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The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on TRIPS and Public Health: Will They Solve the Pharmaceutical Question?

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Introduction.:

The Agreement in Trade-Related Intellectual Property Rights (the TRIPs Agreement) transformed the standing of intellectual property in international law by incorporating into the legal framework of the World Trade Organization (WTO) an improved system of standards for the protection of a full range of intellectual property (IP) rights, including copyrights, patents, trademarks, industrial designs, trade secrets and geographical indications.

In reality, the IP protection framework under the WTO was designed to harmonize basic intellectual property standards in a way to promote investments in innovation, mitigating the increasing risks of unjustified 'free riding' in a globalized market economy. Thus far, this system of IP protection has produced great results in some areas. For instance, it successfully enhanced the protections of geographical indications and safeguards for trademark owners. It has also substantially elevated the returns of technology-exporting countries, and it has done so in a way that leaves incentives and opportunities for entrepreneurs in developing countries who might eventually become capable of competitively producing and exporting highly-valued goods.

However, these same harmonized IP standards have also produced morally contested results. For instance, they are often accused of having impaired the ability of less affluent members of the society to access suppliers in crucial areas such as health care and nutrition. Some go even beyond that, stating that what was intended to improve a rudimentary system of intellectual property has in fact imposed insidious difficulties to the most basic progress of Least Developed Countries (LDCs) and has, furthermore, set forth even higher barriers to the entrance of developing countries to a few important markets.

Nowhere, however, have these conflicting opinions reached a higher level of tension than within the pharmaceutical sector. The TRIPs Agreement has been accused of exerting a negative influence on the implementation of domestic public health policies in several WTO

developing country members. Conforming to TRIPs and, consequently, strengthening the position of pharmaceuticals products with intellectual property, has imposed a substantial challenge for many countries and worsened the access to medicines for the poorest. This situation provoked a very clear reaction worldwide. In fact, public opinion has never advocated so intensely for a change in an international legal regime as it recently has with TRIPs.

This conflicting relation is the product of different understandings of the IP protection regime. The pharmaceutical industry, on the one hand, understands that this system of strict IP protection is absolutely necessary as it grants them the exclusivity needed for the commercialization of certain products and thus incentivizes research and development (R&D) of drugs, including those focused on the needs of the world's poorest. They claim that neglecting their most genuine interests in reality makes the access to crucial medicines much harder for the poorest countries. Developing countries, on the other hand, defend the maintenance of a system of IP protection that also understands their limitations, constitutional duties and, most importantly, the most imminent needs of their population. These countries support TRIPs, but they argue for some flexibility in its interpretation.

The Declaration on the TRIPs Agreement and Public Health made at the Doha Ministerial Conference (the Doha Declaration) attempted to respond to this international demand by clarifying the flexibility of the agreement. It intended to offer a solution that would satisfy both developing and developed countries, resolving the pharmaceutical question on a permanent basis. The Doha Declaration thus affirmed that TRIPs authorizes developing countries to implement domestic public policies in the area of public health, despite the tougher standards now enforceable under international intellectual property law.

Even though the Doha Declaration addressed fundamental points for the future of IP protection in the area of Public Health, it failed in simplifying the existing legal regime for the

granting of compulsory licenses, which is the most relevant mechanism for ensuring the access to affordable medicines worldwide. It also failed to tailor the system to the needs of the poorest countries. The lack of legal certainty on these matters has recently caused panic in the pharmaceutical industry. The implementation of measures supposedly covered by the public health policy exception under the TRIPs framework in countries such as Brazil and Thailand caused the fury of developed countries, revealing the opportunities and risks associated with the usage of this system by developing countries.

This paper intends, therefore, to offer the reader an analysis of the impact of the TRIPs agreement on the access to medicines in developing countries. More specifically, this dissertation aims to elucidate and explain the existing legal regime regulating the grant of compulsory licenses by developing countries for the implementation of domestic programs in the area of public health after the Doha Declaration. This legal examination will be followed by an interesting policy-oriented analysis. In this part of the paper, the cases of Rwanda, Brazil and Thailand will be properly addressed. The intention is to provide an opinion about the system that is currently in place and to analyze whether the Doha Declaration and sequential actions were able to put an end to what was referred to as "The Pharmaceutical Question". Finally, the paper will offer a few ideas for making this system work better.

1.: The TRIPS Agreement – Historical Roots and Coverage

The *Agreement on Trade-Related Aspects of Intellectual Property Rights* is probably the most innovative of the WTO agreements. Whilst references to intellectual property rights were part of the framework of GATT 1947[1], the TRIPs agreement was the first to impose on Members a set of positive obligations to guarantee a minimum level of protection and enforcement of IP rights in their respective borders and territories.

The inclusion of a system for the protection of IP rights in the legal framework of the WTO proved to be necessary for several reasons. To start, it is undeniable that trade and intellectual property are closely connected. For instance, the chance that traded products may be copied, or brand names inappropriately used by competitors clearly constitutes disincentives to investments in innovation and the development of better and cheaper products[2]. These possibilities may also affect trade liberalization if IP rights related to traded goods and services are not minimally protected worldwide.

In addition, the negotiations and the consequent entry into force of the TRIPs agreement were related to the historical failure of international agreements to properly address IP rights. International treaties before TRIPs were highly ineffective, lacking a congruent enforcement mechanism[3]. The TRIPs agreement was then negotiated to address these specific problems.

Regarding this last point, Peter Van den Bossche explains that:

> "*The TRIPS Agreement builds upon the standards of IP protection developed in the context of the World Intellectual Property Organization (WIPO) and embodied in its conventions. It does so by incorporating by reference specific provisions of the relevant conventions, namely the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the IPIC Treaty. The obligations of the TRIPS agreement must therefore be read together with relevant WIPO conventions. However, the TRIPS Agreement does more than simply incorporate the provisions of these*

[1] Peter Van Den Bossche, *The Law and Policy of the World Trade Organization,* 2nd ed. (New York: Cambridge University Press, 2008), 742.
[2] Ibid. 743
[3] Edwin L.-C. Lai, "Was Global Patent Protection Too Weak Before Trips?", *City University of Hong Kong Working Paper,* 1, no.1, (2005): 28.

> *conventions. It supplements and updates the rules of relevant WIPO conventions, as well as expressly providing new rules in some areas. In addition, and more importantly, it creates an obligation on Members to have a system in place for the enforcement of the protected IP rights and links them to the effective and enforceable dispute settlement system of the WTO.[4]"*

The TRIPs agreement, however, does not cover all forms of IP rights. In fact, it applies exclusively to those modalities expressly mentioned in Sections 1 to 7 of this agreement, and a few other forms incorporated through the absorption of those other WIPO conventions. *President Clinton's Submission to Congress of Documents Concerning Uruguay Round Agreements* expressly addresses this topic. In that document, it is clear that "*The intellectual property rights covered by this agreement are: copyrights, patents, trademarks, industrial designs, trade secrets, integrated circuits (semiconductor chips) and geographical indications[5]".*

In terms of applicability, it is possible to say that the TRIPs agreement embodies a few important concepts. For instance, it does not apply retroactively to any acts that occurred before a certain "date of application" for a given Member[6]. However, subject matters that subsisted at that moment are covered[7]. The agreement also creates positive obligations for Members[8]. These states are obliged to give effect to the provisions of TRIPs, but they are free to determine the right method for implementing these measures[9]. It does not, however, require that Members implement more extensive protections than those expressly required[10]. For this reason, it is often said that the TRIPs agreement set up, for the first time, a minimum level of harmonized IP protection worldwide.

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[4] Peter Van Den Bossche, *The Law and Policy of the World Trade Organization,* 2nd ed. (New York: Cambridge University Press, 2008), 885.
[5] Ralph H. Folsom e*t alia*, *International Business Transactions,* 8th ed. (St. Paul: Thomson West, 2005), 881.
[6] *See* Article 70.1 of the TRIPs Agreement.
[7] *See* Article 70.2 of the TRIPs Agreement.
[8] *See* Article 1.1 of the TRIPs Agreement.
[9] Ibid.
[10] Ibid.

The TRIPs agreement also contains a wide variety of principles and rules. It includes, for example, the common WTO non-discrimination obligations of national treatment[11] and most favoured nation (MFN) treatment[12]. Actually, it does so by taking into account the intangible nature of IP rights. Therefore, instead of "like-products" or "like-services", the term "nationals"[13] plays a fundamental role. It also stipulates concrete minimum standards of IP protection and enforcement in national territories[14]. Moreover, it deals with procedural aspects for the acquisition and maintenance of IP rights[15] as well as rules with regards to transparency[16] and dispute settlement[17]. Finally, it created the council for TRIPs[18] in order to allow members to consult on matters pertaining to the agreement.

