LICENSING OF PHARMACEUTICAL PATENTS IN DEVELOPING COUNTRIES

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Abstract

Lack of access toward essential medicine in developing countries is influenced by high drug prices imposed by pharmaceutical companies due to patent protection. This article examines compulsory licensing as possible way for developing countries to overcome patent protection and on that way facilitate possible outcome and provide access to drugs at affordable prices. Based on cases and scholarly articles this thesis analyzes possibilities and benefits of compulsory licensing for pharmaceuticals for developing countries taking into consideration effects on market and pharmaceutical industry. It provides summarized overview of TRIPS and Doha flexibilities in present society.

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Abbreviations

ARV – Antiretroviral drug

DOHA - Declaration on TRIPS Agreement and Public Health

GATT - General Agreement on Tariffs and Trade

HIC – High Income Countries

LDC – Least Developed Countries

LIC – Low Income Countries

NGO – Non Governmental Organizations

R&D – Research and Development

TRIPS – Agreement on Trade-Related Aspects of Intellectual Property Rights

UMIC – Upper Middle Income Countries

WHO – World Health Organization

WIPO – World Intellectual Property Organization

WTO – World Trade Organization

Introduction

Lack of access towards affordable medicine which could counter to the spread of common and all too often deadly diseases reflects everyday life of a large number of people living in the developing world. Millions of people suffer and die every year in developing countries due to minimal heath care and insufficient access to medicine.[1] Inability to afford medicine in developing countries is mainly attributed to the high prices of patented pharmaceuticals products imposed by the pharmaceutical companies which represents one of the main clashes between developed and developing nations in this area and causes a lot of heated and at times angry debate. High prices of pharmaceuticals products are the consequence of strong international intellectual property rights imposed to harmonize the law and protect patent against misuse, but on the other side consequently imposing more limits on already limited access to medicines in the developing countries.

Protection for pharmaceutical patents was introduced as part of minimum standards for the protection of intellectual property, set out in the Trade - Related Aspect of Intellectual Property Rights (TRIPS) . Under the TRIPS, all signatories must provide for the protection of pharmaceutical patents even though it influences the increase of pharmaceutical prices in developing countries.[2] Due to the necessity toward affordable medicine and better public health protection, TRIPS introduced flexibilities in the form of compulsory licensing in order to facilitate a positive outcome. Compulsory licensing is the license to use or manufacture patented product without permission of the patent owner, but without actually "breaking" the

[1]Commission of the European Communities, Progress Reports on the implementation of the European Programme for the Action to Confront HIV/AIDS, Malaria and Tuberculosis, through External (2007-2011), (March 26, 2013) http://ec.europa.eu/development/icenter/repository/COMM_PDF_SEC_2009_0748_F_EN_AUTRE_DOCUMENT_TRAVAIL_SERVICE.pdf

[2] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 2005, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

patent.[3] Even though Article 31 of the TRIPS lays down definition and conditions for use of TRIPS flexibilities, in practice it was unclear in which way countries may use these flexibilities since patents on pharmaceuticals still presented obstacle to medicines.[4]

The Declaration on TRIPS Agreement and Public Health ("Doha Declaration") was adopted in 2001 with the aim to promote a balance in the interpretation and implementation of the TRIPS provisions and supporting rights of governments to protect public health.[5] Doha was mainly welcomed by developing nations since it provided for the protection of public health over the protection of pharmaceutical products.

The purpose of this research is to point out that compulsory licensing is strong and important mechanism for the developing countries on their way toward access to medicines. The background for my research was based on the articles of the main contributors in the field of compulsory licensing of pharmaceuticals, namely Dr Carlos Correa and Ellen 't Hoen who produced work from enactment of TRIPS to shortly after Doha Declaration. In addition, this research also includes recent developments, comments and case studies on the subject of compulsory licensing of pharmaceuticals. Along with the information from the main contributors in this field, it reflects the effect of TRIPS and Doha to present society.

This work does not disregard the importance of patent protection in the field of pharmaceutical patents and incentive for investments into development of new drugs. Apropos, this research examines positive and negative effects of introducing compulsory licensing for pharmaceuticals into developing countries and its effect on market and incentive of pharmaceutical companies to invest into new drug developments.

[3] Ho, M. Cynthia, *Compuslory licensing under TRIPS: An Introduction*, Loyola University Chicago School of Law, Paper No. 2011 -030, 124-156, 124, (2011)
[4] Elen F. M 't Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 39-60, 40, (2003)
[5] South Center Policy Brief, *The Doha declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, No. 7, 1-18, 1, (November 1, 2011)

The work is divided into three chapters. Chapter one provides legal and policy framework, i.e. establishment, purpose and role of two main bodies in this field, TRIPS and Doha. Chapter two examines patents on pharmaceuticals and compulsory licensing, which is explained through introduction of the most spread diseases, incentives for innovations of drugs for those diseases, position of developed, developing countries and pharmaceutical industry. Further, discriminatory pricing in connection with another TRIPS flexibility i.e parallel import is explained, taking into account effects on the market. The last point in second chapter was presentation of three relevant cases, Brazil, India and Thailand, their experience with compulsory licensing and influence on developing world. Chapter three includes post Doha period and further recommendations. Post Doha period is based on implementation of TRIPS and Doha on national level, as well as looking into the current situation in the world between producers and importers, in the sense to see whether balance is accomplished or conflict of interest among them still exists. Last part of chapter three provides some measures for the improvement of compulsory licensing and the role of NGOs in the developing nations.

1 POLICY FRAMEWORK

1.1 TRIPS

Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) is an international agreement administered under the World Trade Organization which sets out the minimum standards for the protection of intellectual property.[6]

1.1.1 General Overview

1995 can be seen as key year in the respect to regulation and protection of intellectual property rights. Up to 1995 and the creation of the World Trade Organization (WTO)[7], national intellectual property rights were mainly unregulated on the international level and under the General Agreement on Tariffs and Trade (GATT) system[8]. Although certain protection of intellectual property rights on the national level was provided as well as protection under Paris Convention[9], that protection did not include any harmonized patent law among countries[10] and provided certain differences among them. Due to those differences the need for a uniform set of rules for the intellectual property rights on the international level was apparent. The response from the international scene was the creation of TRIPS as Annex

[6] Elen F. M 'T Hoen, *„TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way From Seattle to Doha"*, 3 Chicago Journal International Law, 27-46, 39, (Spring 2002)
[7] BBC News, Timeline: World Trade Organization, (March 17, 2013), http://news.bbc.co.uk/2/hi/europe/country_profiles/2430089.stm
[8] Alan O. Skyes, *„TRIPS, Pharmaceutical, Developing Countries, and the Doha „Solution""*, Chicago Law & Economics, Olin Working paper No. 140, 1-31, 3, (February 2002)
[9] WIPO, WIPO Treaties – General Information, (March 17, 2013), http://www.wipo.int/treaties/en/general/
[10] John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance between Intellectual Property Rights and Compassion*, 7 Widener L. Symp. J. 175, 175-201, 178, (2001)

1c of the Establishing WTO Agreement.[11] As noted above, the establishment of TRIPS provided minimum standards for intellectual property protection. In that time, TRIPS represented a novel, important and positive step forward mainly because it linked intellectual property with international trade and brought harmonized patent laws among Member States[12]. The rationale was that similar protection of intellectual property rights would facilitate trade and in a certain way integrate developing and least developed countries into global economy[13]. Additionally, and mainly due to harmonized patent laws, TRIPS brought some "innovations" for some countries like India in the field of patentability of pharmaceutical products[14]. The TRIPS Agreement provides patent protection, for a minimum of 20 years, for products and processes in almost all fields of technology, including pharmaceuticals.[15] The Philosophy behind TRIPS is that they attempt to "strike balance between the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing people to use existing inventions and reactions."[16]

The TRIPS Agreement did not come about over night. It was the result of numerous negotiations in the Uruguay Round from 1986 to 1994[17] and represents one of the most controversial and debated international agreements, especially in the protection of pharmaceutical patents.

[11] WTO, TRIPS Related Aspects of Intellectual Property Rights, (March 17, 2013), http://www.wto.org/english/docs_e/legal_e/27-trips_01_e.htm
[12] John A. Harrelson, *TRIPS, Pharmaceutical Patents, and the HIV/AIDS Crisis: Finding the Proper Balance between Intellectual Property Rights and Compassion*, 7 Widener L. Symp. J. 175, 175-201, 179, (2001)
[13] Margaret Kyle, Anita McGahan, *„Investment in pharmaceuticals before and after TRIPS"*, NBER Working Paper No. 15468, 1-39, 3, (Ocober 2009)
[14] Jean O. Lanjouw, *The introduction of pharmaceutical product patents in India: „Hearthless exploitation of the poor and suffering*, NBER Working Paper No. 6366, 1-52, 1 (January 1998)
[15] WTO, Intellectual Property: protection and enforcement, (March 17, 2013), http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[16] WTO, TRIPS and pharmaceutical patents, Fact Sheet September 2003, (March 17, 2013) http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf
[17] WTO, Intellectual Property: protection and enforcement, (March 17, 2013), http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm

1.1.2 Compulsory licensing

One of the most debated provisions of the TRIPS Agreement is compulsory licensing, its meaning, purpose and application. Compulsory licensing is a governmental grant to someone to produce a patented product without having the patent-holder's consent.[18] Article 31 of TRIPS Agreement provides for compulsory licensing, but using a different phrase. Rather, a phrase "Other Use Without Authorization of the Right Holder"[19]is being used and provides for compulsory licensing, where the phrase "compulsory licensing" is not mentioned anywhere in TRIPS. The Rationale behind this lies in the fact that some provisions of the Paris Convention were incorporated into TRIPS[20], and the Paris Convention in its Articles (namely 5A(2)) provided grants for compulsory licensing.[21] However, it can be reasonably concluded that the words "other use" from TRIPS coincide with "compulsory license" from the Paris Convention and that the language from Article 31 refers to compulsory licensing. Even though there is no definition of compulsory licensing in the TRIPS Articles, WTO on its official webpage provided a definition of compulsory licensing.[22]

In its provisions, from 31(a) to 31(l)[23], TRIPS provides numerous requirements and conditions for the authorization of compulsory licensing. Usually, before obtaining a compulsory license, the proposed user has to made efforts to obtain a patent voluntarily from the patent owner[24]. However, in a "case of national emergencies" or "government use" there

