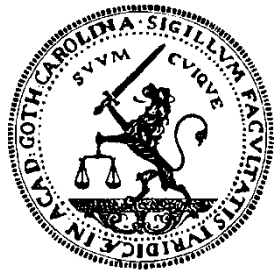

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The role of TRIPS in health innovation and access to medicines in Brazil

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International Human Rights Law and Intellectual Property Rights
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CONTENTS

ABSTRACT

This thesis undertakes an analysis of the current tension between patents law obligations under TRIPS Agreement and human rights, specifically in the context of how the TRIPS Agreement influences health innovation and access to medicines in Brazil. Following a general overview of the interaction between human rights and patent law within the WTO, the central aim is based on the empirical analysis of two Brazilian case studies: “Pharmaceutical Patents on Access to Medicines” and “ONSA Network’s Genoma Program”. The purpose of the first case study is to describe how Brazilian access to medicine was impacted by the incorporation of TRIPS Agreement provisions into Brazil’s legislation, including how the country is making use of some TRIPS flexibilities relevant to the subject matter, as well as assess the consequences of this impact. The second case study is an example of a reaction to the legal framework that followed the TRIPS Agreement and consists of a system of voluntary licensing, based on a collaborative and open approach to innovation, with the outcome of making the research data available free from patent's limitation. Considering that Brazil's intellectual property regime is strongly shaped by global regulation, particularly the terms of the TRIPS Agreement - as the case studies illustrate - the final purpose is to assess how to better accommodate human rights within the WTO, in order to provide Brazil (and other WTO members) with a more secure basis to pursue the balance between patents and human rights.

ABREVIATIONS

ARV: anti-retroviral
Doha Declaration: Doha Declaration on the TRIPS Agreement and Public Health
DS: dispute settlement
DSU: dispute settlement understanding
EC: European Communities
FTAs: free trade agreements
ICCPR: International Covenant on Civil and Political Rights
ICESCR: International Covenant on Economic, Social and Cultural Rights
LCDs: least developed countries
R&D: research and development
TRIPS or TRIPS Agreement: Trade Related Aspects of Intellectual Property Rights
UNDH: Universal Declaration of Human Rights
UN High Commissioner: United Nations' High Commissioner on Human Rights
WHO: World Health Organization
WIPO: World Intellectual Property Organization
WTO: World Trade Organization

1 INTRODUCTION

Current industrial property law is shaped by the Paris Convention for the Protection of Industrial Property (1883)[1] and the Agreement on Trade-Related Aspects of Intellectual Property Rights (1994)[2] (TRIPS Agreement) which established minimum standards of protection that each World Trade Organization (WTO) member has to give to intellectual property, thus limiting flexible national approaches. Since then, the development of science, especially in the fields of plant variety, genes and traditional knowledge, has been challenging the patentability criteria. In addition, an increasing attention to human rights[3] has been challenging States to comply with both patents law obligations under TRIPS Agreement and their responsibility to implement human rights under international covenants, such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), ratified by Brazil in 1992.

Regarding access to medicines, since the 1950s a right to health (in reality a right to health care – with access to medicine being an essential component of it) has been developing in public international law and coming into conflict with the TRIPS Agreement[4]. Right to health is especially provided for in article 25 of the Universal Declaration of Human Rights (UDHR)[5] (1948) and in article 12 of the ICESCR[6] (1966), as well as in regional human rights instruments and many national constitutions[7].

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1 Dated of March 20, 1883, followed by several revisions and amendments, the last one dates September 28, 1979. Available at http://www.wipo.int/treaties/en/ip/paris/trtdocs_wo020.html.

2 GROSHEIDE, Williem. *General Introduction,* in *Intellectual Property and Human Rights: a Paradox*, edited by Willem Grosheide, Edward Elgar Publishing Limited (EE), 2010, p. 4.

3 DREYFUSS, Rochelle C. *Patents and Human Rights: Where is the Paradox?* Molengrafica Series, Forthcoming; New York University, Law and Economics Research Paper No. 06-38; New York University Law School, Public Law Research Paper No. 06-29. Available at SSRN: http://ssrn.com/abstract=929498.

4 HESTERMEYER, Holger. *Human Rights and the WTO.* Oxford, 2007, introduction xxxiv.

5 Which says: "*(1) Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. (2) Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection".*

6 Article 12 of the ICESCR states:
"1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
(b) The improvement of all aspects of environmental and industrial hygiene;
(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."

7 By 2009, 135 countries, including Brazil, had incorporated aspects of the right to health in their national constitutions. WHO, WIPO, WTO. *Promoting Access to Medical Technologies and Innovation. Intersections*

Accessibility of medicine is therefore a central element of the international human rights system[8] and one of the interests of society that have to be brought into balance with the TRIPS Agreement[9].

The TRIPS Agreement acknowledges the necessity to accommodate right to health in article 8.1, which states that:

> "[m]embers may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

In addition, the TRIPS Agreement incorporated the so-called "flexibilities" in order to permit countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies[10]. In practice, however, there is a lot of uncertainty and discussion about how to accommodate human rights within the WTO, as well as a prevailing influence of economic and private interests, making human rights a secondary concern within the WTO system[11].

Due to the TRIPS Agreement, access to medicine has been affected in some WTO member countries. The case of "Pharmaceutical Patents on Access to Medicines", analysed below, demonstrates that, since Brazilian legislators adopted measures to comply with the TRIPS Agreement, there has been a threat to the current health care system in Brazil[12]. Aggravating the situation further, Brazilian legislators also adopted measures not required by TRIPS, presumably due to international pressure and influence of private interests, such as early implementation, a patent pipeline and the prohibition of parallel importation. On the other hand, counter-measures to mitigate the effects of patent law on access to medicines have been adopted, namely compulsory licenses, the prior consent mechanism, the Bolar exception and the Popular Drugstore Program. This case study illustrates that it is far from easy to strike the balance between patent law obligations under the TRIPS Agreement and right to health.

Another reaction to the patent system that followed the adoption of the TRIPS Agreement is the emergence of alternative models which can annul or mitigate the restrictions imposed by patent law,

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between public health, intellectual property and trade. 2013. Available at www.who.int/phi/promoting_access_medical_innovation/en/, p. 40.

8 WHO, WIPO, WTO, *ibidem*, p. 40. "*Although no international tribunal or adjudicative body has yet enforced such right-to-health measures against a state, widespread commitment to health as a universal right does exist"*. CROOK, Jamie. *Balancing Intellectual Property Protection with the Human Right to Health.* Berkeley Journal of International Law, Volume 23, Issue 3, 2005, p. 537.

9 HESTERMEYER, *ibidem*, p. 51.

10 According to WIPO Secretariat. Available at http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html.

11 DREYFUSS, *ibidem*.

12 ROSINA, Monica Steffen Guise, WANG, Thana Cristina de and CAMPOS, Daniel. *Access to Medicines: Pharmaceutical Patents and the Right to Health. in* Access to knowledge in Brazil. Lea Shaver (editor), 2nd edition, Bloomsbury Academia, 2010, pp. 197-198.

including open source[13] and patent pools models[14]. But they require the creation of a legal structure and the agreement of possible patent holders, so they can only work in an organized and structured environment and under specific circumstances. The second case studied herein, the "ONSA Network's Genoma Program", represents one of these alternative models, an open business model consisting of voluntary licensing in order to make research data available free from patent law restrictions.

The empirical analysis of the two Brazilian case studies, "ONSA Network's Genoma Program" and "Pharmaceutical Patents on Access to Medicines", thus raises the question of where the patents legal regime is tending towards and incite scholars to look for solutions to better accommodate human rights within the WTO system.

1.1 RESEARCH QUESTION

The central aim of this work is an empirical analysis of how the incorporation of the TRIPS Agreement's provisions into Brazilian law - including the way Brazil is making use of TRIPS flexibilities and alternative models - impacted medical innovation and access to medicines in the country, and an assessment of the consequences.

1.2 METHODOLOGY AND STRUCTURE

The study is primarily based on the relevant doctrine, followed by WTO case laws, international treaties and Brazilian legislation on the subject matter. Methodology and structure will be as follows:

1. FIRST PART: an axiological approach consisting of an analysis of the relation between human rights and the TRIPS Agreements, followed by a general descriptive approach of how the WTO applies non-WTO law when interpreting its rules or solving conflict of law between WTO and non-WTO law.
2. SECOND PART: empirical analysis of two Brazilian case studies, "Pharmaceutical Patents on Access to Medicines" and "ONSA Network's Genoma Program". The purpose of this empirical analysis is to assess the tension between patent law obligations under the TRIPS Agreement and human rights in practice, as well as the consequences for the Brazilian health care system.
3. The last part consists of a first step solution to better accommodate human rights within the WTO.

[13] Further explained in sub-chapter 2.2.

[14] "*A patent pool is an agreement between at least two patent owners to group their patent rights relating to a specific technology and to license the rights to use these patents to each other and to third parties, subject to certain conditions such as the payment of royalties*". WHO, WIPO, WTO, *ibidem*, p. 119.

2 FIRST PART. TRIPS AGREEMENT AND HUMAN RIGHTS. FUNDAMENTALS

2.1 TRIPS AND ITS UTILITARIAN APPROACH

First of all it is important to note that due to its limited scope, this study will not discuss the history of patent law nor will engage in natural law property arguments to justify patents.[15] This paper assumes that today patents are almost universally justified by utilitarian ideas rather than natural law property arguments.[16] An utilitarianism approach means, according to HELFER and AUSTIN, to employ the analytical tools of utilitarianism and welfare economics to evaluate the trade-offs between incentives and access, and the consequences for the individuals and firms that create, own, and consume intellectual property products.[17]

In fact, legislators have always tried to tailor patent laws to the goal of inducing the introduction of new knowledge within their territory with minimal disadvantages to society.[18] In this sense, article 7 of the TRIPS Agreement puts the objectives of the Agreement as follows:

> "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

According to HESTERMEYER[19], besides promoting a utilitarian public policy rationale for granting patents, namely promoting technological innovation and transfer and dissemination of technology, the above mentioned provision expresses the idea that the TRIPS Agreement seeks to strike a balance between the rights of the patent holder and the interests of the users. However, according to DREYFUSS[20], HESTERMEYER[21], as well as the UN High Commissioner[22], economic and practical considerations prevail in the current patent system and human rights are not a main concern within the WTO system.

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15 Although the natural law argument of the fairness of ownership in one's own inventions has certainly exerted an influence on the development of patent law. HESTERMEYER, *ibidem*, p. 18.

16 HESTERMEYER sums up on page 29 that "*[t]oo many aspects of patent law contradict natural law notions: the fact that inventors have to go through an administrative procedure to obtain a patent rather than having an automatic right in their invention, the loss of all rights of parallel inventors if someone else obtains a patent, and, most prominently, its time-limited character"*. HESTERMEYER, *ibidem,* p. 18.

17 HELFER, Laurence R. and AUSTIN, Graeme W. *Human Rights and Intellectual Property Mapping the Global Interface*, Cambridge, 2011, p. 504.

18 HESTERMEYER, *ibidem*, p. 21.

19 HESTERMEYER, *ibidem*, p. 51.

20 DREYFUSS, *ibidem*, p. 19.

21 HESTERMEYER, *ibidem*, p. 298.

22 HIGH COMMISSIONER on Human Rights. *Report on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights of 27 June 2001*, para. 22.

Accordingly, the United Nation's High Commissioner on Human Rights, in the report on the impact of the TRIPS Agreement on human rights of 27 June 2001, highlighted that, if a human rights approach were a main concern, the TRIPS Agreement would explicitly place the promotion and protection of human rights, in particular those in the ICESCR, at the heart of the objectives of intellectual property protection, but, instead, the TRIPS Agreement expressed them in terms of exceptions. It is worth quoting what was said in the report:

> "[t]he various links with the subject matter of human rights - the promotion of public health, nutrition, environment and development - are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement. A human rights approach, on the other hand, would explicitly place the promotion and protection of human rights, in particular those in ICESCR, at the heart of the objectives of intellectual property protection, rather than only as permitted exceptions that are subordinated to the other provisions of the Agreement."[23]

Although human rights are not a main concern within the TRIPS Agreement, DREYFUSS[24], HESTERMEYER[25] and the UN High Commissioner[26] concluded that patent law obligations and human rights are not fundamentally opposed. The conflict between human rights and patent law is in substance a conflict of norms and, as such, it is up to policy makers to align the patent system with other social interests, including but not limited to ones that are deemed fundamental[27]. In other words, the balance between general public interests in accessing new knowledge and the interests of authors and inventors depends on how intellectual property is actually implemented.

A lot of factors may, in practice, influence the implementation of intellectual property, including how the WTO considers non-WTO law when interpreting its rules or solving a conflict of patent law with another cluster of law. This is analysed in the sub-chapter below.