Given that the level of development of WTO Members varies substantially, the TRIPs agreement specifically acknowledges the difficulties that developing-country Members may face in fully implementing the obligations set out therein. For this reason, important mechanisms were put in place to help Members in their transition towards TRIPs compliance. For instance, transitional periods[19] were established and provisions for technical cooperation[20] were also implemented.

In reality, these provisions intended to address the need for balancing the competing interests of IP rights owners on the one hand, and the interests of less developed countries and the general public on the other. TRIPs was essentially drafted to set up a minimum level of IP protection within the WTO, but it also meant to prevent abuses from IP owners.

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[11] *See* Article 3 of the TRIPs Agreement.
[12] *See* Article 4 of the TRIPs Agreement.
[13] As defined in Article 1.3 of the TRIPs Agreement.
[14] Part II of the TRIPs Agreement contains the mandatory minimum standards of IP Protection that Members are obliged to ensure in their territories and Part III the rules on enforcement.
[15] *See* Part IV of the TRIPs Agreement.
[16] *See* Article 63 of the TRIPs Agreement.
[17] *See* Article 64 of the TRIPs Agreement.
[18] *See* Article 68 of the TRIPs Agreement.
[19] *See* Article 65 of the TRIPs Agreement.
[20] *See* Article 67 of the TRIPs Agreement.

Whether TRIPs has indeed succeeded in achieving its objective of preventing abuses from IP owners is, however, highly questionable. Recent divergences involving important developing countries on the one hand, and private companies in the pharmaceutical industry on the other, have shed light on this specific problem.

On this point, the scholarship of Frederick Abbot is elucidative:

> *"Less obvious, and often more insidious, are the difficulties and social costs that higher intellectual property standards under TRIPS and later FTAs* [Free Trade Agreements] *have created for developing country governments' abilities to maintain the supply of such basic public goods as nutrition and agriculture, education, public health, environmental safety, scientific research and industrial policy (including the maintenance of a competitive rather than a command economy, where so desired). While these countries have unquestionably benefited from a shift to more open markets in the past two decades, their traditional responsibilities for the provision of essential public goods— already limited by a lack of resources and the relative poverty of their citizenries—has been further hampered by the adverse exercise of private rights in technical inputs and in other indispensable knowledge goods that were formerly unprotected, or in the public domain, or otherwise available at lower, more competitive prices.*[21]*"*

For these reasons, it is often said that TRIPs may have impaired the ability of developing countries to implement individual public health policies within their territories. Even though this agreement has been successful in establishing an innovative IP protection system worldwide, it has also fomented inequalities in sectors that are critical for the development of poor countries. Given the importance of this issue for the present analysis, the next part of this paper will cover this specific issue in depth.

1.1.: The Impact of TRIPs on the Access to Medicines in Developing Countries:

Historically, developing country governments have been able to use their discretionary power to regulate public health. Even though the Paris Convention for the Protection of Industrial Property of 1883 (one of the conventions incorporated by the TRIPs agreement) contained provisions concerning patented inventions, international intellectual property law has never constituted a barrier for the implementation of public health programs worldwide.

[21] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 925.

In fact, states were to a great extent free to structure and set up their own patent systems and, as many chose to do, even to deny any patent protection for pharmaceutical products whatsoever.

Regarding this trend, John Barton made valid comments:

> *"A number of developing countries, however, viewed patent law quite differently and deliberately decided to deny patent protection to pharmaceutical products and to grant protection only to processes for producing pharmaceuticals. These countries believe that access to pharmaceutical products is so important that the products themselves should not be patented. The products would be developed anyway for the market in developed countries, and the market in developing countries is so small that it would not provide adequate incentive to develop new products.*[22]"

Under that regime of IP protection, the ability of these countries to access medicines was mostly impaired by their national production capabilities, some specific policies related to public health and their general financial resources. A few other factors were also relevant, including the ability of generic suppliers to successfully develop alternative drugs, the availability of important pharmaceutical ingredients for this industry and, to a larger extent, the pricing policies of the big pharmaceutical companies.

The lack of protection of intellectual property, nevertheless, was not only a pressure relief for developing countries in the area of public health. In reality, this situation also created problems. It is impossible to deny that poor countries' inability to minimally protect the interests of the research-based pharmaceutical industries may have caused their failure to invest in R&D directed at diseases that primarily afflicted the poorer. If, on the one hand, these countries were able to implement public health programs based on their own necessities, regardless of the cost with intellectual property rights, their most eminent needs, on the other hand, were also being neglected by the pharmaceutical industry[23].

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[22] John H. Barton, "TRIPS and the Global Pharmaceutical Market", *Health Affairs*, 23, no. 3 (2004): 146.
[23] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 928.

Regarding this last point, the lessons of Patricia Danzon and Adrian Towse are very elucidative:

> *"Developing Countries (DCs) have two primary needs in access to medicines. The first is access to medicines that target diseases that are prevalent in both high and low income countries at prices DCs can afford, with distribution systems and health care infrastructure to assure effective use. The second need is for development of new medicines to treat diseases that exist primarily in DCs. At the center of the international debate over improving DC access to medicines is the role of patents. Patents are generally considered necessary to encourage R&D, particularly in an R&D-intensive industry such as pharmaceuticals.[24]"*

Nevertheless, the attractiveness of this earlier system of IP protection, from the viewpoint of developing economies, was substantially enhanced after a few middle-income countries built the capacity to produce low-cost generic medicines on a large scale. The establishment of an alternative pharmaceutical industry in places such as Argentina, Brazil, India, Thailand and South Korea made several important low-cost generic medicines widely available, usually at prices affordable even for very poor countries. It also fostered research in those countries. The caveat, at the time, was that most of these generics drugs that were being produced did not respect patents.

This former IP regime was, obviously, profoundly impacted by the entry into force of the TRIPs agreement[25]. More precisely, with the end of the transitional periods for middle income countries in 2005, most producers of low-cost generic medicines would became liable for adopting and enforcing a wide variety of patent protections. The production of generics on an "off patent" basis, for that reason, would be severely threatened if not made impossible at all.

This transition in regimes of IP protection with regard to the pharmaceutical issue was well addressed by Frederick Abbot and Jerome Reichman:

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[24] Patricia M. Danzon and Adrian Towse, "Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents", *International Journal of Health Care Finance and Economics* 3, no. 3 (2003): 183 – 184.
[25] Jessica J. Fayerman, "The spirit of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement", Northwestern Journal of International Law & Business, 25, no.1 (2004): 276.

> "*With the passage of time (and the opening of 'mail boxes' holding pharmaceutical patent applications during the transitional periods), more and more essential medicines (for example, the so-called second- and third-line HIV drugs) will be on patent in all countries capable of supplying them to the world market, at least until the relevant patents expire in those countries. (...) The availability of these drugs will thus depend on the pricing strategies of patent holders and on the countervailing regulatory measures states may adopt to influence them. Moreover, further efforts to tighten international intellectual property standards continue today under the Substantive Patent Law Treaty (SPLT) negotiations ongoing at The World Intellectual Property Organization (WIPO), and especially under Free Trade Agreements and Bilateral Trade Agreements, which adversely affect ministries of health. These ministries have little influence on intellectual property-related negotiations, conducted between trade negotiators, and they often remain powerless to modify or block problematic demands in response to 'take it or leave it' tactics*[26]."

This shift from a morally contested but highly permissive IP protection regime to a system characterized by tougher protections of IP rights has, therefore, impacted the ability of LDCs and Developing Countries to freely and costlessly implement programs in the area of public health. The result was that the poorest countries had their access to generic medicines — especially those focused on their critical diseases – strictly limited. This situation provoked a strong reaction from many WTO members, but also from outsiders such as the media, important academics and NGOs.

Regarding the pressure made by the civil society, Asia Russell categorically affirmed that:

> "*Soaring death tolls, and three years of AIDS and healthcare activists' sustained campaigning, has drawn attention to the public health consequences of strict patent protection. [...] Public health advocates have pointed to the critical importance of using the TRIPS Agreement's so-called safeguards -- measures designed to remedy undesirable potential outcomes from protection of intellectual property rights. An important TRIPS safeguard is "compulsory licensing," whereby a government can license the production of medicine to a third party (for example, a generic drug manufacturer) without the consent of the patent holder. Compulsory licensing breaks up a patent monopoly and prices fall as a result*[27]".

In response to these pressures, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPs Agreement and Public Health (the Doha Declaration) in November

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[26] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 928-929.

