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Green technology patents.

- TRIPS, compulsory licensing and global health.

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Abbreviation	Explanation
AIDS	Acquired Immunodeficiency Syndrome
ARV	Anti-retroviral drugs (for HIV/AIDS treatment)
BIC	Brazil, India and China
EAP	Environment Action Program
Doha Declaration	Declaration on the TRIPS Agreement and Public Health
EU	European Union
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
IP	Intellectual Property
LDC	Least Developed Countries
TEU	Treaty on European Union
TFEU	The Treaty on the Functioning of the European Union
TRIPS	The Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
US	The United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. Introduction

1.1. Background

The WHO has currently pointed out that most people living in Asia should be concerned. “The levels of air quality which we see in India, Pakistan, Iran and China are very worrying”. “Air pollution has a huge impact on human health.”¹ Emerging nations now function as the heart of manufacturing and many developed nations have outsourced their production. However, the world has not yet reached a unanimous agreement regarding emission of carbon dioxide and that is becoming bothersome.

The current state of public health related to air pollution is considered alarming according to the WHO.² Conferences, protocols and treaties are either in process or have been processed to meet the raising demand for a more safe and sound co-habitation. Under the TRIPS agreement, developing and developed countries has the right – under certain circumstances – to exercise their right to emit compulsory licenses for patents that has been determined necessary for the country and public health.

The last two decades have involved endless discussions regarding access to medicine. Some solutions have been presented but the fact is that the issues concerning transfer of pharmaceutical products to LDC members of the WTO has increased as a result of the TRIPS agreement.³ It turned out that when countries could access medicine patents through compulsory license, they did not possess the technique, know-how or necessary equipment to produce the actual pharmaceutical product.

When the Doha Declaration was enacted, there was finally a more clear way on how developing nations and LDC would be able access affordable and necessary pharmaceutical products. Sadly, access to pharmaceutical products such as medicine for instance, is not the only health problem in the world.

¹ See Gardiner, Harris, *Cities in India Among the Most Polluted*, *W.H.O. Says*, New York Times, May 8 2014.

<http://www.nytimes.com/2014/05/09/world/asia/cities-in-india-among-the-most-polluted-who-says.html?>

² Outdoor air pollution, Public Health and Environment (PHE), World Health Organization Available at:

http://www.who.int/phe/health_topics/outdoorair/en/index.html

³ See Moon, Suerie, *Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999-2007)*, Center for International Development, Kennedy School of Government, Harvard University, 2008, p.1.

This thesis is about the possibility to emit a compulsory license, when the state of public health requires so, for a green technology patent. A patent can in general be granted, among several things, for the process of making a product or for the product itself. Green technology patents are in general related to certain types of processes, for instance certain techniques, pharmaceutical products may be produced via a patented process or the patent could cover the specific composition of the product. It is important to point out the distinctions between accessing a certain process patent or a product patent.

The scope of the Doha Declaration involves the promotion and emphasizes the protection of public health, it was also reaffirmed that every member state has the right to determine what constitutes an emergency and what actions are required to handle it. This was reaffirmed in relation to Article 31 of the TRIPS agreement, which means that a member state has the right to grant a compulsory license when it is deemed necessary.

The thesis suggests that it is possible to grant a compulsory license for a green technology patent under the TRIPS flexibilities. However, the thesis also points out complicated issues with defining the health danger and the urgency requirements set forth in Article 31. The current state of the environment is problematic and the WHO has pointed out several issues that could constitute a real danger to health. The issue that there is no real possibility for green technology to transfer to the least developed countries, is also bothersome. Technology preventing or reducing air pollution will be hard to transfer under current circumstances and the current state of the TRIPS agreement does not extend the compulsory remedy beyond the Doha Declaration.

The thesis also identifies the BIC countries as more active when it comes to the use of compulsory licensing. Having this position means that they are the ones pushing the development, considering that they play a part in the disputes that tend to arise afterwards. They have been advocating in international politics since at least 2008, that the TRIPS agreement should be expanded to cover environmental health as well.

1.2. Research question

- The Doha Declaration pointed out the importance of allowing WTO members to take action to secure public health. It was later clarified how to access patented pharmaceutical products, via compulsory license, even without having the necessary manufacturing capabilities. The importance of public health was explicitly stressed, but no clarification regarding environmental issues such as outdoors air pollution were addressed. So how does environment relate to health and what is the scope of the Doha Declaration?

- Green technology and medicine are two different categories, but when it comes to the protection of public health could a compulsory license for a green technology patent be justified?

- Is it necessary to add a separate clarification to TRIPS, regarding access to green technology, and does the TRIPS agreement extend the compulsory license remedy beyond the Doha declaration?

1.3. Delimitation

The reader is expected to possess a good command regarding the TRIPS agreement, the Doha Declaration and the concept of compulsory licensing. The thesis will solely take material from international organizations mentioned in order to provide something that could serve as base for further discussions. BIC are not to be understood as LDC.

The meaning is, hopefully, not to redundantly explain the concept of compulsory licensing. It has been described countless times and more detailed before by reputable scholars and in several renowned legal reviews. However, a certain level of explanation is needed and it will follow us through the thesis.

Due to the limited scope provided for and the slightly complicated task, several areas are just briefly touched upon. These areas that are touched upon are far more complicated than one could possibly explain in this thesis, issues regarding macroeconomic issues, political agendas, infrastructure

development to facilitate transfers of technology etc. This also impacts the depth of the analysis.

With regards to national legislation in the EU, its member states and in the US, very little, yet some emphasize is being made concerning the antitrust aspect of compulsory licensing. The point here is to achieve deeper understanding for the ideas behind the system of compulsory licensing in the domestic legislation, which could support the aim of this thesis. Cases and ideas of particular interest here are those related to “public interest” and “public health”.

The aim is to investigate possibilities for transfer of green technology to BIC from developed countries or from BIC to LDC. Under what circumstances can BIC and LDC access green technology so that they can “leap-frog” into healthy and environmentally sustainable manufacturing. The aim is not to investigate national patent laws for scope of protection.

Where national patent law has been mentioned it is used to find patterns and reasoning and consensus among several nations. This consensus, if present, is used to compare behavior with regards to national legislation in other areas, in international negotiations and for potential arguments.

1.4. Method and Material

Method

Considering the political nature of the topic and the TRIPS it should be mentioned that a majority of the thesis is conducted through teleological interpretation of the relevant articles in the agreement as well as national legislation. The material is then further analyzed through a contextual and comparative method. In this case the compulsory license has been a common denominator throughout the thesis. When comparing national legislation throughout the world, it is used as a complement to TRIPS; it is not the main purpose. It is also made in order to seek consensus among particular aspects of the compulsory license institute in national legislation.

The relationship between our environment and health is investigated in order to find a possible link between the two.

When comparing green technology and medicine in the public health context, a great part of the material has been gathered from articles from

academics, as well as relevant cases, regarding compulsory licensing of medicine.

In order to grasp the international nature of the topic the BIC countries have been given a position in this thesis. BIC has a strong economic position and many times appear as the middleman between LDC and developed countries; India's opportunity to produce medicine for LDC under compulsory licenses as an example. They were also presented because of their opportunity to act on the global political arena.

