socioeconomic factors of population constitutes an obvious absurdity for that it is not possible to advance in health without ensuring some minimal living conditions of people. On the other hand, state-centered international health has given way to GHG where new actors have emerged and have become active in the field of health. It seems difficult to say that current GHG is advancing public health, in the sense of addressing health of people, this including the conditions to maintain a mental and physical well-being, from an integral and all the factors approach. This approach is crucial to ensure the full realization of human potential and dignity. Maybe one of the failures of GHG is thinking that it responds to a previous plan and strategy when contrarily, it is merely descriptive and sometimes ideologically oriented of a set of given facts and circumstances which reveals -in terms of public health- an anarchy full of inefficiencies and shortcomings.

2.2. TRIPS regime and access to medicines. An introduction.

Globalization and access to medicines.

Access to medicines is considered as a cornerstone of the enjoyment of the rights to health and life. Also, it constitutes one fundamental component of the human right to health -as the right of everyone to the enjoyment of the highest attainable standard of physical and mental health-. The process described above as globalization has had an undoubted impact on the access to medicines around the world.

The normative basis of this right is well acknowledged in the Preamble of WHO constitution, art. 25 of the Universal Declaration of Human Rights (UDHR) of 1948, in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the general comment No. 14 (2000) made by the Committee on Economic, Social and Cultural Rights in its interpretation of the normative content of article 12, the 1978 Alma Ata Declaration as long as many other national constitutions which indirectly (135 constitutions include the right to health) or directly (Syria, Philippines, Peru and Mexico) recognize the access to medicines as a citizenry's right. This right implies that medicines should be made available, accessible, affordable, acceptable and of good quality to everyone.

Notwithstanding that, there is a huge discrepancy between this praiseworthy legal desideratum and the reality. According to the Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health⁹⁰, massive inequalities remain in access to health services and medicines around the world. In particular and regarding access to medicines, nearly 2 billion people lack access to essential medicines, i.e. a third of the world's population, living mainly in developing countries, still do not have regular access to essential medicines. A report from WHO and Health Action International on the results of surveys undertaken in 36 countries reported that in the public sector only one third

⁹⁰ Assembly, U. G. (2010). 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. Human Rights Council, Fourteenth session, Agenda item, 3.

of essential medicines needed were available and in the private sector only two thirds of such medicines were available⁹¹. In the context of HIV, as of 2007, only 31 per cent of people living with HIV who needed treatment received it⁹². Improving access to medicines could save 10 million lives a year, 4 million in Africa and South East Asia.

Furthermore, in developing countries, patients themselves pay for 50-90% of the price of essential medicines; this is one of the reasons why over 100 million people fall into poverty annually because they have to pay for health care⁹³Public health spending in both high and low income countries benefits the rich more than the poor. People with the most means and often with less need consume the most care, while those with the least means and most need consume the least care⁹⁴. As it was noted in the 2015 Social Forum organized by the UN Office of the High Commissioner for Human Rights (OHCHR), the lack of access to medicines is now also affecting developed country populations, such as in the European Union and in the United States.

Also and following the Report of the UN International Narcotics Control Board for 2014, three quarters of the world population has no access to proper pain relief treatment, i.e. around 5.5 billion people still have limited or no access to medicines containing narcotic drugs such as codeine or morphine, which went on to point out that around 92 per cent of all morphine used worldwide is consumed by only 17 per cent of the world population, primarily living in the United States, Canada, Western Europe, Australia and New Zealand.

The inability of populations to access medicines has different dimensions; first, as we will see, drugs for poor population are neglected by current pharmaceutical research –only a small percentage of total health R&D is for neglected disease; second, control measures of drugs and the absence, scarcity or poor conditions of health

⁹¹ Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *The lancet*, 373(9659), 240-249.

⁹² World Health Organization, & Unicef. (2009). Towards universal access: scaling up priority HI.

⁹³ World Health Organization. (2014). The World Health Report 2008: Primary health care (now more than ever).

⁹⁴ Ibid.

infrastructures in developing countries and the lack of local production of pharmaceuticals and; third, high costs of medicines due to pricing policies (external reference pricing (ERP), therapeutic reference pricing (TRP), as well as the regulation of manufacturers' selling price and distributor's mark-ups) and the monopolistic prices of some medicines under patent rights and other proprietary rights – affordable access for the poor would reduce profitability for patent owners and allegedly the incentives for investing in pharmaceutical research-. Within the different and somehow complex variables which determine and condition the accessibility to medicines we will focus on their protection by IPRs as they have a significant bearing on their production, price, distribution and access to medicines.

As the above cited Report of the special Rapporteur (2013) indicates, market-oriented approaches to medicines in a highly competitive global marketplace often project issues related to access to medicines as a matter of profit rather than a public health concern. While it is understandable that private pharmaceutical companies should follow such an approach, there is a growing need for States to balance that market-driven perspective by positioning access to medicines in the right-to-health framework. According with the report, this could be only faced by shifting the dominant market-oriented paradigm on access to medicines towards a right-to-health paradigm.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) and access to medicines.

During the recent 2015 UN Social Forum organized by the UN Office of the High Commissioner for Human Rights, Professor Lisa Forman focused on how IPRs has had an impact on drugs pricing, illustrated by the increase of the price of medicines in Malaysia of 28 per cent per year between 1996 and 2005 following the implementation of TRIPS.

Pharmaceuticals pricing remain a key impediment to the access of population to essential medicines. In this regard, needless to say that IPRs have an important impact on the drug pricing and affordability of medicines. Patents and other

proprietary and exclusive rights confer to their owners a legal monopoly to market their medicines, thus, creating artificial scarcity of intangible assets which in fact do not deplete when shared. The monopolist is a price maker –in contrast with a price taker in a competitive market- and seeks the maximum profit by producing and selling a lesser quantity of goods at a higher price than companies would do in a competitive market. The economic reasoning of the market logic tells us that the monopolist or the pharmaceutical patent owner’s target is not reaching or meeting as big demand or number of consumers as possible or selling as many units of products as possible but maximizing profit with an optimal output and this is normally obtained by selling to a “few and affluent people” at a high price that to the vast majority of individuals at a lower price. Therefore, for the patent owner the remaining 80 per cent of humankind is simply not worthwhile because the patentee would lose more from the necessary price reduction than it would gain through an increased sales volume.⁹⁵

The absence of patent protection for medicines in some countries has enabled many developing countries to have access to medicines at an affordable price either because of their own local production or by importing generic versions of medicines from third countries. India had become an international pharmacy, being home of important pharmaceutical manufacturing firms, which used to supply developing countries with cheap generic versions of medicines that were patented in the developed world. Also, the non-patentability of pharmaceutical products gave the opportunity to many countries such as Italy and Spain to acquire basic technology and imitate products patented in industrialized countries through reverse engineering, in order to provide their populations with pharmaceuticals at a lower cost and to develop their own technology and then incipient pharmaceutical industry. Spanish Industrial Property policy was designed to encourage industrial development through emphasizing technology acquisition from abroad, domestic information diffusion, and incremental innovation. Nothing of this would be possible nowadays following the restrictive pro-patent protection adopted by most of the world nations following TRIPS.

⁹⁵ Pogge, T., Rimmer, M., & Rubenstein, K. (Eds.). (2010). *Incentives for global public health: patent law and access to essential medicines*. Cambridge University Press.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (WTO), signed in Marrakesh, Morocco on 15 April 1994. It is therefore an integral part of the WTO. TRIPS provisions which apply to all members, are composed of seven major parts and 73 articles and they cover copyrights and related rights (rights of performers, broadcasters and phonogram producers), layout-designs of integrated circuits, geographical origin indications, trademarks, industrial designs and most importantly for our purposes, protected undisclosed information (business secrets) and patents. TRIPS sets down minimum substantive standards of protection for the before mentioned rights; it establishes procedures and remedies which have to be put in place by member states to effectively enforce IPRs and; it extends basic GATT principles such as transparency and nondiscrimination to IPRs.

Despite the fact that there was a long tradition of international norms governing IPRs issues (specially the Paris Convention for the Protection of Industrial Property of 1883 or the Berne Convention for the Protection of Literary and Artistic Works of 1886), they were focused largely on non-discrimination, national treatment and procedural issues. In this respect, as there were countries adopting full IP protection in the field of pharmaceutical research –granting patents to process and products– there were some other countries which kept the pharmaceutical field free from patents or which permitted generic or national producers to imitate foreign pharmaceuticals (in Spain for example before 1986 new Patent Act, there existed the so-called “national novelty” as one of the patentability requirements, which permitted to national producers to get national patents based on foreign patents). At the time that negotiations for TRIPS began, over 40 countries in the world did not grant patent protection for pharmaceutical products.

All this was changed in 1994. This somehow surprising insertion of this body of law into the WTO was eventually to overcome the difficulties of reaching consensus and compliance within a single-focus organization such as the World Intellectual Property Organization (WIPO), due to lack of reciprocity and conflicting interests between countries which are mainly importers and those which are mainly exporters of

information-based products and services⁹⁶. Unlike other trade negotiations, the TRIPS negotiations were not about freeing trade but about changing domestic regulatory and legal regimes.⁹⁷ Under the WTO framework, adherence to TRIPS is not only required of every WTO member or future one but also enforceable through the WTO's Understanding on Dispute Settlement (DSU) and adjudicative mechanism, administered by the Dispute Settlement Board (DSB) and an Appellate Body to entertain appeals from Panel decisions and trade sanctions for non-compliance – which become much more effective and deterrent for developing countries, many of which are highly dependent on exportations of their raw materials to western markets-. Except for the exceptions and flexibilities we will see later, the fact that art. 27 of TRIPS requires that protection be accorded in all fields of technology, prevents WTO members from excluding pharmaceuticals from the purview of protection.

There has been an important controversy between observers who are concerned about the validity and fairness of “one size fit all” aspect of the TRIPS without regard to the diverse and different socio-economic conditions and development stage of each member state⁹⁸. Even some economists who are in favor of TRIPS highlight the complex relationship between IPR protection and economic development, suggesting that strengthening IPRs may expand growth prospects under certain circumstances but may offer no improvement, or even retard conditions for development, under other circumstances⁹⁹.

Even though in theory TRIPS encompasses a minimum standards regime which formally gives its members the freedom to “customize” and tailor their domestic norms to their specific needs (art. 1.1 TRIPS) the truth is that as it is been observed by some analysts, a formalistic application of TRIPS, the subtle surveillance and the *sotto voce* threat by powerful countries to developing countries are tightly constraining the autonomy of states to regulate and elaborate their domestic

⁹⁶ Ryan, M. P. (1998). Knowledge diplomacy: global competition and the politics of intellectual property. Washington DC: Brookings Institution Press.

⁹⁷ Hoekman, B. M., & Kostecki, M. M. See *supra*note 41.

⁹⁸ Dreyfuss, R. C. (2009). TRIPS and essential medicines: must one size fit all? Making the WTO responsive to the global health crisis.

⁹⁹ Maskus, K. E. (2000). Intellectual property rights in the global economy. Washington DC: Peterson Institute.

legislation in coherence with their interests and evolution and necessities of their population and industrial sector¹⁰⁰.

Taking into account that developing countries are generally net importers of IPRs and intangible assets, TRIPS scheme seem clear in favor of developed nations which are IPRs exporters and have legislation that meet whichever minimum standard is adopted. Therefore and except for the presumed effect of enhancing innovation and incentive medical research and technology transfer, TRIPS has adverse distributive effects since it shifts wealth from developing nations to the developed economies.

The inclusion of TRIPS -and this *prima facie* unfair Agreement for developing nations- into the framework of the WTO was the result of intense lobbying by the United States and its pharmaceutical and media firms, supported by the European Union, Japan and other developed nations at the Uruguay Round negotiations¹⁰¹. In effect, the ideological impulse of TRIPS can be traced back to 1982 when Barry MacTaggart, then chairman and President of Pfizer International published an opinion piece in the New York Times claiming for a global strategy. As profusely explained by some scholars¹⁰², this document reflects the shift of the pharmaceutical industry toward a strategy for a global protection of IPRs and encompasses much of the industry thinking in blaming foreign states for allegedly stealing American inventions. As we will see, one of the most effective action of pro-IPRs lobbyists was to make a link between IPRs protection and legitimate trade.

The global scope of the IPRs through the TRIPS was part of an expanding strategy mainly of the American industry aimed at strengthening their exclusive rights. It was preceded domestically by the creation of the Court of Appeals for the Federal Circuit. This law court has developed and extremely pro-patent jurisprudence rarely mentioning the word monopoly, upholding the interests of alleged innovators by granting them large scale compensatory damages and permanent injunctions. Once

¹⁰⁰ Dinwoodie, G. B., & Dreyfuss, R. C. (2004). TRIPS and the Dynamics of Intellectual Property Lawmaking. *Case W. Res. J. Int'l L.*, 36, 95.

¹⁰¹ Picciotto, S. (2002). Defending the Public Interest in TRIPS and the WTO. In *Global Intellectual Property Rights* (pp. 224-243). Basingtoke: Palgrave Macmillan UK.

¹⁰² Bennett, B., & Tomossy, G. F. (2006). *Globalization and Health* (Vol. 27). Berlin: Springer.

consolidated a pro-patent domestic practice and law, the global strategy was the logic step forward in a gradual agenda pushed by the American pharmaceutical industry to maximize business profits. According to many, the TRIPS Agreement was the result of the will of large US corporations in order to obtain rent for developed nations from two emerging sectors and technologies, digital technology (through copyright, patents and protection for layout designs) and biotechnology (through patents and trade secrets)¹⁰³. In addition to this, the expanding somehow, “insatiable” strategy of pharmaceutical corporations is far from coming to an end. In this sense, the US Department of Commerce was required to review and analyze whether the use of price controls, reference pricing and other measures could constitute a burden to free trade as a nontariff barrier, suggesting that those barriers are detrimental for US consumers in terms of higher prices for their medicines¹⁰⁴.

As we will analyze more deeply, one may wonder how developing countries consented to be subject to this unbalanced international Agreement. In fact, TRIPS were only reluctantly accepted by developing countries in exchange of the prospect of better market access for their textile, clothing and agricultural products. India and Brazil which were home of large generic pharmaceutical industries, were against TRIPS, on the basis of considering that this Agreement would burden the provision of affordable, essential medicines which would hurt their domestic industries in the field. Notwithstanding this, the US, the European Union and Japan defended altogether the signature of TRIPS. They put its signature as the first condition to the main WTO Agreement and annexes.

In exchange of adherence to TRIPS, developing nations were promised to have greater access to agricultural markets of developed countries markets. Ironically,

¹⁰³ Drahos, P., & Braithwaite, J. (2002). *Information feudalism: Who owns the knowledge economy?*. London: Earthscan.

¹⁰⁴ The study which can be found at (<http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>) was published under the title “Pharmaceutical Price Controls in OECD Countries Implications for U.S. Consumers, Pricing, Research and Development, and Innovation” in December 2004 by the U.S. Department of Commerce International Trade Administration and is focused on seven OECD countries: Canada, France, Germany, Japan, Poland, Spain, and the United Kingdom and highlights the cost and loss of opportunity for the US economy of some OECD drug pricing policies. After controlling for price and consumption levels, BCG found that “global revenues would increase by 35 to 35 percent” in the absence of price controls. BCG estimated that absent price controls an additional 10 to 13 new drugs would have been launched over the past decade. BCG estimated that higher revenues and R&D spending would have created 20–30 thousand extra R&D jobs (with even greater increases overseas), and 15–20 thousand additional pharmaceutical jobs.

TRIPS have also increased proprietary rights of developed countries companies over plants and seeds and phytosanitary restrictions are used as indirect barriers to developing countries agricultural products. Also, developing countries were persuaded that TRIPS and IPRS new standards of protection shall foster their innovation process, local production, foreign investment and technology transfer north-south. As we will see, after 20 years of TRIPS, there are important shadows in relation with the announced outcomes and virtues of this Agreement.

Paradoxically and taking into account the impact of TRIPS on health, WHO did not participate into the negotiations leading to the signature of TRIPS. Consequently, not traditionally health-related institutions such as the WTO have gained an undisguised role in world health through its determinant role regarding health services and access to medicines. In this respect, as it has been suggested previously,¹⁰⁵ from the international legal perspective, the center of power for global health governance has shifted from WHO to WTO. Neither is provided in TRIPS any previous analysis or balance on the impact and cost that protection of certain pharmaceuticals may have on public health of the countries where it is to be implemented.

¹⁰⁵ Fidler, D., & World Health Organization. (2002). Global health governance: overview of the role of international law in protecting and promoting global public health. Geneva: World Health Organization.

2.3. Internal exceptions and limitations to the implementation of IPRs under TRIPS.

TRIPS explicit limitations and exceptions.

Within the legal tradition of both national and international law of IPRs, exceptions and limitations have been adopted within the purview of the exclusive rights/monopolies conferred by IPRs. These exceptions and limitations are mostly justified by questions related to public interest which should prevail over other private interests. TRIPS could not constitute an(other) exception to this.

During the negotiations of TRIPS, many developing countries led by India, strove to achieve explicit legal margins to permit national governments to use compulsory pharmaceutical licensing as long as some concessions in the field of parallel importation of pharmaceuticals. In this sense, many poor countries which lack drug manufacturing capability had serious concerns on the accession of India to the TRIPS as this country was their main supplier of drugs. In fact India is still considered to be the “pharmacy of the developing world”. Neither goal was fully achieved but in turn, TRIPS contemplates some windows to a more flexible application of patent exclusive rights.

Exceptions.

Unlike the GATTs and its article XX, TRIPS does not include general exceptions¹⁰⁶. Instead of this general chapeau clause, TRIPS integrates those exceptions into the structure and language of the agreement itself. It is not clear whether art. XX list of exceptions in GATTs could be invoked in a TRIPS case. Even if the fact that the Agreement on Trade-Related Investment Measures (TRIMs Agreement) explicit

¹⁰⁶ Article XX consists of two parts: an introductory clause (the chapeau) and a list of types of measures that fall within its scope and which include among others, those measures: a) necessary to protect public morals; b) necessary to protect human, animal or plant life or health; d) necessary to secure compliance with laws or regulations which are not inconsistent with GATT rules themselves; j) essential to the acquisition or distribution of products in short supply. All these exceptions could be fit into the interpretation and implementation of TRIPS. In fact,

mention to the exceptions under the GATT in article 3¹⁰⁷ makes some authors think that this inclusion is not the legislator's intent for TRIPS –following the *expressio unius est exclusio alterius* principle-, there is no conclusive legal reason to exclude them from applicability in the TRIPS context, especially if we take into account the necessary coherence of the whole treaty which calls for a holistic interpretation of all of its parts¹⁰⁸.

TRIPS provides instead a standard three-part test allowing members to make “Exceptions to the Rights Conferred”. According to article 30 of TRIPS, these exceptions can be implemented as long as they are 1) limited; 2) do not unreasonably conflict with normal exploitation of the patent; 3) do not “unreasonably prejudice the legitimate interests of the patent holder, taking account of the legitimate interests of third parties. The panelists had the opportunity to interpret thoroughly this three-part test exceptions in the dispute DS114 Canada — Patent Protection of Pharmaceutical Products.¹⁰⁹

On the other hand, and according to article 27 of TRIPS, Governments can refuse to grant patents for three reasons that may relate to public health: 1) inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life or health (Article 27.2); 2) diagnostic, therapeutic and surgical methods for treating

¹⁰⁷ all exceptions under the GATT 1994 shall apply, as appropriate, to the provisions of this agreement

¹⁰⁸ In particular, p. 51 of the Report of the Appellate Body on Korea-Dairy case (WT/DS98/AB/R), the Appellate Body says that “In light of the interpretive principle of effectiveness, it is the duty of any treaty interpreter to “read all applicable provisions of a treaty in a way that gives meaning to all of them, harmoniously.”¹⁰⁸ An important corollary of this principle is that a treaty should be interpreted as a whole, and, in particular, its sections and parts should be read as a whole.¹⁰⁸ Article II:2 of the WTO Agreement expressly manifests the intention of the Uruguay Round negotiators that the provisions of the WTO Agreement and the Multilateral Trade Agreements included in its Annexes 1, 2 and 3 must be read as a whole”

¹⁰⁹ The Panel found the so-called regulatory review exception provided for in Canada's Patent Act as not inconsistent with Article 27.1 of the TRIPS, being covered by the exception in Article 30. Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires. However the Panel found that the so-called stockpiling exception the second aspect of the Canadian Patent Act challenged by the EC, was inconsistent with Article 28.1 of the TRIPS Agreement and was not covered by the exception in Article 30 of the TRIPS Agreement. Under the stockpiling exception, competitors are allowed to manufacture and stockpile patented goods during a certain period before the patent expires, but the goods cannot be sold until after the patent expires. The panel considered that, unlike the regulatory review exception, the stockpiling exception constituted a substantial curtailment of the exclusionary rights required to be granted to patent owners under Article 28.1 to such an extent that it could not be considered to be a limited exception within the meaning of Article 30 of the TRIPS Agreement.

humans or animals (Article 27.3a) and; 3) certain plant and animal inventions (Article 27.3b.) As we will see, the most important jurisprudence by Panel on this article involves India (Dispute DS 50 and DS79 both cases India-Patent Protection for Pharmaceutical and Agricultural Chemical Products brought to Panel respectively by the US and EC¹¹⁰) and were brought to the Panel at the early beginning of the existence of the Panel.

Furthermore, article 73 of the TRIPS Agreement governs the use of the "Security Exceptions" (right to take measures to protect essential national security interests or in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security), which may restrict trade in goods. The wording of Article 73 of the TRIPS Agreement is identical to the provision governing trade in goods (Article XXI of the GATT 1994) and the application of the concept is the same as for trade in goods and trade in services. There is no explicit obligation to notify measures taken pursuant to Article 73 of the TRIPS Agreement. However, a Decision adopted by the GATT CONTRACTING PARTIES in 1982 (1982 Decision) states that "subject to the exception in Article XXI(a), WTO Members should be informed to the fullest extent possible of trade measures taken under Article XXI".

Interpretations made by the Panel have raised important critics as to their formalistic approach. First, in the context of article 30, it is been regarded as questionable that the parts of the test are construed as cumulative and the mechanistic interpretation of legal concepts following the legal constructions made by the jurisprudence of the developed countries¹¹¹. Also, some scholars are questioning whether the jurisprudence developed with respect to GATT provisions should apply equally to TRIPS and whether the formalistic approach taken in relation with trade should be implemented when evaluating accomplishment of TRIPS. GATT's jurisprudence has

¹¹⁰ Both cases were requested (2 July, 1996 and 28 April 1997) in respect of the alleged absence in India of patent protection for pharmaceutical and agricultural chemical products, and the absence of formal systems that permit the filing of patent applications of and provide exclusive marketing rights for such products. The Panel found that India has not complied with its obligations under Article 70.8(a) or Article 63(1) and (2) of the TRIPS Agreement by failing to establish a mechanism that adequately preserves novelty and priority in respect of applications for product patents for pharmaceutical and agricultural chemical inventions, and was also not in compliance with Article 70.9 of the TRIPS Agreement by failing to establish a system for the grant of exclusive marketing rights.

¹¹¹ Dreyfuss, R. C. TRIPS and Essential Medicines: Must One Size Fit All? (See footnote 104).

been characterized for having rejected automatically the argument of substantive equality (or offsetting equality) in adjudicating claims for violations of national treatment as there is an insistence on formal equality (a member state does not have room to successfully argue that, although it applies different rules to nationals of different countries, equality of treatment in fact is achieved by viewing the applicable rules as a whole—that is, when the ways in which particular rules offset one another are taken into account-).

For many, it does not seem to make sense that the jurisprudence that has been developed with regard to the GATT's trade provisions should be drawn to TRIPS - with quite remarkable different structure and purpose -. In this sense, there are serious doubts about whether the structural implications attached to the guarantee of national treatment are appropriate to other TRIPS obligations as long as whether the formalistic approach taken to trade should be utilized when assessing compliance with obligations unique to intellectual property, such as minimum protection standards and the open and indeterminate concepts. The decision to subject TRIPS decisions to adjudication within the trade system is said to lead to overly restrictive interpretations that ignores TRIPS principles and objectives and the intentions of the parties which are reflected in article 7 and 8 of the Agreement. In this respect, it is argued that TRIPS panels are requested to consider the overall balance between benefits and detriments and subsequent tradeoffs of TRIPS implementation instead of a strict formalistic approach of its provisions¹¹².

Finally, some scholars demand an IP-specific standard of review tailored to the demands of intellectual property balancing which should have a greater deference to national decision making (giving greater weight to state actions designed to achieve human rights objectives) in evaluating exceptions and limitations to IPRs. Using trade approaches to interpret TRIPS –they argue- is nullifying implementation of those TRIPS provisions supporting the creation of balanced intellectual property protection. A greater deference to national decision making (eventually the frame where IPRs operate) instead, would permit panels to consider the reasons states offer

¹¹² Dinwoodie, G. B., & Dreyfuss, R. C. (2004). *TRIPS and the Dynamics of Intellectual Property [...]* (see previous footnote 106).

for the domestic intellectual property policies in view of balancing different interests¹¹³.

Limitations.

As to the limitations of the rights conferred to the Patent owner, it is very important for our purposes to mention article 31 of TRIPS which has been the object of an interesting debate and legal controversy over its specific interpretation. Article 31 permits national governments to authorize others the use of the subject matter of the patent without the patent owner's consent, including use by the government itself or third parties authorized by government. In brief, article 31 regulates the regime of compulsory licensing of patents. Even though compulsory licenses are applicable to no matter which subject matter of the patent, the truth is that this is usually relevant in the field of pharmaceutical patents. In developing countries, high prices of pharmaceuticals reduce affordability of medicines, and compulsory licensing may be seen as an adequate legal tool to balance IPRs protection and public health. Instead, in developed nations, the higher per capita income and public budgets eventually prevent governments from using compulsory licensing except when there is an economic slowdown or any national emergency.

Thus, national governments can grant a compulsory license within its jurisdiction to manufacture, import or sell a patented product as long as the conditions set out in paragraphs a) to l) of article 31 are met. Among them: making first efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time – except in the case of a national emergency or other circumstances of extreme urgency or public non-commercial use-; paying an adequate remuneration taking into account the circumstances of each case and the economic value of the authorization; the compulsory license has to be used “predominantly” for the supply of the domestic market of the member granting such compulsory use; and that the scope and duration of such use shall be limited to the purpose for which it was authorized.

¹¹³ Land, M. (2012). *Rebalancing Trips*. Michigan Journal of International Law, 33.

The problem with article 31 for many developing countries is that although those countries could grant a compulsory license to manufacture, they do not have the capacity to manufacture the required drugs except they could import them at below-market prices –most likely because they were also manufactured under compulsory license by the exporting country-. The word predominantly used in article 31f) –*any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use*- is not defined leaving open this wording to different interpretations and controversies. It could mean that a compulsory license cannot be used to supply a foreign country in need or that more than 50% of the production must be sold on the domestic market.

Developed nations, particularly the United States, disputed all efforts to a flexible use of the compulsory license system of article 31, even under a public health exigency, and threatened to levy punitive trade sanctions¹¹⁴ and challenged all attempts by the developing nations to use the right to compulsory license patents. The developed nations' pressure on developing nations to comply with some international commitments – even compromising national public needs and goals- has resulted in what has been called by some a “poverty penalty.” The term “poverty penalty” would refer to the cost poorer nations suffer from fulfilling international obligations that require prioritizing trade interests to the detriment of welfare¹¹⁵.

As we will see, the South African case constitutes one of the most illustrative examples of the social mobilization against the effects of the TRIPS agreement and the belligerency of the pharmaceutical lobby regarding a flexible use of the compulsory licenses provided in article 31 of TRIPS. After an intense contestation of the TRIPS agreement and its impact on public health, WTO members accorded the DOHA Declaration which led to the proposition of a new article 31*bis* on 6 December 2005 (aimed at removing the difficulties found for the application of article 31 and creating an additional form of compulsory license related to the export of medicines to countries in need and waiving application of article 31 f) in order to make permanent

¹¹⁴ Ford, S. M. (1999). Compulsory licensing provisions under the TRIPS agreement: balancing pills and patents. *Am. U. Int'l L. Rev.*, 15, 941.

¹¹⁵ Ragavan, S. (2003). The Jekyll and Hyde Story of International Trade: The Supreme Court in *PhRMA v. Walsh* and the TRIPS Agreement. *U. Rich. L. Rev.*, 38, 777.

a decision on patents and public health originally adopted in 2003. This was formally built into the TRIPS Agreement after acceptance of the Protocol amending the TRIPS Agreement by two thirds of the WTO's members. The amendment took effect on 23 January 2017 and replaced the 2003 waiver for members who have accepted the amendment¹¹⁶.

Flexibilities.

A first block of flexibilities provided for by TRIPS results from textual silence of the Agreement, i.e. questions not expressly regulated by it, which permit countries to adopt national legislation adapted to their national interests. In this sense and despite the fact that it imposes certain minimum levels of protection on states and to do so without discrimination, the treaty largely does not specify the manner in which states should go about achieving these goals. In theory, these *lacunae* give state members ample room to enact legislation suited to their necessities. India's legislation is a good example of this approach. India's Patent Law of 1970 excludes for example from patentability the *new use for a known substance* as long as *new form of a known substance which does not result in the enhancement of the known efficacy* (art. 3d).

This article prevents evergreening (new patent applications for a novel product which is in fact only very slightly different from the one which is about to lose its patent protection, thus artificially extending patent protection) as long as it permits that new uses (to treat a different disease) of a known pharmaceutical substance remain in the public domain. Indian Supreme Court has endorsed a pro public health approach regarding the requirements for patentability and it has held the constitutionality of this important article¹¹⁷. Despite the apparent freedom of Indian legislators and judiciary to craft patent law in accordance with Indian needs, there is

¹¹⁶ Members who are yet to accept the amendment currently have until 31 December 2017 to do so. For them the waiver will continue to apply until a member accepts the amendment and it takes effect for it.

¹¹⁷ In the most recent case, *Novartis AG v Union of India & others* in 2013, the Supreme Court of India in a very important ruling stated that the required "efficacy" is not arbitrary but it depends upon the function, utility or purpose of the product under consideration, therefore in the case of pharmaceuticals which claim to cure a disease, the test of efficacy can only be therapeutic efficacy.

an important pressure by the US and other western countries to reduce this margin¹¹⁸.

Other flexibility established by TRIPS is established in Article 41(1), which provides that members shall ensure that enforcement procedures "permit effective action" against acts of infringement and provides that they make available "expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. Article 41(1) does not, however, define "effective" or "expeditious," leaving these terms to be interpreted consistently with local context.

Other important flexibility regarding developing countries and LDCs has to do with exhaustion of rights, i.e., the concept that once a company has sold a batch of its product, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch, which can be exported and imported by other country. In this respect, TRIPS establishes that none of its provisions, except those dealing with non-discrimination ("national treatment" and "most-favored-nation treatment"), can be used to address the issue of exhaustion of intellectual property rights in a WTO dispute. Therefore, even if a country allows parallel imports in a way that another country might think violates TRIPS, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved. The Doha Declaration clarifies that this means that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives -Article 6 TRIPS and Doha declaration 5(d)-.

Finally, it is worth mentioning the flexibility concerning the use exception of IPRs, in particular, of patents which permit the free and unauthorized use of patents for research and experimental purposes. This use is an effective instrument to speed introduction of generic medicines just upon expiration of patents. The research and

¹¹⁸ In Obama's visit to India in 2015, the ONG MSF denounced that one of the purposes of the visit was to put pressure on the Indian Government towards an amendment of Indian Patent Law. The visit was followed by some declarations of Indian Prime Minister saying that India was willing to accept the suggestions of a joint Indo-US working group on intellectual property rights.

early working exception (“Bolar” exception) is permitted under TRIPS. However some countries like the US¹¹⁹ are narrowing the scope of this exception.

Some states have taken advantage of the flexibilities allowed under the TRIPS. More than thirty developing countries have adopted a rule of international exhaustion, many others have excluded diagnostic, therapeutic, and surgical methods from patentability and allowed third parties to use inventions under patent for experimental, scientific, or research purposes. Most also allowed compulsory licensing of patented inventions, although the grounds for issuing such licenses varied.

Notwithstanding this, it can be observed that most of developing countries and Least Developed Countries (LDCs) have been reluctant to fully implement into their domestic legislation some of the most important TRIPS flexibilities. In fact, and according to some commentators the low number of conflicts around the accomplishment of TRIPS may have to do with a somehow, *culture of overcompliance*. In effect, the threat of defending an onerous proceeding and above all, the possibility of sanctions, has contributed to a culture of overcompliance which has prevented member states from implementing and experimenting with flexibilities.

According to an important survey on the implementation of the TRIPS Agreement¹²⁰, a number of states -including many LDCs- have explicitly forgone the flexibilities they would otherwise be entitled to use and have adopted restrictive national laws beyond what is required by TRIPS¹²¹. Paradoxically, some of the poorest countries had the highest levels of protection, while some developing countries with the greatest technological capacity (see the case of India) had mixed approaches to implementation of TRIPS to ensure an adjustment of their patent law to their national needs. Analyzing the legal and political reasons behind this paradox, we can

¹¹⁹ An illustrative example of this is the *Madey* case. In *Madey v. Duke University* (307 F. 3d 1351, 1362 (Fed. Cir. 2002)) the court held that any experimentation at a university which is not limited to actions performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry”, potentially breaches a patent.

¹²⁰ Deere, C. (2008). *The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries*. OUP Oxford.

¹²¹ *Ibidem*. For example, of 106 developing countries surveyed, less than ten expressly included a Bolar provision into their laws

conclude that apart from the eventually poor domestic resources and legal expertise in the area of IPRs, the threat of trade retaliation is especially deterrent for many developing countries and LDCs as many of these countries are strongly trade-dependent. Furthermore, the reduction of unilateral pressure by developed countries (namely the US) as a logical consequence of the institutionalization of trade conflicts hoped by developing countries has not materialized and the Dispute Settlement Understanding (DSU) has not constituted any obstacle to unilateral actions.¹²²

Finally, in order to conclude with TRIPS flexibilities, it is important to mention some procedural flexibilities. In this sense, developing and LDCs were given additional time to comply with the provisions of the Agreement. Developing countries had until January 1, 2000, to implement the Agreement and could optionally delay application of the product patent provisions until January 1, 2005, in certain fields. LDCs were given ten years to implement the treaty, or until January 1, 2005 (This deadline has been extended several times¹²³.)

While there have been some successful cases of implementation of these flexibilities, there is still a long way to go in order to make full use of the potential of these instruments. Many of the poorest countries have enacted IP laws which far exceed the required floor of TRIPS. As many developing countries do not have resources to conduct substantive examination of patent applications, patents are often registered on demonstration that it has been granted by the European or the US patent office. This made developing countries forego the opportunity to implement TRIPS flexibilities while adopting developed countries IPRs standards of protection. Also, the number of countries that have used compulsory licenses is small and the possible limits on scope of patentability have not been optimally used. The main barriers to

¹²² Land, M. *Rebalancing Trips*. Supranote 119.

¹²³ The last extension is due to the Decision on Least Developed Country Members – Obligations under Article 70.8 and Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products adopted by the General Council on 30 November 2015 following a recommendation by the Council for TRIPS. This Decision complements the aforementioned decision to extend the transition period for least developed country Members by waiving certain obligations that would have otherwise been applicable during the transition period. This includes an extension of the waiver to give exclusive marketing rights to pharmaceutical products that was initially put in place in 2002, and also adds a new waiver of the obligation to provide for the possibility of filing mailbox applications. Both waivers apply until 1 January 2033. The Decision was said to be taken with a view to ensuring attainment of the objectives of paragraph 7 of the Doha Declaration on the TRIPS Agreement and Public Health.

the effective and full implementation of these flexibilities are four¹²⁴: 1) lack of supportive legal frameworks; and 2) resource constraints and limited coordination; 3) the continued unilateral pressure from developed countries with important IPRs industries and 4) new international agreements and legal constraints which reduces the scope of TRIPS flexibilities.

As to this last barrier, the new legal constraints post TRIPS are those coming from bilateral or regional Free Trade Agreements (FTAs) between the US or Europe and developing countries which will be analyzed in other chapter –TRIPS Plus- and a more subtle “IPRs enforcement agenda” as represented by seizure of legitimate generic medicines that conflate IPRs enforcement and drug quality control and thereby threaten the integrity of the generic supply chain. In this sense, there are obvious attempts to make a link between patented medicines and drug quality assurance. The so-called “anti-counterfeiting” bills have been mostly adopted in East Africa. By purportedly addressing drug counterfeiting these laws expand dramatically the IPRs enforcement. The Kenyan Anti-Counterfeit Act of 2008 included the obligation for local enforcement authorities to take measures against generic medicines that were fully lawful in Kenya on the grounds that they infringed patents in other countries. While some counterfeit medicines may be of substandard quality, the presumption that all not-branded medicines are unsafe is biased since branded medicines may also not comply with quality standards. In this respect, it is important to separate medicine-quality issues from the IPRs enforcement agenda. Other legal formula resulting from the intense lobbying of IP industries is represented by the controversial European regulation¹²⁵-subject to different claims before the DSU-permitting seizure of goods that were in transit through European ports or other transport hubs even if those goods are legitimate generic medicines both in the origin and in the destination countries.

¹²⁴ El Said, M., & Kapczynski, A. (2012). Access to Medicines: the role of intellectual property law and policy. Global Commission on HIV and the Law Working Paper.

¹²⁵ Council Customs Regulation No 1383/2003 which was replaced by the new EU Customs Regulation 608/2013 (July 19, 2013) or the new EU trademark Directive 2015/2436 have raised important critics by some developed countries (mainly India and Brazil) and some NGOs. These regulations are said to allow wrongful seizures of generic medicines in transit.

2.4. Evaluation and impact of the TRIPS Agreement.

After 20 years of the TRIPS implementation –effective on January 1, 1995- there is not a consistent, unbiased, serious and empirical research on the socioeconomic impact of TRIPS and the achievement of its objectives. However, it is important to bring here some relevant information and data as to the actual impact of TRIPS with regard to the access to pharmaceuticals in the first place and closely linked to it, the accomplishment of the ends and benefits announced by its supporters.

As to the impact of TRIPS on the access to medicines, and in accordance with the before mentioned Report of the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (16 March 2011), massive inequalities remain in access to medicines around the world. In this sense, the Special Rapporteur recalls in the Report that some issues relating to intellectual property laws threatened access to medicines. The Special Rapporteur is clear when stating and concluding that the TRIPS, or at least its application by certain States, remained an impediment to greater access to medicines. Intellectual property rights and competition are seen as the most important elements in the reduction of prices and affordability for all. He also warns against reinforced standards in the area of patent law in free-trade agreements such as TRIPS-plus, which threatened to compound this problem even further.

The 2015 Social Forum organized by the UN Office of the High Commissioner for Human Rights (OHCHR) which took place from 18-20 February and focused on “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” also mentioned TRIPS and TRIPS plus as one important burden to a greater access to medicines.

Also, the Report of the United Nations Secretary-General’s High Level Panel on Access to Medicines¹²⁶ released in September 14, 2016 states that *despite the technological*

¹²⁶ Retrieved from <http://www.unsgaccessmeds.org/final-report/>

progress in the field of health, millions of people continue to suffer and die from treatable conditions because of a lack of access to health technologies and that investment in research and development of health technologies does not adequately address a number of important health needs [...]. Also, the Report says that the proliferation of free trade agreements containing expensive patent and test data protections on health technologies, which exceed the minimum standards for IP protection required by the TRIPS Agreement (so-called “TRIPS-plus” provisions) may impede access to health technologies [...]

Introduction of pharmaceutical patents in markets where those IPRs did not exist, leads to an increase of prices. This premise has been evidenced by different studies which conclude that the absence of product patents and the relative ease of entry into imitative production mean that, in countries without product patents there are significant numbers of small and medium-sized firms producing copies of drugs patented elsewhere, this making drug prices fall markedly in the presence of competing products. This (pre-patent) structure characterizes (or has characterized) a wide range of countries that were studied, including Argentina, Brazil, Chile, India, Italy, Turkey, Korea, Egypt, and Lebanon¹²⁷.

Pharmaceutical industry suggested first that there was no relationship between the drug prices and access; rather, and in relation with the main challenge to health in both developed and developing countries (HIV/AIDS) they argued, that social, political, and infrastructural barriers impeded the broad rollout of complicated HIV/AIDS medications. Pharmaceutical companies finally admitted that prices charged for their drugs in developing countries made them largely prohibitive. However, they also argued that patent protection was necessary to stimulate drug research and development. In the context of the HIV/AIDS some ONGs and civil society organizations such as Treatment Action Campaign (TAC) in South Africa, Oxfam, and Médecins Sans Frontieres had conceptualized the issue differently and drew attention to the issue of patent protection, patent abuses, and the lack of generic

¹²⁷ Maskus, K. E. Intellectual property rights in the global economy [...] supranote 105.

competition in constraining access to HIV/AIDS-related pharmaceuticals¹²⁸. Finally, as we will further see in next chapters, some doubts have been raised as to how effective, necessary and balanced is the current system of IPRs for innovation in the field of health.

Therefore, IPRs imply an increase on medicines which can make these unaffordable for many people, especially but not only in developing countries. Notwithstanding that, one of the reasons predicated of the TRIPS in order to convince developing countries to be bound by it was that the establishment of higher intellectual property standards or their legal implementation would eventually benefit them in terms of stimulating innovation and the capabilities for local production of medicines addressed to their specific health needs. Also, TRIPS was said to be an instrument to promote an effective and necessary technological transfer from developed to developing countries, this contributing to the development of their economies and societies. These benefits are explicitly recognized in article 7 of TRIPS which establishes that IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of its users and producers in a manner conducive to social and economic welfare and to a balance of rights and obligations. It is thus, important to evaluate whether these virtues predicted of the TRIPS have been accomplished as a “compensation” for developing countries adhesion to TRIPS.

In 2011 the WHO published an important study focused on evaluate the trends in the local production of medicines in developing countries from Africa, Asia and Latin America and related technology transfer¹²⁹. This research is very helpful to extract some conclusions as to how TRIPS is contributing or not to foster the promised technology transfer and the establishment of local facilities for the production of medicines. The study pays special attention to the cases of China and especially India since drug companies in these countries are important suppliers of low-priced active pharmaceutical ingredients and finished products domestically and for developing

¹²⁸ Brown, S. (2008). Global public-private partnerships for pharmaceuticals: operational and normative features, challenges, and prospects. *Canadian Public Administration Journal*.

¹²⁹ http://www.who.int/phi/publications/trends-in_local-production-of-medicines.pdf.

countries, and many fear that the introduction of product patents will destroy these industries and lead to increased drug prices.

As to the argument that TRIPS-compliant patent protection would prompt developing country companies to conduct greater R&D for the development of new drugs more suited to local needs, the study finds that among a sample of 166 Indian companies only 37 were major R&D spenders (increasing steadily from 3.89 percent in 2001 to 8.35 percent in 2005/06) while the rest maintained their R&D expenditure around 1 percent. In relation with access to medicines, the report informs that the introduction of generic medicines in Jordan has been delayed as a consequence of amended patent and regulatory data rules (following TRIPS and TRIPS plus), with a significant monetary cost to consumers. China is already experiencing access problems within the category of newer drugs. Some important antiretroviral are simply not physically present on the Chinese market, while others are present, but at prices aimed at skimming only the wealthy market segment.

On the other hand, the Study finds that in the pre-TRIPS situation, because of competition in patented drugs in India, both consumers and Indian producers were able to benefit from the policy environment. After TRIPS, the new policy environment has led to collaborations between Indian companies and TNCs that are restricting competition and both of them are gaining at the cost of consumers.

As to the technology transfer, TRIPS is considered to be weak on imposing technology transfer obligations in developed countries towards developing countries as a legal requirement, although it suggest that the statements referring to this technology transfer may be used as an interpretative device, either to inform the application of other parts of the TRIPS Agreement, or as the basis for political objection to the manner in which TRIPS is being interpreted and applied by developed countries. In this sense, the Study states that although as long as the institutional and governance structures are aligned with increasing protection of IPR, we could expect to see more willingness of firms to license and contract out increasingly important/proprietary technologies to developing country firms, it is also possible that strong intellectual

property protection is liable to stifle technology transfer as technology owners exploit their market power.

Finally, this interesting research warns that worldwide access to medicines, where India and China provide products or sources of price competition, is affected not only by the parameters which determine domestic access in India and China, but also by the IP situation in the importing country since once implemented the new patent legislation, many African countries cannot authorize generic copies unless the patent holder has waived its rights or licensed the patents to generic firms. Account taken of all the cases and specially the Indian and Chinese experience, the WHO study concludes that there is sufficient evidence to support and drive reforms for a proper review and renegotiation of TRIPS.

On the other hand, even though there was reasonable fears that DSU would imply an explosion of litigation against developing countries on TRIPS issues, specially for non-accomplishment of some provisions of the Agreement, the truth is that TRIPS has produced less litigation than anticipated and still less between developed and developing countries. In fact, there have been more cases facing developed state members. Notwithstanding that, this apparent peace, conformity and compliance with TRIPS may be misleading. As some scholars think, although the TRIPS is not being subject to many litigated cases overall, the reason behind can be the fear of many developing countries to face the threat of defending a costly complaint and the possibility of substantial trade sanctions which can significantly hurt their economies, this explaining a culture of overcompliance that has discouraged countries from experimenting with flexibilities protected under the Agreement¹³⁰.

TRIPS and the promise land of innovation.

The discrepancy between what was promised by the global IPRs regime and what has been really achieved is then clearly reflected in the context of the implementation of TRIPS. Theoretically, TRIPS and the implementation of developed countries-IPRs

¹³⁰ Land, M. *Rebalancing Trips*. Supranote 119.

standards generate incentives for innovation and technology transfer (FDI) to developing countries. However, this does not seem to have been the case. In this sense, even if TRIPS statement of Principles and Objectives acknowledges the importance of balancing interests, promoting social welfare and protecting public health, the truth is that adjudicators and legal practitioners lack judicially manageable standards to implement those principles and objectives to satisfy public interest concerns when it comes to specific legislative safeguards or adjudication of cases and controversies¹³¹.

There has been very little or no empirical or theoretical research concerning the effects of increasing IPRs in a developing country with previous lower standards of protection. In the mid to late 1980s, when there was an increasing lobby activity to adopt an agreement like TRIPS, very little empirical or theoretical research existed concerning the effects of increasing IPRs standards all around the world. The limited research that did support the trade-IP linkage with pharmaceutical innovation was generally written by pharmaceutical company funded institutes and academics supporting the pharmaceutical lobby's views¹³².

An important number of scholars and practitioners argue the disadvantages of TRIPS for developing countries. These scholars have serious doubts about the assertion that strong IPR systems foster across-the-board innovation and economic growth. They argue that, even if theoretical incentives for innovation and technology transfer exist as a result of intellectual property protection, this does not necessarily engender sustainable development. In effect, even if high IPRs standards may foster innovation and FDI, the limited local absorptive capability may limit the potential to use it. On the contrary, various studies indicate that the IPR induced influx of FDI and foreign technology reduces domestic innovation incentive and capacity, which impedes long-term economic growth in developing countries.¹³³

¹³¹ Dreyfuss, R. C. (2010). TRIPS and Essential Medicines [...] (see footnote 104).

¹³² Bennett, B., & Tomossy, G. F. (2006). *Globalization and Health* (Vol. 27). Springer.

¹³³ Daley, W. (2014). In search of Optimality: Innovation, Economic Development, and Intellectual Property Rights. GSDR Prototype Briefs.

Letting aside considerations as to how TRIPS restrain national governments to cope with certain public interest concerns, and focusing strictly on the relationship between IPRs and innovation, there are studies which indicate that the optimal level of IPR protection varies across countries (and even by industry) depending on their stage of development. In this sense, harmonization of global IPR protection may not be beneficiary to developing countries given that the industrial technological capability differs significantly across some countries. There is an obvious tension between considerations of IPRs as an instrument which can encourage innovation, technology diffusion and enhance growth and those considerations which warn that stronger IPR protection leads to monopoly power for patent holders, reduces the incentive to innovate and limits the diffusion of knowledge. Before TRIPS, countries had the capacity to adapt their IPR regimes to facilitate technological transfer and to promote their own industrial policy objectives. Today technologically developed countries had lax IPRs systems in their past designed to encourage technology diffusion through imitation. Spain and Italy are two good examples of countries with an emergent pharmaceutical industry which grew one day by imitating foreign technology. As far as domestic capabilities were becoming more sophisticated and they were able to innovate, national legislation increased the level of protection. In the same manner, Japan is commonly conceived as a country which developed its technological “catch-up” and sophistication by first acquiring foreign technologies in advantageous terms and conditions, a process that was permitted by a IPRs legal regime favoring dissemination of knowledge. Furthermore, Korea was able to absorb and develop considerable amounts of adaptive technological information in the absence of meaningful IPRs through the 1970s and early 1980s¹³⁴.

In an econometric analysis commissioned by the non-suspicious US International Trade Commission, it is concluded that IPRs in developing countries do not have a significant positive effect on R&D in developed countries¹³⁵. Also, the positive effects of TRIPS on FDI seem to be ambiguous. While stronger IPR protection in the poorest countries is not likely to lead to substantial benefits in terms of innovation or

¹³⁴ Maskus, K. E. (2000). Intellectual property rights in the global economy [...] supranote 105.

¹³⁵ Maxwell, A., & Riker, D. (2014). Web Version: November 2014. *Journal of International Commerce & Economics*, 75.

technology diffusion, the administrative cost of developing a patent system and the enforcement of TRIPS, along with the potential abuses of market power in small closed markets suggests that such countries could lose out from TRIPS. As some studies suggest, stronger IPR protection in the poorest countries may also inhibit or lengthen the imitative stage of development that seems to be necessary in order to develop innovative capacity in many industries and its impact on technology diffusion is unclear¹³⁶.

Professor emeritus Scherer reaches similar conclusions on this respect. He notes that incentives from IPRs and innovation are far from being automatic, especially when these incentives are implemented in countries where technological capabilities are scarce. Also, he observes that TRIPS has not made pharmaceutical companies reorient their R&D efforts to place more emphasis on third world diseases. Finally, it is interesting to mention his proposal standing for a sort of international commitment conditioning strong patent rights to the compromise that pharmaceutical companies will commit 20% of their R&D budgets to combat diseases of the less developed nations¹³⁷.

Finally, TRIPS may reorient developing countries producers' activity towards more profitable business in the developed world. There are studies revealing that enhanced IP protection in China and the approaching introduction of product patent law in India are already having an effect on the product and market strategies of Indian firms¹³⁸. In effect, the introduction of product patents means that Indian firms have reduced revenue options for the sale of drugs domestically and to low income countries, since generic copies of newer drugs will become illegal. To compensate this revenue loss, Indian firms have increased their emphasis on exporting to the more profitable regulated markets, as evidenced by the large concentration of FDA approved manufacturing.

¹³⁶ Anja, B., & Neil, F. (2012). Intellectual property rights, innovation and technology transfer: a survey.

¹³⁷ Scherer, F. M. (2003). 'Global Welfare in Pharmaceutical Patent Policy. Princeton University, Woodrow Wilson School of Public and International Affairs, Princeton, NJ.

¹³⁸ Grace, C. (2004). The effect of changing intellectual property on pharmaceutical industry prospects in India and China. *DFID Health Systems Resource Centre*, 1-68.

In short, it appears that the promises and expectations of the TRIPS Agreement in terms of technology transfer, foreign investment and general development and growth for developing countries are far from being reached. On the contrary, it seems that other than its negative impact on public health, TRIPS Agreement may have impaired the economic and technological development of many developing countries without any known and tangible benefit.

CHAPTER 3. PHARMACEUTICAL BUSINESS AND THE ROLE OF IPRs IN THE PROMOTION OF GENUINE INNOVATION.

3.1. Big Pharma and beyond: global political economy of health.

Pharmaceutical industry is one of those global realities impacting the life of virtually everyone in the planet. This impact on people's life and quality-of-life makes this businesses one of the most particular industries in the world. There is no business which encompasses as many dimensions as the pharmaceutical industry; in fact, it engages at the same time science, medicine, economics, health, human rights, government, and social welfare. Also, it is one of the industries which has first acquired a global dimension, impact, scope and operation. Because of its impact on every person's life, health and safety, it is a highly regulated industry; this regulation is oriented to succeed in getting patient's wellbeing and safety at reasonable cost. The fact of being a regulated business does not impede pharmaceutical business from being a tremendously profitable industry.

In effect, pharmaceutical industry is not only one of the main industrial sectors of the world but also one of the most profitable. As in 2001 worldwide revenue was around 390 billion US dollars, in 2014 the revenues have tripled reaching a total sum of 1.057 billion US dollars¹. This business had a profit margin of nearly 20% during that year. Also, according to some economic reports², prescription drugs sales are expected to grow at a rate of 5% yearly until 2020. US and Canada have the world's largest market with a 41% share of the total, Europe 27,4%, Japan 9,7%, Africa, Asia and Australia the 16,1% and Latin America the 5,8%³. As to production, the United States accounts for 39% of global pharmaceutical production, slightly more than the 36% European share. Maybe the two main elements driving the activity and success of a pharmaceutical company are innovation and marketing.

¹ <http://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/>

² <http://info.evaluategroup.com/rs/607-YGS-364/images/wp15.pdf>. EvaluatePharma® World Preview 2015, Outlook to 2020 8th Edition – June 2015.

³ http://www.efpia.eu/uploads/Figures_2014_Final.pdf. The Pharmaceutical Industry in figures. EFPIA Key Data 2014.

The pharmaceutical market is generally divided up into the producers of branded-pharmaceuticals, -many of which under patent or any IPR- and generic producers. Although producers of generic have an increasing importance in the market of medicines, the biggest slice of the pie is still enjoyed by the big pharmaceutical companies (Big Pharma) in the race to obtain “blockbusters” –original medicines generating more than 1 billion USD in annual sales-.

Since marginal production costs are relatively low, producers of original pharmaceuticals endeavor to maximize profits during the life of a product by extending the period of market exclusivity and by engaging in promotional activities that aim both to capture as large a market share as possible and to increase the potential market. As we will see further, pharmaceutical marketing expenditures exceeds that of R&D expenditures. Anyway, the operation and the costs of business in different countries are different depending on factors such as regulatory compliance, types of marketing and/or advertising activities permitted and the exposure to liability for safety or quality problems.

Despite the important contributions to human progress, there is growing controversy and even hostility in the relationship between the pharmaceutical industry and the public. As we will see, many ethical issues are raised globally as to the relationship between an activity which is at the core of human life and the pursuit of profit of these transnational companies. According to some, the implicit social contract allowing the pharmaceutical company to emerge and flourish in the second half of the twentieth century in exchange of life-saving and life-enhancing drugs for humanity, is being vanished. Today, many consider that this bargain is unbalanced and that the tremendous profits are not proportionally matched by contributions to the common good. This is compelling some to speak about the necessity of a new social contract between society and the pharmaceutical sector⁴. Before entering the discussion about the current performance of this particular industry, it is important however to have a historical background about the evolution of this industry.

Pharmaceutical industry: past and new business trends.

⁴ Santoro, M. A., & Gorrie, T. M. (2005). *Ethics and the pharmaceutical industry*. Cambridge: Cambridge University Press.

Pharmaceutical industry is a mature industry which is however constantly evolving. The history of this industry is generally divided into three periods; the creation of the industry (period from 1880 to the Second World War), the implementation of formalized in-house R&D programs and fast rates of new drug introduction (1945-1990) and the implementation of genetic engineering in the production and discovery of new drugs (1990-today)⁵.

The birth of the modern pharmaceutical industry can be traced to the mid-19th century. Until this moment, there were no standardized medicines for treating specific illnesses. A patient had customized prescription which would be formulated at the local pharmacy *ad hoc*. The creation of the chemical and pharmaceutical industries began almost at the same time in Europe and in the United States. In Europe it emerged from the chemical industry with expertise in organic chemistry. This was possible due to the important market created from the unification of Germany and the growth of its economy based on heavy industry in the Rhine Valley. However, in the United States the industry evolved in response to the advent of modern transportation and communication—the railroads and the telegraph— and the big market created around. This market made possible the mass production of over-the-counter (OTC) non-prescription drugs based mainly on natural resources. It is important to note that many of the companies which started to produce pharmaceuticals both in Europe and America are still important pharmaceutical players. Among others, we can mention Swiss and German chemical companies such as Ciba, Sandoz, Bayer, and Hoechst and American and British companies such as Wyeth, Eli Lilly, Pfizer, or Warner.

The second epoch of the pharmaceutical industry began with the so-called “therapeutic revolution” in the 1940s which was accelerated by World War II and wartime needs for antibiotics. This provoked the industry's transition to an R&D intensive business. Penicillin and its antibiotic properties which were discovered by Alexander Fleming in 1928, were produced throughout the 1930s, only in laboratory-scale quantities and was used almost exclusively for experimental purposes. With the

⁵ Chandler, A. D. (2009). *Shaping the industrial century: The remarkable story of the evolution of the modern chemical and pharmaceutical industries* (Vol. 46). Harvard University Press.

outbreak of World War II, it was developed a system to produce large quantities of penicillin and major gains in productivity. Also, it laid out a framework where future improvements could take place and be implemented. The commercialization of penicillin marked a watershed in the industry's development. Due to the technical and organizational experience accumulated through the wartime, as well as to the recognition that the pharmaceutical business could be highly profitable, pharmaceutical companies embarked on a period of massive investment in R&D and built large-scale internal R&D capabilities. At the same time there was a very significant shift in the institutional implication around the industry. Public support, public effort and public resources put the bases for a period of great prosperity of the industry⁶. Under these premises, the period from 1950 to 1990 inaugurated a golden age for the pharmaceutical industry grew rapidly and profitably. Also, R&D spending boomed to unknown levels and this effort was followed by an important flow of new pharmaceuticals. Companies like Pfizer, Merck or Bristol rushed towards profitable patents over antibiotics. For instance, penicillin which had not been patented, had gone from costing \$ 3.955 per pound in 1945 to \$ 282 per pound in 1950.⁷

Through these golden years, there was a shift in the technology of pharmaceutical research from random screening to one of "guided" discovery or "drug discovery by design". This steady innovation process was critically dependent on the publicly generated knowledge. The industry directly benefited from the explosion in public funding for health related research that followed the war. This public funded effort was especially important as a source of knowledge about the cause of disease. Smaller firms, and those farther from the centers of public research, were much slower to adopt the new techniques than their rivals.

Pharmaceuticals companies have enjoyed important "isolating mechanisms" and barriers to entry of imitators and new entrants. Several of these barriers have to do with the scale economies in pharmaceutical research, the strength of IPRs, the nature of the regulatory regime for pharmaceutical products, the process of gaining

⁶ Mowery, D. C. (1999). Sources of industrial leadership: studies of seven industries. Cambridge: Cambridge University Press.

⁷ Drahos, P., & Braithwaite, J. (2001). Intellectual property, corporate strategy, globalisation: TRIPS in context. *Wis. Int'l LJ*, 20, 451.

regulatory approval, and marketing and distribution and the organizational capabilities developed by the larger pharmaceutical firms. The postwar pharmaceutical industry has been dominated by American and western European companies. Although Japan was one of the largest pharmaceutical market in the world, Japanese firms have to date been consciously absent from the global industry. Only the Japanese Takeda, for instance, ranks among the top 20 pharmaceutical firms in the world.

The third epoch of the industry has its roots in the use and expansion of the tools of genetic engineering in the production and discovery of new pharmaceuticals based on the molecular biology that emerged with the discovery of recombinant DNA (rDNA) and the techniques of genetic engineering. These new techniques have had substantial implications both for the discovery of new drugs, on the one hand, and for the ways in which they were manufactured, on the other. Genetic engineering has been used first as a process technology to manufacture proteins whose existing therapeutic qualities were already quite well understood in large enough quantities to permit their development as therapeutic agents –this activity permitting a proliferation of new firms manufacturing large quantity of proteins- and as a tool for small molecule discovery –this field being dominated by the large global pharmaceuticals-. These new firms were start-ups, many of them as result of the Bayh-Dole act of 1980, which enabled universities or non-profits, to own and profit from the patents created through public funding. Biotech based pharmaceuticals represents 18% of total worldwide medicine sales in 2012⁸.

These new biotechnology firms were perceived as creators of a Schumpeterian new improved paradigm which would preclude the former one. However, the emergence of these new companies has not resulted in Schumpeterian creative destruction. Different barriers to entry, the dominance of the industry in the downstream market and some organizational competencies of the traditional pharmaceutical companies have permitted these to keep their dominance over the pharmaceutical market.

⁸ Ey & EuropaBio Biotechnology in Europe (2014). The tax, finance and regulatory framework and global policy comparison. Retrieved from http://www.europabio.org/sites/default/files/report/ey-europabio_report_final_1.pdf.

Since the alliance between Eli Lilly and Biotech Genentech in the 80's, most of the major pharmaceutical companies have invested in biotechnology R&D and integrated new firms through collaborative arrangements (equity purchases, acquisitions, mergers, joint ventures and R&D contracts) with the new biotechnology start-ups. Even if new firms were eventually more successful than the traditional pharmaceutical companies, these start ups have needed to seek out partners in the big pharmaceutical companies with the experience and competencies required for clinical development, regulatory approval, and marketing. Therefore, far from being swept away by new entrants, incumbent companies have been reinforced as leaders of the pharmaceutical market through the establishment of complex cooperative interactions with new entrants.

Another feature of this third historic phase is the important disparity between regions in the development of this new scientific paradigm. Despite the global dimension of the scientific development and shared knowledge, there are remarkable differences in industry structure across different regions of the world. As in the United States, the sector has experienced the emergence of new actors - the new startups - and the gradual implementation of biotechnology programs within established firms, Europe has not witnessed the creation of a specialized biotechnology sector. Also, Swiss and British incumbent firms have been more vigorous and aggressive than the French, German, Italian or Spanish firms. In Japan, the large pharmaceutical companies have been particularly slow to embrace the new technology. Institutional flexibility, technology transfer between publicly funded universities/entities and private companies, easy recognition and patents awards on biotech inventions and a more entrepreneurial friendly financial system may explain today's hegemony of US in the biotech industry.

Concentration of the pharmaceutical industry.

The pharmaceutical industry is characterized by a high level of concentration of the business in few hands. Fifteen multinational companies enjoy a remarkable dominant position of the market. Around 65% of the global pharmaceutical market is divided between the top 20 pharmaceutical firms (Big pharma) whose headquarters are

mainly located in the United States, Europe, Japan, or Israel. The vast majority of new inventions are then generated by pharmaceutical companies in developed nations.

Top global pharmaceutical companies by global sales 2015 in billion dollars and market share (by Pharmaceutical Executive).

| | |
|-------------------------------------|--------------------------|
| Novartis (46,1 - 5,1%) | Switzerland |
| Pfizer (44,5 - 4,5%) | USA |
| Roche (40,1 - 3,6%) | Switzerland |
| Sanofi (38,2 - 3,9%) | France |
| Merck (36,6 - 3,7%) | USA |
| Johnson & Johnson (30,7 - 3,1%) | USA |
| GSK Glaxo SmithKline (37,96 - 3,3%) | UK |
| AscatraZeneca (25,7 - 3,1%) | UK |
| Gilead Sciences | USA |
| Abbvie | USA |
| Amgen | USA |
| Teva | Israel (generic company) |
| Bayer | Germany |
| Lilly | USA |
| Novo Nordisk | Denmark |

The top 10 pharmaceutical companies have the 44, 1% of the global prescription drug's market. Most of the top pharmaceutical companies have been the result of mergers and acquisitions; Pfizer (Pzifer, Warner-Lambert, Monsanto); GlaxoSmithKline (Glaxo, Wellcome, Beecham); Novartis (Ciba-Geigy, Sandoz); Roche (Roche, Syntex, Genentech)...

Furthermore, concentration process among few companies is an increasing tendency; in 1985 the 10 largest firms accounted for about 20 percent of worldwide sales, whereas in 2002 the 10 largest firms accounted for 48% of sales. This is, among others, the result of a number of company merger and acquisition operations which is still underway. Indeed, most of the pharmaceutical companies which have stayed in the top 20 between 1995 and 2005 have been involved in mega mergers (larger than \$ 10 billion). A commonly cited rationale for this consolidation by proponents of these mergers is the existence of economies of scale in research and development (R&D) and in sales and marketing. However, despite rising R&D spending the productivity of the pharmaceutical industry, as measured by the number of compounds approved by the Food and Drug Administration (FDA) has deteriorated since 1996.

As we will see, there are important questions and doubts as to the beneficial impact of this concentration process on innovation and R&D productivity. In this sense, the number of new drugs entering clinical trials has declined since 1998, which calls into question the effectiveness of mergers and the economies of scale hypothesis more generally. Moreover, several of the largest pharmaceutical firms have been trading at significantly lower price-to-earnings ratios than many of their smaller rivals, indicating investors believe the larger firms will experience lower growth rates⁹. It seems that this concentration process is not specially grounded in the achievement of bigger efficiency in the creation of new substances and drugs.

Again, there are important disparities among different world regions. From the year 2004, there have been more mergers and acquisitions in the pharmaceutical sector in the Asia-Pacific region compared to North America and Europe. In this period the rate of growth in the Asia-Pacific region has been 37%. In Western Europe the rate of growth has been 11% and in North America it has been 20%. The pharmaceutical market in Eastern Europe has not experienced any increase in the rate of mergers and acquisitions.

⁹ Danzon, P. M., Epstein, A., & Nicholson, S. (2007). Mergers and acquisitions in the pharmaceutical and biotech industries. *Managerial and Decision Economics*, 28(4-5), 307-328.

It is important to note that this acquisition process has also encompassed the acquisition by major pharmaceutical companies of producers or companies of generic medicines. One example of this was the acquisition in 2005 of Hexal, Germany's second-largest generics company, and 67% of its US affiliate Eon Lab by Novartis in an attempt to get a dominant position (and control) in the global business of generics selling "copy cat" versions of pharmaceuticals whose patent protection has expired. It is easy to infer that this kind of operations jeopardize competition in the pharmaceutical market. As we will further see, this is not the only behavior which can be viewed as collusive to competition.

As we have noted before, the concentration process experimented by the pharmaceutical industry does not seem to foster an increasing and faster rate of innovation and creation of new substances. Different studies¹⁰ suggest rather the opposite. In particular, it is said that fewer centers of initiative and decision-making reduces and restricts the incentives and opportunities to carry the creative efforts of small biotech companies into the expensive clinical development and marketing stages and that recent mergers have contributed to the observed decline in the rate of pharmaceutical innovation.

Big Pharma companies as Transnational Companies (TNCs) and its impact on world health.

One of the main features of dominant pharmaceutical corporations is their nature as transnational companies (TNCs). There are different names to refer companies with production activities and ownership of assets abroad; multinational companies, international companies or enterprises. Pharmaceutical multinational companies are Transnational Companies (TNCs) as defined by the UNCTAD because it best represents one of the characteristics of these powerful corporations: the ability to operate, manage, control and develop strategies across and above national frontiers with activities in two or more countries with the capacity to influence others and not just in many of them independently and autonomously. This ability permits

¹⁰ Comanor, W. S., & Scherer, F. M. (2013). Mergers and innovation in the pharmaceutical industry. *Journal of health economics*, 32(1), 106-113.

pharmaceutical TNCs to plan their operations across countries in a manner which maximizes their goals (mainly profits) and their capacity to manage, control and develop strategies across and above national borders¹¹.

TNCs operate normally in industries characterized by oligopolistic structures such as the pharmaceutical industry. In the global scenario, TNCs have increasingly turned their look to the developing world, with some important operational advantages for them; lower wages and operating costs, weak labor unions, lax environmental and health controls, filters and regulations, transfer pricing and favorable tax regime¹². In the pharmaceutical industry there has indeed been an important shift in the supply chain from ICH (International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use) countries to emerging countries. India and China, are currently the biggest producers of active pharmaceutical ingredients (API). This trend will continue as the Indian and Chinese API industries are growing at nearly 19.3% and 17.6% annually. While Italy still remains the world market leader in APIs destined to sectors such as cardiovascular or the central nervous system, China leads in anti-infective APIs with approximately 43% of world market share. Lower production costs in India and China drive much of this growth. For example, to develop, test, manufacture and market a generic medicine in India costs 20-40% of what it costs in the West¹³.

On the other hand, in today's post-Westphalian global system of politics and the global governance context described in chapter 2 where there has been a shift of political authority away from nation states, TNCs such as Big Pharma are emerging as powerful actors in deciding "the who-gets-what" in the health arena (pharmaceuticals constitute one of the main pillars of the health area). These pharmaceutical TNCs not only have acquired and exercise an important authority beyond and outside of the nation states in carrying out structural changes in the areas of world production,

¹¹ Ietto-Gillies, G. (2012). *Transnational corporations and international production: concepts, theories and effects*. London: Edward Elgar Publishing.

¹² De Jonge, A. (2011). *Transnational corporations and international law: accountability in the global business environment*, London: Edward Elgar Publishing.

¹³ Bumpas, J., & Betsch, E. (2009). *Exploratory study on active pharmaceutical ingredient manufacturing for essential medicines. Health, nutrition and population discussion paper. Washington, DC, International Bank for Reconstruction and Development and World Bank.*

technology or mobility of capital but they also constrain the options of states and individuals to make changes in their public policies¹⁴. Sovereignty of states is being gradually eroded as TNCs may initiate international arbitration directly against a state for alleged breaches of their rights (investment treaties). Also, these TNCs consciously sought to influence policies, mainly state behavior in the foreign policy arena¹⁵. As we have seen in the previous chapter, pharmaceutical TNCs played a prominent role in the development of TRIPS, they used their vast influence on policymakers and officials to shape international trade law and expand IPRs into previously unreached markets, -without regard of the social and economic impact of this implementation-¹⁶.

One of the consequences of the power of these TNCs in the pharmaceutical field is the unequal bargaining power of some states versus Big Pharma companies. These negotiations are far from being one between equals. Comparing the GPD between developing countries participating in the public-private partnership Accelerated Access Initiative and the revenues and incomes of the pharmaceutical companies of the initiative, it can be seen that only 6 of the 17 countries' GPD from 2004 is equal to or greater than the pharmaceutical company with lowest total revenues in 2004. Also, the combined worth of the world's top five drug companies 'is twice the combined GNP of all sub-Saharan Africa. This situation substantially compromises some countries negotiating position.¹⁷

Other characteristic derived from the growing importance of these pharmaceutical TNCs is that they tend to make decisions in their head office country and not in the countries where they operate. In this sense, decisions affecting the people of developing countries are made in TNCs offices in cities such as Washington, London or Tokyo, far away from the specific necessities of developing countries population and without any link or political engagement with local communities. Furthermore, TNCs size and power, the jobs they offer to create and the taxes they pay put TNCs in

¹⁴ Strange, S. (1996). *The retreat of the state: The diffusion of power in the world economy*. Cambridge university press.

¹⁵ Ietto-Gillies, G. *Transnational corporations and international production* [...] see supranote 11.

¹⁶ Drahos, P. (1995). *Global property rights in information: the story of TRIPS at the GATT*. *Prometheus*, 13(1), 6-19.

¹⁷ Thomas, C. (2002). *Trade policy and the politics of access to drugs*. *Third World Quarterly*, 23(2), 251-264.

a powerful position to influence government policy. This raises questions about the democratic process itself. Their increasing political role and authority is mainly driven by private interests rather than public interests. This raises important questions as to the legitimacy of some decisions and practices. In this sense, the market domination of the pharmaceutical TNCs enables them to largely dictate what is produced at what price without any democratic control or intervention.

One may question whether the emergence of pharmaceutical TNCs as key players in the health arena and the market driven logic of their decisions have been beneficial or detrimental to people, their rights and their necessities. In this sense, and regarding the access to medicines we have seen that the system is not working in favor of the many or in favor of the general interest. First, pharmaceutical research neglects diseases among the poor¹⁸; only 10 per cent of global health research is devoted to conditions that account for 90 per cent of the global disease burden¹⁹; and second, for most of people, prices of medicines are not affordable; according to WHO estimates, around 85 per cent of the world's population is being priced out of the market for medicines. High prices are therefore one of the major barriers to reliable access. The poor need access to the available life-saving medication at prices they can afford.²⁰ In this sense, medicines account for 20–60% of health spending in developing and transitional countries, compared with 18% in countries of the Organization for Economic Co-operation and Development²¹

Market of Generics.

According to WHO website a generic drug is a pharmaceutical product, usually intended to be interchangeable with an innovator product, which is manufactured without a license from the innovator company and marketed after the expiry date of

¹⁸ Trouiller, P., Olliaro, P., Torreele, E., Orbinski, J., Laing, R., & Ford, N. (2002). Drug development for neglected diseases: a deficient market and a public-health policy failure. *The Lancet*, 359(9324), 2188-2194.

¹⁹ Drugs for Neglected Diseases Working Group. (2001). Fatal imbalance: the crisis in research and development for drugs for neglected diseases. *Paris: Médecins sans Frontières*.

²⁰ Madeley, J. (1999). Big business, poor peoples: the impact of transnational corporations on the world's poor. Baingtoke: Palgrave Macmillan.

²¹ Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *The lancet*, 373(9659), 240-249.

the patent or other exclusive rights. Generic drugs are marketed under a non-proprietary or approved name rather than a proprietary or brand name. A generic drug must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA), generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart. By extension, therefore, generics are considered (by the FDA) identical in dose, strength, route of administration, safety, efficacy, and intended use. The FDA's use of the word "identical" is very much a legal interpretation, and is not literal.

Before the TRIPS has been fully implemented worldwide, producers of patented medicines competed with generic producers. Historically Italy was the main manufacturer of generics. More recently, India played that role. Many industry and academic representatives have referred to India as the "pharmacy of the developing world" to highlight its key role in supplying large volumes of generic medicines around the world. Today, generic production worldwide is associated to the expiry of patents. In effect, expiry of a drug patent allows different pharmaceutical companies to produce the same pharmaceutical and compete in the market with the corresponding decrease of prices of these pharmaceuticals. Also, branded producers often introduce their own generics. The branded producer does not usually need approval to enter the market with a so-called branded generic—also referred to as authorized generic, pseudo-generic, or fighter brand-. Pharmaceutical companies often control subsidiaries that produce and market generics or they license the drug to a generic firm to compete against other generics. In this way, branded producers tend to either deter generic entry or to capture a share of the generic profits.

It is estimated that an optimal reduction of prices is obtained when the sixth or even seventh firm enters the market²². This reduction in prices is also due to the fact that producers of generics do not incur the cost of drug discovery. Also, generic producers do not bear the burden of proving safety and efficacy of the drug by clinical trials as these have been previously proved by their brand-name counterparts. India is still playing an important role in providing access to the low-priced medicines, not only to

²² Reiffen, D., & Ward, M. R. (2005). Generic drug industry dynamics. *Review of Economics and Statistics*, 87(1), 37-49.

developing countries but also to patients in the developing world. However, Indian pharmaceutical production is being subject to a strict control by developed nation's regulators. 21 drug manufacturing plants of India firms have been banned for export of medicines to US in 2013 due to quality concerns. Also, US Food and Drug Administration (USFDA) is conducting surprise inspections at Indian manufacturing sites, which are likely to increase in future²³.

Notwithstanding this, and due to its affordability, the increased use of generic medicines is becoming essential to maintain healthcare systems given the ever increasing pressure on resources. Many national governments have initiated to encourage prescribing and dispensing of generic drugs. Increasing use of generic drugs does not appear to compromise care. In spite of certain interest oriented campaigns addressed to question generic efficacy, safety and quality as compared with their brand-name counterparts, many studies have reported little or no difference in outcomes between the two across a range of products and classes.²⁴

Because of all the above mentioned reasons, generic producers hold an increasing share of the pharmaceutical market. In this respect, it is said that the pharmaceutical industry in some ways resembles an iceberg²⁵. These generic companies actually produce the vast majority of all pharmaceuticals sold. For example, in 2013 84% of the 4000 million prescriptions issued in the USA were filled by generics. Together with the well-known companies, which are collectively known as Big Pharma, and which represent 40% of the market in terms of finance; there are generic companies such as Teva (12th largest pharmaceutical company) or Actavis (19th largest company) which are not known by the general public and with a high probability. Almost 50% of generic medicines are produced by the top generic companies (the Israeli TEVA, the Swiss Sandoz –a Novartis unit-, the American Mylan, the Irish Actavis and the Indian Sun Pharma).

²³ Goyal, A. (2015). 'Pharmacy of the World'is ill?. *Developing world bioethics*, 15(1), ii-ii.

²⁴ Godman, B., Wilcock, M., Martin, A., Bryson, S., Baumgärtel, C., Bochenek, T., ... & Fusté, A. C. (2015). Generic pregabalin: current situation and implications for health authorities, generics and biosimilars manufacturers in the future. *Generics and Biosimilars Initiative journal*, 4(3), 125-135.

²⁵ Taylor, D. (2015). The pharmaceutical industry and the future of drug development.