[18] WTO, Compulsory licensing of pharmaceuticals and TRIPS, (March 17, 2013), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
[19] WTO, Part II – Standards concerning the availability, scope and use of Intellectual Property Rights, (March 17, 2013) http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm
[20] TRIPS Article 2.
[21] Swarup Kumar, "*Compulsory Licensing Provision under TRIPS: A Study of Roche vs Natco Case in India vis-à-vis the Applicability of the Principle of Audi Alteram Partem*", SCRIPTed Vol 7, Issue 1, 135 – 154, 136 -137 (2010)
[22] WTO, Compulsory licensing of pharmaceuticals and TRIPS, (March 17, 2013), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm
[23] TRIPS Article 31
[24] TRIPS Article 31 (b)

is no need to try to obtain a patent voluntary from the patent holder.[25]Even though in a case of compulsory licensing, a patent is granted without authorization of the patent holder, there must be "adequate remuneration" where the amount of economic value of authorization must be taken into account.[26] However, Article 31 does not provide a definition of adequate remuneration and leaves this decision to the Member States to decide.[27]From the provisions concerning remuneration and negotiation on voluntary licenses it can be seen that TRIPS is trying to seek some balance between a governmental grant and preservation of patent holder rights.[28]Additionally, the use of patent should be non-exclusive[29], should be used only for the supply of the domestic market[30], and as for the question of validity it should be subject to legal review of that Member State[31]. From the list it can be seen that reasons for justification of compulsory licensing under TRIPS are not fully developed which may leaves a lot of space for different interpretation of those terms. As for the pharmaceuticals and interpretation of them with the ambiguous terms found in Article 31, a link may be drawn with Articles 8 and 27 of TRIPS Agreement which establishes the relationship between TRIPS and public health.[32] Article 8 states that members may adopt measures to protect public health[33] while Article 27 provides that invention needed to protect public health may be excluded from patentability[34]. For the broad interpretation of Article 31, this would mean that as for the protection of public health, countries may grant compulsory licensing.

[25] TRIPS Article 31 (b)
[26] TRIPS Article 31 (h)
[27] TRIPS Article 31 (j)
[28] Sara M. Ford, "*Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*", 15 Am. U. Int'l L. Rev. 941, 941-974, 960 (1999-2000)
[29] TRIPS Article 31(d)
[30] TRIPS Article 31 (f)
[31] TRIPS Article 31 (i)
[32] Sara M. Ford, "*Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*", 15 Am. U. Int'l L. Rev. 941, 941-974, 961 (1999-2000)
[33]TRIPS Article 8
[34] TRIPS Article 27

Compulsory licensing represents one important tool, accepted globally, which provides balance of public use and exclusive right of patent owner.[35]The TRIPS agreement allows compulsory licensing to "strike a balance between promoting access to existing drugs and promoting research and development into new drugs"[36]. Scholars argue that compulsory licensing would increase the output of the invention and cause price decreasing on the market which would consequently eliminate monopolies[37]. This is one of numerous reasons which may bring diverging attitudes toward this topic. Developing countries believe that morality should prevail and sees compulsory licensing of pharmaceuticals as access to necessary medicines and the preservation of life.[38] On the other side, developed countries were initially reluctant to support it as they believed that broad interpretation of compulsory licensing in relation to pharmaceuticals and public health may lead to an exaggerated situation, where minor health risks will be seen as possible public health threats.

Compulsory licensing dates from Paris Convention, but in the aspect of pharmaceuticals it represents a relatively new, controversial, interesting and more and more debated topic mainly between developed and developing countries, but also between pharmaceutical companies and activist groups on the aspect of access to the life-threatening diseases[39].

[35]Suwan-in, Nattapong, *Compulsory License, a Long Debate on TRIPS Agreement interpretation: Discovering the Truth of Thiland's Imposition on Pharmaceutical Patents,* Asian Journal of WTO & International Health law and Policy, Vol. 7, No. 1, 225-261, 227 (March 2012).
[36] Swarup Kumar, "*Compulsory Licensing Provision under TRIPS: A Study of Roche vs Natco Case in India vis-à-vis the Applicability of the Principle of Audi Alteram Partem*", SCRIPTed Vol 7, Issue 1, 135 – 154, 137 (2010)
[37]Alan M. Fisch, „*Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem"*, 34 JURIMETRICS J. 295, 295-315, 296-297 (1994)
[38] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 2005, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf
[39] Sara M. Ford, "*Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents*", 15 Am. U. Int'l L. Rev. 941, 941-974, 946 (1999-2000)

1.1.3 Interpretation and Implementation

As already noted above, the discussion over TRIPS, especially in the field of pharmaceuticals is a rather controversial one and is so also in terms of implementation and interpretation of TRIPS Agreement. Even though implementing process is a necessary requirement, interpretation is mainly left to the discretion of the state, at least in the regulation of pharmaceuticals. Principles and objectives are laid down in the Articles 7 and 8 and according to Dr Correa they constitute "central piece for implementation and interpretation of the TRIPS Agreement".[40] Proper interpretation of those Articles, and TRIPS in general would lead to a conclusion that the main principle and objective of TRIPS is to "maintain balance in global innovation system"[41]. Further, it should lower the tension between developed and developing nations and in the end the implementation of TRIPS should result in new essential medicines at affordable prices.[42] Most developing countries are in need of medicines and one of the best ways to develop and improve this is through compulsory licensing.[43] In the process of implementing TRIPS provisions and along the path to affordable medicines, developing countries had to introduce reforms and to change their intellectual property laws. Due to totally different regimes, most of which were mainly unregulated, numerous problems arose especially in the area of protection of pharmaceutical products,[44] which eventually influenced TRIPS implementation.

[40] Peter K. Yu, *the Objectives and Principles of the TRIPS Agreement*, Houston Law Review, Vol 46, 797-1046, 1018, (May 2009).
[41] *Ibid.* at 1039.
[42] Elen F. M 't Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 39-60, 42 (2003)
[43] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 2005, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf
[44] Carlos Correa, Implementing the TRIPS in developing countries, (March 25, 2012), http://www.twnside.org.sg/title/ment-cn.htm

The starting point in the implementation process is that all countries, by acceding to the WTO, accept all agreements administered by this organization.[45] However, from the beginning TRIPS provided some benefits and exceptions for the least developed and developing countries in the form of time frames for application of provision. The initial time frame was 5 years (up to 2000) for developing countries and 10 years (up to 2006) for the least developed countries.[46] The time frame for least developed countries was later changed and prolonged to 1 July 2013.[47] On the other side developed countries had only one year to make their national laws conform to the TRIPS Agreement.[48] A least developed country is defined in accordance with the United Nation definition.[49] As for the issue of protection of pharmaceuticals, time frame was prolonged under the Doha Declaration up to 2005 for developing and up to 2016 for least developed countries.[50] Basically, least developed countries got an additional 10 years to meet their obligations and to implement TRIPS provisions. In the process of interpretation and implementation, both Articles 7 and 8 should have played an important role in ensuring, as much as possible, balance between developed and developing countries [51] as well as economic development. However, more and more dissatisfaction is directed toward implementation and interpretation of the Agreement, mainly by developing countries who believe that the Agreement is being largely influenced by the

[45] WTO, Frequently asked questions about TRIPS: Does the TRIPS Agreement apply to all WTO members?, (March 17, 2013) http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm
[46] WTO, TRIPS and pharmaceutical patents, Fact Sheet September 2003, (March 17, 2013) http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf
[47] *Ibid.*
[48] WTO, Intellectual Property: protection and enforcement, (March 17, 2013), http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm
[49] WTO, who are developing countries in WTO? , (March 17, 2013) http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm)
[50] UNAIDS, Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries, 2011, (March 19, 2013) http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2258_techbrief_TRIPS-access-medicines-LDC_en.pdf
[51] Peter K. Yu, *the Objectives and Principles of the TRIPS Agreement*, Houston Law Review, Vol 46, 797-1046, 797 (May 2009).

developed countries and that the consequences will eventually negatively influence world health system. [52]

1.2 Doha Declaration

The declaration on TRIPS Agreement and Public Health ("Doha Declaration"), adopted at the Fourth WTO Ministerial Conference held in Doha, Qatar in 2001 represents a step forward mainly for developing countries by providing access to medicine and health care by simplifying the compulsory license clause and by removing possible legal "battles" and consequences.[53]

1.2.1 Road to Doha and role of public health

The establishment of TRIPS brought important changes in the fields of intellectual property protection, especially in the field of protection of pharmaceutical patents and "forced" its member states that did not have protection of pharmaceutical patents to amend their national laws and make them compliant with TRIPS.[54] However, the implementation of TRIPS and protection of pharmaceutical patents, due to diverse national regimes, was not an easy process and raised numerous concerns for implications and misinterpretation of TRIPS and public health which might occur. Even though TRIPS provides safeguards to mitigate the negative

[52] *Ibid*. at 797
[53]Lalitha N., Doha Declaration and Compulsory Licensing for Access to Medicine, 2009. Paper downloaded from http://ideas.repec.org/p/ess/wpaper/id2216.html
[54]South Center Policy Brief, *The Doha declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, No. 7, 1-18, 1 (November 1, 2011)

effects for both patent protection and abuse, it does not provide guidelines for states how to use these safeguards in practice when they are confronting constant barriers in accessing medical products due to patent protection.[55]

As seen from the developing countries prospective, prior to the Doha Round, developed countries were the major decision makers and it was time to confront them and demand more attention to the developing countries interests and problems. [56] Developing countries thought that developed countries should pay some attention to them and their needs, and to put their interests on the same path as their own. It was apparent and known that developing countries were unable to solve one of their biggest problems - protection of health systems and access to pharmaceutical products. Increased growth of infection and spread of diseases (AIDS, malaria) and financial barriers to affordable medicines that could prevent and cure those diseases, finally encourage developed countries to involve. According to the United Nations Commission on Human Rights report, presented by Alan O. Skyes, TRIPS should be interpreted more flexibly in the promotion of access to drugs since access to drug is a human right.[57]. In order to raise awareness of their problems, "African Group" along with other developing nations made statement to the TRIPS Council expressing their concerns about implications between TRIPS agreement and access to the drugs.[58] As a part of progress, members of World Trade Organization from time to time meet and organize periodic negotiations ("rounds") where old rules are being revised and new rules established[59]. It seems that the "African Group" proposal was not worthless, since in a short

[55]Elen F. M 'T Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 39-60, 39 (2003)

[56] Ian F. Ferguson, WTO Negotiations: The Doha Development Agenda, 2008, (March 20, 2013), http://www.nationalaglawcenter.org/assets/crs/RL32060.pdf

[57]Alan O. Skyes, *„TRIPS, Pharmaceutical, Developing Countries, and the Doha „Solution""*, Chicago Law & Economics, Olin Working paper No. 140, 1-31 , 8 (February 2002)

[58]Carlos M. Correa, Implications of Doha Declaration on The TRIPS Agreement and Public Health, June 2002, http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf

[59] Ian F. Ferguson, WTO Negotiations: The Doha Development Agenda, 2008, 1, (March 20, 2013), http://www.nationalaglawcenter.org/assets/crs/RL32060.pdf

time the Doha Round was organized, issue of access to medicine was discussed and as a result public health was given priority over private intellectual property.[60]

Doha Declaration did not solve all the problems relating to the public health and intellectual property rights, but they made enormous progress by emphasizing that member states may use flexibilities (compulsory licensing, parallel import, production for export, etc.) provided by the agreement in order to protect public health[61].