Material

Well known legal sources are used, such as EU treaties, regulations, the US code and statutes, relevant case law, guidelines, policy statements, commentaries, but also material and agreements from WTO, WIPO, WHO, OECD, as well as articles from academic journals providing legal opinions or ideas regarding the EU, the US and BIC on the topic.

1.5. Structure

In order to understand the layout of this thesis it should be mentioned that Part 2 explains the system for compulsory licensing under the TRIPS, in the EU and in the US.

Part 3 explains the relation and links between the environment and public health in the scope of the Doha Declaration. The use of the term public health comes from the medicine focus in the Doha Declaration.

Part 4 looks back at part 3 in order to make comparisons and connections between different aspects of public health. We look further into policy and the use of compulsory licensing of patents under national emergency and other circumstances of extreme urgency and the determine whether a compulsory license for a green technology patent can be justified.

Part 5 will treat the question whether an additional clarification is an option and if the TRIPS agreement extends the compulsory license remedy beyond the Doha Declaration.

Part 6 presents an outlook in BIC and some observation from current patent regulations, development and BICs possibility to help, to benefit from and to develop LDC.

Part 7 attempts to draw conclusion from comparing part 3, part 4, part 5 and part 6 in order to answer the research questions in this thesis.

2. Compulsory licensing of patents

2.1. International legal framework

The TRIPS was a major initiative in 1994 towards an international standard for protection of IP. But going back to before 1883 there were no international agreements for IP. The Paris Convention was the first international agreement on IP and this effort trying to globalize IP rights was considered a great progress but still lacked important parts. The countries that signed the Paris Convention were allowed to create domestic laws for IP fairly flexibly and therefore they came out differently among the nations. One of the main issues with the Paris Convention was that there was no standard definition of patentable subject matter. Due to the flexibility of the agreement, some countries opted to exclude biotechnology and/ or medicine from what could be patented under national legislation.

In 1967 the next important step towards international harmonization of IP rights occurred. An organization called WIPO was created as a specialized agency under the UN. WIPO still lacked a functioning enforcement mechanism at this point, something that also had been absent in the Paris Convention.⁴

Some of the first steps toward the TRIPS agreement were the discussions that lead to the draft of the anti-counterfeiting regulations, in preparation for the 1986 GATT round. Representatives for the US proposed that all types of intellectual property rights within international trade ought to be considered. A framework for negotiation called “Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods” was later introduced in 1987. However, the participants did not adopt the agreement

⁴ See Halajian, Dina, *Inadequacy of TRIPS & the compulsory license: Why broad compulsory licensing is not a viable solution to the access to medicine problem*, Brooklyn Journal of International Law, Vol 38:3, 2013, p. 1195. Available at: http://practicum.brooklaw.edu/sites/default/files/print/pdfs/journals/brooklyn-journal-international-law/volume-38/issue-3/bjil_v38iii_5.pdf

until 1994, which also made the TRIPS agreement the first international treaty for minimum standards on intellectual property.⁵

Before TRIPS there were more than 100 nations that allowed for compulsory licensing under national legislation.⁶ Compulsory licensing had been part of national legal systems even before it got formalized under TRIPS.

Compulsory or non-voluntary licensing of a patent occurs when a government, without the consent of a patent owner, authorizes itself, its entities or a third party to use the patent based on strong public need. The patent owner might have to tolerate this since the public interest has been deemed so important that it outcompetes the patent owners exclusive right.⁷

Compulsory licensing of patents may also occur in order to maintain an efficient market economy. Most countries have provisions for compulsory licenses, either under their patent law or, as in the US, through anti-trust legislation.⁸ The most common uses of compulsory licensing for the purpose of maintaining efficient competition are to punish abuse of patent rights, punish violations of competition law and to ensure effective competition in the market by granting other parties access to dominant patents that blocks important innovations. Blocking an innovation could mean that someone has an improving innovation that needs an existing patented innovation to function. When addressing the public interest, areas such as public health, environment, security and economic development are main reasons for issuing such license. A government may issue a compulsory license for non-commercial use and the most recent kind of compulsory license allows for export of medicine to LDC, which lacks the capacity to produce that medicine in their jurisdiction.

⁵ See Stern-Dombal, Charlene A. *Tripping over TRIPS: is compulsory licensing under E-bay at odds with U.S. Statutory requirements and TRIPS?* Suffolk University Law Review, 2007. p.249.

⁶ See Bond, Eric, Saggi, Kamal, *Compulsory licensing, price controls, and access to patented foreign products*, Vanderbilt University, 2012, p.3.

⁷ Reichman, Jerome H, *Non-voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*, International Centre for Trade and Sustainable Development (ICTSD), Genève, 2003. p. 10.

Available at: http://ictsd.org/downloads/2008/06/cs_reichman_hasenzahl.pdf

⁸ See The TRIPs Agreement and Pharmaceuticals, *Report of an ASEAN Workshop on the TRIPs Agreement and its Impact on Pharmaceuticals*, Jakarta, 2000, p. 32. Available at:

<http://apps.who.int/medicinedocs/pdf/h1459e/h1459e.pdf>

These types of compulsory licenses are considered compliant with TRIPS Article 31.⁹

2.1.1. The TRIPS agreement

As expressed in Article 28.1, the exclusive rights to a patent gives the owner the right to prevent anyone else from copying, using, selling, importing that subject matter without permission. This exclusive right entitles and assures the owner to use and improve the patent as well as to receive compensation from producing the innovation, licensing or selling it. The right to compensation ought to stimulate risk taking and further investments to improve the patent. Circumstances that surround the exterior environment of patentable subject matter are expressed in Article 27.1 which requires patents to be available “*and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced*”.¹⁰

The right to transfer a patent, or any IP right for that matter, is further established in Article 28.2, the patentee may also enter into voluntary license agreements, such agreements are highly negotiable but could be regulated by national competition laws that could restrict the subsequent use of the license in that market.¹¹

The minimum standard for patent protection promotes a kind of equality when it comes to the patentable subject matter. The TRIPS agreement prohibits denial of a patent application based on the field of technology. For instance, member countries must protect medicine and biotechnology, something that had been left out earlier, under the Paris Convention, in some countries. There are also some limitations to the patent owners exclusive rights set out in the TRIPS agreement, those are covered by article 30 and the possibilities to emit a compulsory license are further stated in article 31. Overall, TRIPS imposed stronger standard protection for IP but also included certain exceptions for the sake of being flexible when dealing with

⁹ Reichman, Jerome H, *Compulsory Licensing of Patented Inventions: Comparing United States Law and Practice with Options under the TRIPS Agreement*, 2006, p. 2. Available at: <http://www.aals.org/documents/2006intprop/JeromeReichmanOutline.pdf>

¹⁰ See Reichman in note 7, p. 2.

¹¹ See Reichman in note 7, p. 13.

extraordinary circumstances.¹² These flexibilities are expressed through the language in Article 31, which allows governments to issue compulsory licenses, under certain circumstances after required criteria has been met. The most important conditions that govern the use of compulsory licensing by WTO members are the following:

- the entity (company or government) applying for a compulsory license should have been unable to obtain a voluntary license from the right holder on "reasonable" commercial terms;
- If a compulsory license is issued, adequate remuneration must be paid to the patent-holder; and a compulsory license must be granted mainly to supply the domestic market.