[27] Asia Russell, "Victory and Betrayal: The Third World Takes on the Rich Countries in the Struggle for Access to Medicines *Russell", Multinational Monitor,* 23, no. 6 (2002): 13

2001[28] to clarify the legal regime available to countervail that problem. This Declaration, actually, "*(...) reconfirmed many of the so-called flexibilities built into the TRIPS Agreement, including the right of Members to issue compulsory licenses on public-interest grounds. The Declaration then provided the mandate for amplifying existing flexibilities by establishing legal machinery to enable countries lacking the capacity to manufacture generic substitutes for costly patented medicines under domestically issued compulsory licenses to obtain imports from countries able and willing to assist them without interference from the relevant patent holders.*[29]"

The minutiae of the system of compulsory licensing as well as the achievements of the Doha Declaration in the area of public health, nonetheless, will be better discussed within the next topic of this paper.

2.: The Legal Framework for the Granting of Compulsory Licenses after the Doha Declaration:

As already stated, the TRIPs agreement was also drafted to prevent abuses that could potentially arise in a regime characterized by the highest standards of IP protection. This is the main reason why important exceptions to the exclusive rights conferred by a patent were embodied in this agreement. For instance, while Article 28 of TRIPs recognized that a patent holder shall have the exclusive right *"to prevent third parts not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for that purposes that product*", Article 31 of TRIPs, entitled "*Other Use Without Authorization of the Right Holder*", recognized the authority of Member states to force the licensing of a patent that would otherwise be protected by intellectual property laws.

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[28] Ministerial Conference, *Doha Declaration on TRIPS Agreement and Public Health,* adopted on 14 November 2001, WT/MIN(01)/DEC2, dated 20 November 2001.

[29] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007):929

In fact, Article 31 of TRIPs refers to a situation where "*the law of a Member allows for the use of the subject matter of a patent without the authorization of the right holder, including the use by the government or third parties authorised by the government".* This other use of a patent without authorization of the right holder is commonly known as "Compulsory Licensing", even though this term is not used in TRIPs agreement.

The legal regime for the granting of compulsory licenses under TRIPs, however, is a very intricate one. To start with, the agreement does not limit the grounds on which compulsory licences may be granted. Yet, it misleadingly suggests a few situations in which it could be held as appropriate: (i) public non-commercial use[30]; (ii) national emergency[31]; (iii) remedying of anticompetitive practices[32]; and (iv) dependent patents[33].

For a long time, countries diverged on the interpretation of these provisions. Developed countries understood that those should be seen as the sole grounds on which the granting of a compulsory license would be justified. Naturally, developing countries contested that understanding. The Doha Declaration, in turn, put an end to this dispute, affirming that "*Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted[34]".*

Nevertheless, it is important to say that the existence of different opinions regarding the possible grounds for the granting of compulsory licenses was never a real barrier in this system. The conditions and limitations laid down in Article 31 for the exercise of that right were in fact the real obstacles to it.

The scholarship of Peter Van den Bossche is very helpful in the process of identifying these conditions and limitations:

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[30] *See* Article 31(b) of the TRIPs Agreement.
[31] Ibid.
[32] *See* Article 31(k) of the TRIPs Agreement.
[33] *See* Article 31(i) of the TRIPs Agreement.
[34] *See* Paragraph 5(b) of the *Doha Declaration on the TRIPs Agreement and Public Health*, adopted on 14 November 201, WT/MIN(01)/DE/2, dated 20 November 2001.

> "*Article 31 (a) of the TRIPS Agreement requires that authorization of compulsory licenses be considered on its individual merits. Therefore compulsory licenses cannot be granted with regard to broad categories of patents. Under Article 31 (b) of the TRIPS Agreement, an attempt must have been made prior to the compulsory license to get the authorisation to use the patent from the patent holder on reasonable commercial terms and conditions. Only if that attempt was unsuccessful within a reasonable period, can the compulsory license be granted. However, there are three exceptions to this requirement: [i] cases of national emergency or other circumstances of extreme urgency; [ii] cases of public non-commercial use; [iii] cases where the use is permitted to remedy anticompetitive practice.*[35]"

The same author further explains that the other requirements for the granting of compulsory licenses within Article 31 of TRIPs are:

> "[i] *that the scope and duration of the use of the patent shall be limited to the purpose for which it was authorized (paragraph (c)); [ii] that such use shall be non-exclusive (paragraph (d)); [iii] that such use shall be non-assignable except with that part of the enterprise or goodwill which enjoys such use (paragraph (e)); [iv] that any such use shall be authorized predominantly for the supply of the domestic market of the authorizing Member (paragraph (f)); [v] that the authorization of such use is liable to be terminated when the circumstances that led to it cease to exist (paragraph (g)); [vi] that the right holder be paid adequate remuneration in the circumstances of each case (paragraph (h)); and [vii] that the decision to authorize such use and the decision relating to the remuneration be subject to review by a court or other independent higher authority (paragraph (i) and (j)).*[36]"

Clearly, resorting to this system of compulsory licensing is highly exceptional, as it is only available to Member states in very few circumstances. However, it has a paramount importance in ensuring the access of developing countries to essential medicines. As it is widely held, compulsory licences may be used to authorize producers of generic medicines to copy a patented drug without the consent of the owner of that right. As of date, this system has been tested in a few circumstances and in most of them the cases were set on the ground of "national emergency"[37].

This is the main reason why the Doha Declaration also addressed and clarified both the meaning and the flexibility of the term "National Emergency". In this document, it was recognized that "*Each member has the right to determine what constitutes a national*

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[35] Peter Van Den Bossche, *The Law and Policy of the World Trade Organization,* 2nd ed. (New York: Cambridge University Press, 2008), 789.
[36] Ibid.
[37] Peter Van Den Bossche, *The Law and Policy of the World Trade Organization,* 2nd ed. (New York: Cambridge University Press, 2008), 789.

emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency[38]*."*

Regarding this point, the work of Peter Van den Bossche is again helpful. The author explains the flexibility that the Doha Declaration gave to the system, as follows:

> "*Epidemics such as HIV/AIDS and Malaria can thus constitute a 'national emergency' or situations of 'extreme urgency' within the meaning of Article 31 (b) of the TRIPs agreement. The Doha Declaration made it very clear that situations of 'national emergency' or of 'extreme urgency' are not limited to short-term crises. In addition, by giving Members the right to determine for themselves what is an emergency, the burden of proof shifts to the complaining party to show that an emergency does not in fact exists.*[39]*"*

In addition to this, the Doha Declaration addressed the important problem of the use of compulsory patents for ensuring access to essential medicines in developing countries. As explained above, Article 31 (f) of the TRIPs agreement requires that the granting of compulsory licenses be authorized predominantly for the supply of the market of the authorising country. Not surprisingly, most of the countries in the WTO lack the ability to manufacture pharmaceuticals.[40] Given that this article prevented "cross-compulsory-licensing" between members for the production of generic medicines, developing countries relied heavily on the existence of the transitional periods for implementing their national programs in the area of public health.

However, this situation was no longer possible after January 1st of 2005. Countries like Argentina, Brazil, India, Thailand and South Korea, which had the capacity of producing generic medicines on a large scale, could no longer serve countries without a manufacturing

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[38] *See* Paragraph 5(c) of the *Doha Declaration on the TRIPS Agreement and Public Health*, adopted on 14 November 2001, WT/MIN(01)/DEC/2, dated 20 November 2001.

[39] Peter Van Den Bossche, *The Law and Policy of the World Trade Organization,* 2nd ed. (New York: Cambridge University Press, 2008), 790.

[40] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007):929

capacity because they had to fully comply with TRIPs[41]. This situation, in persisting, would clearly lead to a worse situation where the poorest countries would no longer have access to affordable essential medicines, even if they granted compulsory licenses.

The Doha Declaration on the TRIPs Agreement and Public Health[42] took the first step to remedy this unfortunate situation, paving the way for the establishment of an alternative system for the granting of compulsory licenses focused on the needs of the LDCs. In fact, in paragraph 6 of the Doha Declaration, the Ministerial Conference of the WTO instructed the Council for TRIPs to find an expeditious solution to that problem before the end of 2002.