1.2.2 Doha provisions and compulsory licensing

Before the Doha Debate, developing nations wanted clarification of the TRIPS and public health, recognition of health problems, access to medicines, clarification or simplification of compulsory licensing and parallel import, and so on. After the conference in Doha, developing nations had more than enough reasons to be satisfied since their prayers were mostly heard and would soon be fulfilled. Paragraph 1 of Doha Debate recognizes the importance of public health problems, mainly in developing and least developed countries that result from HIV, tuberculosis, malaria and other epidemics. [62] Most of the time spent on negotiations in Doha, was spent on Paragraph 4 mainly because, once more, developed and developing nations were not able to find a common language. Finally, Brazil and United States[63], among others reached a conclusion providing that "the TRIPS Agreement does not

[60] Elen F. M. 't Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 39-60, 50 (2003)
[61] WTO, The Doha Declaration Explained, (March 21, 2013), http://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm
[62] WTO, Declaration on the TRIPS Agreement and Public Health, (March 22, 2013), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm
[63] Faced with large number of HIV infected and high mortality rate in 1990s, Brazil started with AIDS program, based on medicines produces locally, with aim to reduce mortality rate. Soon program showed to be more than successful since mortality rate has significantly lowered and Brazil saved a lot of money on hospital costs. Brazil was able to produce drugs locally, and to negotiate lower price due to their Patent Law which allows for

and should not prevent members from taking measures to protect public health" and further support "WTO member' right to protect public health, and in particular, to promote access to medicines to all".[64] As it can be seen from Paragraph 4 of the text, protection of the health and promotion access to medicine is above everything, including patents. So, in a case of a clash between protection of public health and protection of patent, protection of public heath will prevail.

Paragraph 5[65], which is restating Article 31 of TRIPS, under subparagraph (a)provides that any issues should be resolved within the meaning of Articles 7 and 8 of TRIPS Agreement; (b) it is up to member state to determine grounds for compulsory licensing; (c) determines and simplifies the meaning of what constitutes a national emergency and provides that epidemics like HIV, malaria and so on represent a national emergency; and (d) Member States are free to establishes their own regimes (like allowance of parallel import in case of exhaustion). The most important difference between Article 31 and Paragraph 5 (b) is that phrase "compulsory licensing" is finally used. The use of proper wording may raise awareness, mainly about possible utilization of compulsory licensing to meet public health.[66] It can be reasonably concluded that Paragraph 5, in relation to Article 31, simplifies and clarifies it, and provide that Member State has a right to grant compulsory licenses, to determine grounds for it, determine what constitute national emergency and define its licensing regime. The Doha Declaration is not limiting Member States in any way in the granting compulsory licensing. It is up to them to decide what "national emergency" means and what diseases will be threatening for public health.

compulsory licensing. United States was of opinion that Brazilian law is violating provision of TRIPS and brought a case before WTO Dispute Settlement Body. United States eventually withdraw action against Brazil, but these two countries were the main negotiators during the Doha debate in respect to Paragraph 4.

[64]WTO, Declaration on the TRIPS Agreement and Public Health, (March 22, 2013), http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[65] *Ibid.*

[66] Carlos M. Correa, "*Implication of the Doha Declaration on the TRIPS Agreement and Public Heath*." Health Economics and Drugs: Essential drugs and Medicines Policy Series No. 12, 2002.

At the time when the Doha Declaration was enacted, certain disagreements were directed toward paragraph 6 since it was partly left unfinished with recommendation for an expeditious solution, but it still provided that compulsory licensing will be predominantly for supply of the domestic market[67]. It addressed productivity but left importers dependent on exporters.[68] In that time the main aim of compulsory licensing was to supply domestic market, so the owner had opportunity to prevent distribution of his products to other markets because his rights have not expired.[69] However, a solution to this "problem" arrived two years later (announced in 2003, adopted in 2005) in the form of a waiver of Article 31(f) providing that compulsory licensing for public health may be issued either for domestic use or export. One of the amendments of Article 31(f) "allows pharmaceutical products to be made under compulsory licensing to be exported to countries lacking production capacity" without double remuneration[70] to patent owner. Rwanda was first country to announce that it would import cheaper generic medicine under compulsory licensing from Canada as they were unable to produce them locally.[71] This provision should work and help least developed countries who are unable to produce drugs locally to import cheaper generic drugs. However, in order to comply with this provision, member states will need to change their national law once more under which they would be able to export pharmaceutical products. [72]

[67]Lalitha N., *Doha Declaration and Compulsory Licensing for Access to Medicine*, 2009. Paper downloaded from http://ideas.repec.org/p/ess/wpaper/id2216.html
[68] Beal Reed, Huhn Randall „*Trends in Compulsory Licesning of Pharmaceuticals Since the Doha decalration: A database analysis*", Research Article PLoS Med 9(1), January 10, 2012, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154#references
[69]Alberto do Amaral Junior, *Compulsory Licensing and Access to Medicines in Developing Countries*, 2005, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf
[70] WTO, Members OK Amendment to Make Health flexibility permanent, December 2005, (March 23, 2013) http://www.wto.org/english/news_e/pres05_e/pr426_e.htm
[71]Lalitha N., *Doha Declaration and Compulsory Licensing for Access to Medicine*, 2009. Paper downloaded from http://ideas.repec.org/p/ess/wpaper/id2216.html
[72] *Ibid.*

The last paragraph of the Doha Declaration, paragraph 7, regulates the extension of time for compliance and protection of pharmaceutical patents for least developed countries till January 2016.[73]

The Declaration on the TRIPS agreement and public health, fulfilled almost all "prayers and whishes" of developing nations. It did not change TRIPS provisions tremendously; rather it provided certain guiding principles for developing countries on how to get access to medicine. The Declaration distinguishes drugs from other trade commodities and provides right for the countries to maintain flexibilities from the TRIPS for protection of public health.[74]

1.2.3 Implementation and legal status

Many nations up to now have included compulsory licensing provision into their national laws[75]. However, the least developed countries are still facing a number of difficulties in the implementation process. For those that did not amend national law, Doha provides additional time up to January 2016 to implement pharmaceutical patent protection into their national laws, while for the developing countries there is no extension of time for implementation. Extended deadlines for least developed countries along with other benefits are significant to them because they are gaining the opportunity to think about pharmaceutical patent regulation

[73]Beal Reed, Huhn Randall „Trends in Compulsory Licesning of Pharmaceuticals Since the Doha decalration: A database analysis", Research Article PLoS Med 9(1), January 10, 2012, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154#references

[74] Kerry B. Vanessa and Lee Kelly, *TRIPS, the Doha Declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?*, 2007, (March 23, 2013) http://www.globalizationandhealth.com/content/3/1/3

[75] F. M. Scherer and Jayashree Watal, *Post Trips Options for Access to Patented Medicines in Developing Nation,* J Int'l Economic Law 5 (4):913-939, 915 (2002)

they want to amend into their national system but still retaining possibility to import and produce generic medicines.[76]

The Doha Declaration serves as a strong foundation for developing countries to adopt measures and comply with TRIPS provision "without having fear to be dragged into legal battles."[77] Since Doha is not self-executing, both developing and developed countries should adopt Doha Declaration and implement it into their national system.[78]

Ministerial declarations are not "legally binding" within WTO and in the case of dispute national approved treaties will prevail over declaration. However, Doha as interpretive of imprecise obligation of TRIPS would serve as persuasive authority in the case of dispute.[79] Moreover, taking into account content and mode of approval of Doha Declaration it can be concluded that it has same effect as authoritative interpretation. [80]

Even though any member of the WTO has the opportunity to bring complaint before Dispute Settlement Body for the issues covered by the Doha Declaration, this would unlikely happen since by the adoption of the Doha Declaration members exercised their competence to interpret the WTO.[81]

In the conclusion, the Doha Declaration represents an important tool in the interpretation of the TRIPS provisions, clarification of TRIPS flexibilities and promotion of the public health.[82]

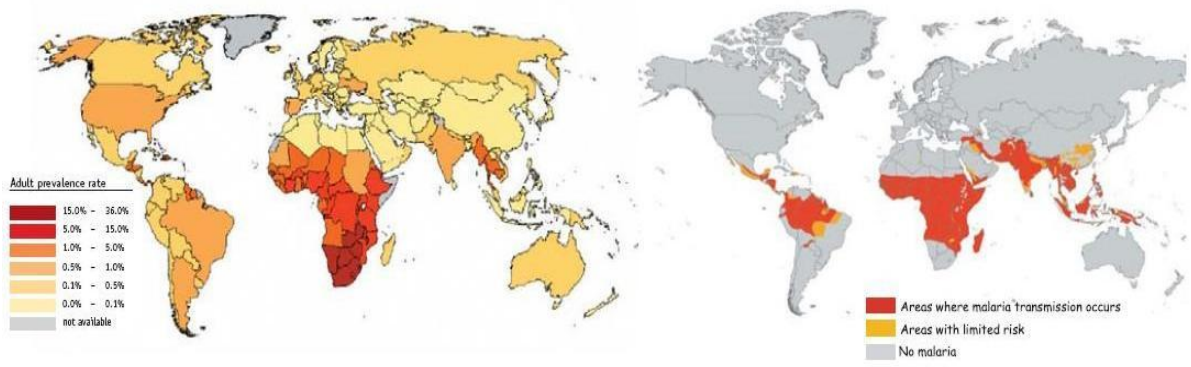
[76] ElenF. M 't Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Challenges, Paris, 39-60, 53 (2003)
[77] Carlos M. Correa, "*Implication of the Doha Declaration on the TRIPS Agreement and Public Heath*. " Health Economics and Drugs: Essential drugs and Medicines Policy Series No. 12, 44, (2002=
[78] *Ibid*. at 45
[79] Alan O. Skyes, *„TRIPS, Pharmaceutical, Developing Countries, and the Doha „Solution""*, Chicago Law & Economics, Olin Working paper No. 140, 1-31, 9 (February 2002)
[80] Carlos M. Correa, "*Implication of the Doha Declaration on the TRIPS Agreement and Public Heath*. " Health Economics and Drugs: Essential drugs and Medicines Policy Series No. 12, 25, (2002)
[81] *Ibid.* at 45
[82] South Center Policy Brief, *The Doha declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, No. 7, 1-18, 10 (November 1, 2011).