Today, the market is experiencing a rise of generic drug prices. Some commentators suggest that this may be produced by the merger and concentration process of the generic industry²⁶ this having the effect of driving up generic prices as competition declines. In 2015 global pharmaceutical merger and acquisition deals were valued at 462 billion dollars. The Israeli Teva For example, has acquired Allergan for 40.5 billion dollars creating a concentration of generic market share that hugely increased the company's power to control prices in a previously fragmented market. Teva now controls around 20 per cent of the global generics industry.

²⁶ Munro, R. (2015). Generic drug pricing—is it becoming a runaway train?. *Prescriber*, 26(22), 5-5.

3.2. The regulatory challenge: proliferation of patents and regime demand.

The pharmaceutical industry is more regulated than any other industry. Because pharmaceutical drugs substantially impact people's quality-of-life, both regulation and the unique channel of healthcare provider (e.g., doctor or pharmacist) and payer (i.e., government or insurer) are designed to protect the patient's wellbeing at reasonable cost²⁷. In this chapter, we are focusing on three sets of rules/regulations which are particularly relevant for the pharmaceutical sector, namely marketing authorization rules, pharmaceutical pricing/reimbursement and IPRs rules.

Regulations for drug approval and marketing authorization.

The European Directive 2004/27/EC defines a "medicinal product" as "(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Medicinal products have certain traits that set them apart from most other consumer products. First, the value of pharmaceutical lies in the knowledge/IP/intangible assets rather than in the chemical constituents; secondly, consumer is usually directed by a third party (doctor or health professional) who does not pay for the product (pharmaceutical) and; third, without the expert advice of an intermediary, few consumers have sufficient information to make rational and informed choices, all this being likely to affect the price.

There are substantial differences in regulation of pharmaceuticals. However the purpose of all these different regulations is aimed at ensuring the safety, quality, and

²⁷ Ding, M., Eliashberg, J., & Stremersch, S. (2014). The pharmaceutical industry: specificity, challenges, and what you can learn from this book. In *Innovation and Marketing in the Pharmaceutical Industry* (pp. 1-18). Springer New York.

efficacy of the pharmaceuticals which are covered under the scope of the regulation. In most jurisdictions, pharmaceuticals must be registered and approved before they are allowed to be marketed. There is usually some degree of restriction of the availability of certain pharmaceuticals depending on their risk to consumers. In this sense, pharmaceuticals are mainly classified by level of control, which distinguishes prescription drugs (those that a pharmacist dispenses only on the order of a physician, physician assistant, or qualified or authorized nurse) from over-the-counter pharmaceuticals –OTC- (those that consumers can obtain by themselves).

Some controversial and unfortunate pharmaceutical cases like the case of the Thalidomide –an OTC pharmaceutical which was marketed first in West Germany in 1957 and which caused 10.000 cases throughout the world, of infants with phocomelia due to thalidomide- led to the enactment of more structured and stringent pharmaceutical regulations over pharmaceutical use and development. Since the early 1960s most countries increased the guarantees and complexity of their approval processes requiring pharmaceutical companies to provide substantial evidence of a new pharmaceutical's efficacy and safety based on adequate and well controlled trials and establishing more controls over the clinical testing of new drug candidates. These new regulations led to important increases in the cost and resources necessary to obtain approval of a new pharmaceutical, and they probably caused sharp increases in both R&D costs and the gestation times for new chemical entities (NCEs). This process of development and approval also increased barriers to imitation, even after patents expired. It was not until the enactment of Waxman-Hatch Act style laws when generic versions of drugs were exempted from undergoing extensive human clinical trials before they could be sold in the market.²⁸

Letting aside the regulatory differences between the different jurisdictions, in the development of a new drug, most of them have a similar path. It begins with the screening of thousands of compounds in order to identify potential medicines. Those compounds are likely to have a promising activity against a particular biological

²⁸ Mowery, D. C. (1999). US Industry in 2000: Studies in Competitive Performance, report of the Board on Science, Technology, and Economic Policy of the National Research Council.

target thought to be important in disease. After this first stage, it begins the preclinical testing where potential medicines from the first stage receive 1 to 3 years of testing in order to assess safety and biological activity against a disease. Moreover different tests monitor chemical purity and stability of a compound, determining what is required for large-scale production of the new medicine. After this, and prior to the clinical testing in patients, the new drug producer must apply for the review of a new drug to be conducted by government authorities. Authorities usually require precise and accurate information about the plans for clinical testing in patients as well as manufacturing procedures, and toxicology studies in animals previous to allowing a producer to initiate clinical testing in patients. On average, from the 250 drug candidates entering the second stage of preclinical testing, just ten drug candidates make it through to the next stage of clinical trials.

The clinical trials involve three or four steps and they are aimed at testing drug candidates in patients in order to verify that those drugs are effective and safe. This stage encompasses can take up to 10 years. In the first phase, researchers test the new drug in a small group of up to 100 healthy volunteers to determine mainly safety and dosing. The second phase contains trials with up to 500 volunteers suffering from a certain disease in order to look for efficacy, side effects, and optimal dose. In the third step, researchers test the new medicine in large trials with up to 5000 patients in hospitals and clinics to determine safety and efficacy in sufficiently large numbers of patients. Parallel to these phases, researchers keep on conducting toxicity tests, planning for full-scale production and preparing the application for approval in the next stage. Upon conclusion of the mentioned phases, it begins the approval procedure which can take 10 months. Throughout this procedure, advisory committees of technical experts review the pharmaceutical producer's application, all the clinical trial results and all the relevant information in order to decide whether the new drug can be approved for human use. Once the new medicine is launched, pharmaceutical companies are required to continue to monitor the approved medicine for safety and generate more data about how the new drug affects

particular groups of patients. These trials are post-approval trials that are sometimes a condition attached by the approval, also called post-market surveillance studies²⁹.

Clinical research is becoming increasingly global, and clinical trials may be conducted across different countries. For example, the number of applications before the FDA for marketing approval supported by foreign clinical trials has increased in recent years and will likely continue to increase in the future³⁰. This increasing globalization of clinical trials poses important challenges to national regulators. Some of these challenges are of ethical nature and they will be analyzed in following chapters.

Pharmaceutical pricing.

Due to the specific features of these products (medicines) and the general interest underlying them because of its direct relationship with people's health, pricing of pharmaceuticals is far from being the intersection between the supply and the demand in a free market. On the contrary, the determination of the pharmaceutical price is the result of a complex set of political, legal and economic factors that, however, do not always satisfy the general interest of the people to have access to affordable medicines.

Medicines account for 20–60% of health spending in low- and middle-income countries. Up to 90% of the population in developing countries purchases medicines through out-of-pocket payments, making medicines the largest family expenditure item after food. In OECD countries expenses of medicines account for 20% of health spending³¹. On the other hand, growth in pharmaceutical expenditures greatly

²⁹ Müller-Langer, F. (2009). Legal and Economic Analysis of Parallel Imports. In *Creating R&D Incentives for Medicines for Neglected Diseases* (pp. 140-199). Gabler.

³⁰ Guidance for Industry and FDA Staff1 FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND Frequently Asked Questions. This guidance has been prepared by the Office of Good Clinical Practice (OGCP) in the Office of the Commissioner (OC) in coordination with the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. It is available at <http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf>.

³¹ With important differences between countries ranging from 30% of countries like Hungary or Greece to 6,5% of Denmark and 7,5 of Norway. OECD (2016), Pharmaceutical spending (indicator). doi: 10.1787/998feb6-en. Retrieved from <https://data.oecd.org/healthres/pharmaceutical-spending.htm> (Accessed on 25 February 2016)

exceeded the rate of growth in other types of health expenditures³² and it grows faster than most of the countries' GDP.

There are many differences across countries regarding the spending per capital on pharmaceuticals and retail prices³³. These cross country differences also take place within OECD countries, between European Union countries and even within a single country. The yearly US dollar per capita spending on pharmaceuticals substantially range among the 1034 dollars/person of the USA and the 288 dollars/person expense of Denmark³⁴. The retail price includes the payment received by the manufacturer plus wholesale and retail mark-ups, plus any VAT or other tax paid by the final purchaser. Accordingly, retail price levels may differ across countries due to differences in the average price for the product received by the manufacturer. However, they can also reflect differences in the distribution margins (wholesale and retail) and in the level of tax included in the price.

It is possible to distinguish up to five stages into the determination of the price of pharmaceuticals³⁵; first the price from the manufactures (normally the most important input of the final price) which depends on the level of competition, the quantity sought by the buyer, the number of alternative buyers in the same country for the same medicine and the price regulation; second the landed price: fees, charges and profits by transporters, insurers and warehouses, level of taxes levied by the state and tariffs on imported medicines; third, the wholesale selling price; fourth the retail selling price (profit margins, costs of storage and transport) and; fifth, the dispensed selling price and VAT.

Price of the manufacturers does not reflect the cost of production plus a margin. In reality, manufacturers attempt to charge the highest price that the consumer would pay in a specific market and institutional environment in order to maximize profits. In

³² Organisation for Economic Co-operation and Development. (2008). *Pharmaceutical pricing policies in a global market*. Organisation for Economic Co-operation and Development.

³³ There are not complete and clear public databases on pharmaceutical prices around the world. However, some illustrative disparities between countries can be observed in the International Drug Price Indicator Guide at: erc.msh.org/priceguide.

³⁴ OECD (2016), Pharmaceutical spending (indicator). (see footnote 31)

³⁵ World Health Organization. (2008). Measuring medicine prices, availability, affordability and price components.

this sense, the relationship between production cost and medicine price is tenuous³⁶. This partly explains the price differentiation (also known as tiered pricing) applied by producers in the different national markets. Selling the same product –medicines– at a different price to different populations or different national markets could be an “equity pricing” when this differentiation intends to improve the affordability of medicines in low-income countries or regions. However, this is not the case of the pharmaceutical market where low-income countries do not always obtain the lowest prices for medicines.

Differences of prices across different countries give path to the so-called “parallel trade” of medicines; the practice of importing pharmaceutical products from a lower-priced country to a higher-priced one without the authorization of the owner of the IPRs associated with the medicines. The underlying justification to allow parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, he or she has no right to control the use or resale of goods put on the market with his/her consent or in otherwise authorized form. In other words, the inventor’s rights have been “exhausted”. In economic terms, the acceptance of parallel imports may prevent market segmentation and price discrimination by pharmaceutical producers.

This reality has received considerable policy attention and there is an ongoing global debate on the issue. As we have seen in chapter 2, the WTO leaves the determination of exhaustion of IP rights up to the individual members. This is stated in Article 6 of the TRIPS. There is currently a tendency to take a more permissive approach to pharmaceuticals, specially a limited regional exhaustion as in the European Union. Court decisions by the European Court of Justice (ECJ) during the last 30 years have applied the principle of free movement of goods within the EU to establish a policy of “community exhaustion” of patent rights and other forms of intellectual property. This is aimed at achieving the goal of a single internal market. Also, there have been proposals in the US to permit parallel imports of pharmaceuticals from Canada (and other countries) in the last several years. Also, developed countries like Switzerland,

³⁶ Loff, B., & Heywood, M. (2002). Patents on drugs: manufacturing scarcity or advancing health?. *The Journal of Law, Medicine & Ethics*, 30(4), 621-631.

New Zealand and Australia have also extended their policies towards a pro-parallel trade approach.³⁷ Parallel trade is most significant between EU countries, but even so only accounts for an estimated 2% of the EU market (share of parallel-traded pharmaceutical products in the main importing Member States stands between 1.7% in Finland and 16.5% in Denmark). Canadian cross-border trade with the United States peaked in 2004 at about 8% of total Canadian sales, which represented only 0.5% of the US market in terms of value³⁸.

On the other hand, parallel trade in patented pharmaceuticals has important advantages for developing (and least developed) countries. Parallel imports are of particular importance in the drug field. As pharmaceutical industry generally sets prices differently throughout the world for the same medicines to maximize profit, importation of a (patented) medicine from a country where it is sold at a lower price will enable more patients in the importing country to gain access to the product. It is widely assumed that an international exhaustion rule would result in the increase of a variety of on-patent pharmaceuticals and consumers would more easily have access to them³⁹. Some countries, especially in countries of the Association of South East Asia Asian Nations (ASEAN) and in other countries of the south hemisphere have adopted international exhaustion principles regarding pharmaceuticals –the Andean Group, the South African Medicines Act, or the Argentinean act-.

Pharmaceutical companies have expressed an important opposition against parallel trading. It has been argued that parallel imports would make companies charge a single price worldwide, leading to an increase in the (supposedly lower) price that may otherwise be charged in low-income countries. Also, the pharmaceutical industry argue that this policy could reduce its profit margins and its ability to recoup R&D investments, all this slowing down innovation of new drugs. Finally, it is said that this figure could make it difficult for health authorities in different countries to sustain differential price controls and regulatory regimes.

³⁷ Kyle, M. K. (2009). Parallel trade in pharmaceuticals: firm responses and competition policy. *International Antitrust Law & Policy*, 339-358.

³⁸ Organisation for Economic Co-operation and Development. (2008). *Pharmaceutical pricing policies in a global market*. Organisation for Economic Co-operation and Development.

³⁹ Nguyen Nhu, Q. (2011). Parallel Trade of Patented Pharmaceuticals: A Discussion from Developing Country Perspective.

Contrary to Pharmaceutical companies' views, some empirical studies reach different conclusions about the impact of parallel trade of pharmaceuticals and recommend a middle way to reconcile all the interest at stake. In particular, in a report commissioned by WIPO, Maskus⁴⁰ -who is not suspicious of being an "alter-globalization activist" finds that the empirical evidence shows that apart from existing substantial price differences across countries in identical, brand-name drugs, *there are many instances of prices that are higher in developing nations than in developed countries.* This fact -the report finds- may be attributed to imperfectly competitive distribution systems and a decision by firms to sell small volumes at high markups to price insensitive consumers in poor countries. On the other hand the Report states that the "Community exhaustion right" in the EU has not implied a price convergence of the European market, a market with significant price differences across countries - transport costs and earn rents by intermediaries jeopardize somehow the expected benefit to drug consumers-. The Report concludes that there is no detectable relationship between parallel imports and R&D performance within OECD nations.

Finally, it is recommended that in order to avoid the negative impact on R&D activity of the pharmaceutical business high income nations could be encouraged to prohibit parallel imports in pharmaceuticals from low-income countries. However, they could permit parallel exports from their markets to poor countries in essential drugs. Additionally, parallel importation by low-income nations should be permitted if they wish in order to avoid problems with high prices charged in low-volume products. At the same time, these countries also should be permitted to ban parallel exports to high-income economies in order to keep supply available locally⁴¹.

Apart from how governments regulate the parallel trade of pharmaceuticals and IPRs exhaustion of rights, governments use a variety of tools, both on the supply side (for

⁴⁰ Maskus, K. E. (2001). Parallel imports in pharmaceuticals: implications for competition and prices in developing countries. *Final Report to World Intellectual Property Organization*, 13.

⁴¹ Taking into account the unilateral engagement taken by some developed countries in order not to import medicines produced from compulsory to manufacture and export to low-income countries (WTO General Council Decision of 30 August 2003) there is no reason to think that the recommended scenario is not possible.

determining both prices as well as the share of prices that are reimbursed) and on the demand side -policies to encourage physicians to prescribe lower-priced generic pharmaceuticals, as well as requirements that patients pay a share of pharmaceutical costs). These measures are aimed at intervening the market and making medicines as available and affordable as possible, specially taking into account that patients have insufficient information on their health needs and largely rely on health professionals to make the treatment decision on their behalf and that patients do not usually pay directly for most pharmaceuticals, which are usually covered by national health systems. Needless to say that government intervention in prices and markets is a controversial topic specially taking into account the hegemony of the neoliberal agenda over other political and economic considerations.

On the supply side, governments through their health systems usually negotiate prices with manufacturers based on a range of different methods, and this is one of the reasons explaining price differences for pharmaceuticals. The most “intrusive” interventions of governments in the pricing of pharmaceuticals are the price controls on the manufacturer (restricting medicine prices to the cost of production plus a profit margin –cost-plus pricing-) and the profit caps on the manufacturer. South African legislation is an example of these measures. The main problems associated to these contention techniques are the difficulties related to the accessibility of reliable and accurate cost information of medicines from manufacturers, especially if these are multinationals, as long as the determination of R&D costs in the cost structure of the medicines. On the other hand, and depending on the bargaining power of the buyer (most low-income countries have a weak bargaining power), low prices can reduce the attractiveness of certain countries to manufacturers and importers which might result in important products not being produced and marketed in a particular country or at least, being marketed with substantial delays⁴².

Another widely used tool for determining prices is external price referencing. Under this mechanism, health authorities set a pharmaceutical’s price based on a

⁴² Cameron, A., Ewen, M., Ross-Degnan, D., Ball, D., & Laing, R. (2009). Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. *The lancet*, 373(9659), 240-249.

comparison with prices in other countries or markets. There is an important controversy on which markets constitute the basket to determine the reference price. The reference price is the price that the buyer is ready to pay. Therefore, the more power have the national or public health systems, the bigger impact and effectiveness will have its decisions in the market. This mechanism can lower substantially pharmaceutical prices, in particular when the reference is based on the lowest comparison prices rather than an average. Most European countries use this mechanism (except UK, Germany and Sweden).

Prices vary substantially between price regulated countries such as most UE countries and unregulated price countries. A review of the prices for 150 pharmaceuticals shows that the average price for this “basket” among 11 EU Member States found a 25% difference between the lowest and highest EU Member State (Germany) as prices in the USA are significantly higher than any of the 11 analyzed EU countries. However, strict regulation of prices has a negative impact on the penetration of generics once the IPRs are expired as reduced profitability keeps generic producers from covering the cost of market entry. Maybe because of that, in unregulated countries, generics have a greater share -it is over 50% of the total volume of pharmaceuticals consumed in the US, Germany, Denmark and Sweden-. Some countries like UK which are based on free-pricing systems, are likewise regulated through other means such as profit control or reimbursement regulation through internal reference pricing and/or use of Health Technology Assessments (HTA).⁴³

Taking into account the fact that patients do not have the expertise to make informed choices –being those decisions made by health professionals-, that neither patients nor health professionals bear the full cost of their treatment and that cultural reasons generate differences in the number of medicines prescribed across countries⁴⁴, it is important for governments to intervene on the demand side. Additionally, the type of remuneration pharmacists receive –if pharmacists take advantage by dispensing

⁴³ Kanavos, P., Vondoros, S., Irwin, R., Nicod, E., & Casson, M. (2011). Differences in costs of and access to pharmaceutical products in the EU.

⁴⁴ Evidence suggests that over 87% of all patient visits to physicians results in a prescription in Spain, Italy and France, but this percentage is lower (less than 75%) in the UK, Sweden and the Netherlands.

more expensive medicines even if cheaper alternatives exist- is important to determine the final price of medicines.

Among the measures on the demand side, it is important to mention those policies addressed to change the prescribing patterns of health professionals and policies targeted at patients including information provision and cost-sharing of medicines. As to the prescribing patterns, in some countries like Spain, prescribing health professionals are instructed to prescribe the active substance rather than the brand name of the medicine⁴⁵. Other measures on the demand side would be the establishment of fixed percentage of the wholesale price (an average of 30 percent of the wholesale price) and capitation systems where pharmacists are reimbursed with a fixed sum based on the number of patients per year or a fixed fee per prescription in order to reduce intermediary margins.

Finally, it is important to note that pricing of medicines in developed countries is mainly a problem for public budgets of governments as citizens expenses are normally covered by national health systems. Universal coverage is however being jeopardized in today's world even in apparently developed countries. In Greece, the recent sovereign debt related crisis has led to a loss in health insurance coverage among long-term unemployed and many self-employed workers. In Spain, undocumented migrants' previous full rights to health care coverage have been seriously limited. In the United States, before the Affordable Care Act (Obamacare) the percentage of the population uninsured was of approximately 15 percent of the total population and this can be reverted again by Trump's administration.⁴⁶

⁴⁵ The recent Spanish Supreme Court Ruling STS 488/2016 of February 2016, has dismissed the motion of the Spanish Pharmaceutical Industry Association against the regulation instructing health professionals to prescribe the active substance instead of using the branded name of medicines. Pharmaceutical companies considered this to be discriminatory against producers of branded drugs and unfairly favoring producers of generic drugs.

⁴⁶ Indicators, O. E. C. D. (2015). Health at a Glance 2015. Retrieved from <http://www.oecd.org/health/health-systems/health-at-a-glance-19991312.htm>

Intellectual Property Rights and pharmaceuticals.

The pharmaceutical industry is said to be –together with the chemical and the biotechnology industry- one of three technology-based industries in which the patent virtually equals the product. Unlike other industries which require expensive and complex manufacturing infrastructures and investments, pharmaceutical producers cannot keep their inventions –new medicines- secrets as medicines can be easily and cheaply replicated by copiers with little capital investment. Patents would be then the only effective way to protect and recoup the great investment incurred to develop new drugs⁴⁷.

Additionally, those standing for a strong patent system – combined with a market without price controls – argue that price controls and a restrictive implementation and application of IPRs explain the shift of a massive flow of investment from Europe into the American industry. As it has been previously explained, these views striving for a stronger global IPRs have been ideologically and financially supported and endorsed by the powerful pharmaceutical industry and can explain the “globalization” of stronger IPRs worldwide either through TRIPS or bilateral TRIPS-Plus international agreements. Some authors have baptized these views as global intellectual property protection (GIPP) ideology.⁴⁸

Apart from patents, the pharmaceutical industry enjoys other types of IPRs for its inventions: supplementary protection certificates and regulatory data protection. Patents are maybe the strongest IPR. A patent is an exclusive right granted to an inventor (individual or legal entity) for a limited period of time in exchange for detailed public disclosure of an invention. An invention is a solution to a specific technological problem and is a product or a process. A patent application includes one or more claims that define the invention. These claims must meet patentability requirements, such as novelty, usefulness, and non-obviousness (following European Patent Convention, the invention must meet novelty, inventive

⁴⁷ Lehman, B. (2003). The pharmaceutical industry and the patent system. *International Intellectual Property Institute*.

⁴⁸ Faunce, T. A. (2006). Global intellectual property protection of “innovative” pharmaceuticals. *Globalization and Health*, 87-107.

step and it must be capable of industrial application). The exclusive right gives the patentee the right to prevent others from commercially making, using, offering for sale, selling, importing, or distributing a patented invention without the owner's consent. Under the TRIPS (art. 27), patents must be available for any invention, in all fields of technology, and the term of protection available should be a minimum of twenty years.

In addition to patents, the Supplementary Protection Certificate (SPC) is another exclusive right conferring to the owner of an invention an additional period of protection. As already mentioned, pharmaceutical industry is heavily regulated by governments to guarantee the safety and efficacy of medicines. This encompasses the obligation of carrying out clinical trials and administrative proceedings and authorizations before the new product enters the market. The lengthy time period between patent filing and placing a product on the market implies that pharmaceutical manufacturers enjoy shorter periods of product monopoly than is the case for other patent dependent industries. In response to this perceived insufficiency of the period of protection conferred by patents to pharmaceutical inventions, many laws have provided for extensions of patent term to compensate for the inability to market inventions due to safety and efficacy regulation. However, it is argued by the pharmaceutical industry that time periods permitted for such extensions do not equal the time lost in ability to market. In terms of its scope, SPC extends the initial patent protection by up to 5 years.

Other type of exclusive right related to pharmaceuticals is the "Regulatory Data Protection" (RDP) is a form of exclusive right which protects a pharmaceutical company's proprietary safety and efficacy data for its new medicine. A pharmaceutical company releasing a new medicine on the market must submit an extensive data as to the new medicine's safety and efficacy, as well as its physical and chemical characteristics in order to obtain the necessary authorization to market its medicine. A producer wishing to obtain a marketing authorization for a generic version of a branded medicine can either 1) generate its own regulatory data to show safety and efficacy of its generic product, or 2) rely on regulatory data submitted to the regulatory authority for the originator of the new drug. The possibility of generics

producers to rely on the originator's safety and efficacy data for generic pharmaceutical approval provides them with significant commercial and economic advantages. RDP prevents generic producers, during a limited period (the limited RDP term), from relying on the previous producer's proprietary data in order to obtain marketing authorizations and market follow-on generic products. Therefore, in order for the producer of generics to market the same/equivalent medicine it must either generate its own data or wait a certain period (RDP term) until it would be permitted to rely on the data provided by the previous producer of the innovative product. Article 39.3 of TRIPS adopts this approach and it requires all WTO Members to protect the data submitted to regulatory authorities against unfair commercial use and disclosure.

Pharmaceutical companies support RDP as an independent IPR, separate and apart from patent protection. The ambiguity of the TRIPs agreement on the issue of data exclusivity has contributed to include this figure in many TRIP-Plus Bilateral Agreements according to the US standards. The term "unfair commercial use" of TRIPS is linked to the responsibility of the Government (Health authorities) for protecting this data. There may be two dimensions of this duty: The first - *non-disclosure*- which keeps generic producers from gaining access to the registration file of the original medicine and; the second - *non-reliance* - is more controversial. Non-reliance prevents the authorities themselves from relying on the registration file of an original in order to compare it to the chemical and toxic levels of a potential generic substitute (so- called bio-equivalence tests). While the US and EU take the position that any form of reliance is prohibited, some other countries such as Canada⁴⁹ consider that this issue is not so clear⁵⁰. Also, pharmaceutical producers have argued that package labels and inserts that contain physician and consumer information are protected by copyright and as such generic producers cannot use similar information, this constituting another setback for generic producers.

⁴⁹ Bayer Inc. v. Canada (Attorney General) (T.D.) Date: 1998-11-03, 1 F.C. 553, T-1154-97 (1999).

⁵⁰ Pugatch, M. P. (2004). Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access. *ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines, Bellagio, Italy.*

In spite of the fact that GIPP ideology is extending its views and IPRs protection worldwide, as it has been evidenced through this dissertation, the current IPRs based system seems to be unlikely to provide acceptable outcomes in terms of achieving public health and in particular, access to affordable medicines. Although IPRs are mainly grounded on utilitarian considerations aimed at balancing incentives for innovation, societal benefits and public welfare, today those legitimate original grounds are rarely claimed or analyzed in relation to pharmaceutical IPRs regime. On the contrary, those legal and philosophical considerations seem to have been replaced with profit maximization analysis.

Furthermore, there have been identified some conducts performed by the pharmaceutical industry which may generate a distortion and abuse of IPRs legitimate aims, this hampering public health and development. These legally doubtful strategies are normally aimed at extending the breadth and scope of IPRs and at blocking or delaying the entry of generics into the market.

Apart from the already mentioned allegations claiming that generic products were less safe, less effective and/or of inferior quality, pharmaceutical companies adopt a number of “extension strategies” of their IPRs which are highly controversial. These measures can be divided into marketing strategies (pricing, promotion, divestiture, differentiation, over-the-counter drugs, and branded generics), R&D strategies (new indications, reformulations, combination drugs, and next-generation drugs), and legal strategies (generic settlements and patenting). However, these strategies –which are openly acknowledged and discussed by the pharmaceutical industry⁵¹-, may amount to an infringement of the Antitrust legislation or constitute an abuse of IPRs-.

Even if the term evergreening has not a legal definition, European Competition Authorities have adopted the European Consumers’ Association’s description of this as a *specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new*

⁵¹ Ding, M., Eliashberg, J., & Stremersch, S. Innovation and marketing in the pharmaceutical industry. (See footnote 27).

*uses of established products...Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent*⁵². In short, originators introduce minor variations in product characteristics and features in order to generate a new patent (a second generation product through a secondary or follow-on patent). In this manner, some pharmaceutical companies take advantage of the law by unduly extending some lucrative blockbuster to block or delay entrance of generics. In legal literature “evergreening” has frequently been considered as an unfair and abusive practice which should be restrained with stricter legislation⁵³.

One of the most illustrative cases was the ruling of the Court of Justice of the European Union⁵⁴ where one originator/producer of a branded under patent medicine were found to have committed two abuses of a dominant position, one of those consisting of the selective deregistration of the marketing authorizations for one medicine capsules in Denmark, Norway and Sweden combined with the withdrawal from the market of that medicine’s capsules and the launch of a new version of that product in those three countries. The abuses found constituted abuses of regulatory proceedings.

Other tactic to be mentioned is the “patent thickets” or “patent clusters”. Pharmaceutical producers file numerous broad and weak patents around the original invention. The original patent (parent patent) is splitted into one or several narrower patent applications (divisional patents). Divisional patents cannot extend the content of the original application nor the protection period. But they can extend the examination period of the patent office (as the examination of divisional applications continues even if the parent application is withdrawn or revoked) and can add to the legal uncertainty for generic companies, as it is more difficult and complex to properly determine the breadth of the originator’s IPRs over the new invention or medicine.

⁵² Competition, D. G. (2008). Pharmaceutical sector inquiry-preliminary report.

⁵³ Bansal, I. S., Sahu, D., Bakshi, G., & Singh, S. (2009). Evergreening-a controversial issue in pharma milieu. *Journal of intellectual property rights*, 14(7), 299-306.

⁵⁴ Case C-457/10 P, AstraZeneca v Commission, Judgment of 6 December 2012.

Other than using litigation in certain instances to deter generic entrants, other pharmaceutical companies' conduct subject to antitrust scrutiny has to do with the settlement agreements⁵⁵ between originators and generic producers, whereby, in exchange for delaying market entry, the generic companies accept compensation payments (reverse payment) or other benefits (license or distribution agreement) from originators⁵⁶. This kind of agreements may raise important antitrust problems when the generic producer agrees on restrictions that go beyond the exclusivity conferred by a patent.

Finally, similar legally doubtful agreements subject to scrutiny are those between originator and generic companies concerning the sale/distribution of generic medicines agreements concluded before the originator's medicine's expiry ("early entry agreements"). The majority of the early entry agreements contained clauses that provided for a certain type of exclusive relationships between the contracting parties. In Europe, half of the early entry agreements were concluded in the last year before loss of exclusivity and may be used to anticipate generic competition by impairing or slowing it. The duration of these agreements exceeded the date of loss of exclusivity on average by more than two years. For most of those agreements, - European DG Competition says- the generic products were the first generic products on the market and, thus, were likely to benefit from certain first mover advantages.

⁵⁵ EUROPEAN COMMISSION Competition DG. 6th Report on the Monitoring of Patent Settlements (period: January-December 2014) Published on 2 December 2015 at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report6_en.pdf.

⁵⁶ Barazza, S. (2014). Pay-for-delay Agreements in the Pharmaceutical Sector: Towards a Coherent EU Approach. *Eur. J. Risk Reg.*, 79.

3.3. Critical aspects of pharmaceutical industry's value chain: innovation not so new.

In today's pharmaceutical business' view the success of a branded drug pharmaceutical company is narrowly related to innovation of new products and its marketing strategy to get as many profits as it is possible from a new product.

Innovation is of key importance for the pharmaceutical sector and for society in general. Innovation has enabled the creation of medicines which have dramatically improved people's life. From a strict business perspective, the launch of an innovative drug may have positive long-lasting economic impacts for the pharmaceutical company which may develop other follow-on drugs based on the innovative one. Other than being fundamental for the success of the business, innovation in the pharmaceutical industry has been featured by the following three dimensions: innovation is a matter of life or death (a firm cannot possibly survive if its innovation level decreases substantially and it can no longer generate new drugs with sufficiently profitable patent protection); it is large in size (means each innovation - new drugs- tends to generate a large amount of revenue for a firm), and it has a finite lifespan (innovations in the pharmaceutical industry have a finite time to create value for its shareholders).⁵⁷

As it has been previously mentioned, and although serendipity and chance still play a role in the process, the discovery and development of new medicines are today more oriented through a more targeted rational path. Most new medicines have been preceded by years of research and development. R&D activities are increasingly costly for companies' budgets. In fact, pharmaceutical companies justify the high prices of medicines and strong IPRs by arguing the huge investments made on R&D and the necessity to recoup them. As it will be analyzed there is a controversy about an eventual productivity crisis of the pharmaceutical industry and a somehow slower innovation pace. In this sense, apparently bigger budgets on R&D are not being materialized in an increasing number of new medicines.

⁵⁷ Ding, M., Eliashberg, J., & Stremersch, S. Innovation and marketing in the pharmaceutical industry. (see footnote 27).

On the other hand, marketing and sales strategies play an important role. Pharmaceutical companies are very aware of marketing strategies to maximize the profit of its innovation. In their attempt to maximize sales and profits out of a new drug, some companies have undertaken some highly ethically controversial marketing actions which will be discussed later. In this sense, pharmaceutical companies have been accused of abusing of the direct-to-consumer advertising (in those few countries where this is legal); unduly orienting health professionals' habits and methods in prescribing drugs and inappropriately influencing institutions and health authorities in setting up their agenda and their decisions.

What is innovation?

Before entering the discussion of the different issues and particularities of the innovation in the pharmaceutical field, it is important to have an insight of what is innovation.

There are different views about what should be meant by innovation. Pharmaceutical industry has adopted a customer-oriented definition of innovation. In this sense, even acknowledging that the market of medicines is particular because a third party usually pays the product, the pharmaceutical industry adopts a customer oriented concept of innovation. In this sense, they argue the consumer should be the ultimate arbiter –or this should be used as a reference- to determine whether a new product is innovative or not. Therefore, other than scientific discoveries, innovation would be also the result of economics, corporate management and marketing⁵⁸.

Schumpeter -probably one of the scholars who has contributed most to the concept of innovation- says that consumer preferences are already given and they rarely are the cause of the economic change (or innovation). In this sense, consumers would play a

⁵⁸ Mestre-Ferrandiz, J., Mordoh, A., & Sussex, J. (2012). The many faces of Innovation. A report for the Association of the British Pharmaceutical Industry (ABPI) by the Office of Health Economics (OHE). Available on the World Wide Web: <http://www.abpi.org.uk/our-work/library/industry/Pages/many-faces-of-innovation.aspx>.

passive role in the process of economic development⁵⁹. On the other hand, starting from making a clear distinction between invention (the inventor produces ideas) and innovation (the entrepreneur gets things done), Schumpeter distinguishes in the process of *creative destruction*⁶⁰ the following types of innovations; the introduction of a new product; the introduction of technological novelties into the production of old products; introduction on new commercial combinations such as new markets or new sources of supply of materials and; introduction of a new structure or new organization of any industry such as the creation of a monopoly out of it⁶¹. For our purposes, innovation in the pharmaceutical field should be rather related to the first, new product-type of innovation.

In particular, from a general interest's view and regarding the public systems of rewards –including public intervention and pricing- dealing with innovation in the pharmaceutical field, one the most important factors in order to consider that we are in presence of an innovation is the therapeutic advance or progress implied by the new medicine. In many legislations such as the Spanish one for example, for purposes of pricing (reference pricing system) innovation plays a role and it is judged in terms of the therapeutic improvement obtained by the new medicine.

In particular, in the field of the pharmaceutical industry, a distinction is made between radical innovation and incremental innovation. As radical innovation implies the introduction of new medicines which can lead to the development of a new industry, incremental innovation are referred to the creation of minor improvements or simple adjustments in an existing product. Radical innovations in the pharmaceutical industry are usually associated with the development of novel chemical entities or new molecular entities (NME)⁶². Furthermore, within NMEs,

⁵⁹ Sledzik, K. (2013). Schumpeter's View on Innovation and Entrepreneurship Management Trends in Theory and practice (ed) Stefan Hittmar Faculty of Management Science and Informatics. *University of Zilina and Institute of Management by University of Zilina*.

⁶⁰ The process of industrial mutation that incessantly revolutionizes the economic structure from within, incessantly destroying the old one, incessantly creating a new one. Schumpeter, J. A. (2013). *Capitalism, socialism and democracy*. Routledge.

⁶¹ Schumpeter, J. A. (1947). The creative response in economic history. *The journal of economic history*, 7(02), 149-159.

⁶² According to the U.S. Food and Drug Administration, a NME is a drug that contains an active ingredient that has never been marketed in the US. <http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#chemtype>.

there are those medicines credited as First-in-Class, meaning drugs which use a new and unique mechanism of action for treating a medical condition. These drugs are normally known as breakthrough drugs in the pharmaceutical marketplace. Together with radical innovation, incremental or follow-up innovation consists of improvements on existing medicines or ingredients, improvements involving greater efficacy, or fewer or less severe side effects, a more convenient dosage regimen, changes in the application method, modified formulations, or new indications (follow-on drugs or me too drugs).

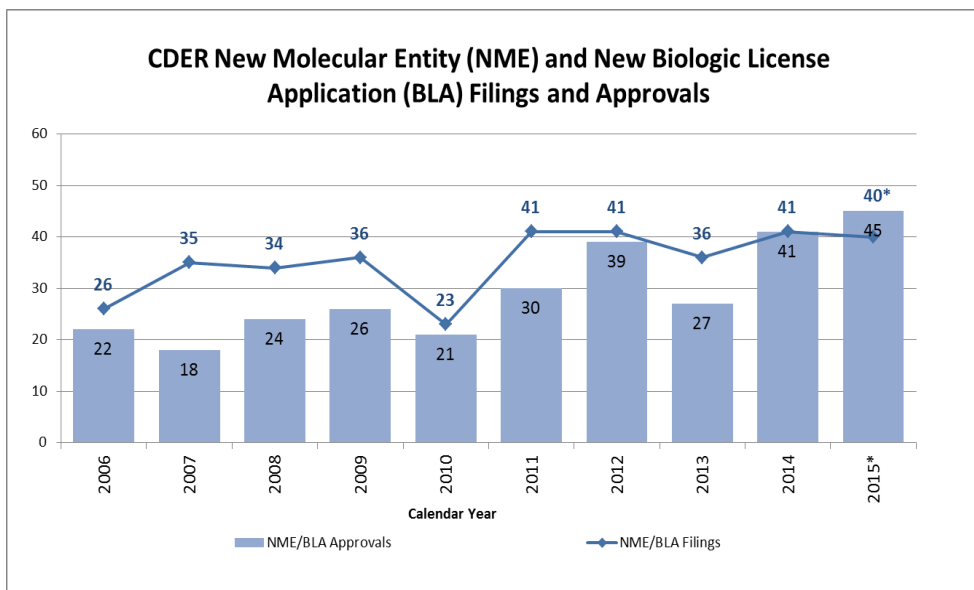
Innovation not so new.

With the exception of the two last years (2014 and 2015), the pace of the introduction of innovative medicines has slowed in the last fifteen years. As in the 90's the average introduction of NMEs was of 41 NMEs a year, the average has decreased to less than 30 NMEs a year since 2000. At the same time, the R&D expenses necessary to develop a new medicine -a radical innovation- has paradoxically increased quite significantly. In this respect, and according to widely circulated study⁶³, in spite of the fact that the most popular cost calculations have been called into question as being overinflated and not very transparent in order to be really and effectively audited⁶⁴, the average cost of developing an innovative new drug is said cost more than \$800 million, including expenditures on failed projects and the value of forgone alternative investments. This corresponds to a study of 2003. According to the European Federation of Pharmaceutical Industry and Associations (EFPIA) that cost would rise to \$1506 million in 2013.⁶⁵ There is then a clear mismatch between the higher costs of R&D expenses to develop a NME and the lower pace in the introduction of NME.

⁶³ DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: new estimates of drug development costs. *Journal of health economics*, 22(2), 151-185.

⁶⁴ Morgan, S., Grootendorst, P., Lexchin, J., Cunningham, C., & Greyson, D. (2011). The cost of drug development: a systematic review. *Health Policy*, 100(1), 4-17.

⁶⁵ http://www.efpia.eu/uploads/Figures_2015_Key_data.pdf



In 2000 NME was 32, 2001 31 NME, 2002 28 NME, 2003 26 NME, 2004 24 NME and 2005 28 NME⁶⁷

More than half of the new brands of drugs introduced in the market were not novel chemical entities or biopharmaceuticals, but improved versions and altered formulations. In this sense, 16 of the 45 novel drugs approved in 2015 (36%) are First-in-Class (meaning really innovative to treat or cure an illness).

As to the higher R&D spending per NME, a Congress of the US study⁶⁸ mentions a number of reasons to explain it; first, higher failure rates in clinical trials because of eventually greater research challenges or a willingness to test riskier drugs in such trials; Second, the shift of the focus of larger pharmaceutical firms away from drugs for acute illnesses and toward drugs for chronic illnesses of developed world -drugs that treat chronic illnesses require larger, longer and more expensive clinical trials-; Third, greater technological complexity in drug development and greater specificity in disease targets have helped to raise average R&D costs, as firms now identify drugs with particular molecular characteristics rather than using trial-and-error methods to find compounds that work in some desired way.

⁶⁶ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm>

⁶⁷ <http://www.efpia.eu/uploads/Modules/Documents/figures-2007-update.pdf>

⁶⁸ <https://www.cbo.gov/publication/18176>

The decline in the production of new NME has contributed to the debate about the eventual crisis of productivity of pharmaceutical industry⁶⁹. Some of the cited reasons explaining the decline in the approval of new medicines are among others the following: 1. the industry does not invest enough in real R&D because of the lower returns of R&D spending. 2. The increasingly stricter approval procedures and the fact that the existing regulatory review process and its standards are not well adapted to the new research technologies 3. Many diseases have been satisfactorily addressed, which limits the space for big medical breakthroughs. Today's pharmaceuticals have already created sufficiently good solutions to the "easy" medical problems, leaving the more challenging and complex diseases (e.g., cancer, HIV/AIDS, obesity, Alzheimer's, Parkinson's, diabetes) 4. The current extent of collaboration in innovation between drug companies could be insufficient 5. The industry has not yet developed the right competences to be successful in developing new treatments that are biological rather than chemical in nature⁷⁰.

However, according to some, the reason why production of NME has decreased seems to be due to the fact that R&D efforts are rather devoted to the development of "me-too" or "follow-on innovation" drugs than to the development of a really innovative drug or NME. Me-too medicines or copycat drugs are drugs which are structurally/chemically very similar to already known drugs, with only minor differences or variations. Producers of me-too drugs are late entrant or market followers of a breakthrough drug. Other than the fact that me-too drugs may have fewer side effects, pharmaceutical industry claims that in today's world there is no such thing as a "one-size-fits-all" drug and therefore me-too drugs would create the necessary variety of similar but different treatments to be available for everybody. In this sense, the availability of extra therapeutic options would be not only clinically advantageous in case of adverse side effects induced by the pioneer drug, but is also economically and socially beneficial⁷¹.

⁶⁹ Cockburn, I. M. (2006). Is the pharmaceutical industry in a productivity crisis?. *Innovation policy and the economy*, 7, 1-32. MIT Press.

⁷⁰ Ding, M., Eliashberg, J., & Stremersch, S. Innovation and marketing in the pharmaceutical industry. (see footnote 27).

⁷¹ Gozner, M. (2004). *The \$800 million pill: The truth behind the cost of new drugs*. Univ of California Press.

It is alleged that pharmaceutical companies have turned to cheaper “me-too” drugs because the development of these drugs is more profitable and it does not encompass the risks and uncertainties associated with true innovation. Both the producer of the breakthrough drug and the market competitor may be more tempted to develop a me-too (or follow-on innovation) drug rather than searching a totally innovative blockbuster drug. As the cost of development of a me-too drug is usually much lower than the cost of developing a breakthrough drug, they are priced at slightly lower level than the price of the pioneer drug in the market.

In effect, incremental innovations are easier to generate and there is a lower risk of failure. Therefore, rather than investing in new pharmaceuticals, a firm may simply switch its manufacturing and marketing efforts to develop and market the next patent-protected successor me-too drug, with little need for extra costs in production or distribution and at almost the same price. This strategy based on sequential incremental innovations, could also overcome the uncertainties associated with the pursuit of breakthrough drugs and generate steady flows of cash instead. In fact, at the time of launching a new drug, many competitors have already accumulated the necessary knowledge to develop it. This is perfectly possible if we take into account that in many occasions, competitors work in parallel on similar research projects thanks to public-funded basic research and scientific knowledge from open and public science.

Me-too drugs’ strategy has received important critics. Incremental innovations developed by competitors are said to erode pioneer drug’s market exclusivity, this diminishing incentives to invest costly breakthrough or radical innovation. This can actually undermine the justification of IPRs and market exclusivity in the sense that R&D investments to develop a me-too drug has been recouped in excess. On the other hand, these improved versions which also enjoy market exclusivity, would not offer additional therapeutic benefits or lower price to patients⁷².

⁷² Petrova, E. (2014). Innovation in the pharmaceutical industry: The process of drug discovery and development. In *Innovation and marketing in the pharmaceutical industry* (pp. 19-81). Springer New York.

Therefore, the observed crisis of the innovative process could rather respond to a change in the pharmaceutical industry's philosophy; a philosophy where the search of profitability would prevail over any other consideration. As a consequence, more money would be invested today in research into the prevention of disease such as drugs to reduce cholesterol than to its treatment. Doing so, it is said that pharmaceutical investments are diverted away from the sick towards the well, away from the old towards the young and away from the poor to the rich⁷³.

Innovative marketing versus innovative scientific discovery.

Pharmaceutical industry justifies a strong patent protection and the high prices it charges to medicines by arguing that their R&D costs are huge and that they need to be recouped. Also, they complain that because of the long administrative procedures to authorize their sale and a more permissive approach to generics, their market exclusivity has been drastically reduced.

Notwithstanding this, it is not clear that neither the cost of developing new drugs nor the uncertainty associated with it are so high as the industry alleges. Regarding the R&D expenditure, apart from some doubts as to the calculation of the cost of developing a new drug, there are important differences between the estimates presented by the Industry (PhRMA) and other public institutions like the National Science Foundation (NSF), being those presented by PhRMA bigger than twice the numbers presented by NSF. Apart from the data base of companies to be taken into account, and according to a study elaborated by the US Congressional Budget Office, those differences are explained by some different criteria when considering what R&D expenditure is. In this respect, PhRMA include spending on phase IV clinical trials (those trials conducted after a drug has already been authorized and has entered the market)⁷⁴. Those post marketing expenditures should not count as R&D expenditure as the drug has been already developed and sold and there is a grey line between real R&D expenditures and marketing/promotional expenses.

⁷³ Schacht, W. H. (2012). Federal R&D, drug discovery, and pricing: insights from the NIH-university-industry relationship. DIANE Publishing.

⁷⁴ <https://www.cbo.gov/publication/18176>

On the other hand, and regarding the uncertainty, it is important to note that it is the expenditure of basic research –the research with highest uncertainty- is mainly and increasingly borne by public funding. A study elaborated by the nonprofit organization Public Citizen reveals that public funding played an important role for the most of the top-selling drugs⁷⁵. Sometimes basic research is configured as a “public good” which is beneficial for the whole society and cannot be neither recouped nor captured by any private company⁷⁶. Letting aside the interesting debate about how much public funding is justified and compensated among society, it is true that public funding bears an important weight of the process to develop new drugs, in particular basic research which is the one with the highest uncertainty, thus importantly reducing the great uncertainty alleged by the Pharmaceutical Industry.

Also, it seems paradoxical that being qualified the investments on R&D as huge by those supporters of strong IPRs, Pharmaceutical companies spend far more on marketing drugs - in some cases twice as much - than on developing them⁷⁷.

| World's largest pharmaceutical firms | | | | | |
|--------------------------------------|----------------------|------------------|---------------------------------|---------------|-------------------|
| Company | Total revenue (\$bn) | R&D spend (\$bn) | Sales and marketing spend(\$bn) | Profit (\$bn) | Profit margin (%) |
| Johnson & Johnson (US) | 71.3 | 8.2 | 17.5 | 13.8 | 19 |
| Novartis (Swiss) | 58.8 | 9.9 | 14.6 | 9.2 | 16 |
| Pfizer (US) | 51.6 | 6.6 | 11.4 | 22.0 | 43 |
| Hoffmann-La Roche (Swiss) | 50.3 | 9.3 | 9.0 | 12.0 | 24 |
| Sanofi (France) | 44.4 | 6.3 | 9.1 | 8.5 | 11 |
| Merck (US) | 44.0 | 7.5 | 9.5 | 4.4 | 10 |
| GSK (UK) | 41.4 | 5.3 | 9.9 | 8.5 | 21 |
| AstraZeneca (UK) | 25.7 | 4.3 | 7.3 | 2.6 | 10 |
| Eli Lilly (US) | 23.1 | 5.5 | 5.7 | 4.7 | 20 |
| AbbVie (US) | 18.8 | 2.9 | 4.3 | 4.1 | 22 |

⁷⁵ Citizen, P. (2001). Rx R&D Myths: The Case Against the Drug Industry's R&D 'Scare Card'. <https://www.citizen.org/documents/ACFDC.PDF>

⁷⁷<http://www.bbc.com/news/business-28212223>

This can be also confirmed by the numbers exposed in the Form 10 and Annual Reports submitted by Pharmaceutical companies every year following legal duties.

As it has been previously observed, business strategists highlight the marketing capabilities of a company as one of the key areas of Pharmaceutical business to be successful. Pharmaceutical companies attempt to maximize profits and capture as large a market share as possible during the life of a product by trying to extend the period of market exclusivity and by engaging in promotional activities. The types of marketing and/or advertising activities vary in different countries.⁷⁸These are carried out imaginatively –and sometimes controversially- through representatives of Pharmaceutical companies, industry sponsored medical events or conferences, journal articles and supplements supporting the company’s drug, direct advertising aimed at doctors and nurses and direct to consumer advertising (only permitted in USA and New Zealand). The problem may arise -as it will be analyzed-, when all the efforts and investments tend to be addressed to ensure a profitable product placement into the market rather than creating new medicines capable of curing diseases.

⁷⁸ OECD Pharmaceutical pricing policies in a global market. (see footnote 32).

3.4. Ethical dilemmas of the drug industry: pursuit of profit at any “price”.

If one introduces the words “drugs” and “ethics” in the search engine of the digital New York Times, one gets 635 articles on this issue, the front page displays the eventually most relevant results among which the following: *Ethics in drug tests; corrupt practices?; Ban on federal Scientists’ consulting nears –about private consulting arrangements between drug companies and scientists-; Ethics in the Lab; Advertising drugs; Medical Ethics in the Dock; Psychiatrist and Drugs (...)*⁷⁹.

In effect, there are many ethical controversies associated with the conduct of the pharmaceutical industries. Furthermore, these controversies are not encapsulated in the academic reign but they constitute the subject of heated debates in the mass media and between people. Different public opinion pools rank pharmaceutical companies at the bottom of reputation of different business sector together with oil companies or tobacco companies⁸⁰. Even if pharmaceutical companies have developed an important array of life-saving and life-enhancement drugs there is an increasing collective belief that drug companies take more from society than what society receives from them. In this sense, according to some, the implicit social contract existing between society and pharmaceutical industry is today unbalanced with companies making bigger and bigger profits as innovation slows down, prices are higher and contributions to the common good are lesser. The main problem seems to be the obvious conflict of interest between pharmaceutical companies’ private interest in maximizing profits and the medical need of people in terms of accessible and affordable medicines. In this sense, the market offers products responding to consumer demand, i.e. consumers with the wealth and ability to pay. Human medical needs however are universal and common between people with means and underprivileged and deprived people.

There are many fronts where this conflict arises, where there is a collision between profit-driven interest and human needs and global population’s wellbeing. Maybe the

⁷⁹ This research was done on March 31, 2016.

⁸⁰ <http://www.fiercepharmamarketing.com/story/big-pharmas-reputation-strikes-out-again-and-profit-perceptions-may-be-blam/2015-08-24>

most recurring ethical controversies have to do among others with the priorities of scientific research and how this research is a profit-driven one; criteria about which patients are to be included in drug trials for hopeful drugs; ethical issues regarding stem cell research; IPRs validity and enforceability when there are other human rights at stake or prices charged to medicines. Due to the purpose of this dissertation and extension reasons, this chapter is focused on two particular issues which have generated interesting debates and analysis; 1) the ethical issues surrounding the conduction of research involving human subjects, in particular citizens of developing countries and other vulnerable subjects; 2) marketing/promotional activities and undue influence of drug companies in their search of profit.

Clinical Trials in developing countries. Some ethical issues.

The number of clinical trials worldwide has increased steadily during the last two decades. Furthermore, clinical research is undergoing the same globalization process as other industries. In particular, clinical research is shifting from high-income countries to low- and middle-income countries. There are many reasons to conduct clinical trials in developing countries, especially the lower cost of conducting trials in low-income countries. Although there are sound economic reasons to explain this shift of location of clinical trials to developing countries in a “global world”, the fact that population of those countries may be in need, that their public health systems do not have the necessary tools to satisfy the same standards of care as they do in the developed world at the time of conducting trials and that regulatory environment may be more lenient, all this may derive in a logic of exploitation which underpins many ethical concerns⁸¹.

We all have been moved by the movie *The Constant Gardener* (2005) a film based on a John Le Carre’s novel where the plot deals with an activist (Rachel Weisz) who is brutally murdered when she discovers the malpractices of a powerful pharmaceutical company which is using African population for fraudulent testing of a drug with harmful side effects that the company knows and deliberately disregards and hides.

⁸¹ Li, R., Barnes, M., Aldinger, C. E., & Bierer, B. E. (2015). Global clinical trials: Ethics, harmonization and commitments to transparency. *GLOBAL HEALTH*.

Leaving aside the dramatic and prosaic tone of the movie and the fact that the plot is pure fiction and it is not based on any actual person, corporation or facts, there have been some real cases where there have been detected some malpractices operated by pharmaceutical companies when carrying out clinical trials in developing countries. Maybe one of the most illustrative cases was the *Rabi Abdullahi v. Pfizer, Inc* case.

In this case⁸² the US Court of Appeals for the Second Circuit ruled that the Nigerian victims and their families were entitled to bring suit against Pfizer in the United States under the Alien Tort Statute alleging that Pfizer may have violated a customary international law norm prohibiting involuntary medical experimentation on humans when it tested an experimental antibiotic on children in Nigeria, including themselves, without their consent or knowledge. Even if Pfizer subsequently settled the case out of court with a 75 million dollars –in a settlement that was subject to a confidentiality clause-, the case is powerful enough to illustrate how some developing countries (specially African countries) have been sites for clinical trials by

⁸² *Abdullahi v. Pfizer, Inc.*, 77 Fed. 2d Cir. N.Y., October 8, 2003. In April 1996, Pfizer, dispatched three of its American physicians to work with four Nigerian doctors to experiment with Trovan on children who were patients in Nigeria's Infectious Disease Hospital ("IDH") in Kano, Nigeria. Working in concert with Nigerian government officials, the team allegedly recruited two hundred sick children who sought treatment at the IDH and gave half of the children Trovan and the other half Ceftriaxone, an FDA-approved antibiotic the safety and efficacy of which was well-established. Appellants contend that Pfizer knew that Trovan had never previously been tested on children in the form being used and that animal tests showed that Trovan had life-threatening side effects, including joint disease, abnormal cartilage growth, liver damage, and a degenerative bone condition. Pfizer purportedly gave the children who were in the Ceftriaxone control group a deliberately low dose in order to misrepresent the effectiveness of Trovan in relation to Ceftriaxone. After approximately two weeks, Pfizer allegedly concluded the experiment and left without administering follow-up care. According to the appellants, the tests caused the deaths of eleven children, five of whom had taken Trovan and six of whom had taken the lowered dose of Ceftriaxone, and left many others blind, deaf, paralyzed, or brain-damaged. The appellants further alleged that Pfizer failed to follow its protocol in ways that might have mitigated the harm suffered by the children. They contend that Pfizer violated the protocol by administering Trovan orally even though oral absorption is difficult for sick children; conducting no testing prior to administering the drug to determine whether Nigeria's strain of meningitis might be responsive to Trovan; failing to determine that the children in the test had meningitis; and failing to either exclude from the experiment children with liver or joint problems or to test for such problems, even though Trovan was known to exacerbate them. Although Pfizer's protocol called for children receiving Trovan to be switched to Ceftriaxone if they did not respond well to Trovan, Pfizer allegedly did not conduct regular blood tests of the children or switch those who suffered from Trovan-related side effects to Ceftriaxone. Appellants claimed that Pfizer, working in partnership with the Nigerian government, failed to secure the informed consent of either the children or their guardians and specifically failed to disclose or explain the experimental nature of the study or the serious risks involved. Although the treatment protocol required the researchers to offer or read the subjects documents requesting and facilitating their informed consent, this was allegedly not done in either English or the subjects' native language of Hausa. The appellants also contended that Pfizer deviated from its treatment protocol by not alerting the children or their guardians to the side effects of Trovan or other risks of the experiment, not providing them with the option of choosing alternative treatment, and not informing them that the non-governmental organization Médecins Sans Frontières (Doctors Without Borders) was providing a conventional and effective treatment for bacterial meningitis, free of charge, at the same site.

large pharmaceutical companies through practices which have raised an array of human rights concerns.

There is a number of international rules guiding the ethical conduct of clinical trials. The first international instrument of this type was the Nuremberg Code of 1947 which introduced, for the first time, the concept of informed consent. The Code, which consists of a series of ten principles, was applied in the final judgement held at Nuremberg, Germany, before a U.S. military tribunal in 1946–7. Also, the World Medical Association’s Declaration of Helsinki in 1964 introduced, for the first time, ethical principles for physicians in the conduct of human research. The Declaration has been amended subsequently being the last amendment introduced in 2013. This Declaration contemplates among others; the specific protection to be received for vulnerable groups and individuals; the necessary adequately informed consent of each potential on the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study; and the fact that every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject.

Most importantly, the United Nations International Covenant on Civil and Political Rights in 1966 recognized, at the international level, the concept of free informed consent, as its Article 7 states that “*no one shall be subjected without his free consent to medical or scientific experimentation.*”

Also, the WHO published the Good Clinical Practice Guidelines (GCP) for Trials on Pharmaceutical Products and the International Conference on Harmonisation (ICH) also published a Guideline on Good Clinical Practice (GGCP) –for adoption by its members; the regulatory authorities of the EU, Japan and US-. ICH’s Guideline has a consolidated version and it has been the subject of criticism for being too focused on formal procedures rather than moral principles as the Declaration of Helsinki

eventually does⁸³. In particular, it has been criticized in the issue of *placebo* use. While the Declaration of Helsinki states that “*the benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best proven intervention(s) [...]*” The ICH’s GGCP does not provide such provision and takes for granted the possibility of using placebo⁸⁴.

Therefore, there has been in recent years an increasing number of international guiding principles for the ethical conduct of clinical testing and clinical trials involving human subjects. Notwithstanding this, there are still some shadows around the effectiveness and actual implementation of these codes. First, it is important to note that although some jurisprudential constructions (as the one mentioned in *Abdullahi v. Pfizer, Inc* which considered certain legal principles of these codes as *jus cogens*), the enforceability nature of these guides are dependent on the implementation to be done by national authorities (ethical codes v. ethical regulation).

Other shortcoming observed in the current system is the lack of transparency in relation with the registration of clinical trials worldwide. Despite the fact that there have been important improvements on clinical trial registration, these have not taken place equally everywhere in the globe. Also, some registered clinical trials would not be of help due to the poor quality of registered trial data and the inaccessibility of trial protocols⁸⁵. Although WHO put in place an International Clinical Trials Registry Platform (ICTRP), it should play a more important role in centralizing and guaranteeing all the standards of care of the Clinical trials involving human subjects. WHO could also explore the creation of international ethical committee review for clinical trials to ensure the idea of dual review (the one carried out by the host country and the international one).

⁸³ Goldacre, B. (2014). *Bad pharma: how drug companies mislead doctors and harm patients*. Macmillan.

⁸⁴ Using placebo versus existent/known effective standards of treatment are known can be misleading when showing the efficacy of a treatment.

⁸⁵ Viergever, R. F., & Li, K. (2015). Trends in global clinical trial registration: an analysis of numbers of registered clinical trials in different parts of the world from 2004 to 2013. *BMJ open*, 5(9), e008932.

On the other hand, it has been criticized the ethical “variability” or interested reading and interpretation of ethics by drug companies depending on the context where those principles are called to operate. In this sense, some authors observe that ethics involves the implementation of mechanisms, tactics and dynamics which go beyond defining instances of moral certainty. These authors denounce cases where contextual factors (crisis and its humanitarianisms) justify occasionally as legitimate, conduct that otherwise or under normal parameters would appear as highly scandalous or unethical. In this regard, existing codes do not impede the creation of “ethics free” spaces associated with humanitarian crisis, precisely because it is disastrous, beyond the reach of regulation. Also, there may be certain temptation by some drug companies to use those “unregulated spaces” to get a fast track and where the long and conventional way is disregarded. In this sense, it would be necessary to shift the focus from normative theory of ethics and ideal conditions, to the way in which the norms are being refashioned and transformed in actual and diverse conditions⁸⁶.

Marketing and advertising techniques: bordering industry’s undue influence.

As it has been noted, there is an obvious conflict of interest arising from the profit-maximizing objectives of pharmaceutical companies and the social goal of optimizing public health outcomes. The efforts and cost of companies’ promotional activities are sometimes twice the investments devoted to R&D towards the development of new medicines. There is an ethical concern about the possibility that these marketing tactics or techniques are bordering the legitimate advertising activity and entering an undue influence of the industry over patients, prescribers, regulators and political establishment.

⁸⁶ Petryna, A. (2005). Ethical variability: drug development and globalizing clinical trials. *American Ethnologist*, 32(2), 183-197.

a) Patients.

Consumption of medicines is gradually increasing in the developed world. According to some recent statistics, about 50% of the population in the US⁸⁷ has used one prescription drug in the last 30 days –around 90% for 65 year old and over population-. This percentage of consumption experiences a gradual increase every year.

Except for the rare cases of US and New Zealand, The direct-to-consumer-advertising (DTCA) is prohibited worldwide. There are specific regulations relating to promotional methods that could lead to the unnecessary or excessive use of medicines. DTCA advocates claim that this technique helps to reduce stigma or shame associated with seeking care –sexually transmitted diseases or mental health problems-. Also they consider that DTCA may improve adherence to medication therapy for chronic conditions and it may be an effective way of targeting clinical problems, which are generally underdiagnosed. Finally, some think that a doctor's monopoly on information and knowledge about health has contributed to an increase in patients' dependency on the medical profession and has reinforced paternalistic practices⁸⁸.

However, most governments consider that DTCA does not contribute to public health but it rather leads to a bigger and eventually inappropriate consumption of medicines. In effect, health information through commercial marketing is likely to be inadequate, biased, untruthful, and restricted mainly to blockbuster drugs. It seems that regardless of the fact that there is a need for the public to become better informed about medical treatment and health issues in general, it should not be the responsibility of the drug industry to deliver this information⁸⁹. In fact, there are studies showing that DTCA increases patients' anxieties and fears of serious illness, and promote the impression that medicine is the only solution to health problems

⁸⁷ National Center for Health Statistics (US. (2015). Health, United States, 2014: With special feature on adults aged 55–64.

⁸⁸ Hasman, A., & Holm, S. (2006). Direct-to-consumer advertising: Should there be a free market in healthcare information?. *Cambridge Quarterly of Healthcare Ethics*, 15(01), 42-49.

⁸⁹ Coulter, A. (2004). Why the ban on direct-to-consumer advertising of prescription medicine should remain in place. *Direct to patient communication: patient empowerment or NHS burden*, 37-43.

(medicalization), giving confusing or partial information about risks and side-effects⁹⁰. Also, Prescribers feel compelled to prescribe medicines that have been actively promoted in the media, this including a shift to less appropriate prescribing, differential effects by patient price sensitivity and drug type, switches to less cost-effective treatment, and sustained sales despite a price increase⁹¹.

On the other hand, and apart from the most obvious impact of DTCA on people, there are other more subtle ways for the pharmaceutical industry to penetrate society and people's day-to-day life. In this sense, there is an increased presence of drugs in our daily life which may be due to what some have qualified as a "medicalization" of society, i.e., the trend to categorize more and more individuals as "abnormal" or the assumption that every problem requires medical treatment. There are many examples of this trend⁹² including the medicalization of some "male" problems such as baldness and sexual impotence or the medicalization of some psychological moods such as "mild" depressions "suffered" by unhappy and distressed people who have been the target of intensive marketing activity. In this sense, only about 5% of all prescriptions are written for severe depression and about two-thirds for mild depressions even if there is no good evidence that those antidepressants will really help to overcome certain natural sadness⁹³.

Also, pharmaceutical industry may exercise an undue influence on patients through its support to patient organizations which become subtle vehicles of marketing. Patient organizations usually are providers of theoretically unbiased and objective information and they often campaign for increased access to certain treatments. Sometimes these organizations share the same interests with the pharmaceutical industry in attempting to influence health policies. However, there are occasions where pharmaceutical industry provides direct funding or valuable contributions to a

⁹⁰ Kim, Y., Kornfield, R., Shi, Y., Vera, L., Daubresse, M., Alexander, G. C., & Emery, S. (2016). Effects of televised direct-to-consumer advertising for varenicline on prescription dispensing in the United States, 2006–2009. *Nicotine & Tobacco Research*, 18(5), 1180-1187.

⁹¹ Mintzes, B. (2012). Advertising of prescription-only medicines to the public: does evidence of benefit counterbalance harm?. *Annual Review of Public Health*, 33, 259-277.

⁹² Conrad, P. (2008). The medicalization of society: On the transformation of human conditions into treatable disorders. JHU Press.

⁹³ House of Commons Health Committee, & House of Commons Health Committee. (2004). *The influence of the pharmaceutical industry*. Fourth report of session, 5, 2005.

patient association and charities. This implication of the pharmaceutical industry with these associations may erode their independence and impartiality specially when there is not the necessary transparency about patient associations' funding. In this sense, a research conducted through internet (Google search strategy) identifying major international patient associations showed that only 4 out of 69 websites stated advertising and conflict of interest policies and that corporate donations were identified in only 7/37 reports and none gave enough information to show the proportion of funding from the pharmaceutical industry⁹⁴.

b) Prescribers of medicines.

Undue influence of the pharmaceutical industry on the health professionals who prescribe medicines and the eventual inappropriate prescription of medicines are issues of particular concern. There is a variety of techniques whose purpose is to influence prescribers' decisions and considerations to certain treatments; direct advertising, organization of medical congresses, pharmaceutical sale representatives and public relations, scientific articles and magazines and other media to communicate the benefits of their products. Sometimes prescribers experience important difficulties in finding unbiased, impartial, scientific contrasted and objective information about the medicines to be prescribed. Pharmaceutical companies have developed sophisticated and subtle instruments to influence the information received by prescribers which find themselves flooded by biased interest driven and partial information on the medicines they have to prescribe to their patients⁹⁵.

One example of the above is the potential conflicts of interests in journal publishing and science advisory panels and the creation of economic bones with scientists and doctors. In a research conducted on the independence of the prestigious Diagnostic and Statistical Manual of Mental Disorders published by the American Psychiatric Association, it was examined the financial ties to the pharmaceutical industry of panel

⁹⁴ Ball, D. E., Tisocki, K., & Herxheimer, A. (2006). Advertising and disclosure of funding on patient organization websites: a cross-sectional survey. *BMC Public Health*, 6(1), 201.

⁹⁵ Goldacre, B. (2014). Bad pharma: how drug companies mislead doctors and harm patients. *Supra* note 83.

members responsible for revisions of the Diagnostic and Statistical Manual of Mental Disorders. Of the 170 panel members, 95 (56%) had one or more financial associations with companies in the pharmaceutical industry. These financial ties are created through permanent or limited collaborations in the field of research funding (42%), consultancies (22%) and speakers bureau (16%)⁹⁶.

Also, medical journals which are an important source of information for doctors and health professionals are riddled with “ghost-writers” which do not present an objective assessment of the merits and disadvantages or dark sides of a medicine, there being a bias towards showing presented medicines in a positive light. Ghost writing consists of those articles which appear under the name and credit of prestigious professionals when they have not written –or conducted the research– themselves but by somebody else who has been committed by the pharmaceutical company. In this sense, approximately 75% of clinical trials published in *The Lancet*, the *New England Journal of Medicine* and the *Journal of the American Medical Association* were industry funded. Also, over 50% of articles appearing in these journals may also be ghost-written⁹⁷.

Many of those scientific publications are based on selective report of medical trials which often miss the negative aspects of a medicine. In a research conducted among 74 FDA-registered studies, 31% of the studies were not published. Whether and how the studies were published seemed to be associated with the study outcome. A total of 37 studies viewed by the FDA as having positive results were published -1 study viewed as positive was not published-. However, studies viewed by the FDA as having negative or questionable results were, with 3 exceptions, either not published (22 studies) or published in a way that, in the research author’s opinion, conveyed a positive outcome (11 studies).⁹⁸

⁹⁶ Cosgrove, L., Krinsky, S., Vijayaraghavan, M., & Schneider, L. (2006). Financial ties between DSM-IV panel members and the pharmaceutical industry. *Psychotherapy and psychosomatics*, 75(3), 154-160.

⁹⁷ House of Commons Health Committee, & House of Commons Health Committee. See supranote 93.

⁹⁸ Turner, E. H., Matthews, A. M., Linardatos, E., Tell, R. A., & Rosenthal, R. (2008). Selective publication of antidepressant trials and its influence on apparent efficacy. *New England Journal of Medicine*, 358(3), 252-260.

In addition to the subtle techniques of influence, there are other promotional techniques which may also be highly objectionable. Other than direct advertisement, doctors are the object of company representative visits and are invited to attend sponsored “educational” events which often include generous hospitalities which have an important effect on prescribing practice. This category of promotional activities has been left to industry’s self-regulation assuming that doctors’ professional expertise and ethics are sufficient to avoid undue influence. However, different manifestations of self-regulation codes and bodies of rules have been criticized as too vague, too weak and too often ignored⁹⁹. This emerging conflict of interest has started to be correctly addressed by certain laws like the Physician Payments Sunshine Act (Sunshine Act) in the United States, and a number of EU Member States such as France, Spain, Belgium or Italy with specific sunshine legislation and disclosure obligations in order to improve the transparency of relationships between physicians and health care companies.¹⁰⁰

c) Regulators and political establishment.

It is difficult to study the influence of the drug industry on public officials and politicians without entering the field of conspiracy theories and other works which turn to be closer to the noir novels’ genre. However, it is important to mention some facts which reveal important links and influence between the pharmaceutical industry, the public administration and public agencies and the political establishment.

According to the Center for Responsive Politics, only in the US the Pharmaceutical industry has spent during 2015 a total of \$238,086,761 for lobbying activities. They also fund candidates’ campaigns (Hillary Clinton has received so far \$490,583) ¹⁰¹. Before the European Parliament, the registered lobbies in the pharmaceutical field

⁹⁹ Doran, E., & Löfgren, H. (2013). Drug promotion in Australia: Policy contestation and the tightening of regulation. *Australian Review of Public Affairs: Journal*, 11(2).

¹⁰⁰ French law n° 2011-2012 on the Strengthening of Health Protection for Medicinal and Health Products which among others, established the obligation to disclose and publish the advantages in kind or in cash exceeding €10, provided directly or indirectly to health care professionals.

¹⁰¹ www.opensecrets.org

are 16 spending a total of 7.381.800 euros¹⁰². Letting aside the earlier mentioned pressure and influence of Pharmaceutical industry for the implementation of TRIPS, there are no clear evidences about the influence that these lobbies have on political decisions but account taken of the amounts devoted to lobbying, it seems clear that they receive some positive reward.

On the other hand, there are different manners by which the industry exerts certain influence on the regulatory agencies. In particular, in 1992 the US Congress passed legislation introducing prescription drug “user fees” for the review of new drugs. This made the FDA dependent on industry for a portion of its funding. This dependence has raised questions about the impartial functioning of the FDA when giving priority to some new drugs for a faster review process even when they do not imply a medical advance¹⁰³.

Also, today the relationship between the pharmaceutical industry and the regulatory agencies is closer. There is a permanent dialogue, exchanges of information and staff, common policy objectives, routine contact and employees who regularly shift positions between the public and the private sides. Even if collaboration between both parties is necessary, there is a risky approach of considering the relationship between the regulatory agency and the pharmaceutical companies as one of provider and client where the pharmaceutical industry is the client which must be looked after. In this sense, it is argued that trust between the regulators and the industry should be based on robust evidence instead of a routine reliance on company’s information and data. Otherwise, there is the danger of failing in the so named regulatory capture which occurs when a regulatory agency advances the private interests of the industry it is committed to regulate instead of acting in the public interest¹⁰⁴.

¹⁰² <http://www.integritywatch.eu/lobbyist.html>

¹⁰³ Hawthorne, F. (2010). *Inside the FDA: The business and politics behind the drugs we take and the food we eat*. John Wiley & Sons.

¹⁰⁴ Dal Bó, E. (2006). Regulatory capture: a review. *Oxford Review of Economic Policy*, 22(2), 203-225.

CHAPTER 4. THE LEGITIMACY CHALLENGE: THE NORMATIVE AND INSTITUTIONAL BASIS FOR REGIME CHANGE.

4.1. Social contestation and crisis of legitimacy of WTO.

On November 30 of 1999, the cradle of the “high-tech” sector, the peaceful and prosperous American city, Seattle which once was described as a “leading apostle of transnational trade” awoke with the biggest civil protests and disturbances of political nature since the Vietnam War era in America. More than 40.000 protesters – students, organized labor unions, NGOs, religious groups, people for fair trade, Direct Action Network...- were congregated to protest against the third World Trade Organization (WTO) Ministerial Conference. They wanted to make it known that the WTO, an institution virtually invisible to the general public, was an undemocratic, anti-labor, and anti-environmental organization that served the interests of corporations over people and the environment¹. The protest degenerated into a major clash where more than 500 individuals were arrested in what became the “Battle of Seattle”². Since Seattle, the premise that trade *per se* fosters peace and prosperity was called into question when no wounded to death.

There have been an important number of studies and analysis about what was the real meaning around the “Battle of Seattle” in terms of contestation against “global governance” and the new international economic regime represented by multilateral economic institutions such as WTO, IMF and the World Bank. In particular, many scholars note that Seattle gave birth to the development of a certain global civil society (GCS) where transnational social movements (TSMOs) and transnational non-governmental organization (TNGOs) would be extending democratic values globally and monitoring rogue states and corporations; the birth of a sort of global conscience,

¹ Taylor, R. (Ed.). (2004). Creating a better world: Interpreting global civil society. Kumarian Press.

² After Singapore (1996) and Geneva (1998), Seattle in the US was officially the third WTO Ministerial Conference. The ministerial conference is the organization’s highest-level decision-making body and it meets “at least once every two years”, as required by the Marrakesh Agreement Establishing the WTO and the TRIPS. The Seattle Ministerial Conference was intended to launch a new round of multilateral trade negotiations that would have been called “The Millennium Round”. The Ministerial Conference included plenary sessions and the Committee of the Whole, as well as four working groups on special topics (Agriculture, Market Access, Singapore Agenda and Other Issues, and Implementation and Rules) and a Group on Systemic Issues.

a global society which would be called to overcome the national margins and having a worldwide scale as the field of its concerns and activity. From a normative perspective the idea of global civil society has also become a fruitful theoretical category to explore in order to revamp certain cosmopolitan ethical tradition based on modern Kantian theories that see in this global civil society the realization and implementation of universalizable moral norms³ and the creation of a global justice movement. Also, as we will see in further chapters, the concept of global civil society has an important attractiveness for many scholars in their attempt to explain and refashion the new political world order.

Notwithstanding this, and according to many, much of what has been described as a new phase in social movement and the creation of a transnational civil society has been certainly overstated. The term “global civil society” would have been vaguely used to refer to many different organizational forms and types of global action, a sort of catchall term for TNGOs and TSMOs and other social movements of all shapes and sizes operating in the international realm. In the light of the Seattle events and the study of the organization, ideational preparation and constituent mobilization behind them, it has been found that in the era of globalization large-scale social mobilization still relies on locally based constituencies and the resources that can be mobilized in national scale following national interests rather than a global mobilization grounded on global interests. This does not imply that the Seattle protest did not encompass an international component and important shifts in the social movement field; in effect, although transnational organizations made a modest organizational contribution to the “revolt”, they provided a core of highly informed activists who played an important role as speakers and authorities on specific issues. But this international element was not decisive at all⁴.

On the other hand, one of the main Battle of Seattle’s contribution to the debate on the new global order has been the fact of becoming a sort of template for dissent and protestation, an example of proceedings, “protest repertoire” and cooperation

³ Kaldor, M. (2003). The idea of global civil society. *International affairs*, 79(3), 583-593.

⁴ Murphy, G. H., & Pfaff, S. (2005). Thinking locally, acting globally? What the Seattle WTO protests tell us about the global justice movement. In *Political Power and Social Theory* (pp. 151-176). Emerald Group Publishing Limited.

between diverse groups which without requiring excessive compromise, met together to protest the WTO, its policies and practices. This mobilization of local and regional communities -negatively affected by the new global economic regime- constituted the example and the first mobilization of these characteristics to which all other global justice protests are compared. The Seattle example has inspired other international meetings and summits around the new economic order.

On the other side of the coin, the Battle of Seattle also witnessed new forms of government repression and the curtailing of some fundamental democratic rights such as the freedom of speech in the never ending dialogue between security and democracy. Examples of these exceptions to the so far unassailable democratic scenario, are *inter alia* the enforcement of illegal “no protest zone” faced by protesters; some efforts to eliminate public participation and democratic accountability by promoting “fast track” executive authority –boosted by Clinton to eliminate the Congressional role in trade negotiations by forcing the legislative branch to either reject or approve the whole of agreements- or; the organization of global meetings in locations where freedom of speech and other democratic rights are restricted as well as public demonstrations (Singapore, Qatar...). All those attitudes raise serious concerns about the ways that the new global regime affects the practice of democracy⁵.