Jessica Greenbaum's comments about this specific instruction are very elucidative:

> *"In paragraph 6 of the Doha Declaration the WTO acknowledged that WTO members with insufficient or no manufacturing capabilities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Paragraph 6 also called for the Council for TRIPS to find an expeditious solution to this problem. [...] In 2003, the WTO addressed the paragraph 6 issue and further clarified the TRIPS agreement. The 2003 General Council Decision on TRIPS and Public Health addressed and modified Article 31(f) of TRIPS, which originally stated that any use of compulsory licensing shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use. The 2003 General Council Decision, which became known as the Paragraph 6 Waiver because it addressed the concerns stated in paragraph 6 of the Doha Declaration, had a major impact on developing countries that could not manufacture drugs domestically. Prior to the Paragraph 6 Waiver, countries were unlikely to import generic medications because member countries with the ability to manufacture pharmaceuticals under compulsory licenses could not export the drugs due to the "domestic market" requirement of Article 31(f).*[43]"

The decision of 2003 was further adopted by the WTO General Council on December 6th of 2005 (The Waiver Decision[44]), with the intention to resolve the problem with Article 31 (f) of the TRIPs agreement on a permanent basis. Nevertheless, this decision will only be

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[41] *See* Article 65.4 of the TRIPs Agreement.
[42] Ministerial Conference, *Doha Declaration on TRIPS Agreement and Public Health,* adopted on 14 November 2001, WT/MIN(01)/DEC2, dated 20 November 2001.
[43] Jessica L. Greenbaum, "TRIPS and Public Health: Solutions for Ensuring Global Access to Essential Aids Medications in the Wake of the Paragraph 6 Waiver", *Journal of Contemporary Health Law & Policy,* 25, no. 1 (2008): 148-149.
[44] General Council, *Amendment of the TRIPS Agreement. Decision of the General Council of 6 December 2005,* WT/L/641, dated 8 December 2005.

effective upon ratification by two-thirds of the WTO community. As of today, the ratification process is still ongoing and shall end no later than December of 2009.

The expected result of these efforts, as Phillip van den Bossche accurately explains, will be that *"when the amendment takes effect, a new article 31 bis as well as a new annex will be added to the TRIPS Agreement, providing that the obligations of Article 31 (f) do not apply with respect to the grant by a Member of a compulsory license necessary for the production of a pharmaceutical product and its export to an 'eligible' importing Member in accordance with the terms set out in Paragraph 2 of the new Annex to the TRIPs agreement.*" An alternative system for the compulsory licensing of generic medicines thus became available within the WTO framework.

The Waiver Decision, nevertheless, imposed several conditions for the utilization of this alternative compulsory licensing system therein implemented. To the dismay of the USA and EU countries, however, it did not limit the application of the Doha Declaration to specific diseases [45]. In fact, the decision applies to the broad category of "*products of the pharmaceutical sector*[46]".

Regarding the conditions imposed, it is fundamental to mention the introduction of two important forms of notification. The first requires that countries disclose their intent in making use of that system. All countries apart from the LDCs have to notify the WTO to be eligible for the Waiver[47]. The second notification introduced by the decision allowed WTO Members to notify their intention of not using this system as an importing country[48]. To date,

[45] Ibid. *See* Paragraph 1.
[46] Ibid. *See* Paragraph 1(a).
[47] *See* Paragraph 1(b) of Article 31*Bis* of the TRIPs Agreement.
[48] Ibid.

most OECD countries have notified the WTO of their intentions of not becoming an importer of generic medicines[49].

Also, in order to be eligible to import medicines in any given case, under Article 31 *bis,* a country must be either an LDC or make a determination that it has insufficient or no manufacturing capacity for the given product. For the calculations of this capacity, the facilities of the patent owners are naturally excluded[50].

In addition, procedural and substantive requirements were introduced to govern compulsory licensing issues of both importing and exporting countries. The former, for instance, must issue a compulsory license prior to the importation and duly notify the TRIPs council, including the name of the product(s) and the expected quantities that will be purchased[51]. Compulsory licenses are thus issued on a case-by-case basis. For the latter group, procedural requirement also play a fundamental role. To start, export countries are also required to issue a compulsory license[52]. Manufactures should only produce and export the exact quantities needed and declared by the importing country[53]. More importantly, the products should be clearly identified for being produced under this system in a way to prevent the predatory commercialization of these products[54]. Finally, the exporting licensee is required to post identification and destination information regarding shipments on a website[55], and it must also notify the TRIPS Council of the issuance of the license and its conditions, including the expected quantities of production and destination[56].

In compliance with Article 31(h) of the TRIPs agreement, the system implemented after the Waiver Decision required that the adequate remuneration be paid in the country of

[49] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 937-938.
[50] *See* Paragraph 2(a)(ii) of Article 31*Bis* of the TRIPs Agreement.
[51] *See* Paragraph 2(a)(iii) of Article 31*Bis* of the TRIPs Agreement.
[52] *See* Paragraph 2(b) of Article 31*Bis* of the TRIPs Agreement.
[53] *See* Paragraph 2(b)(i) of Article 31*Bis* of the TRIPs Agreement.
[54] *See* Paragraph 2(b)(ii) of Article 31*Bis* of the TRIPs Agreement.
[55] *See* Paragraph 2(b)(iii) of Article 31*Bis* of the TRIPs Agreement.
[56] *See* Paragraph 2(c) of Article 31*Bis* of the TRIPs Agreement.

export, taking into consideration the economic situation of the importing country[57]. This important point has given rise to substantial criticism, due to the likelihood that this would create disincentives for producing countries to export under compulsory license conditions.

Finally, the Waiver Decision implemented measures to prevent diversion[58] and non-authorized importation[59]. It also introduced a special regional treatment for LDCs which allows a product imported under a compulsory license by one Member of the group to be re-exported to other members without additional costs[60]. The amendment, furthermore, precluded forms of non-violation causes of action[61], a matter that still lacks certainty in the WTO framework. Lastly, it recognizes the desirability of the transfer of technology, and recommends the "*use of the system in the way which would promote this objective*[62]".

The Doha Declaration thus failed to bring about an administratively simple solution to this issue[63]. As explained at length, the regime of compulsory licensing still remains highly complex. Furthermore, in this alternative system, potential exporting countries received very few incentives to engage in activities of this nature. The merits and problems of this system will be further examined later on. Preceding this, however, is a discussion of three important cases that tested these systems herein described.

3.: A Policy Analysis: The Cases of Rwanda, Brazil and Thailand:

It should now be clear that there are currently two different, but related regimes for the granting of compulsory licenses under WTO law. The traditional model, originally introduced by article 31 of the TRIPs agreement, allows a Member state to grant a particular national manufacturer the right to produce specific goods on an "off patent" basis, if a number of

[57] *See* Paragraph 2 of Article 31*Bis* of the TRIPs Agreement.
[58] *See* Paragraph 3 of Article 31*Bis* of the TRIPs Agreement.
[59] *See* Paragraph 4 of Article 31*Bis* of the TRIPs Agreement.
[60] *See* Paragraph 3 of Article 31*Bis* of the TRIPs Agreement.
[61] *See* Paragraph 4 of Article 31*Bis* of the TRIPs Agreement.
[62] *See* Paragraph 6 of Article 31 *Bis* of the TRIPs Agreement.
[63] Sun, Haochen. "Reshaping the TRIPs Agreement Concerning Public Health: Two Critical Issues", Journal of World Trade, 31, no. 1 (2003): 164.

conditions are met. Concurrently, the Waiver Decision introduced an alternative path for the granting of compulsory licenses, allowing Member states without manufacturing capacities to issue exporting and importing licenses under the circumstances above described.

The first authentic test of this new model happened when Rwanda (an LDC) notified the WTO of its decision to import ARV (Anti-HIV) drugs from Canada in July of 2007. This was an extraordinary example for the WTO. The case, which will be described at greater length below, involved all the elements that justified the creation of this system. The repercussion of this case was, for that reason, highly positive for the developed world. In developing countries, however, it raised concerns and increased the level of distrust for the system.

Prior to this, however, the grant of compulsory licenses in two middle-income countries had already heated up the atmosphere in the pharmaceutical sector. Brazil and Thailand, under the original system of Article 31, but benefiting from the innovations of the Doha Declaration and the Waiver Decision, used compulsory licenses to implement public health policies. The circumstances surrounding their decision as well as the political reactions to them made these cases very interesting for this policy analysis. For this reason, they will be addressed individually below.

It is expected that a thorough understanding of these cases will offer a practical overview of the legal framework discussed above. This will in turn facilitate an assessment of the framework's value, and help determine whether it successfully enhanced developing countries' ability to access medicine. It will further help determine whether the Doha Declaration and the Waiver Decision will likely solve the pharmaceutical issue.

3.1.: Compulsory Licenses in Thailand – Dealing with Budgetary Constraints:

Reports from the World Health Organization repeatedly quote Thailand an example of a country that provides high-quality services to HIV patients. The Thai system's main issue is

the significant expense resulting from the provision of health care in a regime that guarantees universal access to essential medicines. While this problem has always troubled the Thai government, it became progressively more salient after the entry into force of the TRIPs agreement.