2 PHARMACEUTICAL PATENT, ACCESS TO MEDICINE AND DEVELOPING COUNTRIES

Developing countries continually face numerous obstacles on their way to reach desired goals and to become developed country or at least to get one step closer to them. Besides poverty as one of the biggest problems of developing countries influencing inability of people to afford medicines, lack of regulations on public health has also a significant impact on the spreading of diseases since it impedes prevention programs. Malaria, tuberculosis, HIV/SIDA, dengue fever and so on are some of infectious diseases that affect poor people in developing countries.[83]It must be noted that numerous discrepancies in health regulations exists mainly between North and South, but also between East and West taking as an example East and West Europe. These discrepancies are mainly due to socioeconomic situations in the countries. Diseases like tuberculosis are specific for the developing countries and countries with low socioeconomic status[84], while on the other side HIV/AIDS, as specific form, affects both developed and developing countries but is more common in the countries with high risk sexual behavior than for traditional countries with monogamy communities.[85]According to the WHO in 2011, 34 million people were living with HIV/AIDS where more than 95% of HIV infected people is coming from developing countries.[86] Only sub-Saharan Africa counts more than 69% of these cases.[87]Other diseases also impose great threat to public health and endanger human life. In 2010, WHO estimated that there are more than 219 million cases of

[83] Ridley B. David, Grabowski H. Henry and Moe L. Jeffery, *Developing Drugs for Developing Countries*, Health Affairs, 25, no.2, 313-324, 313 (2006)
[84] See European Center for Disease Prevention and Control and WHO, I, 2012, http://ecdc.europa.eu/en/publications/publications/1203-annual-tb-report.pdf. Beside Europe it includes other countries like: China, Russia, Turkey, India, and South Africa.
[85] See HIV and AIDS in Western and Central Europe, (March 24, 2013) http://www.avert.org/aids-europe.htm Beside Europe other countries in Sub-Saharn Africa like South Africa, Nigeria, India, Kenya
[86] WHO, Media Center: HIV/AIDS, Fact Sheet from Novembar 2012, (March 18, 2012) http://www.who.int/mediacentre/factsheets/fs360/en/index.html
[87] *Ibid.*

malaria mostly affecting children in Africa.[88]Beside malaria, tuberculosis, as the third most common disease, according to the WTO counts around 8.7 million disease infected people. Unlike HIV which is not curable, or malaria which is mainly in developing countries, tuberculosis is curable and preventable and present in both developed and developing countries.[89]Figure 1 below provides global picture of malaria and HIV prevalence. It shows that the highest HIV prevalence and malaria distribution is in the Sub-Saharan area. Beside Sub-Saharan area, both diseases are also spread in the South-East Asia and northern part of South America. Unlike malaria, HIV is widely spread and affects most of the parts of South America and Asia, but also Australia, Europe and North America (among which pretty much high rate for developed countries had United States).



Distribution of HIV prevalence

Distribution of endemic malaria

Figure 1[90]

As for the numerous problems, solutions exist but are influenced and slowed down by many factors like barriers in development of drug or unavailability to access them. Access to essential medicines is mainly influenced by the high drug price which is due to patent

[88] WHO, Media Center: Malaria, Fact Sheet from January 2013, (March 18, 2013) http://www.who.int/mediacentre/factsheets/fs094/en/index.html

[89] WHO, Media Center: Tuberculosis, Fact Sheet from February 2013, (March 18, 2013) http://www.who.int/mediacentre/factsheets/fs104/en/)

[90] The Internationalis, *Is Terrorism a bigger threat than AIDS or Malaria?*, July 2007, (March 17,2013) http://www.abytheliberal.com/world-politics/terrorism-bigger-threat-than-aids

protection[91]and so it is reasonable to say that patent on pharmaceutical represents main reason why people in developing countries do not have access or lacks access to AIDS treatment.[92] For infectious diseases in developing countries there has been little or no access to drugs, but for the other, easily treated illnesses like asthma, diabetes or mental illness there is access but the prices of the drugs are beyond the income of the population and therefore not available.[93]

2.1 Patent on Pharmaceutical and Compulsory Licensing

First patent regulations in its coverage did not include any protection of pharmaceutical patents. This was the case up to the middle of the 20th century when developed countries started introducing national pharmaceutical patent regulations in their system.[94]On the other side, developing countries did not provide for the protection of pharmaceutical patents mainly because they believed that patent protection would lead to monopolistic markets and possible abuse thereof and the need for medications is constantly increasing. [95] Rights that patent provide are commonly misunderstood. Patent provides "the right to keep others from making, using, offering for sale, selling, and importing the claimed invention, and thereby provides a

[91] See Meeting Report "*UNDP WHO Workshop on the Examination of Pharmaceutical Patents: Develeoping a Public Health Prospective*", Cape Town, (October 30 2008). pp 8, http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/meeting-report-from-undp-and-who-workshop-on-the-examination-of-pharmaceutical-patents-developing-a-public-health-perspective-/

[92] Combe Emmanuel, Pfister Etienne and Zuniga Pluvia, „ *Pharmaceutical Patents, Developing countries and HIV/AIDS Research"*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 151-168¸151 (2003)

[93] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 2005, 1, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

[94] Combe Emmanuel, Pfister Etienne and Zuniga Pluvia, „ *Pharmaceutical Patents, Developing countries and HIV/AIDS Research"*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 151-168¸152 (2003) „Most industrialized countries, such as United Kingdom (in 1949), France (1959), Germany (1968), Italy and Sweden (in 1970), Japan (in 1976), have introduced patent protection for pharmaceutical inovations".

[95] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 2005, 3, (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

meaningful exclusionary right." [96] Even though the word "monopoly" does not appear anywhere in patent definition, based from the context it can be stated that patent provides for "legal monopoly" during certain period of time. However, with time patents for pharmaceuticals become needed due to a numerous global changes influencing tremendous increase of diseases and consequently necessity for medications. Invention of new drugs is not an easy process; rather it is expensive and lengthy one. According to the DiMassi et al., estimated costs of a developing new drug in the 1990s was around $ 400 million and required 4 to 10 years to develop it. Therefore, taking this into consideration, invention of a new drug should require protection under law or otherwise, as practice showed, drugs were and can be easily copied and put on the market. [97]

Protection of pharmaceutical patents and TRIPS notably influenced access to health care since, due to patent protection, price of medicines increased leaving as a consequence the inability of people in developing nations to afford them. Limiting the access of developing nations toward accession of pharmaceutical products, by imposing economic barriers, increased the already apparent gap between North and South.[98] In order to enhance access to health care "developing countries sought a declaration recognizing their right to implement certain pro-competitive measures, notably compulsory licenses and parallel imports. "[99]In facilitating access to medicines, TRIPS Agreement contains provisions which help developing nations to ease negative effects imposed by pharmaceutical patent regulations. In recent years, significant growth in the number of countries that are using flexibilities provided by the TRIPS is being recorded. More and more countries, especially in Africa, are issuing

[96]Silverman B. Arnold, „Is a patent a monpoly?", April 2004 (March 26, 2013) http://www.tms.org/pubs/journals/JOM/matters/matters-0404.html

[97] DiMasi, J., H. Grabowski and J. Vernon, *R&D costs and returns by therapeutic category*", Drug Information Journal 38(3):211-23; (2004); Margaret Kyle and Anita McGahan, *„Investment in pharmaceuticals before and after TRIPS"*, NBER Working Paper No. 15468, 6, (Ocober 2009)

[98] Possas Christina, „*Emerging Issues: Pharmaceuticals and patents in Developing countries*", Economica, Rio De Janeiro, v.10, n.2, 147-166, 148, (December 2008),

[99] Carlos M. Correa, "*Implication of the Doha Declaration on the TRIPS Agreement and Public Heath*. " Health Economics and Drugs: Essential drugs and Medicines Policy Series No. 12, 10, (2002)

compulsory licensing and changing their national laws either for reducing prices of medicines or to increase access to them.[100]

From January 1, 1995 up to June 6, 2011, 17 nations granted 24 compulsory licenses for 22 pharmaceutical products for different diseases. Some countries like Brazil in 2007 and Thailand in 2010 renewed already given compulsory licenses. Most of the countries provided compulsory licensing for HIV/AIDS, for some or all products. Figure 2 below provides list of the states, by the year, which granted compulsory licensing for pharmaceutical patents.

Year(s)	Nation	National Income Group	Disease	Disease Group	Total Products	Outcome
2001 (2007)	Brazil	UMIC	HIV/AIDS	HIV/AIDS	2	CL/discount
2001	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2001	Canada	HIC	Anthrax	CD	1	Discount
2001–2003	South Africa	UMIC	HIV/AIDS	HIV/AIDS	8	VL/discount/none
2001	United States	HIC	Anthrax	CD	1	Discount
2002	Egypt	LIC	Erectile dysfunction	NCD	1	CL
2003–2004	Malaysia	UMIC	HIV/AIDS	HIV/AIDS	3	CL
2003, 2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2003	Zimbabwe	LIC	HIV/AIDS	HIV/AIDS	All	CL
2004	Mozambique	LDC	HIV/AIDS	HIV/AIDS	3	CL
2004	Zambia	LDC	HIV/AIDS	HIV/AIDS	3	CL
2005–2006	Argentina	UMIC	Pandemic flu	CD	1	VL
2005–2007	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005–2009	Brazil	UMIC	HIV/AIDS	HIV/AIDS	1	Discount
2005	Ghana	LIC	HIV/AIDS	HIV/AIDS	All	CL
2005	Indonesia	LIC	HIV/AIDS	HIV/AIDS	2	CL
2005	Taiwan	HIC	Pandemic flu	CD	1	VL
2006–2007	India	LIC	Cancer	NCD	1	None
2006 (2010)	Thailand	UMIC	HIV/AIDS	HIV/AIDS	1	CL
2007	Rwanda	LDC	HIV/AIDS	HIV/AIDS	1	CL
2007 (2010)	Thailand	UMIC	HIV/AIDS, CVD	HIV/AIDS, NCD	2	CL
2007–2008	Thailand	UMIC	Cancer	NCD	1	Discount
2007–2008	Thailand	UMIC	Cancer	NCD	3	CL
2010	Ecuador	UMIC	HIV/AIDS	HIV/AIDS	1	CL

Totals: 24 Episodes, 17 Nations, 40 Unique Drug-Nation Combinations +2 Categorical CLs. Years in parentheses indicate CL renewals.
CVD, cardiovascular disease.
doi:10.1371/journal.pmed.1001154.t001

Figure 2 [101]

[100] See Meeting Report "*UNDP WHO Workshop on the Examination of Pharmaceutical Patents: Develeoping a Public Health Prospective*", Cape Town, (October 30 2008). p 8-9, http://www.undp.org/content/undp/en/home/librarypage/hiv-aids/meeting-report-from-undp-and-who-workshop-on-the-examination-of-pharmaceutical-patents-developing-a-public-health-perspective-/

[101] Beal Reed, Huhn Randall „Trends in Compulsory Licesning of Pharmaceuticals Since the Doha decalration: A database analysis", Research Article PLoS Med 9(1), January 10, 2012, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154#references

As it shows, in the last 12 years number of countries using compulsory licensing is increasing and compulsory licensing is not provided only for treatment of HIV/AIDS but also for treatment of cancer, pandemic flue or anthrax. It also indicates that some countries issued more than one compulsory licensing like Brazil or Thailand and that outcome may not be same every time. Rather, sometimes it may include only compulsory licensing, sometimes only discount for the drug price and sometimes both of these together.