2.2 APPLICABLE LAW AND AUTHORITATIVE INTERPRETATION BY THE WTO

This section works on the applicable law within the WTO system and paves the way for the second part (Chapter 2), which engages in a descriptive approach of how the TRIPS provisions were incorporated into Brazilian law, including how some flexibilities relevant to the subject matter were interpreted by the WTO and applied in Brazil.

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23 HIGH COMMISSIONER, *ibidem*, para. 22.

24 DREYFUSS, *ibidem*, p. 19.

25 HESTERMEYER, *ibidem*, p. 298.

26 HIGH COMMISSIONER, *ibidem*, para. 22.

27 "*An utilitarian perspective allows policy makers to use the ample arsenal of available tools to make law responsive to changes in innovation and to align the system with other social interests, including but not limited to ones that are deemed fundamental."* DREYFUSS, *ibidem*, p. 19.

2.2.1 FRAGMENTATION OF INTERNATIONAL LAW

According to HESTERMEYER[28], the conflict between the TRIPS Agreement and access to medicine is in substance a conflict between world trade and human rights. However, the national approach to solve a conflict of laws, which is usually based on the concept of hierarchy, including *erga omnes* norms and *jus cogens,* does not work in the same way at the international level due to the fragmentation of international law, explained below.

In national systems there is usually one adjudicatory body that is empowered to solve conflicts of law. At the international level, different regimes are endowed with different adjudication and enforcement bodies, often with limited jurisdiction and empowered to apply only a limited set of norms or give preference to a certain set of norms. These adjudicatory systems can come into conflict by applying the same law differently or by applying different laws and imposing contradictory rulings on a state.

Due to this fragmentation of international law, the conflict between human rights and patent law may have different outcomes at the national and international level. Human rights law is regarded as higher in what could be called the 'moral appeal' than trade or patent law and, in national legislations, it seems natural to grant a superior constitutional function to human rights norms[29] [30]. However, in international law, a true hierarchy is prevented both by the fact that the concept of *jus cogens* still awaits its first real test and by the existence of sectorally organized regimes.[31]

Different from the system of most national laws, the WTO is only empowered to apply one of the conflicting norms[32]. Indeed it does not have to deal with the rules for regime conflict under general international law - it will merely apply the rule it is empowered to apply – and the decision of the tribunal can thus differ from the resolution of the regime conflict that general international law would have imposed[33].

The existence of sectorally organized regimes at the international level leads to a factual hierarchy of regimes, which is independent of the normative hierarchy. According to HESTERMEYER[34], for practical reasons, states will tend to abide by the rules of the regime with the strongest enforcement mechanism even if the rules enforced by this mechanism are inferior to the conflicting rules under both general international law and national law.

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28 HESTERMEYER, *ibidem*, p. 298.

29 WHO, WIPO, WTO, *ibidem*, p. 40.

30 By 2009, 135 countries had incorporated aspects of the right to health in their national constitutions. HESTERMEYER, *ibidem,* pp. 298-299.

31 HESTERMEYER, *ibidem*, p. 298.

32 HESTERMEYER, *ibidem,* p 208.

33 HESTERMEYER, *ibidem,* p 208.

34 HESTERMEYER, *ibidem*, p. 298.

In fact, whereas the human rights regime has a rather weak enforcement mechanism, the WTO regime is second to none[35] in the factual hierarchy due to its effective enforcement mechanism[36]. Therefore, in the international arena, where human rights law is in conflict with WTO law, states will tend to abide by the rulings of WTO dispute settlement organs due to the superior factual hierarchy of the WTO regime.

Considering this practical situation, the decisive question is to what extent the WTO dispute settlement body can apply the human rights norm of access to medicine[37]. In other words, the vital question that needs to be addressed is the question of the use of non-WTO law within the WTO system. Scholars have asked this question with respect to several legal regimes, especially the applicability of environmental law or human rights law within the WTO system.

2.2.2 APPLICABLE LAW AND AUTHORITATIVE INTERPRETATION

Once a WTO panel has accepted a case, it has to decide which law it is empowered to apply. According to HESTERMEYER the treaty setting up a tribunal usually determines the rules the tribunal has to apply. Accordingly, article 7.1 of the Dispute Settlement Understanding (DSU) limits the applicable law in WTO dispute settlement to the covered agreements, unless the parties to the dispute agree otherwise. The WTO adjudicating bodies will also apply non-WTO treaties as applicable law where the covered agreements explicitly refer to them, such as in article XV:9(a) of the GATT.[38]

Scholars have discussed different approaches as to how human rights law can be applied in a WTO dispute settlement: (i) not at all (conceiving the WTO as a self-contained regime), (ii) merely for the interpretation of WTO covered agreements, to the extent that there is no conflict with WTO rules, (iii) along with WTO rules and general international law rules on conflict of norms, or (iv) on a par with WTO rules so that human rights law can be enforced by WTO dispute settlement proceedings.[39]

2.2.3 JURISPRUDENCE ON NON-WTO LAW IN THE WTO DISPUTE SETTLEMENT

The prevailing understanding within the WTO dispute settlement body is that non-WTO treaties (including, in the case of access to medicine, the ICESCR and general international law) can all be taken into account merely in the interpretation of the covered agreements[40]. WTO jurisprudence also understands that although non-WTO treaties can be used as an aid for interpreting the covered agreements,

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35 The TRIPS Agreement sets out the only comprehensive multilateral framework within which to enforce intellectual property rights. WHO, WIPO, WTO, *ibidem*, p. 70.

36 HESTERMEYER, *ibidem,* pp. 298-299.

37 HESTERMEYER, *ibidem.*

38 HESTERMEYER, *ibidem,* p. 225.

39 HESTERMEYER, *ibidem,* p. 299. According to the author, the use of the ICESCR and general international law as an interpretative aid resembles the interpretation of the TRIPS Agreement in light of its object and purpose. However, it is more specific than the latter and connects the interpretation to efforts undertaken in fora such as the Committee on Economic, Social and Cultural Rights.

40 HESTERMEYER, *ibidem,* p. 225 and 299.

they are not part of the applicable law[41] and can not prevail when they contradict a WTO covered agreement.

Case law clearly confirms this understanding. In the case EC- Poultry[42], the European Communities and Brazil had come to sign Agreed Minutes (the 'Oilseeds Agreement') in negotiations under article XXVIII of the GATT before the entry into force of the WTO Agreements. The Appellate Body discussed the relationship between the European tariff schedule and the Oilseeds Agreement and held that only the schedule is part of the covered agreements, not the Oilseeds Agreement. Consequently it is the schedule that forms the legal basis to guide the WTO. The Appellate Body considered that the Oilseeds Agreement could merely be used to interpret the schedule under article 32 of the Vienna Convention on the Law of Treaties[43]. Quoting the relevant parts of the decision:

> "(…) the Oilseeds Agreement is not a "covered agreement" within the meaning of Articles 1 and 2 of the DSU. Nor is the Oilseeds Agreement part of the multilateral obligations accepted by Brazil and the European Communities pursuant to the WTO Agreement, which came into effect on 1 January 1995. The Oilseeds Agreement is not cited in any Annex to the WTO Agreement. (…)
> 80. Furthermore, the Oilseeds Agreement does not constitute part of the "decisions, procedures and customary practices followed by the CONTRACTING PARTIES to GATT 1947" by which the WTO "shall be guided" under Article XVI:1 of the WTO Agreement. These "decisions, procedures and customary practices" include only those taken or followed by the CONTRACTING PARTIES to the GATT 1947 acting jointly.
> 81. It is Schedule LXXX, rather than the Oilseeds Agreement, which contains the relevant obligations of the European Communities under the WTO Agreement. Therefore, it is Schedule LXXX, rather than the Oilseeds Agreement, which forms the legal basis for this dispute and which must be interpreted in accordance with "customary rules of interpretation of public international law" under Article 3.2 of the DSU. (...)
> 83. We recognize that the Oilseeds Agreement was negotiated within the framework of Article XXVIII of the GATT 1947 with the authorization of the CONTRACTING PARTIES and that both parties agree that the substance of the Oilseeds Agreement was the basis for the 15,500 tonne tariff-rate quota for frozen poultry meat that became a concession of the European Communities in the Uruguay Round set forth in Schedule LXXX. Therefore, in our view, the Oilseeds Agreement may serve as a supplementary means of interpretation of Schedule LXXX pursuant to Article 32 of the Vienna Convention, as it is part of the historical background of the concessions of the European Communities for frozen poultry meat."[44]

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41 HESTERMEYER, *ibidem,* pp. 298-299.

42 Dispute Settlement DS69. European Communities — Measures Affecting Importation of Certain Poultry Products. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds69_e.htm.

43 HESTERMEYER, *ibidem,* p. 225.

44 Dispute Settlement DS69. *ibidem*, pp. 29-31.

According to HESTERMEYER, the outcome of the case EC- Poultry would be different if the WTO dispute settlement allowed a non-WTO law to override WTO law[45].

Moreover, in the panel EC – Biotech[46], the WTO dispute settlement body concluded that non-WTO treaties may be relied on in the interpretation of WTO Agreements even where one or more disputing parties are not parties to them[47]. In fact, not all states are part of both WTO and human rights covenants. The International Covenant on Civil and Political Rights (ICCPR) and the ICESCR have been ratified by approximately 85 per cent of the WTO members[48]; notably, the United States has not ratified the ICESCR. In the panel EC – Biotech, after having extensively discussed the relevance of non-WTO law to the interpretation of the WTO Agreements and relying both on article 31(3)(c) and 31(1) of the Vienna Convention, the panel stated that the fact that not the whole WTO membership has signed human rights covenants "*does not necessarily mean that a convention cannot shed light on the meaning and scope of a treaty term to be interpreted"*[49].

2.2.4 JURISPRUDENCE ON GENERAL INTERNATIONAL LAW IN THE WTO DISPUTE SETTLEMENT

WTO adjudicating bodies have made more frequent use of general international law than of non-WTO treaty law[50]. They have generally used rules of general international law[51] in the interpretation of the covered agreements or to confirm an interpretation of the covered agreements, much like they use non-WTO treaty law.

General international law plays a more important roll when it comes to procedure, on which the DSU is silent. HESTERMEYER pointed out several cases regarding the subject matter, as in EC—Bananas[52], in which the Appellate Body first held that a requirement of legal interest was not contained in the DSU to then state that such a requirement could also not be deduced from general international law. In EC—Hormones[53], the Appellate Body concluded that precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying customary international law principles of treaty interpretation in reading the provisions of the Agreement on the Application of

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45 HESTERMEYER, *ibidem,* p. 226.

46 Dispute Settlement DS291. European Communities — Measures Affecting the Approval and Marketing of Biotech Products. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm.

47 HESTERMEYER, *ibidem*, pp. 298-299.

48 HESTERMEYER, *ibidem* pp. 298-299.

49 HESTERMEYER, *ibidem,* pp. 224-225.

50 HESTERMEYER, *ibidem,* p. 226.

51 The Appellate Body has generally taken article 3.2 of the DSU, which prescribes the application of customary rules of interpretation of public international law, to refer to articles 31 and 32 of the Vienna Convention. It also applied other rules of interpretation, such as article 28 of the Vienna Convention, the principle of effectiveness (ut res magis valeat quam pereat), that of in dubio mitius, or the principle of good faith. HESTERMEYER, *ibidem,* pp. 226-227.

52 Dispute Settlement DS27. European Communities — Regime for the Importation, Sale and Distribution of Bananas. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds27_e.htm..

53 Dispute Settlement DS26. European Communities — Measures Concerning Meat and Meat Products (Hormones). Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm.

Sanitary and Phytosanitary Measures (the SPS Agreement)[54]. The best-known example is the Appellate Body's holding on the question of burden of proof in US—Shirts and Blouses[55]. In this case, the Appellate Body determined that "*the burden of proof rests upon the party (...) who asserts the affirmative of a particular claim or defence"*. The justification it cites for this holding is that this rule is generally accepted both by international tribunals and national courts[56].

HESTERMEYER argues that in US—Shirts and Blouses, and in many other cases, the Appellate Body arguably had no choice but to apply general international law as it intrinsically had to rule on procedural questions involved and the DSU was silent on the issue. The same cannot be said of matters of substance, namely claims under the WTO Agreements, on which WTO law is not silent[57].

2.2.5 ACCESS TO MEDICINE AS *JUS COGENS* WITHIN WTO DISPUTE SETTLEMENT

As explained, according to the prevailing understanding within the WTO dispute settlement body, human rights are only used in the interpretation of the covered agreements, they are not part of the applicable law nor can prevail over a WTO covered agreement. As a consequence, a WTO member cannot rely on human rights in the defence against a claim of violation of WTO law absent a basis for this defence in the covered agreements. The situation is different, however, where the human right has attained the status of *jus cogens*.