As one would expect, Thailand had to implement modifications in both national IP laws and national health program in order to comply with the TRIPs agreement. For instance, the country had to guarantee the protection of national and foreign patents and, more importantly, cease to acquire off patents drugs from abroad. As a consequence, national health budgetary expenditures increased radically, reaching 10% of the total government budget.

Attempting to alleviate its budgetary constraints while complying with its mandate of providing universal access to essential medicines, including ARV drugs for the treatment of HIV/AIDS, Thailand engaged in voluntary negotiations with patent owners. Failing to achieve positive results through these negotiations, Thailand decided to go one step further and issued compulsory licenses to achieve its mandate.

The chronologies of these issuances are well reported by Cynthia Ho:

> *"On November 29, 2006, Thailand issued a compulsory license to its Government Pharmaceutical Organization (GPO) on Merck's patented drug Efavirenz (sold by the patent owner under the brand name Stocrin), an effective first line treatment for AIDS that has fewer adverse side effects, including life-threatening side effects, than the generic antiretroviral Nevirapine. Thailand's license stated that it was for non-commercial purposes and for the public interest to help achieve its policy of universal access to antiretrovirals for the 500,000 Thai citizens that need them for long-term use. The compulsory license also stated that the high cost of Efavirenz without a license resulted in many Thai patients having inadequate access. The compulsory license was expected to halve the treatment cost so that more patients could be covered with the eventual goal of having all new patients treated with Efavirenz initially, just as patients are treated in developed countries. [...]A Thai compulsory license on the AIDS drug Kaletra was* [also] *issued to the GPO on January 25, 2007. Kaletra is a patented combination of two antiretrovirals that is often used for patients that become resistant to basic formulations of HIV medications, such as Efavirenz. The Thai government estimated that around ten percent of patients require second-line treatments such as Kaletra within the first few years, or else such patients will die. The Kaletra license was designed to support an increasing number of patients and thus save more lives. Prior to the compulsory license, Kaletra was priced at $2200 per patient per year by patent owner Abbott, a cost that is close to the yearly income of a*

Thai citizen. [...] On the same day, January 25, 2007, Thailand issued a compulsory license to the GPO for Bristol Myers' anti-platelet drug Plavix, a drug useful for treating heart disease. According to the license, heart disease is one of the top three causes of death in Thailand and although some non-drug preventative measures could be taken there is a need for drug treatment to prevent unnecessary mortality. Without the license only twenty percent of government insured patients could access the medicine, which is inconsistent with the Thai policy of providing universal coverage of essential medicine. [...][Finally] Thailand then issued licenses on four cancer drugs in January 2008, on the eve of a change in government administration. Thailand asserted that they were necessary because cancer is currently the number one cause of death in Thailand, and most effective cancer treatments are patented, not covered on the Thai List of Essential Drugs due to their high cost, and thereby inaccessible to Thai citizens. Thailand asserted that cancer is no less serious than HIV/AIDS, accounting for 30,000 deaths a year with 100,000 new cases diagnosed each year. Moreover, Thailand noted that the licenses were critical to prevent either severe economic hardship, including bankruptcy or certain death, without treatment.[64]"

The legality of these compulsory licenses has been widely debated. The complexity and the scope of the actions perpetrated by the Thai Government have divided legal commentators and politicians, exposing the fragility of the system implemented after the Doha Declaration and the Waiver Decision.

Vera Zolotaryova, for instance, showed her dissatisfaction with Thailand's policy, as follows:

"*Thailand's use of the provision to produce Plavix, a heart disease medication, is contentious because it demonstrates that Thailand is willing to invoke the provision for any drug available on the market, even for drugs that are primarily sold to developed countries. Moreover, this is the first time the provision has been used to produce a chronic disease medication and it is unclear if such drugs are an acceptable use of the compulsory licensing provision*[65]."

On a diametrically opposed position, Cynthia Ho defended the legality of Thailand's policy:

"*While there are interpretative issues regarding whether the Thai licenses are appropriate, they are not the same issues raised by critics. All of the licensed drugs--for HIV, heart disease, and cancer--were appropriate subject matter under TRIPS because TRIPS does not limit the use of compulsory licenses to any specific list of diseases and that approach was rejected during negotiations. Moreover, contrary to public opinion, there is no requirement that licenses be limited to emergencies. Accordingly, criticisms that heart disease is not an emergency are simply irrelevant to*

[64] Cynthia M. Ho, "Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS", *North Carolina Journal of International Law and Commercial Regulation*, 34, no.1 (2008): 147-151.
[65] Vera Zolotaryova, "Are we there yet? Taking TRIPS to Brazil and Expanding Access to HIV/AIDS Medication", *Brooklyn Journal of International Law*, 33, no. 1, (2008): 1123.

> *compliance with current TRIPS requirements; how these issues should be considered as a matter of policy (...)*[66]".

It was, nevertheless, on the political stage that Thailand had its decisions more fiercely contested. On this point, the comments of Frederick Abbot proved valuable:

> "*Mandelson* [E.U Trade Commissioner] *further stated that 'Neither the TRIPS Agreement nor the Doha Declaration appear to justify a systematic policy of applying compulsory licenses wherever medicines exceed certain prices'. As the Thai Minister of Public Health pointed out in reply, Thailand had not adopted such a policy, nor was it likely that Commissioner Mandelson had reason to believe that it had. Nonetheless, from the standpoint of WTO law, Mandelson misstates the rules. Article 31 of the TRIPS Agreement does not limit the grounds on which compulsory licenses may be issued, and Paragraph 5(b) of the Doha Declaration states that 'Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted*[67] *"*".

As a concluding remark, it is important to state that this case gained importance because Thailand was the first middle-income country to successfully use the compulsory licensing system created by the TRIPs agreement after the Doha Declaration. More than that, it was fundamental in revealing the legal uncertainty of the regime. As made clear, both developing and developed countries still disagree about the appropriate interpretation of the TRIPs agreement and the scope of the compulsory licensing regime. Furthermore, the case of Thailand demonstrated the political consequences that countries that intend to make use of the system risk may face.

3.2.: Compulsory Licenses in Brazil – Using TRIPs to Protect HIV/AIDS Program:

Brazil's social policies for dealing with the AIDS epidemic have also been recognized as a model for other developing countries. According to the World Health Organization[68], 83% of the patients currently in treatment in Brazil have access to anti-retroviral (ARVs) medicines, which is the highest rate of coverage in the developing world.

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[66] Cynthia M. Ho, "Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS", *North Carolina Journal of International Law and Commercial Regulation*, 34, no.1 (2008): 177.
[67] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 955.
[68] WHO, "Progress on Global Access to HIV Antiretroviral Therapy: A Report on '3 by 5' and Beyond." World Health Organization, Geneva (2006).

Historically, Brazilian health authorities have relied upon state-owned pharmaceutical labs to provide medicines to combat epidemics of infectious diseases. For instance, the well-known Oswaldo Cruz Foundation (FioCruz) has been one of the pillars sustaining this public policy. Regarding HIV/AIDS for example, Fiocruz' pharmaceutical laboratory and others operated by state governments or the public health system were mobilized to ensure compliance with an important national law of 1996, which mandated that AIDS patients should receive free and universal access to treatment. At the start of that free and universal care model, none of the medicines were protected by patents. For a long time, Brazil denied any patent protection for pharmaceuticals, insisting that these should pertain to the public domain. However, after revising its national IP law in 1996[69], in order to comply with TRIPs, eleven of the 17 medicines employed in this public health program became patent-protected, thus significantly increasing the cost for the government.[70]

After conforming its national laws to an accepted level of IP protection, Brazil decided to make use of the beneficial conditions of national emergency and public interest under TRIPs to protect its HIV/AIDS health program. For this reason, the country decided to regulate the issuance of compulsory licenses. Modifications have for example been made to intellectual property laws to allow parallel imports and the competition of generic manufactures with brand name medicines when they go off patent.

Brazil then adopted a very controversial, but rather effective strategy[71] in dealing with the owners of crucial AIDS medicines patents. As it is widely known, the government began

[69] Brazil revised its intellectual property laws in 1996 as a result of US pressures and before the deadlines set by the WTO of 2005 for middle income countries. Brazilian Industrial Property Law (Lei Federal n.° 9.279/96) went, in fact, beyond what was mandated by the TRIPs agreement. It embodied pipeline protections and retroactive protection for pharmaceuticals already patented in other countries but not Brazil. Of the claims that received a pipeline patent, 45% of the total came from the US and only 1.4% from Brazil.