Compulsory licensing, represent an important tool for developing countries in accessing medicines at lower prices by stimulating competition through which prices of medicines significantly decrease. [102]

2.1.1 Pharmaceutical industry

Discrepancy between developed and developing countries in relation to the compulsory licensing causes different approaches among them and hence different possibilities. Those differences are mainly reflected through the pharmaceutical industry and unavailability and lack of affordability to produce medicines. Pharmaceutical companies come from developed countries, meaning that developed countries are the one dictating the development of pharmaceutical industry. As previously noted above, research and development of new drugs cost enormously and pharmaceutical companies do not want to have their product used and produced somewhere without their consent. Moreover, in order to prevent even similar products, companies are seeking and obtaining patent on similar technologies and all for the

[102] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 1-18, 2, (2005) (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

purpose to prevent other competitors of producing and placing it on the market.[103] Basic assumption is that pharmaceutical companies, same as other business entities, work for the maximizing the profit and development of new pharmaceutical product, due to high development cost requires patent protection. However, patent regulation on pharmaceuticals did not lead to any increase in research and development process in developed countries, according to the study conducted between from 1978 to 2002.[104] As for the compulsory licensing, there is no data either supporting or opposing the statement that compulsory licensing reduced research and development investments in developed and developing countries. This is mainly due to the fact that companies are intending to be competitive and on the market in the long run. Moreover, compulsory licensing of pharmaceuticals in developing countries is not affecting the pharmaceutical industry on a large scale since less than 20% of pharmaceutical products come from the market of developing countries which is a pretty small number and can only be an incentive for raising competition in these markets.[105]

For the global diseases like AIDS/HIV, there is an incentive to invest into research and development, while for the diseases that mainly affect developing and poor countries those incentives are usually lacking.[106] In developing countries, most of the people are suffering from "neglected" diseases[107] among which the mostly spread one and the most important one is malaria. There is no expectation from pharmaceutical companies to get at least a positive

[103] Yosick, J. *'Compulsory patent licensing for efficient use of inventions*', University of Illinois Law Review, vol. 2001, no. 5, 1275–1304, 1276, (2001)

[104] Margaret Kyle, Anita McGahan, *„Investment in pharmaceuticals before and after TRIPS"*, NBER Working Paper No. 15468, 1-39, 6 (Ocober 2009)

[105] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 1-18, 9-10 (2005) (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

[106] Margaret Kyle, Anita McGahan, *„Investment in pharmaceuticals before and after TRIPS"*, NBER Working Paper No. 15468, 1-39, 19 (Ocober 2009)

[107] Neglected Diseases, (March 19, 2913), http://rarediseases.info.nih.gov/files/Neglected_Diseases_FAQs.pdf Last visited March 19, 2013. "Neglected diseases are conditions that inflict severe health burdens on the world's poorest people. Many of these conditions are infectious diseases that are most prevalent in tropical climates, particularly in areas with unsafe drinking water, poor sanitation, substandard housing and little or no access to health care. Typically, private pharmaceutical companies cannot recover the cost of developing and producing treatments for these diseases. Another reason neglected diseases are not considered high priorities for prevention or treatment is because they usually do not affect people who live in the United States and other developed nations."

return of investments from research and development from diseases mainly affecting people in developing countries. Since companies work for maximizing the profit, they are investing into research and development for diseases like AIDS/HIV; diseases present on the market of both developed and developing countries and where their investments will eventually pay off.[108] On the other side, "pharmaceutical companies" or small firms in developing countries do not have either technological or financial capital to compete with pharmaceutical companies from developed countries and to produce their own pharmaceutical products.[109]

Use of compulsory licensing for pharmaceutical patents in developing countries may be beneficial to both developed and developing countries. Developed countries, as stronger both economically and politically, should be one step ahead and provide high level of protection for pharmaceutical patents in their countries. This higher level of protection would lead to greater and safer use of compulsory licensing by developing countries. Through this step, it would be possible to adopt different prices on medicines according to the need of the market.[110] Meaning: poorer market lower prices, richer market higher prices. This would lead to increase in prices in developed countries and eventually providing economic balance for pharmaceutical companies.

[108]Ridley B. David, Grabowski H. Henry and Moe L. Jeffery, „*Developing Drugs for Developing Countries*", Health Affairs, 25, no.2, 313-324, 316 (2006)

[109] Combe Emmanuel, Pfister Etienne and Zuniga Pluvia, „ *Pharmaceutical Patents, Developing countries and HIV/AIDS Research"*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 151-168¸159 (2003)

[110] Alberto do Amaral Junior, Compulsory Licensing and Access to Medicines in Developing Countries, 1-18, 14 (2005) (March 22, 2013) http://www.law.yale.edu/documents/pdf/Compulsory_Licensing.pdf

2.1.2 Discriminatory Pricing and Parallel Import

Regardless of scope of industry and market abilities, differential pricing is present in almost every sphere of industry. This is due to different economic characteristic of the consumers as well as market demand. According to Peter Hammer, price discrimination in form of charging higher prices in developed countries and lower prices in developing countries, is due to the variations in economic cost.[111] As in every industry and so in pharmaceutical industry, charging a different price on essential medicines in different parts of the world is mainly due to the rationale business strategy since businesses tends to make profit by selling their products. This rationale business strategy may either be explained by charging high prices or lower prices on different markets. In 2007, after series of compulsory licensing for HIV drugs in Brazil and Thailand, as a part of business strategy, Abbott decided to decrease prices of drugs for developing countries.[112] The theory behind this strategy was simple. It was more beneficial for Abbott to decrease prices of HIV instead to face with numerous compulsory licensing. Peter Hammer, argues that businesses will discriminate when charging different prices to different customers due to their different economic characteristic. He compares this with discount ticket in cinema and segregating customers according to their demands. There is higher demand of students and old people to go to the cinema and watch movies. However, even though having time, they are sometimes short with the money. Therefore, solution comes is form of giving them discount for tickets.[113] This comparison can easy be applied on demand for HIV drugs. In developing world, namely Sub-Saharan Africa, there is constant demand for HIV drugs unlike developed world where demand exist but in much smaller

[111] Peter J. Hammer, „Differetnial Pricinf of essential Aids Drugs: Politics and Public Helath", Journal Of Internationa Economic Law, 883-912, at 883 (2002)
[112] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, *AIDS Treatment in Brazil: Impacts and Challenges*, Health Affairs, vol 28. No 4, 1103-1113, 1108 (July/August 2009)
[113] Peter J. Hammer, „Differetnial Pricing of essential Aids Drugs: Politics and Public Helath", Journal Of Internationa Economic Law, 883-912, at 884 (2002)

scope. Even though having urgent need for HIV drugs, people lack capital to afford it. In the developed world, people have capital but there is no such need for HIV drugs as in developing countries. Therefore, in high elasticity market where increase of price may result with loss of customers, lower price will be charged. On the other side, in low elasticity demand, higher price will be charged since it will not influence customers demand.[114] This business strategy can be more beneficial to the pharmaceutical companies than strategy of charging same, high prices on global market. Charging lower prices is more efficient way and beneficial for pharmaceutical companies to return investments from R&D than receiving royalties from compulsory licensing.[115] Doha Declaration clearly provides that diseases cannot be limited and that protection of public health is above protection of intellectual property rights. This insinuate that charging same prices will in certain way force developing countries to use TRIPS flexibilities and produce generic drugs at more affordable prices. However, discriminatory pricing "influenced" by "principle of exhaustion"[116] may cause difficulties for both pharmaceutical companies and market in general. Principle of exhaustion, clarified by Doha Declaration Article 5(d)[117], provides that member states are free to deal with exhaustion in accordance with their own regimes. This means that when patent holder places patented product on the market, his right to control it within internal market is lost.[118] Charging higher prices on drugs in one market (Ciprofloxacin drug in Mozambique, $740 per 100 units) will cause parallel import into that market from some other market with lower drug

[114] Alan O. Skyes, *„TRIPS, Pharmaceutical, Developing Countries, and the Doha „Solution""*, Chicago Law & Economics, Olin Working paper No. 140, 1-31 , 19 (February 2002)
[115] Danzon PM, Towse A, Differential Pricing for Pharmaceuticals: reconcilling access R&D and Patents, Int J Health Care Finance Econ, 2003 Sep (3) 183-205, 183.
[116] TRIPS Agreement, Article 6
[117] Doha Declaration, Article 5 (d)
[118] "exhaustion of rights doctrine" Black's Law Dictionary (9th Edition 2009), available at *westlaw.com*, (March 28, 2013)

prices (India $15).[119] Under parallel import Mozambique is therefore eligible to import Ciprofloxacin drug from India.