HESTERMEYER sums up the discussion:

> "jus cogens "cannot be contracted out of — indeed, under the Vienna Convention they void any agreement that attempts to do so. This hierarchically superior position would allow a defence against the claim of a violation of WTO law even within WTO dispute settlement. What remains to be discussed is whether the right to access to medicine has attained such a position. It is hard not to feel sympathy with the proposition that it has: does access to medicine not have to prevail over economic interests, particularly where the life of millions is at stake? But the question oversimplifies the issues involved. The doctrine of jus cogens is a relatively young one and is still awaiting its first serious test case. Commonly, only a mere handful of principles are cited as examples of the doctrine, such as the prohibition of genocide. All of these are widely accepted and of comparatively long standing. The same cannot be said for access to medicine: the reluctance of the United States to recognize economic, social, and cultural rights is indicative of the problems the right faces and while this reluctance might have subsided sufficiently in the area of access to medicine in health emergencies to recognize such a right as customary, it is not sufficient to raise it immediately to the status of jus cogens."[58]

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[54] HESTERMEYER, *ibidem,* p. 227.

[55] Dispute Settlement DS33. United States - Measures Affecting Imports of Woven Wool Shirts and Blouses from India. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds33_e.htm.

[56] HESTERMEYER, *ibidem,* pp. 227-228.

[57] HESTERMEYER, *ibidem,* p. 228.

[58] HESTERMEYER, *ibidem,* p. 229.

To sum up, according to WTO jurisprudence, non-WTO treaties and general international law can be used merely as an aid for interpreting the covered agreements, as long as they do not contradict WTO agreements. The Appellate Body goes a step further and applies general international law only to rule on procedural questions on which the DSU is silent, but not in case of matters of substance. Because of these findings and because access to medicine is not undoubtedly understood as a *jus cogens*, a WTO member cannot rely on the right to access to medicine as a defence against a claim of violation of WTO law absent a basis for the defence in the covered agreements[59].

[59] HESTERMEYER, *ibidem,* p. 300.

3 SECOND PART: IMPLEMENTATION OF PATENT LAW. CASE STUDIES

This second part concerns the central claim of this work - to describe how Brazilian access to medicine was impacted by the WTO patent system, as well as assess the consequences of this influence.

This second part engages in the empirical analysis of two Brazilian case studies: "Pharmaceutical Patents on Access to Medicines" and "ONSA Network's Genoma Program". The purpose of the first case study is to analyse how the Brazilian access to medicine was affected by the TRIPS Agreement, including how Brazil is making use of some TRIPS flexibilities relevant to the subject matter. The second case study consists of a trend towards voluntary licensing, based on a collaborative and open approach to innovation and represents a reaction to the system that followed the TRIPS Agreement, with the outcome of making research data available for public use and free from patent law restrictions.

These cases were selected because they deal with conflicts between human rights and industrial property from different perspectives. The analysis of pharmaceutical patents is primarily connect to the law-making decision sphere, while the ONSA Network concerns the creation of alternative models which co-exist with the legal framework, limiting its effect. Moreover, while the analysis of the ONSA Network focuses on innovation, the analysis of pharmaceutical patents focuses on distribution. Both cases, thus, provide a wide and embracing overview of the sometimes-difficult interaction between patent law and human rights.

3.1 PHARMACEUTICAL PATENTS ON ACCESS TO MEDICINES IN BRAZIL. ACCESSIBILITY PERSPECTIVE

Before the TRIPS Agreement came into force, countries were largely at liberty to decide whether they wanted to grant patents and how to construct their patent system, and many countries had chosen not to grant patents for pharmaceutical products[60]. With the adoption of the TRIPS Agreement as part of the WTO Agreements in 1994 and the expiration of most of its transitional periods, all major WTO members will have to adopt patent laws that provide for the grant of pharmaceutical patents[61], as article 27(1) of the TRIPS agreement establishes that patents must be available for all fields of technology, which includes patents for pharmaceutical products[62]. The new patenting situation allows inventors to

[60] In 1988, at an early stage in the TRIPS negotiations, a WIPO report cited 49 countries that either did not grant patent protection for pharmaceutical products at all or only provided a limited form of protection. WHO, WIPO, WTO, *ibidem*, p. 56.

[61] This transition period has been extended twice for all least developed countries (LDCs) members in response to a specific request by the LDC Group. In its decision of 29 November 2005, the TRIPS Council extended the period until 1 July 2013, and on 11 June 2013, it extended this further until 1 July 2021 — or when a particular country ceases to be in the least developed category if that happens before 2021. WTO. *Responding to least developed countries' special needs in intellectual property.* Available at http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

[62] DUNCAN, Matthews. *Intellectual Property Rights, Human Rights and the Right to Health*. *in* Intellectual

obtain patents for a newly invented pharmaceutical product in most countries that can produce the product and hence prevent competitors from making generic versions of the drug for the duration of the patent term[63].

As mentioned above, article 27(1) of the TRIPS agreement states that patents must be available for all fields of technology, including patents for pharmaceutical products[64]. However, with regard to the right to health, one must also take into account article 25 of the UDHR, which says that "*[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care (...)*" and article 12 of the ICESCR, which recognizes "*the right of everyone to the enjoyment of the highest attainable standard of physical and mental health*", further strengthened by the right to enjoy the benefits of scientific progress contained in article 15 (1) (b) of the ICESCR. The case of pharmaceutical patents and access to medicines in Brazil illustrates the tension between these provisions.

In order to situate the context of this analysis, a brief historical introduction is necessary. SHAVER[65] sums up the historical context. Prior to 1996, pharmaceuticals were not eligible for patent protection in Brazil. This allowed the government to rely on cheaper domestic copies to meet its public health needs. The manufacture of inexpensive generic medicines facilitated the creation of a national health system in which every individual was promised free access to comprehensive health care, including treatment, access to facilities and free medicines. Under article 27 of the TRIPS Agreement, however, Brazil was required to start granting patents for medicines[66]. However, since reforming its intellectual property law to comply with the TRIPS Agreement, Brazil has seen its public spending on medicines dramatically increase[67]. Recognizing this reality, the nation's highest court has already shown signs of limiting the scope of the constitutional right of access to medicines. The high cost of patented drugs is thus a key matter to be addressed if the right to health is to be preserved[68].

One of the main reasons for such an increase in drug expenditure was the introduction of patent protection for pharmaceutical products in the country[69]. ROSINA, WANG and CAMPOS cite a study that found that, while total health expenditure went up 9.6% between 2002 and 2006, drug expenditure alone increased by 123.9% over the same period[70], due to patent protection.

Aggravating the situation further, the legislature approved patentability for pharmaceutical products almost immediately, rather than pursuing a more gradual implementation allowed by the TRIPS Agreement, and also implemented two measures not required by TRIPS that further increased the price

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Property Rights and Human Rights: A Paradox, W. Grosheide, ed., November 2009.

63 HESTERMEYER, *ibidem,* introduction xxxiv.

64 DUNCAN, Matthews. *Intellectual Property Rights, Human Rights and the Right to Health*. *in* Intellectual Property Rights and Human Rights: A Paradox, W. Grosheide, ed., November 2009.

65 SHAVER, Lea. *Introduction*. in Access to knowledge in Brazil. Lea Shaver (editor), 2nd edition, Bloomsbury Academia, 2010, p. 16.

66 ROSINA, WANG, and CAMPOS, *ibidem*, p. 182.

67 SHAVER, *ibidem*, p. 16.

68 ROSINA, WANG, and CAMPOS, *ibidem*, p. 197.

69 ROSINA, WANG, and CAMPOS, *ibidem*, p. 182.

70 ROSINA, WANG, and CAMPOS, *ibidem*, p. 181.

of medicines: the granting of pipeline patents and the prohibition of parallel imports[71]. These measures are described below.

3.1.1 MEASURES IN OPPOSITION TO ACCESS TO MEDICINES

3.1.1.1 EARLY IMPLEMENTATION

As a developing country, Brazil could have used the transitional period established by article 65 of the TRIPS Agreement to delay implementing its provisions until 2000. However, rather than pursuing a more gradual implementation, the legislature approved patentability for pharmaceutical products earlier in 1996 (through the Brazilian Intellectual Property Law, federal law No. 9.279/96)[72] as it was prompted by industry pressure, as patent protection allows industries to set monopoly prices and capture royalty revenues from their innovations[73].

HESTERMEZER described the pressure exerted by Section 301 of the US Trade Act of 1974, which led to Brazil changing its patent law in detriment of access to medicines, as a consequence of a threat made by the US to Brazil in 1988 of imposing a 100 per cent 'retaliatory' tariff on Brazilian imports worth $39m:

> "after a section 301 investigation initiated by pharmaceutical manufacturers because of Brazil's refusal to grant patent protection to pharmaceuticals. Brazil regarded the tariffs as a breach of US obligations under the General Agreement on Tariffs and Trade (GATT), as Brazil had no obligation under international law to grant such patent protection [at that time]. A GATT Panel was established in 1989, but the proceedings were suspended when Brazil gave in to the pressure announcing that it would change its patent law. The US withdrew its retaliatory sanctions. Section 301 has remained a divisive issue and its WTO-consistency was challenged before a WTO Panel in 1999"[74] [75].

3.1.1.2 PATENT PIPELINE

As explained, until 1996 Brazilian law did not recognize patents on pharmaceuticals. Only with the TRIPS Agreement and the enactment of law 9.279/96 did such substances become eligible for patent protection in Brazil, in an early incorporation of the terms of the TRIPS agreements, considering that the country could have opened this possibility later in 2000. Moreover, articles 230 and 231 of the mentioned law went even further and included a *pipeline* protection, which was not required by TRIPS. This provision opened the possibility of patenting compounds that were not patentable, provided that certain requirements were fulfilled: (i) the compound was not yet marketed in Brazil, (ii) no serious

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71 ROSINA, WANG, and CAMPOS, *ibidem*.

72 ROSINA, WANG, and CAMPOS, *ibidem*, p. 182.

73 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 197-198.

74 HESTERMEYER, *ibidem*, p. 40.

75 The WTO concluded that those aspects of Sections 301-310 of the US Trade Act brought the dispute are not inconsistent with US obligations under the WTO. WT/DS152/R of 22 December 1999. Available at http://www.worldtradelaw.net/reports/wtopanels/us-section301(panel).pdf.

efforts were made by third parties to exploit the patent subject matter in Brazil until the time of the request, (iii) that a patent had already been granted in at least one other country, and (iv) the patent application had to be filed by within 1 year from the publication of the law 9.279/96. Only a formal examination regarding those criteria was necessary, the national examination requirements regarding novelty, industrial applicability, inventive step were not to be considered[76].

It made possible to apply for patent protection for compounds that would otherwise not have been patentable – either before or after the new patent law. Before the new law, it allowed claims regarding technological fields that had not been recognised as patentable previously, such as pharmaceutical, chemicals and food products[77]. However, even after the Brazilian Intellectual Property Law recognized such fields as patentable, the patent may have been granted in a country that is more flexible with regards to a novel, inventive or industrial application. Thus, some medicines that should not qualify for a Brazilian patent under a conventional analysis might be patented through the pipeline process[78]. The compound could not have been deemed patentable because it would have failed, for example, the novelty requirement, as it would have been known in other countries[79]. As HO illustrates, if Brazil began granting patents on pharmaceuticals in 1996, a drug that was invented in 1993 would fail to meet the novelty requirement in 1996. However, because Brazil provides pipeline protection, the 1993 drug could be considered in the "pipeline" of development and thus be eligible for pipeline patent protection[80]. Another problem with the pipeline mechanism, according to the critical analyses of ROSINA, WANG, and CAMPOS, is that it allows for retrospective patents of medicines already invented. The traditional argument for patent protection, that high prices must be assured to provide incentives for innovation, does not carry weight when considering innovations that have already been brought into the market. Companies benefiting from pipeline patents received an additional reward, at great public cost, without having to invest in any additional innovation[81].

During the established one-year period for patent pipeline application (between 1996 and 1997), 1,182 patent applications were filed in Brazil through this mechanism, many of which are considered essential medicines for diseases such as HIV/AIDS (the drugs lopinavir/ritonavir, efavirenz, abacavir, nelfinavir and amprenavir) or cancer (imatinib, sold under the brand name Gleevec). This has led to patent protection on at least 340 medicines, keeping many of them well at artificially high prices by preventing competition from generic manufacturers[82].

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76 CHAVES, Gabriela Costa and REIS, Renata. *Challenges for the universal access to medicines in Brazil – brief comments from civil society*. Available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCwQFjAA&url=http%3A%2F%2Fwww.sxpolitics.org%2Fwp-content%2Fuploads%2F2009%2F04%2Fchallenges-universal-access-medicines.pdf&ei=fElYUrnMB4Hvswb39YDACw&usg=AFQjCNEs3aXNiIJSaAuOf4vwiYFPV1M-eQ&bvm=bv.53899372,d.Yms, p. 01.