Exactly when a country can issue a compulsory license is not explicitly addressed by TRIPS although it does mention national emergencies, other circumstances of extreme urgency, and anti-competitive practices as possible grounds for compulsory licensing.

Inventions considered necessary to protect the *ordre public* or morale, including inventions that protects human life or health, are excluded from patentability under Article 27(2): which gives further support to the concern for public health. Article 8 and 27 of the TRIPS along with the Doha Declaration, as seen; address the clear relationship between the TRIPS and public health. However, there is no clear definition of measures available to achieve public health.

Articles 30 and 31 apply to patents in all fields, not only patents in the field of health. Article 30 allows for member countries to provide “*limited exceptions*” to a patent holder’s exclusive rights: “*provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*”

Article 31 further describes a general set of exceptions for unauthorized use of patents, in particular the compulsory license exception. The set consists of acts that need to apply or needs to be taken before the grant of a compulsory license. For instance a serious negotiation, under a certain time and under reasonable terms, to obtain a license linked to the patent has to be conducted without an agreement.

¹² See Halajian in note 4, p. 1198.

When the government grants a compulsory license it will be limited in time, the time frame is determined by the circumstances that led to the licensing in the first place, and as stated in Article 31(a), “*authorization of such use shall be considered on its individual merits*”. It is possible to waive the negotiation requisite, but only in cases of “*a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.*” The requirement for adequate remuneration still remains. Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. Article 31(f) has been one of the roots to the Doha Declaration.

Ultimately, Article 66.2 provides an interesting obligation for developed countries. “Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.”

2.1.2. The Doha Declaration

The Doha declaration consists of seven paragraphs. The first four paragraphs deal with the scope, background and principles of the Declaration. Article 1 in the Doha Declaration reaffirms the public health problems in many developing and LDC, “especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics”. The need for the TRIPS agreement to address these problems on an international level are pointed out in Article 2. IP protection is being recognized as important for the development of new medicines but also for its effect on medicine prices in Article 3. Article 4 emphasizes that “the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”

The three last paragraphs deal with substantive issues touching on the scope and the interpretation of flexibilities. In this regard, Paragraph 5(b) both

recognizes compulsory licensing as a key tool for developing countries to limit the exclusive rights of patent holders and their right to determine when that is necessary. Paragraph 6 approaches the important issue of production for export under a compulsory license; that will be discussed further.¹³ Paragraph 7 deals with the question of transitional period for LDC with regard to the implementation of pharmaceutical patent products and the protection of undisclosed test data.

Moreover, the Doha Declaration recognized a problem created by Article 31(f) of TRIPS regarding the use of compulsory licenses. Article 31(f) restricts compulsory licenses to manufacturing goods “predominantly” in the domestic country. Although, it has been suggested that countries may have had the right to export a portion of its production as long as the core function of the license was to supply the domestic market. Considering that many developing countries do not have the manufacturing, infrastructure, or expertise to domestically produce pharmaceutical products and thus these countries would not be able to use a compulsory license.

On August 30, 2003, the WTO General Council reached a solution to this problem recognized in paragraph six of the Doha Declaration. This solution, known as the “Implementation Decision” or “Paragraph 6 Decision,” created a waiver for Article 31(f) of TRIPS by which a country that lacks manufacturing capabilities may now import a specific patented pharmaceutical product, from another country that possess that know-how and manufacturing skills. However, the Paragraph 6 Decision contains a number of restrictions on this waiver, which complicates the importation process.

This also created an opportunity for developing countries with strong industrial capacity such as China and India to export medicine to countries in extreme situations, this would presumably be true in the case where start-up time for domestic production in LDC and the fulfillment of the criteria set forth in paragraph 6 would be time consuming.¹⁴ It would also be complaint with Article 66.2 of the TRIPS agreement.

¹³ Lee, Stacey B, *Can incentives to generic manufacturers save the Doha Declaration's paragraph 6?* Georgetown Journal of International Law, 2013, p. 1398. Available at: <http://www.law.georgetown.edu/academics/law-journals/gjil/recent/upload/zsx00413001387.PDF>

¹⁴ See Andrew, Jennifer R, *Swine flu, bird flu, sars, oh my! Applying the precautionary principle to compulsory licensing of pharmaceuticals under article 31 of TRIPS*, Michigan State Law Review, 2011, p. 418. Available at: <http://www.msulawreview.org/wp-content/uploads/2012/10/2011-2-Andrew.pdf>

2.2. EU legal framework

2.2.1. Treaty on the European Union

The EU is signatory to the TRIPS agreement and the Doha Declaration. The EU has also established several fundamental objectives. Among them article 3(3) TEU that points out that the EU shall work towards sustainability in the internal market among the member states. Sustainability has also guided EU's responsibilities towards countries that are not member states, third countries. In general, the objective of article 21 TEU states that the EU should be guided by democratic values when acting in the global arena. It should also build partnerships with third countries. Of particular interest for this thesis are the relations with developing countries and LDC. When drafting policies or working internationally along with other countries or organizations the EU shall, among several things, "foster the sustainable economic, social and environmental development of developing countries" Article 21(2.d) TEU, it should also "help develop international measures to preserve and improve the quality of the environment and the sustainable management of global natural resources, in order to ensure sustainable development" Article 21(2.f) TEU as well as to "assist populations, countries and regions confronting natural or man-made disasters", Article 21(2.g) TEU.

2.2.2. Treaty on the functioning of the European Union

It is explicit in Article 3(2) TFEU that the EU has exclusive competence to enter into these kinds of agreements. However, compulsory license of patents for public health is not legislated at EU treaty level. However, most countries in the EU have enacted rights under national legislation to provide some kind of compulsory licenses if public interest or public health requires so.¹⁵ The same provisions for compulsory licensing for public health reasons are applicable in the EU as to every other signatory to the TRIPS. This allows for the member states to mandate compulsory licenses when there have been previous good faith negotiations to obtain a license for

¹⁵ Zimmerman, Esther van, Overwalle, Gerrtrui van, *A Paper Tiger? Compulsory License Regimes for Public Health in Europe*, International Review of Intellectual Property and Competition Law, 2011 p.18.

the relevant patent or under the waiver during urgent health emergencies.¹⁶ TFEU points out in article 4 that the EU has an objective to share the competence with the member states in certain areas, relevant areas are set out in Article 3 and 6 of the TFEU. This could explain why the TFEU only provides for compulsory licensing of patents for the sake of maintaining an efficient and competitive market.

Article 11, which is of interest for this thesis, emphasize that: “Environmental protection requirements must be integrated into the definition and implementation of the Union policies and activities, in particular with a view to promoting sustainable development.”

Articles 34, 36, 101, and 102 of the Treaty contain the scope and limitations for that kind of compulsory licensing.¹⁷ These articles relate to the establishment of competition rules necessary for the functioning of the internal market. Article 191(1) TFEU explicitly states that the EU shall promote action on an international level to solve both regional and global environmental issues.