Recent studies have shown that parallel trade of pharmaceuticals between developing countries increases their total welfare, while as for parallel import of developed countries total welfare is decreasing.[120] As for discriminatory pricing, scholars argue that prices should be higher in industrialized countries and lower in developing countries since that is the way for pharmaceutical companies to earn get back costs of production and to remain with incentive to invest into new drug development. Roger Bate and Kathryn Boateng came to the conclusion that price discrimination is maximizing welfare, providing for economic benefits and represents solution to increase access to the drugs, and not the problem.[121]

2.2 Case Study: Lesson from Brazil, India and Thailand

In the practice compulsory licensing has been used by certain developed countries like Italy and Canada as well as certain developing countries like Indonesia, Thailand, Brazil, Ecuador, Ghana, India and so on. Brazil and India are important since they are constantly present on the international scene of compulsory licensing of pharmaceutical patents and they are continually bringing new progress in this field. These countries are using flexibilities provided by the Doha Declaration on TRIPS and Public Health, not only by successfully providing access to medicine to their own citizens but also through mutual cooperation and exchange of services and they are serving as an example to other developing countries by

[119] WHO, Parallel Import, (March 28, 2013), http://www.who.int/trade/glossary/story070/en/
[120] Jelovac Izabela and Catalina Bordoy, *Pricing and Welfare Implications of Parallel Imports in the Pharmaceutical Industry*, International Journal of Health Care, Finance and Economics, 5, 5-21, at 20 (2005)
[121] Roger Bate and Kathryn Boateng, "Drug Pricing and Its Discontents", August 9, 2007, (March 28, 2013) http://www.aei.org/article/health/drug-pricing-and-its-discontents/

showing how cooperation may benefit them.[122] Nowadays, Thailand has also proven to be an important player in compulsory licensing trend. This is due to the fact that in the short time Thailand becomes most active issuer of compulsory licensing, not only for the HIV/AIDS but for cardiovascular diseases and cancer as well.[123]

2.2.1 Lesson from Brazil

Brazil has one of the most successful HIV/AIDS treatment programs in developing world. Their HIV/AIDS prevention program started in 1980s. However in recent years it includes maximum usage of Doha flexibilities for providing access to medicine to treat people with HIV/AIDS.

In 1996, in order to improve access to medicines and to protect public health, Brazil enacted Industrial Property Law which was in compliance with TRIPS provision on protection of pharmaceutical patents from 1995. Patent protection of medicines resulted in their higher costs. Due to need for medicines, Brazil started local production of generic medicines. However, that move was not welcomed by developed countries, namely Unites States, who brought a claim before WTO Dispute Settlement Body. However, due to the public protests United States eventually withdraw their claim. [124]

In the recent years, from 2007 up to now, 2012 Brazil introduced compulsory licensing, and provided guidance to other countries on how to promote access to medicine. In 2007, Brazil

[122] WIPO, Regional Seminar for certain Latin American and Caribean Countries on the Implementation and use of Several Patent Related Flexibilities, Topic 10: *The use of Compulsory Licensing*, Bogota, Columbia, February 2012, (March 27, 2013), http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_bog_12/wipo_ip_bog_12_ref_u10c_binsfeld.pdf

[123] Beal Reed, Huhn Randall „Trends in Compulsory Licesning of Pharmaceuticals Since the Doha decalration: A database analysis", Research Article PLoS Med 9(1), January 10, 2012, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154#references

[124] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, *AIDS Treatment in Brazil: Impacts and Challenges*, Health Affairs, vol 28. No 4, 1103-1113, 1103-04 (July/August 2009)

started to negotiate with Mereck and Co., producers of Efavirenz, to reduce 60% of drug price as they were selling to Thailand government otherwise they would issue compulsory licensing for this drug. Since Mereck did not agree to price reduction more than 30% of original drug price, Brazilian government issued compulsory licensing to import Efavirenz. [125] Under Brazilian Industrial Property Law, Articles 68, 70 and 71, compulsory licensing may be granted in a case of non-exploitation of patent within Brazilian territory, abusive exercise of patent rights and economic power, dependency on another or public interest and national emergency.[126] In 2007, in accordance with Article 71 of Brazilian Law, Brazil declared Efavirenz a drug which is in public interest for treatment of HIV/AIDS, therefore making it eligible for compulsory licensing. Compulsory licensing was granted for period of 5 years, up to 2012 and in that time it was estimated that Brazil saved about $ 237 million by buying Indian generic product for lower price. Even though criticized by pharmaceutical companies, this grant was legal under both national and international patent law. [127]

In the 2012, Brazil announced that they will renew compulsory license for Efavirenz, as soon as it expires. Practice of using Efavirenz showed to be positive decision since 50% of AIDS treatment in Brazil is done using this drug. Only difference in respect to compulsory licensing issued in 2007, would be production process of Efavirenz. Since 2009, supply of Efavirenz was based partially on imports from India and partially from local production. Starting 2012, supply of Brazil with Efavirenz is based solely on local production.[128]

Lesson from Brazil on compulsory licensing may serve as good incentive for other countries on how to promote access to medicine first by trying to negotiate prices than engaging themselves through compulsory licensing into local production or import of generic drugs.

[125] Keith Alcorn, *Brazil issues compulsory license on Efavirenz*", NAM Publications 07 May 2007, (March 25, 2013) http://www.aidsmap.com/Brazil-issues-compulsory-license-on-efavirenz/page/1427206/
[126] Section III of Brazil Law No. 9279 of May 14 1996 (Industrial Property Law)
[127] Alcorn, Keith, "Brazil issues compulsory license on efavirenz", NAM Publications 07 May 2007 (available at http://www.aidsmap.com/Brazil-issues-compulsory-license-on-efavirenz/page/1427206/)
[128] AIDS, "Brazil renews compulsory license for Efavirenz", May 7 2012, (available at http://www.aids.gov.br/en/en/noticia/2012/brazil_renews_compulsory_license_efavirenz)

Brazil influenced global picture on AIDS and access to medicine and showed that treatment of AIDS is possible in developing countries.[129]

2.2.2 Lesson from India

For long time, Indian Patent Act did not contain any patent protection for pharmaceuticals. This was the case up to 2005 when India, due to the necessity to comply with TRIPS, amended its national law and included patent protection for pharmaceuticals. Among the Patent law changes, after Article 92, section Article 92A was added which provides for compulsory license for export and manufacture of pharmaceuticals to the countries with insufficient manufacturing capacities for the countries that granted compulsory licensing. [130]

Before this amendment, India established itself as one of the main suppliers of generic pharmaceuticals to the developing world since there was no protection for pharmaceutical patents. Therefore generic drug companies were producing generic HIV drugs by using different manufacturing process and exporting them to the countries in the developing world.[131] However, even with the Amendment of national law position of India did not change. Up to 2010, due to the low-price and quality medicines, Indian manufactures of generic HIV drugs were dominating and supplying the majority of the market in developing countries. [132] According to the research by Wanning at al. in 2008, 96 out of 100 countries reported that they are purchasing generic antiretroviral (ARV) from Indian generic

[129] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, "AIDS Treatment in Brazil: Impacts and Challenges", Health Affairs, July/Augusts 2009, vol 28. No 4 1103-1113
[130] Section 92A of India Patents (Amendment) Act, 2005
[131] Carroll, Sorcha '*Importing Indian generic drugs following TRIPs: Case studies from Zambia and Kenya*, 1, (2005) (March 26, 2013) http://www.mcmillan.ca/Files/SOCarroll_ImportingIndianGenericDrugs.pdf
[132] Waning B, Diedrichsen E. and Moon S., *A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries*, J Int AIDS Soc. 2010, Sep 14. According to the results, India supplied around 80% of annual market. The number of Indian manufactures supplying market of developing countries was constantly increasing.

manufactures while, only 29 countries reported that they are making their purchase from non-Indian manufactures.[133] Reason why India remained as leading supplier of ARV generic drugs is that 2005 amendment, India included waiver of the TRIPS Article 31(f). India was one of the first countries, along with Norway and Canada, to implement this waiver into their national laws; therefore it was eligible to export generic drugs under compulsory licensing.[134]

India continues to benefits from compulsory licensing. In 2012, India was granted compulsory license to manufacture and sell generic version of cancer drug produced by German pharmaceutical company Bayer due to the claim that Nexavar drug is of public interest and Bayer is imposing unaffordable prices on the Nexavar [135] . Some critic consider this decision rather controversial and believe that it is not reasonable to grant compulsory licensing for kidney and liver disease since they do not constitute "public interest" such as HIV/AIDS, malaria or tuberculosis. Critics would probably have a lot more to say since in March 2013, India granted three more compulsory licenses for patented cancer drugs.[136] It is obvious that India is using TRIPS and Doha flexibilities as much as possible, and other than being inexpensive supplier of drugs, they serve as an excellent example to other countries on how to benefit from compulsory licensing.

2.2.3 Lesson from Thailand

[133] *Ibid*., Table 1.
[134] WTO, Compulsory licensing of pharmaceuticals and TRIPS, (March 17, 2013), http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm Waiver of Article 31(f) provides that compulsory licensing for public health may be issued either for domestic use or export. One of the amendments of Article 31(f) "allows pharmaceutical products to be made under compulsory licensing to be exported to countries lacking production capacity"
[135] Bryan Vogel, *IP: India compulsory licensing case*, Inside Counsel, June 5, 2012; (March 24, 2012) http://www.insidecounsel.com/2012/06/05/ip-indias-compulsory-licensing-case
[136] Mrinalini Gupta, *India: Compulsory Licensing for Three more patented Cancer Drugs*, March 15, 2013; (March 24, 2013) http://www.mondaq.com/india/x/227102/Patent/Compulsory+Licensing+For+Three+More+Patented+Cancer+Drugs

Up to 2006, from the enactment of TRIPS Agreement, Thailand was pretty much on the stand by option in respect to compulsory licensing. In 2006, there was an avalanche of compulsory licenses for pharmaceutical patents in Thailand. This sudden movement was due to the continuing increase in the number of patients suffering from cancer and heart diseases in 2003, as well as in sudden rise of HIV patients.[137] In order to facilitate access to medicine and to prevent increasing rates from further growth, in 2006 and 2007 Thailand issued compulsory licenses for import of generic cardiovascular diseases and ARV.[138]

In 2006 Thailand issued their first compulsory license for drug Efavirenz, intended to treat patients with HIV/AIDS. Shortly after, in January 2007, Thailand issued two more compulsory licenses; one for HIV/AIDS drug named Kaletra (drug used in later phase of HIV/AIDS disease) and other for drug Plavix, used to treat heart disease. One year after, Thailand government issued four additional compulsory licenses on drugs used to treat cancer, where most, including previous one were granted for public non-commercial use[139].

As expected, criticism toward Thai government came from all sides. Most of the criticism was based on the notion that reason for compulsory licensing was illegitimate one, since Thailand was not facing public emergencies. In addition, there was a general notion that purpose of the government was to advance its own budget and not health sector especially since some of the compulsory licenses were granted to government agencies, and that, compulsory licenses were not in accordance with TRIPS provisions therefore they may affect future legitimacy of Article 31.[140]

[137] Suwan-in, Nattapong, *Compulsory License, a Long Debate on TRIPS Agreement interpretation: Discovering the Truth of Thiland's Imposition on Pharmaceutical Patents,* Asian Journal of WTO & International Health law and Policy, Vol. 7, No. 1, 225-261, 228 (March 2012).
[138] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, *AIDS Treatment in Brazil: Impacts and Challenges*, Health Affairs, vol 28. No 4, 1103-1113, 1108 (July/August 2009)
[139] Suwan-in, Nattapong, *Compulsory License, a Long Debate on TRIPS Agreement interpretation: Discovering the Truth of Thailand's Imposition on Pharmaceutical Patents,* Asian Journal of WTO & International Health law and Policy, Vol. 7, No. 1, 225-261, 239 (March 2012).
[140] Jerome J. Reichman, *Compulsory licensing of pharmaceutical patented invention: evaluating the options*, J Law Med Ethics, 2009 Summer 37(2): 247–263.