In the end, the Conference was unable to launch the new round of negotiations, nor was a Ministerial Declaration adopted. The outdoors protests were coupled with the resentment and dissatisfaction of some developing country representative inside the Conference about the efficiency and transparency of the WTO decision-making process. In this sense, developing country representatives were excluded from the so-called “green rooms”, those forums where the most powerful countries did the real negotiating, this leading to a legitimate anger by developing countries. This parallel negotiation exemplifies the sometimes enormous gap between the legal formal process under which the negotiations are carried out and the real political process underneath where the most powerful countries assert and enforce their interests by

⁵ Smith, J. (2001). Globalizing resistance: The battle of Seattle and the future of social movements. *Mobilization: An International Quarterly*, 6(1), 1-19.

offering incentives or by resorting to coercion methods⁶. In any case, in the analyses of the socioeconomic political and institutional context surrounding IPRs and in particular, the global regime of IPRs, this chapter address the institutional environment in which IPRs global regime is anchored ant the crisis of legitimacy of the whole system where IPRs is an integral/constituent piece.

The WTO legitimacy crisis.

Therefore and focusing on the subject matter of this chapter, the Battle of Seattle is widely identified as a turning point for WTO, and more broadly for global economic governance institutions, in particular, a questioning of its legitimacy to adopt and make decisions with an impact upon the lives of billions of people. In this sense, one of the immediate consequences of Seattle was the strong public questioning of the “Club Model” functioning of the trade regime which had been operated until then and the interests and premises under which they worked. For a long period of time, the trade regime coming from GATT had worked discretely, with low profile, -even secretly- in pursuit of a vision of open markets and deeper economic integration. This forum and the trade policymaking process were isolated and shielded from day-to-day politics. This once non disputed manner of operation of the GATTs is no longer admissible. On the contrary, WTO is today often perceived as a “black-box” where elites and multinational corporations dominate and prevail over the common good⁷ affecting everyday’s lives in aspects which are perceived to go beyond the technical issues they were called for.

Dancing with the concept of legitimacy.

Legitimacy is a central concept in political theory for the functioning of any decision-making and political authority. However, it seems easier to detect that there is a missing or deficient legitimacy in a given political regime than to reach an accurate definition of all its contours; when it is functioning well, citizens take for granted that

⁶ Jawara, F., & Kwa, A. (2004). Behind the scenes at the WTO: The real world of international trade negotiations. Zed Books.

⁷ Esty, D. C. (2002). The World Trade Organization's Legitimacy Crisis. *World Trade Review*, 1(01), 7-22.

political authorities are legitimate and that their actions are justified. When it is not functioning and it generates too much of resistance and contestation, the legitimacy issue emerges as one of the motives to be evaluated. In this sense, public acceptance and justification (legitimacy) of the authority and decisions that emerge from the WTO may no longer be taken for granted⁸.

Although debates around the concept of legitimacy are beyond the scope and purposes of this dissertation, it is necessary to clarify some concepts on the issue before entering the analysis of the WTO legitimacy crisis. Legitimacy has been the object of research of different social disciplines such as philosophy, law, sociology, political science or anthropology. There are important and major divergencies around the concept both inter disciplines and intra disciplines. In spite of those discrepancies there seems to be a common ground for understanding this concept: the idea of legitimacy concerns first and foremost the “right to govern” or more precisely, the right to make decisions. Legitimacy is the recognition of the right to govern. In this regard, legitimacy would offer a solution to a fundamental political problem; justifying simultaneously political power and obedience⁹.

The first distinction around legitimacy for our purposes is between the domestic legitimacy and the international legitimacy. Even if both concepts are intimately related, there are important differences regarding the grounds and justification of both legitimacies. Unlike what it relates to domestic legitimacy where political power rest with sovereignty of the people, international law and international institutions are traditionally considered to be legitimate as a result of the consent given by the states (*pacta sunt servanda*). Also, there is held to be a tacit consent to customary international law, i.e. when a state does not raise any objection to certain regularized practice, that state is considered to be bound to customary international law. Furthermore, states are supposed to negotiate and tailor the agreements they enter into by means of reservations and understandings and retain rights of exit to the agreement, convention or treaty. Some exceptions to the requirement of voluntary

⁸ Ibidem.

⁹ Coicaud, J. M., & Curtis, D. A. (2002). *Legitimacy and politics: a contribution to the study of political right and political responsibility*. Cambridge University Press.

consent would be constituted by *ius cogens* norms which bind states no matter whether they consent or not. Therefore, always from a traditional international law perspective, international legitimacy -based on the state's consent- emerges from the idea that states are free and sovereign entities which are the subjects directed to act in international law¹⁰.

In this sense, WTO, an international organization created as a result of an agreement or treaty consented by eventually "free and sovereign" states, would have formal legitimacy to implement the obligations and duties set forth in its constituent treaties. In this logic, TRIPS would be a treaty binding WTO state members since it comes from a legitimate international source.

Notwithstanding this, legitimacy derived from consent by states is experiencing an important questioning. Former international legitimacy of international institutions and/or bodies of international norms was based in a "non-intrusive" international law, an international law which was mostly limited to deal with the relations between sovereign states. Today, international law does no longer encompass interstate relations, but also, as it is the case for TRIPS, it pertains to intrastate relations and therefore, it enters into the regulation of specific issues of the life of individuals alongside domestic law. Besides the traditional sources of interstate international law (treaties, customary law and general principles), new categories of intrastate international law and legislation by International Organizations have emerged with an important impact on individual lives and on some areas such as health, environment or safety. The WTO is a clear example of this as it is entering new and ambitious areas of trade which have an enormous impact on other policy domains such as labor, environment and health (TRIPS). In this new context where structural changes of political authority is shifting decision making power from democratic states to international organizations, the "consent of states" argument to uphold the decision making process at the international stage does not seem to be enough to justify norms which are affecting people's life without a previous public discussion¹¹.

¹⁰ Christiano, T. State Consent and the Legitimacy of International Institutions.

¹¹ Nanz, P. (2006). Democratic legitimacy and constitutionalisation of transnational trade governance: A view from political theory. *Constitutionalism, Multilevel Trade Governance and Social Regulation*, 59-82.

Also, the international legitimacy question is especially important today due to the shift from a set of rules between nations (GATT) to a more formal organization such as WTO with important policy reach and impact.

At this point, it is important to note the clash and the growing contradiction observed between the two dimensions of multi-lateral international legitimacy (the relationship between states in the creation of the international regime and the relationship of each state with its population); from a state point of view, the international agreement or the creation of a multi-lateral international organization has to be eventually and simultaneously acceptable both to the other negotiating parties or states and to their citizens. This is called the normative two-level games, i.e., when governments make commitments to one another and they take collective decisions in a multilateral scenario they simultaneously need to be responsible and accountable to their national populations to retain their domestic/political legitimacy¹². In this sense, there is today a gap between the international regime created by consent of the states and the increasing reluctance of citizens of those states to accept international decisions derived from that regime in areas formerly reserved to their sovereign states and where previous political and “democratic” debate took place before decisions be made. Thus, current international decision-making authorities and processes would fall short of justifying and explaining today their legitimacy which is deeply questioned.

As a consequence of this crisis, during the last two decades, the traditionally neglected field of international legitimacy has received an unusual attention both by multitude academic articles and studies and legal practitioners (international lawyers, judges, NGOs) which attempt to find and determine the criteria to cope with the crisis of international legitimacy and, in particular, with WTO’s legitimacy crisis. The common concern is to identify under which conditions the exercise of power beyond the nation state can be claimed to be legitimate. This leads for example, to the questioning about whether the states or the citizens are the terms of legitimacy

¹² Bellamy, R., & Weale, A. (2015). Political legitimacy and European monetary union: contracts, constitutionalism and the normative logic of two-level games. *Journal of European Public Policy*, 22(2), 257-274.

reference; about the substrate of the political community concerned; or about the democratic character of international institutions adopting decisions affecting people's lives.

Many authors transfer automatically concepts and categories of legitimate authority developed for the domestic context into the analysis of the international legitimacy or the legitimacy of the exercise of power beyond the state. However, by ignoring some basic differences between domestic and multi-level context –differences regarding its subjects and the absence of a real international *demos*- this direct and automatic extrapolation seems to raise more problems than it has solved¹³. Therefore and bearing this important distinction in mind, it is necessary to identify what it is understood to be legitimacy when we speak about WTO crisis of legitimacy.

Even if intimately intertwined, the concept of legitimacy can be formulated in descriptive or normative terms. Descriptive or empirical legitimacy would refer to the *de facto* support and acceptance of the people and public opinion with a given system, being this empirical legitimacy beyond the purposes of this chapter. In normative or prescriptive terms, legitimacy refers to the validity of a given system or political regime following and pursuant to certain normative criteria. There are authors who claim a third way, the *pragmatic-discursive* approach which will be analyzed later and that invokes a rational deliberative process to scrutinize the normative premises and normative criteria of the different and multiple legitimacies¹⁴. Also, there is a distinction between procedural and substantive legitimacy. As procedural legitimacy would be reached by following a procedure, substantive legitimacy would be based on material grounds or judgements on the merits. Again here, it is important to be cautious not to overestimate one over the other; apart from the fact that decisions should come for example from democratic processes, to be legitimate, it would be

¹³ Thomas, C. (2013). The concept of legitimacy and international law. *LSE Law, Society and Economy Working Papers*.

¹⁴ Cornago, N. (2005). Problemas de legitimación del nuevo régimen mundial del comercio: una exploración para internacionalistas. *Globalización y comercio internacional. Actas de las XX Jornadas de la AEPDIRI*, 415-427.

necessary from a deliberative perspective to give rational substantive reasons connected with agreed or constitutional values¹⁵.

Once considered the different dimensions of legitimacy, it is important to review the sources of legitimacy of a system. In the political science literature, there would be three main sources of legitimacy; the functional or systemic, the legal or rule-of-law based legitimacy and democratic sources of legitimacy. In fact, legitimacy will be based on the three sources with a balance between them which will depend upon the context and the type of decision-making and political authority. As functional legitimacy would highlight the efficacy of a given international organization in securing the goals and supplying the goods for which the organization has been entrusted and its capacity, the legal legitimacy emphasizes that an international organization is based on the rule of law, i.e., it observes procedural agreed norms and it goes through stipulated proceedings in its decision making processes. Finally, the democratic legitimacy would refer to the acceptance of a given political system by its citizens and the manner and the extent to which those citizens constituting the relevant political community accept it.

The balance between the three sources of legitimacy depends upon the specific context and system under scrutiny. Sometimes the trade-offs between the three sources seem to be incompatible. In this sense, for example the increase of the democratic dimension of the multilateral system may be considered to threaten its efficiency or the increased legalization of a given international organization is held to erode democratic politics. In particular, legitimacy of international authorities is said to have been traditionally based on efficacy, on their capacity and efficiency to deliver the entrusted outcomes and on the rule of law -international decisions and norms would be legitimized through the procedural requirement of the consent of states-. Finally, and to a lesser extent, democratic dimension of international legitimacy would be covered indirectly through the consent of states as entities which emerge from popular sovereignty. In spite of this and because of the extended reach of

¹⁵ Cohen, J. (1997). Procedure and substance in deliberative democracy. *Deliberative democracy: Essays on reason and politics*, 407.

international norms and institutions and its direct impact on the domestic realm, the democratic dimension of legitimacy has become a hot topic in the academic arena.

Democratic deficit of the WTO regime.

WTO was conceived following neoliberal premises. The neoliberal approach would somehow distinguish and separate international governance from politics or from the political debate. This view claims the functional, utilitarian view as the only basis to justify and give legitimacy to WTO, i.e., norms produced by WTO would be market enhancing by permitting an efficient exchange and free movement of goods, services and capital. Those functions would be a legitimate constitutional basis for the WTO and for international economic regime. In this sense, there would be some constitutional or superior rules –called general rules- such as the protection of free markets, property rights, legal equality and contract law, which would ensure the peaceful cooperation between states and between individuals and would avoid the *conflicts among the short-term interests of individuals risk endangering their common long-term interests*.¹⁶ These superior rules would belong to the realm of technocratic rationality and therefore, they would occupy a place beyond –and above- political debate. These technical decision making process would be technical and undergirded by “science” and thus, and according to this ideological tradition, it should be de-politized. This neoliberal view of the international economic regime has been profusely studied in the context of the EU and European Monetary Union and it is based under the premise that certain economic regulation and decision making cannot be attributed to national states/governments since they would be pressed by their populations and they would be likely to act with a myopic and short-term vision as well as they would free ride on the cooperation of others¹⁷.

Notwithstanding this, and apart from the more than objectionable superiority or prevalence of these liberal rules or values over other values or ends related to redistributive justice, it has been shown that it is more and more difficult to separate

¹⁶ Petersmann, E. U. (1996). Constitutionalism and international organizations. *Nw. J. Int'l L. & Bus.*, 17, 398.

¹⁷ Bellamy, R., & Weale, A. Political legitimacy and European monetary union: contracts, constitutionalism and the normative logic of two-level games. (see footnote 12).

technical regulatory and political distributive policies; many apparently “technical” questions and decisions do require value judgments and are far from being neutral as they encompass distributive consequences and have social impacts. Also, as we have said before, WTO regime is eroding and reducing the room of the autonomy of nation-states, affecting not only foreign trade but also on environmental, consumer protection, health and medical, tax, national security and even human rights policies.¹⁸ Many WTO decisions are perceived as over-reaching and its claim to legitimacy based on “technocratic reasons” gets strained¹⁹.

In view of all these circumstances, we can conclude that the main reason leading to the legitimacy crisis of WTO has to do with the democratic dimension of its legitimacy; i.e. with its perceived democratic deficit. From a democratic viewpoint of legitimacy there would be the concern of safeguarding the priority of democratic politics and political debate over market logic. In this sense, decision making processes invoking technocratic rationality without the input or participation of the citizenry are held to usurp legitimate democratic choices. The main problem of this derives from the presumption of a previously existing political community, a *demos* which in this case should be worldwide. This aspect makes some authors argue that international organizations cannot be democratized due to the heterogeneity of the eventual global citizenry²⁰. In effect, today the international community seems too far from constituting a world parliament and a procedural cosmopolitan democracy at a global level when there is no a global *demos* and the conditions of individual political equality across borders are not yet fulfilled²¹. On the other hand, as we have previously mentioned, traditional justifications of indirect democratic legitimacy by the states’ consent doctrine seems not to be enough in a multi-level, multi-lateral regime which even undermines domestic democracy of national states. This unresolved tension between the international trade regime and the political

¹⁸ Krajewski, M. (2001). Democratic legitimacy and constitutional perspectives of WTO law. *J. World Trade*, 35, 167.

¹⁹ Dunoff, J. L. (1996). Trade and: Recent Developments in Trade Policy and Scholarship--And Their Surprising Political Implications. *Nw. J. Int'l L. & Bus.*, 17, 759.

²⁰ Dahl, R. A. (1999). Can international organizations be democratic? A skeptic's view. *Democracy's edges*, 19-36.

²¹ Besson, S. (2011). The democratic legitimacy of WTO law--on the dangers of fast-food democracy. World Trade Institute Research Papers.

democratic values of most societies and the alternatives proposed to overcome the current disruption and crisis of the system will be discussed later in this chapter.

In particular, TRIPS through the lens of legitimacy.

As we have seen in the chapter 2 of this dissertation, TRIPS is currently the consequence of the market oriented international regime where private property, free trade, efficiency grounds and other neoliberal premises prevail over any other consideration or material value –including health-. Also, TRIPS seems to contribute to impair affordable and universal access to medicines for everyone, deepening the massive inequalities in the access to medicines not only among different nations but also within the societies of the different nations. In that chapter we also mentioned the important objections raised around the indiscriminate implementation of TRIPS along most of world states, i.e. the setting of high standards of protection of IPRs regardless the economic development and specific socio-economic and industrial necessities of each country under the “one size fit all” mantra. Finally, after some years of enforcement and application of TRIPS, we have been able to evaluate the suspiciously low use that developing countries and in general the losers of this new regime have made of the flexibilities, limitations and dispute resolution mechanisms offered by the system as long as the new turn of the screw derived from the TRIPS-plus international agreements which tighten even more the maneuverability of developing countries.

Bearing this in mind, it is now “legitimate” to wonder whether those apparently pervasive effects of TRIPS for the health of most respond and are somewhat the “collateral consequences” of a system that would be however legitimate. From this perspective and as we will see next we can conclude that TRIPS has not been able to build a legitimate system around the IPRs regime. Most importantly, it has not achieved this legitimacy neither from a democratic point of view nor from the traditional neoliberal functionalist viewpoint of legitimacy. This lack of legitimacy from the “functionalist” efficiency approach to legitimacy is even more worrying and unexpected than the already known democratic deficit of the regime. As we will see,

the implemented regime has not been able to meet the expectations, eventual functions and virtues claimed as a justification for its general application.

4.2. Reacting to the legitimacy crisis: scope and limits of WTO strategy for Intellectual Property regime.

The inclusion of TRIPS into the framework of the WTO was the result of intense lobbying by the United States and its pharmaceutical and media firms, supported by the European Union, Japan and other developed nations at the Uruguay Round negotiations²². As we have seen, from a democratic point of view of legitimacy in the international context, consent by states to a particular regime, agreement or institution is essential and it plays a central role to explain the input legitimacy of that regime, agreement or institution. However, it is broadly observed and documented by different authors and commentators that TRIPS was not precisely the result from real consent of all the participating states but the result of the coercion exercised by the US and to a lesser extent by the EC and Japan for developing countries to accept this legal framework. In fact, TRIPS was included in the WTO negotiations despite the insistent opposition and objection of most developing countries; Developing countries did not share the concern of the US to foster IPRs at a global scale within the trade negotiations since the TRIPS were perceived to respond only to the interests of developed countries -as main exporters of IPRs- and because paradoxically, IPRs may be perceived as antithetical to free trade -temporary monopolies with trade restrictive effects-²³. Furthermore, this regime was considered by developing countries as an obstacle to imitate and make affordable and accessible otherwise exclusive goods under IPRs protection -in particular medicines-. It is illustrative to this respect that less than 20 of the 106 developing countries that are today bound by the TRIPS, were involved in the negotiations.

Therefore, unlike what it happens with most international treaties, TRIPS was not the result of the decision making process of different countries that decide to cooperate to be better off in a prisoner's dilemma scenario. Far from benefitting all the parties, as far as TRIPS is concerned, it has been observed that the problem ran only one way; it responded only to the interests of one of the parties to the contract or agreement, in

²² Picciotto, S.. Defending the Public Interest in TRIPS and the WTO. See chapter 2 footnote 107.

²³ Shanker, D. (2003). Legitimacy and the TRIPS Agreement. *The Journal of World Intellectual Property*, 6(1), 155-189.

particular, the industrialized countries that would be the principal exporters of IPRs. Why was then TRIPS approved? The reason why TRIPS was accepted by developing countries must be found in the fear those countries had to get trade sanctions via Section 301 and the withdrawal of aid²⁴. Ironically, the list of the countries suspected of being the biggest infringers of American IPRs - "Priority Watch List" - was topped by those relatively powerful developing countries with their own generics pharmaceutical industries; countries like India, Brazil or Thailand which had expressed their opposition to include IPRs in the Uruguay Round²⁵. In this sense, acceptance of the TRIPS was the consequence of coercion by powerful countries rather than a free decision made by free and sovereign states. In effect, it appears that developing countries went along and adhered to TRIPS in order "not to make themselves better off but to avoid being made worse off"²⁶.

Furthermore, following the three step test to check whether there has been a democratic bargaining to reach an international agreement proposed by Drahos²⁷, it seems clear that TRIPS did not comply with the process to consider it the result of a democratic bargaining between free and sovereign states. Even if from a formalist point of view it could be held that both the first condition -all the relevant interests have to be represented in the negotiating process- and the second -all those involved in the negotiation must have full information about the consequences of various

²⁴ Special Section 301 of the American Trade Act of 1974 is a new provision introduced in 1988 by the American Omnibus Trade and Competitiveness Act of 1988 which allows the U.S. government to impose unilateral trade sanctions to those countries whose protection of IPRs is deemed insufficient and a barrier to US trade. The threat and coercion was profusely discussed by the EC and the Panel in United States – Sections 301-310 of the Trade Act of 1974.172 The EC while describing the effect of Sections 301-310 of the US Trade Act stated "The European Communities maintains that in particular, the constant threat of imposition of unilateral measures has an influence on the behavior and the decisions of the economic operators. In practice, the fact of the filing of a petition or the simple publication of a notice in the Federal Register announcing the initiation of an investigation, within the concrete context of the provisions contained in Sections 301- 310 and the publicly known interpretation given by the US Administration and the Congress created "chilling" trade effects that may range from the slowing down of importation of products to the more radical stoppage of any bilateral trade with the United States in those products."

²⁵ Downes, G. (2010). *The TRIPS agreement: A test of the WTO's legitimacy?*. Limerick Papers in Politics and Public Administration.

²⁶ Marcellin, S. S. (2010). *The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO*. Ashgate Publishing, Ltd.

²⁷ Drahos, P. (2002). *Developing Countries and International Intellectual Property Standard-Setting*. *The Journal of World Intellectual Property*, 5(5), 765-789. The theory of democratic bargaining argues that efficiently defined property rights are more likely to emerge if at least three conditions are met:" - Firstly, all relevant interests have to be represented in the negotiating process (the condition of representation). Secondly, all those involved in the negotiation must have full information about the consequences of various possible outcomes (the condition of full information). Thirdly, one party must not coerce the others (the condition of nondomination).

possible outcomes- were formally met, the third one, i.e. the condition of non-coercion or non-domination was clearly missing in the negotiations leading to TRIPS.

Furthermore, and leaving aside the democratic deficit or questioning of today's international systems which enter domains formerly controlled by domestic democratic governments and are somehow more intrusive into people's life, TRIPS would not be legitimate from a more traditional view which weighs the legitimacy of a given international regime by resorting to the consent between sovereign and free states. The fact that TRIPS is not resulted from real consent, does undermine the legitimacy of the TRIPS. In addition to this, as it has been previously noted, TRIPS would neither achieve the outcomes or virtues which is supposed to bring and therefore it would not be justified from a technical or functional point of view²⁸ or output legitimacy.

Pursuant to the Preamble of TRIPS, the Agreement would be purported to reduce distortions and impediments to international trade, and taking into account the need 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. Apart from the apparent paradox of the fact that artificial monopolies –as it the case for IPRs- be invoked as an instrument to ensure a trade regime free of distortions and impediments, TRIPS has been proved to be very thin in explaining the purposes and the benefits of an international agreement.

Out of the legal wording of the Agreement, TRIPS is said to foster the foreign direct investment and technology transfer, as well as more trade and greater market access as advantages for developing countries. In this sense, it is held that foreign investors would be more willing to transfer technology when this proprietary technology is

²⁸ In this sense, some authors argue that legitimacy of institutions emanates not merely from "inputs", e.g. procedures and accountability, but also from "outputs", i.e. the ability to deliver results. Buchanan, A., & Keohane, R. O. (2006). *The legitimacy of global governance institutions*. *Ethics & international affairs*, 20(4), 405-437.

protected by law²⁹. The Professor of Economics, Keith E. Maskus is the author of the most cited study supporting the positive impact of IPRs in fostering economic development (in terms of economic growth), technology transfer, and foreign direct investment³⁰. TRIPS would then be expected to facilitate an investment-friendly environment in developing countries. Notwithstanding this, as it has been observed in the previous chapter 2, those economic and social advantages are far from being clear and undisputed. China has been one of the main world infringers of foreign IPRs and yet the flows of FDI into the country have been constantly and substantially increased above average over the past decades³¹. If we agree with the fact that a stronger IPRs protection brings economic advantages to a country, the first objection to be made would be why it is necessary an international agreement such as TRIPS instead of an enhancement of IPRs protection by the unilateral action of each country. As Professor Gerhart argues, if IPRs are really effective in fostering development, it would occur spontaneously, *and we need no treaty to create minimum standards and no enforcement mechanisms to enforce compliance with the standards. We rarely need the coercive power of international law to get countries to do what it is in their interests to do. In other words, why was there a collaboration problem to be addressed in the first place?*³²

Following Professor Gerhart, the many times taken-for-granted conclusion about the relationship between intellectual property and development is surprisingly weak. Furthermore, the relationship between a strong IPRs regime and the Foreign Direct Investment (FDI) seems to belong to the realm of beliefs and speculations rather than being supported by empirical data. From the different data we could use to justify this conclusion, it is worth noting the data contained in the Global Innovation Index.³³In

²⁹ Mansfield, E. (Ed.). (1995). Intellectual property protection, direct investment, and technology transfer: Germany, Japan, and the United States (Vol. 27). World Bank Publications.

³⁰ Maskus, K. E. (1998). The role of intellectual property rights in encouraging foreign direct investment and technology transfer. *Duke J. Comp. & Int'l L.*, 9, 109.

³¹ Lanoszka, A. (2003). The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *International Political Science Review*, 24(2), 181-197.

³² Gerhart, P. M. (2000). Reflections: Beyond Compliance Theory--TRIPS as a Substantive Issue. *Case W. Res. J. Int'l L.*, 32, 357.

³³ The Global Innovation Index (GII) is a project that is inspired by the latest research on the measurement of innovation. The core of the GII Report consists of a ranking of world economies' innovation capabilities and results in its 9th edition this year, is co-published by Cornell University, INSEAD, and the World Intellectual Property Organization (WIPO) The Confederation of Indian Industry, du, A.T. Kearney and the IMP³rove – European Innovation Management Academy collaborate as GII Knowledge Partners. <https://www.globalinnovationindex.org/about-gii>

its 2010 report it reviews among other categories the degree of protection of IPRs along the different countries³⁴. In a different chapter the report collects the FDI in each country.

| Countries with biggest FDI (net inflows) | Ranking in the Intellectual Property Protection |
|--|---|
| 1. Bulgaria | 108 |
| 2. Georgia | 99 |
| 3. Guyana | 122 |
| 4. Bosnia | 130 |
| 5. Netherlands | 9 |
| 6. Malta | 38 |
| 7. Mongolia | 117 |
| 8. Serbia | 100 |
| 9. Jordan | 29 |
| 10. Gambia | 34 |
| 11. Cambodia | 102 |

If we compare the rankings of both categories, it is possible to conclude that IPRs regime is not certainly decisive in fostering FDI.

On the other hand, the relationship between the setting of TRIPS standards in developing countries and the impact in terms of promoting more intense innovation processes is not conclusive. In this respect, the number of patents which have an African, Latin American or Caribbean origin has not increased between 2003 and 2013 but have rather slightly decreased representing in 2013 the 3,1% of the total number of applications (in 2003 that figure was of 3,5%)³⁵. Therefore we could conclude that nor from a democratic and legal point of view neither from a functional perspective of legitimacy –in terms of outcomes or benefits associated to a given

³⁴ In the following annual reports from 2010 to date, the category as to the degree of protection of IPRs is no longer available.

³⁵ Economics, W. I. P. O., & Series, S. (2014). *World intellectual property indicators*. WIPO publication, (941E).

regime- TRIPS can be viewed as a perfectly and entirely legitimate regime. On the contrary, it comes clear that the this regime has been imposed to developing countries and that they operate within an intellectual property paradigm dominated by the United States and the EU or rather by the demands of transnational capital³⁶.

Finally, it is worth noting that after 20 years of talks and deadlock WTO not only has not been capable of making progress and concluding the Doha round, but it is a more and more contested international organization. In this sense and following Habermas concept of legitimacy crisis³⁷, WTO seems incapable of overcoming the contestation and resistance that it has generated i.e. WTO structural deficiencies cannot provide the conditions and solve the problems in the manner which is necessary to ensure the continued existence of the system. One of the main structural problems of WTO is precisely its perceived lack of legitimacy.

The Road to the Doha Declaration.

TRIPS constituted a *momentum* in international intellectual property law making. As it has been already noted, TRIPS establishes minimum global standards of protection of IPRs (based on developed nations' standards) and a system of dispute settlement which ensures its enforcement globally. It covers seven areas of IPRs; copyrights (protecting original works of authorship); geographical indications, trademarks, industrial designs, layout designs for integrated circuits, trade secrets and patents. Out of these fields, the patent regime is however, the area where developing countries find more difficulties in complying with TRIPS. Besides the fact that a large number of developing countries had very limited IPRs laws or no laws at all, the requirement of the minimum 20 years protection and the patents on pharmaceutical products implied especially demanding obligations to comply with by developing countries. These demanding requirements were partially explained by the pharmaceutical

³⁶ For a detailed analysis quantifying the negative implications of extending patents to all low-income nations, taking into consideration both innovation and projected price increases, see Scherer, Frederic M. "A note on global welfare in pharmaceutical patenting." *The World Economy* 27.7 (2004): 1127-1142. He asserts that "*It is reasonably well established in the economics literature that, especially in a world of AIDS and resistant tuberculosis epidemics, low-income nations enjoy higher economic welfare when they can free-ride on pharmaceutical innovations made and patented in the first world than when they must pay monopolistic prices for the newest and most effective drugs*".

³⁷ Habermas, J. (1975). *Legitimation Crisis Pa Txt* (Vol. 519). Beacon Press.

companies' concern that cheap drugs for developing countries begin to flood developed country markets and reduce profit margins. Also, maintaining similar drug prices worldwide regardless the per capita purchasing power of people of different countries is explained by the fear of pharmaceutical companies to the pressure that low prices in developing would generate from Western World consumers demanding the same. In fact, many activists involved in the access campaign were also demanding lower prices in pharmaceutical market of the developed world³⁸.

Patents represent the most controversial issue of TRIPS. As countries may have greater incentive to comply with copyright for instance (administrative costs of a copyright system are low and every country has artists, authors and entertainment industries), patent law, and especially pharmaceutical patents face greater opposition and resistance.

In particular, developing countries have been concerned about the impact that this "enclosure" of pharmaceutical knowledge and its monopolization are having on their ability to ensure access to affordable pharmaceutical products, i.e., to pursue public health for their populations. While TRIPS hardly encourages R&D in developing countries for their health needs and most threatening diseases (malaria and tuberculosis) -because of their poor profit potential-, increased levels of patent protection have an important effect on higher prices of medicines which become a barrier to needed treatments and to the accessibility and affordability of medicines. Also, it is not clear whether and how developing countries are enjoying and making use of safeguards, exceptions and limitations to the protection of strong IPRs offered by TRIPS³⁹.

The impact of TRIPS on public health and the debate regarding the primacy of trade and other efficiency-based considerations over health has been especially questioned in the context of TRIPS implementation and interpretation. With the exception of initial developing country resistance, opposition to TRIPS emerged rather later after

³⁸ Lanoszka, Anna. (2003). The global politics of intellectual property supranote 31.

³⁹ FM't Hoen, E. (2002). TRIPS, pharmaceutical patents and access to essential medicines: Seattle, Doha and beyond.

its adoption. Until Doha in 2001, this debate TRIPS-public health was not one of the main issues during the negotiation process. It is somehow ironic that at the Seattle Ministerial the debate TRIPS-Public Health was just mentioned by the Holy See with concern over the lack of technology transfer. At the 2001 Doha Ministerial Conference however, the TRIPS-Public Health issue exploded. The percentage of participants whose statements referred to public health jumped from 10 percent at Seattle in 1999 to 39 percent at Doha. At the Doha Conference and after a strong domestic and international political pressure the WTO declared that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.” Before analyzing the meaning and the path of the Doha declaration, it is important to review the background which preceded and led to it and which constituted one of the major crises of the IPRs regime so far and probably, of the whole WTO regime. The crises leading to the Doha Declaration was motivated by a number of factors which came to shape the debate on TRIPS and public health (access to affordable medicines).

a) HIV/AIDS Global pandemic crisis.

According to UNAIDS⁴⁰, HIV/AIDS pandemic affects 36.9 million people worldwide, living the majority of which in low to middle income countries, particularly in Sub-Saharan Africa. Of the 36,9 million people, 22 million people do not have access to HIV/AIDS treatment. Each day near 10 thousand people die of AIDS. This dramatic pandemic not only affects the health of people but it has an important impact on households, communities, and the development and economic growth of societies. There are several reasons behind the lack of access to essential medicines to treat AIDS or alleviate suffering of it, but one of the main reasons is the high prices of medicines. The drama of this pandemic contributed to focus the attention on TRIPS as an eventual burden or obstacle to access of essential medicines. In particular, TRIPS raised concerns as to the fact that increased patent protection leads to higher prices – out of reach of most people especially of the developing world- and that the enforcement of WTO rules would have a negative impact on local manufacturing

⁴⁰ http://www.unaids.org/en/resources/documents/2015/AIDS_by_the_numbers_2015

capacity and would reduce the sources of generic drugs on which developing countries depended. The AIDS crisis has illustrated more than anything the impact of the patent policy on the access to medicines. In this sense, as prices for a three-drug combination of HIV therapy in 2000 had a price above USD \$10.000 per person per year, generic versions of that therapy could provide that same treatment for less than USD \$ 75 per person and per year. This fact exemplifies that strong IPRs is likely to undermine access to affordable medicines⁴¹.

In contrast to the rhetoric of “free trade” and “property rights” by which TRIPS was wrapped, AIDS/HIV crisis gave rise to an alternative framing of IPRs as a public health issue. Public health emerged so as an increasingly effective counter-discourse to the pro-IPRs activists and lobbyists which successfully made the link between IPRs and the inadequate protection of IPRs abroad and an eventual barrier to legitimate trade. Framing TRIPS within public health debate permits to open a new perspective where a set of diverse and competing interests, rights and duties emerge around implementation and interpretation of IPRs⁴².

Even if AIDS is not the only infectious disease which is seriously damaging the population of developing countries (Tuberculosis and malaria are also on the rise), the fact that AIDS affected also to the developed world and it has attracted an important media interest, made AIDS become an important spur to mobilize activists of the Western World who play an important and complementary role with other voices from the developing world. At the dawn of the new century, pharmaceutical companies went under mounting pressure in order to make essential medicines affordable. As a consequence, in May 2000, five global pharmaceutical companies together with UNAID announced plans to reduce prices of AIDS drugs for selected African countries. Also, former president Clinton issued an executive order saying the government would not interfere with African countries that violate American patent law to obtain cheaper AIDS drugs⁴³.

⁴¹ Rights, I. P. (2002). Integrating intellectual property rights and development policy. *Londres, sèptanbr.*

⁴² Sell, S. K. (2001). TRIPS and the Access to Medicines Campaign. *Wis. Int'l LJ*, 20, 481.

⁴³ <http://www.nytimes.com/2000/05/12/world/companies-to-cut-cost-of-aids-drugs-for-poor-nations.html?pagewanted=all>

However those initiatives were rapidly criticized as cynical attempts to prevent developing countries from using compulsory licensing and other compensatory options. As the NGO Médecines Sans Frontières (MSF) accurately pointed out *This agreement does nothing to stimulate countries' rights to produce or import inexpensive high-quality generic drugs, a key component to long-term, sustainable solutions for improving access to essential medicines*⁴⁴.

b) The role of other international organizations.

As early as in 1996, the WHO first raised concerns about the consequences of globalization and international trade agreements with respect to drug access during its Assembly. A resolution on the Revised Drug Strategy requested its Director General “*to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate.*” This resolution enhanced the WHO the mandate to publish, in 1998, the first guide with recommendations to Member States for implementing TRIPS while limiting the negative effects of higher levels of patent protection on drug availability. Afterwards, in its 54th Assembly (Scaling up the response to HIV/AIDS) in 2001 where debates over IPRs and public health started to flourish everywhere, WHO adopted some resolutions urging WHO Member states *to increase access to medicines, to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order further to promote innovation and the development of domestic industries consistent with international law.*

Also, the European Parliament adopted some important resolutions expressing a clear and surprisingly unambiguous support of a pro-public health approach to TRIPS⁴⁵. I have used the term “surprisingly” because the pro public health premises in

⁴⁴ <https://www.msfaccess.org/about-us/media-room/press-releases/msf-statement-new-unaid-proposal-and-clintons-executive-order>

⁴⁵ The European Parliament resolution on access to drugs for HIV/AIDS victims in the Third World adopted in March 15, 2001 (B5-0182/2001) includes some surprisingly public health approach based views: 1. *Calls for the development of a system allowing developing countries equitable access to medicines and vaccines at*

which this resolution is embedded have not been followed either by the European Commission or EU State Members in the diverse forums.

In August 2000 and August 2001, the UN Sub-Commission on Human Rights adopted Resolution 2000/7 and 2001/13 on IPRs and Human Rights. Those Resolutions stated that TRIPS could affect the enjoyment of Human Rights and they urged all national governments to take fully into account existing state obligations under international human rights instruments. Also, in 1999, the United Nations Development Programme's (UNDP's) annual Human Development Report made a plea for re-writing the rules of globalization to make them work "for people – not just profits." To summarize, at that time there was a growing chorus among diverse international institution which called into question TRIPS and its effects on access to medicines.

c) NGOs and civil society.

In Margaret Archer's analysis of agency⁴⁶, the author draws a distinction between primary agents - constituted by shared involuntary social placement- and corporate agents –able to articulate efficiently what they want to themselves and others-. While IPRs industry actors rapidly became to articulate themselves to efficiently lobby to governments and political power to consider and take into account their stands, it

affordable prices, while expressing its solidarity and support for the Governments of South Africa and Kenya in their struggle to use WTO-compliant legislation to gain access to the cheapest possible life-saving medicines; 2. In this context welcomes the statement by Commissioner Lamy that the Commission supports the right of developing countries to use the safeguards in the WTO/TRIPS Agreement, including compulsory licensing, and the commitment by the Commission to launch a debate in the WTO on reconciling the TRIPS Agreement with objectives regarding health protection in developing countries; 3. Calls on the pharmaceutical companies that issued a legal challenge to the South African 1997 Medicines Act to withdraw from the case; 4. While respecting the intellectual property rights of the pharmaceutical industry, calls on the Commission to strengthen the ability of developing countries to resist the pressure to introduce more stringent patent laws than those currently required under the WTO TRIPS Agreement; 5. Calls on the Commission to work with the Member States to show international leadership in the struggle for life-saving medicines by encouraging technology transfer and support for the strengthening and/or development of local production capacity; 6. Calls for the current review of the TRIPS Agreement to ensure that the rights of developing countries to obtain the cheapest possible life-saving medicines, whether patented or generic, are guaranteed, and further calls on all the interested parties to actively engage in this process;

⁴⁶ Archer, M. S. (1995). *Realist social theory: The morphogenetic approach*. Cambridge university press. Primary actors would be inarticulate in their demands and unorganized for their pursuit, in which case they only exert the aggregate effects of those similarly placed who co-act in similar ways given the similarity of their circumstances (page 185).

took long for the dispersed actors affected by the new IPRs regime on medicines to articulate themselves around a common strategy. This strategy has been named *the Access Campaign*. As it has been accurately described by Susan K. Sell⁴⁷, this strategy/campaign began with the work of the Consumer Project on Technology, Médecines Sans Frontières (MSF) and Health Action International and it was expanding over time to include developing countries, Oxfam, The Treatment Access Campaign, Health Gap, ACT UP Philadelphia and ACT UP Paris.

These NGOs have played a key role in their concerted action to draw attention and call into question those TRIPS provisions which impaired access to medicines. Organized by Consumer Project on Technology (founded by Ralph Nader and James Love in 1995⁴⁸), Médecines Sans Frontières (MSF) and Health Action International, the first international meeting took place in March 1999 at the Palais des Nations in Geneva specifically on the use of compulsory licensing to increase access to AIDS medicines. In November of that year, the same NGOs organized a much more comprehensive and ambitious encounter in Amsterdam. The Amsterdam Conference on Increasing Access to Essential Drugs in a Globalized Economy brought together 350 participants from 50 countries on the eve of the Seattle WTO ministerial conference. The Conference drew up a statement which addressed very different issues on public health and IPRs. In particular, the Conference demanded political action and called for health to be made a priority at the WTO Seattle negotiations with the necessary balance between the rights of patent holders and the rights of citizens. These views were shared by representatives of UNDP, the WHO, the WTO, members of the Governments of the Netherlands and Thailand, as well as nongovernmental organizations attending the Amsterdam conference. Amsterdam also proposed a working group to deal with some issues and concerns that are still highly topical today in the field of compulsory licensing, neglected diseases or R&D funding and innovation⁴⁹. This created an important conceptual framework in the debate of public health and IPRs.

⁴⁷ Sell, S. K. TRIPS and the Access to Medicines Campaign. See supranote 42.

⁴⁸ This Association was founded with the concern in growing drug pricing and in the fact that important and blockbuster drugs such as taxol were developed and publicly funded by the National Institutes of Health which licensed the drug to Bristol-Myers-Squibb.

⁴⁹ The proposed working group on access to medicines would examine a number of important issues in the implementation of the existing TRIPS Agreement, such as: Compulsory licensing of patents, as permitted

d) September 11 Terrorist Attack and subsequent biological attacks.

September 11 terrorist attack over NYC cut short certain optimism about the discourse of globalization –and free trade and all the WTO machinery attached to it–perceived so far by western countries as a bed of roses where nothing but happy progress could happen. Ironically, the terrorist attacks implied the collapse of the World Trade Center, maybe one of the icons of globalization. These attacks had an important impact not only at the economic, political, international relation level but also at a psychological level. In a sense, developed countries became aware that trade negotiations could not be separated from other important issues and realities such as poverty, equity and dignity.

Furthermore and shortly after these dramatic attacks, there followed diverse anthrax attacks in the US producing some casualties and grave illnesses. Both Canada and the US rushed out to stockpile a suitable supply of Cipro, a medicine to treat anthrax. Cipro was in hands of the German Bayer who had IPRs over the medicine. As Canada ordered a million tablets of a generic version of Cipro from a Canadian company overriding Bayer's IPRs (even if there had not been cases of anthrax and the seizure

under Article 31 of the TRIPS Agreement. The working group should look at the best way to bring this article into operation; Allowing for exceptions to patent rights (under Article 30 of TRIPS) for production of medicines for export markets when the medicine is exported to a country with a compulsory licence. This would ensure that countries with small domestic markets can benefit from compulsory licensing; allowing for exceptions to patent rights (under Article 30 of TRIPS) for medical research, so that patents are not used to stop research and hamper the introduction of generic medicines; avoiding overly restrictive and anti-competitive interpretations of TRIPS rules regarding protection of health registration data or other unnecessary regulatory barriers to competition; avoiding restrictive interpretations of trademark rights on issues such as generic labelling and prescribing practices; assessing the impact of inadequate reviews of patentability standards (novelty and usefulness) on access to medicines; Recommending differential rules for essential medicines, such as simplified and fast track compulsory licensing procedures; Examining new paradigms for intellectual property rights and health care, including "burden sharing" approaches for research and development that permit countries to consider a wider range of policy instruments to promote research and development; Assessing the practical burdens on poor countries of administering patent systems and resolving disputes over rights; National governments need to develop mechanisms to ensure funding for research and development for neglected diseases; Innovative approaches to stimulating research in essential medicines need to be devised, including: Increased public and donor funding of health care research; Compulsory research obligations, such as requirements that companies reinvest a percentage of pharmaceutical sales into research and development, either directly or through public or private sector research and development programs; Development of a "Neglected Disease Act" that could be used to stimulate private investment for communicable disease vaccines and medicines.

process of the drug was neither observed), US Government obtained –right after a serious threat to Bayer- a major price concession from Bayer for the supply of Cipro.

Developing countries and the international community were critical with these actions and accused US Government of following double standards, this tarnishing the legitimacy of its stances on the demand of high protection of IPRs. Developing countries were quick to compare national emergencies in both blocks of countries and ask how US could be so belligerent in the protection of IPRs in developing countries even in the face of genuine public health crises. In any case, these events served to show that nobody and no country is immune or is safe to suffer health crises and it raised certain solidarity and calls for a more sensitive approach to the debate of public health and IPRs⁵⁰.

e) Nelson Mandela vs. Big pharma and other David vs. Goliath cases.

In 1997 the South African government, as the result of the HIV/AIDS crisis affecting 50 percent of its citizens in some districts (one in every five South Africans was infected with AIDS) and high prices of anti-retroviral medications enacted its Medicines and Related Substances Control Amendment Act. This Act allowed the health minister to import generic drugs, or compulsorily license patents under the limited exigency of a national emergency expanding the conditions for compulsory licenses and parallel importation to facilitate the capacity of more poor South-African citizens gaining access to cheap anti-HIV/AIDS pharmaceuticals. After some cordial persuasions by the US Government, the US threatened to bring the South African Government before a WTO Dispute. In 1998, the European Commission joined the United States in pressuring South Africa to repeal the legislation. However US Government support dropped at the end of 1999 because of a successful campaign before the American public opinion. AIDS activists effectively highlighted American policies and the consequences of these policies; profoundly embarrassing then-presidential candidate Al Gore confronted at election campaign rallies.

⁵⁰ Singh, K. (2002). Anthrax, drug transnationals, and TRIPS. *Foreign Policy in Focus*, 29.

Under the TRIPS shadow and based on a restrictive interpretation of TRIPS, in 1998, forty-one pharmaceutical companies sued the South African Government before the law courts of South Africa, partly based on TRIPS (and their fundamental right to property), against the South African controversial piece of legislation. A concerted campaign by members of the international civil society, local activists (the Treatment Action Campaign led by the brilliant activist, Zachie Achmat, intervened in the dispute as an *amicus curiae*) and relevant NGOs provoked the withdrawal of the action in 2001 in what it can be seen as one of the first achievements of an “embryonic” international civil society’s conscience. Also, by the time the case finally reached the courtroom in May 2000, the drug companies could no longer count on the support of their home governments.

A similar case took place in Brazil in the US vs. Brazil dispute. AIDS is also a major health problem in Brazil, since the decade of 1990 the Brazilian AIDS program has been quite effective in reducing deaths and providing universal access to antiretroviral treatment. In 2001, the US filed a complaint against Brazil before the WTO DSU arguing that its Patent Law infringed the TRIPS. In particular, art. 68 of the Patent law encompassed what is known as the *Local Working* clause. According to this, compulsory license could be granted by the government in the event that a patented invention was not locally manufactured within three years of the patent grant. US pleaded that this was a protectionist measure inconsistent with TRIPS. Following bilateral consultations both countries announced that they had reached a mutually agreed solution. In particular, they created a bilateral consultative mechanism to be notified before the controverted provision is utilized by Brazil. Brazil has maintained in this respect that the threat of compulsory licensing has helped it to negotiate reasonable drug prices. MSF has praised Brazilian approach to this issue permitting it to pursue universal access to affordable medicines as long as keeping local capacities to manufacture drugs for its population and for people beyond its borders⁵¹. There are other not so happy stories at that time as the one facing Thailand with the US over the former’s plans to produce a generic version of

⁵¹ <http://www.msf.org/en/article/20020305-msf-response-boys-brazil>

certain AIDS medicine. Thailand was obliged to drop its compulsory licensing plans after a strong pressure from the US in 1997 and 1998.

These conflicts seem to be the logical conclusion of a too restrictive, formalistic and pro-IPRs interpretation of TRIPS, an interpretation decontextualized from social realities as long as from other norms and values of bioethics, public health law, or international human rights.

4.3. Doha Declaration and beyond; the shortcomings of quick fix solutions for persistent structural problems.

The Doha Declaration.

The growing recognition of the TRIPS Agreement failures by national governments and the international civil society, led the WTO members to agree the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) at the fourth WTO Ministerial Conference in Doha in 2001. The “African Group” statement to the TRIPS Council about the need to cope with the access to medicines issue initiated preparations for the Declaration. In June 2001, the TRIPS Council held its first session devoted to TRIPS and access to medicines. It was the first time that the TRIPS Council discussed intellectual property issues in the context of public health. The African Group presented a draft text for a Declaration on TRIPS and Public Health. This proposal addressed political principles to ensure that TRIPS did not undermine the legitimate right of WTO Members to formulate their own public health policies. The text also aimed at clarifying provisions related to compulsory licensing, parallel import, data protection, and production for export to a country with insufficient production capacity. For their part, the United States, Japan, Switzerland, Australia, and Canada presented an alternate draft emphasizing the importance of IPRs protection for R&D in discovering new life-saving medicines to treat diseases and thus contributing to public health objectives globally. The EU submitted its own draft, which proposed a solution to the problem of production for exports.

Most academia and NGOs note that the finally approved text more closely resembles the developing countries draft underscoring that public health outweighs IPRs. Also, it was observed that the Declaration gives broad discretion to developing countries in how to manage to cope with TRIPS most negative impacts⁵².

⁵² FM't Hoen, E. (2002). TRIPS, pharmaceutical patents and access to essential medicines... (see footnote 39).

The core of Doha Declaration affirms that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all (Paragraph 4) and it recognized that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. It also states in paragraph 5(c) that: Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. The Declaration also resolves the question of whether TRIPS authorizes parallel trade by noting: The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge.

A key issue remained unresolved in Doha is how to ensure that production for export to a country that has issued a compulsory license, but does not have manufacturing capacity, can take place within a country that provides TRIPS, Pharmaceutical Patents, and Access to Essential Medicines. The cause of the debate was Article 31 (f) of TRIPS which provides compulsory licenses issued by supplying Member to *be authorized predominantly for the supply of domestic market of the member granting the compulsory license*. This provision was criticized by countries with limited or no manufacturing capacity in the pharmaceutical sector as they considered it as a limiting clause due to the fact that it did not allow them to import those pharmaceutical medicines from countries with such capacity through compulsory license.

The Doha Declaration acknowledged the problem in Paragraph 6 -We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement- but it did not resolve it and it mandated the Council for TRIPS to find an expeditious solution to this problem. The US for instance, wanted the draft to

include exceptions for compulsory licensing and parallel importing measures for only the 'big three' diseases, these being HIV/AIDS, tuberculosis and malaria.

This instruction to the Council was finally implemented by a decision of the General Council in August in August 2003 (WTO General Council Decision of 30 August 2003). According to this Decision, it was agreed to waive article 31 (f) of the TRIPS, so that LDC members and other members lacking sufficient manufacturing capacity may import pharmaceutical products created under compulsory license, subject to certain conditions. Under the system established by the WTO General Council Decision of 30 August 2003, provided that these conditions are satisfied, any WTO member may issue a compulsory license to manufacture and export pharmaceutical products needed to address public health problems by an eligible importing Member. In this respect, all LDC members are eligible importing members, and any other WTO member may become an eligible importing member simply by notifying the Council for TRIPS of its intention to use the system as an importer. Even if all WTO member countries are eligible to import under this decision, 23 developed countries announced voluntarily that they will not use the system to import.

The Decision contemplated some conditions for using the system as for example conditions related to the notification (names and expected quantities of the pharmaceutical products); that the products manufactured under the license must be clearly identified and the entirety of the production must be exported to that member; that importing member must take reasonable measures to prevent re-exportation. The impact and benefits brought by this waiver has been limited in practice. On 17 July 2007, Rwanda became the first member to notify the Council for TRIPS of its intention to import a pharmaceutical product under compulsory license pursuant the WTO General Council Decision (concerning a HIV/AIDS pharmaceutical manufactured by a Canadian generic pharmaceutical company) and in turn, Canada's notification as an eligible exporting member to enable the export to Rwanda. This case is the exception rather than the general rule as this has been to date the only notification submitted to the Council for TRIPS. According to some commentators and NGOs, the reasons behind the limited use of this provision by developing countries have to do with its onerous and burdensome character. In effect, in practical terms,

Generic manufacturers have to monitor and handle bureaucracies and administrative process of two administrations.

Furthermore and under certain pressure, the TRIPS council initiated work on the preparation of an amendment to the TRIPS agreement and the proposal was submitted in December 2005. Article 31 was amended by article 31 bis to create an exception to the requirement set out in article 31(f) which requires the use of compulsory license to be authorized predominantly for the supply of the domestic market of the Member authorizing such use. The article 31 bis establishes that *the obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.*

Despite this article implements Paragraph 6 of the Doha Declaration and it seems to constitute an improvement to the existing obstacles of import-exportation when the importing country does not have capacities to manufacture the medicines, the likewise burdensome and onerous nature of the proceeding in place to make this provision effective (expectant to the scope of new article 31bis) together with the open and indeterminate question of the remuneration to the patent owner had reduced substantially the value of this amendment.

Post-Doha.

There are several uncertainties as to the legal status of Doha Declaration. In this sense, this Declaration is not framed as a “decision” and it is not intended to amend the TRIPS Agreement, it would be rather an authoritative interpretation of TRIPS. During negotiations, this was an important point to be taken into account. Some WTO Members feared that the negotiations could lead to changes in TRIPS and wanted to include a confirmation that the Declaration was purely a clarifying exercise.

Even if initially and formally they were happy with the outcome, pharmaceutical companies argued from the beginning that the Declaration was not necessary because:

- a) patents were not a problem;
- b) Weakening patent protection would have devastating effects on the R&D capabilities of the research-based industry. On the other hand, the generic drug industry regretted that the Declaration did not provide an interpretation for the data protection issue addressed in article 39.3 TRIPS. As we have already seen, an overly restrictive interpretation of exclusive data lead to delays in introduction of generic medicines and it may rise to increase barriers to the registration of generic medicines including those produced under a compulsory license⁵³.

After 15 years, many of the problems existing at the time of Doha Declaration remain the same. Even if during the years after Doha the number of compulsory licenses was substantially increased –especially between 2003 and 2005- this figure has diminished markedly since 2006 due to countervailing pressures from major countries⁵⁴. Also and according to Oxfam⁵⁵, little has changed as medicines continue to be unaffordable and trade rules remain a major barrier to accessing medicines (generic medicines). This NGO observes that TRIPS Plus Bilateral Agreements tend to ensure that the strictest levels of intellectual property protection are imposed worldwide thus neutralizing the Doha Declaration. In the same vein, the Discussion Paper elaborated under the auspices of the UNDP⁵⁶ the proliferation of TRIPS-Plus Agreements jeopardizes the application of TRIPS flexibilities to increase access to medicines.

⁵³ FM't Hoen, E. (2002). TRIPS, pharmaceutical patents and access to essential medicines... (see footnote 39).

⁵⁴ Beall, R., & Kuhn, R. (2012). Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis. *PLoS Med*, 9(1), e1001154.

⁵⁵ Malpani, R., & Kamal-Yanni, M. (2006). Patents versus patients: five years after the Doha Declaration. Oxfam International.

⁵⁶ Matthews, D. N., & Correa, C. (2011). The Doha declaration ten years on and its impact on access to medicines and the right to health.

As it has been profusely documented by t Carolyn Deere⁵⁷, Doha Declaration on TRIPS and Public Health explains the shift of pharmaceutical lobby's strategy to strength IPRs through bilateral private Free Trade Agreements ("FTAs") which are not administered by an international institution. In the IP field, these FTAs add to TRIPS protection new more demanding provisions⁵⁸ (TRIPS-plus) and establish an alternative system to settle disputes, these limiting the flexibilities within TRIPS and circumventing the WTO process and therefore the Doha path. Indeed, those developing countries engaged in FTAs negotiations have used TRIPS as a defense against raising TRIPS standards by appealing to TRIPS as the maximum threshold. The shameless prevalence of private interests encompassed in Trips Plus Agreements and the stark exercise of power of developed countries have made some scholars term these TRIPS Plus FTAs as bilateral corporate colonization agreements⁵⁹

There are many examples of TRIPS-Plus FTAs including the criticized Australia-US FTA, FTAs negotiated with thirty-four countries in the Free Trade Area of the Americas Agreement, five Central American countries, the Dominican Republic-Central America FTA, the Southern African Customs Union, Morocco, Bahrain and Singapore, the US-Jordan free trade agreement –as long as many other middle eastern countries- and the currently under negotiation Trans-Pacific Partnership Agreement (TPP) between 12 Pacific-Rim countries and the controversial TTIP US-EU.

The legitimacy crisis affecting WTO and the TRIPS regime, the absence of the announced substantive benefits and outcomes of it and the situation of deadlock after 20 years of its inception, demand a serious reinterpretation of TRIPS regime (including TRIPS Plus) as long as a deep transformation of it.

⁵⁷ Deere, Carolyn. The implementation game: the TRIPS Agreement and the global politics of intellectual property reform in developing countries. (see chapter 2, footnote 126).

⁵⁸ They often include the elimination and reduction of transitional periods, the extension of pharmaceutical patent protection as long as supplementary protection through regulation on exclusive marketing rights and exclusivity data; compulsory licensing is expressly limited, to situations such as "national emergencies of extreme urgency; finally, these FTAs contemplate restrictions on research and early working exceptions (Bolar exception).

⁵⁹ Faunce, T. A. (2007). Globalization and Health: Challenges for Health Law and Bioethics: 87-108

The transit from the grant of privileges to IPRs fundamentalism.

The implementation of TRIPS has been problematic. The poor balance of TRIPS implementation in most of developing countries and the fact that TRIPS and TRIPS Plus often become an impairment to public health and important human rights has been described in preceding chapters in some detail and it is briefly summarized here in order to note the new paradigm of IPRs as a set of absolute rights of private property in what it can be denominated as IPRs fundamentalism.

Unlike it happened previously, TRIPS stipulates that certain minimum standards for IPRs protection –mostly western standards- have to be met by WTO countries. In the patent field for example (the most disturbing IPR for developing countries in socioeconomic terms) TRIPS establishes a minimum protection of 20 years, WTO Members' obligation to protect any invention no matter whether this is a process or a product⁶⁰, specific rules on enforcement of IPRs –a detailed set of enforcement administrative and judicial procedures including counterfeit trade prevention at the borders- protection and among others, the possibility of bringing domestic IPRs regimes under the jurisdiction of the WTO dispute settlement. The previously existing international treaties –The Paris Convention for the Protection of Industrial Property of 1883 and the Berne Convention for the Protection of Literary and Artistic Works- did not establish minimum standards to be implemented by Member States but they basically imposed nondiscrimination between citizens and companies of the different signatory nations –whatever the protection is provided to domestic works and inventions, foreign works and inventions are entitled to get the same degree or level of protection-.

Essentially, TRIPS and the “One size fit all” premise on which is based –decontextualized of the specific socioeconomic situation of countries- are controversial because of the persistence of the asymmetry in the level of development and capacities between developing and developed countries. There is historical

⁶⁰ Many countries like India or Italy and Spain (before the UE accession) did not protect product patents in the pharmaceutical field, local industries were able to reengineer the way some medicines were produced and developed a new process method to get the same pharmaceutical.

evidence teaching us that currently developed and wealthy and innovating countries prospered by imitating first and innovating later. Some authors hold that learning how to innovate is a previous and essential step towards learning how to innovate. In this sense, Korea copied from Japan, Japan copied from the West and the US copied from the European Countries which in their turn copied from each other. This copying and imitative conduct would be illegal today. In this respect, it seems difficult to see why the effects of this historical imitative conduct would not also be true for today's developing countries⁶¹.

While the first European and American IPR laws were designed to ensure a diffusion of knowledge and create a public domain for new inventions and knowledge and as an incentive for technology transfers⁶², protection of the private property of the works and inventions seem to be today the main and even the exclusive rationale behind the new IPRs regime. TRIPS has imposed IPR standards of protection on many developing countries -with no previous legislation on the matter- in a dogmatic manner by asserting like a mantra that IPR regime is one of the essential pillars to ensure economic development. Notwithstanding this, little or no empirical or theoretical research was conducted to dully assess the impact of implementing a western modelled new IPR regime.

Leaving aside the contested economic rationale under which IPRs are deemed necessary for inventors and creators to engage in innovative activity and production, TRIPS were said to bring important long-run benefits to developing countries in terms of economic growth, foreign investment, and technology transfer. However, and in view of some literature and data presented previously in this dissertation, there are not empirical studies showing consistent evidence in the sense that TRIPS has had a favorable economic impact on developing countries. For those countries which have experienced economic growths in the period 1995-2016 it is not easy to make a link between their better conditions and the implementation of TRIPS in their domestic legislation and in any case the economic development is far from being

⁶¹ Dutfield, G. (2008). Knowledge diplomacy and the new intellectual property fundamentalism. *Interpreting and Implementing the TRIPS Agreement: Is it Fair*.

⁶² Lanoszka, Anna. The global politics of intellectual property rights and pharmaceutical drug policies in developing countries. Supranote 31.

generalized to every country. On the contrary, TRIPS may undermine rather than foster economic and technological development. In this respect, an interesting study conducted by a Korean author concludes that IPR protection would hinder technology transfer and domestic learning in the early stage of industrialization and that IPR legislation must fit and adapt the different contexts of development of countries⁶³. Also in Spain, a combination of relatively weak patent protection -including national novelty and process and no product patent in the pharmaceutical field- together with other IPR figures such as industrial designs and utility models, permitted technological learning and minor adaptations and improvements made by local companies and a nascent national technological industry.

As we will see further in next chapters, the progressive strengthening of IPRs emphasizes the property nature of these conventional rights and converts IPRs in *iuris et de iure* rights with almost no exceptions or limitations to be confronted with. Furthermore, this alteration of the IPR regime towards one of its dimensions (represented by the interest of the IPRs' owners) has gone accompanied by an adequate terminology and conceptual framing of the issues. While for much of the 20th century, IPRs and in particular patents were viewed as monopolies –subject to the disciplining evaluation of Antitrust Law- and historically as grants of privilege, today the prominent discursive framing of those is centered in property rights and “right talks”. Instead of privilege we speak of rights. As privileges are expected to go through strict scrutiny in order not to benefit somebody beyond what is just and reasonable, rights suggest that they are natural and deserved. Right talks together with the rhetoric of “free trade” work conveniently to present IPRs and TRIPS in a positive light⁶⁴. Also, there are concerns about the tendency of the new IPRs fundamentalism to label copying as piracy as if both words were synonymous. In 2003, Kamil-Idris, Director General of WIPO linked piracy to terrorism declaring that they exist everywhere and that they are dangerous⁶⁵.

⁶³ Kim, L. (2003). Technology transfer & intellectual property rights. UNCTAD-ICTSD project on intellectual property rights and sustainable development, (2).

⁶⁴ Sell, Susan K. See supranote 42.

⁶⁵ Dutfield, G. (2006). “To copy is to steal”: TRIPS,(un) free trade agreements and the new intellectual property fundamentalism. *Journal of Information, Law, and Technology*, 1, 1.

TRIPS, a concerted marriage without love.

At this point it seems clear that TRIPS has not been adopted in the best social welfare interest of all WTO signatories, especially developing countries which acceded to TRIPS without having consistent evidences of its economic and social benefits. While developed, innovation-producing nations, especially US, were strong and persistent advocates for the strengthening and global extension of IPRs, developing countries showed their reluctance to adopt this strategy since they –as net IPRs’ importers- had reasonable fear to face important and substantial increases in the cost of imported goods and services which embodied IPRs –as it has been the case-. Neither seems to be clear that TRIPS operates in favor of workers and customers in general.

Therefore, it is clear that TRIPS is not the result of seduction or conviction. In fact, it is not the consequence of a shared concern of WTO Members to strengthen IPRS based on philosophical or economic considerations as to the virtues and benefits of IPRs regime. Neither is it the consequence of the ability of TRIPS proponents to show the positive impact on the economy of countries.

As we have mentioned, the reasons explaining the accession of developing countries to TRIPS have to be found in international relations, international political economy considerations and above all, in a new phase of capitalism rather than in the consensual agreement of eventually sovereign convinced and free nation states. Under the undisguised threat of the US and other developed nations, the TRIPS Agreement was presented as part of a WTO package deal where developing countries were forced to adhere to TRIPS in exchange for benefits, concessions and reduction of trade barriers provided for other WTO agreements. Furthermore, beyond the national interests of the proponents of the new regime of IPRs, TRIPS will be framed and will be one of the instruments and pillars of a more comprehensive strategy leading to extend capitalist social relations of production on a global scale. This is made possible not only through political coercion of the US or the most powerful and pro-IPR regime countries but also by a more subtle hegemony (Gramscian hegemony)

where one class or class fraction control other classes via the moral and intellectual leadership of key elements of society and the state apparatus (extended state).⁶⁶

Therefore, TRIPS is an instrumental device and part of the infrastructure of the new international regime –an instrument of Gramscian hegemonic control-, it would respond to a certain model or vision of the world, to the architecture of a new international order premised in neoliberal principles and dominated by global accumulation of capital⁶⁷. Also, TRIPS contributes to solidify a perpetuate economic dependence relations between north and south (center and periphery) and a global division of labor where low-level and unsophisticated activities coupled with lower labor costs reside mostly in the developing countries while technically sophisticated processing and manufacturing, R&D activities, design, finance and other high level innovative and creative activities are carried out in the developed countries imposing their dominant cultural model of production and preserving their technological superiority and control. Consequently, many developing countries suspect that the TRIPS Agreement conceals a policy of technological protectionism intended at consolidating an international division of labor where the industrialized nations generate innovations and developing countries are the “*world maquiladora*” and the market for the resulting products⁶⁸. In this respect, one may wonder why there is no such thing as an effective international agreement on minimum labor standards for workers, an international Agreement for a basic harmonization of certain corporate taxes and financial transactions, both of which (trade related labor standards or trade related tax policies) substantially affecting trade and that would ensure every worker’s dignity, a better distributive policy of wealth and a less distorted social dumping-free trade within the frame of WTO.

⁶⁶ The hegemonic class has to be able to articulate a unifying ideology which presents itself as universal. Hegemony in the new world order would not consist in a particular state’s dominance in the pursuit of its narrow self-interest but rather in pursuing the interests of a transnational class whose interests are presented as universal, consensual and part of a global welfare. The identification of the US as the hegemonic state derives from its capacity to shape the infrastructure within which the capital accumulation globally takes place not only in the interest of US capitalist competitiveness, but in the interest of a transnational class and transnational capital accumulation. In this sense, TRIPS would not be the ideological manifestation of a particular class interest but rather as serving global welfare.

⁶⁷ Richards, D. G. (2004). Intellectual property rights and global capitalism. ME Sharpe.

⁶⁸ Correa, C. M. (2000). Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. Zed books.

4.4. Hierarchy of international law sources and alternative foundation in the field of access to medicines: significance and scope of the Human Rights regime.

Before entering the analysis and study of the different normative and legal constructions that from a deliberative perspective may be argued and applied to transform the current global regime of IPRs into a more legitimate regime, it is worth exploring the existence of other bodies of law, in particular, human rights law which encompass some rules on health and access to medicines that eventually might conflict with some of the most restrictive and decontextualized interpretations of IPRS, in particular in the field of pharmaceutical patents and likewise exclusive rights. Furthermore, Human rights regime and compliance with human rights is for some scholars one of the main pillars of the international legitimacy of international organizations such as WTO. In particular, it is held that international institutions should not violate the *least controversial human rights* and it must ensure people's most fundamental rights⁶⁹. Therefore it is important to review how and to which extent human rights regime may influence, contradict and "alleviate" the consequences and the impact of a global regime of IPRs represented by TRIPS. In this respect, this chapter is not intended to evaluate and study WTO DSU functioning or other judicial or adjudicative processes on IPRs claims but it will rather analyze the eventual conflicts between both legal bodies.

Human rights and access to affordable medicines.

The International Covenant on Economic, Social and Cultural Rights (ICESCR)⁷⁰ has substantially contributed to the codification of the human right to health and the access to medicines as one of its manifestations. As we have previously said, access to medicines would be one of the fundamental components of the human right to health. The ICESCR provides that states parties are obliged to take steps toward the full realization of the highest attainable standard of mental and physical health for all

⁶⁹ Buchanan, Allen, and Robert O. Keohane. (2006). *The legitimacy of global governance institutions*. Ethics & international affairs 20.4, 405-437.

⁷⁰ ICESCR is a multilateral treaty adopted by the United Nations General Assembly on 16 December 1966, and in force from 3 January 1976.

persons. In General Comment 14, the Committee on Economic Social and Cultural Rights (CESCR) has interpreted this article to demand the provision of primary health services and essential medicines as defined by the WHO.

Human rights and IPRs are two different bodies of law which have evolved historically separately until the adoption of TRIPS. The fact that TRIPS has motivated the enforcement of pharmaceutical patents worldwide implies an impact on the access to affordable medicines –in the form of increases of drug prices- and therefore, on the realization of the human right to health that eventually could amount to a violation of it. This eventual conflict between both bodies of law and in particular, between the right to health and the IPRs has become a hot topic especially since the HIV/AIDS crisis and the access to drugs for patients in developing countries which are the most severely affected by the epidemic and it is the subject of important discussions and concerns at the international level.

Resolving the tension between Human rights vs. Intellectual Property rights. Is there a conflict?

First of all, it is important to note that some academics hold that there is not such a conflict between human rights and TRIPS at the level of international principles. In Petersmann's controversial views, WTO objectives of protecting freedom, non-discrimination, and rule of law in the worldwide division of labor, and to thereby increase economic welfare and mutually beneficial cooperation among citizens across frontiers, would complement the human rights objectives of promoting personal and democratic self-development through legal protection of equal basic rights and fulfilment of basic needs necessary for a life in dignity⁷¹. This opinion has been criticized by various authors who claim that the relationship between human rights and market freedom is much more complex than Petersmann shows and who

⁷¹ Petersmann, E. U. (2004). The 'Human Rights Approach' Advocated by the UN High Commissioner for Human Rights and by the International Labour Organization: Is it Relevant for WTO Law and Policy?. *Journal of International Economic Law*, 7(3), 605-627.

reproach Petersmann's tendency to use human rights to achieve economic policy objectives⁷².

In fact, as it is acknowledged by most academics, there may cases where human rights and TRIPS or the global regime of IPRs may come into conflict. Legal systems have developed different techniques in order to resolve those conflicts between different rules which regulate the same subject matter in a different, even contradictory manner. Basically, these techniques are those which make rules derived from a given source to prevail over rules from another source (*lex superior derogat inferiori*). If this first technique is not applicable we resort to the following techniques; a particular rule prevails over a general rule (*lex specialis derogat generali*) and later rule prevails over earlier rules (*lex specialis derogate generali*).

Is global IPRs regime a "self-contained regime"?

Before initiating the analysis of the various techniques for the resolution of potential conflicts of law, it is important to see whether the IPR new regime and in general, the trade regime is subject to be coherent with a more general system which will be the wider corpus of international law, i.e, are WTO rules integral part of the public international law whose rules may potentially conflict with other international public rules? This question is not trivial since there are scholars who regard international law as no more than the sum of fragmented subsystems of law which may constitute normative closure of a particular regime⁷³ in a pluralistic and horizontal framework of international law and thus, they resolve their potential contradictions within their own system of rules and interpretations.

⁷² Howse, R. (2002). Human Rights in the WTO: Whose Rights, What Humanity? Comment on Petersmann. *European Journal of International Law*, 13(3), 651-659. and Alston, P. (2002). Resisting the merger and acquisition of human rights by trade law: a reply to Petersmann. *European Journal of International Law*, 13(4), 815-844.

⁷³ Simma, B., & Pulkowski, D. (2006). Of planets and the universe: self-contained regimes in international law. *European Journal of International Law*, 17(3), 483-529.

The phrase “self-contained regime” was first coined by the Permanent Court of International Justice in the S.S. Wimbledon case⁷⁴ and became popular in the *Teheran Hostages* judgement⁷⁵ where the Court concluded that *the rules of diplomatic law, in short, constitute a self-contained regime which, on the one hand, lays down the receiving State’s obligations regarding the facilities, privileges and immunities to be accorded to the diplomatic missions [...]*. This phrase and the context in which it was used served to some scholars to conceptualize the notion of “self-contained regime” as an entirely autonomous and isolated legal system from general international law, a system which intends to totally exclude the application of general international law, in particular, the consequences and effects resulting from wrongful acts or from the breach of commitments and obligations. WTO with its focus on trade liberalization, and all the machinery of new procedures of dispute settlement and surveillance intended to deliver the regime with the attributes of security and certainty while encapsulating the system and its functioning from any alien and unwanted interference, could be an example of what we have said.

Most international law scholars and lawyers hold that WTO rules and TRIPS are a branch of general international law. In this sense, even international law scholars in favor of WTO rules argue that the fact that many negotiators and lobbyists of the WTO treaty did not think of public international law when negotiating and drafting the WTO treaty is not a valid legal argument to isolate WTO law from the rest of international law.⁷⁶ The Appellate Body of the WTO itself has acknowledged that the GATT is imbedded in general international law, asserting that the Agreement is not to be read in public isolation from public international law⁷⁷. In this sense, despite being a strong regime, WTO rules would constitute *lex specialis vis-à-vis* certain rules of general international law. However, this does not mean that WTO rules are *lex specialis vis-à-vis* all rules of international law since WTO rules have a potential

⁷⁴ Britain et al. v. Germany, (1923) PCIJ Series A01 is a judgment rendered on August 17th, 1923. The case primarily dealt with issues pertaining to attributes of sovereignty, treaty obligations qua internal law, and the jurisprudence related to international canals. The Court was faced with the question whether the provisions of a given specific treaty should be applied by prevailing over other more general rules on watercourses. The Court used the term of “self-containment” to resolve in favor of the application of the specific treaty.

⁷⁵ United States Diplomatic and Consular Staff in Tehran, United States v Iran, Judgment, ICJ GL No 64, [1980] ICJ Rep 3, ICGJ 124 (ICJ 1980), 24th May 1980

⁷⁶ Pauwelyn, J. (2001). The Role of Public International Law in the WTO: How far can we go?. *American Journal of International Law*, 535-578.

⁷⁷ Report on “United States - Standards for Reformulated and Conventional Gasoline” (WT/DS2/AB/R)

impact on almost all other fields of law which should be dully assessed. Also, as it is implied by art. 3.2 of the Dispute Settlement Understanding which sets out that WTO covered agreements must be clarified “in accordance with customary rules of interpretation of public international law”, WTO is partially incomplete in areas such as interpretation, standard of review, burden of proof and other procedural issues for which general international law has to be referred.

Notwithstanding this, and in spite of the fact that the above legal construction of the treaties integrating WTO and TRIPS permit to formally conclude that WTO treaty and WTO dispute settlement are integral parts of public international law and that consequently, they are not “self-contained” regimes, the functioning and jurisprudence to date shows us a quite different picture. In effect, the strict formalism of WTO panels into the interpretation of WTO norms, its official aim of providing security and predictability to the multilateral trading system and the alleged “judicial economy” to avoid pronouncing on issues which are not necessary to resolve the specific complain-every non-trade concern is suspicious of favoring potential protectionism-, has led to a situation where no state has yet invoked human rights obligations in a dispute under the WTO⁷⁸. Furthermore, it is important to take into account that in practice, and in view of the WTO remedial machinery (DSU), states would prefer to comply with specific trade WTO rules such as TRIPS even if that compliance does not fully respect other general international law obligations. In short, TRIPS could have to a great extent succeeded in insulating IPRs from interferences of other bodies of law which demand to frame WTO rules and in particular, TRIPS into a larger global public law and humanitarian health concerns context.

In the opposite direction to the above mentioned “voluntary pursued insulation” of TRIPS autonomous functioning, it is important to say that the mentioned shortcomings of WTO and in particular of TRIPS regime in terms of lack of international legitimacy and democratic deficit together with the increasing openness of WTO to a common culture of international lawyers and international law scholars

⁷⁸ Picciotto, Sol. (2011). *Regulating global corporate capitalism*. Cambridge University Press.

is making this system gradually permeable to general international law considerations other than the specific trade-focused concerns. In effect, in the dynamic tension between universalistic or all-the-factors approach and particularistic view –favoring a factual prevalence of some (neoliberal) values over the remaining considerations- the last word could not have been spoken yet. The intended isolated and autonomous regime which purports to factually put free trade and property at the very first place by giving them a quasi-constitutional status in the new international order, is being –as we have seen in previous chapters- increasingly questioned and threatened by legitimacy challenges which suggests a shifting in the hegemonic discourse towards more inclusive models where internationally recognized ethical positions, counterhegemonic voices and concerns and other type considerations claim their place.

Ius cogens, a beautiful utopia with a difficult landing.

Therefore, and assuming that theoretically TRIPS has to be confronted to other legal norms of public international law, it is important to analyze how WTO rules such as TRIPS coexist with other bodies of law and how the international legal order and some superior rules such as *ius cogens* could affect the IPR system from an international legal reasoning.

As we know, in principle there is not such a thing as a hierarchy of sources in international law. International law is decentralized –fragmented for many- and does not have a central legislator or legislators creating the rules. Furthermore, states are at the same time the legislators of the rules and the subjects of such rules. The lack of formal hierarchy in international law is the result of the assumptions that all rules in the international realm derive from state consent, states which on the other hand are formally equals as creators of law, therefore, they are presumed to have the same binding and formal value. These premises are seen by some international law scholars as necessary to guarantee the neutrality of international law⁷⁹; the same legal value of international rules would contribute to the peaceful co-existence

⁷⁹ Weil, P. (1983). Towards relative normativity in international law. *Am. J. int'l L.*, 77, 413.

between states and to enhance the cooperation –in contrast with subordination– between equal states in the achievement of common goals.