Additionally, in a study provided by the WIPO it was noted that three of the EU member states had specific laws that addressed compulsory licensing of patents for public health reasons, Belgium, France and Hungary. Another seven member states had provisions to meet the need for compulsory license to satisfy the public interest, not explicitly stating public health, but considering the broad formulation they are not excluding it.¹⁸

There are a few ways to handle the implementation of public health under national laws, there is the strict approach as in France for example or the more open approach. An open approach leaves the public health definition untouched and instead provides a concept applicable in many different contexts, although it is not entirely clear and is a less powerful concept than the strict one when applied. The open concept will not be threatened the same way as the strict one over time, the concept of public health changes constantly and the definition today is unlikely the same as it was 50 years

¹⁶ See Tudor, Jarrod, *Compulsory licensing in the European Union*, George Mason Journal of International Commercial Law, vol 4:2, 2012, p. 226.

¹⁷ See Tudor in note 16, p. 223.

¹⁸ Survey on compulsory licenses granted by WIPO member states to address anti-competitive uses of intellectual property rights, WIPO, 2011, p.7.

ago.¹⁹ In France the legislator opted to point out the cases where a compulsory license is justified in Article .L.613-16 FIPC:

“(1) the quantity or the quality of the medicines or methods available to the public is insufficient;

(2) the medicines or methods are only available at abnormally high prices;

(3) the patent is exploited in a manner contrary to public health interests; or

(4) the patent is worked in a manner resulting in anti-competitive practices qualified as such in a final administrative or court decision.”

The previous legislation had an efficient kind of ex-officio compulsory license specifically addressed towards genetic diagnostic patent for breast and ovarian cancer.²⁰

A similar explicit support for public health reasons exists under Belgian patent law. An innovation protected by a patent may be exploited in the interest of public health in general, with accelerated procedures²¹ according to Art.31bis§1 Belgian Patent Act. Although it is not as explicit as under French law, the idea in Belgium is complemented with a ministerial statement that provides examples that could constitute public health risk.²² More interestingly, Belgium does not justify this license through Article 31; instead they base it on an interpretation of articles 8.1 and 30 of the TRIPS.²³

2.2.3. Regulation (EC) No 816/2006

After the Doha Declaration the EU decided to explicitly implement a regulation to clarify how to conduct the export of drugs produced under

¹⁹ See Zimmerman in note 15 p. 24.

²⁰ See Reichman, Jerome H, *Compulsory licensing of patented pharmaceutical inventions: evaluating the options*, Journal of Law, Medicine and Ethics, 2009. p.6. Available at:

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2893582/pdf/nihms204056.pdf> Compare, Rushing, Steven, *Plugging the Leak in § 1498: Coercing the United States into Notifying Patent Owners of Government Use*. *Vanderbilt Journal of Transnational Law*, 2012. “When the United States uses a patent for public, noncommercial purposes, it is required under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to provide notification to the patent owner. However, the United States has never implemented legislation to conform with its obligation and is therefore in violation of TRIPS.”

²¹ *Ibid.*

²² See Zimmerman in note 15, p. 24.

²³ See Reichman, in note 20. p.6.

compulsory license.²⁴ Regulation (EC) No 816/2006 now specifically regulates the use of compulsory licensing for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. It was implemented to achieve a uniform use of paragraph 6 among the member states of the European Union. Also as part of a broader international action to address public health problems in the LDC and to improve access to affordable medicine. Other reasons such as the symbolic meaning of such strong statement and the importance of harmonizing the member states in these effort where important factors when issuing this regulation.²⁵ Two important conditions set out in the regulation are: “1. There are no limits on the scope of diseases. It extends to all medicinal products as defined in Article 1(2) of Directive 2001/83/EC on medicinal products for human use (1), active ingredients and diagnostic kits *ex vivo*. 2. The compulsory licenses are mandatory: "Member States shall grant a compulsory license to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10."²⁶

2.3. US legal framework

Just like the EU, the US is a signatory to the TRIPS agreement, the approach is a bit different under national legislation, the US does not cover compulsory licensing of patents in its patent act; instead it is regulated through anti-trust legislation and some specific statutes that have evolved over time.

Overall, the general assumption about the US is that they unlike many other countries disapprove of compulsory licensing.²⁷ Thus, it is worth to point out the relevant statutes that provide the possibility for the government to grant something similar to a compulsory license. 7 U.S.C. § 2404 states that certain protected plant varieties must be open to use “when the Secretary determines that *such declaration is necessary* in order to *insure an adequate supply* of fiber, food, or feed *in this country* and that the owner is unwilling or

²⁴ See Love, James, *Recent examples of the use of compulsory licenses on patents*, Knowledge Ecology International, 2007, Available at: <http://keionline.org/content/view/41/1>

²⁵ The implementation of the Doha decision at EU level: Regulation 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Available at: http://ec.europa.eu/internal_market/indprop/docs/medicines/implementation_en.pdf

²⁶ See Love in note 24.

²⁷ See Reichman in note 7 p. 21.

unable to supply the public needs for the variety at a price which may reasonably be deemed fair” (italics added). The patent owner is still entitled to remuneration. 28 U.S.C. § 1498 regulates government use of patents and 35 U.S.C. § 203 regulates patents developed through the use of government research funding under the Bayh-Dole Act, last but not least 42 U.S.C. § 2183 states that certain patents can be declared of public interest. Patents of public interest according to this statute are those related to production of atomic energy.

It has been suggested that these statutes do not meet all of the restrictions presented in TRIPS Article 31.²⁸ It could also be mentioned that when it comes to unexploited patents or patents in the interest of the public, the US has never passed any law that authorizes compulsory license of such in general. Although some limited bases for issuing such licenses exist.²⁹

2.3.1. 28 U.S.C. § 1498

It may seem like statutory compulsory licensing of patents in favor of third parties in the United States is not much of an option. The assumed main reason for this is said to be a strong faith in free-market principles. Factors such as return on investment in R&D and efficiency over fairness also play an important role, but the reality is a bit more complex.³⁰ For instance, the government has the power to seize and use a protected patent or IP right, the government is still obliged to pay royalty but allowed to exercise this power.

Furthermore, compulsory licensing could harmonize the US with other countries that require the so-called, local working requirement of a patent. But on the other hand, it has been argued that compulsory licensing might just be necessary when justified through a significant public interest.³¹

Although, the US has not made great use of non-voluntary licensing on public interest grounds as mentioned earlier. However, it has been used to reduce medicine costs, enhance environmental and economic development goals, even for bigger projects, like dam rivers and to generate electricity.³²

In close relation to the attacks on September 11, 2001, several letters were sent out to senators as well as news corporations. These letters

²⁸ See Reichman in note 20. p. 6.

²⁹ See Reichman in note 7 p. 21.

³⁰ *Ibid.*

³¹ See Stern-Dombal in note 5 p. 250.