77 According to Médecins Sans Frontières (MSF). Available at http://www.msfaccess.org/our-work/hiv-aids/article/1307.

78 ROSINA, WANG, and CAMPOS, *ibidem*, p. 185.

79 HO, Cynthia. Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights. Oxford, 2011, p. 229.

80 HO, Cynthia. *ibidem*, pp. 229- 230.

81 ROSINA, WANG, and CAMPOS, *ibidem*, p. 185.

82 According to Médecins Sans Frontières (MSF), *ibidem*.

3.1.1.3 PROHIBITION OF PARALLEL IMPORTATION

According to the UN High Commissioner, a means of improving access to cheaper drugs is through parallel importation[83]. HESTERMEYER introduced the subject matter of parallel import by firstly explaining the doctrine of exhaustion, or the first sale doctrine. Patentees of pharmaceutical products have no automatic right to market the products, as patents do not grant a positive right to use or market the invention, rather they confer negative rights: the right to exclude others from making, using, selling, etc. the product. In other words, patents grant the right to exclude others from competing, which allows the patent holder to fully exploit the value of the invention. However, as HESTERMEYER continues, the right does not give the patentee control over a product after he has placed it on the market himself - the product can then be sold, used, or offered for sale freely and without the patentee's permission. The patent right has therefore been 'exhausted' once the product was placed on the market. This doctrine has come to be known as the doctrine of exhaustion, or the first sale doctrine.[84]

It follows that once the product was placed on the market by the patent holder (or authorized third parties) it can be sold, used, or offered for sale freely and without the patentee's permission for different prices in different countries. Parallel importation thus allows the importing of the product from the country where it is lawfully sold at a cheaper price[85], without necessarily having the consent of the patent holder[86], due to the exhaustion.

The concept of exhaustion has raised little controversy where the patent holder places the product on the national market and thereby exhausts his rights in the same market (national exhaustion). However, whether the same also applies in an international context is one of the most controversial issues in international intellectual property law[87]. As reported in by WHO, WIPO, WTO:

> "[i]n a landmark legal action, a pharmaceutical industry association and 39 of its affiliate companies filed complaints at the Pretoria High Court, alleging, among other things, that South Africa's law on medicines allowed for parallel importation of (HIV/AIDS) medicines and was inconsistent with the TRIPS Agreement. The lawsuit triggered an active campaign led by non-governmental organizations (NGOs) and AIDS activists. During the court procedure, it was revealed that the South African law was based on a WIPO model law and in the end, the companies withdrew their complaints unconditionally in 2001. By that time, many governments and others were convinced that the relationship between the TRIPS Agreement and public health needed to be clarified"[88].

The subject matter is provided for in article 6 of the TRIPS Agreement which states that *"[f]or the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing*

[83] HIGH COMMISSIONER, *ibidem*, para. 48.

[84] HESTERMEYER, *ibidem,* p. 68.

[85] Non-governmental organization Grupo de Trabalho sobre Propriedade Intelectual (GTPI)s' opinion on parallel importation. Available at http://www.deolhonaspatentes.org.br/default.asp?siteAcao=mostraPagina&paginaId=1000.

[86] HIGH COMMISSIONER, *ibidem*, para. 48.

[87] HESTERMEYER, *ibidem,* p. 68.

[88] WHO, WIPO, WTO, *ibidem*, p. 70.

in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". The UN High Commissioner and other scholars have interpreted this article to mean that WTO members are to free establish the system of international exhaustion they consider appropriate, in other words, to decide whether parallel imports will be allowed under national legislation[89]. Accordingly, the WTO organs have conclusively established in the Doha Declaration on the TRIPS Agreement and Public Health, which clarified some of the TRIPS Agreement's flexibilities, that members are free to establish the system of international exhaustion they consider appropriate[90] (in paragraph 5, subparagraph d)[91]. Only this approach allows developing country members to opt for international exhaustion and developed country members to apply national exhaustion, which better aligns the balance between human rights and patent law[92].

The Commission on Intellectual Property Rights[93] concluded that the most beneficial policy for developing countries is to adopt a rule of international exhaustion, allowing them to purchase drugs at the lowest price at which the manufacturer offers them anywhere in the world. Developed countries, however, should not allow parallel imports in the pharmaceutical area from developing countries. This enables companies to price-discriminate and sell their products at low prices in the developing world without the price 'leaking' into the developed world. However, parallel imports will not lower prices below the level at which a manufacturer is willing to sell the drugs[94].

HEATH states that the decision adopted in the Doha Declaration just mean that whatever national stance is taken on the matter of exhaustion, no complaint can be heard in this respect. In his words, "[w]*hile this certainly means that no country can be put in the dock for deciding for or against international exhaustion, it does not necessarily mean that the TRIPS Agreement as such would not favour either one or the other position*."[95]

HESTERMEYER[96] adds that, whilst the right to access to medicine supports the position of leaving WTO members to choose the right approach for themselves, its fundamental flaw is apparent: it is not dispositive. A member that regards article 28.1 of the TRIPS Agreement as conclusively establishing the patent holder's right to prohibit parallel imports will hardly be swayed by the additional argument and might still exert pressure on a WTO member wishing to adopt a rule of international exhaustion[97] [98].

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89 ROSINA, WANG, and CAMPOS, *ibidem*, p. 187.

90 HESTERMEYER, *ibidem*, p. 231 and 259. Also WHO, WIPO, WTO*, ibidem*, p. 182.

91 WHO, WIPO and WTO, *ibidem*, p. 73.

92 HESTERMEYER, *ibidem*, p. 234.

93 The Commission was set up by the British government to look at how intellectual property rights might work better for poor people and developing countries. Available at http://www.iprcommission.org/home.html.

94 HESTERMEYER, *ibidem*, p. 231.

95 HEATH, Christopher. *Parallel Imports and International Trade*. Available at www.wipo.int/edocs/mdocs/sme/en/atrip_gva_99/atrip_gva_99_6.pdf, p. 9.

96 HESTERMEYER, *ibidem*, p. 234.

97 HESTERMEYER, *ibidem*, p. 234.

98 Accordingly, the UN High Commissioner mentioned that the "*use of trade pressure to impose "TRIPS plus"-style IP legislation has been noted before CESCR. This could lead member States to implement IP standards that do not take into account the safeguards included under the TRIPS Agreement which could lead to IP systems that are inconsistent with States' responsibilities under human rights law*". HIGH

Brazil illustrates well this flaw as, although allowed under TRIPS, the country ruled out the possibility of parallel importation.

In fact, Brazil's 1996 patent reforms ruled out the possibility of parallel imports by adopting the principle of national exhaustion of rights and thus failed to make use of an important tool considered legitimate by the WTO, which could improve access to medicines[99]. This allows patent holders to prevent the import of their products into Brazil by unauthorized parties[100], which means, in practice, that pharmaceutical companies may set and enforce higher prices for drugs in Brazil when the same product is lawfully sold at a cheaper price somewhere else in the world.[101]

Along these lines, some non-governmental organizations maintain that the current legislation is contrary to the goals of intellectual property protection established by the Federal Constitution of 1988, aimed at the economic and technological development of the country.

Parallel importation is currently permitted under Brazilian law only if a compulsory license is issued for the product. There are currently some projects of law requiring parallel import to be allowed in Brazil[102].

3.1.2 COUNTER-MEASURES TO INCREASE ACCESS TO MEDICINES

As explained in the sub-chapter 2.1.1 above, in addition to the TRIPS Agreement, Brazilian legislators adopted measures that are in fact in opposition to public health concerns such as early implementation, patent pipeline and the prohibition of parallel importation. Those measures resulted in a particularly difficult transition and constituted a threat to the current health care system in Brazil[103]. The reaction evolved with the adoption of counter-measures to increase the access to medicines.

The first salvo in the battle to increase access to medicine, according to SHAVER, was fired by activists fighting to expand access to anti-retroviral medicines (ARVs)[104], which resulted in compulsory licensing[105] in the late 1990s. The reaction came also with the adoption of other counter-measures by the Brazilian government in order to mitigate the effects of TRIPS: the prior consent mechanism, the Bolar exception and the Popular Drugstore Program[106], analysed below.

COMMISSIONER, *ibidem*, para. 27.

99 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 187-188.

100 ROSINA, WANG, and CAMPOS, *ibidem*, p. 187.

101 ROSINA, WANG, and CAMPOS, *ibidem*, p. 187.

102 ROSINA, WANG, and CAMPOS, *ibidem*, p. 188. Also Non-governmental organization Grupo de Trabalho sobre Propriedade Intelectual (GTPI)s' opinion on parallel importation. Available at http://www.deolhonaspatentes.org.br/default.asp?siteAcao=mostraPagina&paginaId=1000.

103 ROSINA, WANG, and CAMPOS, *ibidem*, p 197-198.

104 SHAVER, *ibidem*, p 10.

105 In this regard, see ROSINA, WANG, and CAMPOS, *ibidem,* and, on compulsory licensing in Brazil and South Africa, the HIGH COMMISSIONER, *ibidem*.

106 All these measures are well explained by ROSINA, WANG, and CAMPOS, *ibidem*.

3.1.2.1 PRICE NEGOTIATIONS AND COMPULSORY LICENSES

Article 31 of the TRIPS Agreement allows for compulsory licences. Compulsory licensing consists of licences granted by the government permitting someone else (or the government itself, which is then called 'government use'[107]) to produce a patented product or process without the consent of the patent owner.

According to HESTERMEYER, compulsory licences are an important tool for safeguarding access to medicines[108] once they can serve three goals: (1) safeguarding the supply of the domestic market with a patented product; (2) promoting competition by creating domestic competitors; or (3) promoting a domestic industry[109]. Practical experiences show that the bargaining power created by just the legal possibility of a compulsory licence can benefit developing countries even where a compulsory licence is not actually granted[110].

The TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing, but attaches several explicit conditions to such a grant, such as authorization on individual merits, prior negotiations, adequate remuneration and possibility of judicial review[111]. The Doha Declaration, which, as stated above, clarified some of the TRIPS Agreement's flexibilities, clarified that each WTO member has "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted"[112].

HESTERMEYER adds that much about the interpretation of article 31 of the TRIPS Agreement remains in doubt and while the right to access to medicine is a useful argument to support a broader and more flexible interpretation, it is merely one argument amongst several and fails to provide legal security for members wishing to make full use of the flexibilities[113].

One of the controversial issues was the limitation of compulsory licences and government use to predominantly supply the domestic market, considering that article 31(f) of the TRIPS Agreement restricted the grant of a compulsory licence for exports. This represented a potential problem for countries that do not have production capacity to manufacture a drug, and therefore wished to import such products, to make use of compulsory licences. article 31(f) was revised following the Doha Declaration to allow for members granting a compulsory licence for the manufacture of drugs for export to members lacking pharmaceutical manufacturing capacities under multiple conditions (such as special labelling/colouring of the drugs)[114] [115].

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107 HESTERMEYER, *ibidem*, p. 239.

108 HESTERMEYER, *ibidem*, p. 300.

109 HESTERMEYER, *ibidem*, p. 239.

110 WHO, WIPO, WTO, *ibidem,* p. 176.

111 HESTERMEYER, *ibidem*, p. 245.

112 WHO, WIPO, WTO*, ibidem*, p. 73.

113 HESTERMEYER, *ibidem*, p. 300.

114 WHO, WIPO, WTO*, ibidem*, pp. 61 and 175.

115 HESTERMEYER, *ibidem*, p. 301.

3.1.2.1.1 PARAGRAPH 6 SYSTEM

According to the WHO, WIPO and the WTO, the Doha Declaration led to the adoption of a mechanism often referred to as the "Paragraph 6 System", established under the 2003 waiver decision and the 2005 Protocol Amending the TRIPS Agreement[116]. The System provides WTO members with an additional flexibility, which is a special type of compulsory licence for export[117], designed to deal with the difficulties of WTO members lacking sufficient manufacturing capacities to make effective use of compulsory licensing under the TRIPS Agreement, as the agreement then stood[118]. The essence of the System is the grant of a compulsory licence by the exporting country to meet the need(s) identified by the importing country[119]. The System applies in a particular access scenario where an importing country needs medicines to deal with a public health problem, but a potential exporting country faces a legal impediment because article 31(f) of the TRIPS Agreement limits supply under a compulsory licence predominantly to the domestic market. The special export licence under the System is free of this constraint, enabling and indeed requiring the full production under a compulsory licence to be exported. Accordingly, the situation addressed by the System would arise only when a country wishes to obtain a particular pharmaceutical product and the product cannot be produced domestically at all, or in sufficient quantities, due to lack of capacity. The preferred producer of the particular product (normally, the cheapest supply that best meets regulatory and quality requirements) is located in a country where a patent is in force on that product and needs a compulsory licence in that country to produce for export[120].