[70] As of 2006, ARVs produced in public labs include didanosine, estavudine, indinavir, lamivudine, nevirapine, ritonavir, saquinavir, zidovudine and zidovudine+lamivudine. ARVs that are imported include abacavir, amprenavir, atazanavir, efavirenz, enfuvirtide (T-20 or Fuzeon), lopinavir/ritonavir (Kaletra), nelfinavir and tenofovir.

[71] Jennifer Bjornberg, "Brazil's Recent Threat on Abbot's Patent: Resolution or Retaliation?", Northwestern Journal of International Law & Business, 27, no. 1 (2006) 199.

threatening to issue compulsory licenses in its negotiations with foreign patent holders, obtaining in the vast majority of cases generous concessions. In one specific case, however, the outcome was different. Brazil requested that Merck reduce the unit prices of its Efavirenz from the current US$1.65 to US$0.65, the price that was offered to Thailand. Brazilian negotiators argued that since they intended to purchase larger quantities of the medicine from Merck, they should receive a deeper discount. Merck, however, maintained that its formula for pricing medicines in developing countries was based on the HIV prevalence rates, which was substantially higher in Thailand than in Brazil, rather than on quantities purchased.

The details of the negotiations involving the Brazilian Government and Merck are well described by Matthew Flynn, as follows:

> "*Merck initially provided a discount of 5%, which increased to 30% in its last proposal thus effectively reducing the unit price to US$1.10.[..] Negotiations also included offers to transfer technology to produce efavirenz. But Brazilian officials rejected company proposals because the transfer was only to be concluded a year before the patent expires in 2012 and with the condition that the active principal ingredient be provided by the company. For Brazilian officials, offers of technology transfer in the area of ARVs have never been acceptable. [...] After nine rounds of negotiations and stocks of the medicine decreasing, Brazil's government issued a decree declaring efavirenz in the public interest and on May 5, 2007, President Lula da Silva announced the compulsory license. Initial purchases of the medicine will come from three WHO pre-qualified companies in India for US$0.45/unit until government-owned companies scale-up production. Royalties to the patent-holder will be paid at 2.5%. Apart from the issues of price and transfer of technology, a number of factors had changed in the run-up to issuing the CL [compulsory license] compared to previous threats to issue one. First, the Ministry of Health employed the public interest clause (or public non-commercial use) in intellectual property legislation instead of emergency use. Since Brazil's AIDS program is considered one of the most successful in the developing world, it could not be considered an out-of-control epidemic.*[72]"

The legality of the Brazilian decision has also been fiercely debated, but the majority of the commentators seem to agree with the position of Vera Zolotaryova:

> *"The DSB will most likely find that Brazil's use of the compulsory licensing provision is valid for three main reasons. First, Brazil has sought prior negotiation with the patent holder Merck and thus satisfies the condition under article 31(b) requiring*

[72] Matthew Flynn, "Brazil's Use of Compulsory Licenses for AIDS Medicines", *Paper presented at the annual meeting of the American Sociological Association,* Sheraton Boston and Boston Copley Place (2008): 14. (Accessed April 21, 2009); available from http://www.allacademic.com/meta/p242498_index.html

> *"reasonable" negotiation with the patent holder. Second, even if Brazil's negotiations with Merck are not considered reasonable, Brazil actions are valid under either the national emergency or the public non-commercial use exceptions of article 31(b), which waive the reasonable negotiating requirement. Finally, Brazil's use of the provision is valid because Brazil may import the generic Efravinez from India under the waiver of article 31(f) provided by the August 30 Decision [...] Although the August 30 Decision allows countries to import generic drugs by waiving article 31(f) of the compulsory licensing provision, the August 30 Decision requires that the importing country establish a lack of manufacturing capacity. [...] However, the August 30 Decision does not require a country to demonstrate that it has no manufacturing capacity in the pharmaceutical sector. In fact, a lack of manufacturing capacity may also mean that a country has some manufacturing capacity in the pharmaceutical sector but that it is currently insufficient to meet its needs. Thus Brazil may argue that it has established a lack of manufacturing capacity to produce generic Efavirenz because its pharmaceutical laboratories are currently unable to produce a safe generic version of the drug. In order to ensure the quality, safety, and effectiveness of the generic drug, Brazil will only use generics produced from laboratories that are pre-qualified by the World Health Organization ("WHO"). Currently, all the laboratories producing generic Efavirenz that are WHO pre-qualified are located in India. Thus, Brazil currently lacks manufacturing capacity to produce generic Efavirenz because its laboratories are not WHO pre-qualified to produce the drug*[73]."

As a result, Brazil saved U$30 million in 2007 and is likely to save up to US$236.8 million by the time the patent expires in 2012. Also, a total of 75,000 of the more than 180,000 patients in Brazil's treatment program are expected to have access to these medicines at no cost. The country, nevertheless, faced a very strong reaction from the developed world. The political cost of paving the way for developing countries on this area may prove to be very high.

To illustrate this, a brief look at Merck & Co.'s press release about the end of the negotiations with Brazil may suffice:

> "*Research and development-based pharmaceutical companies like Merck simply cannot sustain a situation in which the developed countries alone are expected to bear the cost for essential drugs in both least-developed countries and emerging markets. As such, we believe it is essential to price our medicines according to a country's level of development and HIV burden, thereby ensuring equitable access as well as our ability to invest in future innovative medicines. As the world's 12th largest economy, Brazil has a greater capacity to pay for HIV medicines than countries that are poorer or harder hit by the disease. [...] This decision by the Government of Brazil will have a negative impact on Brazil's reputation as an industrialized country seeking to attract*

[73] Vera Zolotaryova, "Are we there yet? Taking TRIPS to Brazil and Expanding Access to HIV/AIDS Medication", *Brooklyn Journal of International Law*, 33, no. 1, (2008): 1113 - 1114.

> *inward investment, and thus its ability to build world-class research and development*[74]."

In the same line, Derek Lowe, an influential commentator of international politics in the US, in an article entitled "*Brazil raises the pirate flag",* made harsh comments about Brazil's decision to issue compulsory licenses:

> "[his] *problem with this, other than the obvious problem* [he has] *with expropriation of someone else's property, is that Brazil is trying to have things both ways. The government spends much of its time talking about how the country is an emerging power, with the 12th-largest economy in the world, huge natural resources, its own successful aircraft industry and space program, and so on. But when it comes time to pay for HIV medications, which are important both medically and politically, suddenly they're a poor third-world country being exploited by the evil multinational drugmakers.*[75]."

These critical views were to some extent counterbalanced by the opinion of respected social scientists, important NGOs, and even legal commentators such as Vera Zolotaryova, who argued that "*Brazil's actions create good policy for the future use of the provision by middle-income countries.*[76] " In fact, this case illustrates that the complex system of compulsory licensing may work for middle-income countries, but that they should be prepared to fight not only to defend the legality of their actions, but also the legitimacy of their policies on the political level.

3.3.: An LDC Finally Tests the Alternative System – Drugs to Rwanda:

It was only on July 17th of 2007 that a Less Developed Country decided to make use of the alternative system of compulsory licensing created specifically for LDCs by the Waiver

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[74] Merck & Co. Inc., "Statement on Brazilian Government's Decision To Issue Compulsory License for STOCRIN™ (Efavirenz)", (2007). (Accessed April 21, 2009); available from http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html

[75] Derek Lowe, "Brazil raises the pirate flag", (2007). (Accessed April 21, 2009); available from http://pipeline.corante.com/archives/2007/05/07/brazil_raises_the_pirate_flag.php

[76] Vera Zolotaryova, "Are we there yet? Taking TRIPS to Brazil and Expanding Access to HIV/AIDS Medication", *Brooklyn Journal of International Law*, 33, no. 1, (2008): 1124.

Decision. Rwanda notified the World Trade Organization's Council for Trade-Related Aspects of Intellectual Property Rights (The TRIPs Council) of its plans to import the HIV-drug TriAvir from the Canadian company Apotex and, consequently, not to enforce any patents granted on that respect in Rwanda. Two months later, as explicitly required by WTO Law, Canada issued a compulsory license allowing Apotex to use nine patented inventions for manufacturing and exporting TriAvir to Rwanda. On October 4, 2007, Canada also notified the Council for TRIPS of the compulsory license, paving the way for the export of those drugs to Rwanda.

The negotiating process that led to this outcome was, nevertheless, very unusual. In fact, it was not the result of Rwanda's efforts, but rather the product of the determination of Médecins Sans Frontières – a notorious NGO - to test the alternative legal framework for the granting of compulsory licenses introduced by the Waiver Decision.