TRIPS and Doha provides that diseases cannot be limited, and that every country can decide on their own what constitutes public emergency and state the grounds for granting compulsory licensing. Thailand government justified these compulsory licenses as matter of public interest since; need to promote access to essential medicines and way to reduce drug prices.[141]

Even though Thailand was facing a lot of negative critics, they benefited from compulsory licensing and, along with Brazil, brought numerous changes and benefits to developing nations, since the prices of the AIDS drugs significantly decreased due to their compulsory licenses for HIV/AIDS drugs.[142]

[141] Suwan-in, Nattapong, *Compulsory License, a Long Debate on TRIPS Agreement interpretation: Discovering the Truth of Thailand's Imposition on Pharmaceutical Patents,* Asian Journal of WTO & International Health law and Policy, Vol. 7, No. 1, 225-261, 240 (March 2012).

[142] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, *AIDS Treatment in Brazil: Impacts and Challenges*, Health Affairs, vol 28. No 4, 1103-1113, (July/August 2009) Abbott was one of the first pharmaceutical companies to lower the price of HIV/AIDS in developing world. It was presumed that trend of compulsory licensing will soon involve large number of developing countries.

3 POST DOHA AND FURTHER RECOMMENDATIONS

In the near future, when the transitional period ends, all WTO members would have to provide protection for pharmaceutical patents. This further means that in order to access essential medicines, countries would have to use flexibilities provided by the TRIPS in the form of compulsory licensing through which they will lower the price of medicines.[143]By using TRIPS flexibilities countries will promote access to medicine and protect public health.

3.1 Implementation on the National Level

At first, countries did not implement pharmaceutical patent protection and waited for the last moment to do this. The basic notion was that patent protection will affect ability for development and exportation of generic drugs of those countries that are capable to produce drugs locally like Brazil and India[144]. However, that notion proved to be wrong since TRIPS and DOHA provide measures like compulsory licensing and parallel import for the purpose of protecting public health, i.e. balancing between patent holder and protection of public health. Even though compulsory licensing and it's relation to public health at first seemed to be unclear, Doha Declaration in Paragraph 4 clarifies that Agreement should be implemented supporting WTO Members rights for protection of public health.[145]

[143]Correa Carlos and Matthews Duncan, „*Dicussion Paper: The Doha Declaration Ten Years on and Its Impact on Access to Medicines and the Right to Healt*", United Nations development program, December 20 2011, at 16, (March 22, 2013), http://www.undp.org/content/dam/undp/library/hivaids/Discussion_Paper_Doha_Declaration_Public_Health.pdf

[144] Alsegard Erik, *Global pharmaceutical patents after the Doha Declaration - What lies in the future*, Volume 1, Issue 1, SCRIPT-ed., at 20, (March 2004)

[145] Doha Declaration, Article 4

However, due to the lack of adequate patent protection, developing countries are facing problems in protection of public health and access to medicine. Therefore, they must amend their national laws in order to implement TRIPS flexibilities which would, through compulsory licensing or parallel import, facilitate access to medicine.[146] For the countries that are still facing problems in the implementation phase, like least developed countries, developed countries should extend their deadline and provide technical and financial support for facilitating implementation process.[147] We are approaching to the deadline, January 1 2016, and so the process of implementation should be accelerated. However, least developed countries will not be able to do it without additional legal and technical assistance of international scene (developed countries, WTO and WIPO), which has proven to be insufficient and inadequate up to now.[148]

11 years after Doha, a significant number of countries amended their national laws and started using TRIPS flexibilities granted to them. Brazil, Zimbabwe, Ghana and Ecuador are just some of the countries which were "rewarded" for amending national laws and now through compulsory licensing provide to their people in some way affordable access to medicines. The fact is that protection of pharmaceutical patents is there, and will remain there. It is apparent that lack of pharmaceutical protection will lead to lack of investments into research and development of new drugs. And new drugs are essential for the well being of our society. Therefore, implementation of TRIPS provisions must be conducted on national levels since it is the only way, and rather useful way, for all to benefit.

[146] South Center Policy Brief, *The Doha declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, No. 7, 1-18, at 7 (November 1, 2011)
[147] Lalitha N., Doha Declaration and Compulsory Licensing for Access to Medicine, at 9, (2009). Paper downloaded from http://ideas.repec.org/p/ess/wpaper/id2216.html
[148] South Center Policy Brief, *The Doha declaration on TRIPS and Public Health Ten Years Later: The State of Implementation*, No. 7, 1-18, at 6 (November 1, 2011)

3.2 Conflicting interests: Producers v. Importers of Drugs

The Doha Declaration provides for a liberal and wider use of compulsory licensing of pharmaceuticals and not just for developing countries but also for developed ones. However conflict of interest, even though smaller in scope, is still present between producers of the drugs which are developed countries and importers of the drugs which are mainly developing countries and least developed countries.

Even before TRIPS came into force, compulsory licensing of pharmaceutical was used in developed countries like the United States, Canada and Germany. As being developed countries they had manufacturing potential and knowledge to produce new drugs, but through compulsory licensing they wanted to spread knowledge and increase innovation. This is to say that for the needs of developed countries and protection of public health, compulsory licensing was an appropriate instrument. On the other hand, with the introduction of TRIPS and compulsory licensing on the international scene, this appropriate instrument was not anymore appropriate. Pharmaceutical companies represented by developed countries believed that "poor countries" would abuse the compulsory licensing system and lead to lower returns from research and development investments'. [149]

In the world of developed nations, namely the United States in 2001, the use of compulsory licensing was justifiable and a proper solution for prevention and fight against a possible anthrax attack. The United States actually threatened to use compulsory licensing for ciprofloxacin in the case that Bayer did not accepted to sell them at half price. [150] In the same period, in the world of developing nations, the fight against already existing disease like

[149] Rafael Pinho Senra de Morais, *Compuslory Licesning of drugs, Parallel Imports and Price Controls*, Getulio Vargas Foundation, Touluse School of Economics, at 6, (March 2009) http://professores.ibmecrj.br/erg/wkshops/2009/papers/20090522.pdf

[150] James Love Packard, *Recent examples of the use of compulsory licenses on patents*, Knowledge Ecology International, KEI Research Note 2007:2, at 3, (March 8, 2007)

HIV/AIDS and use of compulsory licensing was not justifiable and a proper solution. In the 2001, United States filled a complaint in the WTO Dispute Settlement Body against Brazil in respect to their compulsory licensing provisions.[151] These two cases reflect different positions of countries belonging to these two worlds, different understandings and needs that mutually influenced on conflict of interests before but also after Doha.

The Doha Declaration came as a light at the end of the tunnel providing clarification of TRIPS and public health and TRIPS flexibilities for such areas as compulsory licensing, parallel import and production for export. With time, existing conflicting interest came into balance between producers and importers of drugs. Canada and Rwanda, in their mutual cooperation program, showed one way on which conflicting interest may be balanced. By using TRIPS flexibilities, both countries will benefit: Rwanda by importing TriAvir, drug used to treat HIV/AIDS and Canadian company Apotex, Inc from exporting and selling drugs.[152]

As already discussed in Chapter 2, compulsory licensing on pharmaceutical patents does not influence the pharmaceutical industry either in increasing research and development for develop countries or decreasing it in developing countries. Therefore, arguments that at the beginning created conflicting interest between developed and developing nations, showed to be incorrect. However, certain things must still be done in order to balance and bring countries on the same path. Balance may be accomplished by manufacturing and exporting pharmaceutical patents from developed countries into countries facing health problems. On step toward balancing interest was undertaken by the European Union and EC Regulation

[151] *Ibid*. at 14. Due to the large number of HIV infected in 1990s, Brazil started AIDS prevention program based on medicines produced locally with aim to reduce mortality. Program showed to be more than successful. Brazil was able to produce drugs locally, and to negotiate lower price due to their Patent Law which allows for compulsory licensing. United States was of opinion that Brazilian law is violating provision of TRIPS and brought a case before WTO Dispute Settlement Body. United States eventually withdraw action against Brazil.
[152] Royle Matthew and Wessing Tylor, *Compuslory Lisening and access to medicine – Rwanda experience*, February 20, 2008, (March 21, 2013) http://www.currentpartnering.com/2008/02/20/compulsory-licenses-and-access-to-medicines-rwanda-experience/

816/2006 acknowledging that there is no limit on the scope of diseases and providing for requirements and conditions for exporting medicines to the countries that lack manufacturing capacity.[153] Through this step, both producers and importers may benefit. This step would therefore be better than remuneration which should be paid in a case of compulsory licensing, since according to the Raphael de Morais remuneration is insignificant for a big pharmaceutical company having the patent. This is due to the fact that remuneration ranges from 0,5% to 4% of sales value, where sales value usually ranges from 1/10 to 1/50 of original drug price.[154]

Figure 3 below provides classification of compulsory licensing by time period (from one year before Doha to 10 years after the Doha) and by national income group. Figure 3 can be linked with Figure 2 in Chapter 2 which provides a list of the countries that granted compulsory licensing. As it can be seen from the chart, in the period from 2001 and including a little period after Doha to 2002, compulsory licensing was granted 6 times in the upper middle income and high income countries. Namely, before Doha United States and Canada as HIC and Brazil and South Africa as UMIC granted compulsory licensing. Soon after Doha, the first country that issued compulsory licensing was Egypt as a low income country. Figure 2 clearly points out that most compulsory licensing activity (namely eleven) was in the period from 2003 to 2005, where a slight decline in compulsory licensing activity by the HIC is evident (only one country - Taiwan), while at the same time UMIC and LIC are evidencing increasing number of compulsory licensing activities. Moreover, for the first time the least developed countries are appearing on the international scene for compulsory licensing of pharmaceutical patents, like Zimbabwe, Ghana and Indonesia. From 2006 up to 2012, the

[153] James Love Packard, *Recent examples of the use of compulsory licenses on patents*, Knowledge Ecology International, KEI Research Note 2007:2, at 8 (March 8, 2007)
[154] Rafael Pinho Senra de Morais, *Compuslory Licesning of drugs, Parallel Imports and Price Controls*, Getulio Vargas Foundation, Touluse School of Economics, at 7, (March 2009) http://professores.ibmecrj.br/erg/wkshops/2009/papers/20090522.pdf

activity of compulsory licensing is decreasing comparing to the period from 2003 to 2005. In the recent times, there was no activity of compulsory licensing issued by the HIC, and where UMIC, LIC and LDC are evidencing slight decline. In this period Thailand's shown to be most dominated country issuing 4 compulsory licensing for cancer and HIV/AIDS. In the period after Doha, 25 cases of compulsory licensing of pharmaceutical products were brought and almost half of them were in the short period, from 2003 to 2005. Since 2005, there is evident decreasing trend of compulsory licensing.