Despite the above, since the second half of the twentieth century and as a consequence of the Second World War and the creation of the UN, there has been certain emerging hierarchy of some values and rules which are considered to be superior, universal and binding worldwide beyond the state consent itself. Those superior rules are gathered under the term *ius cogens*. The Vienna Convention defines *ius cogens* in its art. 53 as *one 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*. Vienna Convention does not determine the source where those rules of *ius cogens* should derive from. The high status of these kind of rules do not derive then from their source, but it is rather based on its acceptance and recognition by the international community from which derogation is not permitted. Although there is a near-universal consensus about the existence of the category of *ius cogens* norms, the contours of this concept and its scope are however far from being uncontroverted.

One of the first discrepancies on this type of rules is referred to which sources may create *ius cogens*. While some consider that only customary law could create *ius cogens*, other scholars hold however that both treaties and principles of law would be also able to create *ius cogens* norms and rules. Historically *ius cogens* was rooted in the theory of natural law. In this sense, a treaty could be void if it was contrary to natural law, morality or basic principles of international law. The Vienna Convention would come to first codify the concept of *ius cogens*, a concept existing however outside the treaty context⁸⁰. The Vienna Convention (art. 64) clearly establishes the effects and the consequences of the existence of peremptory norms; a treaty is void and null if it conflicts with a norm belonging to *ius cogens*⁸¹. For our purposes it is important to examine whether the human right to health and the access to affordable medicines fall within the category of *ius cogens* or any other category of superior

⁸⁰ Weatherall, Thomas. (2015). *Jus Cogens: International Law and Social Contract*. Cambridge University Press.

⁸¹ Article 64 explicitly states: If a new peremptory norm of general international law emerges, any existing treaty which is in conflict with that norm becomes void and terminates

rules. Once this aspect will be clarified, a second step shall consist of assessing whether TRIPS or certain TRIPS grounded impairments to access to medicines could be considered as amounting to a violation of the human right to health.

As we have mentioned previously, apart from the discussion about the sources, there is also an important discrepancy as to which rules or which content should be considered and categorized as *ius cogens* or peremptory norms. There are some scholars who consider that human rights –in general- should be recognized as having peremptory status –as the European legislation tends to do-.⁸²This is due to the fact that at the time of drafting the Vienna Convention, some states mentioned human rights in their enumeration of peremptory norms. However, the peremptory status of human rights or of all human rights remains controversial and the states have different views on the matter. Some other scholars suggest the existence of three categories of *ius cogens*; 1) the rules protecting the foundations of international order (the prohibition of genocide or of the use of force in international relations except in self-defense); 2) the rule concerning peaceful cooperation in the protection of common interests (freedom of the seas) and the rules protecting the most fundamental and basic human rights, and; 3) rules for the protection of the civilians in time of war⁸³. Also, the *Barcelona Traction case*⁸⁴ is mentioned as a judicial decision which implicitly defines *jus cogens* rules as those *basic rights of the human person* including the prohibition of slavery and racial discrimination and the prohibition of aggression and genocide⁸⁵.

Anyway, it has to be said that even if there is an agreement about the convenience of the existence of a non-derogable moral order informing international relations and its effects and consequences, the definition of *ius cogens* has been an object of sharp disagreement rather than a catalogue of unquestionable and unobjectionable imperative norms. Despite at a first glance and following Vienna Convention *ius cogens* would be at the top of an eventual hierarchy of international law norms, as

⁸² Hannikainen, Lauri. (1988). Peremptory norms (jus cogens) in international law: Historical development, criteria, present status. Vol. 1. Coronet Books Inc.

⁸³ Hossain, K. (2005). The Concept of Jus Cogens and the Obligation Under the UN Charter. *Santa Clara J. Int'l L.*, 3, i.

⁸⁴ *Barcelona Traction case (Belgium v. Spain)*, ICJ Rep. 1970,

⁸⁵ Malanczuk, P. (2002). *Akehurst's modern introduction to international law*. Routledge.

noted by some scholars, the indeterminate contents of these rules gives rise to the suspicion that either *jus cogens* norms are so indisputable that its codification and definition is not necessary and adds nothing to their quality, or so disputed that they never meet the criteria for their creation, namely, the acceptance and recognition by the international community of States⁸⁶.

In this sense, this vagueness of the concept suggest that *ius cogens* does not constitute a closed order with their own immanent coherence and autonomous rationality and “emancipated life” but rather a site of contestation; a *tension ridden juridical field*⁸⁷ where competing views of power and scale of values come to define and give a circumstantial and short-term content; an appreciated but *empty box* which could be filled conveniently with a range of materials which do not respond to the best rational argument or the best “material” for the general interest but to a balance of power. As Umut Özsu explains, *ius cogens* activists and proponents have showed a poor capacity to achieve the emancipation of those special rules, a fact that is due in no small part to the abstract, even speculative, utopianism by which the notion of *jus cogens* (like that of human rights) is ultimately inspired.⁸⁸ In fact, there are virtually no cases where art. 53 has been invoked to invalidate a treaty so the potential and practical application of the supremacy of *ius cogens* remains to be put to the test⁸⁹.

Human rights vs. Human rights?

In any case and following the theoretical exercise of seeing whether the right to health amounts to a *ius cogens* rule, thus having the potential of invalidating TRIPS or certain applications, implementations or interpretations of TRIPS –as it may pose important obstacles to the realization of the right to health in terms of access to medicines-. However, it is noteworthy that we cannot be too optimistic about the results of that confrontation. In this respect and due to the fact that the human right

⁸⁶ Weiler, J. H., & Paulus, A. L. (1997). The Structure of Change in International Law or Is There a Hierarchy of Norms in International Law?. *European Journal of International Law*, 8(4), 545-565.

⁸⁷ Bourdieu, P. (1986). The force of law: Toward a sociology of the juridical field. *Hastings LJ*, 38, 805.

⁸⁸ Özsu, U. (2017). An Anti-Imperialist Universalism? *Jus Cogens and the Politics of International Law. International Law and Empire: Historical Explorations*, 295.

⁸⁹ Pauwelyn, J. (2003). *Conflict of norms in public international law: how WTO law relates to other rules of international law*. Cambridge: Cambridge University Press.

to health is categorized as one economic and social right or third generation right⁹⁰, scholars hold that the right to health would be not a non-derogable right under present international law⁹¹.

Assuming that the human right to health is not an integral part of the *ius cogens* rules - as it is observed by most of scholars-, one may wonder which body of law would prevail in case of an eventual conflict between both. First, it is important to highlight that human rights also encompass the protection of the moral and material interest resulting from creative production and thus, some IPRs dimension could be said to be covered under the umbrella of human rights. In particular, art. 15 of the ESCR Covenant establishes that *The States Parties to the present Covenant recognize the right of everyone: [...] c) to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.* Also, article 27 paragraph 2 of the Universal Declaration of Human Rights provides that *everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.*

However, General Comment 17 (2005) which constitutes an authoritative pronouncement on article 15(1)(c),⁹² shows a remarkable concern in distinguishing the right contemplated in art. 15(1)(c) from IPRs. The repetitive observations and explanations in this sense may seem exaggerated and it even makes the scope of the article depart from the ordinary meaning of its wording and literalism. The first paragraph of General Comment 17 explains that this human right derives from the *inherent dignity and worth of all persons* and that *this fact distinguishes article 15, paragraph 1 (c), and other human rights from most legal entitlements recognized in intellectual property systems.* Although General Comment provides that *whereas the human right to benefit from the protection of the moral and material interests resulting*

⁹⁰ Right to health would imply for States the obligation to refrain from interfering directly or indirectly with the enjoyment of the right; they should take measures to prevent third parties from interfering with the guarantees provided and in positive or active terms, they should adopt appropriate legislative, administrative and other measures towards the full realization of the right.

⁹¹ Cullet, P. (2003). Patents and medicines: the relationship between TRIPS and the human right to health. *International Affairs*, 79(1), 139-160.

⁹² Committee on Economic, Social and Cultural Rights, Thirty-fifth session, Geneva, 7-25 November 2005.

from one's scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments, nothing in IPRS laws prevents individuals and "artisan type authors" from enjoying of IPRs. According to the interpretation given by this Comment, legal entities would not be protected at the level of human rights. Also, there are some who claim that art. 15 (1)(c) should be employed to protect intellectual creations such as "traditional knowledge" which is always out of the scope of protection by IPRs⁹³.

General Comment 17 seem however to be reasonable when saying that the protection provided by article 15 (1)(c) does not *reflect the level and means of protection found in present copyright, patent and other intellectual regimes*. In fact, one may consider that the right to benefit from the protection of the moral and material interests of one's creative work can be materialized by methods or formulas other than exclusive rights granted by IPRs such as public compensation or other type of benefits. This is an important point to be noted i.e. IPRs or exclusive rights is one of the ways –but not the only- by which an author's right might be protected by the State. Furthermore, art. 11.1 of this Covenant provides that *the States Parties to the present Covenant recognize the right of everyone to an adequate standard of living for himself and his family [...]*. This goal "*adequate standard of living*" is directly linked with the *material interests* contemplated in art. 15 (1)(c) in the sense that the protection of the right should contribute to ensure an adequate standard of living. Even if it is not mentioned in the General Comment 17, the *adequate standard of living* could constitute an interesting threshold to be taken into account when there is a conflict between IPRs and other rights or interests, i.e., we could use this measure (does the protection contribute to an adequate standard of living?) at the time of striking an adequate balance between all the interests at stake, since many times IPRs provide their owner with a compensation remarkably beyond that corresponding to the threshold of an adequate standard of living.

⁹³ Cullet, P. (2007). Human rights and intellectual property protection in the TRIPS era. *Human Rights Quarterly*, 29(2), 403-430.

On the other hand, article 17 of the Universal Declaration of Human Rights (UDHR) establishes that everyone has the right to own property alone as well as in association with others (paragraph 1) and that no one shall be arbitrarily deprived of his property (paragraph 2). In spite of the fact that in this thesis it is held that IPRs do not have the attributes of real property, and that the mention of this right in the UDHR was certainly controversial, the recognition of the human right to property and the usually unproblematic inclusion of IPRs under the right to real property may add another argument to hold that some dimensions of IPRs may belong to the realm of human rights⁹⁴. In any case, despite the pronouncements that all human rights are indivisible, interdependent, interrelated and normatively equal, there is a tendency to establish certain hierarchy within the sphere of human rights at the top of which they we will find *ius cogens* rules. While most States and International Organizations have accepted –at least from a theoretical perspective- a wide ranging corpus of legal obligations in the human rights and humanitarian areas, the strength and scope of those obligations may be different depending on the value attached to the corresponding norm. There are scholars who identify even six normative categories of international law with various implications in terms of human rights hierarchy.⁹⁵

This being so, in a hypothetical violation of the human right to health and a conflict between human rights law and IPRs, which one should prevail? According to the Office of the High Commissioner for Human Rights in an eventual conflict between both bodies of law, human rights should take precedence when it reminds all governments *the primacy of human rights under international law over economic policies and agreements* and called on states to ensure that TRIPS should not negatively impact on the enjoyment of human rights⁹⁶. Also, there are some who see the combination of article 55 of the UN Charter -which provides that UN shall promote among others the observance of human rights- and article 103 -which establishes that in the event of conflict between obligations under the UN Charter and obligations under any other international agreement, UN Charter obligations shall

⁹⁴ Art 17 of UDHR is often framed within the field of natural persons regarding their possessions where property is used for personal consumption rather than production.

⁹⁵ Seiderman, I. D. (2001). Hierarchy in international law: the human rights dimension. *Intersentia*.

⁹⁶ Sub-Commission on Human Rights resolution 2001/21

prevail-, as an additional argument to claim the *de jure* primacy of human rights over obligations resulting from TRIPS.

Therefore, the following question to be raised is whether TRIPS can be said to be at certain point in violation of the human right to health, in which cases and under which conditions. In this respect, CESCR General Comment No. 14⁹⁷ establishes different types of violations of the human right to health in its paragraph 46 to 52. In particular, within the category of *acts of commission*, the CESCR mentions the *formal repeal or suspension of legislation necessary for the continued enjoyment of the right to health or the adoption of legislation or policies which are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health*. Therefore, if compliance with TRIPS leads to rises in drug prices and the destruction of local pharmaceutical industries which lead to reduced access to pharmaceuticals, this could imply in theory a substantive violation of the human right to health and ultimately the human right to life and the ESCR Covenant –a “deliberately retrogressive” step-.

Notwithstanding that, the judicial pronouncement –or by any other adjudicatory organ- on the violation of the human right to health by TRIPS seems difficult to be effectively made. On the one hand, ESCR Covenant does not require immediate full implementation of the right to health but to achieve *progressively the full realization* of it (art.2) without establishing a precise deadline as it is for example, the case for TRIPS implementation deadlines. Also, while TRIPS obligations are precisely drafted and backed by an effective dispute settlement mechanism, human rights treaties and covenants are drafted in much broader and vague terms and there is no any enforcement mechanism. On the other hand, states are required to attempt to reconcile all their international obligations and to avoid conflicts. In this sense, it could be argued by those favoring the implementation of TRIPS that States could make compatible both international obligations –human right to health and TRIPS obligations- by adopting measures to offset price increases such as providing public subsidies to make medicines affordable for the poorest –as it was suggested by the

⁹⁷ Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, on 11 August 2000 (Contained in Document E/C.12/2000/4)

World Bank⁹⁸- and/or investing public resources for R&D addressed to diseases of developing countries.

Therefore, in order to conclude this chapter, it is important to note that human rights regime does not seem to be a helpful instrument or a valid framework to balance or to offset TRIPS worse effects at least in a simple and direct way. First, the preemptory status of some superior norms, such as the primacy for all human rights, remains controversial. Prevalence of human rights resides in the rhetoric realm of the “*ought to be*” rather than in the field of effective applications of law. Furthermore, the pervasive disagreement about the scope and definition of human rights does not permit human rights to constitute a sufficient basis for the legitimacy of international law⁹⁹. Many of the commitments embodied in the human rights treaties and covenants are expressed in vague and idealistic language rather than prescribing legal, detailed and enforceable obligations. In this sense, in most cases human rights would constitute moral aspirations with a controversial and diluted legal value.

However, human rights could play an important role as an instrument to measure and value the “moral density” of certain decisions in a democratic deliberative-dialogue context. Human rights could constitute an ethical threshold of certain international decisions, in particular those decisions concerning TRIPS and IPRS regime with an impact on public health. Human rights should therefore contribute to define and determine the framework and limits of the application of TRIPS and global IPRs regime as a conceptual tool to frame TRIPS discourses, a valid standard to be claimed and argued by all the voices and actors involved in public health so as to allow the recovery of international legitimacy and effectiveness of some international decisions which are today highly contested and challenged due to its reductionist and partial interest bearer character.

⁹⁸ Global economic prospects and the developing countries 2002: making trade work for the world's poor where it states that [...] remove from patent eligibility those drugs that are on, or will be on, the WHO Essential Drugs list, it is unlikely that such discrimination by product would be acceptable... A better alternative is to use public funds to purchase drugs or licenses [...]

⁹⁹ Meyer, L. H. (2009). *Legitimacy, justice and public international law*. Cambridge: Cambridge University Press.

CHAPTER 5. GLOBAL PUBLIC GOODS AND GLOBAL PUBLIC INTEREST: TOO GLOBAL TO BE TRUE?

5.1. Health and Global Public Goods.

After having considered the new international scenario, its institutional dimension and the market-oriented policies of health at a global scale, we have identified a number of “market failures”. In this sense, we have identified certain conduct of the pharmaceutical industry which jeopardizes the right to health (and access to medicines) while it does not ensure any of the virtues announced by their supporters. Finally, we have reviewed the crisis of legitimacy of today’s called global governance, in particular that related to WTO and TRIPS, a crisis that is related to its democratic deficit and its shortcomings in complying with certain goals. This chapter will go through the legal and institutional *formulae* proposed by hegemonic forces of globalization as a mechanism to compensate/alleviate the denounced failures and ramping inequality.

The concept of Global Public Goods (GPG) in the context of international governance is borrowed from the public economics literature. It has been devised as a way of addressing and giving response to certain global problems by implementing international cooperation. Taking for granted and assuming the paradigm of Globalization, some authors¹ observe that many of today’s international challenges could be explained by an important undersupply or wrong supply of global public goods. While in the past, most areas and issues of public policy were of national reach and therefore, they were addressed by national governments overcoming the failures of the market and providing national public goods, nowadays, many of the problems affecting human beings spill across borders and national states are overwhelmed and unable to properly handle these problems of international dimension. These authors argue that a globalized world would require the adoption of a theory of global public goods, a political solution based on the cooperation between states and other private

¹ Kaul, Inge, et al., eds.(2003). *Providing global public goods: managing globalization*. Oxford: Oxford University Press.

agents to achieve crucial goals to society such as financial stability, human security, health or the reduction of environmental pollution. Thus, in the absence of world government, GPGs should be supplied through *the anarchic and horizontal system of international governance*², i.e., multilateral cooperation.

Assuming that the theoretical model of GPG does not question the present trade and IPRs regime, it is important for the purposes of this thesis to explore whether and how this figure may be applied to health, in particular, to the problem suffered by some developing countries finding difficulties in ensuring to their population the access to medicines as result –among others- of the global IPRs regime implemented by TRIPS and TRIPS Plus. In this sense, GPG would be analyzed within the category of exogenous remedies proposed by today's system which attempt to counterbalance the undesired effects of the allegedly inevitable globalization process.

From public goods to global public goods.

The idea of “public goods” can be traced back to David Hume’s discussion of providing for the “common good”³. Also, economists like Adam Smith, David Ricardo and David Malthus drew attention to the necessity of some sort of concerted action to provide the community with public or collective goods. Notwithstanding this, a general and systematic theory of public goods in the economics literature was formulated by the economist Paul A. Samuelson in 1954 in his article “The Pure Theory of Public Expenditure”. Samuelson considered two categories of goods; ordinary private consumption goods and *collective consumption goods* (public goods). This last category of goods would be those consumption goods which *all enjoy in common in the sense that each individual’s consumption of such a good leads to no subtraction from any other individual’s consumption of that good*⁴. Therefore, these types of goods are non-rivalrous, i.e., they may be consumed by one consumer without preventing simultaneous consumption by others.

² Barrett, Scott A. (2001). Financing global public goods. Global Public Policies and Programs: Implications for Financing and Evaluation, Proceedings from World Bank Workshop (Washington, DC: World Bank).

³ Sagasti, F., & Timmer, V. (2008). An approach to the CGIAR as a provider of international public goods. *A contribution to the work of the Independent Review Panel (IRP) of the CGIAR*.

⁴ Samuelson, P. A. (1954). The pure theory of public expenditure. *The review of economics and statistics*, 387-389.

This concept was applied to political science by Mancur Olson in 1965 in his book "*The logic of Collective Action*"⁵. The most interesting point raised by Olson is the questioning of the premise that groups of individuals with common interests usually attempt to advance collectively those common interests. On the contrary, Olson observes interestingly that in the absence of coercion or some other special device or incentive to make individuals act in their common interest, rational, self-interested individuals will not act to achieve their common or group interests but their individual interests. Hence, without selective incentives to motivate participation, collective action is unlikely to occur even when large groups of people with common interests exist. This professor argued that individuals in any group attempting collective action will have incentives to "free ride" on the efforts of others if the group is working to provide public goods. Needless to say that this could also be the case for states or other international actors -when speaking of collective or multilateral action- in the international arena.

In the realm of international relations scholarship, the notion of global public goods raised an important interest throughout the 1990s. Joseph Stiglitz extended the concept of public goods to the international scenario⁶ and Todd Sandler observed that actions at the national or regional level were no longer sufficient to tackle with global challenges⁷. However, the concept of Global Public Goods (GPG) has gained a prominent relevance in the context of the UN's Millenium Development Goals and it was popularized by researchers associated with the United Nations Development Program (UNDP) and the World Bank⁸. In particular, UNDP sponsored a research project (International Development Cooperation and Global Public Goods) led by Inge Paul, the Director of the UNDP's Office of Development Studies from 1995 to 2005. These works were closely linked to foreign aid and the result of this project was captured in 3 books.

⁵ Olson, M. (1971). *The logic of collective action: Public goods and the theory of groups*, second printing with new preface and appendix (Harvard Economic Studies).

⁶ Stiglitz, J. E. (1995). *The theory of international public goods and the architecture of international organizations*. Department for Economic and Social Information and Policy Analysis, United Nations.

⁷ Sandler, T. (1997). *Global challenges: an approach to environmental, political, and economic problems*. Cambridge University Press.

⁸ Ferroni, M. (2000). *Reforming Foreign Aid: The Role of International Public Goods*. Washington, DC: World Bank.

The first book (*Global Public Goods: International Cooperation in the 21st century*)⁹ was published in 1999 and it was an initiatory theory on GBGs. In this book, UNDP brought GPGs from the national scale to the international realm. From the very beginning the book recognizes that in order to cope with the new transnational issues, it is necessary to overcome the failure of the markets which can be achieved by means of GPGs and that there are inadequate incentives for the private sector to supply GPGs. Also, the book claims that we should be willing to spend money on these GPGs through innovative mechanisms that would go beyond the concept of official development assistance.

According to this first book, in order for national public goods to qualify as global, GPGs must cover more than one group of countries (groups determined by regional forums, trade blocs, defense alliances or clubs); their benefits must reach a broad spectrum of the global space and; they must meet the needs of the present generation without jeopardizing those of future generations. Categorization of public goods as global public goods is said to require a careful assessment and impact analysis as well as participatory policy dialogue among all concerned actors and beneficiaries. Furthermore, this book suggested three categories of GPGs: 1) natural global commons –such as climate and environmental issues-; 2) human-made global commons –such as transnational infrastructures or the world’s common heritage and; 3) global intangible conditions such as peace, health and financial stability. Also, authors of this theory distinguish between final GPGs which may be tangible (environment) or intangible (peace or financial stability) and Intermediate GPGs such as international regimes which contribute towards the provision of public goods.

Due to criticism about the fuzziness of the concept, the second book (*Providing Global Public Goods: managing Globalization*)¹⁰ was published in 2003. The second of this series of works redefine in a broader sense the definition of GPG as goods that are in the public domain and it adopts a more political approach to GPGs. In this sense, it

⁹ Kelleher, David. (2000). *Global Public Goods: International Cooperation in the 21st Century*. *International Review of Public Administration* 5.2: 153-156.

¹⁰ Kaul, I., Conceicao, P., Le Goulven, K., & Mendoza, R. U. (Eds.). (2003). *Providing global public goods: managing globalization*. Oxford: Oxford University Press.

explains that GPGs are largely a matter of public policy choices. Finally, the UNDP published a third book in 2006 (*The New Public Finance: Responding to Global Challenges*)¹¹ where the working group explored a number of new policies and financing instruments to cope with globalization deficits and negative effects.

What is a global public good?

Focusing on GPGs as it has been theorized by the above mentioned Project underpinned by the UNPD, a GPG has been usually defined by its counterpart, private goods. Unlike private goods which tend to be excludable and rival in consumption, GPGs have two essential characteristics: Non-excludability and non-rivalry. Non-excludability means that it is either impossible or prohibitively costly to exclude those who do not pay for the good from using or consuming it; once the good has been produced, its benefits accrue to all. The non-rivalry property implies that any one person's consumption of the public good has no effect on the amount available for others; it does not detract anything from its consumption by other, additional person.

According to the traditional definition of public goods, it is argued that because of their nature as non-rivalrous in consumption and non-excludable, public goods are generally undersupplied and have to face free riding problems. This phenomenon refers to the lack of incentives for private agents to finance supply of public goods when they can rely on others to pay for their provision. This undersupply of public goods is referred to as a case of market failures. In a national context this undersupply or market failure justifies state intervention which traditionally provides public goods by adopting public policies and binding decisions to coordinate and regulate the necessary resources for that purpose. However, at a global scale and in the absence of a global government or superior authority and lack of legal obligation, provision of GPGs can only be obtained –they argue- by effective and real cooperation between both states and private actors (civil society, NGOs, enterprises).

¹¹ Kaul, I., & Conceição, P. (2006). *The new public finance: responding to global challenges*. Oxford: Oxford University Press.

Therefore, GPGs theory is especially concerned on the analysis of the incentives for international cooperation (collective action), the study of the underlying structure of incentives that promote or discourage collaboration among individuals, groups or nation-states and the free ride problem that it arises therefrom, a free ride problem which is based on the assumption that states or “rational” actors would tend to pursue exclusively their self-interest. Hence, the states would be initially reluctant to cooperate if they can benefit of a certain good without the necessity to pay for it. Based on new institutional economics and game theory, authors of GPG concept analyze the incentives and conditions to booster international cooperation.

Notwithstanding this, the important shortcomings faced by the concept of GPGs which will be further discussed, has motivated a more and more complex and confusing configuration of the concept. In this sense and recognizing that only a few goods qualify as purely private or purely public, GPGs’ theorists find intermediate categories of impure GPGs in the pure private-pure public continuum. Hence, impure public goods would fall into two categories; goods that are non-rivalrous in consumption but excludable are club goods and goods that are mostly non-excludable but rivalrous in consumption are common pool resources which tend to be overused in the absence of rules and binding mechanisms to regulate their use or consumption.

A new proposal on public goods defended by Inge Kaul adopts a new definition integrating three elements (the triangle of publicness); public goods have to be inclusive, i.e, individuals and groups must have access to the good (publicness in consumption); based on participatory decision-making and involvement of all major actors and stakeholders including developing countries and non-state actors (publicness in provision) and must offer a fair and meaningful deal for all (public in the distribution of benefits). Advocates of GPGs hold that providing GPGs offers important and timely suggestions on how to move in a more feasible and systematic way towards a fairer process of globalization that works in the interests of all. As we will see, this new proposal constitutes a new step forward in moving away the concept of public good from its original economic sense, thus distorting even more its meaning and scope.

One important feature to remark about the theory of GPG is the prominent role given to private actors other than governments in the provision of GPG. In this sense, the production of GPG is said to be the result of a “multi-actor” activity, involving the public at large, civil society organizations, private enterprises and the state. Also, as we will see and in order to avoid a growing concern about the possibility that GPGs would be financed by new taxes, GPGs promoters explained that financing public goods is a question of optimizing allocation of existing resources rather than raising more funds.

Is there room for Health in GPGs theory?

Most economists think that good health is not properly a GPG but a private good¹². Besides the vagueness of the concept, framing health within the category of GPGs tends to emphasize the instrumental nature of health as a condition to facilitate the globalization process, i.e., the smooth development of global capitalism and creation of a global market. In spite of the fact that some considerations are made regarding social exclusions and equity, GPGs theory under the UNDP project takes a similar approach when GPGs study comes to health. In this sense, the above mentioned UNDP project’s first book (Global public goods: International cooperation in the 21st century) considers health as an instrument at the service of capitalism and market functioning; *people and companies are more likely to invest in countries where health risks are manageable [...] Not surprisingly, a strong correlation exists between health and wealth. Creating a healthy environment, then, would seem to make good economic sense* (p. 111). In similar terms the second book when it states for example that *an educated and healthy population generates important private and public benefits. Educated people tend to be more productive and to contribute more to economic growth and development [...]* (p.85). This approach is well aligned with hegemonic actors of the new scenario such as the World Bank which makes the case that good health is critical to economic development.¹³

¹² World Health Organization. (2002). Global public goods for health: The report of working group 2 of the commission on macroeconomics and health.

¹³ World Bank. (1993). World Development Report 1993: Investing in Health. New York: Oxford University Press retrieved from <https://openknowledge.worldbank.org/handle/10986/5976>.

The above mentioned extensive publications emphasize two dimensions of health as a GPG; on the one hand, global epidemiological surveillance and the problematic raised by the reluctance of governments to report disease outbreaks and the lack of capacity of many countries to monitor public health and secondly; global non communicable diseases due to bad consumption habits which are more and more global. As part of bad global consumption habits, global tobacco control and the control of other illicit addictive substances are said to have strong public goods characteristics.

GPGs theory notes that health interdependence is deepening as result of globalization, this posing new challenges and problematic issues. As to the first challenge (global epidemiological surveillance), it is held that the increased mobility of people and goods in the world there may be increasing health risks and threats everywhere in the world. Because of that, precise and complete information about current and existing risks is of great interest and benefit to all countries and therefore international health surveillance would constitute a GPG itself since knowledge about the world's health is non-rivalrous in consumption and non-excludable. GPG theory is then devised to foster international cooperation in disease surveillance through specific proposed measures which tend to overcome the suspicion of affected countries in sharing the information and contribute to the creation of the identified GPG –affected countries would fear the negative impact of the publicity about a health outbreak in terms of faltering tourism, investments or even trade embargoes-.

As to the treatment for non-communicable diseases as a GPG, it is first assumed that it is mostly private –the risk factors associated with non-communicable diseases are often related to individual choices in lifestyle and human behavior such as diet or lack of exercise-. However, it is held that due to globalization many health threats derived from emerging infections, environmental threats and behavioral pathologies have today a planetary reach and the characteristics to become a global public bad. For instance, it is argued how consumption of tobacco (and addiction to it) is not a totally voluntary and free personal action but it is highly determined by the powerful behavioral influence of commercial advertising. Also, passive smoke is hazardous and most tobacco-related costs would be passed on to the public through medical

insurance and social security. All this -it is argued-is a strong motive to consider that global tobacco control –as well as control of illicit addictive substances facilitated by transnational shipment and money laundering- may be a global public good.

Similarly one of the most serious studies about the application of the GPG concept to the health -Global public goods for health; health economic public perspectives¹⁴- identifies three main issues related to health GPGs: (1) the control or eradication of select communicable conditions (including polio, tuberculosis, antimicrobial drug resistance), and the health consequences of a number of global environmental "bads" (such as the global climate change or the depletion of the ozone layer); (2) the importance of knowledge (including medical knowledge, genomics knowledge, or public health infrastructure and knowledge) as a critical element to improve to people's health; and (3) how to enable global public goods for health, such as international law, health regulations and financing. Interestingly for the purposes of this thesis, this study introduces knowledge in the field of health as an eventual GPG. Pharmaceuticals are mostly based on knowledge obtained through sophisticated and costly processes. Pharmaceuticals patents' subject matter is referred to knowledge, knowledge about different compounds for the treatment of diseases. In this sense, the non-rivalrous and non-excludable nature of knowledge (also the knowledge covered by IPRs) would make it *a priori* the perfect candidate to become a GPG.

GPGs and access to medicines.

However, the UNDP project did not address the access to medicines and the pharmaceuticals –the knowledge implied in it- as potential candidates to become GPGs. In general, this GPGs approach does not question the global IPRs regime. UNDP project somehow takes for granted this new regime as part of the inevitable process of globalization. Among the new economic realities caused by "global change" the mentioned seminal UNDP's first book (p. 287) expressly recognizes the link between patent protection of new technologies under trade-related Intellectual Property agreements and the fact that benefits of new technologies developed in the global

¹⁴ Woodward, David, and Nick Drager (2003). *Global public goods for health; health economic public perspectives*. Oxford: Oxford University Press.

market are unaffordable to the poor. On the contrary, IPRs and pharmaceutical patents are even seen as a safeguard for the provision of knowledge as a public good¹⁵.

Therefore, GPG theory takes for granted the “propertization” of knowledge in the form of IPRs and patents. GPG theorists keep a favorable view about the IPRs regime as the indispensable mechanism to spur innovation in the pharmaceutical field and provide new pharmaceuticals for the society, this including people living in developing countries. It is believed somehow that innovative products developed in wealthy markets will probably later ‘trickle-down’ to the developing world. In this sense, GPGs theory would be addressed to resolve and alleviate the failures/shortcomings of the current system of IPRs formally reflected globally in TRIPS.

The specific consideration of medicines as GPG has been discussed in the context of the AIDS pandemic and the difficulties experienced by some countries to have access to anti-retroviral treatments. The importance of these patented medicines -in the fight against AIDS- reframed medicines from being understood as private goods to eventual GPG¹⁶. The fact that AIDS also affected developed world, and in particular, a social sector with deep links with media –artistic and gay communities- probably facilitated a worldwide solidarity and political mobilization regarding the rights of developing countries to access generic versions of costly, patented antiretroviral drugs to treat HIV/AIDS¹⁷.

Notwithstanding that, and taking into account that GPG theory takes for granted and does not question the IPRs regime as a valid tool to foster innovation and new medicines, the emphasis of GPG theorists in the pharmaceutical field has been centered around its financing; who pays what and for whom. In this sense, a special focus has been placed on the underfunding of the so-called “neglected diseases” that

¹⁵ Brandi, C. (2010). Intellectual property rights as a challenge to providing global public goods: the cases of public health, food security and climate stability.

¹⁶ Moon, S. (2009). Medicines as global public goods: The governance of technological innovation in the new era of global health. *Glob Health Gov*, 2(2), 70.

¹⁷ t Hoen, E. F. (2009). The global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and public health. *AMB*.

predominantly affected poor populations. In effect, it is acknowledged that the current regime and dominant institutional arrangements for the development of new medicines, in which the market fixes research priorities, lead to underfinance R&D investments in neglected diseases. According to the Global Forum for Health Research, 10/90 Report on Health Research reflects that only 10 percent of the world's R&D dollars are addressed to improve health conditions affecting 90 percent of the population. This reality was considered to be an unethical imbalance that needed to be corrected¹⁸. This concern is said to be justified and coherent with GPG new paradigm of global health which deals with the health needs of the people of the whole planet versus national health and international health which is predominantly focused on the control of epidemics across the boundaries between nations¹⁹.

In this respect, GPG's characterization of governance and global health fits well into the previously analyzed Public-Private Partnerships (PPPs) previously analyzed in chapter 2 and their role regarding neglected diseases where public administrations partner with private agents such as companies, corporations and non-governmental organizations to develop new tools for health needs specific to the developing world.

The new PPPs are viewed as a new instrument to cope with shortcomings of the existing regime of IPRs²⁰. While respecting the current IPRs regime, PPPs would be then the response to the new challenges posed by the globalization process in the sense that PPPs would work for the provision of GPGs by investing in medicines for neglected diseases; by making them affordable for all and; by mobilizing public and private expertise and resources. Among diverse PPPs - Bill & Melinda Gates Foundation, Medicines for Malaria Venture (MMV, 1999), Global Alliance for TB Drug Development (2000), Institute for OneWorld Health (IOWH, 2001), the Drugs for Neglected Diseases Initiative (DNDi, 2001), the Foundation for Innovative Diagnostics (FIND, 2003) - it is very illustrative of this new thinking the Malaria Vaccine Initiative (MVI, 1999), which purports to achieve the vaccine against malaria which must

¹⁸ Global Forum for Health Research (Organization). (2002). *The 10/90 Report on Health Research, 2001-2002*. Global Forum for Health Research.

¹⁹ Brown, T. M., Cueto, M., & Fee, E. (2006). The World Health Organization and the transition from "international" to "global" public health. *American journal of public health, 96*(1), 62-72.

²⁰ Sandler, T., Arce, M., & Daniel, G. (2002). A conceptual framework for understanding global and transnational public goods for health. *Fiscal Studies, 23*(2), 195-222.

ensure that malaria vaccines are not only available but also affordable. To achieve this goal, MVI make a call to international donors, agents of the industry, government, national, regional, and international policymakers and academia to invest their resources and political and intellectual capital for malaria vaccine delivery and use²¹.

Following this scheme, the private sector would be in charge of developing new pharmaceuticals for diseases that affect the developed world, funded by a combination of public support for basic research and monopoly profits from sales of patented medicines and PPPs would undertake the responsibility of combatting the neglected diseases for which market mechanisms had failed to attract sufficient investment, and must be financed by philanthropists and donor governments. However, as we have previously seen, PPPs have raised numerous concerns regarding its sustainability along time due to its donor-dependent nature; its obscure and opaque governance mechanism, lack of representation and participation of southern stakeholders and the management of its conflicts of interest – how priorities are set, allocation of resources - or distortion of public systems of health of the countries where PPPs operate. Ultimately, PPPs may be reinforcing existing power and decision-making imbalances rather than advancing true global cooperation²².

Furthermore, PPPs may be at best, a helpful instrument to cope with the problems rising around neglected diseases but there remain still for developing countries, the serious problems associated with the access and affordability of pharmaceuticals for diseases affecting both north and south. Pharmaceutical companies are willing to contribute with PPPs in combatting neglected diseases as this contribution may give them a more friendly and kind commercial image before their customers with no cost in terms of loss of profits, competitive advantage or disclosure of relevant and confidential information.

However, pharmaceutical companies are significantly more reluctant to cooperate where sizable profits are at stake. In this sense, we will be in front of the typical case described by GPGs theory; considering pharmaceuticals as GPGs, we could see how

²¹ <http://www.malariavaccine.org/malaria-and-vaccines/access/financing>

²² Soane, J. (2010). Health for Some: The Political Economy of Global Health Governance.

these public goods are undersupplied by the market because there is no commercial incentive to produce them. Also, it would be necessary to deal with the classic economic problem with public goods: underinvestment and free-riding and how this lack of investment and incentive would require public provision or financing. GPGs theorists face then the challenge of determining who should pay for the affordable provision of patented medicines. Apart from vague calls to collective action of international actors and new governance arrangements, as we will see below GPGs does not seem to be able to articulate any formula to resolve the problem of ensuring universal affordability of pharmaceuticals or how to share the burden of pharmaceutical research alternative funding.

5.2. Access to medicines as a GPG: not good enough?

As we have seen, the concept and the theory of GPG to the international relations realm has been originated and advanced by the UNDP –the team composed of Professor Inge Kaul and her collaborators- and it has been resulted in three books. Borrowing the notion from the public economics literature, GPG theory proposes a model to cope with certain international problems resulting from the globalization of many realities and processes and whose resolution goes beyond national boundaries. GPGs have been used to describe almost every international progress from peace, knowledge, financial stability, global environment or security; in positive terms (something that has to be created such as knowledge) and negative (the absence of something such as terrorism). The same UNDP team has proposed more and more complex version of GPGs referring to pure GPG, impure GPGs, club goods (those goods that having non-rival properties are however excludable such as that knowledge subject to IPRs protection), global, regional and national public goods and some initially private goods which become public.

Ultimately, GPGs is addressed to deal with the traditional problem of international cooperation, i.e. collective action problems at the international level, and the free rider challenge. While nation states have sufficient prerogatives and powers (taxing powers and the monopoly of the use of force) to produce public goods which are not created by the market, GPGs production is argued to be dependent upon cooperation among nation states and other actors. However this cooperation is far from being easy to implement. On the one hand, it would be necessary to share mutual interests and understandings – neither nation-state nor other actors will contribute to the provision of GPGs if they do not get any benefit – and there is always the risk that no one would cooperate if they can free ride on the investment of others. Therefore GPGs theory comes to deal with old acquaintances in the realm of international relations. As to health and access to medicines, GPGs theory does not address this issue from an integral perspective, it conceives health as an instrumental element to permit and optimize market functioning. Among its recipes, GPGs theory entrusts the problem of the access to medicines to PPPs, a previously overviewed formula which casts a large shadow over its real benefits and which has been critically contested.

Dispersed nature of the concept.

In spite of the initial enthusiasm and strong advocacy generated, GPGs proposal has received a number of important critiques. One of those critiques, which have been in fact acknowledged by the theory sponsors themselves – who have tried to reorient some of the characterizations and scope of the concept – , are referred to the dispersed, expansive nature and lack of concreteness of the concept. In effect, such expanded definition of what it is a GPG risks making the concept subject to arbitrariness, distortion, malleability and somehow, irrelevance. Some of the most severe critics of GPG theory argue that GPGs are better understood as a rhetorical device than as an analytical tool²³. In fact, in 2003 the authors of the seminal book on GPGs released a second book on GPGs in response precisely to the fuzziness of the concept.

GPGs are an umbrella, a catch-all concept under which a diverse and sometimes contradictory number of issues (clean air, health, knowledge, education, absence of terrorism, property, peace, security, financial stability ...) ²⁴ fit in an idealistic, certainly naïf and politically correct manner. The comprehensive nature of the term is made possible due to the abstraction of the concept. The persistent abstraction of the concept avoids systematically the complexity of the real issues as long as the operational aspects of the political solutions and measures to be adopted in order to implement this open “wish list”. Saying that health or knowledge or financial stability are GPGs does not seem to add anything new. The real challenge is precisely the manner in which those GPGs can be achieved and how to manage the different conflicts of interest around the different choices. As we go down to the ground we can see that ensuring health or good education for everybody depends on how we manage material resources that are not unlimited but rival and excludable. This is precisely the challenge it has to be dealt with and for which GPGs theory does not seem to have any specific remedy. As it has been observed by some scholars, the

²³ Long, D., & Woolley, F. (2009). Global public goods: Critique of a UN discourse. *Global Governance: A Review of Multilateralism and International Organizations*, 15(1), 107-122.

²⁴ In the previously mentioned first UNPD book *Global Public Goods: International Cooperation in the 21st century* the following cases are studied as GPGs: equity and justice, market efficiency, environment and cultural heritage, health, knowledge and information, peace and security.

urgency to demonstrate the utility and applicability of this concept has transformed a rigorous and restrictive concept into a slogan and a product of wishful thinking²⁵.

Also, much of GPGs theory is just descriptive or explanatory of certain realities but it does not prescribe the ways to achieve those tangible outcomes, situations or GPGs. Nothing is said about how to finance and materialize these GPGs. Except for vague references to the need of an adequate allocation of resources –public and private- or the obvious consideration of the production and financing of GPGs as the result of a “highly political process” GPGs theory does not give any new formula or mechanism to finance and produce GPGs so the most important questions about financial aspects and how to produce GPGs at global scale remain too open and unanswered.

Regarding health, as we have seen, while the UNDP explicitly addresses the strategies devoted to monitor and control and restrain cross-border spread of communicable diseases. Paradoxically nothing is said in the PNUD project about access to medicines which seem to be the indispensable instrument to combat both communicable and non-communicable diseases. Subsequent academic constructions of GPGs have explored the possibility of considering pharmaceuticals and access to medicines as GPGs and the public-private partnerships as an example of new formulae to ensure the provision of GPGs – in particular, to get the necessary investments to develop pharmaceuticals to combat the “neglected diseases”. However, as we have suggested regarding PPPs, the perspective on health of GPGs and in particular, the approach to pharmaceuticals and access to medicines tends to hide the conflicts and interests at stake surrounding access to medicines and the pharmaceutical business. In this sense, GPGs ignores the complexity of health and all the factors and conflicts of interests involved.

²⁵ Carbone, M. (2007). Supporting or resisting global public goods? The policy dimension of a contested concept. *Global Governance: A Review of Multilateralism and International Organizations*, 13(2), 179-198.

GPGs as a rhetoric device justifying a hegemonic discourse.

As we have mentioned, GPGs theory has been criticized as being a rhetorical device rather than an analytical, scientific, helpful tool. On the one hand, an excessive dispersion and abstraction of the concept of GPGs does not bring any input – or little input – to cope with the main challenges of today’s world and international scene. On the other hand, GPGs do not enter the details and the operational aspects necessary to achieve certain outcomes under the term GPGs. Neither does it handle some of the contradictions implied in the conceptualization of different GPGs whose materialization could happen not to be compatible.

Therefore, the validity of GPGs as an analytical or scientific tool remains highly controversial and its contribution to improve today’s challenges and conditions, almost null or non-existing. In this sense, GPGs theory has been said to belong to the realm of the family of *political manifestos* rather than being a tool for serious analytical research. However, what it seems clear is that GPG theory could play an important discursive role in legitimizing the current and hegemonic system of values and interests. In fact, GPGs theory is committed to the stability of the system and consequently –as we have seen with the IPRs regime- it does not question the status quo or the structural causes and forces behind it²⁶. Under this perspective, GPGs theory is everything but new and it could be adequately explained and framed within the theory of hegemonic stability of Kindleberger²⁷.

Charles Kindleberger links the “stability” of the world economy to unilateral leadership – a gentle way of talking about hegemony – of a dominant power. Based on this theory, it is explained how the hegemon or hegemons would be willing to provide GPGs²⁸. This willingness is far from being an altruistic gesture, on the contrary, the hegemon benefits greatly from a well-ordered system and the cost of supplying them born by the hegemon is less than the benefit obtained in terms of influence, privileges

²⁶ Constantin, François. (2002). *Les biens publics mondiaux: un mythe légitimateur pour l'action collective?*. Editions L'Harmattan.

²⁷ Kindleberger, C. P. (1986). *The world in depression, 1929-1939* (Vol. 4). Univ of California Press.

²⁸ Haggard, S., & Simmons, B. A. (1987). Theories of international regimes. *International organization*, 41(03), 491-517.

and advantages associated with providing the others with certain GPGs. That hegemon or hegemony – some authors argue that there may be more than a single leader sharing hegemony²⁹- would be also able to articulate a unifying ideology which presents itself as universal and creates the basis for hegemonic domination.

Furthermore, it is important to note that it is not usual that hegemony provide pure public goods, in the sense of being unconditionally non-rival and non-excludable but most regimes put in place mechanisms to enhance and ensure compliance through exclusion – especially in the WTO and to a lesser extent in the European Union -. As examples of these “carrot and stick” mechanisms would be precisely the WTO promise of free trade and open markets without barriers to agricultural products as long as every country accepts the adherence and implementation of a given – demanding- IPRs regime, or the commitment of developed countries with technological assistance and technological transfer to developing countries in exchange for adherence to non-proliferation agreements or, finally the grant of European Structural Funds to peripheral Europe associated with budgetary austerity of southern governments.

By hegemony at the international level we do not refer merely to an order among states or a state centered hegemony. Following Robert Cox³⁰, we hold that state power and apparent hegemony states are instrumental to other interests and they are controlled by certain dominant classes and dominant modes of production. This dominant mode of production penetrates into all countries connecting social classes and interests of different countries. Additionally, this hegemony implies the consent of other controlled classes which accept that control/domination not only through coercive methods but also by means of intellectual leadership and other softer and subtle methods (the *extended state* in Gramscian terms). This hegemony, furthermore, is reflected in universal norms, institutions and mechanisms which lay down general rules of behavior for states and for those forces of civil society that act across national

²⁹ Lake, D. A. (1993). Leadership, hegemony, and the international economy: Naked emperor or tattered monarch with potential?. *International Studies Quarterly*, 37(4), 459-489.

³⁰ Cox, R. W., & Sinclair, T. J. (1996). *Approaches to world order*. Cambridge: Cambridge University Press.

boundaries, rules which support the dominant mode of production³¹. Therefore, hegemony is related to and framed within the international capitalist system rather than within the world political system of national states.

In this sense, GPGs approach to health in general and to the access to medicines in particular fits to perfection into the dominant and hegemonic view of pharmaceuticals and pharmaceutical knowledge as marketable commodities worldwide. This has been made possible thanks to the invaluable and indispensable assistance of the global IPRs regime without which, there would not have been a global market for these intangibles. As we have previously seen regarding the prelude to TRIPS, this scenario has been spurred and realized by powerful transnational corporations which illustrate, maybe in one of the crudest and least subtle example of the last decades, the influence of corporate lobbies over the government and the servile stance of states at the service of corporate interests, interest which sometimes seem to be far from people necessities.

Distributive consequences of GPGs theory.

Closely related to the above, it is necessary to highlight that GPG theory has important distributive consequences in terms of winners and losers. These distributive consequences are somehow disguised in the overarching approach made by its proponents in the academic debate. The distributive impact or consequences of GPGs may be distinguished in three dimensions³²; 1) regarding the terms of cooperation and contribution to produce the GPGs; 2) the choice to produce some GPGs over others in a world of limited resources and; 3) conflict among different GPGs which may turn to be contradictory.

Regarding the first dimension (terms of cooperation); as we have said, GPGs theory is focused on articulating cooperation between different international actors –states

³¹ Cox, R. W. (1983). Gramsci, hegemony and international relations: an essay in method. *Millennium*, 12(2), 162-175.

³² Shaffer, G. (2012). International law and global public goods in a legal pluralist world. *European journal of international law*, 23(3), 669-693.

and other private entities- to produce GPGs. This cooperation is mostly based on the premises of the prisoner's dilemma adopted from game theory. Prisoner's dilemma does not consider eventual distributive consequences of the different choices; it takes for granted that states share a common interest which is more easily reachable if they cooperate, being the first barrier to cooperation the fear to be cheated by others. However the prisoner dilemma's approach ignores the distributive nuances of the choices adopted and the terms implied in the cooperation terms; distribution of costs and benefits resulting from cooperation³³. In fact, when states cooperate, they do not decide in binary terms: cooperation or lack of cooperation but they arrange and negotiate specific terms of cooperation which imply different distributive issues on how much each one must contribute and how many rewards is entitled to receive.

Secondly, actors often have different preferences about which GPGs should be produced in a world of limited resources. They face opportunity costs and they may decide not only which GPGs to produce or which production they are able to contribute to but also how much and to which extent they are ready to contribute or to fund in order to provide a given GPG.

Finally, different GPGs can be contradictory and they may conflict with each other. Account taken of the diversity of the outcomes to be produced as GPGs it turns unavoidable to find GPGs which interfere at best with each other and which may be incompatible and contradictory. For instance, as we have previously suggested, in the field of the access to medicines, there may be involved many GPGs such as public health, patent protection, free knowledge, human rights, free trade and so on. Production of all these goods may conflict irremediably. Enforcement of patent rights under TRIPS can constitute incentives for the production of new knowledge in the form of new pharmaceuticals and therapeutic treatments but this protection can impair access to medicines and human rights to health as long as distorting liberalized trade.

³³ Krasner, S. D. (1991). Global communications and national power: Life on the Pareto frontier. *World politics*, 43(03), 336-366. Krasner explains how cooperation have distributive consequences. In the context of cooperation in the field of telecommunication, allocation of electromagnetic spectrum, he notes that while all the actors are better off with some form of cooperation, coordination affects them differently in terms of distribution of rewards. This different distribution may make conflicts arise over how and why that distribution is operated.

Therefore, GPGs dynamics is somehow oversimplified, GPGs have important distributive consequences that have not been properly reviewed or studied. Choices over GPGs involve the prioritizing of certain values and interests over other legitimate interests and perspectives. Therefore and even if within the definition of GPGs we can find the non-rivalry and the non-excludability, GPGs may be rivalrous between them and conflicts may arise over which GPGs produce, how much contribute for their production and how many rewards each actor or state is entitled to.

GPGs recent historical survey.

Other than the above mentioned conceptual shortcomings and ideological bias, it is important to examine the reception and practical utility and implementation of GPGs theory along these recent years. That will permit us to assess the real and effective impact of this theory and the perspective of its future application and feasibility.

Following the first publication in 1999 of the UNDP of the GPGs project, this concept has imbued a large part of the debate on international development and in general on globalization –and the possibility that an adequate provision of GPGs could help to overcome the negative impact of some consequences of globalization-. Both international organizations –UNDP, World Bank or the Organization for the Economic Coordination and Development (OECD)- states (EU, Germany, France, Sweden ...) and philanthropic associations and foundations (Melinda Gates or Soros Foundation) have resorted to the discourse of GPGs. Notwithstanding that, GPGs concept as an instrument to transform the reality of our world has become irrelevant in the international arena and it could be at best, a rhetoric device to *post* support and justify realities, facts and policies from a specific perspective.

The first problem to begin with regarding the application of this concept was related with the “additionality” question or how the provision of these GPGs should be financed. Countries in the developing world had concerns on the possibility that the

so called Official Development Assistance (ODA) -the government economic aid of developed countries designed to promote the development and welfare of developing countries- was diverted to the provision of GPGs. According to some, this was not a question of diverting funds from ODA to a different purpose since donors had allocated for decades some of the substantial quantities of ODA to finance public goods such as international agricultural research or research on disease eradication, even without the explicit conceptual frame of GPGs³⁴. Other analysts considered that an important part of that aid, ODA, was being diverted to GPGs provision and that this aid should not be used for financing eventual GPGs³⁵.

Other GPGs researchers explored the possibility of raising new financial resources to finance GPGs³⁶ mooted as alternatives or supplements to a simple schedule of governmental contributions: use of IMF Special Drawing Rights (SDRs); globally coordinated taxes (on arms exports, deep-ocean mineral rents, international air transport, greenhouse-gas emissions, consumption of fossil fuels or currency transactions –Tobin tax-). Apart from the controversial EU financial transaction tax (EU FTT) a proposal made by the European Commission and embraced by 10 EU member states³⁷, those FTTs enacted in Brazil, South Korea and India and Bernie Sanders’ proposal³⁸ of a FTT as part of his campaign for the Democratic Party’s presidential nomination, none of the alternative ways of financing GPGs seem to have been implemented on a large scale. On the other hand, the UNDP held that financing GPGs did not mean raising additional resources but a better allocation of existing resources.

Furthermore, attempts to include GPGs in the international multilateral agenda met with an important resistance from both developing and developed countries. In the preparatory process of the Financing for Development (FfD) Conference of Monterrey

³⁴ Te Velde, D. W., Morrissey, O., & Hewitt, A. (2002). Allocating aid to international public goods. In *International Public Goods* (pp. 119-156). Springer US.

³⁵ Anand, P. B. (2004). Financing the provision of global public goods. *The World Economy*, 27(2), 215-237.

³⁶ Clunies-Ross, A. (2004). Alternative ways of paying for global public goods. *Journal of International Development*, 16(7), 971-982.

³⁷ The tax would only impact financial transactions between financial institutions charging 0.1% against the exchange of shares and bonds and 0.01% across derivative contracts.

³⁸ <https://berniesanders.com/issues/reforming-wall-street/>. His campaign proposed a financial transaction tax to reduce risky and unproductive high-speed trading and other forms of Wall Street speculation; proceeds would be used to provide debt-free public college education.

in 2002 and after an intense controversy preceded by a report –the Zedillo report which explicitly contemplated the necessity of the provision of GPGs and a first economic assessment-³⁹, all reference to GPGs concept was excluded from the final papers and resolutions (Monterrey consensus). In spite of the support of GPGs by some prominent American analysts⁴⁰ –aligned with the hegemonic stability theory- US and Japan strongly opposed to this concept questioning economic and political foundation of GPGs. In particular, they were not in favor of exploring any additional international taxes, levies or user fees to finance provision of GPGs. The final consensus reflected their views in favor of international trade as an engine from development, FDI and traditional international financial and technical cooperation for development⁴¹.

On the other hand and account taken of the uncertainty about additional resources to finance GPGs, developing countries feared that this concept could divert funds from ODA to the provision of these intangibles which additionally could be not based on recipient’s needs. On the contrary, GPGs framework was perceived by some as a new subtle form of conditionality, nothing more than another imposition by the North to the South which implied a soft alternative to the neoliberal approach to development.

After the new opposition faced by GPGs supporters in the World Summit on Sustainable Development Johannesburg, South Africa of 2002, an International Task Force on GPGs was established in 2003 by France and Sweden with the support of the UNDP, and other EU Member states (namely Germany, Denmark and Austria) and a permanent Secretary in Stockholm. This initiative reached a consensus on the definition and a list of six priority areas –among which the control of communicable diseases by increasing knowledge for vaccines and treatment-. In 2006, a first document was published with some suggestions on new policies and financing instruments of GPGs. However, these efforts were overlapped and diluted by other

³⁹ Assembly, UN General. Fifty-fifth session. High-level international intergovernmental consideration of financing for development.(agenda item 101) Report of the High Level Panel on Financing for Development. A/55/1000.

⁴⁰ Nye Jr, J. S. (2002). The American national interest and global public goods. *International Affairs*, 78(2), 233-244.

⁴¹ UN A/CONF.198/11. Report of the International Conference on Financing for Development, Monterrey, Mexico 18-22 March 2002.

events, approaches and initiatives of the international agenda which somehow attracted more attention and consensus. The best evidence of this and of the abandonment of GPGs concept is that the web page of its main supporter⁴² -- is no longer operative.

Once analyzed the conceptual and practical reasons to show the failure of GPGs concept as a device to help solving some of the current challenges of our time, in particular the worldwide access to medicines, one could wonder whether GPGs could at best offer guidance in the financing and provision of global health programs by providing with a framework for collective action at the global level and by demonstrating the advantages for the rich in helping the poor as long as providing a rationale for industrialized countries to use national health budgets to complement traditional aid as it is suggested by the WHO⁴³.

⁴² www.gpdtaskforce.org

⁴³ Smith, Richard D. (2003). *Global public goods and health*. Bulletin of the World Health Organization 81.7: 475-475.

5.3. Global Public Interest overcoming state borders.

In this section we will review the scope and the meaning of public interest and other associated institutions such as public policy, or *ordre public*. In this sense, it is important for the purposes of this thesis to learn the role of these figures as legal mechanisms to offset and counterbalance what it would be unwanted consequences of an eventual “rigorous and ruthless” application of global IPRs norms. In particular, it will be examined the possibility of using these figures as exceptions to the application of IPR norms or juridical defences to be raised in the context of a litigation for IPRs breach, for instance, infringement of a pharmaceutical patent. Also, it will be analyzed whether there is an international dimension of these traditionally national figures and the feasibility and potential of these figures in order to transform the current IPRs regime.

Public interest between politics and the law.

On the occasion of the transition from a political regime based on the sovereignty of the states to the multilateral and multilayered new global architecture -still in process of definition-, a renewed interest has emerged around the concept of public interest and global public interest as a figure to articulate conveniently the perceived melting between previously well separate public and private spheres. Public interest is a recurrent term which is profusely used in a wide variety of contexts. In this sense, and in order to achieve a more integral insight of what public interest implies, we must consider this concept from a threefold perspective; a formal-legal dimension, i.e., the way in which public interest has been defined from the different legal traditions and legal practitioners; a pragmatic-discursive dimension or the contextual interpretations given to the term “public interest” from the different disciplines of knowledge and; a historic-critical approach to the public interest which will permit us to achieve a more precise and historically contextualized meaning and effective/real

use of this concept along the diverse political transformations of our world⁴⁴ –this third dimension will be addressed in the following section-.

Starting from the formal-legal dimension, public interest belongs to the realm of indeterminate legal terms. Despite its ubiquitous nature in political philosophy, economics or legal literature (public law but not only), and the numerous attempts to define this term, there is not a precise and concise definition of it. Public interest is an elusive concept, an ambiguous and fluid term with multiple connotations which mostly accompanies and confers legitimacy to a given political or judicial decision. In this sense, legislators, public agencies and law courts take recourse in the term “public interest” as an argument for justifying certain actions and decisions but there are not true efforts to define the term exhaustively. Some scholars consider that rather than indeterminate, public interest would be an abstract institution which only attains determinateness when is juxtaposed with a specific legal rule or decision⁴⁵. Hence, the notion of public interest would be a deontological rather than an ontological concept, a normative rather than a descriptive one. Ultimately, it is a counterfactual construction such as Habermas’ ideal speech situation. Also, according to some Administrative Law scholars, indeterminate legal terms are not that indeterminate but they would have a “sphere of positive certainty” (what is certain to be), a “sphere of negative certainty” (what is certain not to be) and a “halo of doubt and uncertainty”⁴⁶.

Despite the difficulty, probably insurmountable, of establishing a specific, concrete, steady and objective definition of the contours of the public interest, this notion gathers some specific features. First, it denotes an interest of the society as a whole. In this sense, public interest is something else than the mere aggregation of individual interests or social factions, it should be “generalizable” to the whole society. Hence, public interest is not the interest of a majority of members of the public but an

⁴⁴ Cornago, N. (2013). De la filosofía política a la gobernanza global: un acercamiento crítico a la noción de <interés público global>, Bouza, N, García-Segura, C. Rodrigo,A, eds *La gobernanza global del interés público global*. Madrid: Tecnos.

⁴⁵ Belohlavek, Alexander J. (2012). *Public Policy and Public Interest in International Law and EU Law*. CYIL-CZECH YEARBOOK OF INTERNATIONAL LAW: Public Policy and Ordre Public: 117-147.

⁴⁶ Moreno, F. S. (1976). *Conceptos jurídicos, interpretación y discrecionalidad administrativa*. Madrid: Editorial Civitas.

abstraction about what is best for the society as a whole⁴⁷. Upon the fiction that the common interest of society can be discernable and identifiable, public interest would benefit every citizen by giving priority to the “common good”. As it happens with other counterfactual constructions (for instance, the previously analyzed legitimacy), it is easier to detect when the ideal is not realized than defining it in a specific manner. Hence, the public interest is often defined “ex negativo”, i.e. by identifying interpretations, decisions or application of the concept that are not in the interest of the society as a whole⁴⁸.

Furthermore, and in order to approach conveniently to the meaning of the notion of global public interest, it is important to be aware of the somehow different significance that this term has in the different legal traditions; Civil/Continental law and Common law systems. While Continental law emphasizes the role of the state in protecting the public interest and it provides civil servants of the public administration with the power to enforce their decisions considered to be in the common interest, the definition of public interest in Common law jurisdictions encompass not only governmental matters but also private conduct that impacts a broad segment of society and/or that affects a community in a manner similar to that of a governmental entity⁴⁹. These different approaches to the notion of public interest are grounded on the historical experience and perceptions of the public and private realms. In this sense, and in reaction to totalitarianism after World War II, any substantive conception of public interest in the common law system was suspicious

⁴⁷ Cox, JW Roxbee. (1973). The appeal to the public interest. *British Journal of Political Science* 3.02: 229-241.

⁴⁸ Steffek, Jens. (2015). The output legitimacy of international organizations and the global public interest. *International Theory* 7.2: 263-293.

⁴⁹ *Damon v. Ocean Hills Journalism Club*, 102 Cal. Rptr. 2d 205, 85 Cal. App. 4th 468, 85 Cal. 4th 468 (Ct. App. 2000) stated the following: “The definition of “public interest” within the meaning of the anti-SLAPP statute has been broadly construed to include not only governmental matters, but also private conduct that impacts a broad segment of society and/or that affects a community in a manner similar to that of a governmental entity. (See *Macias v. Hartwell*, supra, 55 Cal.App.4th at p. 674, 64 Cal.Rptr.2d 222; *Church of Scientology v. Wollersheim* (1996) 42 Cal.App.4th 628, 650-651, 49 Cal.Rptr.2d 620.)” “Matters of public interest . . . include activities that involve private persons and entities, especially when a large, powerful organization may impact the lives of many individuals.” (*Macias v. Hartwell*, supra, 55 Cal. App.4th at p. 674, 64 Cal.Rptr.2d 222.) In *Macias*, the court found that campaign statements made during a union election constituted a “public” issue because the statements affected 10,000 union members and concerned a fundamental political matter—the qualifications of a candidate to run for office. (Id. at pp. 673-674, 64 Cal.Rptr.2d 222.)” A strategic lawsuit against public participation (SLAPP) is a lawsuit that is intended to censor, intimidate, and silence critics by burdening them with the cost of a legal defense until they abandon their criticism or opposition. Such lawsuits have been made illegal in many jurisdictions on the grounds that they impede freedom of speech.

of opening the door to totalitarianism so that the idea of public interest came to be formulated in the purely proceduralist terms of interest-group no matter what the substantial outcome be⁵⁰.

The resort to the public interest is materialized in various and different legal contexts in both Continental and Common Law systems; first, some Administrative Lawyers and scholars of Administrative law note that this indeterminate legal concept is a tool to reduce the margin of discretion of public administration and government agencies which, following the public interest mandate, would be obliged to act upon the premises of justice and reasonableness⁵¹; Another way of using public interest – specially in Continental law systems an European Union law and the European Convention on Human Rights (ECHR)- is in relation with some limitations on individual's rights where there is a "public interest" justification for doing so. Such justifications are often raised in the context of the processes of compulsory expropriation where public interest provides meaning and significance to the main ground of "*causa expropriandi*" necessary to effect the expropriation. Hence, public interest would be a legal limitation on the absolute right to property⁵².

Also, ECHR sets forth that individual's rights are not necessarily absolute and it is permissible, in some circumstances, for States to place limitations on an individual's rights where there is a "public interest" justification for doing so (article 2.4 of the Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms securing certain rights and freedoms other than those already included in the Convention and in the First Protocol thereto).

On the other hand, legislation often uses the term "public interest" by requiring a named decision-maker to take decisions in the light of "the public interest". Those

⁵⁰ For a more extended review of the historical evolution of this, see Horwitz, M. J. (1982). The history of the public/private distinction. *University of Pennsylvania Law Review*, 130(6), 1423-1428.

⁵¹ García de Enterría, E. (1962). La lucha contra las inmunidades del Poder en el derecho administrativo (Poderes discrecionales, poderes de gobierno, poderes normativos). *Revista de Administración pública*, 13(38), 159-205.

⁵² Sentencia del Tribunal Constitucional. STC 48/2005, de 3 de marzo de 2005. Cuestión de inconstitucionalidad 48/1998 Planteada por la Sala de lo Contencioso-Administrativo del Tribunal Superior de Justicia de Canarias en relación con la Ley del Parlamento de Canarias 2/1992 de 26 de junio, sobre declaración de utilidad pública de la expropiación forzosa de varios edificios en Santa Cruz de Tenerife para proceder a la ampliación de la sede del Parlamento.

appeals are frequently made with regard to certain types of information which are subject to a “public interest” test; that is, the public authority that holds the information must decide whether or not the “public interest” favors disclosure of the information to an individual who is requesting it. In the event that the authority concludes that the information should not be disclosed, the individual may challenge that decision before law courts in order that the judiciary determines whether, as a matter of law, the “public interest” requires disclosure.

Other than appeals to the “public interest”, a new practice of law has emerged around the concept of public interest in some Common law systems which may be helpful for us to better define or approach to this indeterminate legal term “Public Interest Law”. It is not a body of law or a legal field, the definition of public interest law would be referred to a practice of law whose distinctiveness comes from the clientele public law lawyers represent. Instead of serving powerful economic interests, it stands for the advocacy of otherwise under-represented or vulnerable individuals, especially those living in poverty. This new practice of law has been called public interest law. In the US public interest law traces its origins to the Civil Rights Movement of the 1960s –some of them rallied behind Reverend Martin Luther king’s “dream”- when an increasing number of American law school graduates began to seek social “relevance” in their work and a positive impact on the social issues that were debated within American society at that time. They defined themselves as public interest lawyers in order to distinguish themselves from “corporate attorneys”. As it has been noted by some, these original premises and purposes have moved toward a procedural definition of “public interest law” as representation of the unrepresented and underrepresented⁵³, this –the prevalence of procedural terms rather than the achievement of substantial targets- being the cause of an eventual crisis of public interest law.

Even if public interest law does not encompass a different body of law or an accurate definition of public interest, this perspective has permeated the performance of the three branches of the state in the US. One example is the creation in some

⁵³ Esquivel, D. R. (1996). The identity crisis in public interest law. *Duke Law Journal*, 46(2), 327-351.

jurisdictions of departments of the Public Advocate in States⁵⁴ or its judicial recognition which contributes to confer it an autonomous and meaningful entity and reality. As an illustrative example of this, the Court in *Mt. Laurel Tp. v. Dept. of Public Advocate of NJ* noted that “[...] *The practice of public interest law is a much needed catalyst in our legal system. It helps to create a balance of economic and social interests and to assure that all interests have a fair chance to be heard with the help of an attorney. Public interest lawyers today provide representation to a broad range of relatively powerless minorities — for example, the mentally ill, children, and the poor of all races. They also represent neglected but widely diffuse interests that most of us share as consumers and as individuals in need of privacy and a healthy environment. [Marshall, "Financing Public Interest Law Practice: The Role of the Organized Bar]" The vital need to hold the government accountable to those it serves and the need to provide legal voices for those muted by poverty and political impotence cannot be overemphasized. The Public Advocate goes far toward satisfying these needs, thereby nourishing and revitalizing our political system. The legislative definition of "public interest" constitutes a realistic attempt to create an effective advocate for the general public [...]*”⁵⁵

Similarly to “public interest law” in the US, and in an effort to recapture its legitimacy during the 1970s⁵⁶, Indian judiciary has developed a judicial mechanism known as Public Interest Litigation (PIL) which purports to protect the rights of India’s impoverished and disadvantaged citizens and through which law courts may assume a more legislative role in enforcing rights by issuing writs of mandamus that force the government to pass legislation dealing with rights disparities. PIL invokes the Constitution, in particular article 21 (*No person shall be deprived of his life or personal liberty except according to procedure established by law*) in order to enforce various socioeconomic rights such as rights to education, clean air, food and clothing⁵⁷.

⁵⁴ Schraub, J. J. (1975). Office of Public Counsel: Institutionalizing Public Interest Representation in State Government, *The Geo. LJ*, 64, 895.

⁵⁵ *Mt. Laurel Tp. v. DEPT. OF PUBLIC ADVOCATE OF NJ*, 416 A.2d 886, 83 N.J. 522 (1980).

⁵⁶ During the historical period known as the Emergency Period (June 25, 1975 to March 21, 1977), Minister Indira Gandhi—the daughter of India’s first prime minister, suspended elections and civil liberties in response to great political instability. Many citizens were expecting the Supreme Court to intervene. The Court failed to do so and instead capitulated to Indira Gandhi’s autocratic tendencies. The Supreme Court’s expansion of locus standi, therefore, is explained by its efforts to recapture its legitimacy.

⁵⁷ Holladay, Z. (2012). Public Interest Litigation in India as a Paradigm for Developing Nations. *Indiana Journal of Global Legal Studies*, 19(2), 555-573.

Public interest is a term which has been developed, for the most part, on the level of national states. If as we have seen, the notion of public interest seems to be doomed to imprecision and ambiguity, global public interest is still more imprecise and obscure. It is certainly difficult to find studies addressing the notion of “global public interest” from a scientific perspective. As it has explained for the first time by Alfred C. Aman in 1999 during the third annual Snyder Lecture at the University of Cambridge in the Lauterpacht Center for International Research⁵⁸, the fact that national states are immersed in the globalization process and that they are themselves agents of globalization, make it necessary to identify and achieve a definition of “global public interest” which would be the result of a political discourse that going beyond national interests would seek to consider the interests of humankind, conceived of from a global point of view. This first mention and analysis of the global public interest is confined to its use into domestic law. In this sense, the author wonders whether domestic law of national states could encourage a political discourse of this kind.

More recently, an original study which seeks to include public interest considerations (especially human rights, corruption and the environment) within the realm of international investment law, defines global public interest as comprising all interests inhering *a pivotal importance for the international community* and thus bearing relevance on both the domestic and international level⁵⁹. Despite the fact that both studies mention expressly the existence of global public interest as something different to what would be national public interest, neither study really attempts to give a clear and precise definition of global public interest so that it would be reasonable to say that the “sphere of certainty” of this indeterminate legal term is that it is global, its global character and that the sphere of uncertainty of the global public interest is still greater than its national version.

⁵⁸ Aman Jr, A. C. (1999). Proposals for Reforming the Administrative Procedure Act: Globalization, Democracy and the Furtherance of a Global Public Interest. *Indiana Journal of Global Legal Studies*, 397-419.

⁵⁹ Kulick, Anthony. (2012). *Global Public Interest and International Investment law*. Cambridge, Cambridge University Press.

Global Public Interest at the service of discursive constructions in the international realm.

Even though it does not seem realistic to flesh out a scientific definition of public interest, never mind that of global public interest, it is interesting for the purposes of this dissertation to explore the discursive-pragmatic approach of the notion of public interest, the ideological and political context where the concept of public interest is framed following the different perspectives on the international order and the role of international law.

In fact, some scholars explain the indeterminacy of public interest arguing that it is an instrument to achieve certain social and political goals rather than an end in itself⁶⁰. Hence, significance and scope of public interest is and it has been shifting along time and geography –different legal traditions- from a public interest based on a metaphysical idea of natural law and the common good –and the eventual risk of interpretations which may pave the way to totalitarianism-, to a public interest which is purported to be democratically defined and legitimated to ensure the realization of a greater number of private interests –and the associated risk of the tyranny of the majority- or to a public interest which should be the result of an authentic and real deliberation which must precede the decision making about its definition and which requires every citizen to reason and to be able to distinguish between their private interests and the public interest –this is in our view the most desirable option for a real democratic and balanced definition of this indeterminate concept-. Therefore, the actual significance of this notion would be better explained by the political process and the political debate which precedes its use and its appellation rather than in the attempt to get a scientific definition of the notion.

In this sense, public interest would play different discursive/rhetoric roles following different theories or constructions of international law, international politics and international order. From liberal political premises a first approach would consider global public interest as having -in the international context between states- the same

⁶⁰ Calera, N. L. (2010, December). El interés público: entre la ideología y el derecho. In *Anales de la Cátedra Francisco Suárez* (Vol. 44, pp. 123-148).

character and the same role as public interest in domestic legal systems. This first approach is based on a conception of international law as the body of law which strikes a balance between rights and duties among States as equal and sovereign subjects of international law where the principle *pacta tertiis* -a treaty does not create either obligations or rights for a third State without its consent (Art. 34 Vienna Convention) - informs and governs international law. Based on the distinction between private and public made by domestic law, global public interest would be analogically interpreted as the figure protecting the interest of the global community that goes beyond the “particular” –private- interests of national states. Those interests would be referred to issues to which the international community as a whole should cooperatively respond. Hence, international rules embodying those issues would be creating the legal order protecting the public interests of the international community as a whole.⁶¹

In this approach to international politics as a scenario of cooperation between equal states in order to cope with eventually increasing transnational challenges, it would be included the so called “global administrative law” whose emergence is said to be *little-noticed* and factual and which would encompass various transnational systems of regulation or regulatory cooperation as result of international treaties and more informal intergovernmental networks of cooperation, shifting many regulatory decisions from the national to the global level governed by transnational administrative bodies—including international organizations and informal groups of officials—that perform administrative functions but which are not directly subject to control by national governments or domestic legal systems. Global public interest in this context would be promoted through the transparency, participation and accountability achieved by those multi-level and cooperative structures with shared responsibility in decision-making⁶².

Also, private international law or norms of conflict of laws -where concepts of public interest or public policy can impede the application of foreign law or international

⁶¹ Komori, T. (2016). *Public interest rules of international law: towards effective implementation*. Basingtoke: Routledge.

⁶² Kingsbury, Benedict, Nico Krisch, and Richard B. Stewart. (2005). The emergence of global administrative law. *Law and contemporary problems* 68.3/4: 15-61.

law- are held to play a role beyond the national borders. Thus, it would be rejected its conventional characterization as purely domestic law, it is argued instead that private international law contributes to effect an international ordering of regulatory authority in private law, structured by international principles of justice, pluralism and subsidiarity.⁶³

Another approach which has become a regular issue of debate since the turn of the 21st century has been elaborated around the concept of *global constitutionalism* as the development of certain levels of decision-making capacity beyond the state – associated with the demand for constitutional governance- and where public interest would refer to a specific type of rules. Global constitutionalism, part of larger inquiries into global governance, has raised the interest of different disciplinary perspectives such as sociology, international law or political philosophy among others. From a more classical legal doctrine and legal thought, global constitutionalism would be based on the idea of the international and institutional order as a constitutional system where a global constitutionalism is in process of creation pivoting upon *ius cogens* norms and *erga omnes* obligations that materialize universal values and somehow, hierarchically superior norms which would prevail over other international rules and norms and that would bring order to an otherwise fragmented legal order⁶⁴; by specifying hierarchy among rules, global constitutionalism would be seen then as an instrument to cope with the otherwise chaotic system full of contradictory norms, overlapping institutions and regimes and numerous conflict, thus contributing to create more certainty.

As a matter of principle and except for some scholars⁶⁵, global constitutionalism would emerge independently from a world constitutional charter expressly charged with that task (elaborate “the constitution of the world”). At the peak of these “constitutional” norms there would be the *jus cogens* norms which have been reviewed in the previous chapter. The European Court of Human Rights (ECHR) for

⁶³ Mills, A. (2009). The confluence of public and private international law: justice, pluralism and subsidiarity in the international constitutional ordering of private law. Cambridge: Cambridge University Press.

⁶⁴ Walker, N. (2008). Taking constitutionalism beyond the state. *Political Studies*, 56(3), 519-543.

⁶⁵ Fassbender, B. (1998). The United Nations Charter as constitution of the international community. *Colum. J. Transnat'l L.*, 36, 529.

example, has expressly invoked the constitutional character of the European Convention on Human Rights to justify its departure from established rules on treaty reservations⁶⁶. Some have seen in this approach of the ECHR a nascent and inspiring “cosmopolitan legal order”⁶⁷. Also in this context, they come to play what some authors have called “public interest norms”. Public interest norms are not part of the *jus cogens* category of norms, but they would have *erga omnes* effect on the ground that they serve a global public interest and so binding on all states -even without their consent-. This approach is held to purport to address the free-riders problem faced in many fields of international relations and it is also related to the provision of GPGs⁶⁸.

However, as it is noted by some scholars, the claim that constitutionalization can bring order to an otherwise highly fragmented legal order is highly controversial. That argument presupposes a broad global agreement around core values that simply does not seem to exist. In this sense, the status of a set of norms as constitutional would be a contingent social fact that rests not on textual provisions, but rather on the “Constitution’s acceptance as authoritative in the present” and on facts external to the constitution. Also, some view this defense of global constitutionalism as a political effort by specific international actors –the powerful ones-, to claim normative priority for one set of international legal norms over alternative norms⁶⁹. Also, it is questioned whether global constitutionalism does not mask the perpetuation/universalization of dominant political forms, in particular those corresponding to the liberal democratic

⁶⁶ Loizidou v. Turkey, 310 Eur. Ct. H.R. (ser. A) 23 (1995) or Kadi and Al Barakaat International Foundation v. Council and Commission, 2008 E.C.R. I. 6351 (2008) where the Court said among other things that [...] *It follows from all those considerations that the obligations imposed by an international agreement cannot have the effect of prejudicing the constitutional principles of the EC Treaty, which include the principle that all Community acts must respect fundamental rights, that respect constituting a condition of their lawfulness which it is for the Court to review in the framework of the complete system of legal remedies established by the Treaty [...]*

⁶⁷ Sweet, A. S. (2012). A cosmopolitan legal order: Constitutional pluralism and rights adjudication in Europe. *Global Constitutionalism*, 1(01), 53-90.