It started when Canada amended its national law in May 2004, allowing national companies to obtain compulsory license for the export of generic medicines. Médecins Sans Frontières, benefiting from the Canadian advanced trade regime, contacted Apotex who agreed to produce a fixed-dose combination of the three HIV/AIDS drugs known as TriAvir. Among the nine Canadian patents that were related to the drugs, four were owned by the Glaxo Group, two by the Wellcome Foundation, two by Shire Biochem and one by Boehringer Ingelheim and Dr. Karl Thomae GmbH[77].

However, complications with the Canadian Patent Act and the Health Authority of Canada substantially delayed Apotex's ability to produce and export the drugs. In addition, the company failed to fulfil the requirements for a compulsory license under the Canadian Patent Act because there was no importing country at the time. Médecins Sans Frontières had difficulty finding an importing country, since the government of most LDCs were reluctant to

[77] Goodmans LL.P., "Application Pursuant to § 21.04 of the Patent Act" (2007). (Accessed April 21, 2009); available from http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/Home

have their name related to such a transaction, possibly because of the criticism that Brazil and Thailand encountered after they resorted to compulsory licenses.

Even though Rwanda was not Médecins Sans Frontières' favourite country, it signalled its inclination to test the import/export mechanism in 2007. With a transaction partner, Apotex could then obtain an exporting compulsory license from the Canadian Government for the sell and export of 15.6 million tablets of TriAvir to Rwanda.

This case represented the first real application of the alternative mechanism set up by the WTO to safeguard access to medicines for countries lacking the capacity to manufacture drugs. Unfortunately, it proved to be unjustifiably complex given its original goal of facilitating the access to affordable drugs. Clearly, LDCs and Developing countries still do not have the right incentives to meet their needs by utilizing this mechanism. In addition, manufacturers are severely discouraged from engaging in transactions of this type. Not surprisingly, no other country has tested this mechanism since its conception.

Holger Hestermeyer's comments regarding the implications of this case for the future of the alternative compulsory licensing mechanism are very elucidative. They thus serve well as closing remarks:

> -"*The first application of the mechanism shows that it is too cumbersome to work effectively. Rwanda could have imported a similar combination drug from India, which is available at $0.14 per tablet and not yet affected by India's new patent legislation. It would only have had to impose a compulsory license in its own territory, and possibly not even need this step, as it is not clear whether any of the nine inventions have been patented in Rwanda. [...] Apotex concluded that the mechanism would have to be changed to work effectively. The process proved cumbersome and the generic manufacturer has few incentives to go through with it. It is not economic to produce for merely one importing country, and it is difficult to convince countries to notify the WTO of their need to import. Additionally, Canada imposes a maximum term of two years for the compulsory license, not enough to recoup the investment for producing a generic drug. [...] Given the defects of the mechanism, the Director General of the European Generic Medicines Association concluded at a hearing of the European Parliament that it is unlikely that any company in Europe would make use of the mechanism.*[78]"

[78] Holger P. Hestermeyer, "Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines", *The American Society of International Law Insights*, 11, no. 28 (2007): 1.

3.4.: The Merits and Demerits of Actual Compulsory Licensing Regime:

The aforementioned compulsory licenses on patented medicines issued by Thailand, Brazil and Rwanda reveal that the WTO's system for counterbalancing the strict regime of IP protection implemented by TRIPs still lacks legal certainty and effectiveness. However, these cases also confirm that the system may work if a few modifications are made.

The cases emphatically demonstrate that the system's complexities create disincentives for countries at all levels of development to use the flexibilities introduced by the TRIPs Agreement and reconfirmed by the Doha Declaration. In addition, they make clear that developing countries and LDCs in particular are very reluctant to make use of the compulsory licensing regime due to the likely political implications of doing so. The reasons for this are fairly simple. This compulsory licensing system, for example, clearly disregards the reality that the poorer the country, the more dependent it is of international aid. The incentives, then, are mistakenly placed here. It is undeniable that the poorer the developing country is, more fundamental the access to affordable medicines becomes. But, concurrently to that, the dependence of that country on international aid increases. The result is that even in need, developing countries (especially LDCs) may not engage in activities of this type, afraid to be seen as hostile to foreign direct investment and, consequently, as adversary to the interests of those who may have the means to provide aid. For these reasons, it is undeniable that the existing political pressure for the unconditional protection of patents impairs the ability of those in greatest need to make use of the system.

However, it is also important to acknowledge that the cases of Brazil and Thailand proved that political pressures can no longer be used as a means for misrepresenting international legal rules. Given the widespread availability of information nowadays, NGOs, legal commentators and the independent media may legitimate countries' actions, thus supporting the implementation of national policies in the area of public health. In addition, the

WTO's dispute settlement body may play a fundamental role by confirming that these actions were in accordance TRIPs.

In addition, it became clear that the Doha Declaration paved the way for a broad understanding of this system. It indeed clarified fundamental points in the complex legal framework of TRIPs, but it failed to bring about a simple solution to the pharmaceutical question. Today, it is much more likely that a middle-income country such as Brazil or Thailand will make use of this system than an LDC such as Rwanda. This system thus requires further adjustments.

Equally important is the acknowledgement that if these actions are successfully maintained, being considered in compliance with the TRIPs agreement, they may represent a victory of the Article 31bis Amendment and, consequently, of those countries that made de Doha Declaration possible. As a result, other countries, possibly even LDCs, may be incentivized to engage in similar activities, finally giving the system the dynamics and legal certainty it needs.

If these actions also motivate the pharmaceutical industry to review their pricing strategies in developing countries, mainly with regard to the so-called orphan drugs and crucial medicines such as those for the treatment of HIV/AIDS, the Doha Declaration could lead the WTO to achieve a great victory in the field of Intellectual Property. However, that outcome is still highly unlikely.

The Doha Declaration, for that reason, might not be able solve the pharmaceutical question by itself. Nevertheless, it constitutes a fundamental step in that direction. It might even be said that, at the time, the Doha Declaration achieved more than could be expected, considering that the WTO is still a fragmented political organization. However, it is indisputable that this system needs to be further amended to better harmonize the conflicting interests surrounding this issue. As of today, just a very few countries would dare to challenge

the interest of the EU and the USA in this field. That situation, nonetheless, will not be tolerated for much longer. LDCs and Developing countries will certainly demand further clarifications in the near future and may even argue for the implementation of a simpler, more inclusive system for the granting of compulsory licenses. The last part of this paper is devoted to suggestions for improving the current system.

4.: Making the System Work:

As was stated above, the Doha Declaration and the Waiver Decision were arguably the best available alternatives at the time for counterbalancing the strict IP protection system implemented by TRIPs. These documents, however, failed to put in place a mechanism able to fulfil that goal. This is the main reason why developing countries often argue for a legal reform in the IP system currently enforced by the WTO.

In fact, the cases studied above recognize the excessive formalism and complexity of the administrative and legal barriers that impede the use of compulsory licenses by LDCs and Developing Countries. However, they also suggest that this system may be made workable if a few important measures are implemented.

For instance, an important change in the negotiation strategy of the three main players in this impasse (Developed Countries; Developing Countries and the Pharmaceutical Industry) may end up creating the appropriate political environment for the amendment of key provisions of the TRIPs agreement, leading the WTO to work out a win-win solution to this problem. The details of this strategy are better described below.

4.1.: Negotiating Effectively:

The conflicting relations between the three parties are still the product of developing countries' willingness to provide public goods in the area of public health, developed countries' desire to safeguard the private rights of patentees, and the pharmaceutical industry's desire to maintain complete control over its pricing policy worldwide. A solution to

these different viewpoints should start with negotiations at the political level. Specifically, parties should agree on general goals and limits for the use of compulsory licences.

An agreement on these grounds does not necessarily need to be reached at the WTO. For instance, developed countries could recognize that compulsory licenses are indeed a valid strategy in dealing with public health, provided that developing countries make a prudent use of them. These latter countries should then take the initiative in promoting national laws that clearly define permissible uses of compulsory licenses. By voluntarily restraining their ability to use the compulsory licensing system under TRIPs to certain predefined cases, developing countries might incentivize developed countries to adapt their own national laws to allow their nationals to make a coherent use of the compulsory license system, becoming exporters of generic drugs and thus assisting countries in need of affordable medicines.

Once this dispute is somehow settled among countries, the pharmaceutical industry will be forced to review its pricing policy, shifting from the current "*low-quantity-high-margin pricing strategy, to a high-quantity-low margin*[79]". Such a negotiated solution to this problem would promote equality and social justice and should, therefore, be incentivized.

4.2.: Guaranteeing Research and Development in the Pharmaceutical Sector:

This type of solution, some argue[80], could potentially affect the R&D capacity of private undertakings, affecting humanity in a more significant way in the long-run. This position, however, is highly controversial and, if accurate, may be remedied. For instance, specialists argue that marginal cost plus 5% of royalty may serve as a fair basis for the recoup of R&D expenses[81].