The Paragraph 6 System might assume a greater significance, considering that implementation of full patent protection for pharmaceutical products in India, coupled with the approaching expiry of transition periods in LDCs, could make it more difficult in the future to procure generic versions of new medicines[121]. However, according to HESTERMEYER[122]:

> "the Decision is unlikely to restore to Members without manufacturing capacity the advantages of the situation before 2005. Before that date, large generic manufacturers in India started operations for many drugs already because of the Indian market and Members could then simply buy the generic drugs from them. Now, generic manufacturers will often have to decide whether to incur the investment necessary to start producing a new generic drug on the sole request of a compulsory licence by a small, poor, importing Member. Apart from HIV/AIDS drugs, where manufacturers might automatically assume follow-up requests from other Members, the necessary economies of scale are unlikely to be reached under the Decision. Also, delays caused by the intricate legal mechanism are inevitable".

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[116] This outcome, providing an additional legal pathway for access to medicines, has special significance as the sole amendment proposed to any of the WTO multilateral trade agreements since their adoption in 1994. WHO, WIPO, WTO, *ibidem*, p. 177.

[117] WHO, WIPO, WTO, *ibidem*, pp. 177 and 224.

[118] WHO, WIPO, WTO, *ibidem*, pp. 23 and 224.

[119] WHO, WIPO, WTO, *ibidem*, p. 225.

[120] By 2012, one special export licence under the System has been exercised. In that instance, the licence was used by a Canadian company to ship medicines to Rwanda. WHO, WIPO, WTO, *ibidem*, p. 178.

[121] WHO, WIPO, WTO, *ibidem*, p. 179.

[122] HESTERMEYER, *ibidem,* p. 301.

3.1.2.1.2 COMPULSORY LICENCE IN BRAZIL

The subject matter was a breakthrough in the battle to increase access to medicine in Brazil. A brief historical introduction is necessary to understand the reasoning behind the issuing of compulsory licenses by the Brazilian government.

As explained by ROSINA, WANG, and CAMPOS[123], faced with the challenge of continuing its HIV/AIDS program at a considerably higher cost, the Brazilian government started negotiations in 2001 with the major pharmaceutical companies. Backed by the threat of compulsory licensing—a process permitted under articles 68 to 71 of the Brazilian Industrial Property Act—the government was able to effectively negotiate with pharmaceutical suppliers, managing to secure reductions in prices[124] and a technology transfer agreement. Since then, new attempts were made at negotiations, but the results were less and less effective. In the beginning of 2007, the government experimented with a new approach: after several months of unsuccessful negotiations, on April 24, the Ministry of Health declared *efavirenz* a drug of national public interest, an important ARV drug used by a third of Brazilians receiving treatment through a national programme[125]. On May 4, Presidential Decree no. 6.108 granted a compulsory license for the drug's patents—based on public interest and for non-commercial use only. The medicine was initially imported from India, where it was produced off patent[126], and later manufactured in Brazil. Brazil reported to the TRIPS Council that it had taken two years to locally produce the medicine, partly because the patent law does not require applicants to disclose all information necessary for the commercialization of the end product[127].

Brazilian law allows for a compulsory licence when a patent holder exercises patent rights in an abusive manner or by means of an abuse of economic power proven by an administrative or court decision. Compulsory licences may also be issued in cases of national emergency or public interest. The terms "national emergency" and "public interest" are defined in the Presidential Decree on Compulsory Licensing (Decree 2301/99)[128]. According to the UN High Commissioner, this links closely with the provisions of the TRIPS Agreement, which allow for the use of a patent without the authorization of the right holder in certain circumstances, including "*in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use*" [129].

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123 ROSINA, WANG, and CAMPOS, *ibidem*, p. 190-191.

124 Using the threat of compulsory licensing, the Brazilian government negotiated significant price reductions on efavirenz and nelfinavir in 2001, lopinavir in 2003, the combination of lopinavir and ritonavir in 2005, and tenofovir in 2006, thus it has demonstrated that legislation which provides for the effective and expeditious use of compulsory licences can be a useful asset in negotiating lower prices for ARV. WHO, WIPO, WTO, *ibidem,* p. 176.

125 WHO, WIPO, WTO, *ibidem,* p. 176.

126 ROSINA, WANG, and CAMPOS, *ibidem,* pp. 190-191.

127 WHO, WIPO, WTO, *ibidem,* p. 176.

128 According to the decree, a national emergency is understood to be a condition of impending danger to the public, even if existing only in a part of the national territory. Further, there are considered to be within the public interest those facts, among others, related to the public health, nutrition, protection of the environment, as well as those of primordial importance to the technological or social and economic development of this country. HIGH COMMISSIONER, *ibidem,* para. 55.

129 HIGH COMMISSIONER, *ibidem*, para. 77.

In 2000, the United States requested consultations with Brazil arguing that provisions of Brazil's industrial property law fail to comply with the "local working" requirement for the issuance of a compulsory license. The United States asserted that the "local working" requirement can only be satisfied by the local production — and not the importation — of the patented subject-matter. More specifically, the United States noted that Brazil's "local working" requirement stipulates that a patent shall be subject to compulsory licensing if the subject-matter of the patent is not "worked" in the territory of Brazil. The United States further noted that Brazil explicitly defines "failure to be worked" as "failure to manufacture or incomplete manufacture of the product" or "failure to make full use of the patented process". The United States considered that such a requirement is inconsistent with Brazil's obligations under articles 27 and 28 of the TRIPS Agreement, and article III of the GATT 1994[130]. In response, NGOs complained using the language of human rights and the right to health. The United States and Brazil subsequently notified the WTO Dispute Settlement Body that a mutually agreed understanding had been reached to settle the dispute. In fact, according to DUNCAN, the United States had stepped back from further confrontation on this issue, subject to a bilateral understanding to the effect that, should Brazil seek to issue a compulsory license on grounds of failure to work the patent locally, it would consult the United States before doing so[131].

The continued existence of the safeguard provisions on compulsory licences in Brazil was considered by the Report of the UN High Commissioner on the impact of the TRIPS Agreement as being helpful in improving the implementation of the Brazilian HIV treatment programme[132].

3.1.2.2 THE PRIOR CONSENT MECHANISM

The prior consent mechanism is another attempt to improve access to medicines in Brazil. Until 2001, the Brazilian Industrial Property Office (INPI) was the only body authorized to consider patent applications for pharmaceutical products. Brazilian federal law 10.196/01, however, instituted the prior consent mechanism, providing that the grant of patents for pharmaceutical products and processes shall be subject to prior consent by the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária - ANVISA), an autonomous regulatory agency which, among other functions, administers the National Sanitary Surveillance System, monitors prices of drugs and medical equipment, and regulates and inspects the production of generic medicines in the country[133].

According to ROSINA, WANG, and CAMPOS, it means that when an application for a pharmaceutical patent is filed, the INPI first analyses whether it meets patentability and formal requirements that have been determined by the Brazilian Industrial Property Act. The applications are then sent to ANVISA for a second and separate analysis. This second stage of review is intended to guard against the danger that a weak examination process could lead to the granting of a patent to an already patented product or process, which results in the extension of protection, delaying the generic manufacturer's entry into the market[134]. Strict patentability criteria and strict patent examination supported by patenting examination guidelines contribute to prevent strategies employed to delay the entry of generic competition, such as

[130] Dispute Settlement DS199. Brazil — Measures Affecting Patent Protection. Available in http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

[131] DUNCAN, *ibidem*, p. 13.

[132] DUNCAN, *ibidem*, p. 14.

[133] ROSINA, WANG, and CAMPOS, *ibidem*, p. 191-192.

[134] ROSINA, WANG, and CAMPOS, *ibidem*, p. 191-192.

"ever-greening"[135], a process where minor innovations to patented innovations are themselves patented, which can effectively extend the life of the patent beyond the original granted period and hold up other research efforts[136].

3.1.2.3 THE REGULATORY REVIEW EXCEPTION (BOLAR EXCEPTION)

Another TRIPS flexibility analysed herein is provided for in article 30 of the TRIPS Agreement which states that:

> "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties".

According to HESTERMEYER[137], the precise scope of the permissible exceptions is hard to gauge as the wording of article 30 of the TRIPS Agreement is notoriously vague. A WTO Dispute Settlement Panel[138] has defined the term as "*the exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not an infringement*"[139]. The Bolar exception and research exception or experimental use exception[140] are commonly cited as types of "limited exceptions"[141].

A Bolar exception[142] allows third parties to manufacture limited quantities of patented drugs without seeking a license, specifically for approval purposes. The purpose is to facilitate the availability of generic drugs as soon as the patent of a branded drug falls into the public domain[143]. Because the approval process can be lengthy, Bolar exception patents can reduce the time it takes for generic drugs to reach the market.

According to ROSINA, WANG, and CAMPOS, the introduction of generic versions of branded drugs in the market improves access to medicines because prices are immediately lowered through new competition. As the government spends less to buy the same drugs, it also becomes possible to buy larger quantities and bargain for even better prices[144].

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135 WHO, WIPO, WTO, *ibidem*, p. 13.

136 HIGH COMMISSIONER, *ibidem*, para. 40

137 HESTERMEYER, *ibidem*, p. 235.

138 Canada - Pharmaceutical Patents: Dispute Settlement DS114. Canada - Patent Protection of Pharmaceutical Products. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

139 WHO, WIPO, WTO, *ibidem*, p. 134.

140 The experimental use exception allows science to progress despite the fact that a technology is patented. HESTERMEYER, *ibidem*, p. 238

141 HESTERMEYER, *ibidem*, p. 238.

142 The name Bolar originates from a lawsuit brought in U.S. courts between Roche Products Inc. and Bolar Pharmaceutical Co in 1984. It is also known in literature as early working of the patent. ROSINA, WANG, and CAMPOS, *ibidem*, p. 195.

143 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 194-195.

144 ROSINA, WANG, and CAMPOS, *ibidem*, p. 194.

The Bolar exception was analysed by the WTO in the Panel Canada - Pharmaceutical Patents[145]. As HESTERMEYER explains, the adequacy of two provisions of the Canadian Patent Act to the TRIPS Agreement were discussed: the first was a Bolar exception and the second a Stockpiling exception. A Stockpiling exception allows competitors who invoked the Bolar exception to manufacture and stockpile the patented goods during a period of six months before the expiration of the patent, so that they have a sufficient amount of goods on stock, as well as the possibility of marketing their product domestically or abroad, so they could start selling the product immediately upon the expiration of the patent term.[146]

The Panel held that article 30 of the TRIPS Agreement establishes three criteria that a measure must meet to qualify for the exception: (i) it must be 'limited', (ii) it must not 'unreasonably conflict with a normal exploitation of the patent', and (iii) it must not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The Panel adopted a very narrow definition of the term 'limited', arguing that the term 'exception' already implies a limited derogation which is narrowed even further by the word 'limited' and concluded that the Stockpiling exception was not limited, as it allowed competitors to 'make' and 'use' the patented product during the last six months of the patent term without imposing any limitation on the production of goods. The Bolar exception, on the other hand, was considered limited, as it only allowed very few acts of making and using the patented product, namely those necessary for the regulatory approval process only[147]. The panel added that the measure must not unreasonably conflict with a normal exploitation of the patent, which consists of the right to exclude competition during the patent term. The Panel went further and considered a period of market exclusivity after the expiration of the patent term to be part of the normal exploitation, as competitors need some time to build an inventory before they can enter the market. In contrast, it considered the additional period of market exclusivity gained because of a regulatory approval process not to be part of the normal exploitation of the patent, so that a Bolar exception does not conflict with the normal exploitation[148].

According to HESTERMEYER, the vague wording used in article 30 of the TRIPS provides an entry point for the right to access to medicine[149], but, considering the above mentioned Panel, the WTO failed to do so. According to the author[150], the Panel focused exclusively on the interests of the patent holder and its inquiry whether these interests are compelling, absent any basis for such a requirement, seem to indicate that it will let the rights holder's interests prevail where these are compelling. The Panel took into consideration the legitimate interests of the patent holder, but not, at least not in equal footing, the interests of third parties, of which access to medicine indubitably is one. Finally, HESTERMEYER

145 Dispute Settlement DS114. Canada - Patent Protection of Pharmaceutical Products. Available at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm.