³² See Reichman in note 7 p. 5.

contained anthrax that managed to kill 5 people.³³ The fear that it might be a very dangerous kind of anthrax strains³⁴ caused the Human Health and Services Secretary, at that time, to take action to improve the access to the necessary medicine, against the anthrax bacteria, ciprofloxacin. The German company Bayer held the patent to this drug, under the name Cipro. However, Bayer would not be able to meet the requested demand until two years later. During these negotiations with Bayer, Thompson threatened to use Section 1498 to access the generic ciprofloxacin. There was a serious concern that new attacks could negatively affect the public health and therefore necessary preparations had to be made.³⁵

A similar case occurred when handling the preparations for a potential bird flu epidemic. Roche held the patent for the medicine, Tamiflu. Just as in the case with Bayer, Roche would not be able to meet the demand within the necessary timeframe. A possibility to license the production of the generic version was presented as an option³⁶ and later used in negotiations by the US to ensure access to necessary medicine in the case of an outbreak; again under the threat of using Section 1498. Roche where then required to invest in laboratories in the US to be able to supply the Tamiflu, to ensure the production if an outbreak of the bird flu would take place.³⁷

2.3.2. The eBay and the Vitamin Technologist cases

One important case, mainly anti-trust related, but still worth mentioning, considering that the court explained some interesting points regarding the public interest was *eBay Inc. v. MercExchange, L.L.C.* It turned into a very important decision in the history of compulsory licensing in the US. Even though the Supreme Court did not emit a compulsory license per se, it rather created a kind of common law compulsory license. The Court held that when the public interest outweighs the interest of a patent-owner, one must apply a four-factor test. If the public interest is considered favorable after

³³ The Federal Bureau of Investigation, Famous Cases and Criminals, Available at: <http://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax/amerithrax-investigation>

³⁴ Love, James, *A better way of stockpiling emergency medicines*, Financial Times, 2005. Available at: <http://www.cptech.org/ip/health/tamiflu/love10282005.html>

³⁵ Ciprofloxacin: the Dispute over compulsory licenses, Available at: <http://www.cptech.org/ip/health/cl/cipro/>

³⁶ See Love in note 34.

³⁷ <http://www.cptech.org/ip/health/tamiflu/hearingexcerpts11082005.html>

applying the test, appropriate remedy is damages rather than injunction. By doing so the court managed to create what might seem like a common law compulsory license.³⁸

It has traditionally been very uncommon for a patent owner to be denied injunction in favor of public interest or public health.³⁹ In *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found* the patent owner in the case had developed a way to add vitamin D to food. When the patent owner refused to process margarine, also known as the butter of the poor, with the patented technology, the court explained that even though the patent was valid, it would opt to protect the margarine consumers. The public's interest would otherwise be affected and injunction was denied, mostly to prevent a disease known as rickets that was common among the poor.⁴⁰

3. The scope of the Doha Declaration

3.1. The public health focus

Ever since the ratification of the TRIPS agreement, pharmaceutical patents have been a hot and controversial topic. The problem is that developing countries have typically not been able to buy new medicines or access essential medicines, particularly to treat AIDS. One of the main objectives of the Doha Declaration was to acknowledge public health issues and WTO members right to protect public health. It created a process for member countries with insufficient manufacturing capabilities to access generic versions of patented drugs without violating TRIPS IP standards.

Health in general and access to medicine in particular has evolved as a key driver of socioeconomic progress during the past decade according to WTO; more resources are now being invested in health. However, poverty is still one of the main factors of poor health. The problem with poor health is that it keeps people in poverty; it is a negative loop.⁴¹ Adding up the fact that

³⁸ See Andrew in note, 14, p. 410.

³⁹ See Allen, Scott A, "Justifying" the Public Interest in Patent Litigation, Indiana Law Journal, 2008, p. 1048. Available at: <http://ilj.law.indiana.edu/articles/12-Allen.pdf>

⁴⁰ See Brandt, Michael C. *Compulsory licenses in the aftermath of eBay inc. V. Mercexchange, L.L.C.: the courts' authority to impose prospective compensatory relief for patent infringement*, Federal Circuit Bar Journal, 2008.

⁴¹ See The WHO agenda, the WHO webpage Available at: <http://www.who.int/about/agenda/en/index.html>

manufacturing is being outsourced to regions where health conditions are not optimal, with cheap labor, sometimes less strict labor legislation⁴² and environmental regulations, this negative loop will probably remain intact.

Strong IP rights may complicate the process to use health related patents, specifically pharmaceutical patents, when they are needed the most. However, there have been times where the use of compulsory licensing has been useful in order to gain access to patented technology and in those cases particularly pharmaceutical products.⁴³

The reaffirmation that TRIPS is to be interpreted and implemented in a way to protect public health and particularly to promote access to medicines makes it apparent that members have the right to take necessary action to avoid urgent health crises and that TRIPS should be seen from a public health concern perspective. The Doha Declaration specifically points out that Article 31 does not limit the base for what a compulsory license may be issued; the countries have the right to determine what is to be considered national emergency or other circumstances of extreme urgency. Although it is helpful that clarity has been added to these elements of the compulsory licensing regime under the TRIPS Agreement, these provisions of the Doha Declaration just confirm previously unambiguous text of the TRIPS agreement.

While developing countries have pushed for a broad interpretation of the Doha Declaration, and therefore a long list of diseases for which patent rules should be relaxed. Paragraph 6 actually opened up a new opportunity for accessing essential drugs. Countries, which have obtained a compulsory license to produce drugs, are meant to supply their domestic market, but when they lack the capacity to produce the relevant drug they face trouble. Paragraph 6 allows for the import of drugs, produced under a compulsory license in another country, to countries that are unable to produce it themselves.⁴⁴ Drug companies and their respective governments on the other hand have advocated for a narrow interpretation of the Declaration.

⁴² See Foroohar, Rana, *Bangladesh Factory Collapse Will Force Companies to Rethink Outsourced Manufacturing*, Time Magazine, April 30 2013, <http://business.time.com/2013/04/30/bangladesh-factory-collapse-will-force-companies-to-rethink-outsourced-manufacturing/>

⁴³ See Beall R, Kuhn R, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis. PLoS Med 9(1): e1001154. doi:10.1371/journal.pmed.1001154, 2012, p. 3.*

⁴⁴ See Andrew in note 14 p. 417.

According to the paragraph 6 decision pharmaceutical product means: "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;" Paragraph 1 reads: "We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

Apart from compulsory licensing, parallel importing, action against anti-competitive acts in the pharmaceutical market, limiting patent scope and approving production of generic medicine has generated successful results related to the Doha Declarations goal to protect public health at the same time as supporting efficient transfer of technology.⁴⁵

Furthermore, balancing IP rights and public health is not only a complicated relationship, it is important for the development of *new medicines*. Especially to further develop towards the original intention of the Doha Declaration, where the TRIPS is supposed to be interpreted in a way so that it promotes this access to pharmaceutical products. Additionally, the TRIPS agreement also function as support for technological innovation. The transfer of technology should benefit both producers and users in a way that makes it compatible with social and economic welfare according to Article 7.