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[79] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 930.
[80] Nevin M. Gewertz and Rivka Amado, "Intellectual Property and the Pharmaceutical Industry: A Moral Crossroads Between Health and Property", Journal of Business Ethics, 55, no. 1 (2004): 307.
[81] Kevin Outterson, "Patent Buy-Outs for Global Disease Innovations for Low- and Middle- Income Countries", Am J Law & Med 32, no. 1. (2006): 159-161.

If that is indeed correct, compensation schemes on these bases could be required in the cases of compulsory licenses. As of today, what is to be understood as adequate compensation is still uncertain and should be clarified by the system. In the cases studied, for example, while Thailand pays just 0.5% in royalties to the patent owners, Brazil pays 2.5%. While this is still below the 5% threshold, it is likely that developing countries would agree to settle around that.

In addition, publicly funded research may be used to counterbalance the disincentives that such a policy may create. Developing countries may consider, for example, the creation of joint consortiums for the research of tropical and orphan diseases, or even stimulate the formation of public-private partnerships in the area of medical research. Similarly, developed countries may consider fostering their research by inserting a residual "public research tax" in the final price of specific drugs targeted to the wealthier individuals in their respective countries.

4.3.: Making the System Less Costly:

It is essential to diminish the high transactional costs associated with a single state action. As the cases described, the economic, legal and technical complexities discourage LDCs from engaging in these activities. These countries clearly do not have the capacity to deal with TRIPs. More than that, the current system dissuades potential exporting companies in developed countries from engaging in these deals. In the case of Rwanda, Apotex (the Canadian exporter) had to pay royalties and could only produce the exact amount of the generic drugs authorized by the compulsory license. This framework, therefore, neglects the existence of economies of scale and scope, penalizing the companies willing to help those in need of medicines at the lowest price possible.

From the perspective of the private exporter, the possibility of producing just a small quantity of a product in a once-in-a-lifetime transaction does not justify the investment.

Furthermore, from the importing country's point of view, the fact that the private exporter has the duty to determine with its trade authority (often a developed country) the amount to be paid to the patent owner neglects the fact that, ultimately, that cost will be born by the importing country (often an LDC or a Developing Country). Hence, the latter should have the right to influence that royalty estimation. Once again, developing countries are serviced with mechanisms that seem not to work in reality.

4.4.: Insulating Countries From Unjustified Political Pressure:

This legal framework could also be amended to countervail the influence that a few governments and the pharmaceutical industry have in the international political context. The reality illustrated in the cases above clearly demonstrates that the system for the use of compulsory licenses will only be exercised by middle-income countries with a respectable political presence.

In order to make this system effective, it is then very important to legally support the LDCs' and Developing Countries' ability to make a coherent use of this system. An interesting solution could be implemented at the level of the WTO, or even through the United Nations, World Bank or the World Health Organization, by establishing a system of protection against sanctions and reprisal.

Regarding this point, the lessons of Jessica Greenbaum are indeed valid:

> -"*Despite the WTO attempts to assure developing countries that using compulsory licensing to address public health crises such as HIV/AIDS is acceptable, developing countries still fear reprisal. A specific commitment by developed countries like the United States should be issued so that those countries facing health crises can feel safe in their ability to use the TRIPS compulsory licensing schemes. Unfortunately, a specific commitment in the form of a public announcement - such as what occurred when the United States withdrew litigation against Brazil - has not been effective. More effective means should involve the threat of sanctions from other international organizations, such as the United Nations or even from the WTO, towards countries who engage in trade reprisal. This may prove difficult because it is hard to determine when trade reprisals are a response to compulsory licensing. If sanctions and pressure are placed on powerful countries, perhaps this would be enough to deter countries from trade reprisal and assure developing countries that they need not worry. Fear*

> *from developing countries will also begin to dissipate over time as more countries use the TRIPS waiver.*[82]"

4.5.: Implementing a Pooled Procurement Strategy Among Developing Countries:

The system could also be revised to allow block negotiations in the area of public health. LDCs and Developing Countries should be incentivized to find collective solutions to their problems. Actually, an intelligent solution for this problem would follow the rationale suggested by Frederick Abbot, who formulated a system characterized by a pooled procurement strategy among developing countries:

> "*A more promising strategy is to think in regional or sub-regional terms, with a view to standardizing procedures, to lowering the transaction costs of all participating countries, and to stabilizing the availability of medical supplies that all the participating countries are likely to need. On this approach, a group of developing countries interested in price regulation of pharmaceuticals could harmonize and coordinate their policies in this regard. With or without price regulation, a pooled procurement strategy would provide incentives to the originator pharmaceutical companies themselves to become 'low bidders' under supply contracts offered by a centralized procurement authority. [...]A pooled procurement strategy would also greatly enhance the procurement agency's opportunities to stimulate direct investment in local production facilities within the region and to obtain support for training and research to enhance that region's own capabilities*[83]*."*

The formation of a pool of regional countries would certainly help developing countries to obtain better terms on collective arrangements, countervailing, for instance, the political pressure of the pharmaceutical industry and the governments of EU countries and the USA. Moreover, such a strategy could potentially lead countries to obtain the concession of patent holders, the reduction of the costs with individual compulsory licences and, more importantly, it may help developing countries to fulfil those ideals of technologic transfer rights and technical cooperation.

4.6.: A Closing Remark:

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[82] Jessica L. Greenbaum, "TRIPS and Public Health: Solutions for Ensuring Global Access to Essential Aids Medications in the Wake of the Paragraph 6 Waiver", *Journal of Contemporary Health Law & Policy,* 25, no. 1 (2008): 161.

[83] Frederick M. Abbot and Jerome H. Reichman Abbot, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPs Provisions", *Journal of International Economic Law* 10, no. 4, (2007): 973.

The WTO community should finally recognize that at the heart of the pharmaceutical debate lies the fact that the world community needs to solve this important problem wisely. The Doha Declaration recognized the collective obligation to promote access to medicines for all. It was, nevertheless, unable to put in place a system that would guarantee that. As increasingly recognized even among developed countries, there is no private market solution to that goal. In order to guarantee medicines for all, the WTO will have to adjust its system of compulsory licenses, or adopt an alternative solution that recognizes the necessity of governments to step in. Failure to confront this truth will result in an endless cycle of conflicts that may even threat the existence of the WTO itself.

Conclusion.:

The historical roots, structure and innovations of the Agreement in Trade-Related Intellectual Property Rights (TRIPs) were at the core of this paper. These issues were discussed as a basis for an even more challenging discussion: the influence of this agreement on the access to critical medicines in developing countries.

It was seen that the experienced shift from a morally contested but highly permissive IP protection regime to a system characterized by tougher protections of IP rights have indeed impacted the ability of both Less Developed Countries (LDCs) and Developing Countries to freely and costlessly implement programs in the area of public health. The result was that the many citizens of the poorest countries had their access to affordable medicines strictly limited.

Understanding the urgency of rectifying this problem, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPs Agreement and Public Health (the Doha Declaration) in November 2001 to clarify important points of the TRIPs agreement with regard to the use of compulsory licenses by developing countries. Furthermore, it paved the way for the Decision of the General Council of December 6th 2005 (the Waiver Decision) that implemented an alternative system for the utilization of compulsory licenses by countries without a local manufacturing capacity.

Both the original system for the granting of compulsory licenses under Article 31 of the TRIPs agreement and the new system implemented by the Waiver Decision were the object of a meticulous legal analysis set with the intention of elucidating their complexities. These regimes were, furthermore, subjected to a policy analysis that took into consideration the outcome of the cases of Rwanda, Brazil and Thailand.

As a result, it was found that the system currently in place at the WTO for counterbalancing the strict regime of IP protection implemented by TRIPs still lacks legal certainty and effectiveness. While the Doha Declaration recognized the collective obligation

to promote access to medicines for all, it failed to put in place a system that would guarantee that. Finally, it was observed that the WTO mistakenly placed the incentives for the utilization of compulsory licenses. Clearly, just a few middle-income countries with an important political presence may afford to use these beneficial instruments for protecting their national public health programs.

These cases, nevertheless, raised expectations that these systems may work if a few modifications were put in place. The final part of this paper suggested some measures that could serve that end, acknowledging that the Doha Declaration might not be able to solve the pharmaceutical question on its own. As a recommendation, it was said that the WTO community should finally recognize that at the heart of the pharmaceutical debate lies the fact that the world community needs to solve this endless problem wisely. For that reason, all parties involved in this battle should make reciprocal concessions. A failure to confront this truth may end up threatening the existence of the WTO itself.

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