⁶⁸ Pauwelyn, Joost. *Conflict of norms in public international law: how WTO law relates to other rules of international law*. (See Chapter 4 footnote 89). Such an approach however is considered to be both risky and unfounded. First, because of some questions raised about when is a norm in everyone’s public interest and who decides this matter. Second because it could threaten in the author’s view, the function of international law as provider of a neutral framework for co-operation. In this sense, it is said that recognizing protection of the environment as a “global common” is one thing but to impose detailed treaty obligations on non-parties to achieve that global common is quite another.

⁶⁹ Dunoff, J. L., & Trachtman, J. P. (2008). A Functional Approach to Global Constitutionalism. Harvard Law School Harvard Public Law Working Paper No. 08-57

tradition and practice that creating or maintaining a possible hegemony of certain powerful states, of a political practice and of a predominant culture⁷⁰.

Furthermore and beyond these approaches which in many occasions are premised upon the extension of domestic legal or constitutional thinking, ideas and doctrine to the new world order and where public interest would play a similar role but with different subjects and recipients both at the domestic and the international scale, there are also some other radical views which question the traditional pillars and paradigms upon which most political, legal and philosophical theories and doctrines have been constructed and which, with some variants, place the state at the center of their *rationale*.

Inspired on the theoretical and conceptual work around transnational legal theory, legal pluralism⁷¹, and systems theory developed by the German sociologist Niklas Luhman⁷², transnational constitutionalism challenges the distinction between the domestic and the international legal order and focuses its attention on the emergence of norm creation outside the state's law-making apparatus –different sectors of world society develop a global law of their own- and outside the confines of both private and public international law where law and even more state law are just a particular form of societal communication without occupying any superior or privileged place⁷³. This approach which some have called Postmodernism highlights the fragmented nature of society and the complexity and multiplicity of voices, interests and social dimensions and rejects the existence of shared values or the concept of a public interest which would be shared and recognized by all the members of society. Following this perspective which considers that the erosion of sovereignty of states and of the traditional legal institutions and legal framework comes from “below”⁷⁴ through an increasing melting and fusion of the state with market spheres of norm

⁷⁰ Schwöbel, C. E. (2010). Situating the debate on global constitutionalism. *International Journal of Constitutional Law*, 8(3), 611-635.

⁷¹ Teubner, Gunther. (1996). *Global Bukowina: Legal pluralism in the world-society*. GLOBAL LAW WITHOUT A STATE. Gunther Teubner, ed., Dartmouth: 3-28. In Teubner's view, the modern experience is of a fragmented rather than a uniform globalization in which politics has lost its leading role.

⁷² Luhmann, Niklas. (1990). *Political theory in the welfare state*. Amsterdam: De Gruyter

⁷³ Zumbansen, P. (2012). Comparative, global and transnational constitutionalism: The emergence of a transnational legal-pluralist order. *Global Constitutionalism*, 1(01), 16-52.

⁷⁴ Sassen, Saskia. (2003). *The state and globalization*. *Interventions* 5.2: 241-248.

creation *-lex mercatoria-*, global public interest would be nothing more than a naïf conceptual construction, a politically fabricated illusion, a utopian vision of a global, systematic and unified global order.

Public interest in TRIPS.

TRIPS Agreement uses the term “public interest” in two articles. Other than article 63 where public interest is mentioned as an exception to the disclosure of confidential information, article 8 of TRIPS refers to public interest within the article devoted to the principles under which TRIPS must be interpreted and implemented. Article 8(1) lays out the public interest principle in the TRIPS Agreement. In particular, article 8(1) states that “*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 socioeconomic and technological development, provided that such measures are consistent with the provisions of this Agreement.*”

Article 7 (Objectives) and article 8 (Principles) are two concessions which reflect in large part the concerns of developing countries during the negotiations of TRIPS. As a reaction to the proposal of developed countries addressing the protection of IPRs within the frame of the GATT system, developing countries proposed another legal text where they insisted on the need to link IPRs, its implementation with economic and social development objectives. Needless to say that the final text essentially embodies and contemplates priorities and norms proposed by the developed world and when article 7 and 8 would be a sort of consolation prize for developing countries⁷⁵.

This block of articles (objectives and principles) could play an important role in the political and judicial processes both of which become complementary in the WTO context; the threat of WTO dispute process shapes multilateral and bilateral political

⁷⁵ Yu, Peter K. (2009). The objectives and principles of the TRIPS agreement. *Houston Law Review* 46: 797-1046.

negotiations and political contexts and interpretations inform judicial decisions.⁷⁶ Hence, developing countries have explored the use of articles 7 and 8 to support their positions with a more than limited success as we will see in next chapter. Professor Correa has been probably one of the most salient academics exploring the potentiality of those two articles in favor of the interests of developing countries.

When speaking of the necessary measures for promoting the public interest in sectors of vital importance to their socioeconomic and technological development [...] TRIPS does not offer any definition either for public interest or of the meaning of sectors of vital importance to their socioeconomic and technological development.

Regarding public interest in the context of IPRs (in particular of Copyright) Gillian Davies states in his thesis (p. 1) that whether a particular act is “in the public interest” is not subject to any objective tests and that inherent in the noble motive of the public good is the notion that, in certain circumstances, the needs of the majority override those of the individual, and that the citizen should relinquish any thoughts of self-interest in favor of the common good of society as a whole⁷⁷.

Regarding the *sectors of vital importance to their socioeconomic and technological development*, Professor Correa argues that each member state should be able to decide what constitute those sectors by looking at their interests, development goals and necessities⁷⁸. Notwithstanding this, this “public interest” safeguard has to face two important constraints -both added by developed countries when negotiations were at their last stage-; the first has to do with the so-called “necessity” requirement and the second one with the “consistency” requirement which obliges member states to adopt measures *consistent with the provisions of the [TRIPS] Agreement*.

The first constraint (necessity) is explained by the wording of the provision. The article does not state that members could implement those measures which they deem to be fit in order to fulfill their vital interests and socioeconomic goals but

⁷⁶ Shaffer, G. (2004). Recognizing public goods in WTO dispute settlement: who participates? Who decides? The case of TRIPS and pharmaceutical patent protection. *Journal of International Economic Law*, 7(2), 459-482.

⁷⁷ Davies, G. (2002). *Copyright and the public interest* (pp. 76-77). London: Sweet & Maxwell.

⁷⁸ Correa, C. (2007). Trade related aspects of intellectual property rights: a commentary on the TRIPS agreement. *OUP Catalogue*.

explicitly states that only can take measures which are (objectively) necessary for those purposes. The objectivity given to the required necessity of the measures makes its interpretation subject to potential WTO review regarding its validity and consistency with TRIPS⁷⁹.

The second constraint (consistency) is even worse and it could have a blocking or crippling impact on the application of this article. In effect this article could impede to invoke an exception -not foreseen under the Agreement- to the compliance of exclusive rights protected by TRIPS. To overcome this hurdle, Correa defends that article 8 should be read together with article 7 and its effective interpretation in terms of balance of interests between owners of rights and society in general in order to remove the potential inconsistency of certain measures with IP exclusive rights. Also, the Ministerial Declaration and the Doha Declaration on public health which are generally viewed as the only serious attempt made by the WTO system so far to combat a certain decontextualized pro-IPRs and pro-developed countries approach to TRIPS and so finding a balance between all the interest at stake, gives article 7 and 8 a higher legal status as indispensable references to interpret the Agreement. In this sense, paragraph 9 of the Ministerial Declaration explicitly states that [...] *the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.* Furthermore, paragraph 5(a) of the Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001, states the following: *In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.* Hence, despite the fact that those articles are “should” provisions rather than “shall” ones, there is room to consider that TRIPS provisions must be read consistently with its principles and objectives reflected in articles 7 and 8.

⁷⁹ Cann Jr, W. A. (2004). On the Relationship between Intellectual Property Rights and the Need of Less-Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply under a Theory of Progressive Global Constitutionalism. *U. Pa. J. Int'l Econ. L.*, 25, 755.

Other than its role as an interpretative instrument to counterbalance the hegemonic approach standing for an expansive implementation of IPRs as exclusive rights and to justify an open and broad interpretation of key provisions of TRIPS such as strengthening the necessary technical cooperation and technology transfer provided in art. 66.2 and 67, patentability exclusions established in art. 27.2 and 27.3, exceptions to IPRs application (art. 30) or compulsory licenses (art. 31), the “public interest” safeguard/exception provision may be used defensively, i.e., constitute a defense and an exception to the straight forward implementation of TRIPS and application of IPRs. In this manner, developing countries could use this provision in the WTO dispute settlement process to provide defense and support for their measures⁸⁰. In this sense, we could even think of the development of a public interest defense to the eventual IPRs infringement as it is usual in some common law jurisdictions in relation to copyright infringement⁸¹. However, as we will see next, the use of this institution as a real counterbalance against the hegemonic mainstream discourse has been rare or non-existing.

Furthering the bewilderment with two other old acquaintances Ordre public and Public policy.

In close connection with public interest, *ordre public* and public policy are elusive legal notions which have the potential to interfere the application of international law. In particular, both figures are legal concepts which have a large tradition in Private International Law as judicially administered exceptions to otherwise applicable foreign law (or international law) on the grounds that its application would offend against the forum’s concept of fundamental norms⁸². Even if both figures are analogue, they are not exactly equivalent. As public policy exception has a common law origin, *ordre public* is identified with civil codified law and has a

⁸⁰ Reichman, J. H. (2000). The TRIPS Agreement comes of age: conflict or cooperation with the developing countries. *Case W. Res. J. Int'l L.*, 32, 441.

⁸¹ Mendis, D. (2003). The historical development of exceptions to copyright and its application to copyright law in the Twenty-First Century. *Electronic Journal of Comparative Law*, 7.

⁸² Forde, M. (1980). The “Ordre Public” Exception and Adjudicative Jurisdiction Conventions. *International and Comparative Law Quarterly*, 29(2-3), 259-273.

statutory source. In spite of its statutory origin, *ordre public externe* –the exception to foreign law application- is also dominated by judicial and juristic interpretations⁸³.

As with the notion of *global public interest*, the notions of public policy and *ordre public* are not limited to national or domestic fundamental norms or values but they could be based on the idea of international public policy or “transnational” public policy derived from international law, basically from *jus cogens* norms. Although this idea has been developed mostly in the context of international arbitration where it has been used to recognize the public dimension of a dispute, it could be equally applicable in national courts; if a foreign or international law or judgement is considered to be repugnant to international –constitutional like- public order, domestic court could not apply it. This decision process would imply a “vertical” balancing of competing international norms and make some international norms and commitments prevail over others thus having national or domestic courts the potential to somehow shape a sort of international superior or constitutional norms.⁸⁴

Many international treaties provide themselves for an *ordre public* or public policy exception to their standards. The safeguards available in the TRIPS are more restrictive than those contemplated in Article XX⁸⁵ of the GATT –general exceptions to its applicability- or XIV (a) of the WTO General Agreement on Trade in Services –enabling states to take measures necessary to protect public morals or to maintain public order-. However, TRIPS also mentions the *ordre public* within its provisions. Other than the general “public interest”, TRIPS uses the narrower term “*ordre public*” in article 27(2) of the TRIPS. Article 27(2) expressly states that *Members may exclude from patentability inventions, the prevention within their territory of the commercial*

⁸³ Murphy, K. (1981). The traditional view of public policy and *ordre public* in private international law. *Ga. J. Int'l & Comp. L.*, 11, 591.

⁸⁴ Mills, Alex. (2009). The confluence of public and private international law... See supranote 63.

⁸⁵ As we have previously explained, commentators have explored and discussed whether the general exceptions in article XX of the GATT are applicable under the TRIPS Agreement. Many conclusions in this respect are skeptical over such application. In this sense, the European Communities—Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Panel Report, WT/DS174/R seems to strengthen that skepticism. As the panel declared, ‘there is no hierarchy between the TRIPS Agreement and GATT 1994. On the other hand, in India—Patent Protection for Pharmaceutical and Agricultural Chemical Products, Panel Report, WT/DS50/R, the Panel stated that TRIPS is an integral part of the WTO system, which itself builds upon the experience of over nearly half a century’ under the GATT.

exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. In doing so, TRIPS endorses a longstanding tradition in Patent law in order to exclude from patentability those inventions which might be contrary to morals or public order. In the European context, the European Patent Convention (art. 53 a)) establishes that European patents shall not be granted *in respect of inventions the commercial exploitation of which would be contrary to ordre public or morality.* In a very similar way, the Indian Patents Act (section 3b)) excludes from patentability those inventions contrary to public order and morality. Even if US patent law does not contemplate this kind of exclusions, such requirement has been fixed and acknowledged by Courts.

In spite of the greater conciseness and definiteness of the notion of public order in comparison with the notion of public interest, there would be still room to use this concept in a manner conducive to promote the interests of developing countries in ensuring the access to medicines by their populations. In this sense, Professor Correa suggest that developing countries could suspend the patentability of certain pharmaceutical products on grounds of *ordre public* which should be configured beyond its traditional moorings. This could also constitute an exception to the “noncommercial exploitation” of otherwise patented pharmaceutical products if such products were distributed on a not-for profit basis⁸⁶.

⁸⁶ Correa, C. M. (2000). Integrating public health concerns into patent legislation in developing countries (p. 53). Geneva: South Centre.

5.4. Public interest and *ordre publique*, hostages of its past.

Following Professor Cornago's threefold approach to the concept of global public interest, it is important at this moment to review from a *historical-critical* approach the evolution and the development of this concept within the historical evolution of the distinction between private and public interest or within what it has been perceived as "common good". This historical-critical analysis could give us the necessary lens and perspective to value adequately the scope and potential of the notion of global public interests and other associated terms as a transforming or defining tool at this precise moment when it is observed the creation of a new global institutional and legal architecture. From the Roman *utilitas communis* or *publica* to today's global public interest or Global Public Good, the notion of public interest or *intérêt général* (as this concept has been coined by the French political and legal tradition) has gone through very different historic phases and it is then the depository of multiple meanings and connotations.

Leaving aside certain philosophical lines of political thought for whom it is very questionable the existence itself of the public interest or the possibility of a consensus around it, the different approaches and historic conceptualizations of the public interest have attempted to achieve the significance of the common good as both an instrument and goal of the political action.

Notwithstanding this, or rather because of this, the notion of public interest has been historically variable and contingent, and deeply anchored in the distinction between the public and the private realm devised at each historical period⁸⁷; while the conception of public interest after the Second World War was clearly distinguished from private self-interest, and the state (*l'Etat protecteur*) and the international community were charged to create institutions (Bretton Woods, UN) addressed to intervene in the economy and in other fields to transcend the private self-interest⁸⁸,

⁸⁷ Horwitz, M. J. (1982). The history of the public/private distinction. *University of Pennsylvania Law Review*, 130(6), 1423-1428.

⁸⁸ In fact, prior to the 1980s, ranging from building highways to perform directly public services in the fields of education, energy, health or transport, governments took on a variety of tasks that the private sector previously had performed. In most Western Europe countries governments nationalized companies, whole

during the last decades since 1971 –when the previous system collapsed- we have observed that a new conception of the public interest and the state makes its way. In this new conceptual framework under the premises of the neoliberalism⁸⁹, the state and the public interest are called to become guards and facilitators of the free market and be reflection of the sum of the vectors of private conflict. In this context, some commentators observe that rather than retreating, the state is used to enable a new order of regulation by enforcing socially and politically acceptable new forms of capitalism. In this new order, new forms of governance also provoke the reassertion of the public interest.⁹⁰ Furthermore, as observed by some scholars when analyzing the competition policy and antitrust law, the concept of public interest has had the effect of legitimizing neo-liberal assumptions regarding private, individual, economic interests through the shift over time of the policy language and discourse of public interest and by using this concept to secure hegemonic control to legitimate the interests of dominant groups⁹¹. Finally and after the crisis of 2008, and some perceived excesses of the free market and capitalism, we are today living an era of uncertainty –*Brexit*, unexpected presidential win of Donald Trump, rejection of TTIP and other trade agreements and the apparent collapse of the previous regime- where the global public interest or any attempt to build a global order on political, democratic and collective basis are conspicuous by their absence.

Public interest, an ally of the hegemonic ideology.

Therefore, it may be observed that on behalf of the public interest many and substantially diverse policies and approaches have been adopted intermittently along time and different jurisdictions and political cultures. Notwithstanding this, all the different implementations and understandings of this notion have in common its

industries, banks, and health care systems. Many of the European current automobile industry has a state public funding origin such as Fiat, or Seat.

⁸⁹ Goodman, J. B., & Lovemen, G. W. (1990). Does privatization serve the public interest?. *Harvard Business Review*, 69(6), 26-8.

⁹⁰ Levi-Faur, D. (2009). Regulatory capitalism and the reassertion of the public interest. *Policy and Society*, 27(3), 181-191.

⁹¹ McDonald, J. (2007). Legitimizing private interests Hegemonic control over the public interest 'in National Competition Policy. *Journal of Sociology*, 43(4), 349-366.

supportive role to the hegemonic ideology and political thought at any given time. Needless to say that global public interest does not constitute any exception to the national public interest's tradition.

Following Gramscian concept of “common sense”, public interest would be part of a hegemonic process to promote the dominant ideology. The hegemonic process builds consent by discursively aligning the public interest with the interest of the dominant elite. This process would leave a limited number of choices for the public to form an opinion or make a choice⁹². In this sense, the hegemonic ideology of today would be dominated by the western corporate capitalism; a new, global regime of accumulation characterized by an unprecedented international mobility of capital and, among others, the commodification of knowledge globally and its insertion into the circuit of capital, becoming TRIPS a helpful instrument for the effective creation of the new global capitalism by easing that global commodification (of knowledge). Hence, in a context where global capitalism has dominated the range of discourses, it has also dominated and configured the notion of public interest and global public interest to such extent that it is difficult to raise alternative discourses and definitions of it⁹³.

Thus, the notion of public interest has traditionally been a faithful partner, a fellow traveler of the hegemonic ideology at the different historical stages. It is difficult then to devise the notion of public interest as an instrument capable of transforming the reality or bringing about change. We could say then that the concept of public interest has never had emancipatory force or capacity as it has never been decisive for any political or institutional transformation. On the contrary, public interest has deployed an undisguised tendency to endorse hegemonic ideology and practice. In this respect, the same applies to the concept of global public interest. Global public interest as well as it happens with GPG would play a discursive role in the sense of explaining the current scenario, a legitimizing instrument of the international regime without any pretension to promote changes in the *status quo*⁹⁴.

⁹² Artz, Lee, and R. Kamalipour Yahya. (2003). *Globalization, Media Hegemony and Social Class*. New York: SUNY Press.

⁹³ l'Etang, J. (Ed.). (2012). *Public relations: Critical debates and contemporary practice*. Routledge.

⁹⁴ Coussy, J. (2002). *Biens publics mondiaux: théorie scientifique, réalité émergente et instrument rhétorique. Les Biens Publics Mondiaux. Un mythe légitimateur pour l'action collective*.

Due to its lack of emancipatory power or of autonomous character in order to promote transformations or to bring about change and its condition as a discursive element which mostly accompanies mainstream hegemonic ideologies or political thoughts, law courts are indisposed to reliance on these elusive concepts and actually eschew its frequent use⁹⁵. As it is observed by some commentators the fact that law courts do not determine clear legal and policy foundations for its application makes its use or the use of these indeterminate legal concepts such as public interest, or public policy or public order, be frequently discouraged⁹⁶.

Public interest in the context of the global IPRs regime and TRIPS.

As to the invocation or use of public interest or *ordre public* in the context of TRIPS or the global IPRs regime, it has to be noted that within the WTO dispute settlement, the use of articles 7 and 8 (where the principle of public interest is embodied) has been irrelevant in the 34 cases which have been filed so far. The panels of the DSU take views which are mostly focused on the IPR's owners and IPRs owners' economic interests.

The Panel Report in the dispute Canada-Patent Protection of Pharmaceutical Products⁹⁷encompasses the most illustrative and extensive debate around the extent and scope of the "public interest" clause embodied in articles 7 and 8 of TRIPS. In particular, the EC alleged that Canada's legislation regarding the so-called regulatory review exception and so-called stockpiling exception were not compatible with its obligations under the TRIPS Agreement, because they did not comply with the full protection of patented pharmaceutical inventions for the entire duration of the term of protection envisaged by Articles 27.1, 28 and 33 of the TRIPS Agreement.

⁹⁵ Murphy, Kent. Traditional View of Public Policy and Ordre Public in Private International Law. See supranote 83.

⁹⁶ Mills, A. (2009). The confluence of public and private international law: justice, pluralism and subsidiarity in the international constitutional ordering of private law. Ca,mbridge: Cambridge University Press.

⁹⁷ WT/DS114/R. 17 March 2000. European Communities v. Canada. Dispute Settlement 114.

In supporting the validity of its patent legislation, Canada as well as other third parties involved in the dispute (in particular Brazil, Thailand, India and Poland) raised the necessity of finding a balance between owner's IPRs and other "public interest" considerations. In this sense, those parties standing for a liberal reading of articles 30, 7 and 8 of TRIPS argued that *intellectual property rights were not conferred in a vacuum, and that the TRIPS Agreement therefore did not aim to achieve a degree of protection for those rights which would unduly prejudice the vital public interest in social and economic welfare or the rights of others [...]* (p.19).

On the other hand, those who were opposed to a broader understanding of article 7 and 8 raised two set of arguments; the first set of arguments is based on a formal and narrow interpretation of the text argued that the phrase of article 8.1 "provided that such measures are consistent with the provisions of this Agreement" *demonstrated that the public health, nutrition and other public interests were to be considered subordinate to the protection of the IPRs insofar as the minimum rights guaranteed by the TRIPS Agreement were concerned [...]* (p. 53). Also, in EC view, *articles 7 and 8 are statements that describe the balancing of goals that had already taken place in negotiation the final texts of the TRIPS Agreement [...]* (p. 154). The second set of arguments has to do with the definition of public interest, for those who stood for a restrictive interpretation of the exceptions of the rights conferred by a patent, public interest was also achieved by granting IPRs to a patent owner since the grant of patent rights goes beyond the *simple unilateral grant of rights to a patent owner: it was a contract between the State and individual innovators in which the consideration for the grant of patent protection was the disclosure of the innovative knowledge and the public interest in promoting investment in the research and development of new pharmaceutical products [...]* (p. 104).

Neither this Panel nor any WTO panel and Appellate Body have made any definitive interpretation and application of Articles 7 and 8 of the TRIPS Agreement, their scope and their role in balancing all the interests and objectives at stake. As it has been observed by some commentators, the Panel avoided elaboration of the content and implications of Articles 7 and 8.1 in this case, despite the specific mentions and

references made by the parties in their submission⁹⁸. Interestingly, Canada contended that these provisions “call for a liberal interpretation of the three conditions stated in Article 30 of the Agreement, so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies”. In spite of considering that the so-called regulatory review exception⁹⁹ was consistent with TRIPS, the Panel seems to adopt a restrictive reading of articles 7 and 8 when it states that *In the Panel's view, Article 30's very existence amounts to a recognition that the definition of patent rights contained in Article 28 would need certain adjustments. On the other hand, the three limiting conditions attached to Article 30 testify strongly that the negotiators of the Agreement did not intend Article 30 to bring about what would be equivalent to a renegotiation of the basic balance of the Agreement. Obviously, the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions. The words of those conditions must be examined with particular care on this point. Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes [...] (p. 154)* thus, suggesting that the balance between the owner's IPRs and the other public interest considerations are basically defined in the literality and the wording of the TRIPS Agreement.

Also, the reading of those two articles made by the Panel distinguishes those two provisions from the operative or substantive provisions, thus making those articles even weaker and keeping them in the realm of “may” and the “wishful thinking”. In this sense, according to some commentators, article 8 could hardly constitute a legal basis for justifying an exception –different from those expressly established under the agreement- but rather a policy statement to explain the *rationale* under arts 30, 31 and 40.¹⁰⁰

⁹⁸ Yu, Peter K. The objectives and principles of the TRIPS agreement. See supranote 75.

⁹⁹ Under the regulatory review exception, potential competitors of a patent owner are permitted to use the patented invention, without the authorization of the patent owner during the term of the patent, for the purposes of obtaining government marketing approval, so that they will have regulatory permission to sell in competition with the patent owner by the date on which the patent expires

¹⁰⁰ Gervais, D. J. (2003). The TRIPS Agreement: drafting history and analysis. sweet & maxwell.

Furthermore, although the case is not related to patents, in EC - Trademarks and Geographical Indications (Australia vs. EC)¹⁰¹, and in the course of explaining why the TRIPS Agreement did not contain a general exceptions provision and how there is no hierarchy between TRIPS and GATT, the Panel referred to the principles of the Agreement set out in Article 8.1 stating that [...] *These principles reflect the fact that the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement. [...]*” This interpretation (post-Doha) of article 8 of TRIPS is especially restrictive compared to more liberal readings of the “public interest clause” and it jeopardizes governments’ room to implement TRIPS commitments in accordance with their particular interests and needs. In fact, when the Panel states that the fact that IPRs are negative rights permits that other public policy objectives may be pursued without interferences into the IPRs regime. Also, it implies that modifying or restricting the scope of IPRs should be the ultimate resort to be considered when other public interest needs knock the door.

In a more recent case European Union and a Member State - Seizure of Generic Drugs in Transit (in phase of consultations), India requested consultations with the European Union and the Netherlands regarding the repeated seizures on patent infringement grounds of generic drugs originating in India but transiting through ports and airports in the Netherlands to third country destinations. India alleges among other things that the measures at issue are, in several respects, inconsistent with article 8 of TRIPS and the August 2003 Decision on TRIPs and Public Health. India considers further that the measures at issue also have a serious adverse impact on the ability of developing and least developed countries to protect public health and to provide access to medicines for all¹⁰². WTO DSU will have the opportunity to

¹⁰¹ WT/DS290/R. 15 March 2005. On 17 April 2003, Australia requested consultations with the EC concerning the protection of trademarks and to the registration and protection of geographical indications for foodstuffs and agricultural products in the EC.

¹⁰² WT/DS408/1 19 May 2010

clarify, nuance and specify the sense and scope of article 7 and 8 regarding the role of public interest.

Ordre public exception: how and where.

Although the original proposal of article 8 suggested by developing countries mentioned additional measures to protect ‘public morality’ and ‘national security’ following GATT article XX precedent, both areas were omitted in the final version of Article 8. These measures, however, are somehow foreseen in article 27.2 and 73 of the TRIPS.

As we have previously said, Article 27.2 explicitly states that Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. On the other hand, article 73 further enables member states to pursue their essential security interests and to fulfill obligations under the United Nations Charter in relation to the maintenance of international peace and security.

Article 27.2 of TRIPS embodies in this manner a traditional legal exclusion to patentability. The exclusion of *ordre public*, public order or “morality” vary from jurisdiction to jurisdiction as the scope of application and interpretation as to whether is moral or not depends largely upon cultural values and idiosyncrasy. Although there have not been specific cases for the DSU to define and clarify the scope of “ordre public” and morality under the TRIPS, WTO has had the opportunity of expressing its views about *ordre public* and morality with respect to other GATT Agreements. In the Internet Gambling case¹⁰³, the Panel made a distinction between morality and public order. While morality grounds are referred to “standards of right

¹⁰³ WT/DS285/R 10 Nov 2004. WTO United States: Measures Affecting the Cross-Border Supply of Gambling and Betting Services—Report of the Panel.

or wrong conduct maintained by or on behalf of a community or a nation”, public order is directed to preserve the “fundamental interests of a given society, which would include the maintenance of the rule of law”. In this sense, the Panel recognized that there is no single meaning of “public morals” and “public order” as “these can vary in time and space, depending upon a range of factors including prevailing social, cultural, ethical and religious values”. In this respect, the Panel showed that it was open to accord some sensitivity and sphere to the involved WTO member in defining and applying those terms in accordance with their own system and axiology of values. That autonomy or sensitivity though is not absolute since the Panel has to implement those terms and give them effect as a matter of treaty interpretation.

This certain autonomy or sensitivity given to the values and interpretations of each nation when it comes to define the concepts of *morality or ordre public*, is relevant in order to foresee whether DSU could accept an interpretation of the *morality or ordre public* of article 27.2 in the sense of permitting exceptions to patents which are considered to impair, for example, the access to medicines or other public health purposes.

Article 53(a) of the European Patent Convention establishes that European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to “ordre public” or morality and that such exploitation shall not be deemed to be so contrary because it is prohibited by law or regulation in some or all of the Contracting states. In the European context, this exception has been invoked in cases related to biotechnology inventions and living organism.

Maybe the most illustrative and with greater media resonance was the case of Onco-Mouse¹⁰⁴. For our purposes and leaving aside the interesting debate about patentability of living organisms, it is noteworthy that both in the Onco-Mouse case and in other similar cases (T 356/93), the Board of Appeal of the European Patent Office defines *ordre public* in the context of patents as an exception which *covers the*

¹⁰⁴ Decision of 3 October 1990 19/90 (Technical Board of Appeal) and 6 July 2004, T 0315/03 (Boards of appeal). The Onco-Mouse is a type of laboratory mouse (*Mus musculus*) that has been genetically modified using modifications designed by members of Harvard University to carry a specific gene called an activated oncogene in order to make them more vulnerable to cancer.

protection of public security and the physical integrity of individuals as part of society. This concept encompasses also the protection of the environment. Accordingly, under Article 53(a), inventions the exploitation of which is likely to breach public peace or social order (for example through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to "ordre public". Also, the European Patent Office has held in the different cases when it has had the opportunity to analyze the ordre public or the morality exception that *the exceptions to patentability under Article 53(a) EPC have to be narrowly construed, irrespective of whether or not the exploitation of the invention for which a European patent has been granted is prohibited by law(s) or regulation(s) in some or all of the contracting states.* Therefore, in the European context the ordre public exception must be narrowly interpreted and it does not contemplate any socio-economic consideration in order to appreciate its applicability.

The US system has never had a similar exception of morality or public order in its patent legislation but it has been rather a creation of law courts which have fixed the contours of these indeterminate legal terms. However, Anglo American law courts' tradition has been traditionally reluctant to rely on public order and have used it or invoked very rarely¹⁰⁵. In the fifties of the twentieth century the US Patent Office (USPTO) started banning patents on gambling machine on morality grounds¹⁰⁶. However as it has been declared in more recent cases¹⁰⁷, law courts have considered that the rule which would mandate invalidating patents because one can use the item for deceptive or illegal purposes is no longer good law. Many commentators and law practitioners share the view that morality should have nothing to do with patents¹⁰⁸. In fact the same Onco-Mouse (Harvard Mouse), was fairly quickly granted by the USPTO even if there was an intense public debate with media resonance in the case. The focus of the USPTO to grant patents related to living organisms has been on the subject matter of the invention rather than on morality grounds. However, as it

¹⁰⁵ Murphy, K. (1981). The traditional view of public policy and ordre public in private international law. *Ga. J. Int'l & Comp. L.*, 11, 591.

¹⁰⁶ Merges, R. P. (1987). Intellectual property in higher life forms: the patent system and controversial technologies. *Md. L. Rev.*, 47, 1051.

¹⁰⁷ See *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-67 (Fed. Cir. 1999).

¹⁰⁸ Enerson, B. D. (2003). Protecting society from patently offensive inventions: the risk of reviving the moral utility doctrine. *Cornell L. Rev.*, 89, 685.

happens in the European context, in the US patent system these judicially-created exceptions do not take into account socio-economic considerations to justify the application of the public order or morality exception to patentability.

The Indian Patent Law in turn contemplates a provision regarding the public order and morality exceptions to patentability. While the former provision stated that *‘What are not inventions – an invention the primary or intended use of which would be contrary to law or morality or injurious to public health;’* an amendment was brought in 2002 to comply with TRIPS and it now recites: *‘3(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.’* Therefore, there was formerly a specific emphasis on public health which has been so reflected by law courts.

In particular, in the case of *Novartis AG v. Union of India & Others*, the Indian Intellectual Property Appellate Board (IPAB) rejected the patentability of a pharmaceutical compound *Gleevec* (a compound having valuable anti-tumor properties used for the treatment of Leukemia). Apart from arguing its lack of inventive step (section 3d), the IPAB court held in its judgment of June 26 2009 that the price of the medicine whose patentability was being challenged, was *too unaffordable to the poor patients in India*, that this patent could *create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective* and that this would have a *disastrous effect on the society as well*. As a result, IPAB considered that the alleged invention was not worthy of *a reward of any product patent* because its exploitation *could create public disorder* and that is expressly prohibited by section 3(b) of the Indian Patent Law. Although not grounded specifically on article 3(b)¹⁰⁹, in a long, detailed and interesting ruling, the Indian Supreme Court upheld the Indian Patent Office and the IPAB’s rejection of the Novartis patent application.¹¹⁰

¹⁰⁹ Indian Supreme court did not enter to analyze the scope of public order of 3(b). In Supreme Court’s own words [...] *for the purpose of these appeals we need only to focus on clause (d)*[...] (paragraph 93. Page 93)

¹¹⁰ Supreme Court of India. Civil Appellate Jurisdiction. Civil Appeal No. 2706-2716 of 2013

Therefore, and even if not explicitly endorsed by the Supreme Court, we could say that the Indian judiciary has given an interpretation of the exception of public order as a notion with the potential of encompassing socio-economic considerations of the patent application and IPRs regime such as the unaffordable price of pharmaceuticals. This interpretation of the notion of public order (together with a greater sensitivity to national values and understandings of public order and morality as expressed by some GATT decisions) opens an interesting and innovative jurisprudential line which could be certainly replicated by law courts of other jurisdictions.

In any case, except for the above mentioned liberal interpretation of the indeterminate concept of *ordre public*, it does not seem that neither public interest nor public order have had the capacity and the potential to be exceptions to the application of the IPRs regime. Its use as exceptions to the scope of exclusive rights and as counterbalances of the IPRs owner has been testimonial or non-existing. Furthermore and unfortunately for developing countries, the requirements provided in Article 8 have seemed to create the perverse effect of privileging IPRs over other arguably more important socio-economic goals, such as providing access to essential medicines. The foregoing is even more certain for the “global public interest” which is becoming an exotic concept living on some cosmopolitan shelves.

Concluding with a procedural and ethical proposal for Global public interest.

As we have seen, the definition and the contours of public interest is historically variable, contingent, elusive and somehow, excessively tied to power and hegemonic mainstream. This has made this notion unfit and unsuitable to transform the reality and to become a pivotal axe or element for change. The already problematic condition of public interest is combined with new uncertainties around the notion of global public interest which seems to be even more irrelevant as an instrument to reshape today's international architecture and justify certain collective actions at a global scale.

The analysis of the main theoretical approaches which have dealt with the notion of the public interest reveals conflicting positions regarding the concept and its scope. While some theories questioned even the existence and the feasibility of this notion in view of the impossibility of consensus, either due to the fragmented dimensions and different interests of individuals (postmodernism) or because the division of society into antagonistic classes (Marxism), the theories which have studied this figure with the intent of giving a specific meaning with defined legal effects (mainly the utilitarian and the contractarian approaches) have proved to be incomplete, ineffective and unsuccessful as to their pretension of giving it legal substantivity and autonomy from undue interferences of power and other non-public interests. Public interest and global public interest in the context of IPRs regime engenders –as it could not be otherwise- similar difficulties than public interest does in other legal fields.

It is at this point that it could be noteworthy to question whether the relevance of this concept resides in how to elaborate that public interest rather than in its specific meaning. The emphasis should be therefore on the procedure, on the manner in which the consensus is constructed. Once we have renounced to achieve a precise significance of the notion of public interest and in order to make the public interest be an operative concept to guide and justify political decisions and to monitor them –i.e. to evaluate that the decisions have been adopted in furtherance of that public interest- the public interest should be the result of a socio-political debate on the objectives and priorities of society based on a model of deliberative democracy and communicative action. In this sense, from an approximate deontological concept of public interest, the identification of it should be the result of a case by case evaluation and the demonstration that the action in question reflects the public interest¹¹¹. This democratic-process to define on a case by case basis what the public interest is, and in particular, what the global public interest implies can only be achieved at a global scale through communicative action¹¹².

¹¹¹ de Córdoba, Manuel Benabent F. (2010). Public interest in political philosophy. A necessary ethical and regulatory concept for territorial planning. *Boletín de la Asociación de Geógrafos españoles* 53.

¹¹² Habermas, J., Habermas, J., & McCarthy, T. (1985). *The theory of communicative action* (Vol. 2). Beacon press.

Communicative action is based on human capacity for rationality and human capacity to communicate through argumentation. Argumentative speech is only possible when the participants get rid of their personal interests and act without coercion in an ideal community or ideal public sphere where there is an undistorted and argumentative dialogue, a mutual search of understanding and joint learning from which the best argument emerges. It is from the best argument –accepted by all- from which the notion of public interest is identified at the time.

Being aware of the difficulties of recreating this ideal argumentative dialogue in an aseptic public sphere where pure reason rules combined with the elusiveness of the notion of global public interest, this “deontological” approach may become however a helpful tool to justify collective and political actions, dynamic decision-making process and evaluate their legitimacy and their accordance with the idea of public interest at every step. Also, if we assume that public interest must be the result of a socio-political process free of private, less respectable interests, it may be claimed the implementation and adoption of mechanisms in all the decision-making processes which entail participation and discussion of a plurality of voices and interest at stakes. In this sense, the Washington Declaration on Intellectual Property and the Public Interest¹¹³ or the recent Report of the UN Secretary General’s High-level Panel on access to medicines which has been the result of an important participation of a diversity of actors and agents, could be a good starting point to reshape the policies on IPRs regime.

¹¹³ Flynn, S. M., Baker, B. K., Kaminski, M. E., & Koo, J. (2012). The Washington Declaration on Intellectual Property and the Public Interest.

CHAPTER 6. THE HISTORIC NATURE OF IPRs AS A SOCIAL CONTAINER: THE ENCLOSURE OF KNOWLEDGE WITHIN A NEW HISTORICAL PHASE OF CAPITALISM.

Previous

We have previously seen how the international IPR regime implemented by TRIPS is impairing the access to pharmaceuticals by an important part of the world population. Furthermore, we have analyzed the political, legal and philosophical basis under which the new international architecture and the IPR regime are constructed. In this analysis, we have been able to detect several and large shadows of the current regime which is intimately linked to its legitimacy or the lack of it. Finally, along the previous chapters and specifically in the last one, we have examined the internal mechanisms contemplated by the TRIPS Agreement to reconcile the diverse interests at stake, the exceptions to the regime and other counterbalances to the IPRs owner's exclusive interests. Also, we have reviewed some figures and principles of international law such as public interest or public order and some political proposals directed to correct the market failures (Global Public Goods) in order to value its impact on the regime of IPRs and its capacity to satisfy other types of concerns and interests.

Once we have discussed the above mentioned issues and having attested the limited results and impact of TRIPS internal and external mechanisms to counterbalance the interests of IPRs owner's regime, we are in a position to address the main proposals and the most relevant thesis suggested by this dissertation. In this sense, in these two last chapters we are going to uncover first the real causes behind the expansion and enhancement of IPRs as a manifestation of a new and voracious phase of the development of capitalism and how this process is somehow distorting the nature, scope and philosophical foundations of IPRs as a legal institution which is the result of a contingent, historic, political and shifting process rather than well defined, absolute, pre-existing natural rights. In this sense, IPRs regime would encompass or

“contain” a set of social values, values, and functions which are historically and thus, IPRs would be a “social container” rather than an autonomous and invariable legal institution.

We will secondly consider the opportunity of modulating the scope of the exclusive proprietary rights of the IPRs from a *iuris tantum* test based approach, i.e., if we assume that IPRs are intended to achieve certain social goals and that they were not preceded in their creation by any tragedy of the commons scenario, *ça va de soi* that even if presumed, there may be occasions where that cause/effect may be questioned and challenged giving way to the necessity of testing whether the announced or presumed social goals are being effectively met and therefore, whether the privilege of monopoly granted through IPRs is worthy maintaining or if it has to be adjusted, modulated, superseded or even suppressed. In this sense, IPRs are not natural rights which confer their owners with absolute and decontextualized rights no matter which the socioeconomic circumstances are and which their socioeconomic impact is. On the contrary, IPRs do not qualify as pure property, they are not simple fee. Hence, IPRs encompass instrumentally some of the prerogatives or entitlements of the conventional property rights and they are conferred to their title owners as long as those fulfil their social function.

On the other hand, it will be reviewed in the last chapter some changes of the global architecture in order to make the system coherent. We suggest to transit towards models where participation and deliberative processes of argumentation could take their place and enable a greater legitimacy of the system in terms of promoting that all the voices and interests (hegemonic and counter-hegemonic) are heard and that the general interest is achieved and accepted by most. Furthermore, these more deliberative forums and decision-taking processes are important to ensure that the test of legal coherence can be performed and that the all-the-factor approach decisions are fair and balanced.

6.1. Intellectual property as the result of a historical, contingent and shifting social process: Its beginnings.

Why to explore the historical origins of Intellectual Property.

The historical perspective of IPRs reveals that IPRs and the global IPRs regime are not an autonomous and trans-historical reality or the product of an objective, dispassionate economic and inalterable *rationale* that we should take for granted but it is rather the result of a contested and sometimes controversial political process which is not settled or closed but historically shifting and open to change and transformation.

In this sense, our approach to the history of IPRs is located within a critical framework. Following the thoughts of Susan Sell¹, in analyzing the current IPRs regime we reject the problem-solving approach held by Robert Cox in the sense of taking for granted certain realities with the entire prevailing social and power relationships and the institutions into which they are organized². On the contrary, a critical insight of IPRs origins and evolution permits us to call into question IPRs' current justification. In this sense, it is important in order to conveniently review the current regime to be aware of the evolution of IPRs as a product of three elements which are on the basis of the political economic history of the IPR regime, namely the political conception or the ideas about the ownership of knowledge; the character of the technologies (material capabilities) subject to the protection of IPRs and technical change which require new ways of addressing these issues and; the legal institutions, i.e. the legal construction of IPRs. This permits us to call into question the origins of IPRs and their current justifications.

These three elements have been shifting along the history of IPRs which has fluctuated between settlement and contestation in a permanent process that has

¹ Sell, S., & May, C. (2001). Moments in law: contestation and settlement in the history of intellectual property. *Review of international political economy*, 8(3), 467-500.

² Cox, Robert W. (2000). *Social forces, states and world orders. Beyond international relations theory.* International Relations: critical concepts in political science 4.

vacillated between the public-regarding benefits of the dissemination of technical advances and the legitimate economic rewards accruing to those controlling such intangibles (dissemination and competition versus private appropriation, protection and exclusion). Settlements or balances or imbalances at a certain historical moment are placed somewhere in between these two extremes of the road (sometimes favoring exclusion some other times favoring dissemination) and are the result of the interplay between contingent and political ideational, institutional and material forces³.

This approach is presented as an alternative to both realist and functionalist perspectives of IPRs history. While Realism overstates the importance of the states and has limited its focus on the state as legislator who creates the institution of IPRs, it fails to account for the role of private actors who have prompted changes in IPRs – especially in the ideational and material, technical dimensions- both directly and through the state and other institutions (*historic bloc*).

On the other hand, Functionalism links IPRs with the historical development of general IPRs, and justifies IPRs in terms of efficiency. Just as conventional property rights which emerged as signals in the market operation, to provide predictability in economic relations –where local community trust cannot be relied on and protection by force is impracticable in a modern market with multiple and anonymous agents-, IPRs too would be justified on efficiency grounds, as an efficient solution for society. However this approach ignores first that IPRs does not face any tragedy of the commons scenario but it creates scarcity out of unlimited knowledge and it intends to make this *ex-lege* scarcity legitimate. And secondly, Functionalism does not acknowledge the political process behind efficiency and it eludes the big question; efficiency for what and efficiency for whom. In effect, the efficiency searched by society in terms of dissemination of knowledge is not the same as for the IPRs owner seeking for protection, exclusion and benefits or private gains. Efficiency may be applied in both contexts; the IPRs system may be efficient in promoting dissemination or in generating private gains for their owners but in neither case they are assessed

³ Sell, S. (2004). Intellectual property and public policy in historical perspective: contestation and settlement. *Loy. LAL Rev.*, 38, 267.

other type of societal consequences of the system such as its distributive, educative or cultural impact. In this sense, the very definition of what constitutes IP benefits some at the expense of others –medicines, processes, biotech, indigenous knowledge- and the regulation as to who and in what terms controls certain knowledge innovations has important distributional consequences making IPRs an instrument of power and the basis for further accumulation of power⁴.

Chronology and significant moments in patent law history.

The regulation of IPRs has been always a form of public policy. As we have said previously, the history of IPRs and of patents in particular, has been the product of a contested political process leading to diverse phases of settlement or institutionalization. In this back and forth historical process, phases where patents we called into question and phases of strengthening of IP proprietary rights and their protection have followed one another over the last centuries.

Apart from some form of patent rights in Ancient Greece and grants in the form of letters patent issued in England by the sovereign to inventors who petitioned and were approved, the Venetian Patent Statute of March 19, 1474, is said to be the first statutory patent system in the world. The Statute which is written in old Venetian dialect, provided that [...] *should it be legislated that the works and contrivances invented by them [men with clever minds] could not be copied and made by others so that they are deprived of their honour, men of such kind would exert their minds, invent and make things that would be of no small utility and benefit to our State. Therefore, the decision has been made that, by authority of this Council, any person in this city who makes any new and ingenious contrivances not made heretofore in our Dominion, shall, as soon as it is perfected so that it can be used and exercised, give notice of the same to the office of our Provveditori di Comun, having been forbidden up to ten years to any other person in any territory and place of ours to make a contrivance in the form and resemblance of that one without the consent and license of the author. [...] But our Government will be free, at*

⁴ Ibidem.

its complete discretion, to take and use for its needs any of the said contrivances and instruments, with this condition, however, that no one other than the authors shall operate them.

However, the first known patent is thought to have been issued more than fifty years earlier in 1421 to Filippo Brunelleschi. Apparently Brunelleschi, the architect of the Firenze Duomo, had designed a new type of ship to transport marble for the cathedral along the shallow River Arno and a patent was granted in this respect. The act was then the codification of prior customs and practices⁵. In any case, this Statute encompasses many of the basic principles of today's patent law. In particular, it explicitly linked innovation to the granting of monopoly; it codifies general rules to the granting of patents rather than conferring occasional individual favors (*gratiae*) in response to individual petitions⁶; remarkably, it is focused on protecting individual inventors rather than organized groups or companies referring to those men's *honour*; finally, it also mentions the benefit and utility of those inventions for the society and it also establishes the discretion of the government to take and use the invention.

In any case and prior to the formalization of the different patent laws, patents were royal privileges for the monopolistic exploitation of new techniques or, especially, unfamiliar devices which were brought from elsewhere and introduced into the sovereign's territory. Sovereigns used those instruments to attract and retain talented artisans in their territory in an attempt to limit imports and promote exports inspired by the mercantilist economic theories of the moment.

Sovereigns used this system also to benefit certain families and courtiers (some with debts owed to the Crown) by enabling them to profit from monopolies. This seemed to be the English case where the grants of letters patent were issued mostly for tax reasons. The number of objectionable grants of letters patent (Latin *literae patentes*, "letters that lie open") issued by the Crown for monopolies to persons who just could

⁵ Nard, C. A., & Morriss, A. P. (2006). Constitutionalizing patents: from Venice to Philadelphia. *Review Of Law And Economics*, 2(2), 223-321.

⁶ Kostylo, J. (2008). Commentary on the Venetian Statute on Industrial Brevets (1474). *Primary Sources on Copyright*.

afford to pay for them without any merit, and the fact that letters patent were granted for basic products such as salt (causing important price rises) led to a public outcry and to the enactment of the English Statute of Monopolies of 1624. James I of England was forced to revoke all existing monopolies. Since then the King could only issue letters patent to the inventors or introducers of original inventions for a fixed number of years. It is regarded as the foundation of the present British patent system. This act which is the first statutory limitation of the royal prerogatives, is also interpreted in terms of the beginning of the transformation of the English state, from feudal to a modern one (where the estate of the monarch is distinguished from that of the state) and so, a landmark in constitutional history.

This inaugurated new British patent system established important barriers of entry to patent applicants by means of very high costs and fees which limited access to property rights in inventions, this favoring the wealthy elite. Another important feature is that the “first and true inventor” was interpreted as to include importers of inventions that had been created abroad. Hence, it was applied as criteria the *relative* novelty of inventions, thus giving importance to the diffusion and technology transfer implied in patent system (in letters patent). The important point of this Statute for our purposes is that invention patents were viewed above all, as an exception to the “abusive” royal monopolies. Therefore, it is important to bear in mind that in their genesis, IPRs constituted exceptional monopolies granted in view of certain social benefits. The configuration of IPRs as exceptional monopolies and justified or contingent privileges gives IPRs an unstable institution or entitlement to be held as long as they are not the product of an abusive grant; that they comply with their intended purposes and social benefits.

After the English Statute which announced deep political, economic and societal transformations in the English society, similar laws were enacted across the European continent and in America as the transit from the Ancient Regime to Modernity took place.

Industrial capitalism and the emergence of modern national patent systems.

Therefore, the transition from the *Ancien Régime* to Modernity and a new phase of capitalism known as “*industrial capitalism*” is at the origin of the emergence of the modern national patent laws (end of 18th century and 19th century). Preceded by previous social and political changes in Great Britain, the new era is characterized by new manufacturing processes and new production methods (Industrial Revolution). The political transition included going from a system of privileges and prerogatives of certain classes under absolute monarchies to the empowerment of the bourgeoisie who supported the principles of constitutional government and of natural right against the Law of Privilege of the feudal regime.

The new economic rationality seemed to require certainty as to the merits to be the beneficiary of a monopoly⁷. All this had a reflection in the previous patent system. In this sense, patents began to be viewed as a fair reward to their creators, as a right, a form of intellectual property right, rather than a privilege. This implied that patents could be “formally” –even if fees were still too high- accessible to everybody, to every person beyond those members of the elite, there was a clear move to a systematic and objective process of granting patents or exclusive rights. Furthermore, certain utilitarian arguments seemed to be used to justify the new patent systems⁸. In any case, the different patent laws were designed and adjusted to foster the economic development and national necessities of their societies.

A good example of this and of the somehow “revolutionary” character of these new rights was the modern French patent system⁹ established by the law of 1791 enacted by the Revolutionary Assembly and based on the *Rapport du chevalier Stanislas de Boufflers*. In that report, and following some Diderot’s and Locke’s thoughts, the right to patent is viewed as a natural right and as a contract between the inventor and the

⁷ For an interesting view about the links between the industrial revolution the emergence of capitalism and the patent system see MacLeod, C. (2002). *Inventing the industrial revolution: The English patent system, 1660-1800*. Cambridge University Press.

⁸ Vidaurreta, G. E. (2011). De cómo el criterio utilitarista de justificación primó en los albores del sistema de patentes: estudio de casos: Inglaterra, Estados Unidos y Francia: desde el medioevo a la primera revolución industrial (Master’s thesis, Buenos Aires: FLACSO. Sede Académica Argentina).

⁹ Galvez-Behar, G. (2006). *Genèse des droits de l’inventeur et promotion de l’invention sous la Révolution française*. Lille: IRHIS Lille

society by which a temporary monopoly is granted to the inventor in exchange of the full disclosure of the secret of the invention. The new patent system is intended to end with the previous regime of discretionary privileges. Also, the British patent system was mentioned as a model to follow due to the flourishing of the arts and science that the British patent system had enabled (*une grande corporation d'arts et métiers: effrayante association, dans laquelle et les plus habiles ouvriers et les premiers manufacturiers et surtout les genies les plus inventifs de toutes les nations s'empresment à se faire agréger*).

The French patent law also adopted the “relative novelty” of the inventions, so importers of technology, the first introducer of an invention covered by a foreign patent could enjoy the same “natural rights” as the patentee of an original invention or improvement. Some other remarkable features of the French patent law were that medicines and methods to produce medicines were excluded from protection and that patents were void if their owners attempted to file a patent overseas on the same invention (in a curious attempt to limit the diffusion of originally French inventions).

The United States, the today's most belligerent advocate of the expansion of strong IPRs and strong prerogatives of IPRs' holders, has been credited as having developed the world industrial and economic supremacy on the basis of its favorable treatment of inventors and inventive and creative activity. As some studies suggest, American patent system could have been on the basis of its economic growth and successful industrial and technological progress¹⁰.

However, it is noteworthy remarking that in the US, the "public-regarding" conception of IPRs prevailed until well into the 20th century over the private interests of the IPRs' holder. The first Article of the U.S. Constitution includes a clause regarding IPRs with the following wording: to “*promote the progress of science and useful arts by securing for limited times to authors and inventors the rights to their respective writings and discoveries.*” Therefore, IPRs are created in the American Constitution in view of their social utility or purpose and with a neat utilitarian scope,

¹⁰ Moser, P. (2005). How do patent laws influence innovation? Evidence from nineteenth-century world's fairs. *The American Economic Review*, 95(4), 1214-1236.

i.e., as an instrument to achieve *the progress of science and useful arts*. In the first half of the 19th century, the judiciary was very concerned on overcoming the eventual incoherence as to the extent to which a democratic and market-oriented political economy was consistent with exclusive rights. Courts explicitly attempted to implement decisions that promoted economic growth and social welfare in a clearly utilitarian interpretation of the patent law¹¹.

The US Congress quickly passed a patent statute in April 1790. The historical record indicates that the legislature's creation of a uniquely American system was a deliberate and conscious process with many different views and opinions. One of the main concerns of the debates was how to encourage the introduction of foreign technology, especially from UK and the convenience of adopting the patents of importation as it was the case of the British practice¹². Notable figures such as George Washington were strongly favorable to use the patent system to import foreign technology. Also Hamilton, in his 1791 Report on Manufactures asked the government to attract skilled artisans and foreign inventions for the economic development of America¹³.

American patent act rejected patents of importation¹⁴ and provided strong protection for US citizens and restricted patent property to foreigners. Americans could not obtain patents for imported discoveries, but the earliest statutes of 1793, 1800 and 1832, restricted patent property to citizens or to residents who declared that they intended to become citizens. As such, while an American could not appropriate patent rights to a foreign invention, he could freely use the idea without any need to bear licensing or similar costs that would otherwise have been due if the inventor had been able to obtain a patent in this country. In 1836, the stipulations on citizenship or residency were removed, but were replaced with discriminatory patent fees:

¹¹ Khan, B. Z. (2002). Intellectual Property and Economic Development: Lessons from American and European History." Commission on Intellectual Property Rights, London. In Proceedings of the Conference on How IPRs could Work Better for Developing Countries and Poor People.

¹² British Common law had interpreted the Statute of Monopolies "true and first inventor" language to include the original inventor as well as the first introducer of the invention or the technology.

¹³ Hamilton, Alexander. (1913). *Report on manufactures (1791)*. State Papers and Speeches on the Tariff: 19.

¹⁴ Ben-Atar, D. S. (2008). *Trade secrets: Intellectual piracy and the origins of American industrial power*. Yale University Press. He speculates that the 1790 Act and its official rejection of "technology piracy" was a façade for an unofficial policy designed to facilitate technology piracy.

foreigners could obtain a patent in the U.S. for a fee of three hundred dollars, or five hundred if they were British. After 1861 patent rights (with the exception of caveats) were available to all applicants on the same basis without regard to nationality. Furthermore, the 1832 and 1836 laws stipulated that foreigners had to exploit their patented invention within eighteen months.

Therefore, the recent history shows that America was throughout most of the nineteenth century a net importer of technology and that American legislator adopted a strategy consisting of favoring domestic invention and of discriminating foreign inventions. This was intended to serve national public interest by encouraging technology transfer. Foreign technology was then introduced without any additional cost of the inventor's monopoly right and there were sufficient incentives in place for national inventors. The US had access to the world's technology at a lower and optimum cost. Furthermore, the evolution of the origins of the US Patent system reveal the protectionist roots of the US patent system and the national patent system suited to the needs of its economy¹⁵

In fact, the favorable treatment for American inventors versus their foreign counterparts has been maintained until recently in the different American patent regulations, the jurisprudential understanding of the law (*Hilmer Doctrine*) and other interpretations around the grace period and the first to invent rule discriminated foreign inventors. TRIPS made some provisions of the American Patent Act illegal among others for barring foreign inventors the right to use foreign dates of invention to procure patents¹⁶.

Thus, by the beginning of the nineteenth century, the three leading powers UK, France and America had adopted modern patent protection and it was spread to most other main countries during the first half of the 19th century; Russia (1812), Prussia (1815), Belgium and Netherlands (1817), Spain (1820), Sardinia (1826), surprisingly Vatican State (1833), Sweden (1834) and Portugal (1937). In this respect, it is

¹⁵ Hubbard, W. (2013). Competitive Patent Law. *Fla. L. Rev.*, 65, 341.

¹⁶ Leffel, Kevin L. (1992). Hilmer Doctrine and Patent System Harmonization: What Does a Foreign Inventor Have at Stake. *Akron L. Rev.* 26: 355.

noteworthy that some of today's innovative and developed countries such as Netherlands –which repealed its law in 1869- and Switzerland –which rejected proposals for a national patent system in 1849 and 1867- did not have patent legislation in force for most of the 19th century this permitting them to protect and promote their start-ups and their small and medium size companies which basically were followers in the technical and economic fields and which could copy and produce inventions freely without any royalty burden.

During the period of 1850-1875 the tension and controversy around IPRs emerged again between those defending the patent system and the monopolies related to IP and those who stood for an international system of free trade without any encumbrances or privileges which were perceived as an undue impairment to free trade and liberalism. Free trade supporters viewed IPRs as an illegitimate privilege that could not be maintained between jurisdictions as it constrained the free trade.

As it has been profusely documented by Fritz Machlup¹⁷, from 1850 onwards, there was an important anti-patent movement all around Europe. The opponents to the patent system demanded not merely reform but the abolition of it. The government of Prussia decided to oppose the adoption of a patent law by the North German Federation and in December 1868 Chancellor Bismarck announced his objection to the principle of patent protection. In Switzerland, the only industrial country of Europe that had remained without patent legislation, the legislature rejected proposals to enact patent legislation during the second middle of the XIX century considering patent protection to be “pernicious and indefensible.” In effect, the patent system was conceived as something diametrically opposed to the free-trade movement of that period. According to Machlup, in the attacks on patent protectionism, free trade arguments were used and economists were always unanimous in the condemnation of the system –this included the *Economist*, the famous magazine which is today known for being a strong supporter of TRIPS-. In this anti-patent wave, Netherlands repealed its patent law in 1869 saying that “a good law of patents is impossibility”. In this country, between 1860 and 1865 most important

¹⁷ Machlup, Fritz, and Edith Penrose. (1950). The patent controversy in the nineteenth century. *The Journal of Economic History* 10.01: 1-29.

patents covered inventions made abroad. A lobby of small and medium-sized enterprises successfully urged the abolition of the Patent Act as an *obstacle to the growth of industry and prejudicial to the national prosperity*¹⁸.

After an intense propaganda between 1867 and 1877, this anti-patent tide turned in 1873 –following also the rise of nationalism and protectionism and a great economic depression- and the champions of patent protection eventually prevailed. A German Bill in 1871 said that it was fortunate that an economic crisis had caused backers of the pernicious theory of free competition and free trade to turn away from such foolishness and embrace patents¹⁹, this was a victory of the allied forces of protectionism. The British resolved the “patent controversy” in 1883 by enacting reforms that increased access to patent system, reduced patent protection to seven years, and provided for a stricter examination of applications, forfeit of patents not worked after 2 years, and compulsory licensing of patents.

Once free trade was called into question, opposition to IPRs lost its momentum; according to Professor May, intellectual property was still seen as a restriction of trade but such restrictions, provided they served the national interest, were no longer problematic²⁰. According to some, this settlement moment fixed a discourse justifying IPRs “as an acceptable and legitimate form of monopoly”. The idea of knowledge as property to ensure the efficient use of resources became widespread and accepted in Machlup words, paving the way for the next development of multilateral institutions and legal framework to facilitate an increased international commerce in intangible assets²¹.

¹⁸ Sell, S. (2004). Intellectual property and public policy in historical perspective: contestation and settlement. *Loy. LAL Rev.*, 38, 267.

¹⁹ Marshall, A. (2012). *The Surprising Design of Market Economies*. University of Texas Press.

²⁰ May, Christopher. (2008). The World Intellectual Property Organisation and the Development Agenda. *Global Society* 22.1: 97-113.

²¹ See *Id.* Supra note at 17.

6.2. The progressive expansion of IPRs along with new requirements of capitalism.

The second industrial revolution: towards a multilateral setting of IPRs.

While the first industrial revolution was basically led by UK on the basis of the steam engine and the development of the textile, iron and shipbuilding industries, the second industrial revolution was based by the progress experienced by chemical, oil and electricity industry and the emergence of new transport means and the invention of telegraphy, all of which was likely to facilitate the world commerce and the creation of large business with international ambition²². Also, economic and technological leadership was gradually shifting from UK to the US and Germany. In the second revolution, patents played a starring role²³.

The American previous preference for weak protection was shifting in the second half of the 19th century as American companies began to achieve technological breakthroughs. This is well reflected in the predatory conduct of the Edison Company which strongly pressed for the implementation of strong IP protection standards while attempting to get most IPRs related to the electric light to secure that specific market in an extremely litigious and predatory manner. On the other hand, in Germany, the founder of the Siemens Corporation entered the political arena and became a member of the German Parliament in order to promote the 1877 German Patent Act provisions ensuring the company's ownership of the inventions instead of the individual inventors²⁴-the German patent act excluded the term "inventor" in favor of "applicant" to enable firms to claim patent rights in employees' innovations-. In this way a new business model started its path, a business model based on important marketing and research and development departments which eclipsed the previous "inventor-individual entrepreneur" system and where Lockean

²² Murphy, C. N. (1994). *International organization and industrial change: global governance since 1850*. London: Polity Press.

²³ Between 1840 and 1910, the annual number of patents granted in the US increased more than fifty fold.

²⁴ Sell, S. (2004). *Intellectual Property at a Crossroads: The Use of the Past in Intellectual Property Jurisprudence: Intellectual Property and Public Policy in Historical Perspective: Contestation and Settlement*. *Loy. LAL Rev.*, 38, 267-2347.

considerations of IPRs as a just reward for human work remained in the background²⁵.

The international element in the field of IPRs consisted of bilateral agreements between countries, most of which operated around the national treatment principle and reciprocity. In this way, states could secure protection for their authors and inventors in foreign jurisdictions. But this protection was never satisfactory and it was felt the necessity of adopting international instruments for the cooperation between the different jurisdictions in the field of IPRs. In 1873 the Austro-Hungarian Empire wanted to host a World Exhibition in Vienna. These international fairs were very relevant but both American and German inventors showed their reluctance to participate as they feared that their inventions were not properly protected. The Empire then adopted a temporary law providing protection for foreigners in order to foster their participation. Due to this event and under the pressure of patent lawyers and engineers, the German Government held a Congress in Vienna to deal with those issues. Several follow-up congresses (in 1878 and 1880) paved the way for the 1883 Paris Convention which created an international Union for the Protection of Industrial Property.

In similar terms and circumstances the Berne Convention for the protection of copyright was adopted by some states –not the US-. Since that moment until TRIPS Agreement, nations were free to pass legislation and address IPRs in the terms they suited fit but signatories of those multilateral agreements were obliged to extend their domestic protection to foreigners, citizens of the other member states (principle of national treatment). From that moment on, the twentieth century saw the proliferation of numerous international agreements in the field of IPRs such as the Madrid Agreement for trademarks in 1891, Hague Agreement in 1925 for designs, the International Convention for the Protection of New Varieties of Plants of 1961, the Patent Cooperation Treaty of 1970 and the Treaty on Intellectual Property in respect

²⁵ For an explanation of the differences between inventor and innovator and the change of paradigm see Schumpeter, Joseph, and Ursula Backhaus. (2003). *The theory of economic development*. Springer US. 61-116. In this book it is explained how the concepts of inventor and innovator are different and how innovation is to be distinguished from “invention” (even where inventor and innovator are the same person), especially when invention is restricted to new ideas of a mechanical or technical nature. Innovation involves the (1) commercial application of (2) any new idea.

of Integrated Circuits of 1989. This was accompanied by the rise of international institutions which were at certain point superseded by WIPO, an agency of the United Nations. It is noteworthy that these international structure and legal frame did not imply the harmonization of technical rules, States maintained an important room and sovereign maneuver to set out their IPRs standards²⁶.

In this back and forth process and “swings of the pendulum” the last 20th century has known phases of strengthening of exclusive rights and private protection together with other periods of questioning of the IPRs regime and weakening of its scope. During the late 19th century and 20th century big corporate and business conglomerate and corporate cartels emerged around patents and other IPRs. Not only Edison purchased or merged with rival companies through predatory patent litigation, other firms also formed corporate cartels –General Electric through the Incandescent Lamp Manufacturers Association or the patent pool implemented in UK by British Thomson-Houston, Siemens and the General Electric Company through the Tungsten Lamp Association in 1912 or the Phoebus Agreement- by setting up patent cross-licensing, price-fixing and market collaborative arrangements based on their IPRs. These IPRs based cartels contributed to change the structure of the market from one of free trade to a monopolistic or oligopolistic one²⁷. The patent system and the uncritical view of IPRs –in contrast with the debates of the previous century between free trade and IPRs- were an important instrument to facilitate cartel solidarity and conduct. More and more sectors were impregnated by these cartels which subordinated competitive risk to security and control at the expense of consumers and society²⁸. The Supreme Court decision in in *Henry v. A.B. Dick Company* in 1912²⁹ is credited to be the moment when the economic power of patents reached its highest point.

²⁶ Drahos, P. (1999). The universality of intellectual property rights: origins and development. *Intellectual property and human rights*, 13-41.

²⁷ May, C., & Sell, S. K. (2006). *Intellectual property rights: A critical history*. Boulder: Lynne Rienner Publishers.

²⁸ Cutler, A. Claire, Virginia Haufler, and Tony Porter, eds. (1999). *Private authority and international affairs*.(see chapter 2 footnote 26).

²⁹ *Henry v. AB Dick Co.*, 224 U.S. 1, 32 S. Ct. 364, 56 L. Ed. 645 (1912). The company required the purchaser to buy the unpatented A.B. Dick’s ink when buying the patented mimeograph machine. This today obvious anti-competitive tying clause was held legal and valid by Supreme Court saying that the patentee could extract whatever price or other concession as a consideration for granting a patent license, including the required purchase of un-patented article.

Questioning of the Patent system as contrary to Antitrust.

This entire context changed after World War II. Cartels, monopolistic and oligopolistic strategies were seen as suspicious instruments at the service of economic nationalism –associated to militarism and to the Japanese and German defeated nations- and contrary to the international liberal economic order which was the new paradigm that the leading US wanted to “reestablish” in the planet. This approach justified the creation of the Bretton Woods institutions, the United Nations, the GATT and the European Economic Community. This multilateral, economic liberal perspective was associated to democracy, freedom, competition and welfare in contrast to cartels and inter-firm cooperation linked to German militarism. This encompassed somehow the return to the principles of weaker IPRs and free competition public regarding conception of patents.

The tide turned again the patent system which started to be considered as suspicious and some of the patent system’s more restrictive aspects came under attack. As noted by Professor Porter³⁰ in 1942 Fortune Magazine called for *abolishing the protection which the patent system gives to monopolistic practices*. From 1940s to the 1970s, the patent system was scrutinized and monitored under the requirements of vigorous antitrust standards and judicial review. It was a period which some have referred as Dark Ages for patents. Patent were perceived as monopolies giving a market power to be under antitrust review.³¹Also, there were several cases of patent misuse in the 1940s. In this sense, patent misuse³² became a usual defense against patents in infringements law suits.

It is at this time when American Senate made an assignment to Professor Fritz Machlup in order to research and review the patent system and its social utility³³, -

³⁰ Cutler, A. Claire, Virginia Haufler, and Tony Porter, eds. (1999). *Private authority and international affairs* [...] (See chapter 2 footnote 26). .

³¹ Silverstein, D. (1991). Patents, science and innovation: historical linkages and implications for global technological competitiveness. *Rutgers Computer & Tech. LJ*, 17, 261.

³² Morton Salt Co. v. GS Suppiger Co., 314 U.S. 488, 62 S. Ct. 402, 86 L. Ed. 363 (1942).

³³ Machlup, F. (1958). *An economic review of the patent system* (No. 15) US Government Printing Office.. In this respect, it is very interesting to show the American legislator’s concern on the patent system at the time:

which carried out his research following an assignment made by the American Senate-. In this respect, it is worthy to bring here Professor Machlup's certainly interesting conclusions on the patent system:

If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of its economic consequences, to recommend instituting one. But since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it. This last statement refers to a country such as the United States of America—not to a small country and not a predominantly nonindustrial country, where a different weight of argument might well suggest another conclusion.

Some remarks about patent system in follower countries: the case of Spain.

Spain adopted its patent system after the liberal revolution taking place in Spain under the influence of France and the French patent system³⁴. As the Real-Decreto of 1811 copied many of the provisions of the French Patent system of 1791, the first Spanish patent law was passed in 1820. As a follower country, Spain had rates of development lower than the most developed countries at the time –Britain, France-. Spanish legislation on patents intended to spur economic growth and development. Once Spain overcame –at least formally- the arbitrariness of the discretionary grant of patents/privileges, the Spanish patent system had on the transfer of foreign

US Government Printing Office. for the Subcommittee on Patents, Trademarks, and Copyrights as part of its study of the United States patent system, conducted pursuant to Senate Resolutions 55 and 236 of the 85th Congress. It is one of several being prepared under the supervision of John C. Stedman, associate counsel of the subcommittee.

The patent system has, from its inception, involved a basic economic inconsistency. In a free-enterprise economy dedicated to competition, we have chosen, not only to tolerate but to encourage, individual limited islands of monopoly in the form of patents. Almost 3 million of these have issued in the course of United States industrial history. This inconsistency has been rationalized in various ways. It is pointed out that the patent monopoly is limited both in scope and time; that this monopoly is more than balanced by the inventive contribution; that patented inventions are not actually monopolistic in fact because they are subject to competing alternatives and substitutes; that such monopoly as does result is unobjectionable because the public is deprived of nothing it had previously possessed; and so on. Such explanations may render the conflict less serious, but they do not resolve it.

³⁴ González, J. P. S. (1995). Propiedad industrial y revolución liberal: historia del sistema español de patentes (1759-1929). OFICINA ESPAÑOLA PATENTES MA.

technology one of its major concerns. This was reflected in the Spanish system which contemplated patents of introduction or “national novelty” i.e. importers of inventions which were new in Spain could obtain the same patent rights for the imported invention as real inventors. In this sense, patents of introduction were granted to entrepreneurs who wished to produce foreign technologies that were new to Spain, with no requirement of claims to being the true inventor.

Therefore, the sole objective of these instruments was to enhance innovation and production in Spain. This was reflected in the fact that introduction patents enjoyed a term of protection of only 5 years (this encouraged the production of items covered by the introduction patents after which exclusive rights expired, the country could benefit from dissemination of that foreign technology). Also, there were working requirements for patents which had to be worked within 2 years (in the patent law of 1820) and 3 years in accordance with the law of 1929. Interestingly, the “working requirement” was interpreted as the obligation to either manufacture and implement the invention in Spain or grant a exploitation license to a third party (“*puesta en práctica*.” Chapter V of the Spanish patent law of 1929. Art. 94).

On the other hand, pharmaceuticals (*preparaciones farmacéuticas y medicamentos*) were excluded from patentability. Until 1986 when Spain joined the European Community (today’s EU), only devices and processes leading to certain pharmaceuticals were permitted to be covered by a patent.

The Spanish example of patent law shows how the different patent laws of the nations were designed according to the stage of development where national laws were intended to be applied and how they reflect the political-economic context of the time as long as fulfill the needs of a particular stage of industrial development. While technological leader would prefer strong protection for its innovations, a follower will favor access and exploitation over protection³⁵. Also, patent law was used strategically to achieve or at least not impair certain social goals. The fact that it was not possible to get a patent on pharmaceutical products seems to be evidence of it.

³⁵ Trebilcock, M. J., & Howse, R. (2005). *The regulation of international trade*. Philadelphia: Psychology Press.

Paving the way to the new era of patent strengthening.

Going back to the American context regarding IPRs regime, it is noticeable that the negative (sometimes hostile) attitude toward strong patent protection came to a halt in the 1980s. Starting with the famous *Dawson Chemical Co. v. Rohm & Haas Co.*,³⁶ and following with the *Chakrabarty* case, the Supreme Court noted the importance of the patent system as an instrument to stimulate invention and innovation and placed the public policy of supporting patent rights on “equal footing” with supporting free competition and interpreted the faltering patent law’s history in favor of broader patent protection³⁷. Maybe concerned by the technological race against other trading nations such as Japan, IPRs became increasingly valued as tools to increase innovation and competitiveness of the economy³⁸. Furthermore, in 1982 the US Department of Justice issued its new antitrust standards which were more “patent friendly”. In this sense, these guidelines established that antitrust laws should not be applied in a way that hinders the renewed emphasis on competitiveness. Finally, as it is known, the establishment of the Court of Appeals for the Federal Circuit in 1982 enshrined a pro-patent approach³⁹.

The creation of the Federal Circuit generated intense political debate as the impact of these law courts on the IPRs regime. Critics feared that the Court of Appeals for the Federal Circuit would strengthen patents and exclusive rights of their titleholders. In effect, this specialized court has developed an important pro-patent jurisprudence; it mostly upholds the interests of titleholders over purported copiers; it rarely uses the term “monopoly”; it seems to be ready to grant generous compensatory damages and permanent injunctions and the social impact of an absolute interpretation of IPRs over public health or other fields are rarely discussed or taken into consideration. Between 1982 and 1990, this court upheld on appeal 90 percent of patents initially determined to be valid and infringed (compared with 62 percent in the various

³⁶ *Dawson Chemical Co. v. Rohm & Haas Co.*, 448 U.S. 176, 100 S. Ct. 2601, 65 L. Ed. 2d 696 (1980).

³⁷ Maggs, P. B. (1980). New Life for Patents: *Chakrabarty* and *Rohm & Haas Co.* *The Supreme Court Review*, 1980, 57-75.

³⁸ Kastriner, L. G. (1991). The revival of confidence in the patent system. *J. Pat. & Trademark Off. Soc'y*, 73, 5.

³⁹ Susan Sell. See supra note 3.

relevant courts between 1953 and 1978 and it reversed on appeal only 28 percent of patents held invalid at first instance compared with 12 percent previously⁴⁰.

Both the Dawson (and Chakrabarty) cases and the creation of the Courts of Appeals for the Federal Circuit are perceived as pivotal elements of the shifting of configuration of IPRs towards a model which embraces a pro-private proprietary approach to IPRs and a profit-making ideology without nuances or considerations to other social factors. In this context, discourses related to the necessary protection of investments and revenue increase are emphasized over the social grounds which originated the IPRs. In this sense, the analysis of the US background is important because it was here where the new discourse began in an explicit and neat manner in favor of the process of globalization of IPRs; before extending this new paradigm worldwide, it was necessary to settle solid and consistent basis domestically in the US.

The structure of global capitalism is on the basis of this shifting of IPRs regime. Capitalism has evolved to a new paradigm which produced pressures on the domestic environment for IPRs protection towards a global regime of IPRs. However, as we have seen, IPRs regime is a contingent product of history and it has gone through different historical phases and interpretations as to its scope and purpose. What it was once a lawful act it is today seen as an act of “piracy” and conversely, what it was perceived as a threat to the free market and economic growth it may be seen today as a necessary *stimulus* to the economic competitiveness within free market. IPRs regime emerged triumphant from the ideological battle between free trade and exclusive rights held in the period between 1850 and 1875; the capitalist elites around the world largely adopted the liberal arguments that linked property rights with incentives to invest and liberal markets (an ideological premise consecrated later by TRIPS).

Furthermore, the apparent contradiction between exclusive rights and antitrust – which viewed IPRs titleholders as agents having relevant market power (or dominant position) and thus, subject to strict antitrust standards- was somehow loosen in favor

⁴⁰ Faunce, Thomas Alured. (2006). Global intellectual property protection of “innovative” pharmaceuticals.(See chapter 3, footnote 48).

of an IP friendly application of the antitrust law. In this respect, the most recent battlegrounds of antitrust versus IPRs take place in the field of digital economy especially in Europe where antitrust authorities have been belligerent against certain conduct deployed by technological giants such as Microsoft⁴¹ or Google⁴². In this sense, it seems to be logic that the legal monopolies granted by patent laws extend only as far as the patentee's own use or reasonable exploitation of the invention. Also, some American commentators note the delicate balance existing between the desire to encourage innovation by rewarding inventors with exclusive rights to their inventions and, on the other hand, the desire to promote competition in the marketplace. Therefore, if a patent titleholder attempts to leverage the advantage of a patent *beyond its intended boundaries, the patent owner may be held to have committed "misuse"*⁴³.