146 HESTERMEYER, *ibidem*, p. 235.

147 HESTERMEYER, *ibidem*, p. 235.

148 HESTERMEYER, *ibidem*, p. 235.

149 HESTERMEYER states that "*[w]ith respect to limited exceptions under Article 30 of the TRIPS Agreement access to medicine mitigates in favour of a broad interpretation. In particular, access to medicine has to be taken into account in defining 'normal' exploitation and 'legitimate' interests and Article 30 of the TRIPS Agreement has to be read as an exception to the rule of non-discrimination in Article 27 of the TRIPS Agreement".* HESTERMEYER, *ibidem*, p. 235.

150 HESTERMEYER, *ibidem*, p. 237.

mentions that, due to the narrow interpretation of the provision in the Panel Canada - Pharmaceutical Patents, the WTO would not permit an exception under article 30 that could meaningfully enhance access to medicine in the developing world, such as governmental non-commercial use—permitting the government to produce the medicine and to provide it to parts of the population[151].

3.1.2.3.1 BOLAR EXCEPTION IN BRAZIL

Brazilian law 10.196/2001 created a Bolar exception, speeding up the administrative procedures to enable the immediate entry of generic versions of drugs into the pharmaceutical market once patents expire[152].

However, in 2006 a Bill was proposed in Congress (PLS n. 29/2006) requiring whoever requests the registry of a drug within the Brazilian health surveillance agency to prove themselves as the owner of the related patent – a single sentence requirement with a huge impact on access to medicine as it provides a linkage between patent protection and medicine registration. According to CHAVES and REIS, if approved, the Bolar exception would be annulled and this is very compelling evidence of how TRIPS-plus provisions are trying to make their way beyond bilateral or regional free trade agreements in developing countries[153] (further explained in sub-chapter 2.1.3.1). The bill was rejected in 2009[154].

3.1.2.4 POPULAR DRUGSTORE PROGRAM

Another example of a step taken by the Brazilian government to promote access to medicines mentioned by ROSINA, WANG and CAMPOS is the Popular Drugstore Program. . Created by Decree 5.090/04, this measure was originally designed to improve access to essential medicines for patients that use the private health system, as private health insurance policies typically do not cover out-patient drug costs. In practice, however, the program has been widely used by patients when public hospitals fail to provide the medicines on time[155].

The program works both through state-sponsored drugstores and private drugstores that choose to participate. The Ministry of Health buys medicines from private and public industries and the participating drugstores resell them at up to 90% below market prices[156].

There is an ongoing debate over whether the government can establish a program that provides access to medicines at some cost when there is a constitutional right to health granting the right to receiving them at no cost at all. ROSINA, WANG, and CAMPOS concluded that the budget constraint is a reality to be taken into consideration and that it would be detrimental for courts to eliminate initiatives such as the Popular Drugstore Program that fall short of the ideal constitutional expectation of free access, since popular drugstores have been effective in expanding access to medicines, especially for Brazilians with lower incomes[157].

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151 HESTERMEYER, *ibidem*, p. 239.

152 ROSINA, WANG, and CAMPOS, *ibidem*, p. 195.

153 CHAVES and REIS, *ibidem*.

154 Available at http://www.senado.gov.br/atividade/materia/detalhes.asp?p_cod_mate=76662.

155 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 195-197.

156 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 195-197.

3.1.3 COMMENTS ON PATENTS AND DISTRIBUTION

The impact of patents on access is complex[158]. On the one side, the pharmaceutical sector depends on patents to shoulder the high costs of testing, development and approval of goods; in addition, some innovations, as in the case of pharmaceuticals, are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of intellectual property[159]. Moreover, patents requires disclosure, and so facilitate the production of generic versions when the patent term expires. They also provide a more secure environment for the transfer of technology, especially for developing countries, as well as a useful instrument for obtaining finance (venture)[160]. On the other hand, patents may create barriers to the enjoyment of fundamental rights, especially by increasing the price and creating a barrier for generic versions.

HELFER and AUSTIN state that, as a matter of principle, flexibility mechanisms provide breathing space for governments to promote a wide range of objectives that conflict or are in tension with expansive intellectual property protection rules, but they are insufficiently connected to the protection of fundamental rights and freedoms[161]. The WTO interpretation of article 30 of TRIPS Agreement in the Panel Canada-Patent, mentioned in sub-chapter 2.1.2.3, denotes this assertion.

This dilemma of where to strike the balance between protecting intellectual property rights and promoting public access to knowledge is evident in the above case study of patents and access to medicines in Brazil, which reflects the uncertainty and discussion about how to accommodate human rights within the WTO. In fact, there is a constant battle between the adoption of measures towards stricter patent protection and towards greater access to medicines.

3.1.3.1 TRIPS-PLUS

There is a prevailing interference of economic private interest in the arena of intellectual property[162] and this may lead to the adoption of standards of intellectual property protection higher than those required under TRIPS Agreement or to the adoption of measures aimed at reducing the effectiveness of limitations on rights under the TRIPS Agreement[163]. These measures are commonly know as TRIPS-plus and may result from multi-lateral, plurilateral, regional and/or national intellectual property rules and practices and have the effect of increasing the level of protection for patent right holders and reducing the ability of developing countries to protect the public interest, including health,

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157 ROSINA, WANG, and CAMPOS, *ibidem*, pp. 195-197.

158 WHO, WIPO, WTO, *ibidem*, p. 13.

159 HIGH COMMISSIONER, *ibidem*, para. 37.

160 WHO, WIPO, WTO, *ibidem*, p. 13.

161 HELFER and AUSTIN, *ibidem*, pp. 508-509.

162 HELFER and AUSTIN, *ibidem*, p. 505.

163 MUSUNGU and DUTFIELD, *ibidem*, p. 3.

environment, food and nutrition[164]. In other words, the adoption of TRIPS-plus provisions may result in a patent system that is inconsistent with States' responsibilities under human rights law[165].

In fact, there has been an increasing tendency in the arena of intellectual property for countries to enter into economic integration arrangements, such as free trade agreements, bilateral investment treaties and other economic integration arrangements in various bilateral and regional configurations - as those terms overlap, hereinafter the term free trade agreements (FTAs) will refer to any kind of trade agreement[166] -, in parallel with multilateral agreements, a development that is presenting significant systemic challenges for the multilateral system[167] as it impose obligations with respect to patent law that threaten the flexibilities of the TRIPS Agreement that have so fervently been fought for[168].

As HESTERMEZER[169] pointed out, this web of international obligations in the patent field has a triple effect. Firstly, it often obligates developing countries to not make use of the flexibilities of the TRIPS Agreement. Secondly, it commonly imposes minimum patent standards that go well beyond the standards put down in the TRIPS Agreement. Thirdly, its intricate structure involving multiple treaties with slightly different provisions adds to the pro-patent argumentative ammunition of developed countries, discouraging developing countries from using any of the flexibilities to avoid pressure, even where technically they might be allowed to use the flexibilities. HESTERMEZER explains that:

> "[FTAs vary] widely, from merely reiterating TRIPS provisions to explicitly limiting TRIPS flexibilities or imposing additional obligations: eg some FTAs require patent term extension for the factual curtailment of the patent term as a result of the marketing approval process of pharmaceuticals, some the grant of 'new use' patents, others ban parallel imports, limit the grounds for the grant of compulsory licences, or require more extensive protection of test data. Even where these agreements simply re-

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[164] By limiting the ability of these countries to: (i) promote technological innovation and to facilitate the transfer and dissemination of technology; (ii) take necessary measures to protect public health, nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development; or, (iii) take appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort by right holders to practices which unreasonably restrain trade or adversely affect the international transfer of technology. MUSUNGU, Sisule F, and DUTFIELD, Graham. *Multilateral Agreements and a TRIPS-plus World: The World Intellectual Property Organization (WIPO),* 2003. Available at http://www.quno.org/resource/2003/12/multilateral-agreements-and-trips-plus-world-world-intellectual-property, p. 3.

[165] HIGH COMMISSIONER, *ibidem*, para. 27.

[166] "*These agreements have been dubbed regional trade agreements (RTAs), free trade agreements (FTAs), bilateral trade agreements (BTAs), or (the term used in recent reports by the World Bank and the WTO) preferential trade agreements (PTAs), reflecting the fact that many agreements are not "regional" but can cover countries which are geographically dispersed, and that such agreements provide for preferential tariffs on many goods. These terms often overlap, and several can, in effect, apply to the same agreement, depending on the characteristics of the agreement being considered. For the purposes of this study, the term "FTAs" is used in reference to any kind of trade agreement*". WHO, WIPO and WTO, *ibidem*, p. 83.

[167] WHO, WIPO, WTO, *ibidem*, p. 83.

[168] HESTERMEYER, *ibidem*, p. 287.

[169] HESTERMEYER, *ibidem*, pp. 291-292.

> peat TRIPS language, they can limit a country's TRIPS Agreement flexibilities, as the FTAs are interpreted independently of the TRIPS Agreement. Also, decisions taken by the WTO in the context of the TRIPS Agreement, such as the Doha Declaration, (…) are not binding with respect to the FTAs. (...) It is not just the flexibilities already achieved that are at risk, but also the ability to further change and develop the TRIPS Agreement system—at least to the extent that standards are to be weakened".

These kinds of agreements are in general legal and within the margin of appreciation[170] of States. Depending on the situation, however, competition law can play an important role as a potential correcting factor[171].

In its 2012 report on the attainment of the Millennium Development Goals (MDGs)[172], the UN noted that TRIPS flexibilities facilitating local manufacturing and importation of essential medicines appeared to be more broadly incorporated in national laws, but that the use of these flexibilities may be hampered by FTAs[173].

Doctrine illustrates as a clear example of external pressure the Section 301 of the US Trade Act of 1974. As explained in sub-chapter 2.1.1.1, Section 301 proved to be an effective tool in promoting US interests and, regarding the Brazilian access to medicines, it led to the adoption of patent on pharmaceuticals earlier than required under TRIPS Agreement. Sub-chapter 2.1.1.2 introduced patent pipeline, which can be appointed as another example of a measure adopted as a result of political pressure from developed countries or private industries[174]. Other measures mentioned in chapter 2.1, including the prohibition of parallel importation and the bill to annul the Bolar exception, may also be a consequence of trade pressure.

This sort of trade pressure, together with the analysis in chapter 1.2 of the fragmentation of international law and that States tend to abide by the rules of the regime with the strongest enforcement mechanism[175], which, in comparison to human rights fora, is the WTO system, makes the balance of human rights and patent law impaired in practice.

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[170] The term "margin of appreciation" refers to a doctrine of judicial deference developed by the European Court of Human Rights and means the "degree of discretion that a human rights tribunal is willing to grant national decision makers who seek to fulfil their obligations under a human right treaty". HELFER, Laurence R. *Adjudicating Copyright Claims Under the TRIPs Agreement: The Case for a European Human Rights Analogy,* 39 Harvard International Law Journal 357-441 (1998). Available at http://scholarship.law.duke.edu/faculty_scholarship/2020.

[171] WHO, WIPO, WTO, *ibidem*, p. 183.

[172] The MDGs are a set of eight international development goals – all of them related in some way to improving physical, mental and social well-being - to be achieved by 2015. WHO, WIPO, WTO, *ibidem*, p. 42.

[173] WHO, WIPO, WTO, *ibidem*, p. 42. Also, DREYFUSS, *ibidem*, pp. 11-12.

[174] HO, Cynthia, *ibidem*, pp. 229. Also, according to Médecins Sans Frontières, "[p]*ipeline patents are a 'TRIPS Plus' mechanism, that is they introduce intellectual property barriers to accessing affordable medicines over and above what is the international minimum standard".* MÉDECINS SANS FRONTIÈRES, *ibidem.*

[175] HESTERMEYER, *ibidem*, p. 298.

3.1.3.2 REACTION IN ORDER TO IMPROVE ACCESS TO MEDICINES

According to SHAVER, over time, activists fighting to expand access to medicines were joined by other groups with common interests in making products or data available in the public domain, including farmers in the developing world concerned about rights over seeds, educators concerned about access to learning materials and even software developers disturbed by the expansion of patents to computer code, forming a loose movement under the banner of "access to knowledge"[176]. Regarding access to medicines, the pressure from these activists may result, for example, in the adoption of flexibilities permitted under TRIPS, as it was noticed in the case of compulsory licence regarding HIV drugs (sub-chapter 2.1.2.1) and the lawsuit against South Africa regarding the allowance of parallel importation (sub-chapter 2.1.1.3).

Another reaction consists of the creation of alternatives models such as open source (see sub-chapter 2.2) and patent pools[177], as well as measures to stimulate research regarding neglected subjects, such as, among others, grants[178], prizes[179], advance market commitments[180], tax breaks for companies[181], priority review vouchers[182], and a proposal to negotiate an international treaty on research and development (R&D) for neglected diseases[183]. To round up this chapter, an overview of an open source model adopted in Brazil to foster innovation in the biotechnology sector is presented.

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176 SHAVER, *ibidem*, p. 11.