3.2. The relationship between public health and environment

In order to emit a compulsory license under the TRIPS there has to be a link between the public health risk and the patent needed. Therefore we need to find the link between health and environment. The WHO has conducted many investigations, during an expert consultation, in connection with Rio+20, air pollution was pointed out as a large and increasingly growing threat to public health. Among many causes of death, over 3 million deaths per year may be linked to outdoors air pollution, with the biggest impact in

⁴⁵ See Pradhan, Nikil, *Moving towards a sustainable future: Replacing TRIPS with a new international regime for Intellectual Property and sustainable energy technology transfer*, Wisconsin International Law Journal, University of Wisconsin, 2013. p. 170.

developing cities.⁴⁶ When pollution rises, developed nations have tackled this by research green technology alternatives, new legislation to meet these issues and special programs to incentivize innovation. However, the problem has not stopped, and probably will not for a long time, since we are polluting more as a world than ever before.⁴⁷ Fact is that more people are dying worldwide from air pollution than HIV/AIDS today.⁴⁸

Air pollution is divided into indoor air pollution and outdoor air pollution. Indoors air pollution is typically related to breathing toxic smoke while preparing food over open fire or similar, while outdoors air pollution is typically related to energy production. Combustion of fossil fuels and biomass is still considered the major impact on climate change. Heating and industrial production are other big sources of outdoors air pollution.⁴⁹

Many WHO reports focuses on issues in developing countries, a study from the National Climate Assessment in the US points at issues related to climate change in the developed world as well. Climate change was found to cause higher levels in ground-level ozone, which is associated with several health issues. These issues ranges from asthma related emergency room visits, premature deaths and diminished lung function.⁵⁰ Another rising environmental issue is heat; warm weather conditions and dry areas are increasing risk for wildfires. Apart from being dangerous in general, wildfires also emit carbon monoxide, which have negative effects on air quality. When humans or animals breathe the air it increases many of the abovementioned problems, as well as the risk for respiratory and cardiovascular hospitalizations and bronchitis. Cardiovascular diseases are the number one cause of death in the world (just a part of those deaths can be related to climate change though).⁵¹ The projections are that problems with carbon monoxide

⁴⁶ WHO, *Health indicators of sustainable energy in the context of the Rio+20 UN Conference on Sustainable Development*, 2012, p. 2. Available at: http://www.who.int/hia/green_economy/indicators_energy2.pdf?ua=1

⁴⁷ World Bank Data, *CO2 emissions (kt)*, <http://data.worldbank.org/indicator/EN.ATM.CO2E.KT/countries/1W?display=graph> 2013-12-08.

⁴⁸ Compare http://www.who.int/gho/hiv/epidemic_status/hiv_007.jpg and Raquel A Silva et al, *Global premature mortality due to anthropogenic outdoor air pollution and the contribution of past climate change*, 2013 *Environ. Res. Lett.* 8 034005.

⁴⁹ See WHO in note 46, p. 5.

⁵⁰ National Climate Assessment. *U.S. Global Change Research Program, Climate change impacts in the United States*, 2014. Available at: <http://nca2014.globalchange.gov/highlights/report-findings/human-health>

⁵¹ WHO, *Health indicators of sustainable energy in the context of the Rio+20 UN Conference on Sustainable Development*, 2012, p. 2. Available at: http://www.who.int/hia/green_economy/indicators_energy2.pdf?ua=1

will increase and that it will have harmful impacts on public health.⁵² The problems related to wildfire and exposure to carbon monoxide are the very same as in the WHO report regarding indoors air pollution in areas where open fire is common for cooking.

The EU emphasizes that environmental challenges are global and must be handled through a joined global incentive. This cannot be done without the cooperation among the countries in the world.⁵³ Back in 1973 the EU took its initial step towards an environmental policy. This was the start for the EAP.⁵⁴ Since then there have been 7 EAPs in total, it has been concluded that Europe possess great potential for innovation and that this could both support developing countries while reducing the impact of the environment.⁵⁵ The 7th EAP has the following priority objectives in Article 2.1(i) *to increase the Union's effectiveness in addressing international environmental and climate-related challenges*.⁵⁶ More importantly it was also acknowledged in the 7th EAP that environmental problems imposes **significant risks for human health and well-being** (emphasize added).⁵⁷

Just like among its member states, the EU is supposed to promote and let its action be guided by principles for sustainability. The EU is also supposed to assist populations, countries and regions that are facing natural or man-made disasters. Disasters which have been defined by the United Nations Office for Disaster Risk Reduction as: “A serious disruption of the functioning of a community or a society involving widespread human, material, economic or environmental losses and impacts, which exceeds the ability of the affected community or society to cope using its own resources.”⁵⁸

As we can see environmental problems exists in various forms and in different parts of the world. The link between climate change and health issues

⁵² National Climate Assessment. *U.S. Global Change Research Program, Climate change impacts in the United States*, 2014. Available at: <http://nca2014.globalchange.gov/highlights/report-findings/human-health>

⁵³ The 7th Environment Action programme, Decision of the European Parliament and of the Council on a general union Environment Action Programme to 2020 *"Living well, within the limits of our planet"*, Strasbourg, 2013. Available at: http://ec.europa.eu/environment/newprg/pdf/PE00064_en.pdf

⁵⁴ See Hey, Christian, *EU Environmental Policies: A short history of the policy strategies*, EU Environmental Policy Handbook, p.18. Available at: <http://www.eeb.org/publication/chapter-3.pdf>

⁵⁵ COM(2004) 38 final, *Stimulating Technologies for Sustainable Development: An Environmental Technologies Action Plan for the European Union*, The European Commission, Brussels, 2004, p. 4. Available at: http://eur-lex.europa.eu/LexUriServ/site/en/com/2004/com2004_0038en01.pdf

⁵⁶ See 7th EAP note 53.

⁵⁷ *Ibid.*

⁵⁸ See United Nations Office for Disaster Risk Reduction. <http://www.unisdr.org/we/inform/terminology>

exist, so what is the best way to combat these health issues? While disease and epidemics are usually treated with medicine, these health issues cannot be treated this way. Breathing the air while cooking over open fire inside is a medical problem, but it is even more of an educational problem. We need to educate or innovate to prevent this from happening. The same goes for wildfires; preventative measures needs to be put in place here as well. As a result of climate change, we see increased temperatures that eventually cause this. Innovation in order to reduce greenhouse gas emissions and creating awareness must be top priority here.

In the end it comes down to two categories here, small-scale change and large-scale change. When talking about small-scale changes it refers to educating people in areas that lacks education, promoting latrines, outdoors cooking or use of contraception to prevent disease, these categories can then be divided into communicable and non-communicable diseases.⁵⁹ Large-scale changes refers to climate change, increased air pollution and effects that will take a lot longer to change, unless we can access cheap and effective innovations, produce energy in the best way possible and have our leaders work towards sustainability.

4. Compulsory licensing of green technology

4.1. Defining green technology

The term, green technology, is widely used for any kind of clean technology or environmental friendly innovations. More specifically the term relates to products or innovation used to promote sustainability, reduce greenhouse gas emissions, or otherwise to diminish our impact on climate change.⁶⁰ The range of products and systems has been established in a non-exhaustive list, “IPC Green Inventory”, by the International Patent Classification Committee in order to make it easier to find patent information regarding green technology.⁶¹

⁵⁹ Fact Sheet, The top 10 causes of death, WHO, 2011. Available at: <http://www.who.int/mediacentre/factsheets/fs310/en/index2.html>

⁶⁰ See Chu, Jonathan, *Developing and diffusing green technologies: The impact of intellectual property rights and their justification*. Washington and Lee Journal of Energy, Climate, and the Environment, 2013. p. 56.