Therefore, the entire back and forth process of the history of IPRs between a public regarding approach and an exclusivity pro-titleholder perspective or the last battleground in the context of the digital economy between IPRs and Antitrust legislation reveals to us that there is not any everlasting settlement in this area; every settlement, including the settlement encapsulated in the TRIPS Agreement, is subject to historical transformation, change and questioning.

⁴¹ In *Microsoft Corp v Commission of the European Union* (EU) T-201/04 it was decided a case against Microsoft for abuse of its dominant position in the market. Following an approach indicating by the Competition Commissioner Kroes who stated she believes open standards and open source are preferable to anything proprietary, the EU fined Microsoft an additional €899 million (US\$1.44 billion) for failure to comply with the March 2004 antitrust decision. This represented the largest penalty ever imposed in 50 years of EU competition policy until 2009, when the European Commission fined Intel €1.06 billion (\$1.45 billion) for anti-competitive behavior.

⁴² Recently on 14 July 2016, the Commission decided to initiate antitrust proceedings against Google's mother company Alphabet in case AT.39740 within the meaning of Article 11(6) of Council Regulation No 1/2003 and Article 2(1) of Commission Regulation No 773/2004. The Commission intends to investigate the way in which Google displays its own comparison shopping service and that of competitors in its general search results.

⁴³ Durham, A. L. (2013). *Patent Law Essentials: A Concise Guide*. ABC-CLIO.

6.3. The new enclosures resulting from the globalization of IPRs regime.

The international history of IPRs is often divided into three rough periods marked symbolically by different international agreements; the first period, characterized by the absence of international protection (end of 18th century until the end of the 19th century), the second period beginning at the end of the 19th century when some countries agree to the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886) until the end of the 20th century and the third period, the so called “global period” which we will analyze next and that is said to emerge with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1994⁴⁴.

Linking IPRs with trade

After the Second World War and resulting from the decolonization process, more and more developing countries joined the Paris and the Berne Convention. These conventions were based on the one-vote-one-state system and developing countries started to demand a model of IPRs international regime which should be fit to their stage of development and to their condition as net importers of foreign technology. Developed countries were not able to advance their agendas for expansion of the IPRs regime and the adoption of global minimum standards for IPRs through the WIPO forum –these attempts found an important resistance by most of WIPO members-. Neither did WIPO have an effective mechanism to enforce eventual IP standards worldwide. Furthermore, thanks to the fees charged under the Patent Cooperation Treaty (PCT)⁴⁵WIPO is not dependent on its member’s contributions and it has a great autonomy to sustain its activities, being mostly free from undue pressures or hegemonic manipulation⁴⁶.

⁴⁴ Drahos, Peter. (1999). The universality of intellectual property rights... (see footnote 26).

⁴⁵ The Patent Cooperation Treaty (PCT) was signed on the last day of the conference on 19 June 1970. The Treaty entered into force on 24 January 1978 and it provides a procedure for a single international application to protect inventions in each of its contracting parties. The PCT filing establishes the applicant’s priority date of the patent and saves time and expenses otherwise required as result of multiple national application procedures. A PCT application does not itself result in the grant of a patent since there is no such thing as an international patent since the grant of a patent is a prerogative of national or regional authorities.

⁴⁶ Richards, Donald G. Intellectual property rights and global capitalism. See chapter 4 footnote 67.

In this sense, the developing nation's discontent with the prevailing structure of IP relations reflected in the conventions administered by WIPO was expressed as early as 1952 at the Geneva Conference where the Universal Copyright Convention was adopted and later at Brazzaville Conference in 1963. In Brazzaville, it was expressly stated that international copyright were designed to *meet the needs of countries which are exporters of intellectual works* and that for their universal application it was *required review and re-examination*⁴⁷. This context and the voting system in force at WIPO enabled developing countries to succeed in adopting the Stockholm Protocol of 1967 where some provisions on compulsory licensing, exceptions to copyright and term of protection were favorable to developing countries' interests.

Interestingly, critics of the Paris Convention complained about the treatment of compulsory licensing by this International Agreement. The Convention established the possibility for members to compel the IPRs holder to work or to issue a compulsory license whenever the titleholder's monopoly was considered to constitute an abuse of monopoly power -including restriction of output with a view toward increasing prices above the cost of production or failure to produce at all-. From the IPRs titleholder's perspective, the profit-driven logic might require that the patent be worked in only a few locations from which export to other markets. However, patent-granting countries considered that IPRs and patents should be useful in contributing to create employment and technology transfer. Also, compulsory licensing was resorted for products and production processes that serve some social welfare goals, such as public health or the environment.

All these shortcomings of WIPO are identified as the cause motivating the movement to establish the TRIPS agreement as part of the multilateral trade negotiating system and institutional framework. The integration of the global IPRs regime into the trade system of GATT and WTO had many advantages for the US and the main exporters of knowledge-based products and services. Via this linkage IP standards could reach all the states members of the multilateral trading system and those which like China,

⁴⁷ From the Preamble to the recommendations adopted by the Brazzaville Conference, August 10, 1963, as quoted in Olian Jr, I. A. (1973). *International Copyright and the Needs of Developing Countries: The Awakening at Stockholm and Paris*. *Cornell Int'l LJ*, 7, 81.

wanted to join it. The GATT offered the possibility of implementing high standards of protection of IPRs and a dispute system to enforce them. Also, in spite of the fact that the WTO decision making process is based upon the principle of one-member-one vote –and developing countries would enjoy the majority of votes-, the particular system of “consensus”-based decision-making and the informal meetings –formally contemplated in WTO regulations- permits developed nations to exert control over WTO main decisions⁴⁸.

Ironically, for this approach to be assumed and workable, it was needed to make a drastic turn from the traditional understanding held by the economists and the academia during the second half of the 19th century and part of the 20th century as we have previously noted. While the economic mainstream of the western societies during the end of the 19th century (in particular in the period from 1850 to 1875) were contrary to IPRs as an unacceptable privilege/monopoly which impaired free trade between nations, in this new context when it was seen the necessity of linking IPRs and trade, the lack of a minimal harmonization of IPRs protection all around the world was considering as an element distorted the free trade governed by WTO rules.

In this respect, it is argued that weak or nonexistent protection of IPRs or patents distorts *natural trading patterns and reduces the ability of firms to transfer technology abroad*. Also, it is held that low or nonexistent patent protection *may lower the world's R&D by reducing incentives, and thereby diminish worldwide growth*⁴⁹. Furthermore, in Maskus' words, *the GATT could only be invoked as an appropriate forum for the negotiation of disciplines on international policies that different levels of IPRs tend to*

⁴⁸ Consensus-based decision-making not only deprives developing countries from making full use of the equal status that they share with their more developed counterparts as a result of the Agreement; in fact, at times it may be found to actively work to the detriment of developing countries. First, consensus decision-making, as opposed to unanimity, means simply that no decision is formally objected to by any member present at the meeting. However, the key assumption here is presence in the meeting; the consensus-based decision-making procedure 'ascribes considerable importance to having a permanent presence or, perhaps more accurately, an active “knowledgeable presence” at Blackhurst, R., Lyakurwa, B., & Oyejide, A. (1999, September). Improving African participation in the WTO. In *Paper commissioned by the World Bank for a Conference at the WTO* (pp. 20-21).

⁴⁹ Taylor, M. S. (1994). TRIPS, trade, and growth. *International Economic Review*, 361-381.

*distort trade flows, or, in other words, that IPRs trade related. Differential patent laws influence international trade*⁵⁰.

As we have described in previous chapters, on 15 April 1994 in Marrakech, more than one hundred countries signed the GATT Agreement After a coercive and not too subtle negotiation, marking the culmination of the 12-year-long Uruguay Round and establishing the World Trade Organization, which officially came into being on January 1, 1995. As of July 2016, the WTO has 164 members representing more than 96% of global trade and 96% of global GDP.⁵¹As we know, one of the agreements is the Trade-Related aspects of Intellectual Property rights (TRIPS) contained in Annex 1C of the Final Act Embodying the Results of The Uruguay Round of Multilateral Trade Negotiations.

TRIPS Agreement has important consequences in the global capitalist economy. In the so-called “information society” control over knowledge replaces control over matter and it emerges as the ultimate source of power. The previously mentioned interplay between contingent and political ideational, institutional and material forces plays here an important role when it comes to define which information is commodified, in which terms and with which legal scope. In this sense, what means information society or Knowledge-Based Economy (KBE) and the game rules governing this new economic paradigm or new phase of capitalism are hegemonic narratives⁵² and also the result of a political, contingent and specific process serving some interests at the expense of others.

First, as we know, it requires every member to implement high or western-type standards of IPRs protection; in doing so and as we will see next, TRIPS Agreement creates new spatial and material enclosures over previously public domain intangibles or intellectual commons. As we have seen previously, TRIPS Agreement extends the patent subject-matter to virtually all fields of technology, it raises the

⁵⁰ Maskus, K. E., & Penubarti, M. (1995). How trade-related are intellectual property rights?. *Journal of International economics*, 39(3), 227-248.

⁵¹ https://www.wto.org/english/news_e/archive_e/acc_arc_e.htm

⁵² Sum, N. L., & Jessop, B. (2013). Competitiveness, the knowledge-based economy and higher education. *Journal of the Knowledge Economy*, 4(1), 24-44.

term of patent protection to twenty years, it redefines the usually working requirement of the patents⁵³ and it narrowly regulates the exceptions and the regime of compulsory licenses of the patent. Second, it requires states to implement effective legal and administrative measures to enforce IPRs both in the civil and in the criminal jurisdiction. Third, it establishes a dispute resolution system and a Council for TRIPS to monitor the compliance of TRIPS. Both instruments have proved very effective in order to ensure compliance with TRIPS, specially its deterrent effect and the fear for many developing countries that the failure to meet their obligations could result in important commercial sanctions with dramatic consequences to their economies. This could explain the observed overcompliance of TRIPS that we have mentioned in previous chapters. Finally, through the worldwide commodification of certain knowledge, TRIPS has decisively contributed to create a global profitable market of certain intangibles or information which became commodities and whose main beneficiaries at the moment are those who were its main proponents⁵⁴.

The new global enclosures.

TRIPS Agreement reflects better than anything today's tendency to implement global processes of commodification and appropriation of knowledge as one of the main manifestations of global capital accumulation⁵⁵. Previous to analyze how TRIPS has created those new global enclosures, it is important though to clarify what commodification implies. Knowledge commodities emerge in the contemporary capitalism and the paradigm of the knowledge based economy where, following

⁵³ Article 27 specifies that patent rights are enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. This wording of TRIPS intends to avoid the practice of some developing countries that in the same manner as today's developed countries did in the past, imposed the local working requirement on certain strategic categories of products (in particular pharmaceuticals and agrochemicals) to use IPRs at the service of development, dissemination of technology and other social goals. See. Matthews, Duncan. (2003). *Globalising intellectual property rights: the TRIPS Agreement*. Routledge.

⁵⁴ Regarding the creation of a global market around intangibles and information it is noteworthy to mention some figures. In this sense, and according to the Balance of Payments Statistics of the International Monetary Fund, the receipts from charges for the use of intellectual property have climbed from 41,29 US Dollar billions in 1994 to 318,7 US Dollar billions in 2015, almost ten times the volume of operations. According to that database, while in 1990 the US received 16,64 US dollar billions in 2015 the US received 124,66 US Dollar billions. On the payment's side, India's bill for example has increased from 72,46 US Dollar millions in 1990 to 5 US Dollar billions in 2015 or Honduras from 3 US Dollar millions to 46,36 US Dollar millions. <http://data.worldbank.org/indicator/BX.GSR.ROYL.CD>. Visited on January 20, 2017.

⁵⁵ Capital accumulation as the dynamic that motivates the pursuit of profit as a human action which seeks to optimize profits by maximizing revenue while minimizing costs.

Professor Jessop, knowledge has become the most important factor of production and the key to economic competitiveness. However, the role of knowledge in the economic shift is not new, it has always been behind the major shifts associated with technological revolutions. What seems to be new today is the *growing application of knowledge to the production of knowledge in developing the technical and social forces of production; and the increased importance of knowledge as a fictitious commodity in shaping the social relations of production.*⁵⁶

In this context dominated by profit-oriented, market-mediated activities, certain knowledge has become a commodity (capitalist or fictitious -quasi-commodity-) ready to be sold around the world. As knowledge is a non-rivalrous good –it is not depleted by use- it can only become a commodity insofar as it is made artificially scarce and when its use or access is made dependent on the payment of rent or a royalty via the institution of IPRs as the reward for suppliers of knowledge or information which as IPRs owners may earn super-profits out of their legal monopolies. It is important to remark the distinction between the capitalist and the fictitious character of knowledge as a commodity. In this sense, it is said that knowledge has become a fictitious commodity because much of the knowledge has not been produced to be sold but the decision to sell it and thus, converting it into a commodity has come thereafter. On the other hand, capitalist commodities would refer to that knowledge which is the result of a profit-oriented labor process. In Jessop's views, knowledge is a collective generated resource and it is mostly a fictitious commodity because even if it has been produced within capitalist relations of production much of its creative process embeds previous knowledge existing in the public domain or intellectual commons⁵⁷.

Furthermore, in the operation of becoming a commodity, knowledge goes through different processes and deep social adjustments; first it is disentangled from physical goods and it acquires autonomy as an independent and exchangeable good and it is so integrated into the profit-oriented labor process – or social class relations of

⁵⁶ Jessop, Bob. (2000). The state and the contradictions of the knowledge-driven economy. *Knowledge, space, economy*: 63-78.

⁵⁷ Jessop, B. (2007). Knowledge as a fictitious commodity: insights and limits of a Polanyian perspective. In *Reading Karl Polanyi for the twenty-first century* (pp. 115-133). Palgrave Macmillan US.

production by divorcing intellectual labor from control over the means of production that it deploys –⁵⁸; second it is separated from its social roots and social motives which motivated its production. As a commodity knowledge is valued under the premise profitable/unprofitable getting rid of previous codes to distinguish and consider knowledge as true/false or sacred/profane or distributive/exclusive, it is so transformed from a collective resource (intellectual commons) into exclusive property (IPRs) and; third knowledge does not circulate along domestic closed units (through reciprocity and/or distribution) but is allocated through profit-oriented markets and product-consumption process that is controlled by the logic of capital accumulation⁵⁹. In this respect, we could say that the way in which the global pharmaceutical sector conducts its business and the profit driven performance of its research and innovative activities –and how profit seeking prevails over any other (social) consideration- seem to fit perfectly into the patterns described above. In this sense, we could say as Professor Picciotto that pharmaceutical companies are devoted to seek pills for affluent people’s ailments.

Notwithstanding this, there are inherent tensions and contradictions which do not permit to treat all knowledge as if it were a simple commodity. While “intellectual commons is fundamental to the production of knowledge”⁶⁰-and its use-value may increase when shared thanks to network economies and cooperative “wikipediative” efforts and attitudes-, IPRs are on the basis of accumulation of informational capitalism; whereas every capital wants free access to knowledge, it also seeks profit by charging for knowledge that it supplies. This contradiction is not new but it somehow reproduces the inherent contradiction of capitalism between the socialization of productive forces and private control of the means of production (intellectual commons versus IPRs, information society vs. information economy, public regarding approach vs. exclusivity one). States are charged with resolving

⁵⁸ German Patent Act of 1877 including the provision which contemplated the company’s ownership of individual inventor employees’ inventions as result of Siemens’ influence and pressure over the German legislature or the US Supreme Court decision of 1871 in *United States v. Burns*, which amended the 1791 Patent Act to permit employment contracts to include a clause requiring employees to assign patents or other invention rights to the employer, are a clear reflection of this process of knowledge towards capitalist commodities.

⁵⁹ Jessop, Bob supra note 57.

⁶⁰ Dawson, A. C. (1998). The intellectual commons: A rationale for regulation. *Prometheus*, 16(3), 275-289. Quoted by Jessop supra note 53.

these contradictions and balance the necessity to stimulate innovation processes through IPRs and the dissemination of knowledge as extensive as possible through the protection of the intellectual commons. As we have seen, the states address this issue differently depending mostly on their economic development stage.

TRIPS Agreement has substantially strengthen the global commodification and appropriation of knowledge in order to give way to informational capitalism. TRIPS is however part of a new wave where knowledge that was thought to be either intellectual commons or uncommodifiable is covered now with new or newly extended IPRs. Some have seen in this process of “appropriation of knowledge” a process “analogous to the enclosure of common land in England in the Eighteen Century”⁶¹ or the Second enclosure, this time referred and focused on knowledge⁶². In particular, TRIPS has enable an unprecedented material and spatial expansion of IPRs imposing on many developing countries the obligation to protect and propertize knowledge that in the past was part of the public domain, strengthening the scope and term of proprietary rights on IPRs and providing for categories of knowledge which were new to most countries (both developing and developed countries) and which have to be commodified now (material enclosures).

Other than creating IPRs protection in countries which had a lax or non-existing IPRs regime or expand the protection of some traditional categories of IPRs –term of 20 years for patents, new definition of working requirement and procedural means to ensure compliance- TRIPS provides cover on a global basis via art. 27 (*...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application...*) to the commodification and “propertization” of new categories of knowledge.

⁶¹ For some interesting views in this matter Dardot, P., & Laval, C. (2015). *Commun: essai sur la révolution au XXIe siècle*. la Découverte, and Mattei, Ugo.(2011) *Beni comuni-un manifesto*. Editori Laterza or Peekhaus, Wilhelm. (2009). Primitive accumulation and re-appropriation of the information commons.

⁶² Boyle, J. (2003). The second enclosure movement and the construction of the public domain. *Law and contemporary problems*, 66(1/2), 33-74.

Leaving aside the protection/commodification of new categories of knowledge affecting copyright (Digital Millennium Copyright Act or the European Database Protection Directive) or trademarks (trademark antidilution rulings), in the field of patents there has been a substantial, sometimes controversial expansion of IPRs over categories of knowledge which were previously uncommodifiable or part of the intellectual commons such as business methods, some biotechnology “inventions” and plants. In this sense, it is important to distinguish between intellectual commons which are referred to categories of knowledge whose property is collective and subject to their own norms of access and use and protected from private appropriation but which could be eventually private from that knowledge which is *terra nullius* (public domain) and in principle, it is not capable of appropriation (these two categories are however contingent and they will depend on the previously mentioned interplay of ideational, material and institutional dimensions). In this sense, it is important to remark that the concept of intellectual commons seems to be a reaction against the overwhelming expansion of IPRs to fields of knowledge which were previously considered to be uncommodifiable and part of the public domain. The reaction against the privatization of certain commodified knowledge has been in many cases the creation of an intellectual commons which implies a collective property which intends to safeguard the collectively use-value of certain knowledge against its privatization.

Following professor Picciotto observations on the matter⁶³, the main focuses of expansion of patents over previously uncommodifiable knowledge has to do with the “isolation” principle which enables to claim patent rights on grey areas between a discovery (not patentable) and an invention. This has been an important turning-point for the life-sciences industries. Since the previously mentioned *Diamond v. Charkabarty* ruling the door was opened to speculate about commodification of diverse categories of knowledge which were previously conceived as discoveries or uncommodifiable. Some examples of the former can be found in the patent applications for partially gene sequences, known as expressed sequence tags (ESTs) resulting from the Human Genome Project publicly funded; patents related to specific

⁶³ Picciotto, Sol. *Regulating global corporate capitalism*. See Chapter 4 footnote 78.

genes responsible for the beneficial properties of plants or formulations of natural elements –previously known to particular communities and groups- in a manner which has been denominated “biopiracy”; patents on cell lines derived from the spleen taken from a leukemia patient without consent, a practice and a commodification endorsed by the California Supreme Court in the case *Moore v. Regents of University of California*⁶⁴ or; the protection of plant varieties through *sui generis* protection and plant patents whose titleholder under some legislations retain IPRs to propagation thus being able to create an unsurmountable dependency for individual farmers⁶⁵.

Apart from the contradiction previously mentioned within the capitalism logic itself, this expansion of the IPRs regime, namely the patent regime has generated some important social controversies. Biotechnology patenting became highly contested on technical and ethical grounds. From the ethical and moral perspective as we have examined in the previous chapter, patenting of living organisms was challenged on moral grounds in Europe. The main ethical concern has to do with what is seen as the commodification of life forms, and “appropriation of life”⁶⁶. Due to the fact that the IPRs titleholder may be entitled to claim rights in the progeny of certain patented animal or plants, it may happen that a genetically modified animal or plant could be governed by a IPRs license instead of by an outright sale. Genetically Modified Organisms (GMOs) is still also very controversial not just for ethical motives but because of their impact on health and the environment.

Another highly controversy raised by the new enclosures is associated with the capacity of pharmaceutical and agribusiness firms to take advantage of traditional knowledge on formulations with healing effects or intended for other collective social uses –often explained by the biodiversity-richness of those areas inhabited by traditional communities- and extract from it knowledge over which they may claim private property rights in spite of the fact that that knowledge was perceived as being part of the public domain. The process of identification of bioactive compounds and

⁶⁴ *Moore v. Regents of University of California*, 793 P.2d 479, 51 Cal. 3d 120, 271 Cal. Rptr. 146 (1990).

⁶⁵ This is somehow reflected in “Consumed. What are you eating” a film (2015) by Daryl Wein distributed by Netflix in 2016.

⁶⁶ Bowring, F. (2003). *Science, seeds and cyborgs: Biotechnology and the appropriation of life*. Verso.

commercialization of new products based on biological resources many of which were intuitively enjoyed by traditional and indigenous communities has been called bioprospecting. As result of a number bioprospecting projects some helpful compounds and extracts have been screened and shaped the subject matter of diverse patent applications. Many of these “appropriation” practices have been considered as activities of biopiracy by local communities⁶⁷ who paradoxically could be even prevented from using formulations of plants -which have been used for a very longtime- on the grounds that they infringe new patent rights⁶⁸. This situation led to different social activists to denounce this abusive practice⁶⁹. These controversies around the new enclosures of traditional knowledge have been sometimes addressed by developing countries governments and some scholars through the lens of the IPRs perspective. In this sense, new IPRs formulations have been proposed such as eventual community’s IPRs or “benefit-sharing” based models. Also, it has been suggested that this knowledge could be used as a strategic tool to take advantage of the TRIPS Agreement⁷⁰.

Notwithstanding the above, it cannot go unnoticed that some of those solution proposals are based precisely on the paradigm (commodification and appropriation of knowledge) from which this sort of controversies emerges and that traditional communities may have concerns which do not have to do with sharing of economic benefits but with other considerations related to their beliefs, values or even religion. This also has motivated the creation and formulation of regimes of collective property or intellectual commons such as the open source software⁷¹ which govern the access and use of common or collective property eventually under the premises of

⁶⁷ Mooney, P. (2000). Why we call it biopiracy. *Bioprospecting, Oslo*, 37.

⁶⁸ Svarstad, H., & Dhillon, S. S. (2000). Responding to bioprospecting. From biodiversity in the South to medicines in the North. Spartacus Forlag.

⁶⁹ One of the most illustrative fights against the enclosure of traditional knowledge is represented by the case of the neem tree. In the 90’s the US Department of Agriculture and WR Grace received several US and EPO patents on methods of controlling fungal infections in plants using a composition that included extracts from the neem tree (*Azadirachta indica*), which grows throughout India and Nepal and whose virtues had been known in India for some 2000 years. In 2000 the European patent was successfully opposed by several groups from EU and India including the EU Green Party, Vandana Shiva, and the International Federation of Organic Agriculture Movements (IFOAM) on the basis that the fungicidal activity of neem extract had long been known in Indian traditional medicine. WR Grace appealed, and lost that appeal in 2005 after an important demonstration before the EPO office in Munich on the day of the hearing. For further information see Shiva, Vandana. (2016). *Biopiracy: The plunder of nature and knowledge*. North Atlantic Books.

⁷⁰ Dutfield, G. (2001). TRIPS-related aspects of traditional knowledge. *Case W. Res. J. Int’l L.*, 33, 233.

⁷¹ Hess, C., & Ostrom, E. (Eds.). (2007). *Understanding knowledge as a commons: from theory to practice* (pp. 41-81). Cambridge, MA: Mit Press.

maximizing the collective social interest. In this sense, we could say that the creation of intellectual commons today is a defensive reaction to the excessive appropriation and privatization of knowledge, some of which is fundamental –or in the upstream space- to advance and to further progress and downstream research.

TRIPS or the expansion of capitalist social relations of production on a global scale: A critical eclecticism approach.

With this context in mind, it is hard to understand how most WTO members in their condition of net importers of technology or knowledge-based products and services could agree to be bound on TRIPS. As we have said, TRIPS implies the expansion of IPRs and it is the most effective instrument for the creation of new territorial (global) and material enclosures at a global scale. Commodification of certain knowledge encompasses the unfolding of knowledge-based products in two commodities and thus, it carries two commercial transactions; the tangible product which is governed by an outright simple sale and the intangible, the IPRs embodied in it, which are transmitted under a license which controls and restricts the use of it (computer program, a music CD, a pharmacy pill or even the progeny of a plant or animal). Naturally, this unfolding justifies an increase in price, especially due to the exchange value of the intangible part of the purchase.

In order to explore the last causal factors explaining the emergence of TRIPS and to explain the real motives why states joined the TRIPS Agreement and agreed to the apparently onerous conditions represented by TRIPS, we will follow the “critical eclecticism” approach exposed by professor Donald G. Richards⁷² where he analyzes the issue from different traditional critical perspectives, namely the world systems theory; Gramscian hegemony and internationalization of capital. All three perspectives are complementary in explaining the dependency type relations created by the economic bonds created under the new global legal architecture, in particular, TRIPS Agreement; the economic explanation of the capital accumulation through the commodification of knowledge and the interests of some capitalist practices in

⁷² Richards, Donald G. (2004). *Intellectual property rights and global capitalism*. See Chapter 4 footnote 67.

seeking technological rents; the description of the process of how a hegemonic transnational capitalist class succeed in achieving its goals by instrumentally using the state and creating and unifying ideology which is presented as universal.

Contrary to the official narrative –hegemony ideology- according to which TRIPS would permit that developing countries were beneficiaries of larger foreign investments as long as technology transfer and, in short, their modernization and technological catchup with the most developed countries, the truth is that as we have seen in previous chapters, there is not economic evidence of those announced benefits. As we have mentioned previously, not only has the new IPRs regime been irrelevant to explain the flows of foreign investment or the transfer of technology North to South, but domestic incentives to innovation are also not demonstrated in developing countries⁷³.

We have examined in chapter 4 the numerous shadows casted on the negotiation process leading to the final act subscribing the TRIPS Agreement and the more that dubious legitimacy of such so negotiated agreements. In this respect, it is still considered by many international commentators that the TRIPS Agreement is a concession of developing countries to developed countries, a concession which was made under duress and without adequate compensation beyond the opening up of some markets to the goods of developing countries. Bearing this in mind, it is important to identify at this moment the real forces, logics and reasons leading to the adoption of TRIPS and the global IPRs regime.

From the World Systems Theory's approach, and the analysis of the international agreements as a field of battle or a contest between nations and power relationships TRIPS would be an attempt by powerful countries, namely the US and to a lesser extent by Europe and Japan which acting in the pursuit of their own national self-

⁷³ If we compare for example the number of patent applications of residents of different developing countries we can see that TRIPS has had a little impact or no impact at all. According to the Balance of Payments Statistics of the International Monetary Fund, the number of patent applications of residents in Bangladesh in 1990 was of 32 (44 in 2014), in Guatemala in 1990 27 (10 in 2014), in Honduras 6 in 1990 (6 in 2014), Zambia 7 (14 in 2014) or Nigeria 12 in 1990 (50 in 2013). On the other hand the number of patent applications by residents in the US was of 90.643 in 1990 and it has been increased to 285.096 in 2014. <http://databank.worldbank.org/data/reports.aspx?source=2&series=BX.GSR.ROYL.CD&country=>. Visited on January 21, 2017.

interest, try to perpetuate its dominance over economic relations. In this sense, as it is described by Professor Drahos⁷⁴, the strategy to push a global IPRs regime by the US was preceded by the widespread fears over the loss of US competitiveness and certain feeling of decadence of the country as result of the loss of the war in Vietnam, the emergence of new regional leaders such as India and Brazil and powerful competitors like Japan with an important trade surplus in its trade relationship with the US and the myth that this story of success was constructed on the presumed theft of American ideas and know how. All this led to the conclusion that stronger property rights were needed to protect America industry and ideas.

In this sense, TRIPS would be part of a strategy to maintain the world hegemony of the US (and Europe and Japan as necessary accomplices of this trip) by establishing the terms of trade or the game rules customized to the powerful countries interests at the expense of the weakest countries. Under the official discourse of TRIPS would lay an agenda of underdevelopment and dependency of peripheral developing countries towards the center constituted by developed countries. According to Professor Correa⁷⁵, TRIPS would respond to an American strategy of technological protectionism with the aim of consolidating an international division of labor where northern countries generate innovation and knowledge based products whereas southern countries would be providers of raw material and the market for northern products. In similar terms, professor Drahos views TRIPS as an *institutional project of information feudalism, that is the project of acquiring and maintaining global power based on the ownership of knowledge assets.*⁷⁶

The widening gap between North and South or center and periphery is also explained by the logic of the knowledge based economy. As professor Jessop explains, if knowledge based or knowledge intensive companies in the information economy are to maintain above average- profit rates (also because the unfolding of physical and intangible commodities), less technologically sophisticated companies will get below-

⁷⁴ Drahos, P. (1995). Global property rights in information: the story of TRIPS at the GATT. *Prometheus*, 13(1), 6-19.

⁷⁵ Correa, Carlos M. (2000). Intellectual property rights, the WTO and developing countries: the TRIPS agreement and policy options. (see chapter 4, footnote 68).

⁷⁶ Drahos, P., & Braithwaite, J. (2003). Hegemony based on knowledge: The role of intellectual property. *Law Context: A Socio-Legal J.*, 21, 204.

average profits offering products and services with less exchange value. This would be another driving force behind globalization insofar as less profitable firms are forced to relocate or outsource to lower cost production sites and countries and being able to compete in terms of lower price. This would strengthen the tendencies towards unequal exchange and development associated with globalization⁷⁷

In the pharmaceutical sector, it is noteworthy that the strengthening of IPRs and harmonization of IPRs standards can lead to raise the cost of technological spillovers, reduce the rate of spillovers, and reduce the assimilative capacity of the small firms that tend to dominate the industries of the semiperipheral countries, and slow or even prevent the development of the pharmaceutical industries in these countries which eventually and historically have been more sensitive and responsive to the health need of their local communities who in contrast, cannot afford the center-based pharmaceuticals⁷⁸. Also, as Professor Drahos notes, this may affect an important factor in economic growth, human capital or "*knowledge embodied in people*"⁷⁹ which may be impaired by unfit IPRs law by restricting dissemination of knowledge through the pricing mechanism.

Even if this analysis is certain in identifying the national self-interest of some powerful states, namely the US to explain the adoption of TRIPS and the strategy to succeed in carrying out their political agenda, maintaining their hegemony and keeping international relations based on dependency, it is somehow superficial and oversimplifies the real and complex factors behind the adoption of this new IPRs regime. In particular, it takes for granted that nations and univocal units without fissures and with a perfectly determined and defined national interest. This perspective ignores also the competing interests and conflicting classes within the same state. In this sense, in peripheral states, there may be also privileged sectors of population who can advance their careers and vital projects in perfect tune with the hegemonic forces of the world economy⁸⁰.

⁷⁷ See Bob Jessop supra note 54.

⁷⁸ See Richards G. Donalds supra note 69

⁷⁹ See Drahos, Peter, supra note 26.

⁸⁰ See Matthews, Duncan, supra note 50.

Furthermore, the interests at stake in TRIPS and the contradiction and controversies around this international agreement are better explained by the distinction that separates competitive from monopoly capital or by the tension between those positions promoting the privatization, commodification and appropriation of knowledge versus those supporting public domain, intellectual commons and public regarding approach to IPRs. Naturally, different states are situated differently in this regard, southern states tend to defend policies favoring a public regarding approach of knowledge and developed countries the proprietary understanding of the IPRs regime but this is not always like that and political positions of the states are a consequence rather than the cause of the TRIPS Agreement which as an international regulatory infrastructure of globalization, responds to a deeper process of capital accumulation.

In fact, the decision of implementing developed countries' IPRs standards worldwide rather than being designed in consideration of the general interest of a specific nation, in particular of the US, was the result of an important pressure of transnational companies and business, transnational capital which make the US government represent their interests. The role played by the US government seeking the adoption of TRIPS goes beyond state-centered theories and hegemonic stability theories of international relations or maximizing the social welfare of its citizens; being these considerations important, they were not decisive to implement the strategy deployed by the US. The story about how the TRIPS Agreement was forged following the transnational business penetration in the core of political decision-making processes of the US Government via the Advisory Committee for Trade Negotiations (ACTN) chaired by the CEO of Pfizer⁸¹ suggests that rather than by public interest considerations, the position and standing of the US is better explained by its condition as representative of a transnational capitalist class; an hegemonic one which involves the consent of the controlled classes –via the coercive capabilities of the state and the intellectual leadership of key elements of civil society- and the

⁸¹ For an interesting and exhaustive explanation on the precedents of the negotiation see Drahos, P. (1996). Global law reform and rent-seeking: the case of intellectual property. *Journal of Political Economy*, 988, 1002.

instrumental use of the state through the Gramscian termed mechanism of the *extended state*⁸².

Therefore, at the core of the reasons explaining the implementation of the IPRs regime on a global scale is the desire of a hegemonic transnational capital to capture and maximize as fully as possible the rents associated with their knowledge based commodities as an instrument to get extraprofits in the profit-driven logic of capital accumulation. IPRs would be the basis for those extraprofits (based on the commodification of knowledge) and monopoly rents –IPRs permit them to consolidate longer term advantages and technological rents which would otherwise go away as a consequence of free riders or further innovations-. In this sense, much of IPRs global regime could be explained by the unproductive, rents-profit-seeking activities. Once the IPRs have been secured, many IPRs titleholders may be more interested in conducting rent-seeking activities rather than investing in further innovation and this produces a logic distortion in the pattern of economic activity. In fact, the pathway observed by the global pharmaceutical business analyzed in previous chapters seems to match with this described behavior pattern. The Italian case⁸³ where pharmaceutical companies successfully challenged the Italian legislation which excluded pharmaceutical products from patentability has showed us that the use of more patents or exclusive rights does not imply more investments in R&D.

Hence, the desire of a hegemonic transnational business and class for profit, their capacity to create a hegemonic ideology –presented as universal- based on their particular interests and the instrumental state at the service of their interests –which are sometimes wrongly perceived as the general interest-, all this creates the propitious *historic bloc*, the guiding threat which articulates (manipulates) forces of the state and the civil society and that *provides a better guide to their behavior than their imagined nationalistic allegiances*⁸⁴. In this sense, the theory of public choice⁸⁵

⁸² Cox, R. W. (1993). Gramsci, hegemony and international relations: an essay in method. *Cambridge Studies in International Relations*, 26, 49-49.

⁸³ Scherer, F. M., & Weisburst, S. (1995). Economic effects of strengthening pharmaceutical patent protection in Italy. *IIC-INTERNATIONAL REVIEW OF INDUSTRIAL PROPERTY AND COPYRIGHT LAW*, 26(6), 1009-1024.

⁸⁴ See Richards, Donald G see Chapter 4 footnote 67.

which “dispassionately” analyses the political decision-making process as a transaction business where public good or the preferences of the general public are subordinated to private interests of interest groups and rent-seekers could certainly and sadly make sense in this case.

⁸⁵ Farber, D. A., & Frickey, P. P. (1991). *Law and public choice: a critical introduction*. University of Chicago Press.

6.4. Philosophical foundations of IPRs: the contradictions of an interpretation of IPRs as absolute rights versus IPRs as a set of rights/privileges with property prerogatives.

Why resorting to the philosophical foundations of IPRs?

As we have seen in the previous section 1, IPRs, or better, the ideational, technological and institutional dimensions behind the protection of knowledge through IPRs are the result of a political, historical and contingent process which has been shifting along the (brief) history of IPRs. In section 2 we have examined the unprecedented expansion of IPRs spatially and materially. In effect, the IPRs regime has become global and new enclosures have been created over knowledge previously considered to be part of public domain and/or over intellectual commons. The material and spatial expansion of IPRs have converted these rights in absolute property rights, in a legal institution which operates in the knowledge based economy as a mechanism for capital accumulation on a global basis. Furthermore, the global IPRs regime does not take into due account the instrumental nature of IPRs, the aims informing their inception and their social function for the common good. The new institutional approach of IPRs has implied a *iuris et de iure* application of IPRs which deeply contradicts their nature as an instrument for the procurement of superior goods, it fails in the achievement of the purported aims and it does not accomplish their social function.

Considering the above, in the next sections of this chapter we are analyzing the instrumental nature of Intellectual Property as opposed to the consideration of IPRs as absolute rights. In this regard, Intellectual Property is a legal institution created mainly for the procurement of certain social goods, in particular to operate as an incentive for creativity and technical and scientific progress of the society where it is implemented (*to promote the Progress of Science and useful Arts*). With the aim of accomplishing this key role in society, the institution of Intellectual Property contemplates the granting of a set of rights to the IPRs titleholder with some property-right related features and prerogatives. However, as we will see in next section about property, IPRs legal configuration and content differs substantially

from “genuine” property rights making IPRs a category of *sui generis* property rights or rather, a legal institution, a set of rights temporally “vested with property prerogatives”.

Therefore, the philosophical foundations of IPRs may be very helpful to us in order to understand the grounds justifying IPRs and their inherent social functions in such a manner as to claim a revised and more contextualized application and implementation of IPRs in the different jurisdictions. In this sense, we should escape from certain “institutional fetishism” i.e. the belief that abstract institutional conceptions such as intellectual property, free trade or free civil society have a single, natural, necessary and inevitable institutional expression⁸⁶ and being open to a different interpretation and implementation of certain legal institutions like IPRs, an insight of IPRs which far from being willful, and discretionally creative, become more coherent with their nature and social grounds which justified their creation and give their current legitimation. As we will see, even in the case of those philosophical justifications that view IPRs as quasi absolute rights, IPRs are contextualized in a social context where they play an instrumental role, comply with certain social functions and contemplate certain social duties.

Theoretical rationale of Intellectual Property Rights.

As we have previously seen, IPRs and in particular patent rights are based on intangible non-rivalrous goods. Goods which are non-rival are goods that can be enjoyed simultaneously by an unlimited number of consumers. IPRs create then artificial scarcity of non-rivalrous goods where otherwise there would not be. Through the IPRs and the “propertization” of certain knowledge or intangible goods, her owners are granted a bunch of rights vested with property prerogatives, among which the most prominent is the legal monopoly which enables its owners to exclude others from access to them without the titleholder’s consent. The authors analyzed hereunder are those philosophical authors and philosophical schools which are generally invoked to support different interpretations of IPRs.

⁸⁶ Unger, R. M. (1996). What should legal analysis become?. Verso.

IPRs as natural rights based on a simplistic interpretation of Lockean theory of property.

Diverse arguments tend to justify the creation of Intellectual Property or the property-prerogatives based system or the “propertization” paradigm over some intangible goods. A first set of arguments have to do with natural rights considerations inspired in Locke’s writings about property. Locke deals with property in the Chapter V of his *Second Treatise*⁸⁷. In the context of the commons, Locke states the following: [...] *God, who has given the world to men in common, has also given them reason to make use of it to the best advantage of life and convenience. The earth and everything in it is given to men for the support and comfort of their existence. All the fruits it naturally produces and animals that it feeds, as produced by the spontaneous hand of nature, belong to mankind in common [...] every individual man has a property in his own person (owns himself); this is something that nobody else has any right to. The labor of his body and the work of his hands, we may say, are strictly his. So when he takes something from the state that nature has provided and left in, he mixes his labour with it, thus joining to it something that is his own; and in that way he makes it his property [...].*

Locke is frequently cited and invoked in the context of IPRs. As it is explained by Drahos, the willful construction of a theory of IPRs based on Locke general thinking is explained by the desire to find ideological legitimacy by those who defend a configuration of IPRs as natural property rights, as quasi-absolute rights which are not subject to any other consideration or nuance⁸⁸. The element of labor and the mixing metaphor in order to create private property -without the necessity of the consent of the other commoners- permit the advocates of an absolute view of IPRs to hold that private property rights are part of the state of nature, that they are previous to the state and that they are not dependent for their existence upon convention or positive law.

⁸⁷ Locke, J. (2014). *Second Treatise of Government: An Essay Concerning the True Original, Extent and End of Civil Government*. John Wiley & Sons.

⁸⁸ Drahos, P. (1996). *A philosophy of intellectual property* (Vol. 1). Aldershot: Dartmouth.

In this sense, IPRs would be justified on the basis of the creator's moral entitlement to hold as property the fruits of her labor (Labor theory). This would be a moral justification based on justice considerations; it seems to be fair that one could be the owner of what she creates. Furthermore, within these considerations there are arguments justifying IPRs holding that "but for" the creator, there would not be work and therefore, granting an exclusive right to the creator does not deprive anybody of something that otherwise would not exist. Therefore, the author of the creative works would be fully entitled to the property of her work⁸⁹.

Notwithstanding this, Lockean theory on property and its application to IPRs are not as unanimous and simple or absolute as one could think and it has been the subject of diverse –sometimes opposed– and lively interpretations which are beyond the purpose of this dissertation. While for some commentators such as Tully, Locke's thinking justifies not the right of private property but the commons⁹⁰, for others like Macpherson, Locke's theories provide a moral foundation and legitimation for capitalism, unlimited private accumulation, bourgeois legitimation and a political theory of appropriation⁹¹.

Furthermore, there are a number of remarks which deserve specific attention and which question the somehow simplistic interpretation of Locke's work as supportive of IPRs as natural rights. First, despite the fact that Locke derives property rights (IPRs) from natural law, private rights would not be absolute but instrumental and subordinated to the prevalent rights to life and self-preservation⁹². Second, it is important to frame Locke's reflections on the historic period when they were made. In effect, natural rights were called to play a revolutionary political role. In this respect, it is noteworthy noting that Locke deals with property in the chapter 5 of the

⁸⁹ Sidgwick, H. (1901). *The principles of political economy* (Vol. 132). Kraus.

⁹⁰ Tully, J. (1982). *A discourse on property: John Locke and his adversaries*. Cambridge University Press. This author explains how wealthy landowners were attempting to enlarge their estates by enclosing the Commons without the consent of the commoners. Their justification was that they could make better use of the land than could the commoners. Three Bills to legalise enclosure without consent were introduced in the House of Commons, 1664, 1661 and 1681, but they were defeated. As he explains, Locke's theory serves explicitly to legitimate the rights of the commoners against the enclosing landlords.[...]

⁹¹ Macpherson, Crawford Brough. (1964). *The political theory of possessive individualism: Hobbes to Locke*. Oxford: Oxford University Press.

⁹² Drury, S. B. (1982). Locke and Nozick on Property. *Political Studies*, 30(1), 28-41.

Second Treatise of Government, a work where Locke develops his theory about Government and which is considered an open challenge to the absolutist monarchical government. Contrary to the idea that the kings were Adam's heirs and consequently they held the legitimacy to rule the world, he is also opposed to the Adamite theory of property by which property has come under the dominion of the aristocracy as heirs of the original owners of the land. In introducing the labor element, Locke undermines the aristocratic origin of property.

On the other hand, and following Locke's logic, IPRs can be considered as a fair reward to their creators and inventors, i.e., it is a question of justice that an inventor or an author receives a reward and that she can make a living out of it –individuals had to exist by their labor-. However, from the moment that their work and their capacity are commodified and that their intellectual work and implied IPRs are the property of the company or firm which hires them (owner of the means of production), the argument which links IPRs with the “just reward” is certainly diluted since the reward received by the original creator or inventor may be far from being just or proportional to the creation of capital for the firm where the original individual inventor came up with the innovative work.

Also, it is not clear which is the specific object of the property right affected by labor, its precise demarcation. In this sense, it is remarkable Nozick's teasing example when he is wondering whether he may claim property rights in the ocean by mixing his tomato juice with the ocean⁹³. Furthermore, in today's complex processes of production where a bunch of actors, legal entities and elements are implied in the innovation of products and services, where the romantic image of the individual inventor represents a *rara avis* among the patent owners, especially as far as the development of patentable knowledge is regarded –where innovation is the result of more and more sophisticated and industrial processes-, demarcation and extent of the object of the property right following this labor perspective has become a difficult -when not discretionary- task.

⁹³ Drahos, see supra note 85.

Finally, in order to comprehend the general picture of Lockean approach to property, it is important to refer Lockean *provisos*⁹⁴; the acquisition of private property from the commons would be limited by certain so-called *provisos*: property would be conditional upon a person leaving in the commons enough and as good for the other commoners (sufficiency proviso) and a person cannot take more out of the commons than they can use to advantage (spoliation proviso). It is also said that the reading of Lockean writings and its application to IPRS cannot be limited to just one or at most two (typically, spoliation and sufficiency) provisions but also to the third proviso (*charity proviso* in Locke's First Treatise) saying that an individual has a right to the surplus of others when that individual is starving or lacking any necessity of life, this giving us a new more balanced and complete Lockean liberal theory of property⁹⁵ and IPRs.

Therefore, from a Lockean perspective, IPRs would be far from being absolute. Apart from the historical and circumstantial context of Locke's thinking which requires an updated reading of his –then “revolutionary”- work –some commentators have even considered that property arrangements after the introduction of money are justified primarily by utility rather than natural right⁹⁶-, the so-called by Nozick⁹⁷ Lockean provisos, establish important limitations for the acquisition of private property from the commons, limitations which take into due account the social impact of private property and the necessary common good which has to be safeguarded.

Personality based justification for IPRs; Hegel and Kant.

A second set of approaches –especially developed in the continental European legal tradition- would be based on personality-based considerations, saying that some creations are intimately associated with her creator's personality and unique spirit; a certain relationship of property to individual will, individual choice, individual freedom and personal autonomy. This approach is partly inspired on Hegel and

⁹⁴ Widerquist, K. (2010). Lockean theories of property: Justifications for unilateral appropriation. *Public Reason*, 2(1).

⁹⁵ Merges, R. P. (2011). *Justifying intellectual property*. Harvard University Press.

⁹⁶ See Drury, supra note 89.

⁹⁷ Nozick, R. (1974). *Anarchy, state, and utopia* (Vol. 5038). Basic books.

Kantian theorization of property, a “personality theory” that describes property as an expression of the self. These theories also conceive private property rights as crucial instruments to the satisfaction of some fundamental human needs.

For Hegel, property plays a dual role. First and most importantly, property is the embodiment of personality,⁹⁸ in particular, the first embodiment of personality in the process to achieve absolute freedom; freedom not to be understood as an absence of restraint for the individual but rather as a “realization of necessity”⁹⁹ (the ability of the individual to understand what they rationally must do), a state of being which is to be situated in a given historical context. Property in this sense will help the individual to make a transition from a subjective world (self-consciousness) to the objective reality (a manifestation of one’s personality in a particularistic, determined manner). According to Hegel, individual’s goes through a process where property is framed in the first stage of an evolutionary process (personality to morality, morality to ethical life, family to civil society, civil society to state), thus property is not an absolute reality but it is intended to be an instrument, to contribute to the development of personality. Secondly, less importantly in Hegel’s work and related to the development of the personality, property helps the individual to satisfy her biological necessities.

Hegel entrusts to the state the task of protecting the property of its citizens; property is not viewed as an end in itself but it plays an instrumental role within the tense and delicate balance of three subsystems of the state: the political, the civil and the ethical dimensions, three of which constitute the state. Civil society represents the self-interested individualism, the subjective impulse where institutions protecting property are framed, civil society may pose a danger to the ethical life of the state and thus it has to be tempered by the ethical dimension (the set of shared values, attitudes and approaches to life of a given community) for only the ethical life of the state makes it a community. Hence, even if Hegel talks of an “absolute right” of appropriation, it is necessary to put in context his views on property as an instrument to externalize and recognize individual’s will - externally and before others-, in the

⁹⁸ Hegel, G. W. F. (2015). *The philosophy of right*. Hackett Publishing.

⁹⁹ Ryan, A. (1984). *Property and political theory* (p. 118ff). Oxford: Blackwell.

first stage of an evolutionary process (an instrument at the service of the development of personality). Furthermore, Hegel –who at the end holds a bourgeois model of society- is aware of the extremely needy individuals and the duties of the state and the civil society in order to offset the consequences of a system creating a legion of impoverished class¹⁰⁰. For Hegel, the state cannot be merely the compliant arm of civil society and of individual's subjectivism and their property claims, this sort of ascendancy of civil society and its subjective individualistic interests could provoke the imbalance of the mentioned balance of the three dimension and be ruinous for the state. If the state became a mere servant of the proprietarian elements of civil society, the capacity of the state to protect the ethical life of the state would be certainly impaired for individual participation in the larger ethical life of the community is the final stage of the individual's journey to freedom¹⁰¹.

Referring to intangible realities or knowledge which could be subject to property (to Intellectual Property), Hegel distinguishes between physical property and intellectual property as the latter may affect differently to personality and the individual's will. In this sense, Hegel expresses his hesitations in calling *such gifts, knowledges, powers, mere things, because although they may be bargained for as a thing, they have an inner spiritual side*¹⁰². This understanding of intangibles may support our consideration of IPRs as *sui generis* property or as *rights vested with property prerogatives*. Thus, Hegel acknowledges the possibility that a mental product can be *externalized and directly converted into an object, which it is possible to others to reproduce*. In this respect, as to the reproduction capacity, Hegel distinguishes between those hand-made reproductions of an original artistic work in respect to which Hegel considers to be *essentially a product of the copyist's own mental and technical ability* –not infringing the original artist's rights- and those more automatic reproductions such as those literary facsimiles in which case the reproduction right belong to its original author. In this respect it is noteworthy that Hegel resorts to a labor based argument to justify the consideration as a servile copy – *the way to reproduce such things, as mere things, is a matter of ordinary skilled labor-* or one deserving certain acknowledgement - .

¹⁰⁰ Waldron, Jeremy. (1990). The right to private property.

¹⁰¹ See Drahos, supra note 85.

¹⁰² See Hegel, supra note 95.

However, Hegel does not seem to hold an absolute view of the right of the original author or inventor over their right to consent the reproduction. He explicitly notes that *the justification of the right of the author or inventor cannot be sought in his arbitrarily making it a condition [...]* and seems to be aware of the importance of common knowledge in the process of learning and the difficulties to draw the line between original work deserving “property rights” and that knowledge which becomes a necessary element in the process of learning. In Hegel’s own words *it is not possible to state accurately, and establish explicitly by law and right, just how far the new form, which accrues through repeated expression, should transmute the scientific treasure or the thoughts of others, who are still in external possession, into a special mental possession of the person who re-constructs them; how far, in other words, a repetition of an author’s work should be called a plagiarism. Hence plagiarism must be a question of honor, and should be refrained from on that score.*

Following a “personality type” approach to property, Kant explains property as an instrument for the individual to expand her range of freedom. In this sense, certain vital projects of human beings require control over external objects and property would ensure that control. Furthermore, in Kant’s view, the author’s work is an expression and a manifestation of her ideas and an expression of her personality and thus, it deserves a moral respect. Kant’s view on property is said to inspire most authors’ rights jurisprudence and legislative European civil systems protecting authors’ moral rights. Recognition of moral authors’ rights would be so based on the understanding of dignity advanced by Kant. In this sense, author’s creation would be also a means of exchanging thoughts and it is related to the personal and inalienable right of every man to express and communicate her ideas. This approach contributed to create the theoretical basis for the modern doctrine of moral rights¹⁰³.

On the other hand, IPRs would also be justified on the ground that they create social and economic conditions conducive to creative intellectual activity, which in turn is important to human flourishing. Kantian approach to property is far from being

¹⁰³ Suhl, N. C. (2001). Moral rights protection in the United States under the Berne Convention: A fictional work. *Fordham Intell. Prop. Media & Ent. LJ*, 12, 1203.

absolute, or categorical. In this sense, as it happens with the Lockean charity proviso, Kant's Universal Principle of Justice –individual freedom has to coexist with the fundamental freedom of any other person- encompasses obvious constraints on private property rights which are limited by the freedom of others. In this respect, Kant argues that one's property claims are only valid insofar as they take into account the freedom of all others as well. As a result of these premises, Kant's theory is said to hold two nuclear values; the dignity and worth of every individual and the importance of the community of human kind¹⁰⁴.

Critics of the personality-based arguments are focused on the important shortcomings of this approach in today's world and the circumstances surrounding nowadays production and creation of intangibles. On the one hand, personality-based theory would not justify the creation of the IPRs regime on intangible goods since there would be other instruments and means which could also satisfy the ethical or moral rights of creative or inventive individuals. Furthermore, this personality based argumentation posed reasonable doubts on whether or not personality is present in every case and every intangible covered by IPRs. Intuitively, artistic or literary works may embody better her author's personality than a pharmaceutical compound; it is held that while some copyrightable works such as poems, songs, paintings or movies are receptacles for personality, the justification does not seem to fit well into other categories of works covered by IPRs such as computer software, pharmaceutical patents or microchips which normally embody utilitarian solutions to specific needs¹⁰⁵. Also, some innovative processes imply a collective effort of large teams of people contributing to a part of creations and works owned by corporate entities, a creative process where the "romantic" figure of the single inventor in her lab is more and more diluted. In effect, the corporatization of the production of most intangibles covered by IPRs, today's real world conditions in the industries producing IPRs invalidate the idealized myth of the lone creator while corporations use the IPRs system to advance their own self-interests¹⁰⁶.

¹⁰⁴ See Merges supra note 95.

¹⁰⁵ Hughes, J. (1988). The philosophy of intellectual property. *Geo. LJ*, 77, 287.

¹⁰⁶ See Merges, supra note 95.

The Utilitarians. Maximizing pleasure for all.

Utilitarians seek to maximize total utility. The father of Utilitarianism Jeremy Bentham describes utility in terms of the sum of all pleasure resulting from an action minus the suffering of anyone involved in the action following the principle according to which *it is the greatest happiness of the greatest number that is the measure of right and wrong*.¹⁰⁷ Utility maximization is considered to be a guiding behavioral rationale for economic actors with the aim of allocating the resources of the market in the most efficient manner. Utilitarians provide important support to property rights and its role in the economic system. Bentham whose thinking was premised on the then nascent capitalism, defended that happiness consisted in four subordinate ends of the legislative process; subsistence, abundance, equality and security. Security was the prevalent end of the law and in case of conflict between equality and security, preeminence was to be given to security (security as to the certainty about one's property rights and that one will enjoy the fruits of her labor)¹⁰⁸.

Logically enough, utilitarian arguments are the most influential justifications of modern IPRs regime. Goals such as incentives to innovation, dissemination of knowledge or the promotion of the progress of science and useful arts (US Constitution) are constantly cited and mentioned in defense of IPRs and as explanatory memorandums of many IPRs norms and laws. The traditional utilitarian justification for IPRs is well known; as ideas require time and investment to be created and produced and may be copied freely without depriving others of their use coping with important free riding problems, it becomes necessary to give creators an exclusive right in order that they could recoup the investment made and IPRs would contribute to that end as an incentive for new knowledge which is ultimately good for society. In this sense, it is considered that absent the protection of IPRs most would

¹⁰⁷ Bentham, J. (1996). The collected works of Jeremy Bentham: An introduction to the principles of morals and legislation. Clarendon Press.

¹⁰⁸ Bentham, Jeremy, and R. Hildreth. (1864). Principles of the civil code.

prefer to copy ideas rather than investing time and resources to create new ideas and knowledge.

Apart from the legitimate doubts as to whether the creators or inventors are most strongly motivated by the prospect of having a monopoly and substantial economic profit and surplus (disregarding noneconomic motives to create), and whether the maximum utility is effectively achieved by restricting knowledge and information flow instead of permitting its free dissemination, IPRs may be counterproductive as IPRs may discourage innovation by reducing and impairing follow-on innovations based on improvement of IPR protected knowledge¹⁰⁹. However, it is noteworthy that rather than challenging the utilitarian rationale as a valid approach to justify IPRs regime, and the instrumental nature of IPRs, critics and debates are focused on casting doubts about the real gains and announced virtues of the IPRs system. In fact, as we have previously seen in the analysis of the TRIPS Agreement and its announced benefits, many of the arguments invoked to justify its adoption and its necessity are predicated on unproven or even disproven empirical claims.

Other philosophical justifications.

There are also other theoretical justifications some of which may be slight variants of the traditional sets of philosophical theories analyzed above. Some of those are rooted in the proposition that IPRs should contribute to the achievement of a just and attractive culture. This theoretical construction derives from different schools of thought such as the Legal Realists, and the various proponents (ancient and modern) of classical republicanism¹¹⁰.

On the other hand, professor Lemley distinguishes between standard justifications for IPRs which would be *ex ante* justifications i.e. the goal of IPRs is to influence the behavior that occurs before the right comes into force and the new justifications

¹⁰⁹ Heller, M. A., & Eisenberg, R. S. (1998). Can patents deter innovation? The anticommons in biomedical research. *Science*, 280(5364), 698-701.

¹¹⁰ Fisher, W. (2001). *Theories of Intellectual Property, New Essays on the Legal and Political Theory of Property*. Cambridge.

identified by the professor in the practice of US law, justifications which are not based on the incentive to create new ideas but centered on the evolutive process and management of those ideas that IPRs permit afterwards (*ex post* justifications). In particular, they consider IPRs as an important incentive for IPRs titleholders to do follow-on innovation and improvement of existing innovations and how IPRs are necessary to control overuse of information (tragedy of the information commons). Both justifications are strongly challenged by Lemley as theories without empirical support and tending to hold strong, and quasi perpetual IPRs which question the market capacity to produce efficient outcomes¹¹¹.

Some final remarks on philosophical foundations of IPRs.

In spite of the fact that the legal configuration of IPRs are partly rooted in many of the above moral considerations, it is important to say that the most extended and accepted justification for the existence of IPRs nowadays is of an utilitarian nature; it is based on economic rationale utilitarian arguments, i.e. IPRs are perceived as a way to get maximization of net social welfare. IPRs are in this sense, believed to constitute the necessary incentive for inventors to engage in creative and innovative endeavors. Unlike tangible assets, the tragedy of the commons -the idea that property held in common may be harmed by overuse- does not take place. The problem for intangible assets is just the opposite; the risk is rather one of underproduction. It is argued that inventors might fail to invent or create for fear of free riding by others –new entrants without those sunk costs- losing all competitive advantage as original inventors/creators. As some inventions are costly to create and the costs of it are front-end, fixed costs, IPRs will enable the inventor to recoup those fixed costs.

Also, from this utilitarian rationale, IPRs are held to fulfill one important goal other than being an incentive for innovation; IPRs system permits a complete and sufficient disclosure of the invention to the public that will enable other skilled people in the pertinent field to research and use the invention; being this spread of new inventions beneficial to the transfer of technology and in general, to society. In this sense, IPRs

¹¹¹ Lemley, M. A. (2004). Ex ante versus ex post justifications for intellectual property. *The University of Chicago law review*, 129-149.

would constitute a social contract between society and creators/inventors by which a monopoly is granted to the IPRs owner in order to recoup her efforts and being encouraged to keep on innovating in return of disclosing the relevant information on the protected invention. We have previously seen how different national governments have used IPRs system as an instrument for the achievement of different strategic purposes of the national economy.

The important point of revising philosophical justifications of IPRs is not to explore a rhetoric metaphysical analysis of the legal institution made of IPRs. For the purposes of this dissertation this analysis and the importance of utilitarian arguments to justify the economic prerogatives inherent to IPRs monopolies serves us to conclude that IPRs are not absolute quasi-natural rights but contingent historical and political creatures of law. Those who invoke Locke or Kantian and Hegelian justifications of IPRs implicitly tend to suggest that IPRs, and in general property rights are previous to law and previous to the state. This doctrinal approach to IPRs is not trivial; the configuration of IPRs as quasi natural absolute rights enables their titleholders to claim an application of IPRs decontextualized and without regard to the socioeconomic context or socioeconomic impact of IPRs in the spatial and time dimensions where IPRs are applied. In contrast, the instrumental nature implied in the utilitarian approach to IPRs confers the states to monitor whether these rights fulfill the social goals they are called to advance. Ironically, those who support a “natural rights-based absolute proprietarianism” of IPRs are the least fitted candidates to be the holders of a natural rights version of IPRs since Lockean or Hegelian views on property and subsequent interpretations of IPRs are mostly inspired on creative or inventive individuals who present very few similarities with today’s corporations devoted to intensive production of commodified intangibles.

CHAPTER 7. THE SOCIAL FUNCTION OF INTELLECTUAL PROPERTY FOLLOWING PARAMETERS OF DELIBERATIVE DEMOCRACY.

Introductory notes.

In previous chapters we have observed that the expansion of IPRs regime towards a conception of absolute quasi natural rights -that emphasizes the private proprietary aspects over other dimensions of this social legal institution- disregards the nature and legal grounds which justify and explains its existence and enforceability as a social, contingent, historic and political institution at the service of specific social functions.

The mentioned evolution of IPRs, its strengthening and its spatial and material expansion to new categories of knowledge and intangibles is not the result of any empiric research which supports this approach in view of the outcomes provided by in the sense of better contributing to achieve the social goals attributed to IPRs. On the contrary, it has been revealed that this new configuration of IPRs creates important global dysfunctions and that, far from encouraging innovation and the progress of all societies, the current patent regime as a system of incentives may block follow-on innovation or slow it. Also, as we have seen regarding the pharmaceutical field, the patent system may foster rent-seeking or anticompetitive conducts rather than investments in real innovations or novel products with effective new therapeutic effects. Furthermore, the implementation of a global IPRs regime as it is the case of the TRIPS Agreement or TRIPS-Plus agreements may impair the development of some developing countries –with different degrees of development and different social and economic needs- and the access to certain knowledge or goods which are crucial for the welfare of the population. In particular, pharmaceutical patents may conflict with the desirable access to medicines by large number of people who cannot afford them because patents raise the price to insurmountable thresholds.

In fact, the expansion of IPRs rather responds to the characteristics of a new phase of capitalism which requires the commodification of knowledge and information in its constant process of capital accumulation over new realities and goods. The globalization of IPRs also contributes to keep the hegemony of developed countries and especially, of global capital that now operates at global scale overcoming national borders, national limitations and expensive and time consuming bureaucracies, procedures and different regulations.

The new paradigm of the global IPRs regime focused exclusively in securing IPRs as absolute quasi-natural rights has thus forced a denaturalization of IPRs which entails undesirable consequences and carries a negative impact in socioeconomic terms. The attempts of resorting to other legal bodies of international law -such as human rights law- in a scenario of legal pluralism or other political collective actions of governance -like global public goods- have showed important shortcomings in their role as measures to counterbalance IPRs regime negative impact. Therefore, this dissertation holds the thesis that the excesses and negative consequences of a *iuris et de iure* and decontextualized application of IPRs could be remedied by recovering the real nature and scope of IPRs. In this sense, IPRs would be a social institution integrated by rights vested temporarily with property prerogatives. In the core of their definition and scope, IPRs would be a legal instrument called to fulfil certain social functions and pursue the general interest following deliberative democratic parameters in order to properly identify and weigh all the interests as well as hegemonic mainstream and counterhegemonic voices in a global public sphere.

In this sense, it is noteworthy that in the recent debates of the TRIPS Council, some countries have highlighted the importance of evaluating TRIPS provisions in the light of principles other than the mere and strict protection of private property –enforcing the principles contemplated in article 7 and 8 of TRIPS-. Some commentators hold that the development of such global welfare standards, and the evaluation of TRIPS provisions in light of them, requires wide-ranging public discussions. *We are still only*

in at the initial stages of the debate over the framing of an international IPR regime that can adequately reflect global welfare standards¹.

Likewise, the final report of the U.K. Commission on Intellectual Property Rights states that intellectual property rights should be regarded “*as instruments of public policy which confer economic privileges on individuals or institutions solely for the purposes of contributing to the greater public good*” and that the conferred privileges should be “*a means to an end, not an end in itself*”. Such an emphasis is important, because interest groups, the Commission held, *often lose sight of the basic mission of the WTO which, as stated in the preamble of the WTO Agreement, is to promote trade and economic development, not to protect the interests of particular private IPR-holding interest groups.*² Therefore, a new conceptual framework of the IPRs more coherent with the nature and scope of these *sui generis* property rights and the identification of a global public sphere where public interest and deliberative democracy could be advanced become necessary to overcome the dysfunctions and failures of the current regime, to compensate or minimize the negative socioeconomic impact and to provide it with greater institutional legitimacy.

¹ Picciotto, S. (2002). Defending the Public Interest in TRIPS and the WTO. See chapter 2 footnote 107.

² Barton, J. H. (2002). Integrating intellectual property rights and development policy: Report of the commission on intellectual property rights. Commission on Intellectual Property Rights.

7.1. Putting IPRs in context; a comparative review of the social function of property and IPRs.

IPRs system are today widely and mainly based and justified on social utility and instrumental considerations. In this sense, propertization of intangible assets or conferring property prerogatives over intangibles are said to promote innovation – which eventually will not be undertaken if not properly rewarded and protected from free riding problems- and facilitate dissemination of relevant information, all of which contributes to the development of science and industry and it is beneficial to the society where this exclusive rights system is implemented.

As we have seen in the previous sections, IPRs are the result of a contingent, political and historic process which are therefore, subject to changes and transformation. As it happened with other legal institutions like the history of corporations and the history of property itself, IPRs have transited different phases; from being a privilege granted by the state, eventually became a right and then finally property itself to be protected by the state³. As it often happens, the origins of IPRs as a creation of the state and the social function entrusted to them are gradually and purposely forgotten. Hence, it becomes necessary to rectify certain absolutist and expanding interpretation of IPRs as quasi natural rights and emphasize the social function which justifies IPRs existence and implementation.

It will be next briefly reviewed the foundations and function of traditional property as a helpful and healthy exercise to remark the prevalent social function of IPRs as *sui generis* rights vested with property prerogatives. In this sense, we will see that even if there are some justice-regarding motives to justify the reward granted by IPRs, the social function of IPRs and the instrumental nature of these particular rights outweigh any other consideration and they are significantly more pronounced regarding IPRs than it is the case for conventional property. This will allow us to claim an interpretation which must be coherent with IPRs inherent social function

³ Marshall, Alex. *The Surprising Design of Market Economies...* (see chapter 6, footnote 19).

and nature and whose application cannot be based on a *iuris et de iure* premise but on a *iuris tantum* presumption which logically enough may be rebuttable on a case by case basis.

The purpose of this section is to highlight that it is not necessary to resort to other bodies of law or legal institutions or international instruments in an eventual scenario of legal pluralism where different self-contained regimes overlap or compete with each other in addressing and regulating the same reality and where some legal values or institutions emerge as a counterbalance to offset the most negative and unwanted legal institution of IPRs as we have seen in previous chapters. On the contrary, IPRs themselves are conceived to fulfill certain social functions. Only this social function justifies IPR's very existence and therefore, they have to be implemented and interpreted accordingly. In this sense, it is important to unmask the fake debate and dialectic tension between what it would be economically rational, desirable and efficient -which is associated with strong quasi natural-absolute IPRs- and those approaches tending to take into account the socioeconomic impact of IPRs and the necessity of finding a balance between all the interests at stake and which are conceived and presented by the hegemonic neoliberal ideology as naively pertaining to the wishful thinking and to the realm of impracticable ingenuity from a presumed "objective and real" economic rationale.

Property and its social function.

At the center of most debates of political economy and other social and philosophical disciplines has been the issue of property. The thoroughly review of this institution is beyond the purposes and extent of this dissertation. However, in order to adequately address the nature and scope of IPRs, it is important to note which conceptual frame of property we assume as the basis to consider the social function of IPRs. In this sense, we can say in advance that we are not challenging the existence of property. In our cultural context and the development of our civilization, property has been legitimized by society as an instrument necessary to develop one's personality and autonomy. Historically and during the seventeenth and eighteenth century, property rights of individuals and the possibility that everybody could be owner were in fact

associated with the process of empowerment and emancipation of individuals against absolute monarchs and absolute regimes (Locke's time), many members of society pertaining to the third estate became citizens, equal citizens before the law who were entitled to hold property rights⁴. As Professor Drahos explains, it seems unconceivable that the development of human personality and the protection of individual interests can take place in the absence of property rules that guarantee the individual possession⁵.

However, it is noteworthy that property is considered for our purposes, as a social legal institution which makes sense within the existence of the state and that it is also the product of a contingent, political and historical process and thus subject to changes. In effect, the emancipatory role played historically by individual rights of property -which were linked to the ideals of freedom and equality of all human beings- does not mean that property rights are neither natural rights nor absolute rights. On the contrary, property rights are instrumental rights intended to fulfil certain social functions and be calibrated according to the social context and social need. In particular, we will emphasize those legal conceptualizations which view property as a social institution that encompasses both a set of rights and a set of duties, property as a set of socially accepted rules of conduct, a set of rules which govern the relations between the owner and the other members of society rather than between the owner and the things⁶.

Following the above mentioned approach of property, property rights fulfill different social functions. One of these functions consists of promoting efficiency in the market, in particular to respond to the need for signaling in market relations. As resources are scarce, the risk of conflicts as to who may possess and benefit of them may multiply exponentially to infinity; neither community norms of trust nor protection by force - which is impracticable due to its transaction cost and the number of transactions to be enforced at any one time- are enough to maintain a modern market where

⁴ Skinner, Q. (1978). *The Foundations of Modern Political Thought: Volume 2, The Age of Reformation* (Vol. 2). Cambridge: Cambridge University Press.

⁵ Drahos, Peter. (1999). *The universality of intellectual property rights...* (see chapter 6, footnote 26).

⁶ May, C. (2013). *The global political economy of intellectual property rights: The new enclosures?* (Vol. 3). Routledge.

anonymous actors and transaction agents operate on recognizable universally accepted parameters. Therefore, property regime would permit to give certainty and predictability in economic activities and exchange and thus, it is said to constitute a necessary instrument for the efficient allocation of scarce economic resources. In this sense, the state plays a fundamental role in recognizing and legitimizing possession by creating property rights beyond the mere possession by those with the capacity of protecting themselves from dispossession in a scenario without law.

Notwithstanding this, efficiency has neither one meaning nor does it constitute the whole picture of property. In effect, efficiency has different versions depending on which “efficiency” is prioritized by hegemonic forces; efficiency favoring society or collectivity versus efficiency favoring individual interests. Also, being scarce as they are, allocation of resources by conferring property rights over them has important distributive effects, and therefore the manner how this allocation is made becomes a central issue of the state’s economic policy⁷. In this respect, as the professor of political economy, Richard Ely interestingly stated; property *must serve social interests* and that *welfare of society must come first*. In his definition of *police power*, this professor held that it is for the judge *to declare what private property carries with it and what it does not carry with it* and that the state has the *power to interpret property and especially private property and to give the concept a content at each particular period*⁸.

A second often mentioned function of property, in particular of private property –in the seventeenth century was a move to conceive of property as something that could only be owned privately- has to do with being an incentive for work and efficient production. According to Bentham⁹, property provides individuals with reasons to labor; property rights are needed to vanquish *natural aversion to labor* and be an incentive to labor and industry. Also Adam Smith seems to consider property as an incentive for workers in order to improve their property; this incentive –property-

⁷ Alexander, G. S. (2008). *Commodity & Propriety: Competing Visions of Property in American Legal Thought, 1776-1970*. University of Chicago Press.

⁸ Ely, R. T., Orth, S. P., & King, W. I. (1914). *Property and Contract in their Relations to the Distribution of Wealth* (Vol. 1). Macmillan.

⁹ Bentham, Jeremy. (1887). *Theory of legislation*. Trübner & Company.

may make things better in a more suitable manner than government intervention could implement¹⁰. The school of economic analysis of law tends to justify property as the instrument to create *incentives to use resources efficiently*¹¹. In connection with this, Garret Hardin introduced the metaphor of the *tragedy of the commons*¹² which justified private property rights based on the potential of overuse of common property. Inspired on the enclosure movement in England during mainly the eighteenth century¹³ and the economic outcomes of this process which apparently led to an unparalleled productive increase¹⁴, many have seen private property as an important incentive to manage resources efficiently and large-scale investments addressed to improve property and avoid the tragedies of overuse and underinvestment¹⁵. Ironically, as it has been noted by Picciotto¹⁶, Hardin's famous article and the tragedy of the commons metaphor was intended to call for stronger public regulation in the realm of property and private freedoms rather than for justifying stronger private-property rights¹⁷.

Finally and most important for the purposes of this thesis is the social function of property. While it is uncontroversial that private property has limits, it is less accepted or rather ignored –especially nowadays- that property has a social function and that owners may have obligations. However, as some commentators argue, a mere rights-based theory does not account for the fullness of the private property institution and taking into account its instrumental nature, property also encompasses specific and general duties which cannot be adequately articulated in terms of correlative rights and duties between and among individuals. In fact, other

¹⁰ West, E. G. (2003). Property rights in the history of economic thought. *Property rights: Cooperation, conflict, and law*, 20.

¹¹ Posner, Richard A. (1973). *Economic analysis of law*.

¹² Hardin, G. (2009). The Tragedy of the Commons*. *Journal of Natural Resources Policy Research*, 1(3), 243-253.

¹³ By the enclosure movement is meant the process –mostly through Parliamentary acts (inclosure acts)- by which the passed from being farmed following the ancient system of open field and common land to being privately owned. Once enclosed the use of land became restricted to the owner and it ceased to be communal land for communal uses. See for an interesting analysis and debate: Neeson, J. M. (1996). *Commoners: common right, enclosure and social change in England, 1700-1820*. Cambridge: Cambridge University Press.

¹⁴ Ernle, R. E. P. B. (1917). *English Farming Past & Present*. Longmans.

¹⁵ James Boyle explains that in the previous common land situation, the feudal lord would not invest in drainage systems, sheep purchases, or crop rotation that might increase yields from the common since he knew all too well that the fruits of his labor could be appropriated by others. See Boyle supra note 59.

¹⁶ See Picciotto supra note 60.

¹⁷ However, new concepts of public property and commons –also intellectual commons- have started to emerge suggesting that it is possible to govern the commons without tragedy. Between others see Ostrom, Elinor. (2015). *Governing the commons*. Cambridge university press.

than the most explicit and immediate individual rights-based approach to property, it becomes necessary to consider other dimensions, other non-rights based arguments in order to apprehend the whole picture of all the contours of this social institution with a deep impact in its allocative and social consequences. In this sense, theories exclusively based on property as individual rights ignore important aspects of this social institution as the societal values and goals which is served to advance and the duty-based dimension of property, whether these duties are conceived as being intended to serve values in society or whether they are grounded in more individualized theories or ethical categories of right action (in terms of good or moral)¹⁸.

Unlike the traditional liberal view of property which defines property rights in terms of negative duties on both the state and other individuals of society –both of which are refrained from interfere into individual rights to property- the social function of property implies that other than external limits, property has internal limits in order that property has to fulfill the social role which is called to play. In this sense, the owner could not do whatever she wants with her property and should put her property in line with the interest of society. Property rights owe their existence to the act of recognition made by the state and the law to certain possessory situations which furthermore are normally understood to be legitimate under social accepted parameters. Consequently, the state and the means of the state devoted to protect property rights will be only deployed when the property rights in question fulfill their social function. When the owner is not acting in a manner consistent with her property-duties, the state is entitled to intervene to punish, reorient or to encourage due performance of rights¹⁹.

The French professor León Duguit is credited as one of the intellectual fathers of the so-called *social function of property* views in modern property law. As early as in 1912, Duguit attempted to overcome the limits posed by the positivist approach to law as it was deemed rigid and unreal. Duguit rejects the classical liberal approach of individual rights of property for being excessively metaphysical and unreal. In this

¹⁸ Hudson, A. (2003). *New Perspectives on Property Law: Obligations and Restitution*. Cavendish Publishing.

¹⁹ Foster, S., & Bonilla, D. (2011). *The social function of property: a comparative law perspective*.

sense, he challenges the premises under which liberal conception is grounded; first he challenges the isolated individual supposed by liberalism and emphasizes the deep interconnections between members of society to meet their physical and spiritual needs and; secondly, he remarks the connections between the social economic needs of the community and the allocation of resources which is legitimized and protected by the state through the social institution of property. In his opinion, liberal conception of property based on individual rights ignores the social reality whose central element is the interdependence between people. Hence, solidarity (derived from interdependence between people) would be a social fact rather than a political objective²⁰.

The social function of property is not just a rhetoric and academic issue but it has crossed the doorstep of the libraries and universities and it populates important positive norms and regulations, namely in Europe and Latin America. Article 153 of the Weimar Constitution, article 42 of the Italian Constitution of 1947 or article 33 of the Spanish Constitution of 1978 for instance include explicitly the idea of the social function of property. In particular, art. 33 of the Spanish Constitution²¹ acknowledges the right to private property and inheritance and it expressly states that *social function of property shall define the contours of the right to property in accordance with laws*.