177 See footnote 14.

178 A grant can stimulate small or medium-sized enterprise to finance initial research for a medicine on a neglected disease and bring a potential new medicine through Phase I trials, at which stage it may be possible to attract commercial funding. Grants are paid irrespective of the results achieved. WHO, WIPO, WTO, *ibidem,* p. 117.

179 "*Prizes work as a pull mechanism in R&D by increasing the rewards for success, thereby making investment more attractive and the delivery of a specific product more likely*." WHO, WIPO, WTO, ibidem, p. 117.

180 "*Advance market commitment (AMC) agreements aim to create greater incentives for the R&D of a specific product either through market creation or through risk reduction.*" WHO, WIPO, WTO, ibidem, p. 118.

181 Tax credits for R&D expenditures enables companies to account for expenditure on R&D against their tax liabilities. See WHO, WIPO, WTO, ibidem, p. 118. The US federal Orphan Drug Act, which was introduced in 1983 to address research and development in rare or "orphan" diseases, entitles the company undertaking the research to tax advantages and extended marketing exclusivity. GIBSON, *Intellectual property, medicine and health. Current debates*, Ashgate, 2009, p. 181.

182 "*A priority review voucher (PRV) is a scheme which aims to reward companies that develop health products that address small markets or limited patient groups as is the case also with neglected diseases. The PRV entitles a company to receive priority review (i.e. quicker review by the responsible regulatory authority) for any additional health products that would not otherwise qualify for priority review. A company can use this scheme to advance the marketing date of a potential "blockbuster" product, thus generating increased and earlier revenues from that product*". WHO, WIPO, WTO, *ibidem*, p. 119.

183 See WHO, WIPO, WTO, *ibidem*, p. 119.

3.2 ONSA NETWORK'S GENOMA PROGRAM. INNOVATION PERSPECTIVE

This section presents a case study of São Paulo's "virtual institute" for genomics research: the Organization for Nucleotide Sequencing and Analysis, or ONSA Network, launched in 1997. The case shows Brazil's efforts to stimulate development in an emerging biotechnology sector[184], using an open source model.

Open source models first appeared in the field of software development as a reaction to legal protection[185] and were later adopted in other fields as copyright, biotechnology and drug discovery[186].

Open source drug discovery and development builds on two principles borrowed from open source software development. First, open source drug discovery is based on the idea of collaboration, i.e. organizing and motivating groups of independent researchers to contribute to research projects. Second, it is based on an open approach to patents which makes the outcome of that research generally available, either through the public domain or through the use of customized licences[187].

According to the 2013 WHO, WIPO, WTO Report, the success of open source models in the information technology (e.g. web technology and the Linux operating system) and biotechnology (e.g. human genome sequencing) sectors highlights both the need and the potential to initiate a similar model in health care, such as an open source model for drug discovery. Several open source drug discovery projects are currently under way. Most have secured financing either in the form of government grants or from philanthropic sources. These funds are used to cover administrative expenses and may also be used to fund access to laboratories, computer facilities and payment to researchers[188].

The ONSA Network is an open research model for access to knowledge, which works in the following way: the foundation of the ONSA Network is based on a system of coordination between laboratories, facilitated by public funding[189], with a decentralized decision-making process but working towards a single goal. As OCTAVIANI explains, the membership of this network is open to any researcher who is willing to participate and is granted by a contract between the participating laboratory and the São Paulo State Foundation for Research Assistance (FAPESP). Under the terms of the contract, sequencing laboratories receive DNA material, equipment, training and a specified payment per base pair of finished sequence. In return, members are obliged to share results in a central data repository through the internet, at a prescribed standard of quality, within one year. As soon as a laboratory successfully delivers a sequence, it can apply for a second assignment[190]. How they achieve this sequence is up to the participating laboratory. Each individual laboratory is responsible for its own project management in a democratic organization of production towards a single scientific objective. In this way, the project's

184 SHAVER, *ibidem*, p. 7.

185 MIZUKAMI, Pedro Nicoletti and LEMOS, Ronaldo. *From Free Software to Free Culture: the Emergence of Open Business. in* Access to knowledge in Brazil. Lea Shaver (editor), 2nd edition, Bloomsbury Academia, p. 13.

186 See a model of an Indian open source drug discovery at WHO, WIPO, WTO, *ibidem*, p. 119.

187 WHO, WIPO, WTO, *ibidem*, p. 117.

188 WHO, WIPO, WTO, *ibidem*, p. 117.

189 OCTAVIANI, Alessandro. *Biotechnology in Brazil: Promoting Open Innovation. in Access to knowledge in Brazil. Lea Shaver (editor), 2nd edition, Bloomsbury Academia, 2010,* pp. 136-137.

190 OCTAVIANI, *ibidem*, p. 137.

founders seek to build comparable genomics research capabilities, but at a lower cost and shorter start-up time[191].

To sum up, the ONSA Network is based on three key elements: (i) a research environment stimulated by a state agency in coordination with universities and public funding agencies, (ii) decentralized implementation, and (iii) virtual publication of data via the internet[192].

OCTAVIANI concludes that the ONSA Network empowered peripheral laboratories in two ways:

> "[f]irst, participation in the project was open to laboratories with no previous experience in DNA sequencing. The project funding enabled such laboratories to purchase state-of-the-art DNA sequencing machines, and to train their student technicians in its operation. In this way, research tools and the relevant technical expertise spread throughout the state university system. Second, because the participating laboratories were encouraged to work in tandem on a common project, the joint accomplishments were of a scope that none of the laboratories could have achieved independently"[193].

The accomplishments so far achieved under the ONSA Network are impressive and have helped to forge a reputation for Brazilian science in a field previously dominated by researchers in more developed countries[194]. OCTAVIANI sums up:

> "[i]n 1999 the Genoma Program achieved its original goal, producing the world's first complete genomic sequence of a plant pathogen. (…) Two new goals were set in 1998: sequencing 50,000 sugar cane genes involved in plant development and sugar content and investigating their roles in resistance to diseases and adverse climate and soil conditions. The ONSA Network began its first project with human health applications in 1999. The Human Cancer Genome Project identified one million sequences of Brazil's most frequently-occurring tumors before the end of the following year. The Clinical Cancer Genome Project was later established to develop new diagnosis and treatment methods based on these genetic insights. Soon thereafter, ONSA Network established a project to sequence genes of a parasite responsible for schistosomiasis, an under-researched disease endemic to parts of Brazil. In addition to achieving ever more ambitious sequencing goals, the Genoma Program's objectives in the area of technical capacity-building were also a success[195].

OCTAVIANI also points out that this open research model has since been successfully applied to other public research goals and that its success demonstrates that non-proprietary approaches to scientific research can be highly successful and efficient[196].

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191 OCTAVIANI, *ibidem*, p. 134.
192 OCTAVIANI, *ibidem*, p. 136.
193 OCTAVIANI, *ibidem*, p. 138.
194 OCTAVIANI, *ibidem*, p. 138.
195 OCTAVIANI, *ibidem*, p. 135.
196 OCTAVIANI, *ibidem*, p. 141.

In fact, the role of the patent system in developing a new medical technology depends not only on legislative and regulatory settings, but also on a variety of choices made by individuals, from a public-sector research programme or a private-sector company, at different stages of the development process, as to whether and when to obtain patent rights, and how to exercise them. They may rely on exclusive commercial positions, or may draw from a range of nonexclusive and open licensing structures, waivers of rights and specific non-assertion undertakings[197].

3.2.1 COMMENTS ON PATENTS AND INNOVATION

3.2.1.1 PATENTS AND PUBLIC FUNDED RESEARCHES

Considering that patents are limited commercial rights and that they are essentially driven towards economic reward[198], as studied in the first part of this work (sub-chapter 1.1), there is an ongoing discussion if patent protection should be granted to research conducted in public universities/organisations or with public funding, or if an open research model would be more suitable for the purpose of promoting innovation[199].

In reviewing the patent system in the context of the broad sweep of innovation policies, the 2013 WHO, WIPO, WTO Report distinguishes three mechanisms for promoting innovation: (i) publicly funded innovation carried out by academic institutions and public research organizations; (ii) publicly funded research undertaken by private firms – notably through public procurement, research subsidies, soft loans, R&D tax credits and innovation prizes; (iii) privately financed and executed R&D, financed through the marketplace rather than government revenues and incentivized through the patent system, which is one mechanism of government policy that promotes innovation[200].

In the pharmaceutical sector there has been significant interaction between universities and public institutions, which carries out the basic research, and the private sector, which develops and commercializes medicines based on this research[201], and it is not easy to distinguish when the public sphere ends and the private starts. Moreover, while open source initiatives seem ideally suited to promote pre-competitive research, they do not as yet have the capacity to ensure delivery of finished health products to patients or to ensure that products are steered through costly development phases. As a consequence, open source initiatives have had only a minor impact on public health[202].

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197 WHO, WIPO, WTO, *ibidem*, p. 126.

198 HIGH COMMISSIONER, *ibidem*, para. 38.

199 The events surrounding HIV/AIDS medication served as a catalyst for the debate once, despite the fact that much of the research for the first AIDS drug AZT was conducted by publicly funded institutions, a private corporation obtained patents in many countries for the use of AZT in the treatment of AIDS. HESTERMEYER, *ibidem*, p. 293. In fact, "*[t]he fact that BW could obtain a patent on the use of AZT in AIDS treatment seems surprising considering that the compound was synthesized by Horwitz with US public funding, tested for antiretroviral activity by Ostertag with German public funding and tested for activity against HIV by the NCI, again with US public funding".* HESTERMEYER, *ibidem*, p. 6.

200 WHO, WIPO, WTO, *ibidem*, p. 108.

201 WHO, WIPO, WTO, *ibidem*, p. 106.

202 WHO, WIPO, WTO, *ibidem*, p. 117.

In the lawmaking sphere the tendency is towards the extension of patents to universities and government institutions. In this regard, it is worth mentioning as an example of greater patent protection Brazil's 2004 Innovation Law. This was inspired by the U.S. Bayh-Dole Act 5[203], which actively encouraged university researchers to seek and commercially exploit patents on their academic discoveries[204], as well as affirmed the rights of universities and other public-sector researchers over research resulting from external federal funding[205]. A number of universities have developed extensive patents portfolios and many of the new companies focusing on biotechnology are originally spin-offs from universities[206].

DREYFUSS mentions scholars who turned their attention to licensing limitations in an attempt to deal with the tendency to extend patents. As an example, Yochai Benkler and his coauthors have worked on a solution against the increasing tendency of universities to patent work that would previously have gone into the public domain. They advocate something called "Equitable Access" licensing: universities could continue to patent, but they would be obliged to require licenses to engage in various public interest related activities. Geertrui Van Overwalle suggests that universities should engage in "two tiered" or "dual" licensing, where they would modify their royalty schemes according to the status of the licensee or its intended use: license out their technology cheaply if the use was for humanitarian or developmental purposes, while charging commercial entities much more[207]. But the practical and political feasibly of such solutions are questionable.

3.2.1.2 UNDUE RESTRICTIONS ON RESEARCH

The UN High Commissioner added that the grant and exercise of intellectual property can lead to undue restrictions on medical research, which could run contrary to the requirement under article 15 of the ICESCR to balance the protection of private interests with the promotion of the wide dissemination of medical knowledge. It was mentioned, in particular, that the practice of granting broad patents can lead to patents being used to block research efforts. This issue is relevant where research into a final product or process relies on several levels of innovation, all of which are susceptible to patent protection. In such cases, patents on innovations from the early stages of research can be used to control and possibly block life-saving innovations that depend on the use of the first innovation.

This issue has become particularly prevalent in the area of biomedical research[208] and brings one more argument in favour of an open access model for new fields of research. In this connection, DREYFUSS[209] mentions a study by SAFRIN, in which it was stated that patent rights in sequences of small fragments of genes are controversial because very little real work is needed to find them, very little is known about what they do even after their genetic sequence is determined, and yet their scope can be quite broad. Research efforts relating to them risk being blocked by a patent. For SAFRIN, banning

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[203] See, e.g., Bayh Dole Act, 35 U.S.C. §§ 200-212 (2000), leading case in the US on permitting universities to own patent rights in federally funded research.

[204] DREYFUSS, *ibidem*, p. 11.

[205] GIBSON, *ibidem,* p. 180.

[206] WHO, WIPO, WTO, *ibidem,* p. 106.

[207] DREYFUSS, *ibidem*, p. 17-18.

[208] HIGH COMMISSIONER, *ibidem*, para. 40.

[209] DREYFUSS, *ibidem*, p. 17

patents on this subject manner would therefore be very welcome[210]. Accordingly, the 2013 WHO, WIPO, WTO Report mentioned that it is unclear whether the patent system provides incentives for invention that is far from market application, such as basic science research[211].