⁶¹ See Chu in note 60, p. 56-57.

At a first glance green technology and pharmaceuticals have both things in common as well as underlying differences. They are similar in that sense that they solve global issues, these issues also needs to be solved on an international level. In economic terms they could be considered “non-rival” when it comes to the consumption. Breathing the air that has been filtered through a patented product will not be affected if one person or the whole population is doing it. The same usually goes for medicine, if someone is given ARV medicine, it will likely not affect the opportunity to give another person ARV medicine. The supply in both cases will likely be steady.

Encouraging development of green technology obviously requires benefits for the innovator. Just like the pharmaceutical industry spends a lot of money in R&D to push new products to the market. Innovative engineering will be a key component in making these new technologies accessible, both physically and economically and therefore relevant protection is necessary. The US took on an interesting program in the end of 2009 to promote innovation of green technology. It was a dedicated route to ensure faster protection and thus a faster way to the market for patents. One of the statements made during the opening was that *“Every day an important green tech innovation is hindered from coming to market is another day we harm our planet...”*. Through the US Patent and Trademark Office innovators could then specifically apply to have their green technology innovation put on the patent examination highway.⁶² President Obama has also stated that for the development of the US and its position, *“it's critical for us to lead by example by becoming more energy efficient and by sharing scientific breakthroughs.”*⁶³ Innovators need the support from governments.

International trade and cooperation between targeted industries and governments will then be an essential aspect for transferring the innovations to the global community. Compared to pharmaceuticals, green technology also has other capital needs. Pharmaceuticals tend to require big initial investments in R&D, once the ingredients and the process are established the cost of production and marketing are fairly steady or even decreasing. Green technology on the other hand will require a steady stream of capital throughout

⁶² http://www.uspto.gov/news/pr/2009/09_33.jsp

⁶³ See Fair, Robert, Does climate change justify compulsory licensing of green technology? Brigham Young University International Law & Management Review, 2009, p. 23.

the entire lifespan, R&D, installation, service, repair and other post-sales necessities.⁶⁴

So in the end, pushing green technology has to happen on a global level to be effective and to bring down prices. This push is important because even if one country has a very developed and environmental friendly industry, moving production to other regions can result in increased air pollution due to weaker regulations. Air pollution and climate change is not limited to the borders of one nation, since it affects the whole world. This could theoretically work the other way around as well, having an industry moving to a more regulated region, but what is really important here is a unified framework for agreeing upon climate goals. But having every country determining their respective climate strategy will cause frustration around the globe. Both the EU and the US have developed frameworks and international conferences that have taken place in Kyoto, Rio and Copenhagen, to name a few, aim to achieve exactly this, but we are not there yet.⁶⁵

As climate change and development of green technology remains a complicated problem, we need to combine efforts and perspectives to progress. IP can provide solutions if built upon the TRIPS and the Doha Declaration, with a strong emphasize on the connection between innovation and public health. Differentiating between public health issues, such as epidemics and public health issues, as climate changes will probably be less frequent in the future, since both of them are likely to be equally acknowledged as threats against public health.⁶⁶

4.2. Compulsory licensing of green technology

Even though compulsory licensing is permitted, it has not been frequently used.⁶⁷ In total there were 24 identified episodes of compulsory licensing between 1995 and 2011, all of them related to the medical field, not all episodes lead to the granting of a compulsory license but still involved the threat or the use of one.⁶⁸

⁶⁴ See Pradhan in note 45, p. 169.

⁶⁵ See Pradhan, in note 45, p. 167.

⁶⁶ See Pradhan, in note 45, p. 174-175.

⁶⁷ See Bond *et al* in note 6 p. 3.

⁶⁸ See Beall in note 43, p. 3.

Considering that there has never been a compulsory license for a green technology patent to protect public health, neither have there been any cases questioning its validity, most material for recent debates comes from emerging countries or scholars in developed countries. Both of them are pointing out the current state of the environment. It is clear that the environment is not the main focus addressed in TRIPS, but public health is, and therefore we must interpret what is included under actions to protect public health. It is not ruled out that green technology could be included.

As much as there is likelihood for granting this kind of compulsory license, the reality will probably be a lot more complicated than the theory. Making parallels between these two fairly different industries, pharmaceuticals and green technology, in the context of compulsory license raises problems. When licensing a product, either under a voluntary license or the non-voluntary, compulsory, license, the specific kind process or product could vary greatly. As for the case of medicine, medicine is, roughly explained, usually produced through a chemical process by mixing and measuring various chemicals into a little product that has a designated purpose. Once the mix is established the production cost tends to be pretty low. This also makes the category pretty defined; it has further been defined indirectly through the Doha Declaration in some ways. The epidemics mentioned there must have a medicine correlating to them. The specific drug is therefore more or less known.

Green technology however is not necessarily very defined, even if we adopt the International Patent Classification Committees definition, this invention could be pretty much everything within the scope. So we would have to make an analysis every time for what patent that is best suited to the environmental problem. We would further face other interesting complications.

So if we assume that a LDC would grant a compulsory license for a green technology patent, there would have to be a corresponding threat to public health. So the question now is whether the current state of the environment is considered so alarming to public health that it could constitute a national emergency or other circumstances of extreme urgency explain under Article 31 (b) and therefore would justify compulsory licensing of green technology.

4.3. Health and urgency

Two of the most important states to define before deciding whether to enter into negotiation or to by pass negotiation for a compulsory license are the current health of the population and the urging need for health improving measures. It is obvious that not all states can be urgent, but the trick will be to define when it is urgent enough, or when the state is not urgent, long-term health risk is considered negative enough.

Defining health and urgency under TRIPS will direct us to Article 31(b) and Article 8.1. There must be a national emergency or other circumstances of extreme urgency. Measures allowed to coop with such state are the once considered necessary to protect public health. So public health must be in danger. A brief look at WHO's position on air pollution gives us this indication: *"Air pollution is a major environment-related health threat to children and a risk factor for both acute and chronic respiratory disease."*⁶⁹

Using a measurable fact, like child mortality, caused by the danger has been suggested as useful in general and using data from the WHO in particular, this is an accessible source of information and acknowledge worldwide. In the case of epidemics, like the ones stated in paragraph 5(c) in the Doha Declaration, one could possibly base the decision on the WHO 6-phase system.⁷⁰ This system estimates the urgency of an epidemic and could be a complement to governmental organizations whose report concludes the need for an emergency based compulsory license.

Fact here is that, even if it is dangerous, outdoors air pollution for instance, is not recognized as an epidemic, and even if it were it would be hard to determine the stage of it. There is however a margin of error provided through cases at the WTO Appellate Body. When it is hard to determine the stage, a precautionary measure taken for the sake of public health, without completely established scientific proof, could be considered tolerable⁷¹ but again, in relation to epidemics.

On the other hand it is not completely ruled out that outdoors air pollution could constitute the kind of emergency that is mentioned in Article 31 (b). A compulsory license could in that case be granted on the basis of the

⁶⁹ World Health Organization, Air Pollution, Children environmental health Available at:

<http://www.who.int/ceh/risks/cehair/en/>

⁷⁰ See Andrew in note 38 p. 442.