Spanish Constitutional Court has developed a rich jurisprudence around the concept of the social function of property. According to the highest interpreter of the Spanish Constitution, property encompasses a bunch of rights, a set of negative limitations and also duties which may imply positive obligations which –the Court says- are within the legal definition of property rights. These set of duties for the owner are

²⁰ Duguit, L. (1920). Les transformations générales du droit privé depuis le Code Napoléon. In his conferences in Buenos Aires Argentina, Duguit argues that legal institutions are constantly adjusting to practical needs of society. [...] *les lois positives, les codes peuvent subsister intacts dans leurs textes rigides: par la force des choses, sous la pression des faits, des besoins pratiques se forment constamment des institutions juridiques.*

²¹ Article 33 of the Spanish Constitution establishes that: 1. Se reconoce el derecho a la propiedad privada y a la herencia. 2. La función social de estos derechos delimitará su contenido, de acuerdo con las leyes.

established following the values or interests of the community, i.e., the purpose or social utility that each category of goods subject to property is called to fulfill”²²

There have been even some statements of the Constitutional Court which declare that the social function of property is part of its essential content or “core” of the property right²³. As examples of the social function of property, law courts mention for instance the obligations of the owners of buildings or real state integrating the Spanish Historical Heritage to be responsible for the good maintenance, preservation and safeguard of them. Also, the social function of property has been alleged to determine the manner in which agricultural exploitation has to be made in certain types of farms or the transfer of land to be implemented by the owner of urban estate in favor of the state.²⁴In some Latin American jurisdictions also the social function of property has emerged as an important element of the contents and definition of the right of property²⁵.

In the US no legal norm includes explicitly the expression of “social function of property” and this particular concept of “social function of property” seems to have had a limited influence in the US legal system and practice. Notwithstanding this, there are scholars who consider that social obligations and social responsibilities or duties are attached to the social institution of property in US law as this is manifested in the development of certain jurisprudence²⁶. Maybe the most prominent American author analyzing what he calls collectively “social obligation” theories,²⁷is the professor Gregory S. Alexander. In his work *the social-obligation norm in American*

²² SSTC 37/1987, 26 March or SSTC 89/994, 7 April. In this cases the Constitutional Court states that La Constitución reconoce un derecho a la propiedad privada que se configura y protege, ciertamente, como un haz de facultades individuales sobre las cosas, pero también y al mismo tiempo, como un conjunto de deberes y obligaciones establecidos, de acuerdo con las leyes, en atención a valores o intereses de la comunidad, es decir, a la finalidad o utilidad social que cada categoría de bienes objeto de dominio esté llamada a cumplir.

²³ Some Spanish commentators consider this type of declarations as being rhetorically exaggerated and not consistent with the real meaning of this legal institution. See in this respect de Santiago, J. M. R. (2008). Las garantías constitucionales de la propiedad y de la expropiación forzosa a los treinta años de la Constitución española. *Revista de administración pública*, (177), 157-194.

²⁴ SSTC 6/1997, 20 march.

²⁵ For a more extensive review see Mirow, Matthew C. (2011). Origins of the Social Function of Property in Chile. Ankersen, Tom, and Thomas Ruppert. (2006). *Tierra y Libertad: the social function doctrine and land reform in Latin America*. dos Santos Cunha, A. (2011). The social function of property in Brazilian law. *Fordham L. Rev.*, 80, 1171.

²⁶ See Foster, Sheila supra note 125.

²⁷ Alexander, G. S. (2011). Pluralism and Property. *Fordham L. Rev.*, 80, 1017.

*property law*²⁸, the author challenges the classical liberal rights-based view of property and defends that the social-obligation norm is implicit in different legal doctrines of American property law such as the eminent domain, cases adjudicating remedies for nuisance, historic preservation laws, environmental regulations, or beach access rights among others.

In similar terms as Duguit's idea of social function of property, Alexander presents the human being as a social and political animal (human beings are not alone and self-sufficient beings) who needs other members of the community to promote the capabilities that are essential to human flourishing (conditions *enabling human beings to live lives worthy of human dignity*). As a consequence, individuals have an obligation to others in their respective communities *to promote human flourishing* and property owners shall be obliged to use property accordingly. The social-obligation norm implicit in property law implies the obligation to share property *at least in surplus resources*. Using an argumentation which reminds us of the *Lockean* proviso, the author holds that the state may compel the wealthy to share their surplus so that the needed could develop her capabilities. The state's role though is limited by the same principles of human flourishing, i.e., freedom, practical rationality and sociality (solidarity in Duguit's "European" words). These social obligations inherent in property are justified as necessary to cultivate the conditions for human beings to live worthy lives and promote just community relations where justice *means something more than simply aggregate wealth-maximization*²⁹ and to promote just social relations. In Alexander's view, American academia and law courts have failed to explicitly identify the social obligation norm implicit in property law because of the hegemony of the school of law and economics, an approach which is considered to be morally *anemic to do justice to the values inhere in those obligations* (social-obligations of property).

²⁸ Alexander, G. S. (2008). The social-obligation norm in American property law. *Cornell L. Rev.*, 94, 745.

²⁹ *Id.*

7.2. IPRs grounded in their social function.

Propertization of intangibles and denaturalization of IPRs.

Hence, as a summary of the above, we can say that property is a political, contingent, historic and social institution that consequently may be subject to changes in response to social and political needs of each time and place. It is a conventional institution constructed by the state and the law which legitimizes it. It is not something previously existing but it rather protects certain possessory interests giving them a status of “property”. Thus, property rights are dependent on the support of the state which enforces law within socially legitimated parameters.

Therefore, property emerges as an institution that is justified on the grounds of the functions it is called to fulfil. In this sense, justifications of property have been founded on the role of property as an instrument for the efficient operation of markets and efficient allocation of scarce economic resources; secondly, as an incentive for the efficient use and productivity of property and to avoid an scenario of a “*tragedy of the commons*”; last, as a legal institution which must contribute to the common good or flourishing of society (social function of property).

Regarding IPRs, the reality which IPRs are called to regulate (knowledge or intangibles) differs substantially from the tangible and scarce resources which are the subject matter of conventional, “genuine” property. This diversity affects consequently the foundations and justifications of IPRs as a legal institution in the sense of emphasizing on a more remarkably manner than conventional property the instrumentality and the social function of IPRs. However, the trend of IPRs regime has been recently quite the opposite; the IPRs regime has evolved towards the expansion of IPRs and its conceptualization as absolute rights which appeals to its consideration as quasi-natural rights that disregard the real nature, function and justification of these *sui generis* IPRs. In fact, as we will see, rather than property, the institution of IPRs would be better defined as being an institution integrated by rights temporarily vested with property prerogatives called to fulfill certain social functions.

Unlike genuine property, the non-rivalrous and non-excludable nature of knowledge, inventions, intangibles, expressions or ideas and the fact that these can be used and reproduced endlessly and simultaneously by an indefinite number of people without their consumption being depleted implies that the function of property as an instrument to permit the efficiency of the market and the efficient allocation of *limited* resources (avoiding never ending bilateral conflicts) does not make sense in the context of the subject matter of IPRs. Also, the support needed by the state to protect, legitimate and enforce this type of property is significantly more intense and it requires more resources since first, IPRs imply the artificial construction of scarcity of intangibles through legal instruments and second, as intangible resources are not naturally limited (as it is the case when it comes to tangible goods), the state has to be constantly vigilant to ensure that the use of information or knowledge is limited to those that are authorized to use it by IPRs titleholders.

Furthermore, IPRs cannot either be justified as an incentive to the efficient use of an existing good. In fact, the construction of scarcity and the creation of exclusive rights on information and knowledge could actually be detrimental to the potential use and social utility of naturally unlimited intangible resources. In the same token, the tragedy of the commons announced by Hardin is not either applicable when it comes to the non-rivalrous, non-excludable and unlimited information goods. Quite the opposite, some commentators note that IPRs and the artificial scarcity created by them may provoke the tragedy of the anti-commons³⁰ in the sense that patents can deter and block further innovation. In particular, and regarding patents, some commentators hold that in those cases where innovation in an industry is sequential and cumulative, IPRs, and particularly, patents may block subsequent innovations as it happens in the software industry and as it may be the case in the biotech and pharmaceutical industry. As we have previously seen for pharmaceutical patents, the monopoly granted by IPRs on certain intangible assets is sometimes –when it is interpreted in a restrictive and narrow interpretation of Pharmaceutical IPRs- used to create unjustified bottlenecks against competition and prevent follow-on innovation blocking new inventions based on past discoveries and/or knowledge. Also, it is

³⁰ Heller, Michael A., and Rebecca S. Eisenberg. (1998). Can patents deter innovation? ... (see chapter 6 footnote 109).

noted that this system may make the Research and Development (R&D) be inefficient as this can duplicate each other's efforts (secretive R&D processes and works) and waste resources. The existing empirical studies in this respect are far from being conclusive³¹.

Account taken of the above, it becomes clear that the social function of IPRs and its instrumental character constitute the main justification of this institution and the elements that defines the core of these rights. Also, that IPRs are not genuine property rights but they are rather rights vested with property prerogatives which are granted as long as IPRs fulfil their social function. In particular, IPRs and the patent system are intended to be an incentive for scientific progress and dissemination of valuable information to the public. As an incentive to avoid eventually a scenario of underproduction of knowledge, IPRs attempt to overcome the eventual undersupply of ideas and intangibles due to the risk that the incapacity to exclude competitors and nonpaying consumers (free riders) may deter the efforts and the investments necessary to develop new ideas and improvements of the current state of the art. In the absence of some legal solution it is said that there could be a significant underinvestment in some technical fields such as the pharmaceutical industry because of the practical impossibility of keeping secret the formulae and the threat that competitors would easily reproduce and copy the subject matter of the invention without having incurred in any expense so having an unfair competitive advantage.

Alternatives to IPRs regime?

The premise that the system of IPRs or state-enforced monopolies which artificially create scarcity as being the best or the only solution to incentivize innovation is more than questionable³². It is not unusual to find from time to time scholar views standing

³¹ Hahn, R. W., & Hahn, R. W. (Eds.). (2005). Intellectual property rights in frontier industries: software and biotechnology. AEI Press.

³² Bettcher, D. W., Yach, D., & Guindon, G. E. (2000). Global trade and health: key linkages and future challenges. *Bulletin of the World Health Organization*, 78(4), 521-534. They argue that the premises of patent protection, (to stimulate innovation and generate money for research and development), fail to recognize that considerable research and development is conducted using government monies, that patents and intellectual property rights are relatively recent phenomena, that innovation and research and development has occurred

for alternative systems to IPRs, in particular, publicly funded reward systems³³. Once the award is granted to the creator, the innovation falls into the public domain and is available to everyone who is willing to produce/market it. As to the value of this economic reward, some commentators consider that it should be based on the volume of use of the information –such as the sales volume of a book- and on some measure of its utility. Use and utility may be accounted for in this sort of alternative reward system and both factors are said to reflect socially optimal valuations rather than merely those of the individuals able to afford the monopoly price³⁴.

As it was pointed out by Nobel Prize Joseph Stiglitz at the Hearing before the Subcommittee on Primary Health and Aging of the Committee on Health, Education, Labor, and Pensions of the US Senate in 2012, *The patent system may even have adverse effects on innovation, because the most important input into any research is prior ideas; and the patent system encourages secrecy, just the opposite of the openness that is the hallmark of successful universities and academia more generally.*

Recently, it has been discussed the “Prize Fund” Bill project as a partial alternative to the current IPRs system. The Medical Innovation Prize Fund (S. 1137, 112th Congress) is a proposal to change the system of rewards to foster R&D investments in certain areas. This project is interestingly based on the separation between the markets for products from the markets for innovation. The proposed legislation discussed by the American legislature would eliminate patent and other intellectual property barriers to the introduction of generic medicines. Instead of product monopolies, it would be implemented a new Medical Innovation Prize Fund as a reward, that would provide more than \$80 billion in annual rewards for useful

in the absence of patent protection, and that intellectual property rights are afforded only when a country has achieved a certain level of economic development. Also see Shavell, S., & Van Ypersele, T. (2001). Rewards versus intellectual property rights. *The Journal of Law and Economics*, 44(2), 525-547 where the authors conclude that IPRs do not possess a fundamental social advantage over reward systems paid by the government and that an optional reward system—under which innovators choose between rewards and intellectual property rights—is superior to IPRs.

³³ Kapczynski, A., & Syed, T. (2013). The continuum of excludability and the limits of patents.

³⁴ Calandrillo, S. P. (1998). An Economic Analysis of Property Rights in Information: Justifications and Problems of Exclusive Rights, Incentives to Generate Information, and the Alternative of a Government-Run Reward System. *Fordham Intell. Prop. Media & Ent. LJ*, 9, 301.

investments in R&D for new medicines and vaccines. Research placed in the public domain would also be eligible to receive rewards from the Prize Fund. In distributing the rewards, they would be valued those innovations which constitute a real improvement to health benchmarked against existing pharmaceuticals, de-incentivizing “me-too” or copycat pharmaceuticals. This Fund also encompasses rewards to those persons or communities that as an open source contribution openly shared knowledge, data, materials, and technology on a royalty-free and nondiscriminatory basis.

This provision in favor of open source providers embraces the contributions of the discussion on the applicability of Open Source models in non-software contexts such as the pharmaceutical sector. This applicability has been profusely discussed in academic literature. Despite some important reticence to extend open source models beyond software contexts, there is a growing interest in applying them in fields like biology and biotechnology, especially as a result of the success of non-proprietary initiatives (SNP Consortium and the HapMap project). Regulation on Open Source models recognizes that there is an alternative, more open and collaborative approach to innovation that has proven itself successful in a number of areas of research. According to Stiglitz the prizes *"would create a powerful economic incentive to open source knowledge, data, materials and technology, which should directly benefit product developers."*

The “open source” model has showed an important success in the industry of software development. This model has its origins in the norm-based Mertonian framework for conducting scientific research where the scientists (software developers) work openly, without secrecy and without exclusionary proprietary rights. In this model, an intangible is made freely available to anyone who can modify or build on it or improved upon the condition that his own work would be reciprocally subject to the same condition. There is an important literature

speculating about the applicability of the open source model of innovation to other areas such as biomedical or pharmaceutical industry³⁵.

In the face of the current proprietary and secretive routine of biomedical and pharmaceutical research, it is raised the possibility of implementing an open and collaborative science for certain innovations in the biomedical and pharmaceutical fields. Given the cumulative nature of research in these areas, this open and collaborative model would in theory make R&D more efficient, would reduce the transactions costs resulting from complex licenses (between parties with different bargaining power) and it would eliminate the secrecy based and exclusionary-proprietary problems which at certain point, may impede or erode the follow-on innovation and research as long as provoking a reallocation of effort away from less commercially valuable projects. In short, it explores the possibility of creating a commons out of pharmaceutical/biotechnological/biomedical knowledge. Also, this type of models have been thought as an alternative to a somehow exhausted pharmaceutical industry who seems to be less and less able to develop pharmaceutical blockbusters and new compounds despite, as we will see, the important increase in pharmaceutical R&D in recent years.

There is today an Indian consortium inspired on this model under the name of Open Source Drug Discovery (OSDD) which is aimed at providing a global platform where *anyone can collaborate and collectively endeavour to solve the complex problems associated with discovering novel therapies for neglected tropical diseases like Tuberculosis, Malaria, Leishmaniasis [...] OSDD envisions making drugs available at affordable prices that afflict the developing world by expanding resources for research through open collaboration and sharing*³⁶. The drugs developed by OSDD will be made available like a generic drug, without any IPRs encumbrance. Currently, more than 1500 registered participants from 31 countries are working on more than 100 projects posted online. Also, this Consortium has entered international bilateral agreements with other institutes as the Systems Biology Institute of Japan.

³⁵ Srinivas, K. R. (2010). Open Source Drug Discovery A Revolutionary Paradigm or A Utopian Model?'. Incentives for Global Health Patent Law and Access to Essential Medicines, Pogge, T., Rimmer, M., Rubenstein, K., Ed. Cambridge: Cambridge University Press, 263-283.

³⁶ www.osdd.net

In this sense, Open Science, with its curiosity-driven, investigator-initiated agenda and priority and publication-based incentives, is a distinctive and vital component of the biomedical innovation system. Over the long run, biopharmaceutical research productivity depends critically on the contributions of open science. Some of these contributions are easy to see, such as the generation of new knowledge, new models, new data, and trained personnel that are available to industry. Others are more subtle. For example, some of the unique institutions of Open Science such as peer review, publication, and replication of experiments provide important "managerial infrastructure" to commercial science, where pharmaceutical companies use their employees' participation in the wider scientific community to monitor and reward research activity. Open Science also plays an important role as a public "truth-telling mechanism" on complex and difficult questions relating to safety, efficacy, and utilization of drugs.³⁷

Therefore, the possibility of implementing this alternative innovation-system based on an open and collaborative model is in fact a reality which may emerge as a workable model in the long run at least for the discovery of pharmaceuticals for neglected diseases. Also, it is noted that this collaborative and open research can work in the case of upstream knowledge projects/compounds that as in the software industry, can be used for the development of private downstream applications³⁸. Notwithstanding this, it is noted that it is necessary to be cautious with the extension of this collaborative and open model to every field of science, in particular to the pharmaceutical sector. In this sense, some empirical studies note that patents on pharmaceuticals are crucial to recoup the large costs associated with preclinical and clinical R&D in this field³⁹. Before taking a categorical position on this matter is then important to know that the new paradigm could be complementary to the traditional IPRs based R&D and that it is indispensable to assess which kind of industry is addressed, which capital investment is necessary to innovate beyond the existing

³⁷ Cockburn, I. M. Is the pharmaceutical industry in a productivity crisis?. (see chapter 3, footnote 69).

³⁸ Rai, A. K. (2004). Open and collaborative research: A new model for biomedicine. Hahn, R. W., & Hahn, R. W. (Eds.). (2005). *Intellectual property rights in frontier industries: software and biotechnology*. AEI Press.

³⁹ Cohen, W. M. (2005). Does open source have legs. *Intellectual property rights in frontier industries: Software and biotechnology*, 159-75.

state of the art, which kind of knowledge is attempted to develop (upstream/downstream), as well as its social interest or the beneficiaries of it.

IPRs as a legal institution temporally vested with property prerogatives.

Despite the above, we share Machlup's views previously cited that since we have had a patent system for a long time, it would be irresponsible, on the basis of our present knowledge, to recommend abolishing it. In effect, it does not seem reasonable nor is it viable in the medium term to substitute the patent system for other type of public incentive of innovation. Notwithstanding this, it is important to recall the instrumentality of IPRs and the patent system and the necessity to adjust this incentive-reward system on a case by case basis instead of carrying out an automatic, absolute, *iuris et de iure* application of IPRs in order to make IPRs perform correctly and coherently; IPRs would be valid rights as long as they are suitable instruments to achieve the social goals entrusted to them. In particular, patent rights are instrumental rights intended to serve societal needs and interests –ideally democratically identified by society- that justify their protection and enforceability. In this regard, the evidence shows that the patent system -as a policy and social instrument to encourage inventions and technical progress- has been more effective in certain industries like pharmaceuticals or chemicals, and less so in electronics, and even that it has little direct effect in other industries, especially in services⁴⁰so even a different treatment of IPRs depending on the field could be considered to optimize the use of this legal “instrument”.

The social instrumentality of IPRs is actually implicit in the regulation of this special institution -remarkably in the field of patents- which differs from the regulation of “genuine” property; In our view, IPRs are not genuine property but an institution temporally vested with property prerogatives conferred to IPRs titleholder in order to advance certain social functions. In this respect, there are different aspects of IPRs law that permit us to reach and uphold this consideration; in this sense, property rights are not granted to no matter which knowledge, information or expression but

⁴⁰ Guellec, D., & de La Potterie, B. V. P. (2007). The economics of the European patent system: IP policy for innovation and competition. Oxford University Press on Demand.

only to those intangibles that the law considers to contribute to the progress of the state of the art. Because of this, the inventor that by her own means develops an invention is not entitled to any right on it (apart from its free use for her own purposes) if she had the misfortune of being preempted by other inventor who applied patent protection for the same subject matter before in time. Furthermore, patent rights are come into existence upon public registration instead of by its mere creation (as it is the case for copyright). This can be interpreted as the state's acknowledgement that the invention in question deserves monopoly rights. Also, this different treatment given to copyright-protected assets and patent subject matter reveals that the utilitarian dimension is more remarkable when it comes to patents than it is in the case of copyright where the personality-based justifications may have a more pronounced sense and reflection.

On the other hand, it is noteworthy that unlike "genuine" property whose vocation is permanence and perpetuity over time –derived from conceptualizing property as a bunch of rights which are attached to things instead of rights in the context of social relations-, patent rights are temporary rights and they expire upon a period of 20 years after the filing date –art. 33 TRIPS- and the existence and enforceability of rights are subject to the payment of annual fees without which payment patent rights expire (art. 116 Spanish Patent Law).

Finally, other difference between IPRs and "genuine property" and which is very illustrative of the social function of IPRs and in particular of patents, consists of the fact that many national laws contemplate the obligation that patent rights expire if the subject matter of the patent is not used in a period of time. In this sense, no use of the patent makes it becomes part of the public domain–art. 83 of the Spanish Patent Law-. The implicit social function of IPRs and in particular of patents, derive also from the regime of compulsory licenses and free use of patents. Those uses escape from the consent of the patent titleholder and are closely related with especially sensitive public regarding cases as long as with collective and community interests. In this respect, compulsory licenses are foreseen for instance, for cases associated with improvements of patents developed by an inventor other than the inventor of the preexisting patent owner (in which case a cross-license regime is implemented

between the first and second inventor) or compulsory licenses grounded on public interest and social utility –art. 86 of the Spanish Patent Act-. Regarding uses exempted from the patent owner’s authorization, in most national legislations it is permitted the experimental use of the subject matter of the patent, the non-commercial use of it, and the use of the invention within the private sphere for private purposes or the preparation of master formulas of pharmaceuticals by the pharmacy or drugstore⁴¹.

All these legal traits of the IPRs regulation and in particular of patents, clearly suggest the prevalent functionalist and utilitarian nature of the IPRs institution -in particular of patents- and its condition as an instrument of the state at the service of its strategy and purposes. This is also coherent with the fact that both private international and public international law recognize the right of sovereign states to regulate property rights, to adjust them to economic and social circumstances (during the drafting of article 17 of the Universal Declaration it was agreed that ownership of property was subject to national laws, but that there was no need to state this in the Declaration)⁴².

The social dimension of IPRs is even more remarkable if we take into account that knowledge and new ideas are the result of social rather than individual creation; i.e., it is also due to earlier inventors and scientists who have provided the foundation for the new contribution as long as to society as a whole; this also includes professors, family, universities and society which have created the necessary conditions for the inventor or creator to come up with the new invention. It is therefore, the consequence of a social process rather than a process exclusively developed in an individual sphere and therefore, a social product rather than an individual one. In particular, most patents are largely the result of costly processes of research where a multiplicity of actors takes part and that it is mostly funded by public institutions. In this respect, a study carried out at the end of the 90’s revealed that seventy-three

⁴¹ The experimental use exception is being questioned and restricted in the US jurisdiction. See in this respect,; Cai, M. (2004). *Madey v. Duke University: Shattering the Myth of Universities' Experimental Use Defense*. *Berkeley Technology Law Journal*, 175-192.

⁴² Drahos, Peter. (1999). *The universality of intellectual property rights...*(see chapter 6, footnote 26).

percent of the patents cited by US industry patents are public science⁴³. Hence, today's tendency towards the expansion and security of IPRs and its conceptualization as absolute, quasi natural proprietary private rights and its *iuris et de iure* treatment overtly contradicts IPRs nature and foundation as legal institution consisting of rights vested with property prerogatives addressed to fulfil particular social functions. As a result, it seems urgent to reconfigure and reshape the current IPRs regime to its founding and justificatory nature and economic role following democratic parameters.

Saddlebags for the return journey of IPRs to their nature.

Therefore, there is an obvious tension between the interests of the IPRs titleholder and the public interest in having full and free access to knowledge and its dissemination to the benefit of society. Law and legal practitioners should reconcile correctly all the interests at stake in accordance with the purposes, *rationale* and social function implied in the regulation of IPRs. In this sense, rather than resorting to other institutions or external bodies of law to compensate or counterbalance IPRs application and impact, it becomes necessary to apply and interpret IPRs themselves correctly, i.e., following the principles inspiring and justifying its existence and its enforceability. In this sense, IPRs application has to succeed in handling the delicate balance between all the interests at stake in a manner that ensures the social function and public interest embedded in the core of this legal institution.

In this sense, the proportionality principle claimed by Professor Merges in relation to IPRs shows the necessity of pursuing that balance along IPRs life in order to achieve IPRs entrusted social goals. Hence, the "societal" interest of IPRs should be reviewed first into the structure of the right from the moment it is granted (time limits, exceptions to patentability, claims covered by the patent), secondly, law courts should make sure that IPRs do not coalesce with social interest and the *rationale* of IPRs, and thus they have to prevent conferring disproportionate leverage on a titleholder and; third, the rewards and benefits obtained from a creative work have to be just without

⁴³ Narin, F., Hamilton, K. S., & Olivastro, D. (1997). The increasing linkage between US technology and public science. *Research policy*, 26(3), 317-330.

ignoring the social interest in each innovative work; i.e., the just reward has to be substantial as to constitute an effective incentive for innovation but the system cannot provide cover for interpretations and implementations of IPRs where IPRs are decontextualized of the social context in which they are applied; where private interest of the titleholder prevails over the prevalent social function implied in IPRs as an instrument for the advance of the public interest; where practices of abuse of rights distort the core and purpose of IPRs.

Therefore, either when considering IPRs first as an instrument to maximize social welfare (incentive to innovation and dissemination of information) and secondly, as an ethically accepted reward to her creator, the idea of proportionality –the balance of all the interests- should play a central role in the IPRs regime. IPRs, the reward those IPRs imply, should be proportioned to effort, the value and the significance of the work covered by the right. Proportionality principle should play a central role both into the inception of IPRs and into their implementation, when they are used, when they are infringed and when their scope is determined. Under this principle, it should be checked on a case by case basis when legal entitlements based on IPRs give someone a disproportionate reward and power –over knowledge- beyond what makes sense and beyond the purposes and the social function of IPRs, given the circumstances.

In this sense, and despite the today mostly accepted instrumental nature of IPRs system as a tool to achieve some legitimate social ends and benefits, it is surprising the lack of economic analysis of questions regarding the cost-benefits of the IPRs system and its optimum implementation and use. In fact, the discussions carried out in the last century and the concerns around the economic rationale and impact of the IPRs seem to have been completely sidelined. Even if we accept that IPRs system may have been working in certain sectors where it is necessary a legal instrument to recoup investments (pharmaceutical sector), it seems clear that a one-size-fits-all approach to cover all the intangible realities does not make sense. In this respect, what is missing today is a continuous analysis of the impact of IPRs and a dynamic and permanent adjustment of IPRs to the socioeconomic circumstances at any given time.

Also, the use, application and interpretation of these rights vested with property prerogatives have been automatic, *iuris et de iure*; a dogmatic application which does not encompass any questioning or objection as to whether those IPRs are accomplishing the goals which justify their existence and implementation or not. In effect, a pharmaceutical patent owner can exclude others from using the intangible goods covered under her title regardless the effective impact of her exclusive right in the market and into the society where that patent is being implemented. Despite the fact that the *raison d'être* of IPRs has to do with their instrumental nature, -i.e. as a tool to foster innovation, technology transfer and dissemination of information-, and therefore its social function is far more noticeable than property rights related to tangible goods, there is not any serious approach which reviews the fulfillment of the goals for which they have been conceived, whether the benefits for society outweighs the private benefits for the IPRs' owner and if the investments made to develop certain intangible goods have been fairly recouped.

This question remains unresolved today. There is a number of unresolved questions as to the optimal balance between the *propertization* of some intangibles, the suitability, scope and effectiveness of the incentives so generated and the negative impact of restricting access to a naturally unlimited good. The proportionality principle suggests us that IPRs could constitute an economic return which substantially exceeds the deserved reward for the investments made for the contribution to social welfare and for the risk of failure, this restricting access to the covered intangible unnecessarily and in an inappropriate manner. Also, the protection term which is generally identical to all intangible goods covered by patents might be considered as arbitrary and far from being optimal into the necessary tradeoff between the private benefits and fair reward for the innovation on the one part and the interests of society on the other hand.

Furthermore, TRIPS has contributed to break the balance between the reward given to the *innovator* and the social benefit provided by that innovation; the now potential extension of IPRs worldwide affects substantially the proportionality principle, the reward granted by IPRs and IPRs instrumental nature. As we have said IPRs regime is mainly premised under the belief that creating an artificial monopoly on intangible

new and innovative intangibles constitute an incentive for innovation; i.e., the purpose of artificially creating scarcity of an unlimited good such as knowledge is to incentivize innovation –and investment on innovation- and disseminate valuable information among population and society. Thus, being this the rationale behind the creation of IPRs, the application of the IPRs cannot be *iuris et de iure* but it should be subject to an analysis about the conveniences/benefits of it versus the disadvantages/inconveniences produced by this instrumental legal institution. If granting of IPRs has a social function, what about if this system is not fulfilling the aims and the ends for which it has been created? What about if the reward granted by IPRs substantially overwhelms the social function to be accomplished by its institution?

On the other hand, TRIPS Agreement is the reflection of the extreme *denaturalization* of IPRs; If a patent owner was supposed to be sufficiently rewarded by an exclusive right covering all the territory of a certain nation state, what does it happen when this monopoly on the same innovation is rewarded with a temporary monopoly that is likely to be extended at a global scale? What about if this exclusive right does not constitute any incentive for innovation in a country missing the basic technological infrastructures to even absorb the know-how implied in that patent? In this sense, it is noteworthy that TRIPS has created a further asymmetry between the announced social benefits of the IPRs regime and the private interests of their titleholders; while TRIPS Agreement has increased substantially the reward given to the IPRs titleholder who has now the potential to enjoy a worldwide legal monopoly, the social benefits and the social function of IPRs have not been grown accordingly and it is not automatically extended to all the jurisdictions where a given patent is applied and enforceable.

Striking the balance by challenging some of the presumptions implied in IPRs.

Needless to say that it does seem neither rational nor fair to claim that all the countries have to contribute to pay the bill resulting of the reward of the innovator without simultaneously enjoying any of the eventual benefits associated with an artificially created legal monopoly which is intended to fulfil certain social functions.

Otherwise, there would be a manifest disconnection between the reward-based incentive, private gains and the prevalent public and social rewarding dimensions of IPRs; a decoupling which should be fixed in order to reinstate the balance of the tradeoff involved in IPRs on proportional and rational terms.

Therefore, the next step is wondering how this “reinstatement of the balance” between all the interests at stake has to be effected when it comes to the regulation of IPRs. In this sense, there is *iuris tantum* presumption that IPRs fulfill their social functions and it is required to analyze whether this presumption is actually effected in a given context. In this respect, we believe that the spatial framework of the analysis has to be the sphere integrated by national jurisdictions. On the other hand, the moment when this evaluation has to be made corresponds to the second phase of IPRs life i.e., when law courts or other *interpreters of the law* and adjudicators have to consider the impact of IPRs or have to settle a given dispute or conflict associated with the enforceability of IPRs.

In effect, taking into account that even if standardized, IPRs are national rights, the spatial framework to consider the socioeconomic impact and performance of IPRs has to be the national jurisdiction where IPRs are applied –regardless of whether the evaluator could be a national or an international adjudicator-. It is in the national context where the evaluation as to the impact of IPRs and the maintenance of the balance of the constellation of interests has to be done since the performance and impact of IPRs vary substantially between countries in different stages of development and with different needs and cultural patterns while there is no such thing as global government or global collective action which takes care of the consequences of IPRs and the welfare of humanity as a whole.

In the specific context of the pharmaceutical sector for instance, it is clear that the socioeconomic impact of enforcing pharmaceutical patents has to be effected in national terms. As we have mentioned previously, it would not be logical –nor would it be fair- to claim that for this analysis the benefits of the innovation have to be evaluated in global terms, i.e., that all the countries have to pay the bill of a legal monopoly because innovation benefits everybody while the impact and the negative

consequences of commodifying knowledge and having monopoly prices in terms of access to medicines have to be faced exclusively by national means since there are not so far global instruments to cope with the shortcomings and the failures of the system. This does not mean that we disregard international solutions or global responses to the failures of the system and of the IPRs global regime. On the contrary, it is necessary to develop global standards to take into due account national or regional realities and be able to acknowledge the necessary flexibility in the application of an instrumental institution such as IPRs, moving away from *one size fits all* formulae which usually tend to decontextualize and denaturalize the nature and *rationale* of IPRs and which are on the basis of an absolute quasi-natural rights application of IPRs versus the more convenient consideration of IPRs as a set of privileges vested with the prerogatives of property.

Unlike the other patent requirements (novelty, inventive and industrial application) which have to be met at the time of applying the patent, the evaluation as to the impact and use of the exclusive rights has to be necessarily effected when IPRs have been implemented and enforced in a given national society. Although it is logical to think that this evaluation is going to be made in a dispute resolution process, there is nothing in TRIPS to preclude national legislators -by legislating property- from including a judicial declarative process where law courts could declare that the use of property or the use of a given pharmaceutical patent is contrary to the prevalent public interest and social function that the use of the patent must observe since it is for national legislators to define the specific contours of property and the inherent social function within it.

In this sense, IPRs laws are premised upon previously defined legal concepts such as property which have to be duly assessed and considered in national terms and in accordance with national interests and needs especially when IPRs do not pertain to the realm of genuine property but they are rather a legal institution vested with property prerogatives. Hence, the process of defining property and considering whether property or IPRs as *sui generis* property as a legal institution integrated by rights or privileges vested with property prerogatives is a *prius* or a preliminary question that precedes the application of specific IPRs laws or in particular, patent

laws. Therefore, articles 30 and 31 of the TRIPS Agreement -regulating exceptions to the enforceability of the owner's IPRs- cannot limit or condition the previous national definition of the contours of property and the evaluation as to the specific performance of property or IPRs in relation to its inherent social function. In fact, the application of articles 30 and 31 –and those of the specific patent law- should come next, as one of the specificities of those particular rights, once the use of the patent – the rights vested with property prerogatives- is presumed to be valid and it is enforceable since its use is in accordance with the parameters of its social function.

On the other hand, and in the context of a dispute or a litigation process for IPRs or patent infringement, the eventual infringer of the exclusive rights conferred by for instance a pharmaceutical patent could challenge plaintiff's claim on the grounds that the specific patent does not fulfill the social function entrusted to it –and which justifies the conferring of property prerogatives-. In this sense, the validity of IPRs and in particular, of pharmaceutical patents at a given moment must be *iuris tantum* in order to be fully enforceable; i.e., the presumption that these exclusive rights fulfill their inherent social functions –and that they are consequently vested with property prerogatives- may be rebuttable if it is proved that the patent is being used in a manner contrary to the social functions entrusted to property in general and to IPRs in particular.

Other than the general functions of IPRs mentioned before (as an incentive to innovation and dissemination of information), what is social function will depend on the national definition given to property and to IPRs in particular following democratic deliberative democratic parameters in view of the socioeconomic national context where IPRs are called to be applied. In defining these parameters, the categories of human rights and public interest take on their full significance as an integral part of the social function to be fulfilled by property and IPRs; i.e., instead of confronting property and IPRs versus Human Rights or public interest as if they were conflicting bodies of law, both elements (RRHH and public interest) are internalized in the legal institution of property as they come to integrate part of the sense and the scope of its social function. In this sense, some authors claim for an integrated vision

of International Law where IPRs should be interpreted in accordance with principles of human dignity⁴⁴

Furthermore, in evaluating enforceability of IPRs and fulfillment of its social function, it would be necessary to review the reward granted to the IPRs titleholder, the impact of IPRs in the society where they are implemented and the benefits they provide in terms of flourishing of that society. For instance, when considering a pharmaceutical patent in a developing country, the analysis as to the social function of property should entail the assessment about the reward given to the titleholder – since this could be considered excessive in view of the necessary balance⁴⁵-, the price of the medicine in relation to the average salary of the population of the country, the investment of the pharmaceutical company in researching neglected diseases affecting the country, or the technological transfer effected to the country in terms of ensuring dissemination of knowledge and providing the country with the capacity to absorb the new knowledge and even to innovate. Therefore, from democratic deliberative parameters, international and national interpreters and adjudicators of law shall apply and enforce IPRs in such a manner as to ensure that these instrumental rights vested with property prerogatives fulfil with the social function and the prevalent public interest of the particular society where those IPRs are called to be implemented.

Finally, it is noteworthy that this instrumental approach to IPRs is perfectly coherent with the principles and objectives announced in article 7 and 8 of TRIPS. In effect, by saying that *the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the*

⁴⁴ Hernández, X. S. (2010). La protección de la salud ante la regulación internacional de los productos farmacéuticos. Marcial Pons.

⁴⁵ Interestingly, in the case AES Summit Generation Limited AES-Tisza Erömű Kft v. The Republic of Hungary, ICSID Case No. ARB/07/22, Award of September 23, 2010. The Arbitral Tribunal –under the International Center for settlement of Investment Disputes) held between others the following: [...] *Having concluded that Hungary was principally motivated by the politics surrounding so-called luxury profits, the Tribunal nevertheless is of the view that it is a perfectly valid and rational policy objective for a government to address luxury profits. And while such price regimes may not be seen as desirable in certain quarters, this does not mean that such a policy is irrational. One need only recall recent wide-spread concerns about the profitability level of banks to understand that so-called excessive profits may well give rise to legitimate reasons for governments to regulate or re-regulate.* (p. 10.3.34) Therefore, under some parameters of international economic law, excessive profits (or luxury profits) would justify regulation or *re-regulation* by national governments.

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, article 7 of the TRIPS Agreement recognizes both the instrumental nature of IPRS and its implicit social function since it states certain objectives to be achieved (technological innovation, transfer and dissemination of technology, social and economic welfare) and it also speaks of obligations adhered to IPRs. On its part, article 8 establishes as principles of the TRIPS Agreement that *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, provide that such measures are consistent with the provisions of this Agreement.* Both principles and objectives expressed explicitly in the TRIPS Agreement provide room for alternative interpretations and applications of today's global IPRs regime.

7.3. Transforming the regime from premises of deliberative democracy.

The trend towards the expansion of IPRs and particular, of patents towards new material and spatial enclosures of knowledge coupled with a strict, absolute definition of property rights and an overprotection of the private proprietary interests of the titleholders of IPRs -who have seen how their rights have become global without any further contribution to the innovation and progress of society-, has ignored the nature of IPRs as historical, contingent and political rights vested with property prerogatives which have been designed to fulfill certain social functions and serve the prevalent public interest implied in these *sui generis* property rights. One factor explaining this “evolution” or rather, *denaturalization* of this legal institution is the fact that the development and interpretation of IPRs have been dominated by a neoliberal hegemonic epistemic community who favors private interests of proprietors, has narrow and biased values and facilitates processes of unrestricted capital accumulation. Therefore, it is necessary to inoculate counterhegemonic voices and reasons, interests and needs that currently IPRs do not reflect, including the prism of human rights discourse and the public interest insight in such a manner as to foster that IPRs interpretation and implementation will fulfill their social functions.

The emergence of well defined, secure property rights at a global scale is part of a much broader historical process that we are living today and which, as we have suggested along this dissertation, goes beyond the particular “evolution” of IPRs, patents or pharmaceutical patents. Notwithstanding this, the political process leading to a global IPRs regime and in particular, pharmaceutical patents have displayed the unacceptable failures and shortcomings of the current system and it could have served to initiate an alternative process which questions the premises under which the so called “globalization” is being constructed and the legitimacy of the decision making processes and methods. As some political theorists hold, by introducing and providing room for counterhegemonic voices and opinions, it would be possible to recover legitimacy and to a certain extent, to reconstruct democracy based on political principles, institutions and practices adapted to the new forms of public sphere deliberation and post-industrial capitalism characterized by global production

and marketing networks beyond the national state framework. Habermas suggests that democratic deliberative processes may be adapted to a global and decentered society. This approach to democratic decision making processes would no longer need to operate within the notion of society exclusively centered in a given national state and it could solve problems in ways unavailable to representative systems.

In this sense, and following professor Picciotto, decision-making should be the result of active democratic participation based on discursive reasoning i.e., instead of the pursuit of individual interests the aim is to reason as to which one is the best solution. While accepting that there is no such thing as an absolute and objective standard of truth since perspectives are subjective, truth can be the result of the *deliberative interaction between perspectives* i.e., the objective truth can be obtained through the process of subjective interactions, this being the *most basic justification for democracy*. In this interaction, the communicative interaction -the manner how the process of public reasoning is carried out- becomes crucial in order to identify inequalities of power and imbalances in capacities to participate in public reasoning and to ensure conditions to foster informed participation in deliberative decision-making rather than expert or elite deliberation⁴⁶.

Public Health, the opening door to counterhegemonic voices.

As we have seen, TRIPS is part of a hegemonic strategy towards a new international regime which favors the international accumulation of capital in the name of the global welfare. This strategy has been conducted by transnational actors which have been able to articulate a hegemonic discourse adopted by hegemonic countries. The instrumental use of IPRs has distorted the nature of IPRs emphasizing and strengthening their property dimension and the interests of their owners over any other social considerations. However, TRIPS has not been successful in implementing peacefully and without controversy the new global regime of IPRs. In particular, the field of pharmaceutical patents and due to their important impact on public health

⁴⁶ Picciotto, Sol. (2000). Democratizing the new global public sphere. Working paper, Lancaster University. Retrieved at <http://www.lancs.ac.uk/staff/lwasp/demglobpub.pdf>.

and to the human right to health is presented as a case where TRIPS hegemonic ideology has suffered a setback and the counterhegemonic movement has opened a door, a path to rewrite and reinterpret TRIPS.

In spite of its limited effects and impact, the Doha Declaration marked a significant momentum in the counterhegemonic struggle over IPRs. This incomplete victory has served to show that the ideological debate is not closed and that the door has been opened for counterhegemonic reflections and considerations. In effect, TRIPS and the regime of IPRs have been called into question as they have entered and affected basic human needs and values such as health. The different crisis generated by TRIPS and some partial retreats of the hegemonic interests boosting TRIPS, have revealed the important conflict of interests between different actors and the unbalance balance in IPRs between public and private reward, a crisis, also a legitimacy crisis which cannot be longer silenced and must be handled from a new and probably more generous approach.

Apart from the use that the proponents of counterhegemonic views of TRIPS can make of the TRIPS own channels, i.e., TRIPS Council –empowered to oversee and monitor the implementation of TRIPS-, the DSU and the continuing negotiations over the multilateral trading regime, and which will be explored in further chapter, TRIPS has placed interestingly IPRs issues in the top of the agenda of diverse fora such as the UN or the WHO. In these fora the activity and discussions encompass the negotiation of new treaties, reinterpretation of existing treaties or the approval of declarations, guidelines, recommendations, resolutions, reports and other “norms” of soft law which undoubtedly influence and interfere in the TRIPS regime. According to some, this renewed interest for IPRs has to do with a strategy of regime shifting by developing countries, NGOs and other counterhegemonic entities which are dissatisfied with TRIPS and are seeking new ways and paths to compensate, recalibrate, or reinterpret it.⁴⁷In this sense, these counterhegemonic entities would be seeking different international regimes whose institutions, purposes, actors and mandates are more favorable and are more aligned to their own interests. From these

⁴⁷ Helfer, L. R. (2004). Regime shifting: the TRIPs agreement and new dynamics of international intellectual property lawmaking. *Yale J. Int'l L.*, 29, 1.

fora, counterhegemonic forces are challenging settled principles and legal practice in the field of IPRS in an attempt to reshape the international regime towards a legal landscape more convenient to their interests from deliberative democratic processes.

In this context there are more and more explicit positions and reflections pointing to TRIPS as a hurdle to access to affordable medicines. The Global Commission on HIV and the Law (convened by UNDP) for example issued a publication⁴⁸ where it explicitly claims that *strong patent law applied to pharmaceuticals in developing countries undermines access to medicines and compromises the human right to health* and that *there is little reason to expect that stronger patent rights in developing countries will lead to any substantial offsetting gains in innovation for the affected countries* and it concludes that *from both economic and human rights perspectives, the optimal patent policy in developing countries would likely be to exclude patents on medical products altogether, as many once did.*

Maybe the most recent and important initiative of this approach is represented by the UN Secretary General's High-level panel on access to medicines launched in November 2015⁴⁹. The scope of this initiative is *"to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies."* As we will see, the contributions and reflections provided are very diverse as long as qualified so it is expected that it will generate a deep and interesting debate. In fact, the industry has rushed to present a counter-report hand in hand with the Hudson Institute –declared to be a research organization promoting American leadership and global engagement for a secure, free, and prosperous future- which under the name *"The Patent Truth About Health, Innovation and Access"* criticizes the bias of the UN initiative and mention different factors other than patents as the real reasons to explain the lack of access to affordable medicines⁵⁰.

⁴⁸ El Said, Mohammed, and A. Kapczynski. Access to medicines: The role of intellectual property law and policy... (see chapter 2, footnote 130).

⁴⁹ <http://www.unsgaccessmeds.org/#homepage-1>

⁵⁰ <http://www.hudson.org/research/12622-the-patent-truth-about-health-innovation-and-access>. Among other factors, they include the lack of good governance, poor physical infrastructure and distribution systems, a

Transforming the regime from deliberative democracy basis

The crisis and the growing contestation of TRIPS, especially as pharmaceutical patents are concerned, are narrowly linked to the lack of legitimacy and legitimating procedures of this regime and the perceived democratic deficit of it as we have seen previously in Chapter 4. Consequences of this lack of legitimacy have to do with the coercion exercised for the adherence of developing countries to TRIPS and the unjust and poor –even detrimental- outcomes provided for by the global extension of western type IPRs in developing countries. Regardless the specific arguments and substantive propositions to improve/transform the current regime which will be addressed further in this chapter, and absent a global *demos* or a global government with the capacity to create political order -making and enforcing the law through the monopoly over the use of force-, the manner and proceedings suggested to overcome the democratic and legitimacy deficit and crisis of this regime should be grounded on the idea of deliberative democracy following Jürgen Habermas' work⁵¹.

This methodological approach not only permits us to explore the eventual overcoming of today's WTO crisis and deadlock through inclusive and argumentative bases but also, it is a useful tool to reveal and show the real interests behind the current architecture and functioning of TRIPS beyond the global and presumably universal interests as they are presented today by the hegemonic ideology, i.e., the manner in which international regimes operate mainly by the conventions of power politics delivering coercion based decisions, fake consensus and unjust and inequitable outcomes.

As we have mentioned, theories of deliberative democracy⁵² emphasize procedural issues of decision-making. In this sense, equality between participants is a must in a

shortage of healthcare facilities and providers, insufficient public health spending, corruption, taxes and tariffs on medicines, and the lack of policies that promote economic growth and incentives for individuals and businesses to develop new technologies so their countries can grow and prosper

⁵¹ Habermas, J. (1996). *Between facts and norms*, trans. William Rehg, London: Polity Press, 274-328.

⁵² Bohman, J. (1997). *Deliberative democracy: Essays on reason and politics*. Boston: MIT press.

deliberative democracy scenario, i.e., the reciprocal and mutual recognition of each other as equal political agents in discourse is a precondition for fair procedures⁵³. Also, it is important the quality and transparency of knowledge and relevant information in order to maximize that the best arguments see the light and be properly adjudicated. However, procedural fairness is a necessary, but not sufficient condition to guarantee outcome fairness. Just and democratic outcomes or decisions can be achieved only by rational discourse. For Habermas rational deliberation is not about an autonomous reason that calculates independent of society but a '*communicative rationality*' that acts in concert with others. Deliberative democracy is about a socially generated dialogue of reason, the "to and from" of argument and counter-argument.

In this sense, collective decisions should be founded not in the mere aggregation of interests of its members but on arguments in a process of mutual learning and honest reasoning to achieve a mutual and genuine consensus. Arguing implies that actors try to seek a communicative consensus about their understanding of a situation as well as justifications for the principles and norms guiding their action. Argumentative rationality also means that the actors in a discourse are open to be persuaded by the better argument of others ignoring relationships of power and social hierarchies. Argumentative and deliberative action attempts not to attain one's interest, but to seek a reasoned and genuine consensus. Actors' interests and preferences are therefore subject to discursive challenges and are prepared to change their views and opinions or even their interests in light of the better argument. Also, unlike "bargaining" the mere aggregation of interests where only mutual assessment counts in a dyadic logic –mutual trading of costs and benefits-, arguing follows a triadic logic, references to a mutually acknowledged external authority to validate empirical or normative assertions⁵⁴.

⁵³ In this sense, WTO has an important potential to implement deliberative practices. Despite the fact that WTO operates through a de facto system based on the economic power and the size of a country's market, decision-making processes theoretically have in their favor that they are consensus based with a juridical notion of member equality (one-member-one-vote).

⁵⁴ Risse, Thomas. (2004). *Global governance and communicative action*. Government and opposition 39.2: 288-313.

The goal of this rational argumentative activity is to achieve a genuine consensus. Consensus would be reached only through the *force of the better argument*. A consensus produced through argumentation not power politics. This consensus implies that all affected by agreed decisions or rules –also the foreseeable consequences and side effects of their general observance- would consent to them and would jointly accept them without coercion; this consensus giving force and legitimacy to just decisions as the affected would become convinced by the moral validity of the rule in question. As Habermas remarks, deliberative action contributes to reach substantially just outcomes since at the very least decisions taken by genuine consensus ‘enhance the perception of the outcome being fair and balanced’ and also to get the common good, being a positive perception a vital ingredient in any process of institutional legitimation.

Furthermore, these models of deliberative democracy can take place as long as there is a public sphere. Public sphere –whose definition has an evolving interpretation and conceptualization-, is a social site where equal citizens deliberate dialogically and arguments are publicly exchanged on State issues and other matters of common interest under suitable conditions to conduct a deliberative and argumentative activity. This *locus* of debate is distinct from the state and the economy –governed by power and money- and it is the place where collective and democratic will is processed and political decisions justified⁵⁵. In the last conceptualization of public sphere, Habermas acknowledges the plurality of publics, i.e., there is no such thing as “the public” but the existence of diverse *publics* and deliberations and forms of communication circulating through different forums⁵⁶.

⁵⁵ Habermas describes the political public sphere as a sounding board for problems that must be processed by the political system because they cannot be solved elsewhere. To this extent, the public sphere is a warning system with sensors that, though unspecialized, are sensitive throughout society. From the perspective of democratic theory, the public sphere must, in addition, amplify the pressure of problems, that is, not only detect and identify problems but also convincingly and influentially thematize them, furnish them with possible solutions, and dramatize them in such a way that they are taken up and dealt with by parliamentary complexes. Besides the "signal" function, there must be an effective problematization. The capacity of the public sphere to solve problems on its own is limited. But this capacity must be utilized to oversee the further treatment of problems that takes place inside the political system. I can provide only a broad estimate of the extent to which this is possible.[...] In complex societies, the public sphere consists of an intermediary structure between the political system, on the one hand, and the private sectors of the lifeworld and functional systems, on the other. It represents a highly complex network that branches out into a multitude of overlapping international, national, regional, local, and subcultural arenas. (Between facts and norms)

⁵⁶ Maia, R. (2007). Deliberative democracy and public sphere typology. *Estudos em Comunicação*, 1(2007), 69-102.

In the context of international legitimacy and multilateral/multilevel political authority -such as it is represented by WTO and the international IPRs regime- and in the absence of global democratic representation and/or voting by a global demos, many International Relations scholars have seen this model of deliberative democracy as an adequate way and methodology in order to increase the democratic legitimacy of governance mechanisms⁵⁷. The virtues of this approach is among other that it permits to involve all the affected –also the counterhegemonic contributions, reasons and concerns-, and it ensures the accountability and traceability of decisions in the sense that they should be confronted to review in terms of their validity from rational argumentation standards. Also, genuine and reasoned consensus from rational deliberation would greatly enhance the legitimacy of the rule and would increase the degree of voluntary compliance of the rule.

However, the procedural conditions to conduct a real and genuine deliberative process –equality between participants, transparency and access to relevant information, equal consideration of all viewpoints and no time-constraints among others- are part of an “ideal discourse situation” whose conditions are hardly replicable in real life. As we have seen for example in the context of the WTO, the participants, i.e., the Member States hold unequal status, they do not attempt to pursue a common good neither do they reflect upon collective interest issues and are unwilling to listen to others carefully and show reluctance to change their agenda or their viewpoints. Instead of reaching genuine consensus based on rationale argumentation many decisions and public consensus are the result of domination, coercion and political power. Current WTO functioning and decision making is characterized by the poor quality of deliberations and decisions which are based on political calculations and bargaining of compromises and trade-offs⁵⁸.

Even from a logistic point of view, many developing countries do not have the resources, capacity and expertise for effective deliberation and unlike other

⁵⁷ Nanz, Patrizia. Democratic legitimacy and constitutionalisation of transnational trade governance... (see chapter 4 footnote 4).

⁵⁸ Kapoor, I. (2004). Deliberative Democracy and the WTO. *Review of International Political Economy*, 11(3), 522-541.

organizations WTO does not provide its members with substantial technical assistance. Also, the epistemic power to define global economic governance is rooted in the hegemonic neoliberal ideology which permeates WTO culture and nourishes the liberal trade theory discourse. Critical voices are weak and developing countries encounter difficulties to bring about new voices and new ideas. Following Higgott and Erman, *the dual ability and opportunity to both formulate policy and advance policy – is constrained not only by capacity and cost, but also by the residual strength of existing liberal, rationalist norms within the core epistemic and political groupings at the WTO.*⁵⁹

In this respect, political public sphere and civil society would play a key role in order to cope with the above mentioned distortions and problems of today's international trade system and of the TRIPS regime. A public sphere –based on an informed and critical civil society encompassing all voices- which could enhance the equality, accountability, liberty and justice of the political process through deliberative and argumentative action. Unlike formal deliberative decision in the political arena, in the public sphere there would be deliberative practices through informal processes of opinion-formation and will-formation which could identify social problems and counterhegemonic perspectives outside the agenda of formal politics and bring them into formal negotiations of political decision-making. Also, it would be able to critically scrutinize political decisions and require accountability (in terms of rational justifiability of decisions). Even if it is difficult to imagine the way in which the public sphere can operate in a contemporary large-scale, global and pluralist society, it is important to open the process of political deliberation to public scrutiny in order to conform transnational public spheres (World Social Forum, government officials, social activists, scientific experts, NGOs, associations, representatives of minorities, or advocacy groups of a multitude international, national, regional, local and/or subcultural arenas all affected by multilateral decisions).

Therefore and in spite of today's shortcomings in WTO functioning, deliberative democracy views are an important instrument that could improve both the legitimacy

⁵⁹ Higgott, Richard, and Eva Erman. (2010). Deliberative global governance and the question of legitimacy: what can we learn from the WTO?. *Review of International Studies* 36.02: 449-470.

problems of WTO by providing voice opportunities to various currently ignored stake-holders and the problem-solving capacity of international organizations through deliberation. Also, models based on deliberative democracy may inform the necessary reforms of WTO and the global regime of IPRs and mark the path of what it should look like; a forum which must be inclusive - no one is excluded from articulating topics considered to be relevant to her interests and no relevant information is left out-, coercion free, open, transparent and symmetrical. In the last chapter we will analyze various proposals to tackle these problems and to enable that arguing and deliberative process be at the center of the negotiation system and decision making processes. Beyond the WTO bodies and organs, deliberative democracy premises constitute also a valid methodologic approach to assess the functioning of different levels of both domestic and international venues with lawmaking and/or implementation authority in the field of the global IPRs regime which become crucial for the regime change.

In this sense, today, most states find themselves in the positions of being law takers rather than law makers; i.e., national legislators have to implement and administer regulatory standards which have been determined somewhere outside their national borders. Also, supranational regulatory order becomes the target and the realm of interest group activity and influence which seek rents to a powerful transnational capital rather than the common good or the general welfare. All this implies a new form of domination, a domination *based on the rule of law*⁶⁰. By implementing democratic deliberative spaces and forums, it is intended to emancipate national decision making processes in such a manner as to permit national interpretations of IPRs which, far from being discretionary or arbitrary, respond to foreseeable and certain democratic deliberative parameters agreed globally in view of the interests, values and needs of the national or regional society where IPRs are to be applied. Furthermore, at a global scape democratic deliberative processes are proposed to overcome the lack of legitimacy of international regulatory activity and adoption of global standards by emancipating of undue and biased influence and making all the

⁶⁰ Drahos, Peter. (1996). Global law reform and rent-seeking... (see chapter 6, footnote 81)

process more democratic, transparent, participatory and inclusive of diverse voices and counterhegemonic views.

In this respect, the previously mentioned Report of the UN Secretary-General's High-Level Panel on Access to Medicines released in September, 2016⁶¹ has been elaborated following a debate and discussion which could be close to be a deliberative forum. The Report is divided into four chapters; Health Technology Innovation and Access; IP Laws and Access to Health Technologies, New Incentives for R&D of Health Technologies and Governance, Accountability and Transparency. Other than dealing with many of the issues addressed in this dissertation and after reaching similar conclusions⁶², the Report makes important remarks about governance, accountability and transparency.

Besides the fact that the report itself is the result of the participation of diverse groups of individuals from various backgrounds, experiences and continents-including a public call for contributions around the world- and that according with the document the discussions took place in an atmosphere of mutual respect and that despite different views of participants they reached broad consensus on many aspects, i.e., that something similar to a global public sphere was created to discuss a global issue, the Final Report in its chapter 4 tackle the issues of governance, accountability and transparency and it puts forward a set of considerations for promoting transparency, governance and accountability which could contribute to create an interesting forum and space for deliberative processes of debate and decision and that will be mentioned and discussed in the next section.

⁶¹ Final Report of the UN Secretary-General's high level panel on access to medicines September 2016, available at: <http://www.unsgaccessmeds.org/final-report/>

⁶² The Report reveals among others that investment in R&D of health technologies does not adequately address a number of important needs and that the imperative to respect patents on health technologies could create obstacles to the public health objectives of WTO members (p. 7); that sometimes patent laws do not encourage genuine innovation (versus evergreening of medicines) and that do not contemplate flexibilities because of capacity constraints and undue political and economic pressure; that market-driven R&D has permitted the development of many improved health outcomes but has also gaps and shadows in health technology innovation and access (p.8); that public-private partnerships tend to be fragmented, disparate and insufficient to deal with priority health needs on a sustainable and long term basis. Importantly the Report recommends that public funders of research must require that knowledge generated from public funded research be made freely and widely available through publication in peer-reviewed literature and seek broad, online public access to such research. (p.9)

7.4. Embracing a global public sphere to deliberate and define democratic parameters in the interpretation of IPRs and implementation of pharmaceutical patents.

In the previous section and in previous chapters we have reviewed the shortcomings of today's global approach and global regulation in terms of both intertwined concepts of legitimacy and democratic nature. In this context, we have also seen that global IPRs regime is other reflect of this new global architecture whose driving force is the neoliberal agenda and the needs of the new version of capitalism (supercapitalism or global capitalism). Therefore, and with the purpose of suggesting an alternative process of globalization and especially an alternative reading and interpretation of IPRs, in this section we will explore first whether there is margin to think of public deliberative sphere as a space or forum enabling the conditions for making the regime more democratic and more legitimate in the sense of being more inclusive and participative of all the affected actors. Secondly, and regarding the subject matter of this thesis, the global public sphere should entail transparent and traceable modes of public reasoning about how to better incentivize genuine innovation for all (neglected diseases too) while ensuring affordable access for everybody. This could permit to adequately define and adopt the democratic parameters under which IPRs have to be implemented in order that they fulfil their social functions and that the public interest prevails and human rights respected. In this manner, these rights/privileges vested with property prerogatives should serve the interests and needs of society and its citizens.

In this global public sphere there would be at least four key dimensions or conglomerates of interests and concerns which contribute to the configuration of power; state based national and international institutional framework (also the judicial and law adjudicator), global operation of pharmaceutical business, global media and global civil society. The public sphere composed of at least these four elements should be oriented to discuss and reason how to bring about the aforementioned aim (how to incentivize genuine innovation and ensure affordable access to medicines). Today, there is an obvious imbalance among these four dimensions, being the interests and views of the global pharmaceutical business

which prevail over the rest of actors and what has been impregnating the other dimensions. In particular, we have seen that the imperative to respect pharmaceutical patents from an absolute quasi natural rights approach, constrain national governments to achieve their own public health objectives as long as their development needs and innovation public policies and puts the international law and the state at the service of the lucrative interest of the pharmaceutical industry instead of permitting affordable access to medicines. In this sense, national legislators and officers administer standards which have been adopted outside of a given state, in many occasions as we have seen regarding WTO after opaque processes which are not the subject of any “democratic check”.

The necessity for reform in global health is not unique to the field of health or the pharmaceutical business. In fact, global reform is nowadays a hot issue with no solution in sight. Following Professor Boaventura de Sousa Santos⁶³, we can say that the hegemonic discourse of globalization and governance has excluded many people from participation in social issues, relations of power and allocation of resources. The state’s previous role as the instrument to ensure distributive policies and establish the political social contract -for among other things, agreeing upon allocation of resources- has been replaced for the market rule, considered as being more efficient under the mantra of privatization, marketization and liberalization worldwide. Although the new paradigm of governance or the proposals on global public goods have been presented as political pathways to overcome the more and more obvious market failures, growing inequality and unjust outcomes, today we are aware that this is part of the strategy of consolidating the hegemonic neoliberalism; in particular, by presenting it as a politically guided creation, governance attempted to give certain legitimacy to the new established regime based on market rules and capital accumulation.

The conclusion that governance and neoliberal governance are two sides of the same coin is derived rather than from the values and concepts usually encompassed by

⁶³ de Sousa Santos, B. Beyond neoliberal governance: The World Social Forum as subaltern cosmopolitan politics and legality. *Law and globalization from below: Towards a cosmopolitan legality*, (see Introduction footnote 2).

governance -which in fact echoes some of the aspirational features of deep democracy-, from the silences it keeps on concepts such as popular participation, social conflicts, social justice or redistributive justice. Furthermore, governance attempts to depoliticize important social issues as being questions pertaining to the technical realm without saying that the process of depolitization itself is a highly political option and entrust the state the task of creating the space for non-state regulators once it has withdrawn from being the social regulator. Therefore, instead of being at the service of a project of social inclusion and social redistribution, the concepts and formulae usually associated to governance such as problem solving, self-regulation, partnership and coordination and so on, seem to be at the service of exclusion and economic polarization.

The important part here is that the paradigm of governance and the decision making-process at global scale exclude a large proportion of world population from participation by keeping them in “non-existing” status and denying the inherent conflicts in the allocation of resources. Even if some of the new formulae of governance can bring some benefits -as it is the case of the Public Private Partnership in the field of health-they do not implement the conditions to enable popular participation or social redistribution as a matter of right; i.e., it is not emancipatory⁶⁴.

Account taken of the global scale of the new strategy and of the process of accumulation of capital that has been released from the constraints created by some welfare states and their redistributive policies, the ideal of a global public sphere where global decisions have to be discussed, confronted and adopted under democratic deliberative parameters seems to be a necessary counterpoint to the expansive and rapacious nature of today’s global capitalism. It also has to give room to the excluded by the current neoliberal globalization and being able to introduce counterhegemonic voices who challenge the conceptions of world development under the hegemonic discourse of globalization and governance at the service of the endless process of accumulation of capital. Once national governments have been displaced from their role as social regulators and spaces to manage and handle

⁶⁴ Ibidem.

conflicting interests and absent a world government where to convey the social conflicts and to agree the social contract, it is crucial to create forums that while ensuring democratic popular participation and being inclusive of all the voices, aspirations and sensitivities, contribute to fight against social exclusion and promote social emancipation by fostering social redistribution as long as recognition of difference.

Some precisions about global public sphere.

By global public sphere we want to invoke forums where decisions come from and after democratic inclusive deliberative processes. In this sense, it is important to be aware that the somehow bucolic Habermas' public sphere composed of individuals speaking face to face in a rather small space of a cafeteria does not longer exist –if it ever did- and that we live in the age of mass media and internet social networks. While Habermas is aware of the decay of the bourgeois public sphere due to the emergence of today's mass-media which paved the way *from a press that took ideological sides to one that was primarily a business* and that *the public sphere became a field for business advertising*⁶⁵, it is important for our purposes to reconstruct a conceptualization of the public sphere as an analytic tool, getting rid of the historical circumstances implied by Habermas' analysis. In fact, the concept of public sphere is highly helpful and must have evocative power to monitor and scrutinize whether a given decision-making process or forum enables the implementation of inclusive democratic deliberative process where decisions are taken by rational collective consensus ensuring equality between participants, transparency and access to relevant information. Also, an instrument to evaluate whether decisions are justified

⁶⁵Habermas, Jürgen. (1991). *The structural transformation of the public sphere: An inquiry into a category of bourgeois society*. MIT press. Habermas holds that mass media have become complexes of societal power which threaten the critical functions of publicists' institutions since the new business approach to the mass media view this as an exchange commodity valued in terms of its effectiveness to attract publicity and advertising and it makes mass media more accessible to the pressure of certain private interests. Very precisely and interestingly Habermas says that *whereas the press was able to limit itself to the transmission and amplification of the rational-critical debate of private people assembled into a public, now conversely this debate gets shaped by the mass media to begin with. In the course of the shift from a journalism of private men of letters to the public services of the mass media, the sphere of the public was altered by the influx of private interests that received privileged exposure. The separation of public and private spheres implied that the competition between private interests was in principle left to the market as a regulating force and was kept outside the conflict of opinions.*

and traceable thus permitting accountability. Even if these conditions are part of an ideal discourse situation, they serve us to value the (democratic) quality and legitimacy of a given decision.

By using the term global (public sphere), we do not mean that the dynamic and the proposed democratic deliberative process have to be delinked from specific national realities. On the contrary, we have said before that the social function of IPRs has to be reviewed at the national level, pursuant to national needs, socioeconomic realities and strategies. Notwithstanding that, in many occasions the state is no longer the center of political decisions or is not the only center of decisions but decisions and debates that affect the national space have been “transnationalized”. The transfer of “political” power outside the national borders has not brought about a parallel transfer of the formal instruments of representative democracy which take place in national states. Furthermore, other than global/transnational actions or decisions with national consequences, there are national or local actions or decisions that may have even unintentionally a global impact contributing to its reproduction in other local spaces.

The case of South Africa and the strong popular mobilization against the prices of AIDS and antiretroviral medicines pressing the pharmaceutical companies to withdraw their legal claims against compulsory licensing is very illustrative of what we have said. First, the popular pressure was addressed to support the decision of the national state of South Africa about expropriating the HIV/AIDS pharmaceutical patents to enable an affordable access to those medicines i.e., the government and the national population joined together against pharmaceutical companies and their TRIPS fostered IPRs since the state is no longer the privileged center of decisions in this regard. Second, the success of this joint struggle had an impact beyond South African borders and it shook the foundations of the global IPRs regime as well as inspired similar reactions in other locations. In this respect, the cases of Thailand, Kenya or Guatemala constitute examples of how some developing countries have struggled to implement the TRIPS Agreement in a manner that protects public health with the complicity (and the pressure) of civil society in fighting for the right to

access affordable medicines⁶⁶. Hence, national and global dimensions are narrowly intertwined and interrelated in today's world.

As we have said before the global public sphere of health would be anchored between at least four dimensions which shape the configuration of power in this field of pharmaceuticals and access to medicines. First, the institutional framework, it is the dimension where formal decisions are made and where the game rules are established. It is composed of both national states including law adjudicators (mainly law courts at national scale) and international institutions which have a direct impact (WTO and WHO) or less direct one (WIPO, UN, World Bank or IMF); second the operation of the pharmaceutical business as subjects which provide most of the health related goods and services which are the object of regulation. They have to adjust their conduct within the possibilities given by the market –including the concerns and interests of consumers-, the game rules established by institutions and the limits established by social pressure. It is also noteworthy the tendency of making corporations more and more accountable through soft law mechanisms such as corporate responsibility or “compliance”⁶⁷and criminal liability of companies. The operation of the business is also an indispensable channel of information since markets and their failures provide us information as to what is profitable and how operators are incentivized and to do what. These are key points in order to evaluate the functioning of the industry and the reality and effectiveness of the proposals for their improvement; third, the dimension of mass media is also a public sphere and contributes to regulate other public spheres by providing participants with information or just the opposite, creating misinformation. It can therefore play a crucial role in enabling contestation and critical perspective and echoing counterhegemonic voices. Finally, civil society would consider the non-state organizations identified as belonging to civil society⁶⁸. While the first two dimensions (institutions and industry) are the places where relevant and formal decisions are made, the two last (media and civil society) are the dimensions which may control

⁶⁶ Ford, N. (2004). Patents, access to medicines and the role of non-governmental organizations. *Journal of Generic medicines*, 1(2), 137-145.

⁶⁷ Compliance is a legal service addressed to provide the companies with tools and instruments of due diligence and self-control in order to prevent them from incurring any liability (mainly criminal).

⁶⁸ Germain, R., & Kenny, M. (Eds.). (2004). *The Idea of Global Civil Society: Ethics and Politics in a Globalizing Era*. Routledge.

and monitor the two other and thus adjust their operation to acceptable and democratic standards. Except for the dimension regarding the operation of the business which has been previously reviewed in chapter 2, we are going to analyze next the three other dimensions.

Global civil society. Does it really exist?

We do know that capitalism and transnational companies and some international institutions enabling the neoliberal type globalization are global; however the existence of a real and *active* global civil society may give rise to serious doubts about its reality. It is obvious that it does exist a worldwide population who is the target of transnational political decisions –in broad sense and including business global strategies- and who goes through multiple cultural, economic and social transnational processes. What we want to review here is whether there exists an *articulated* global social society which could play the indispensable role of representing the popular participation at the global public sphere, this including the counterhegemonic voices.

The relative attractiveness of this concept-idea can also be a double-edged sword which may conceal certain attempts to reshape the global political order after the breakdown of the cold war –and the release of all the potential capitalism from welfare state’s constraints and concessions- and which see global civil society as an interesting conceptual instrument to explore, as well as an apparently benign value to promote with the intent of legitimizing the neoliberal political order at global scale. In this sense, the idea of global civil society could represent a powerful instrument to exclude, delegitimize or silence groups or practices considered to be “uncivil” ⁶⁹ and so consolidating the dominant hegemonic neoliberal agenda by not even recognizing the existence of counterhegemonic voices (“sociology of absences” in Boaventura de Sousa Santos’ words). Also, global civil society can be employed as a type of catchall term comprising CSOs and social movements of all shapes and colors operating in the international scenario losing sight of their transformative and emancipatory potential. Furthermore, there are some commentators who challenge the very notion

⁶⁹ Kaldor, M. (2003). The idea of global civil society. (See chapter 4 footnote 3).

of global civil society; they hold that in the absence of a global state there are serious collective action problems for global mobilization and identity formation. The dictates of nation-state premises –national, linguistic and cultural differences framework– would frustrate any form of global society and power⁷⁰.

Being that true and being aware of the shortcomings of the role of a real and active global civil society, we consider that there is space to conform and share a joint perspective of global issues from diverse national and motivational and ideological origins and concerns. Again, the aspirational existence of a global civil society may become an important analytical instrument to evaluate and transform the current system towards democratic parameters. In this sense, by civil society we do not mean the civil society understood by liberal political theory i.e., the idea of civil society as opposed to the state (which inherently would oppress and limits it)⁷¹but a civil society representing the democratic interest of people and citizens. More precisely, it becomes crucial to see the manner how a global civil society or the idea of a global civil society could review, monitor and counterbalance the neoliberal globalization i.e., certain expansion of capitalism which does not know restrictions/limits at the global scale and that does not take into due account the interests and needs of population, in particular of the excluded. In this sense, we have to focus on genuine civil society organizations (CSO) which are non-state and non-commercial and ignore those “civil society” manifestations which are rather dominated by business organizations or imbued with business strategies.

The idea of a global civil society responds then to the necessity of overcoming the absence of citizens’ common good in the current construction of the international architecture. Hence, if many relevant and key decisions are taken at the global level, there have to be mechanisms for increasing the responsiveness of global institutions to the demands of individual citizens. Procedural democracy of national states at the global level could not achieve at this moment or in a reasonable half term a world

⁷⁰ T Tarrow, S. (2001). Transnational politics: contention and institutions in international politics. *Annual Review of Political Science*, 4(1), 1-20.

⁷¹ Santos, B. D. S. (2002). The processes of globalization. *Revista Crítica de Ciências Sociais and Eurozine*, 1-48.

citizenry represented by a world parliament. Once we have assumed that dialogue and democratic inclusive deliberation open to all civil society groups and which take place at many levels, are the next best option it is important to identify an active, a real global civil society and CSOs which really represent individual citizens and common good as a “functional equivalent” or an “alternative mechanism” for democratizing global governance.⁷²

Furthermore, it is helpful to bear in mind the different global civil society organizations. Other than the multiplicity of motives which are at the origin of CSOs, the relevant distinguishing element for our purposes among associations is whether they question or not the current regime. In fact, there are CSOs which do not question the current regime and the causes behind it; they are rather focused on the consequences of its malfunctioning without holding any critical discourse. Their focus is on the private rather than on the public, on the social rather than on the political, on the micro rather than on the macro⁷³. On the contrary, there are CSOs which frame their actions in a broader concept of political activism and which question the current hegemonic regime giving voice to counterhegemonic voices against neoliberal globalization and governance. Those CSOs are genuine agents of citizens’ interests and the channels for inclusive popular participation being the necessary catalyst for regime transformation toward a more democratic system by actualizing a global public sphere.

On the other hand, certain dilemmas have emerged as to whether deliberation, debates and “struggles” between conflicting interests have to be carried out at a national or a global level. This dilemma cannot be resolved in terms of an excluding dichotomy. As we have mentioned regarding WTO protests in Seattle, a multiplicity of actors with different motives, concerns, origins and territorial scope were joined together against something that was perceived as a global agenda affecting all of them. Seattle initiated the path showing that cooperation was possible among diverse

⁷² Kaldor, M., Anheier, H., & Glasius, M. (2003). *Global civil society*. Cambridge: Polity.

⁷³ Santos, Boaventura de Sousa, *vid supra* at 61.

local activist communities supported by global groups that provided the resources for mass mobilization around global justice issues⁷⁴.

Likewise, and assuming that democratic emancipation is grounded on the principle of equality and the principle of respect for difference, there may be a tendency that some CSOs are totally inclined to stand for just a segmented concern (feminists, LGTB, indigenous or black or animal rights supporter movements) ignoring the general view of the broader political context where they are inserted. This tendency may be dangerous in the sense that the emancipatory value of some movements may be gobbled up and jeopardized by partial concessions of the regime at the expense of providing the system with seeming legitimacy while maintaining the structural causes of exclusion and injustice.

However, the above is not always the rule. In this respect, it is remarkable and fairly encouraging the recent role played by the feminist movement. On last January 21 and one day just after the presidential oath of Trump, over 5 million women worldwide came to march to vindicate their rights but also to invoke a fairer world. This spontaneous demonstration and protest of women extended globally and went beyond the specific vindication of the status of women. Especially illustrative of this, it is the speech addressed by the black activist Angela Davis during that march when she explicitly said that *the march was the ground zero of the struggle for social justice*⁷⁵.

Regarding health, the above mentioned perspective of global civil society in terms of contestation and critical approach to the hegemonic configuration of the global IPRs regime as the manner to actualize a global public sphere in this field has somehow taken place following the HIV/AIDS crisis that as we have said, opened the door to

⁷⁴ Murphy, G., & Pfaff, S. Thinking locally, acting globally? ... (See Chapter 4 footnote 4).

⁷⁵ It is noteworthy to reproduce here some of the words pronounced by the important black activist: [...] "The struggle to save the planet, to stop climate change, to guarantee the accessibility of water from the lands of the Standing Rock Sioux, to Flint, Michigan, to the West Bank and Gaza. The struggle to save our flora and fauna, to save the air—this is ground zero of the struggle for social justice. "This is a women's march and this women's march represents the promise of feminism as against the pernicious powers of state violence. And inclusive and intersectional feminism that calls upon all of us to join the resistance to racism, to Islamophobia, to anti-Semitism, to misogyny, to capitalist exploitation. "Yes, we salute the fight for 15. We dedicate ourselves to collective resistance. Resistance to the billionaire mortgage profiteers and gentrifiers. Resistance to the health care privateers. Resistance to the attacks on Muslims and on immigrants. Resistance to attacks on disabled people. Resistance to state violence perpetrated by the police and through the prison industrial complex. Resistance to institutional and intimate gender violence, especially against trans women of color [...]."

certain counterhegemonic voices which explicitly questioned the regime and confronted it with other powerful and legitimate social interests such as public health. As we have previously mentioned, the *Access to medicines campaign* initiated a counterhegemonic struggle which explains among others the posterior Doha Declaration on TRIPS (probably the main victory NGOs have achieved so far in the access to medicines). In fact some commentators situate the first coalition of CSOs against the IPRs global regime as early as 1996 with occasion of an event organized by Health Action International (HAI) in Bielefeld (Germany); Important CSOs such as HAI, Act Up, Health GAP, Third World Network, CPTech, Quakers UN office in Geneva, or the more renowned Medicines Sans Frontiers and OXFAM (and its Cut the cost campaign) adhered to the movement.