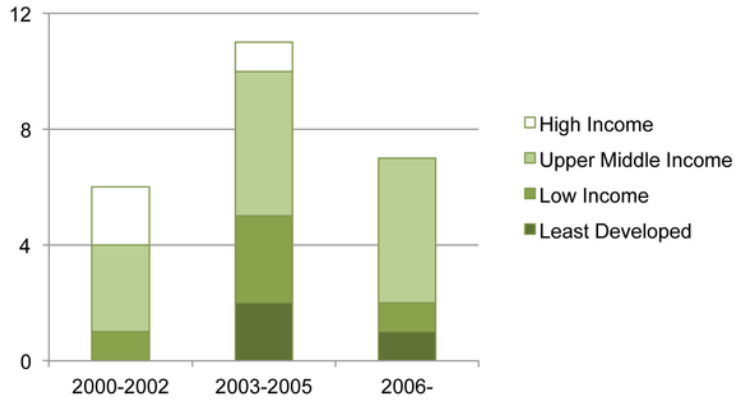


Figure 3 [155]

There is no reasonable explanation why this trend is decreasing since Doha promotes access to health without obstacles, and the data obtained from countries using compulsory licensing shows positive results. Thailand issued four compulsory licensing in a short period which indicates that this mechanism benefits them. Moreover, India, Brazil, Zimbabwe, Ecuador are just some of the countries enjoying flexibilities provided by TRIPS and Doha without any difficulties and promoting access to medicine.

Even though the number of compulsory licensing cases has grown after Doha, there were no clashes between states like in the few years before Doha (South Africa, Brazil). In my

[155] Beal Reed, Huhn Randall „Trends in Compulsory Licesning of Pharmaceuticals Since the Doha decalration: A database analysis", Research Article PLoS Med 9(1), January 10, 2012, http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154#references

opinion, main reason is because Doha provided clear guidelines for compulsory licensing and access to medicine, and promoting public health over the interests of patent holder. Since Doha, diseases cannot be limited and each state has freedom to determine what constitute public health crisis and what are the grounds upon which compulsory license is granted.[156]

Looking into period from Doha to now, it is apparent that Doha brought numerous positive changes in respect to the use of compulsory licensing which consequently balanced conflicting interests between developed and developing nations.

3.3 Measures to improve compulsory licensing

Even though TRIPS Provisions and Doha provide numerous requirements and conditions for compulsory licensing there are still some options and measures available in order to facilitate the granting of compulsory licensing and by that access to medicine.

3.3.1 Compulsory licensing and Alternative Dispute Resolution

Under current legislation, the competent authority for granting compulsory licensing is the national authority, which vary from country to country but usually it is either a department of the executive branch or a judicial court.[157] It is known from everyday life that litigation processes and response from national authorities, like department of the executive branch, usually takes a lot of time and beside it can be rather costly.

[156] Doha Declaration, Article 5
[157] Correa M. Carlos, *Guide for Application and Granting of compulsory licenses and authorization of government use of pharmaceutical patents*, WHO/PHI/2009, at 11, (March 26, 2013), http://apps.who.int/medicinedocs/documents/s19902en/s19902en.pdf

On the other hand, Alternative Dispute Resolution like arbitration may be a good solution for the process of granting compulsory licensing. Compulsory licensing is not an everyday process which judges in the national system face. Therefore, just one of the advantages of having an arbitrator before a judge is competence and legal expertise in this field; moreover due to the neutrality of the arbitrator, speedy and probably a less costly procedure.[158]

Similar solution for improving compulsory licensing is provided by the Productivity Commission of Australian Government, where instead of submitting applications for compulsory licensing to their Federal Court, same should be submitted and arbitrated by proper dispute resolution body. One of those bodies may be either Australian Competition Tribunal or Copyright Tribunal of Australia or some new tribunal established for these matters.[159]

As already discussed, compulsory licensing of pharmaceuticals represents one highly debated topic having on the one side developed countries and pharmaceutical companies and on the other side developing countries and NGOs. Before granting compulsory licensing, courts are faced with possible ways to protect public health on one side and pharmaceutical companies with their already established goal to maximize the profit on the other side. It is not unusual to hear arguments that host states tend to rule with a bias toward host state when granting compulsory licensing. Therefore, arbitration can play an important role by balancing interests between patent holder, patent holder's state and host state[160] by providing a neutral decision.

[158] Tibor Varady, John J. Barcelo III, Arthur T. von Mehren, International Commercial Arbitration 27, at 26, (5th Ed. Thomson/West 2012).
[159] Productivity Commision of Austalian Government, *Compulsory licensing of Patents*, at 28, (August 2012), http://www.pc.gov.au/__data/assets/pdf_file/0018/119061/patents-issues.pdf The Producitivity Commision is the Australian Government's independent research and advisory board on a range of economic, social and environmental issues affecting the welfare of Australians. Its role is to help governments make better policies, in the long term interest of the Australian Community.
[160], Peter B. Rutledge, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation, and International Arbitration*, 13 N. C. J. L & Tech On. 149 (2012).

3.3.2 Raising awareness and role of NGOs

NGO's generally, play an important role in raising international awareness toward the emerging issues which developing countries face in the attempt to access medicines. Their influence on the international scene became especially apparent by placing emphasis to the TRIPS provisions, mainly to the compulsory licensing provisions, as a possible way to increase access to medicine.[161] In 1999 they organized the "Amsterdam Conference on Increasing Access to Essential Drugs" the aim of which was to call for and promote heath as a priority over intellectual property rights. During that Conference they drew up the "Amsterdam Statement" which called for establishment of Working Group on access to medicines which would work within WTO and consider how trade policies influence developing and least developing nations. Besides protecting intellectual property rights, rights to have access to medicine should also be acknowledged.[162] Their intention to protect public health did not stop here, and their influence was and is noted widely.

Due to the high HIV mortality rate, in the 1990s Brazil initiated local production of medicines in order to reduce mortality. Even though their program was more than successful, United States thought that Brazil was violating TRIPS provisions and brought a claim against them. Before the case was resolved, the United States withdrew their claim. The reason for this outcome was the enormous influence of NGOs which through numerous media, public protests and even court claims, lobbied the government to provide care for public health and

[161] Elen F. M 't Hoen, *TRIPS, Phrmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond*, in J.P. Moatti, B. Coriat, Y. Souteyrand, B. Barnett, J. Dumoulin, and Y.A. Flori, Economics of AIDS and Access to HIV/AIDS Care in Developing Countries, Issues and Chalanges, Paris, 39-60, 46, (2003)
[162]WHO, *WHO Drug Information*, Vol.13, No.14, at 223, (1999), http://apps.who.int/medicinedocs/en/d/Jh1461e/1.4.html) „The Conference whas organized by Health Action International, Médecins Sans Frontières, and Consumer Project on Technology. The Conference took place in Amsterdam, the Netherlands, November 25-26, 1999"

AIDS treatment. Eventually, due to this huge controversy, the protection of public heath prevailed.[163]

NGOs strengths can be further reflected through the experience of Kenya. Even though facing high HIV mortality rate, due to the TRIPS provisions and protection of intellectual property rights, limited care was provided. Something had to be done, so NGOs, along with other African states, advocated new essential medicine strategy which would eventually lower the pressure imposed on patent protection.[164] Kenya is facing a long way toward better future, but certainly NGOs contributed a lot by raising awareness in the society for the problems affecting developing countries.

NGOs are continuously present and ready to work on the all world "fronts". Recognizing problems that India is facing, NGOs started the fight against patents and commenced process seeking compulsory licensing for cancer drugs.[165]

The role of NGOs should not be neglected since their influence on the international scene, as the evidence shows in recent years, is enormous and has brought numerous positive changes.

[163] Nunn Amy Stewart, Elize Massard da Fonseca, Francisco Bastos and Gruskin Sofia, *AIDS Treatment in Brazil: Impacts and Challenges*, Health Affairs, vol 28. No 4, 1103-1113, (July/August 2009)
[164] Sihaya Ben, *Patents, paralel importation and compulsory licesing of HIV/AIDS Drugs: The experience of Kenya*, 2005; (March 20, 2013), http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm
[165] Vinay Ganti, *NGO to push for compulsory licesing of cancer drugs*, August 8, 2008; (March 20, 2013) http://www.thinkchangeindia.org/2008/04/09/ngo-to-push-for-compulsory-licensing-of-cancer-drugs/

CONCLUSION

Compulsory licensing is a strong and important mechanism for developing countries on their way toward access to medicine by circumventing patent regulations in accordance with the TRIPS provisions. The fact is that diseases are spreading and people in developing countries either do not have access or cannot afford medicines due to high prices imposed by patent protection on pharmaceuticals. This paper provided an overview of possible benefits of compulsory licensing on developing countries which are on their way toward access to medicines. Supporting evidence used in this paper were recent compulsory licensing experiences from Brazil, India and Thailand.

This paper showed that TRIPS and Doha brought numerous positive changes for developing countries in respect to promotion of public health and access to medicine. However, these changes are not possible without amendments of national law in respect to pharmaceutical patent protection and compliance with TRIPS and Doha provisions. Compliance represents an important step forward for developing countries. It allows them a use of flexibilities, such as compulsory licensing, which is helpful in their fight with public health problems and it provides them an access toward affordable medicines. Brazil, India and Thailand are example of how countries should use compulsory licenses, and how mutual cooperation may be beneficiary to their own citizens, as well as it may contribute to a global price reduction of AIDS/HIV drugs.

Nevertheless, this paper did not disregard the importance of patent protection in the pharmaceutical field, as well as possible effects on the future investments into development of new drugs due to compulsory licensing. The results showed that granting compulsory licensing for pharmaceuticals in developing countries did not either positively or negatively influenced incentive to invest into new drug development. Additionally, this paper provided short overview of discriminatory pricing of pharmaceuticals, its benefits for the developing

countries in form of lower drug prices in comparison with industrialized countries and benefits of parallel import. In the conclusion part, this thesis showed that conflict of interests between pharmaceutical companies (producers) and developing countries (importers), or generally between developed and developing countries still exist, but in much smaller scope than at the beginning of 21st century.

Compulsory licensing represents effective tool for developing countries to promote and protect its public health, at the same time while increasing its total welfare.

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