Moreover, according to the UN High Commissioner, the WHO has identified situations where standards for the grant of patents can contribute to ever-greening, a process where minor innovations to patented innovations are themselves patented, which can effectively extend the life of the patent beyond the original granted period and hold up other research efforts[212], as already mentioned in section 2.1.2.2.

3.2.1.3 UNPROTECTED TRADITIONAL KNOWLEDGE

The UN High Commissioner also highlighted that traditional medicines play an important role in the health care of all countries, and that while existing patent systems can promote the health care innovations of these communities, the particular nature of this knowledge and of the knowledge holders might require significant adaptation or amendments to be made to intellectual property legislation for protection to be comprehensive since traditional medicines have been appropriated, adapted and patented with little or no compensation to the original knowledge holders and without their prior consent[213].

3.2.1.4 ORPHAN DISEASES

Another concern is that in a purely patented model, innovations that might be important - from a human rights rather than a business perspective - are less likely to be pursued. In this regard, innovation in medical technologies for neglected diseases[214] suffers from market failure as conventional patent-based incentives do not correspond with the nature of demand for treatments of these diseases. A key factor is the limited purchasing power of both governments and patients in the countries where such diseases predominate[215].

These "orphan drugs", most of then tropical and subtropical diseases of developing countries[216], in particular tuberculosis and malaria[217], as well as their development and improvement, are a key concern for the WHO, according to which: *"questions remain as to whether the patent system will ensure investment for medicines needed by the poor. Of the 1,223 new chemical entities developed between 1975 and 1996, only 11 were for the treatment of tropical diseases*"[218].

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210 SAFRIN, Sabrina. *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*. American Journal of International Law, Vol. 98, October 2004; American Journal of International Law, Vol. 98, October 2004. Available at SSRN: http://ssrn.com/abstract=658421.

211 WHO, WIPO, WTO, *ibidem*, p. 108.

212 HIGH COMMISSIONER, *ibidem*, para. 40

213 HIGH COMMISSIONER, *ibidem*, para. 26, 40-51.

214 Rare diseases or where the market for suitable medicines and treatments is small. GIBSON, *ibidem*, p. 181.

215 WHO, WIPO, WTO, *ibidem*, p. 115.

216 GIBSON, *ibidem*, p. 181.

217 HIGH COMMISSIONER, *ibidem*, para. 38 and 44.

218 HIGH COMMISSIONER, *ibidem*, para. 44.

As previously mentioned, some measures have been adopted to address neglected diseases such as open source drug discovery and development, grants, prizes, advance market commitments, tax breaks for companies, patent pools and priority review vouchers[219]. However, theses initiatives have had only a minor impact on public health - as explained in sub-chapter 2.2.1.1 - especially in developing countries.

[219] WHO, WIPO, WTO, *ibidem*, pp. 116-119. See footnotes 178 to 183.

4 TOWARDS SOLVING THE PROBLEM

As explained in the first part of this work, according to WTO jurisprudence, non-WTO treaties and general international law can be used merely as an aid for interpreting the covered agreements, as long as they do not contradict WTO agreements. In addition, where human rights law is in conflict with WTO law, states will tend to abide by the rulings of WTO dispute settlement organs due to its more effective enforcement mechanism in comparison to the human rights system. In conclusion, the balance between human rights and patent law is in practice impaired.

In addition, the intellectual property regime of some WTO members is strongly shaped by global regulations, particularly the terms of the TRIPS Agreement[220]. The case "Pharmaceutical Patents on Access to Medicines in Brazil" illustrates the impact of the TRIPS Agreement in the Brazilian health care system and how the country struggles to balance the compliance with TRIPS with the maintenance of its health care system. Considering the current international scenario, a WTO member cannot merely rely on the right to access to medicine as a defence against a claim of violation of WTO law absent a basis for the defence in the covered agreements[221].

Considering these findings, according to HESTERMEYER[222], a first step solution to the conflict between the TRIPS Agreement and access to medicine — at the core a conflict between WTO and human rights law— can only be achieved by giving human rights law a stronger status within the WTO system[223].

But how could the WTO Agreements better accommodate human rights? The UN High Commissioner stated that an important aspect of the human rights approach to intellectual property protection is the express linkage of human rights in relevant legislation. This would clearly link States' obligations under international trade law and human rights law. The UN High Commissioner then concluded that this would assist States to implement the "permitted exceptions" in the TRIPS Agreement in line with their obligations under the ICESCR[224].

According to HESTERMEYER, such an amendment could take the form of a WTO human rights treaty or it could include the ICCPR and the ICESCR by reference, or the creation of an exception allowing members to break TRIPS obligations to protect human rights. Moreover, much like in national systems, human rights provisions could be endowed with a superior status, allowing them to prevail over traditional WTO law in case of a conflict[225]. However, the negotiations of the Doha Declaration showed that the political feasibility of the above mentioned initiatives is questionable, as political opposition prevents endowing the human rights regime with a stronger enforcement mechanism[226].

Considering the these difficulties, HESTERMEYER concludes that a less ambitious and most likely

[220] OCTAVIANI, *ibidem*, p. 145.

[221] HESTERMEYER, *ibidem,* p. 300.

[222] HESTERMEYER, *ibidem*, p. 287.

[223] HESTERMEYER, *ibidem*, p. 287.

[224] HIGH COMMISSIONER, *ibidem*, para. 68.

[225] HESTERMEYER, *ibidem*, p. 287.

[226] HESTERMEYER, *ibidem*, p. 288.

route for the importation of human rights law into WTO law is through WTO jurisprudence[227]. The author maintains that it is time for WTO jurisprudence to step in and start using human rights law in the interpretation of the WTO Agreements[228].

Another argument is that WTO dispute settlement and WTO members are not entirely free to decide to which extent TRIPS flexibilities are going to be adopted or to which extent patent rules shall be interpreted in accordance to human rights approach. The CESCR, in its General Comment No. 17, expressed its view that parties are obliged to strike an adequate balance whereby the private interests of authors should not be unduly favoured but adequately balanced with the interest of the public in enjoying broad access to their productions. The CESCR states that, ultimately, intellectual property is a social product and has a social function and parties thus have a duty to prevent unreasonably high costs for access to essential medicines[229].

Accordingly, resolutions of the United Nations Human Rights Council[230] call upon member states to promote access to medicines, including through the full use of the TRIPS Agreement and the flexibilities it provides.

In this sense, the Doha Declaration has served as a catalyst for developing coherence at the international level. It made public health issues a central focus of work carried out by the WTO on intellectual property and international trade and supported WTO members to use, to the full, the provisions in the TRIPS Agreement for the purpose of promoting access to medicines for all[231].

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[227] The security exception of article 73 of the TRIPS Agreement could provide an entry for human rights concerns. "*Relying on a modern, broad definition of security that includes large-scale threats to human rights, a WTO panel can invoke the provision to allow Members facing public health crises including India and Brazil to refuse the grant of patents for drugs to treat pandemics altogether. Such a holding would ensure that generics to treat pandemics remain available—even if the medicine is still under patent protection in the developed world*". HESTERMEYER, *ibidem*, p. 289.

[228] HESTERMEYER pointed out that is well worth remembering that in the European Union human rights were imported via the judiciary too. "*The treaties of the European Communities did not provide for human rights protection. It was the European Court of Justice (ECJ) that began to apply fundamental rights as general principles of law, drawing inspiration from member states' constitutions and international treaties on which the member states collaborated. WTO panels could follow the example and apply human rights provisions as part of general international law, which (...) includes access to medicines"*. HESTERMEYER, *ibidem*, p. 288.

[229] WHO, WIPO, WTO, *ibidem*, p. 41.

[230] Resolution on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the context of development and access to medicines: A/HRC/RES/17/14; Resolution on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health: A/HRC/RES/15/22; Resolution on access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health: A/HRC/RES/12/24; Reports of the Secretary-General on access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria: A/HRC/7/30, E/CN.4/2006/39, E/CN.4/2005/38, E/CN.4/2003/48.

[231] WHO, WIPO, WTO, *ibidem*, p. 19 and 73.

5 CONCLUSION

The pharmaceutical sector stands out in terms of its dependence on patents primarily to shoulder high costs of testing, developing and approving goods, and because some innovations, as in the case of pharmaceuticals, are generally relatively easy to reverse-engineer and thus are open to easy copying in the absence of intellectual property[232]. Moreover, the protection and enforcement of intellectual property can provide a more secure environment for the transfer of technology, especially for developing countries and also be a useful instrument for obtaining finance (venture)[233].

However, intellectual property may also create barriers to the enjoyment of fundamental rights. It provides a basis for charging higher prices for drugs and for technology transfer, which can restrict access[234]. Besides, it may cause undue restrictions on research.

Therefore, the question that remains is how to strike the right balance between protecting intellectual property rights and promoting public access to knowledge[235]. Considering this dilemma, the first part of this work gave a general overview of how the WTO deals with human rights. Briefly, it was explained that the TRIPS agreement was designed under a functional approach and that it did not take a human rights approach on its inception, thus giving emphasis to patent law rather then pursue the balance between these competing regimes. Moreover, according to WTO jurisprudence, non-WTO treaties and general international law can be used merely as an aid for interpreting the covered agreements, as long as they do not contradict WTO agreements. They are not part of the applicable law nor can prevail over a WTO covered agreement. Because of these findings and because access to medicine is not undoubtedly understood as a *jus cogens*, a WTO member cannot rely on the right to access to medicine as a defence against a claim of violation of WTO law, absent a basis for the defence in the covered agreements[236].

In addition, where human rights law is in conflict with WTO law, states will tend to abide by the rulings of WTO dispute settlement organs due to its effective enforcement mechanism, whereas the human rights regime has a rather weak enforcement mechanism at the international level. To aggravate the situation further, there is a prevailing interference of economic and private interests and international pressure on WTO members leading to the adoption of measures not required by TRIPS that are in opposition to public health concerns. In conclusion, the balance between human rights and patent law is in practice impaired.

The second part engaged in a empirical analysis of two Brazilian case studies: "Pharmaceutical Patents on Access to Medicines" and "ONSA Network's Genoma Program", in order to demonstrate how the Brazilian health system was affect by the TRIPS Agreement and the consequences of it.

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232 HIGH COMMISSIONER, *ibidem*, para. 37.

233 WHO, WIPO, WTO, *ibidem*, p. 13.

234 In particular, as added by the UN High Commissioner, the World Bank has noted that intellectual property rights can sometimes prevent the distribution of potential international public goods helpful to poor countries, which can seldom afford the prices charged by patent owners. HIGH COMMISSIONER, *ibidem*, para. 42.

235 DUNCAN, *ibidem*.

236 HESTERMEYER, *ibidem,* p. 300.

The case “Pharmaceutical Patents on Access to Medicines in Brazil” illustrates the dilemma of, on the one hand, protecting intellectual property rights, with the adoption, by Brazilian legislators, of early implementation, patent pipeline and the prohibition of parallel importation; and, on the other hand, promoting public access, with the adoption of counter-measures to increase the access to medicines and to mitigate the effects of TRIPS, namely compulsory licenses, the prior consent mechanism, the Bolar exception and the Popular Drugstore Program. It was also pointed out examples of interference of economic private interests in the arena of intellectual property, leading to measures that go beyond the TRIPS Agreement’s minimum standards.

Another example of a measure aimed at mitigating the effects of the patent system is the second case study, namely, the “Brazilian ONSA Network’s Genoma Program”. The ONSA Network is an open source model based on a collaborative and open approach to innovation, with the outcome of making research available in the public domain. The case denotes that under certain circumstances, for example research conducted within public institutions, an alternative model - free from the patent law's restrictions . can be more suitable. Open source initiatives, however, require a legal construction and the agreement (waiver of rights) of all possible patent holders. Considering that in the pharmaceutical sector there is usually a joint participation of public funding and private companies in order to deliver a finished health product, private corporations may not agree to waive their patent rights. Therefore, so far, open source models have had only a minor impact on public health. The appropriateness by private companies of patents which resulted from public funded research, and other issues such as undue restrictions on research, unwillingness to focus on orphan diseases and unprotected traditional knowledge, are still waiting for a better solution.

To sum up, both the first and second part of this work denotes that the balance between human rights and patent law is in practice impaired. As so, there are, in the first instance, calls for the international trading system to give greater consideration to human rights concerns in order to provide WTO members with a more secure basis to, relying on the right to health, adopt measures that may be in detriment to patent law.

Some scholars have suggested possible solutions but the practical and political feasibility is a great barrier. As a first step, a less ambitious and most likely route for the importation of human rights law into WTO law is through WTO jurisprudence. In this regard, the WTO should step in and start using human rights law in the interpretation of its rules in line with the understanding that intellectual property is a social product and has a social function and parties thus have a duty to balance the interest of the patent holders with the interest of the public in enjoying broad access to their products.

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