A crucial factor to explain the success of the global coalition was the manner they functioned. They coordinated concerted action among North and South CSOs with national and international scope and social movements either at the grass-roots level or focusing on international processes. While national CSOs in developing countries put pressure on their governments (Brazil or South Africa) to safeguard public health and promote access to medicines, global CSOs helped ease the pressure from developed countries and pharmaceutical transnationals on developing country trade negotiators and socialized the conflict to the public opinion. As a result of the performance of this coalition of CSOs, IPRs are now seen as remarkable political issues rather than as purely technical matters thus entering the global public sphere. In this regard, the CSOs' network gained ground in the Access Campaign because it successfully highlighted how stringent patent laws can imperil public health in the context of the HIV/AIDS crisis.⁷⁶

Most of the CSOs which were active in the Access to Medicines still remain active in the field and they provide effective advocacy and campaigning, including use of media, development of campaign slogans and presenting the issues in pedagogical manner to the general public. CSOs perform important tasks for the actualization of the global public sphere such as research, strategy development, legal and technical

⁷⁶ Sell, S. K., & Prakash, A. (2004). Using ideas strategically: The contest between business and NGO networks in intellectual property rights. *International Studies Quarterly*, 48(1), 143-175.

expertise, institutional presence, monitoring of international institutions, national governments and pharmaceutical companies and dissemination of relevant information to the public.

Conventional Mass media.

The evolution of the mass media, internet and social networks and their impact on society and democracy are interesting and challenging matters in contemporary discussions which would deserve a specific dissertation. In this section we would like to remark the importance of this dimension in creating the conditions to achieve an effective public sphere where implementing deliberative and democratic processes of discussion on public issues.

In this sense and as we have previously mentioned, far from the editorialist nature and small format which could represent the media of the eighteen century –closer to the idea of the public sphere-, mass media has gone through a process of commodification. This process has also entailed the privatization of some previously publicly funded media, the creation of big media conglomerates⁷⁷, their political use and their global character. For many commentators this has raised important issues of conflicts of interests which deeply impair participatory democracy and the independence and critical role of mass media⁷⁸.

In this sense, media has entered the mercantile logic under which commercial imperatives and audience-attracting activities prevail over any other consideration and over the necessity that mass media could inform the members of a society in order that they are able to participate -as informed members- in a public sphere. In the end, market forces coupled with public policy *have tended to opt for private gains over the public interest*⁷⁹. The precariousness on which the media business is based

⁷⁷ Bagdikian, B. H. (2014). *The new media monopoly: A completely revised and updated edition with seven new chapters*. Beacon Press.

⁷⁸ McChesney, R. W. (2015). *Rich media, poor democracy: Communication politics in dubious times*. New Press, The.

⁷⁹ Curran, James. (1991). *Rethinking the Media as a Public Sphere*. *Communication and Citizenship: Journalism and the Public Sphere*, edited by Peter Dahlgren and Colin Sparks. Routledge.

today with professionals and journalists badly remunerated and its economic and structural interaction with globalizing capitalism and consumer culture impair the critical potential of mass media and its engagement with democratic values beyond those formal democratic standards.

From the standpoint of creating a real public sphere, the commodifying and mercantile logic of mass media impairs the access to relevant information, increasing differentials in access, bringing about asymmetries and further eroding the ideal of universal citizenship. As liberal tradition approach justifies that media should be based on the free market to guarantee media's independence from the state, a more progressive approach notes that free market can never be a totally adequate basis for organizing the media since it results in a system biased in favor of hegemonic, dominant class interests⁸⁰ which does not represent many subordinated sectors of society.

Furthermore, commercial rationality of mass media has contributed to the segmentation of audiences depending on socioeconomic and educational characteristics of people, purchase power and consumption habits of "consumers". Fragmentation has eroded the former role played by national "serious" public media –mainly in Europe- as a public space for national discussion i.e., the decline of certain public sphere for national politics. These different audiences often respond to social movements that link experiences of everyday life (from sport disciplines to dietary habits or fashion tendencies or even Game of thrones followers). This social phenomenon is facilitated by the customization and flexibility permitted by the new technologies and internet. These new segmented media markets generate international "communities" beyond national boundaries. However, as it mostly happens in social networks, these "communities" rarely encompass a normative vision which may be eventually translated into political or collective action. On the contrary, and inspired on Byunng-Chul Han's vision of our contemporary societies⁸¹ they rather contribute to the reaffirmation of multiple self or multiple "narcissuses" who are not able to joint together and create a collectivity which transcend them.

⁸⁰ Id.

⁸¹ CHUL HAN, B. (2014). *La agonía del Eros*. Herder. Barcelona (España).

Notwithstanding this, institutions –in a broad sense-, the processes of “globalization” and the social order are anything but stagnant and therefore are subject to changes and transformations. Truthful and exhaustive information is a must to create a public sphere where governments, private sector and other actors are held accountable for the impact of their actions. In this sense, the main challenge today is to establish information mechanisms and structures in the public interest which shall include different viewpoints, forms of expression and which encourages full and active participation and somehow citizenship.

In this respect, it is noteworthy that mass media are key instruments with a view to promote communication and exchange within the public sphere. Specially, media contributes to inform and educate the members of a society in the sense of promoting a public reasoning which should encompass questioning of established or hegemonic perspectives from a critical engagement⁸² i.e, if a public sphere emerges from discursive interaction of citizens, audiences (the condition that all citizens could be members of that audience) are a previous step and a precondition of the creation of a public sphere integrated by citizens as members of that audience. According to some commentators, media should play a role of vigilant against injustices and wrongdoings, thus becoming an agent who scrutinizes critically the exercise of power (the power exercised either by the state or by corporations or other actors)⁸³.

The emergence of internet and social networks.

On the other hand, the emergence of internet has motivated important transformations in mass media and it is somehow behind the crisis of traditional mass media. Internet and the multiplicity of sources of information it encompasses has eroded the traditional journalistic control over the information market. Internet promotes informational self-determination of the audience and makes them more independent from traditional mass media. This alters the role of journalism and

⁸² Germain, R. (2010). *Global politics and financial governance*. Palgrave Macmillan.

⁸³ Carroll, W. K., & Hackett, R. A. (2006). Democratic media activism through the lens of social movement theory. *Media, culture & society*, 28(1), 83-104.

journalism professionals and undermines the power of official sources. Even if internet raises certainly some doubts as to its limited access to certain kinds of information, a tendency to increase rumors and hoaxes, false information and bias, Internet has also become a watch dog and an effective instrument to monitor official mass media⁸⁴.

Furthermore, some social networks like Twitter have become themselves a source of information, somehow competing with traditional media (both physical and online versions of traditional media). In fact, some empirical studies reveal that social networks, in particular twitter, gives coverage to certain issues which were ignored by traditional channels⁸⁵. Furthermore, internet and social networks contribute to create global virtual communities modelled around different themes and categories than traditional media, national boundaries and political interests. Hence, Internet and social media provides us with an effective instrument to create a global public sphere by permitting inclusive participation, greater access to information, and opportunities to engage in public speech. Also, it is interesting to see the links and connections between traditional media and social networks. On the one hand, many journalists are embedded in social networks where they obtained information since Twitter for instance has become a leading source of breaking news⁸⁶ and sometimes they are also influencers of the virtual world.

However, it is questionable whether social networks and internet actually encourage undertaking collective action in order to provoke transformations of the system or are just forums of at best individual self-realization, showcasing of individuality or self-reflection when no stark narcissism. Some commentators note that expectations generated by internet some years ago have not been met. In this sense, it is said that internet reflect the same inequalities, linguistic division, and the conflicting values and interests of the real world; that internet did not refresh democracy neither did

⁸⁴ Bucher, Hans-Juergen. (2002). Crisis communication and the Internet: Risk and trust in a global media. *First Monday*, 7(4).

⁸⁵ Zhao, W. X., Jiang, J., Weng, J., He, J., Lim, E. P., Yan, H., & Li, X. (2011, April). Comparing twitter and traditional media using topic models. In *European Conference on Information Retrieval* (pp. 338-349). Springer Berlin Heidelberg.

⁸⁶ Kwak, H., Lee, C., Park, H., & Moon, S. (2010, April). What is Twitter, a social network or a news media?. In *Proceedings of the 19th international conference on World Wide Web* (pp. 591-600). ACM.

transform the economy and that internet did not result in a renaissance of journalism as it was previously thought⁸⁷.

In our view this analysis is important since it makes us depart from certain ingenuity when considering the “magic virtues” of internet –which is a mere instrument reflecting the reality of our society-. However, we think that these conclusions are premature and too pessimistic as to the potential role played by the internet and the social networks in the configuration of global society. In particular, it seems to be too soon to value the real impact of internet on next generations’ lives and interactions. For our purposes it is important to highlight first the emancipatory potential of internet and social networks to promote a real global public sphere which includes counterhegemonic voices and counterbalances hegemonic power and official mainstream. We consider that one of the reasons why it has not played all the emancipatory potential that it was once announced is due to the slower process of creating global communities or rather the awareness about the emergence of a community itself and about the power of an instrument like internet; today it is more and more usual to see how decisions made at a local scale –in local communities- may be strongly contested from below through sometimes spontaneous other times organized collective voices created in the context of social networks which have a direct impact on political decision making processes. In this sense, collective action fostered by means of internet and social networks encompasses the previously mentioned continuous dialogue and connection between the local and the global.

In this sense, from the Arab Spring to the "indignados" protests in Spain and the Occupy movement or the recent women’s march, social networks represent new forms of protest. Cyberspace is not however composed of an army of internet addicted peoples detached from physical reality. On the contrary, according to some scholars, the use of social networks contributes to construct emotional bonds which permit to overcome the sense of isolation, dispersion and passivity showed by today’s citizenry -fallen prey to neoliberalism’s attack on all forms of public space- in a project of re-appropriation of public space, i.e., social networks function like channels

⁸⁷ Curran, J., Fenton, N., & Freedman, D. (2016). *Misunderstanding the internet*. Routledge.

of emotional conduits in order to reconstruct a sense of togetherness and viability of collective actions among a spatially dispersed geography of individuals, so as to facilitate its physical gathering in public spaces. Therefore, other than permitting monitoring and traceability of decisions, social networks are means and instruments to create emotional bonds and sense of community, propitiate physical gatherings recovering physical public spaces and connecting local struggles with global challenges. This could constitute the pillars of an effective and democratic global public sphere which ensures inclusive and democratic participations and which reflects an increasing contemporary feeling of individuals who stand for direct action, direct democracy and direct face to face contact and who reveal a deep distrust regarding traditional representative systems which are perceived hierarchical, opaque and elitists⁸⁸.

In this regard, it is noteworthy that in a recent empiric study by the Berkman Center for Internet & Society at Harvard University about the dynamics of the networked public sphere over proposed legislation in the US, the outcomes reveals that the discussion process entails many voices and organizations most of which are not traditional sources of power in shaping public policy in the US thus presenting quite an optimistic view of a deliberative, diverse and decentralized public sphere that –the study says- *exhibited broad participation, leveraged topical expertise, and focused public sentiment to shape national public policy*⁸⁹.

Furthermore, it is especially remarkable some global platforms like Change.org or avaaz.org whose operation fits right into the local-global dialogue based parameters previously explained in the sense of facilitating a global cybernetic platform where a dispersed constituency achieves a feeling of togetherness around specific -mostly local- realities and from where it is promoted local collective action⁹⁰. Avaaz.org was

⁸⁸ Swann, Thomas. (2012). *Tweets and the Streets: Social Media and Contemporary Activism*. Plutopress.

⁸⁹ Benkler, Y., Roberts, H., Faris, R., Solow-Niederman, A., & Etling, B. (2015). Social mobilization and the networked public sphere: Mapping the SOPA-PIPA debate. *Political Communication*, 32(4), 594-624.

⁹⁰ For instance, Avaaz webpage reports that when Monsanto started to build a mega genetically modified seed factory in Argentina, courageous local leaders physically blocked the construction. Then Avaazers stepped in to amplify their fight with a million voices worldwide. Together we went door-to-door, ran opinion polls showing massive local opposition, helped elect a city council opposed to the factory, and ran targeted campaigns to local and national politicians until Monsanto was forced to abandon the plant. <https://avaaz.org/page/en/highlights/>

co-founded in 2007 -by Res Publica⁹¹, MoveOn.org -an American non-profit progressive public policy advocacy group- and by Service Employees International Union and it counts on more than 44 million of members along 194 countries - operating under the claim of *being a global web movement to bring people-powered politics to decision-making everywhere*-. Avaaz is rather (but not only) focused on global issues such as climate change, free and open internet for all, or the creation of bigger massive marine reserves and presented in a single format for different languages -with some slight differences- and dealing with the same topics in all the versions. Although Avaaz is declared not to support any specific ideology, the truth is that this platform often supports causes considered progressive⁹².

On the other hand, Change.org which operates under the claim *empower people everywhere to create the change they want to see*, was also founded in 2007 and it claims to have more than 100 million people in 196 countries. Change.org seems to be addressed to deal with demands of local communities and it has differentiated versions of demands adjusted to the different national communities. There has been debate and criticism around the fact that Change.org is a for-profit business despite using the .org domain suffix rather than the commercial .com. and around the fact that petitions are rather focused on first world problems⁹³. In any case, Change.org reports and claims as its own some important successes and victories in the health field⁹⁴. With the described distinctive aspects of both platforms, both spaces are definitely contributing to create a public sphere by echoing diverse voices and by including the questioning of hegemonic decision making processes.

Institutional dimension and democratic deliberative process.

Last but not least, it is important to analyze the performance of the complex national and international institutional framework in favor of promoting dialogue and public

⁹¹ Res publica is a community of public sector professionals dedicated to promoting good governance, civic virtue and deliberative democracy.

⁹² <https://en.wikipedia.org/wiki/Avaaz>

⁹³ https://en.wikipedia.org/wiki/Change.org#In_Spain

⁹⁴ such as the fact that the FDA has allowed Tekmira Pharmaceuticals to use its drug TKM-Ebola in infected patients under its policy of "compassionate use." -with this expanded access, Tekmira is able to provide TKM-Ebola for treatment to people with confirmed or suspected Ebola virus infections-.

reasoning i.e., democratic deliberative processes. In this regard, it becomes necessary to identify the dual role of the institutions as facilitating agents for deliberative processes and as forums where democratic deliberative processes may take place. In this analysis, special attention will be addressed to international institutions with impact in the realm of health and to national and international judicial and dispute settlement processes as legal adjudicators and last interpreters of law.

The above mentioned Report of the UN Secretary-General's High-level Panel on Access to Medicines offers a helpful diagnosis and guidance as to how implement at global scale certain conditions to improve governance, accountability and transparency. In reality those conditions are the premises enabling the creation of a public sphere and the implementation of democratic deliberative processes. In particular, the adoption of some of the recommendations suggested by the Report would enable internationally agreed and shared premises for the definition of the social function of IPRs and pharmaceutical patents following democratic deliberative parameters. As we have seen, this definition (social function of IPRs) would be referred to the national framework and depend on the specific socioeconomic context where those pharmaceutical patents are called to be applied by national adjudicators. The distinctive issue here is that public reasoning carried out by national law adjudicators at the time of enforcing IPRs would be based on premises and data and methodology agreed at a global scale and thus, it would depart from eventual arbitrary, capricious interpretations of law avoiding critics about its impartiality and giving certainty to private agents by establishing a model based on –alternative- rule of law.

Therefore, as enabling agents to permit public spheres with informed members, institutions have the power to put in place mechanisms to provide law adjudicators with reliable data and relevant information to make adequate judgements and considerations other than strengthening transparency.

In this sense, WTO shall be bound to certain figures and assessments made by WHO or other international institutions focused on global health or development. In this sense, WHO could be perfectly in charge of among others; establishing a list of low

and middle income countries where the implementation of IPRs can be challenged in view of their difficulties to fulfill with universal access to medicines; validating national lists of essential medicines depending on the characteristics of each country⁹⁵; in addition to the Global Price Reporting Mechanism and in a context where international exhaustion of IPRs is not contemplated, establishing thresholds above which it is considered that prices impair access to medicines (for instance GDP per capita or purchase power); establishing degrees of therapeutic innovation of new medicines as some public health systems have started to do; managing reliable and updated information as to R&D costs to bring about an innovative pharmaceutical –to be able to value the fairness of the reward given by IPRs- and profits gained by each product and any public funding received in the development of the health technology, including tax credits, subsidies and public grants; together with WIPO and WTO, WHO could also establish standards as to what implies transfer of technology and which guarantees are necessary to ensure a real and effective transfer of technology; WHO should be notified by pharmaceutical companies about actions taken to promote access to health technologies and the efforts and investments made to procure innovation regarding neglected diseases; WHO could also elaborate templates (maybe following the so-called *Ruggie Principles*) with the factors and the methodology necessary to previously prepare assessments about the impact of granting pharmaceutical patents in a given national market and implement a system to record all the transactions of transfer of technology to developing countries. This assessments as to the impact should be submitted together with the patent application or extension before the corresponding national or regional patent offices. In this respect, national governments need to implement an integrated, systemic and holistic approach to these issues and assess the impact of healthcare-sensitive provisions within the patent system instead of dealing with them in a sectorial, dispersed manner among the different departments and policies⁹⁶.

⁹⁵ Regarding the confusion between national essential medicines and the international essential medicines list developed by WHO, Dr. Hogerzeil stated that any national list was more important, as it referred to the specific needs of the country; he also cautioned, however, that, in circumstances where a large country with many health problems had only some 30 essential medicines on its list, this was clearly not enough and, in such cases, the WHO list should perhaps be taken as a reference (special Rapporteur. 16 March 2011). That is why, list of essential medicines has to be national in scope but internationally validated.

⁹⁶ Mercurio, B., & Kim, D. (Eds.). (2017). *Contemporary Issues in Pharmaceutical Patent Law: Setting the Framework and Exploring Policy Options*. Abingdon: Routledge.

All this information could contribute to higher degrees of transparency of the system and help law adjudicators (especially national judges) to assess whether IPRs and pharmaceutical patents are fulfilling the social functions they are called to achieve and whether and to which extent they deserve legal protection and enforcement in a given national market. Also, these data are the basis for that civil society could elaborate the so-called “shadow reports” to scrutinize governments and companies’ performance and make them accountable as long as to remark misinformation, failures and unaddressed issues.

Also, at the national level, it is possible to develop alternative regulatory strategies to address correctly the mandatory implementation of a global IPRs regime and the development of a global system of patent office administration –which enables a cheaper and quicker patent application worldwide- with other interests such as access rights. In this respect, it is noteworthy some aspects of the Brazilian patent model such as the necessary consent of the National Sanitary Surveillance Agency for the granting of pharmaceutical patents. Article 229-C of law 0.96/200 provides that *the allowance of patents to pharmaceutical products and processes will depend upon the previous consent of the National Sanitary Surveillance Agency (ANVISA)*. In this manner, patent applications on pharmaceuticals go through the different phases of the Brazilian Patent Office but the final grant depends on ANVISA’s consent. ANVISA carries out a substantive analysis of the patent application to determine whether in fact there really is an invention and that is novel thus improving the quality –and ensuring the therapeutic novelty- of patents and ensuring that patents are in line with national interest in both IPRs and public health policies. The fact that ANVISA has rejected patents approved by the Patent Office has raised a number of critics by pharmaceutical corporate lawyers who criticize that an independent group of health experts with patent training now have a veto role over pharmaceutical patent examinations⁹⁷.

On 15 April 2013, it was announced a further change in the administrative rules relating to prior consent procedure involving ANVISA. According to new rules,

⁹⁷ Drahos, P. (2008). Regulating Patent Offices: Countering Pharmaceutical Hegemon.

ANVISA will only examine cases where the subject matter of a patent application is considered to be “contrary to public health” when the application relates to; a pharmaceutical product or process which poses a health risk; a product, the use of which has been banned in Brazil, or a process producing such a product; or a pharmaceutical product or process which is of interest to the policies or medicines or pharmaceutical assistance within the National Public Health System; and said product/process does not comply with the requirements of Brazilian IP Law.

WTO reform towards a decision making based on a democratic deliberative model.

Much has been written on this issue⁹⁸. Also, in chapter 4 of this dissertation we have analyzed the lack of legitimacy of WTO and of the global IPRs regime enabled by TRIPS. In this context, it is suggested that deliberative democracy offers some helpful conceptual and methodological tools to address some of the poorly democratic international decision-making in place. In this sense, without wishing to engage in repetition and assuming that WTO has considerable deliberative potential, we will mention below a number of proposals discussed so far to improve WTO functioning towards a democratic deliberative forum. Other than the decision making processes by formal consensus which often entail unequal negotiations where public reasoning is replaced by relations of power, it is noteworthy the following considerations:

First, taking into account that due to different circumstances governments and states –especially developing countries- do not represent their population needs and that some transnational corporate agents lobby and have a great influence on these international fora, some commentators suggest that WTO should implement mechanisms enabling CSOs to participate in the agenda setting process of the WTO.

⁹⁸ For an in-depth reading see Picciotto, S. (2006). The WTO as a Node of Global Governance: Economic Regulation and Human Rights Discourses. *Human Rights and Global Justice.*; Coffey, P., Coffey, P., & Riley, R. J. (2006). *Reform of the international institutions: the IMF, World Bank and the WTO*. Edward Elgar Publishing; Gerhart, P. M. (2003). The Two Constitutional Visions of the World Trade Organization. *U. Pa. J. Int'l Econ. L.*, 24, 1; Guan, W. (2014). Consensus Yet Not Consented: A Critique of the WTO Decision-Making by Consensus. *Journal of International Economic Law*, jgu004; Hannah, E., Scott, J., & Wilkinson, R. (2017). Reforming WTO-civil society engagement. *World Trade Review*, 1-22; Higgott, R., & Erman, E. (2010). Deliberative global governance and the question of legitimacy: what can we learn from the WTO?. *Review of International Studies*, 36(02), 449-470.

Representatives of civil society maybe from the World Social Forum may propose issues to be addressed by WTO members around not only trade-related subjects currently in WTO treaties but also in issues such as labor standards (the controversial “social clause”⁹⁹), poverty alleviation, debt and finance or sustainable development¹⁰⁰. Also, further transparency of the decision making processes are required to avoid opaque, secretive spaces and enable CSOs to scrutinize the performance and the positions of deciding members and make them accountable.

Second, it is missing a more intense cooperation and integration of WTO with other international organizations. Linkages of WTO with WIPO for IPRs or Office of the High Commissioner for Human Rights (OHCHR) or United Nations Development Programme (UNDP), and especially WHO regarding pharmaceutical patents are more than evident. Those other international organizations should be duly represented in the decision making process of WTO at the time of presenting legal or executive proposals affecting specific fields. This representation could be at first materialized through mandatory previous impact assessment reports to be publicly available.

Third, developing countries’ participation should be ensured by providing WTO secretariat with sufficient resources and staff to assist technically to developing countries and their representatives. Furthermore, developing countries of different geographic areas should be duly represented in Green Room and other informal meetings.

Dispute Settlement Understanding and the Appellate Body. The case for an ‘all the factors’ approach

Much of the power of WTO and what makes WTO unique is the procedures address to enforce its rules through adjudication of disputes between member states and the quasi-judicial nature of its Appellate Body (AB). If a member state considers that a

⁹⁹ Chan, A. (2003). Racing to the bottom: international trade without a social clause. *Third World Quarterly*, 24(6), 1011-1028.

¹⁰⁰ Hannah, E., Scott, J., & Wilkinson, R. (2017). Reforming WTO-civil society engagement. *World Trade Review*, 1-22.

measure adopted by another member state has deprived it of a benefit accruing to it under one of the covered agreements and after a 60 day period of consultations, the complainant state may request the establishment of a Panel composed of three members appointed ad hoc by the Secretariat of the WTO. Decisions made by the Panel can be appealed before the Appellate Body. Unlike the Panels, the Appellate Body is a permanent institution composed of seven members -three of whom shall serve on any one case serving in rotation- appointed for a four-year term, renewable once among *persons recognized authority, with demonstrated expertise in law, international trade and the subject matter of the covered agreements generally and unaffiliated with any government* (art. 17 of the Understanding on Rules and Procedures Governing the Settlement of Disputes). The Appellate Body takes decisions in the form of *reports* to the Dispute Settlement Body (DSB). These reports have to be adopted within thirty days. States are required to implement the decisions within a reasonable period by bringing their domestic regulations into line with the report.

Due to the unique WTO system ensuring the enforceability of its decisions (reports), the Appellate Body (AB) has become an international economic court in all but name¹⁰¹ which has the power to review the validity of regulations and even laws enacted by legislatures. The approach taken by AB to interpret WTO meta-regulation rules (rules governing how states should regulate)¹⁰² has been considered as being too formalist by stressing a literal approach to interpretation of WTO law as if this was a self-contained, self-referential system of rules which often conceals a chosen policy outcome¹⁰³. In this respect, and taking into account that WTO rules have an important impact in other areas of law –which do not have the same effective compliance mechanisms- some commentators suggest that WTO obligations do not constitute a self-contained regime and thus it should be interpreted in line with other provisions of international law, including human rights¹⁰⁴. Other commentators

¹⁰¹ Neuwahl, N. A. (2001). JHH Weiler (ed.), *The EU, the WTO and the NAFTA-Towards a Common Law of International Trade*. *European Foreign Affairs Review*, 6(1), 144-145.

¹⁰² Morgan, B. (2003). The economization of politics: Meta-regulation as a form of nonjudicial legality. *Social & legal studies*, 12(4), 489-523.

¹⁰³ Picciotto, S. (2005). The WTO's appellate body: Legal formalism as a legitimation of global governance. *Governance*, 18(3), 477-503.

¹⁰⁴ Pauwelyn, Joost. *The Role of Public International Law in the WTO: How far can we go? ...* (See chapter 4 footnote 76).

consider that it is necessary to construct a superior framework that elevates to a primary position some superior public goods and values such as access to knowledge, access to medicines, cultural diversity and biological diversity. In this sense, interpretation of WTO rules would be subordinated to these principles, to be supported only where they prove to be consistent.¹⁰⁵

Furthermore, the thesis held in this dissertation, i.e., the conceptualization of IPRs as a set of contingent, historical, political rights/privileges vested with property prerogatives as long as they fulfil with their social functions in relation to which IPRs are instrumental, does not even need to resort to other bodies of law or depart from the same IPRs legislation to qualify or temper the absolutist, *iuris et de iure* application, implementation and interpretation of IPRs. A plain, literal interpretation of WTO rules, in particular of TRIPS cannot be used as a pretext to promote an interested, partial and neoliberal reading of IPRs which decontextualize IPRs from the socioeconomic and political context where IPRs are implemented. On the contrary, we have seen that a full of sense an optimal policy in the realm of IPRs regime involves more than conferring a set of proprietary rights to their titleholders and it requires the monitoring of their application and implementation in the specific social and economic context and the assessment as to the achievement of the political and legal goals associated with their enforceability. In this sense, IPRs should be presumed to fulfil the social functions that justify their enforceability but this presumption may be open to be subject to rebuttal on the basis of what is really happening with the application of the specific IPRs whose full enforceability is claimed.

In order to make the DSU and AB process conducive and prone to this new paradigm related to the interpretation of IPRs in accordance with its real nature, AB and DSU process should transit towards a model of discussion close to a public sphere where the debate of the conflicting issues and perspectives should follow democratic deliberative parameters of public reasoning about the scope of IPRs its instrumentality and the social function fulfilled at the specific socio economic context

¹⁰⁵ Malbon, J., & Lawson, C. (Eds.). (2008). *Interpreting and implementing the TRIPS agreement: is it fair?*. Edward Elgar Publishing.

at issue. Without prejudice of the nature of international law and WTO process¹⁰⁶ compared to national law and national judicial process or just because of this, WTO dispute settlement and AB quasi-judicial process should entail different aspects enabling the system to be closer to a real deliberative public sphere and gain so in legitimacy.

In this sense, different proposals have been suggested regarding transparency and a greater involvement and participation of civil society through the mechanisms of *amicus curiae* briefs¹⁰⁷; while under the rubric of transparency it is defended the possibility of opening the panel and the appellate hearings to the public, *amicus curiae* briefs –already contemplated in DSU rules if they are “*pertinent and useful*” (EC-Sardines (2002)-, a greater involvement of civil society could be achieved through the general acceptance of submissions by CSOs and other actors and representatives of the civil society of reports as *amicus curiae* reports (Also unsolicited ones). Also and in order to strengthen the information of participating members and civil society, in cases where pharmaceutical patents may impair access to medicines and rights to health, submission by WHO of health impact assessment reports should be established as mandatory expert reports in the process.

The role of the Judiciary: a safeguard for a genuine and coherent application of law?

The role of the judiciary as the most authoritative law adjudicator and interpreter of law becomes one of the cornerstone pieces for the materialization of an interpretation of law in accordance with the interpretative approach presented in this dissertation. It is not that we consider judges or law courts as heroic agents (or angels) of change who would be part of a virtuous species of human beings insulated

¹⁰⁶ See Yerxa, Rufus, and Bruce Wilson, eds. (2005). *Key issues in WTO dispute settlement: the first ten years*. Cambridge University Press, where the authors note that a balance has to be found between 1) “great expectations” and legal and political realism in the sense that unlike national law where subjects are subordinated to the authority of state power, international law relies on coordination among formally equal states; and 2) between the judicial and the diplomatic; even if WTO process is more and more judicial there is still room for *diplomatic flexibility*.

¹⁰⁷ Evans, D., & de Tarso Pereira, C. (2005). DSU review: a view from the inside. *Key issues in the WTO dispute settlement: the first ten years*. Cambridge University Press, New York. The participation and involvement of CSOs has met opposition from others who emphasize the government-to-government nature of WTO.

from the sins and corruptions from the rest of mortals and capable of bringing about spectacular social transformations. The relevance of judges and law courts for our purposes is that it is mostly at this stage (judicial) when it should be implemented a coherent application and interpretation of the legal institution of IPRs as a set of historically contingent and political rights vested with property prerogatives for the fulfilment of their inherent social functions. In fact, the main problem and dysfunctions observed in the pharmaceutical patent system have raised from a formal, absolutist interpretation of IPRs, as quasi natural rights which has distorted the instrumentalist nature of IPRs, in particular of pharmaceutical patents and has decontextualized the nature of pharmaceutical patents as legal instruments aimed at incentivizing genuine therapeutic innovation as long as coexisting with other democratic values, goods and goals such as public health and access to medicines on a fair, balanced and rational basis. Rather than the (also important) enactment of legal amendments, this thesis holds and claims a more rational and coherent application of IPRs by law adjudicators in view of the historic, legal and political foundations of IPRs.

Hence, the potential and adequacy of the judiciary to put in place an interpretation based on the approach held in this dissertation follows three lines of motives; first that law adjudicators are in charge of scrutinize and monitor IPRs along their life and thus they can analyze the impact of pharmaceutical patents on a case by case basis in the specific socioeconomic context where IPRs are being applied; second, that the presumed independence of law courts and judges and certain institutional structures and guarantees may contribute to shield their decisions from undesirable influence and capture of judicial behavior and judicial decision making; and third, the potential of the judicial system, especially constitutional courts as spaces for deliberative democracy. The perspective taken here about the role of the judiciary in relation with IPRs application is anchored and it is the subject of more intense and general debates about the role of the judiciary and the separation of powers and which range from those visions conceiving the judiciary as mere "*law enforcers*" (positivism) to those theories which view the judiciary as active agents of change (judicial activism) and all the intermediate considerations among both extremes.

In particular, and beginning from the first set of motives; the social function of property, namely, the social function of pharmaceutical patents can be mostly analyzed and scrutinized once the right at issue has been entered the legal order and it is susceptible of being enforced i.e., the grant of exclusive rights based on a pharmaceutical patent law which is protected by IPRs law of a given country does not imply *per se* that those exclusive rights or legal monopoly are been used in a manner contrary to the social functions that give IPRs -and the specific pharmaceutical patent- meaning, value and ultimately, enforceability against infringers. On the contrary, IPRs are *presumed* to fulfil their inherent social functions.

However, logically enough, that presumption (being used in accordance with their social functions) could be challenged by a third party –private citizens, or a manufacturer of generics or the state itself- other than the titleholder of IPRs mostly in the context of a legal dispute about the infringement of the exclusive rights granted by pharmaceutical patents, or a declarative process about the no-infringing nature of certain uses of the patented subject-matter or even an eventually instituted process address to declare that a pharmaceutical patent (or certain IPRs) does not fulfil its inherent social functions. Therefore, the analysis as to the adequate use of IPRs will be mostly elucidated before the judiciary. The problem does not lie in the legal wording of the law but in its interpretation. It seems clear that the very same legal wording may bring about substantially different outcomes depending on the premises under which law is interpreted and applied.

In line with what has been said by prominent IP scholars such as Lessig, Lemley or Merges, IP policy cannot be reduced to the provision of a clear set of property rights – and then getting the government out of the way-¹⁰⁸, but it is necessary to keep track of the performance of those rights beyond the initial conditions of appropriation, to monitor their socioeconomic impact and the conduct deployed by their titleholders to ensure that IPRs and pharmaceutical patents are fulfilling their inherent social functions. In this sense and, apart from the role played by other institutions and civil society within a desirable public sphere –and with substantial and traceable

¹⁰⁸ Merges, Robert P. *Justifying intellectual property*. (see chapter 6 footnote 95).

information- in monitoring the pharmaceutical companies conduct in a given country, it will be mostly for the judiciary to value and decide on a case by case basis the adequacy of the use of IPRs, and in particular of pharmaceutical patents.

Inspired on an Aristotelian perspective of the judicial function, it is noteworthy that the nature of practical reasoning and the evaluation of whether certain pharmaceutical patent rights deserve to be adequately enforced goes beyond the phase of law enactment and it is elucidated on a case by case basis; there is no such thing as universal and clear rule fitting all the cases we are discussing. Decisions on this field will be intensely and inevitably fact dependent. As in the Aristotelian metaphor¹⁰⁹ where while the stone is what really matters, the contour of that stone is not always clear, and reasonable people may reasonable discern its shape, lawmakers cannot anticipate all circumstances and it is for the judges to develop an objective understanding of the law and justice adapted to the case at issue, a decision which will be the result of a reasoning process which is inevitably interpretative and contestable. In this sense, we are not thinking here of a judge creating new law, but - paraphrasing partly Professor Gregory S. Alexander¹¹⁰-, we mean a *lawful judge, the judge who realizes that legality means supporting the legal framework as a whole. Acting equitably, Aristotle tells us, is not acting outside or against the law. Much to the contrary, equity actually promotes the law by making it operate better; the legal system works best when legislators know that defects in their products will not necessarily result in injustice* because, -we would add- law adjudicators will interpret the law within the specific socioeconomic context where the law is applied and by considering the legal framework as a whole.

Secondly, as we have mentioned in this thesis, neoliberal globalization has reduced governments' maneuver in different ways in order to eliminate the state constraints of a global accumulation of capital free from burdensome state regulation and redistributive policies. As we have seen, the adoption of TRIPS is anchored in this neoliberal logic and in the process of expansive commodification of information even when this scenario and new international architecture was contrary to the views

¹⁰⁹ Crisp, Roger, ed. (2014). *Aristotle: Nicomachean Ethics*. Cambridge University Press.

¹¹⁰ Alexander, Gregory S. *Pluralism and Property*. (see footnote 27).

expressed by many developing countries whose consent to the creation of the new IPRs regime is questionable. Instead of pursuing an overall welfare improvement of some kind which benefits society as a whole, some legal enactments and reforms follow other less reasonable and less respectable logic which has been even elevated to the category of academic theory by some neoliberal economists under the rubric of the previously mentioned Public Choice Theory¹¹¹. As it is explained by this theoretical approach, governments and international institutions have been often captured by self-interested groups instead of being concerned on the achievement of the common good. As noted by Professor Drahos, not all legislation can be explained in this way (as being the result of undue influence) but there is little doubt that IPRs regime is a case in point.¹¹²

In this sense, and as it is even recognized by scholars of the Public Choice Theory¹¹³ the judiciary seems to be better equipped to resist exogenous pressures and be insulated from interests alien to the due judicial reasoning process. The institutional and social –the social perception and psychological self-perception of being the agents of justice- constraints seem to be effective to promote the independence and autonomy of the judicial behavior and judicial decision making process and limit forms of misbehavior and abuse. Like Caesar’s wife, judges must be above suspicion and this higher standard may insulate them in a more effective way from obvious demands of lobbies and the political process where political actors have the permanent risk of not being elected in the following election and are the target of constant pressure from constituents and special interest groups. On the contrary, in the realm of IPRs, the cases that mostly provoked pressures on judges and law courts have come from public opinion and public media where the controversies at issue give rise to democratic vindications that claim independence of the judiciary against

¹¹¹ As Public choice theory can be a helpful instrument to explain how political decision-making follows the achievement of particular interests and it results in outcomes that conflict with the preferences of the general interest, our criticism comes from the fact that this approach is limited because it is based on the skeptical perception of individuals totally devoid of morals and it does not account for cases and individuals who act in accordance with ethical values other than self-interest.

¹¹² Drahos, Peter. (1996). Global law reform and rent-seeking... (see chapter 6, footnote 81).

¹¹³ Epstein, Richard A. (1990). The independence of judges: The uses and limitations of public choice theory. *BYU L. Rev.*: 827.

undue influence of big corporations' pressures and interests¹¹⁴ or from the government's intervention. In this regard, some commentators suggest that citizen activists and CSOs are on the basis of constitutional change or fundamental laws.¹¹⁵

Furthermore, the jurisprudential nature of the judicial organs and the fact that they decide on a case-by-case basis encapsulate the judiciary from WTO meta-norms and its mechanism of dispute settlement. In effect, it would not be reasonable at this moment that national judicial decisions would be subject to judicial review by an international panel like the one of WTO.

Also, article 3 of the Rules and procedures governing the settlement of disputes establishes as the basis for a claim before the DSU the following: *The prompt settlement of situations in which a Member considers that any benefits accruing to it directly or indirectly under the covered agreements are being impaired by **measures** taken by another Member is essential to the effective functioning of the WTO and the maintenance of a proper balance between the rights and obligations of Members.* Even if the term *measure* has been interpreted broadly to encompass many actions of states, the ordinary meaning of measure does not contemplate judicial decisions which are elucidated to a particular case and lacks the general character of the actions under the concept of measures to be challenged. The term measure has been interpreted within the ordinary meaning of measure as it is used in article XXIII 1b) which contemplate a law or regulation enacted by government as long as governmental actions and *other instruments which are applicable generally and are similar in character to the instruments explicitly referred to.* Because of its particularity, judicial decisions cannot be either subject to WTO monitoring¹¹⁶.

Finally, law courts, and specially, constitutional courts regarding legal systems anchored in civil law tradition, have an important potential to facilitate the conditions

¹¹⁴ Protests against the pharmaceutical companies for having sued the South African Government reveals what we have said. <http://www.independent.co.uk/news/business/news/protest-in-britain-as-drug-companies-sue-south-african-government-5366011.html>

¹¹⁵ Cole, David. (2016). *Engines of Liberty: The Power of Citizen Activists to Make Constitutional Law*. Basic Books. The author notes how CSOs are crucial to speak for, lead and enable the movements and have the capacity to press for change.

¹¹⁶ Dispute DS76. Japan — Measures Affecting Agricultural Products.

of a public sphere where deliberative dialogue and public reasoning takes place. In effect, as it happened in the Greek cities where the public sphere was also constituted in discussion (*lexis*), *which could also assume the forms of consultation and of sitting in the court of law*¹¹⁷, in today's proceedings carried out in trial in a courtroom, parties to the litigation have to persuade an audience (the judges and/or the jury) by reference to generally acknowledged legal principles, norms and values. Thus, they must resort to the logic of arguing in order to be able to make their case. The institutional context of a law court, thus, facilitates that deliberation and argumentative dialogue could ultimately operate. In this sense, some commentators distinguish between the informal public sphere which is the domain where ordinary citizens discuss matters of public concern, and the political public sphere which is the domain where policy makers and other public official formulate and finalise laws where the courts of law would be together with parliament a good example.

As it is noted by professor Mendes, a (constitutional) court might not care about being deliberative since there is not any historical or theoretical motive requiring that approach and that a non-deliberative court may still be functional and justifiable. However, courts and specially courts that make an effort to be deliberative –from a necessary awareness of its limitations and complexity- and to go through public deliberative reasoning to administer justice enjoys of a powerful legitimating credential and makes a relevant contribution for a political regime¹¹⁸.

The deliberative reasoning is specially emphasized at the level of constitutional courts and judicial review when important public and heavily political debates and constitutional disputes are the object of constitutional scrutiny. In these debates, judges are expected to hear and take into account diverse voices and points of view in order to support and justify their decisions with good public reasons which are expected to be embraced by society and keep the social order. The possibility that constitutional courts may overturn democratically enacted laws, justifies that the manner in which this decision making process is made gains importance. In this

¹¹⁷ Habermas, J. (1991). *The structural transformation of the public sphere: An inquiry into a category of bourgeois society*. MIT press

¹¹⁸ Mendes, C. (2013). *Constitutional courts and deliberative democracy*. Oxford University Press.

sense, one of the main objections to judicial review is raised around whether electorally unaccountable judges in a democracy should be able to declare unconstitutional, and so overturn, the laws and decisions made through ordinary democratic political processes¹¹⁹. In responding this question (the democratic questioning of judicial decisions) and other than the argument which says that judges or constitutional judges ensure compliance of enacted legislation with the “will of the constitutional founders”, there is one more relevant reason in relation with the concept of democracy; it is held that democracy cannot be equated with simple majoritarianism and thus, constitutional democracy prevail over majoritarian rules. This is said to better guarantee an appropriate and necessary system of checks and balances for an adequate functioning of the state. In this sense, the judiciary and in particular the judicial review is seen as a stage in a long term conversation and dialogue between the legislator (also international) and the broader public sphere; the court would play a “public reasoner” role which would attempt to be responsive to arguments it hears and it would become a dialogical actor that questions and challenges legislature and executive¹²⁰.

National law courts and especially constitutional courts are especially fit to interpret and implement the monopoly rights associated with IPRs and pharmaceutical patents in accordance with the nature of this legal institution of IPRs as rights vested with prerogatives of property for the fulfilment of social functions, in particular, among others with public health concerns¹²¹. The judiciary is embed in national reality and society and it is apt to elaborate precise socioeconomic impact assessment about the performance of IPRs and pharmaceutical patents as long as the conduct observed in the IPRs titleholder regarding the promotion of I&D for neglected diseases, or the transfer of technology operated and other factors affecting the national society which is the spatial context where IPRs are enforced and that is the reference frame to be adopted in order to qualify and evaluate whether IPRs are fulfilling their social functions. Taking into account the nature of WTO norms as meta-norms and in order

¹¹⁹ Zum, C. F. (2007). *Deliberative democracy and the institutions of judicial review*. Cambridge University Press.

¹²⁰ Mendes, Conrado. *Vid supra* at 114.

¹²¹ The previously mentioned indian case of *Novartis Novartis AG v Union of India & Others* Civil Appeals Nos 2706-2716, 2728 and 2717-2727 of 2013 Supreme Court of India (1 April 2013) is a very good example of what we are saying.

that judicial decisions are duly integrated within the global legal order and to promote predictability and certainty in the application of law –mainly, in the eyes of foreign investors-, national courts should mirror and implement standards and thresholds set up by international institutions -as we have previously mentioned regarding the eventual functions of WHO-.

Also, in view of the fact that national courts usually are vehicles through which international law enters domestic legal systems¹²², national courts decisions and especially constitutional courts may contribute to create a common global understanding about IPRs and pharmaceutical patents emphasizing their instrumental nature and defining democratic deliberative parameters that IPRs and pharmaceutical patents have to observe in order to be qualified as to fulfil the expected social functions which justify their enforceability. This “informal” common global understanding of national courts, especially constitutional courts, can be achieved through what it has been called “constitutional cross-fertilization”¹²³ around the interpretation and conceptualization of IPRs. Finally, the proportionality analysis¹²⁴ could also be crucial to recover the balance between all the interests at stake when it comes to IPRs, in particular to pharmaceutical patents.

¹²² Attanasio, John B. (1995). Rapporteur's Overview and Conclusions: Of Sovereignty, Globalization, and Courts. *NYUJ Int'l L. & Pol.* 28: 1.

¹²³ Slaughter, Anne-Marie. (1999). *Judicial globalization*. *Va. J. Int'l L.* 40: 1103. While opinions rendered by the courts of other national legal systems are never formally binding, they have an increasing importance as authoritative arguments. In fact, there are more and more examples of national constitutional courts which turn to foreign decisions for different perspectives on similar issues.

¹²⁴ Proportionality analysis describes a particular legal technique of resolving conflicts between human or constitutional rights and public interests through a process of balancing. This technique of balancing, deliberating and analyzing from proportionality premises seems to be extremely appropriate and suitable for the evaluation of IPRs and in particular pharmaceutical patents, their private proprietary aspects and the other rights and societal interests at stake. For an analysis of proportionality analysis' contribution to global understanding of judicial techniques and interpretation and implementation of law, see Sweet, A. S., & Mathews, J. (2008). Proportionality balancing and global constitutionalism. *Colum. J. Transnat'l L.*, 47, 72.

CHAPTER 8. CONCLUSIONS.

My research on this project started in the winter of 2014. Since then, many things have changed especially in the political arena. We can observe the emergence of new and unpredictable political movements and forces reaching the power and national governments which have quarantined the previous global architecture and which in some cases have even showed their intention to go back to a new era of protectionism and nationalism. Paradoxically, many of those who criticize the process of globalization are however staunch advocates of liberalism and harsh capitalism. In this sense, some of those new political movements qualified as populist or nationalist are not against globalization because of the inequality generated by it but because it has led to a shift of benefits from some capitalist to others in what seems to be a fight between capitalists rather than between capitalist advocates and social justice defenders (Trump or Le Pen are good examples of what I have just said).

For the purposes of this thesis, it is important to bear in mind the above since we can account that although there may be attempts to stop the current process of globalization and to boycott today's global architecture, there is not any serious institutional or political questioning of the shortcomings of the regime in terms of equality and social injustice that the system provokes but at best, a lamentation about who are the new wealthy from a system, an unlimited capitalism, which seems to be structurally unjust. Therefore, the shadows on the functioning of the global IPRs regime raised by this dissertation –mostly regarding patents-, the explained motives behind this state of affairs and the suggested interpretation and implementation of IPRs -in particular pharmaceutical patents-, remain rabidly topical.

Although I started the research on this topic three years ago, the interest for how TRIPS Agreement was affecting the performance of the pharmaceutical industry and the fate of the disinherited of this world can be traced back to my professional beginnings at the corporate law firm more than ten years ago. I studied IP law attracted by the idea of defending creators and extravagant inventors whose interests and deserved reward could be easily diluted into the “law of the strongest”. However,

I learned quite soon that my approach was naïf and that intangibles were part of a very profitable business of commodities which under the logic of market had lost their soul and their romantic –to my eyes- condition. The research has obliged me to enter other political and economic domains and other academic disciplines such as political science, philosophy or international relations. The different analyses adopted by all those perspectives have permitted me to have a richer and more integral part about what is going on in the known as “process of globalization” as long as about the performance of the pharmaceutical industry. Also, this multidisciplinary process has given me a deeper knowledge and comprehension of the nature IPRs and of patents as the result of a contingent political, historical and economic process which is thus subject to change and transformation.

On the other hand, apart from presenting our considerations about the reasons leading to the current situation and a review on the proposed measures to compensate the failures of the system in ensuring access to medicines for all, the thesis propose and alternative interpretation of IPRs, in particular of patents. Furthermore, the proposal formulated by this thesis responds better to the philosophical foundation of IPRs and to their genuine nature as instruments aimed at fulfilling certain social functions. Finally, the suggested interpretation of IPRs is followed by a proposal on the method or the approach which would be convenient to implement to make effective the necessary adjustments on the interpretation of IPRs. In this respect, the thesis upholds deliberative democracy and deliberative reasoning as an appropriate tool to cope with the deficit of legitimacy of the system and the necessary definition of indeterminate concepts such as social function or public interest.

The research presented in this thesis has yielded a number of substantial conclusions which I would attempt to summarize in a clear and orderly manner. To this end, I will follow the same order as the chapter integrating this thesis.

In the first place, contrary to what some people think, the process of rapid changes we are experiencing nowadays under the term of “globalization” conceals the reality of a new phase of capitalism development which some commentators have baptized as “supercapitalism”. *Supercapitalism* has implemented a number of policy changes

which are narrowly associated with the neoliberal agenda. In this sense, the neoliberal agenda has succeeded in imposing like a *mantra* the adoption of the same policies everywhere; deregulation, liberalization of markets of goods and services (especially of financial markets), budget austerity, privatization and reduction of public services (expansion of the commodification process of goods and services previously in the public domain or accessible to all), flexibility and precariousness of labor market and a strengthening of property rights. Values such as competition, efficiency and effectiveness are sacralized as objective and scientific standards which must be advanced by states and must prevail over other considerations such as equality or social justice which are seen as pertaining to the realm of wishful (and naively political) thinking. In this sense, the term globalization is biased and it advances a hegemonic vision of globalization by supporting the process of accumulation of capital and expansion of market and commodification worldwide.

The strong legitimation of markets and other has enabled private interests to handle areas which were previously under public control and the political room of national states has been drastically constrained and reduced. All this has provoked certain emptying of the traditional democratic and political processes which are seen sometimes as hostages of external non democratic mandates and guidelines. All this has had a clear reflect in the field of health. The market driven logic has also impregnated the functioning of health which is seen as other market (another one) with promising opportunities of business. For instance, WTO an international institution focused on the promotion of free trade, has paradoxically become the most influential institution for health issues thanks to its system of dispute resolution and its capacity to enforce its rules. Meanwhile, WHO languishes in its function as an institution focused on technical issues without political influence.

Another feature of the new global scenario in the field of health is the emergence of new actors with an important impact on health and on access to medicines. According to the new paradigm of governance, private actors are involved in the handling of public issues which were previously a matter of public authorities. While global governance and the participation of private profit seeking driven actors are explained in terms of a wishful political cooperation aimed at resolving those market failures

which are overwhelming to public states, the reality is that this implication has given rise to a multiplicity of problems when it comes to health. In this respect, the Public Private Partnership which are presented as a good manner of establishing cooperative bonds between private and public logics, has showed important and sometimes unsurmountable difficulties which challenge and question its suitability to cope with the health problem in the developing world due to its lack of transparency, its western vision, its undue distortion of local public health systems and local priorities and its instability; in the sense that it is not guaranteed that PPPs can be maintained over time and finally, the conflict of interests implied in the relationship and exchange of information between the private sector and public authorities.

Furthermore, although there are some commentators who view today's fragmented architecture as an orderly mess where there is a logic at the bottom which make the different actors be complementary and specialized in their own function (an optimistic liberal view similar to the invisible hand of the market), the truth is that the system represents an example of anarchy where many efforts are duplicated and dispersed, an anarchy where the law of the strongest is imposed and that makes the market logic prevail over any other consideration of public health or universal access to health services such as the access to medicines. Also, by making health a sectorial field to be dealt with, the link equity-health is decoupled and health is mostly perceived as a necessary element or ingredient for the society to be fully productive.

Finally, the signature of the TRIPS Agreement constitutes one benchmark in the development of capitalism, in particular, by linking free trade and all its international machinery (particularly the binding nature of its dispute settlement system) with IPRs, IPRs defenders have achieved that IPRs protection is provided worldwide pursuant developed economies' standards. The explicit limitations and exceptions provided by TRIPS are generally underused due to the implicit threat of western countries or because poor capacity of developing countries to make use of them. In any case, we conclude that after more than 20 years since its signature, TRIPS has not brought the benefits and virtues which were once announced. In this sense, it does not appear that TRIPS has contributed to bring about greater technology transfer,

innovative processes or foreign investments. On the contrary, it may have jeopardized public health and access to medicines.

Secondly, one of the main actors in the new scenario of health and in particular in the access to medicines and pharmaceutical patents are integrated by the pharmaceutical industry. The performance of the pharmaceutical business has evidenced substantial and severe shortcomings regarding the conditions to facilitate affordable medicines for all. Pharmaceutical industry is composed of traditional companies which have resisted the entrance of new entrants to the profitable business. It is also controlled by few hands which tend to get concentrated in fewer hands through mergers and acquisitions. Due to the fact that medicines are sensitive products tightly related to human health and life, pharmaceutical industry is highly regulated. However, regulation does not guarantee the optimal functioning of the system and pharmaceutical industry has important resources and it strongly lobbies and put pressure on governments and public agencies in order to get an acceptable legal and normative framework fit for their interests.

Notwithstanding this, one of the main concerns about the performance of the pharmaceutical industry is its preponderant and excessive profit seeking of its activity. In this sense, pharmaceutical industry claims for stronger IPRs to recoup the vast amount of money addressed to develop new medicines are somehow contradicted by the fact that there seems to be a tendency to have a poorer result in terms of new developed compounds and by the fact that pharmaceutical companies spend larger amounts of money on marketing and advertising. This is true even if we take into account that this is a regulated industry that except for USA and New Zealand, and that direct to consumers publicity and advertisements are prohibited or strictly monitored. In this sense, many questions arise about whether there is not so much scientific innovation but marketing innovation. Also, there are *me too* (similar versions of patented medicines with slight changes) medicines whose development is cheaper and which may be more profitable than investing in a totally new medicine. These tactics may cause the *evergreening* of pharmaceutical patents beyond the patent term and it constitutes a fraud, a corruption of the system and an undue use of the patent regime which is aimed at promoting real innovation of medicines in their therapeutic dimensions.

Finally, as far as the second part is concerned, there are numerous ethical conflicts which arise around medicines and which receive media resonance. Among those, it is important to highlight the clinical trials with humans in the developing world and the conditions under which those trials are carried out which sometimes challenges basic principles of human dignity and human rights. Also, there are important controversies related to the sometimes aggressive and misleading advertising and marketing techniques of the pharmaceutical companies. In particular it is problematic the techniques deployed by the pharmaceutical industry to unduly influence medical professionals and prescribers of medicines through an important variety of tactics (this including paying generously the staying costs for the attendance to biased sponsored congresses of pharmaceutical problems and remedies or publications based on partial research or partially disclosed outcomes). On the other hand, it is also observable a sometimes undue influence and pressure on regulators and the political establishment for the enactment of norms favorable to the interests of the pharmaceutical industry.

Thirdly, other than the shortcomings and market failures observed in the functioning of the global regime and also because of that, international institutions are going through a severe crisis of legitimacy. In this sense, there have been installed an intense questioning and a deep mistrust in today's global economic governance. In particular, WTO and also because of its important scope and influence has been subject of criticism which is directly linked with its perceived lack of democratic character coupled with the parallel loss of the power of states and the erosion of its sovereignty. Thus, as those perceived "far" institutions adopt political decisions, there is not in place the traditional process of decision making where state democracy or popular participation operated.

Definition of legitimacy is a harsh task and its comprehension is not easy. Noticeably, it is said that we can tell when a given system is not legitimate or does not have legitimacy but it is harder to define the concept. Also, following traditional categorizations, it can be said that domestic legitimacy is different from international legitimacy. Despite these difficulties, we identify three dimensions/faces/sources of

legitimacy which should coexist altogether in order to qualify a regime as being legitimate; the functional or systemic legitimacy, the legal or the legitimacy based on the rule of law and the democratic sources of legitimacy. Hence, it is upheld that legitimacy must be based on the three sources in a balanced manner. Under this premise, we must conclude that WTO and in particular TRIPS have important legitimacy issues. In particular, from the functional source of legitimacy we see that TRIPS Agreement is not working out in the manner it was expected since it does not advance in the announced virtues and effects in terms of promoting foreign investments, transfer of technology and general economic development. On the other hand, TRIPS Agreement does not seem to be freely adopted by numerous countries which were forced to accept and sign an Agreement which was perceived as contrary to their interests. This vitiated consent would invalidate the adoption of an agreement which would be held contrary to the rule of law and to legal parameters of international law. Finally, and taking into account the meta-normative character of WTO and TRIPS rules and their direct impact on the citizenry's life and conduct, it is demanded a more democratic process in the adoption of norms and making decision process.

The lack of legitimacy of WTO and the TRIPS Agreement has triggered a reaction consisting of a vigorous contestation of the regime by diverse formal and forces and organizations. These protests have been successful in forcing the regime to bring about proposals addressed to compensate or satisfy the main demands of those against the regime reflected in WTO functioning and the TRIPS Agreement. In this sense, we can say that "public health" has opened the door to counterhegemonic voices and critics to the neoliberal agenda governing worldwide. Resulting from that opposition Doha Declaration on TRIPs and Public Health was approved within WTO system. Even if Doha implied an important victory and a step forward in the acknowledgement of values related with human dignity and human rights, the truth is that the real impact of this important Declaration is rather limited.

Finally, the analysis of human rights and IPRs must be reviewed in the context of legitimacy since legitimacy has to do with a system informed by the logic of human rights; two bodies of law which may be perceived sometimes as contradictory or

conflicting. While human rights contemplate the human right to health and to the access of affordable medicines, the patent system and pharmaceutical patents may jeopardize this access by making drug access unaffordable. In this sense, other than analyzing the operation of public international law and the eventual existence of eventual self-contained regimes for the case of TRIPS, we consider that both bodies of law should be interrelated under a shared coherence. As to the existence of a conflict between prescriptions of both bodies of law, we can observe that the predicated hierarchy of most basic human rights under the umbrella of *jus cogens* has not had reflect in practice. The controversies around which human rights pertain to the category of *jus cogens* and about the real content and definition of them have placed them in a difficult stand-by, in a discursive ethos without emancipatory potential. Also, the detailed provisions of the TRIPS Agreement versus the more dispersed and vague language of human rights suggests that the confrontation of both bodies of law before a given normative conflict will not be very helpful. Also, some creative and inventive manifestations may be also subject to both IPRs and Human Rights so hypothetically it could happen that there could be a conflict between diverse human rights. Even if human rights' emancipatory force is weak, human rights play an important role at the time of informing and impregnating the application of other bodies of law. In this sense, we believe that the application and implementation of IPRs should be embedded in the language and the approach conferred by human rights as instruments to ensure human dignity.

Fourthly, GPGs and global public interests have been formulated and mentioned as legal and institutional instruments in order to respond to the market failures and the challenges of collective action oriented to address the globalization process under political and more "human" processes. Borrowed from economics, GPGs theory attempts to apply this figure to the resolution of the problems in the context of globalization. This theory has been the result of the UNPD Program at the beginning of this century. GPGs approach calls for collective action of public and private actors to provide GHGs whose lack of provision are said to be at the origin of the observed shortcomings.

In spite of the good reception that GPGs received at its debut, its evocative power and its practical utility was gradually diluting as the criticism revealed GPGs shortcomings. On the one hand, health does not receive a specific treatment by (UNPD) GPGs theory except for some excerpts which address health as an instrumental factor in favor of greater productivity and free markets and fluid traffic of trade. Furthermore, GPGs is neither clear nor concise. Far from being a scientific and analytical tool, GPGs theory does not question any of the premises of today's global regime which GPGs theory takes for granted and assumes as irreversible. In fact the authors of this theory have published three books in an attempt to achieve a theoretical consistence which does not mean to be successful in view of the poor repercussion of this theory nowadays. Also, the ambitious pretensions of GPGs do not have a consistent translation to practice and reality when it comes to details. In this sense, GPGs approach does not specify which measures have to be adopted in order to make their purposes effective. On the other hand, GPGs theory does not account for the distributive consequences that a given decision may bring about. In this sense, some GPGs may be incompatible and it is necessary to opt for one or another, this election having important distributive consequences which GPGs do not consider. Because of all this, GPGs should be rather categorized as a rhetoric device directed to justify the hegemonic discourse under which the global architecture has been constructed.

The concepts of public interest, public policy and *ordre public* are old acquaintances of the legal tradition. On the occasion of the transition from a political regime based on the sovereignty of the states to the multilateral and multilayered global architecture, a renewed interest has emerged around these figures in an attempt to articulate conveniently the perceived melting between previously well separate public and private spheres. Apart from the formal legal meanings in the different jurisdictions (more state centered in the case of Roman legal traditions and not necessarily linked with government but occasionally in response to government intervention in Common Law jurisdictions) this indeterminate legal term has found room in the TRIPS Agreement, in particular in the general principles embodied in art. 7 and article 8. Also, in the field of patent law the *ordre public* exception to patentability is a traditional legal figure with its own contours. In this manner, those inventions

contrary to fundamental interests or morals of a given community have been said to be non-patentable. However, and with the exception of some very interesting Indian case law where it was upheld that unaffordable medicines could be contrary to public order, i.e., public order was defined in socio-economic terms, the use of public interest or *ordre public* has had a limited potential in providing an alternative interpretation of law, and in particular, of IPRs and patents.

The analysis of the main theoretical approaches which have dealt with the notion of the public interest reveals conflicting positions regarding the concept and its scope. While some theories questioned even the existence and the feasibility of this notion in view of the impossibility of consensus, either due to the fragmented dimensions and different interests of individuals (postmodernism) or because the division of society into antagonistic classes (Marxism), the theories which have studied this figure with the intent of giving a specific meaning with defined legal effects (mainly the utilitarian and the contractarian approaches) have proved to be incomplete, ineffective and unsuccessful as to their pretension of giving it legal substantivity and autonomy from undue interferences of power and other non-public interests. Public interest and global public interest in the context of IPRs regime engenders –as it could not be otherwise- similar difficulties than public interest does in other legal fields.

From a *historical-critical* approach of the concept of public interest, we can conclude that the different historical conceptualizations of the public interest have attempted to achieve the significance of the common good as both an instrument and goal of the political action. This notion has been contingent and shifting over time and it has been anchored in the distinction between what has meant the public and the private realm devised at each historical period. However and following the Gramscian approach to “common sense”, we can observe how historically the notion of public interest has been defined or customized to the hegemonic needs and to the dominant ideology at any time. In this sense, today’s hegemonic ideology is dominated by the neoliberal ideology which promotes new process of accumulation of capital characterized by an unprecedented international mobility of capital and the commodification of knowledge. Hence, the notion of public interest and global public interest have been today impregnated by the hegemonic discourse which stands for

liberalization, deregulation, efficiency and unrestrained accumulation of capital by reducing the role of the state in the economy and getting rid of the restraints previously represented by welfare state, distributive policies and public services which are viewed as inefficient and burdensome to the free development of market.

It is difficult then to devise the notion of public interest as an instrument capable of bringing about change and alternative interpretation of law. We can conclude then that neither public interest nor global public interest has emancipatory power as it has never been decisive for any political or institutional transformation. On the contrary, it has showed a natural tendency to endorse the hegemonic ideology at any time. In this sense, global public interest, as it happens with GPGs, plays a discursive role directed to legitimize the established order, the status quo thanks to its seemingly objective semblance.

It is at this point that it could be noteworthy to question whether the relevance of this concept resides in how to elaborate that public interest rather than in its specific meaning. The emphasis should be therefore on the manner in which the consensus is constructed. Once we have renounced to achieve a precise significance of the notion of public interest and in order to make the public interest be an operative concept to monitor political decisions—i.e. to evaluate that the decisions have been adopted in furtherance of that public interest- the public interest should be the result of a socio-political debate on the objectives and priorities of society, a shared understanding of the common good based on a model of deliberative democracy and communicative action. In this sense, the identification of public interest should be based on a case by case evaluation and the demonstration that the action in question reflects the public interest. This democratic-process to define on a case by case basis what the public interest is, and in particular, what the global public interest implies can only be achieved at a global scale through communicative action. In this respect, the Washington Declaration on Intellectual Property and the Public Interest or the recent Report of the UN Secretary General's High-level Panel on access to medicines which has been the result of an important participation of a diversity of actors and agents, could be a good starting point to reshape the policies on IPRs regime.

Fifthly, as we have said at the beginning of this thesis, application of law has been decontextualized from the socioeconomic reality law is called to regulate. This disconnection of law from reality has motivated some severe dysfunctions by undermining the substance, nature, scope and social functions of legal institutions. In fact, this *depolitization* of law may be a highly political option. In this sense, and in order to propose a consistent alternative to the current interpretation of law and IPRs, it is a must to revise the philosophical foundations of this legal institution, its historic evolution and the social needs IPRs are intended to respond.

In this sense, we can conclude that IPRs is the result of a contingent, shifting, historical and political process subject to contestation and change. In this sense, the history of IPRs has fluctuated between settlement and contestation in a permanent process that has vacillated between the public regarding benefits of the dissemination of technical advances and the legitimate economic rewards in exchange (dissemination and competition versus private appropriation, protection and exclusion). Settlements or balances or imbalances at a certain historical moment are placed somewhere in between these two extremes of the road (sometimes favoring exclusion some other times favoring dissemination) and are the result of the interplay between contingent and political ideational, institutional and material forces over time. Today, IPRs regime has evolved towards a conception of absolute quasi natural rights that clearly emphasizes the private proprietary aspects over other dimensions of this social legal institution.

Also, we have observed that the prevalent philosophical justification for IPRs today is of utilitarian nature, especially as far as patents are concerned –where the brilliant inventor individual is an exception within modern and sophisticated innovative processes supported by impersonal teams and controlled by corporations-. IPRs are perceived as a way to get maximization of net social welfare. IPRs are in this sense, believed to constitute the necessary incentive for innovative actors or pharmaceutical companies to engage in creative and innovative endeavors. Unlike tangible assets, the tragedy of the commons -the idea that property held in common may be harmed by overuse- does not take place. The problem for intangible assets is just the opposite; the risk is rather one of underproduction. It is argued that inventors might fail to

invent or create for fear of free riding by others –new entrants without those sunk costs- losing all competitive advantage as original inventors/creators. As some inventions are costly to create and the costs of it are front-end, fixed costs, IPRs will enable the inventor/pharmaceutical companies to recoup those fixed costs and sometimes (as it seems to be the case for pharmaceuticals) huge investments.

The important point of revising philosophical justifications of IPRs is not to explore a rhetoric metaphysical analysis of the legal institution made of IPRs. For the purposes of this dissertation this analysis and the importance of utilitarian arguments to justify the economic prerogatives inherent to IPRs monopolies serves us to conclude that IPRs are not absolute quasi-natural rights but contingent historical and political creatures of law. Those who invoke Locke or Kantian and Hegelian justifications of IPRs implicitly tend to suggest that IPRs, and in general property rights are previous to law and previous to the state. This doctrinal approach to IPRs is not trivial; the configuration of IPRs as quasi natural absolute rights enables their titleholders to claim an application of IPRs decontextualized and without regard to the socioeconomic context or socioeconomic impact of IPRs in the spatial and time dimensions where IPRs are applied. In contrast, the instrumental nature implied in the utilitarian approach to IPRs confers the states the obligation of monitoring whether these rights fulfill the social goals they are called to advance.

In this sense, today's premises informing IPRs regime towards a conception of absolute rights where the private proprietary aspects prevail over other dimensions of this social legal institution disregards the nature and legal grounds which justify and explains its existence and enforceability as a social, contingent, historic and political construction at the service of specific social functions.

The mentioned evolution of IPRs, its strengthening and its spatial and material expansion to new categories of knowledge and intangibles is not the result of any empiric research which supports this approach in view of the outcomes provided by it or because it better contributes to achieve the social goals attributed to IPRs. On the contrary, it has been revealed that this new configuration of IPRs creates important global dysfunctions and that, far from encouraging innovation and the progress of all

societies, the current patent regime as a system of incentives may block follow-on innovation or slow it. Also, as we have seen -regarding the pharmaceutical field- the patent system may foster rent-seeking or anticompetitive conducts rather than investments in real innovations or novel products with effective new therapeutic effects. Furthermore, the implementation of a global IPRs regime as it is the case of the TRIPS Agreement or TRIPS-Plus agreements may impair the development of some developing countries –with different degrees of development and different social and economic needs- and the access to certain knowledge or goods which are crucial for the welfare of the population. In particular, pharmaceutical patents may conflict with the desirable access to medicines by large number of people who cannot afford them because patents raise the price to insurmountable thresholds. Neither is evidenced that implementation of TRIPS is bringing about the promised technology transfer and more foreign investments.

In fact, the expansion of IPRs rather than being the result of a shared understanding about the virtues of IPRs worldwide, it responds to the imperatives of a new phase of capitalism which requires the commodification of knowledge and information in its constant process of capital accumulation over new realities and goods. Because of that this material and spatial expansion of IPRs has been known accurately as the second enclosure. The globalization of IPRs also contributes to keep the hegemony of developed countries and especially, of global capital that now operates at global scale overcoming national borders, national limitations and expensive and time consuming bureaucracies, procedures and different regulations. In this sense, TRIPS Agreement would advance the interests of a transnational capitalist class where profit maximization and capital accumulation prevail over considerations of national allegiance, patriotism or identity. Hence, TRIPS Agreement would be part of a more comprehensive strategy and it would fulfill an important function in this new phase of capitalism or globalization process, a new function addressed to facilitate international accumulation of capital that of securing property, by defining knowledge as property and making a commodity out of certain knowledge or knowledge-based production which were previously free in the public domain.

The new paradigm of the global IPRs regime focused exclusively in securing IPRs as absolute quasi-natural rights has thus forced a denaturalization of IPRs which entails undesirable consequences and carries a negative impact in socioeconomic terms. The attempts of resorting to other legal bodies of international law -such as human rights law- in a scenario of legal pluralism or other political collective actions of governance -like global public goods- have showed important shortcomings in their role as measures to counterbalance IPRs regime negative impact. Therefore, this dissertation holds the thesis that the excesses and negative consequences of a *iuris et de iure* and decontextualized application of IPRs could be remedied by recovering the real nature and scope of IPRs. In this sense, IPRs would be a social institution integrated by rights vested temporarily with property prerogatives. In the core of their definition and scope, IPRs would be a legal instrument called to fulfil certain social functions and pursue the general interest following deliberative democratic parameters in order to properly identify and weigh all the interests as well as hegemonic mainstream and counterhegemonic voices in a global public sphere.

Sixthly and finally, based on a conception of law which is not contrary to social change and that it has not to be the exclusive vehicle of hegemonic interests and visions but which it may encompass alternative interpretations, this thesis proposes an alternative and a more than justified new reading of the IPRs regime. Also, and in order to avoid legal interpretations that take the risk of being forgotten in comfortable public libraries' shelves, the thesis proposes the implementation of specific institutional changes inspired on models of deliberative communication and deliberative democracy.

In this sense, this thesis emphasizes the basic instrumental character of IPRs and the social functions that IPRs are called to fulfil. In this sense, and because of the rational substrate which justify the existence itself of IPRs, the social function of IPRs and its instrumentality constitute an integral part of these special rights in a much more pronounced manner than it is the case for traditional property over intangibles. In fact, and based on the features of intangibles and knowledge and the social needs behind its formulation, this dissertation upholds that IPRs are not genuine property but they would be better conceptualized as a "legal institution vested with temporary

property prerogatives". This conceptualization seems to be more adequate than being catalogued as another category of property or special property.

Property is an institution which attempts to resolve the scarcity and limited nature of tangible goods. Property would promote efficiency in the market, in particular it would respond to the need of signaling in market relations. As resources are scarce, the risk of conflicts as to who may possess and benefit of them may multiply exponentially to infinity i.e., it plays a crucial role for the allocation of scarce economic resources. A second function of property has to do with the consideration that property is an incentive for work and efficient production. According to Bentham, property would be needed to vanquish *natural aversion to labor*. In connection with this, Garret Hardin introduced the metaphor of the *tragedy of the commons* which justifies the existence of property rights as a measure against the overuse of common property. Finally, property has a social function i.e., property rights are not absolute or unlimited but they have to put in line with the interests of society.

However, the institution of Intellectual property is not originated as the response to the scarcity of resources and the eventual chaos of conflicts fighting for the same limited goods. Quite the opposite, IPRs imply the creation of an artificial scarcity by law since the non-rivalrous and the non-excludability of knowledge make them naturally accessible to everybody at the same time. Furthermore, the creation of scarcity by the state implies a special effort and deployment of public resources to make that scarcity effective. Neither is the tragedy of the commons applicable to IPRs since the problem of intangibles and knowledge is one of underproduction (it is argued that there will not be creative or inventive processes without incentives). Therefore, the main justification of IPRs is an instrumentalist one; being incentives to promote creative and inventive activity, the technical progress and sharing knowledge to the whole of society. Therefore, IPRs are a legal institution vested with temporal property prerogatives and its fate is the fulfillment of social functions. Hence, account taken of the instrumentality of IPRs, it would not make sense to enforce and implement IPRs when they do not fulfil their social functions. Even if we accept that IPRs system may have been working in certain sectors where it is

necessary a legal instrument to recoup investments (pharmaceutical sector), it seems clear that a one-size-fits-all approach to cover all the intangible realities does not make sense. In this respect, what is missing today is a continuous analysis of the impact of IPRs and a dynamic and permanent adjustment of IPRs to the socioeconomic circumstances at any given time.

Also, the use, application and interpretation of these rights vested with property prerogatives have been automatic, and dogmatic application of law without questioning or objection as to whether those IPRs are accomplishing the goals which justify their existence and implementation or not. In effect, a pharmaceutical patent owner can exclude others from using the intangible goods covered under the patent regardless the effective impact of her exclusive right in the market and into the society where that patent is being implemented. Despite the fact that the *raison d'être* of IPRs has to do with their instrumental nature, -i.e. as a tool to foster innovation, technology transfer and dissemination of information-, and therefore its social function is far more noticeable than property rights related to tangible goods, it is surprising that there is not any serious approach which reviews the fulfillment of the goals for which they have been conceived, whether the benefits for society outweighs the private benefits for the IPRs' owner and if the investments made to develop certain intangible goods have been fairly recouped.

In this sense, it is upheld that instead of interpreting IPRs in an absolute manner without evaluating the cause-effect relationship (*iuris et de iure*), there should be a presumption that IPRs are valid in the sense that IPRs fulfill their social function. However, that presumption should be rebuttable if it is proven in the context of a given case that IPRs are not fulfilling their social function. Social function of IPRs must be predicated in relation to the nation where those IPRs are enforceable. Also, in order to avoid the eventual uncertainty (it is said that foreign investors are reluctant to invest in countries without a foreseeable rule of law system) and perceived discretion of national law and national authorities in determining what social function is, may be overcome by an appropriate dialogue between the global and the national spheres i.e, the determination about whether IPRs are fulfilling their social functions has to be the result of the analysis as to the social impact and necessities of

the national society and the application of internationally established standards as to what is for instance, technology transfer, affordability, or investments on I&D.

Furthermore, this thesis upholds the possibility of using law (perceived as part of the hegemonic mainstream) as an emancipatory tool, as a vehicle able to encompass non-hegemonic voices and of deploying law in counter-hegemonic debates and struggles in what professor De Sousa has called the *expansion of the conception of the politics of legality*. With a view to make this effective, incorporate an application of law, and in particular of IPRs, in accordance with their social function, decision making processes at national and global scale and somehow a different interpretation of law should be anchored in active democratic participation based on deliberative and discursive reasoning. Absent a world government and before a formal interpretation of law (at the service of the neoliberal process of globalization), democratic deliberative processes are suggested to be able to overcome the shortcomings of the global architecture and the global IPRs regime in terms of greater legitimacy of the system, and a shared and more democratic character of decisions. While accepting that there is no such thing as an absolute, incontrovertible and objective standard of single truth, shared truth can be the result of the deliberative interaction between different perspectives. Hence, the objective truth can be obtained through the process of subjective interactions, this being the *most basic justification for democracy* (in Piccioto's words).

The alternative interpretation of IPRs as a legal institution vested with temporary property prerogatives directed to fulfill their inherent social functions, may be possible implementing democratic deliberative processes and a public sphere where it would be possible to implement transparent and traceable modes of public reasoning about the challenges of IPRs; how to better incentivize genuine innovation for all (also neglected diseases) while ensuring affordable access for everybody. This could permit to adequately define and adopt the democratic parameters under which IPRs have to be implemented in order that they fulfil their social functions and that the public interest prevails and human rights respected. In this manner, these rights/privileges vested with property prerogatives should serve the interests and needs of society and its citizens. The review of the four dimensions affecting the

outcome of the IPRs regime (institutional framework, business environment, global media and civil society) sheds light on the real possibility of creating a public sphere where deliberative democracy encompasses counterhegemonic voices and a friendly context to an alternative application of IPRs law, an application that turns to be more coherent with the genuine significance of IPRs.

I want this thesis provides a modest but consistent contribution to encourage to a change of paradigm in the interpretation and understanding of the institution of IPRs, a new turn (another one) in the necessary balance between public and private regarding interests on the ground of IPRs to correct today's illogic and exacerbated version of IPRs as absolute rights of property decontextualized of the social environment where they are applied and devoid of their legal significance, foundation and *raison d'être*. In this attempt, I am persuaded that deep and long lasting changes derive from civilizational and cultural change and societal values which occur over a long period of time. Because of that, the changes proposed here are not going to be the result of a revolution from day to day but they are intended to impregnate step by step the practice of a fairer and more human law.

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