⁷¹ See Andrew in note 38 p. 443.

environmental “emergency”.⁷² The most complicated issue will be to justify the urging need for it, at least in the case for a country that wish to waive the negotiation requirement under Article 31(b). Seemingly, the procedures required to prompt the waiver are said to be fairly complicated. The idea of having an efficient and flexible solution when drastic crises occur is fading away due to procedural barriers. Nonetheless, what is considered “a national emergency or other circumstances of extreme urgency”?⁷³

4.4. National emergency or other circumstances of extreme urgency

The uncertainty of Article 31 proposes a potential risk towards the member countries. Considering again that “*authorization shall be considered on its individual merits.*” Also means that when waiving the good faith negotiation requisite the members are exposed to risk. Waiving the good faith negotiation is, as we have learned, allowed during “national emergency or other circumstances of extreme urgency or in cases of public non-commercial use,” But this also set high requirements on the analysis and the definition of what kind of health risk that fulfill those criteria. Incorrectly waived, a country could face trade sanctions. Additionally, since the definition could be up for discussion, when one country considers the use unjustified the dispute might not be far away.⁷⁴

It could be concluded from Article 8 that precautionary measures must be necessary. To further investigate what necessary is, we examine Article 8 alongside the GATT agreement.⁷⁵ TRIPS Article 8.1 allows countries to “*adopt measures necessary to protect public health,*” compared to GATT XX(b) that allows for actions “*necessary to protect human, animal or plant life or health.*” The WHO similarly advises that necessity should be a *crucial consideration* for nations invoking compulsory health measures.⁷⁶ It should also be mentioned that a precautionary measure could not be more trade

⁷² Wong, Sarah M, *Environmental initiatives and the role of the USPTO's green technology pilot program*, Marquette Intellectual Property Law Review, 2012, p. 243.

⁷³ See Andrew in note 38. p. 418.

⁷⁴ See Andrew in note 38 p. 408.

⁷⁵ See TRIPS Article 31(b), Compare GATT XX(b).

⁷⁶ See World Health Org., Ethical Considerations in Developing a Public Health Response to Pandemic Influenza, WHO/CDS/EPR/GIP/2007.2, 1, Available at:

http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf

restrictive than necessary and is reflected in Article 8.1. Regardless of whether a precautionary compulsory license is issued to prevent an urgent crisis under Article 31(b) it would have to pass the same control and necessity analysis as if justified under Article 8.1 or GATT XX.⁷⁷

As precautionary measures are gradually getting more accepted among policymakers, a shift is observed is moving towards public health from environmental health, it used to be the case that precautionary measures were only used in cases relating to environmental health, but the case now seems to be a mix of the two, it is gradually moving towards the becoming the same.⁷⁸ In conclusion one could put forth the following criteria for the use of precautionary measures to prevent national emergency or other circumstances of extreme urgency:

- (i) *there must be a threat of grave or irreversible damage to public health if action is not taken;*
- (ii) *there must be an uncertainty of risk associated with that threat;*
- (iii) *a good faith assessment of that risk must be performed; and*
- (iv) *the measure must be necessary to achieve the desired health objective.*⁷⁹

4.5. Justifying compulsory license of green technology

There is a strong correlation between public health and environment as stated in part 3. The TRIPS agreement does not define what measures that are allowed to use in order to achieve public health. That is up to the every member state to determine. Health is something that is of importance and should be both promoted and facilitated under the TRIPS agreement. Both disease and climate change constitutes a threat against public health. So far there are no known cases where a compulsory license for green technology has been emitted to protect public health, not as a reaction to a current situation or as a precautionary measure. It is likely going to be complicated to define the threat, extreme urgency or national emergency to public health when emitting a compulsory license for a green technology patent. One of the main

⁷⁷ See Andrew in note 38 p. 435-436.

⁷⁸ See Andrew in note 38 p. 418.

⁷⁹ See Andrew in note 38 p. 440.

differences here has been pointed out as the very defined usage of medicine for instance and the rather less defined usage of green technology when it comes to public health. It has been suggested that a compulsory licenses issued in the public interest can address environmental and/ or public health.⁸⁰ Support for granting a compulsory license for green technology is possible under the TRIPS agreement and there is no explicit prohibition from doing so.⁸¹

Recent development shows that it might be possible to widen the scope and at least expand beyond the “classic” use: ARV medicine. However, this may not apply to green technology. One interesting case occurred in Thailand, the government emitted a compulsory license for a heart disease medicine. The heart condition has been suggested to be a “*long-term health problem*”. During the time that Thailand emitted the compulsory license, the current health minister strongly emphasized the balance between spreading access to essential drugs and support for innovation. The importance of creating access for the poor and marginalized was explicitly stressed considering that it used to only be accessible to wealthy consumers.⁸²

The actual heart disease could at least be considered less immediate than the consequences of an HIV/AIDS infection and could therefore resemble the long-term eruption of environmental pollution better⁸³. So based on that, arguing that environmental pollution that causes more deaths than HIV/AIDS does annually⁸⁴ could be considered a long-term health problem like heart diseases is at least a possibility.⁸⁵

Additionally, precautionary measures could rightfully be implemented to achieve desired minimum level of health, by preventing urgent, public health crisis, such as a dangerous spread of disease, if no other options are possible to implement instead of the precautionary measure. Considering that the precautionary measure infringe an IP right, a member state should always, at least, consider other options before doing so.⁸⁶ Furthermore the EU has considered environmental problems a significant risk for human health.⁸⁷

⁸⁰ See Reichman in note 9 p. 12.

⁸¹ See Fair in note 63 p.24.

⁸² See Pradhan, in note 45, p. 171.

⁸³ See Fair in note 63 p. 24.

⁸⁴ See note 48.

⁸⁵ See Fair in note 63 p. 24.

⁸⁶ See Andrew in note 38 p. 435.

What eventually complicates the issuing of a compulsory license for green technology is the length between the actions that leads to the problems related to air pollution for instance.⁸⁸ While certain epidemics could be hard to predict, the flexibilities presented in the TRIPS along with Doha Declaration could allow for compulsory licensing as a precautionary measure during such threats against public health. Paragraph 6, as discussed earlier, provides a viable solution for transferring pharmaceutical products and technology to LDC, but no explicit statement related to green technology. Article 31 of the TRIPS could also support the use of compulsory licensing of a green technology patent as a precautionary measure. But just as in the case during an outbreak of a crisis, a country that issues the compulsory license as a precautionary measure will still be exposed to a potential WTO complaint if not issued properly.

So taking this into consideration, using Article 31(b) of the TRIPS to issue a compulsory license for a green technology patent to protect public health and supporting that through Article 8.1 the action could be justified.

Lastly, it is important to point out counterarguments, both WIPO and the EU has pointed at that the fundamental difference between the market structure in the pharmaceutical industry and the green technology industry is significantly different. Therefore it would be more complicated to start allowing for compulsory licensing of green technology⁸⁹; at least without a thorough structure.

5. Extending the compulsory license remedy

5.1. Transferring green technology patents

So far a compulsory license for a green technology patent has never been emitted and the idea of doing this so relatively new. Compulsory licensing is usually associated with medicine, but it has been suggested that it

⁸⁷ See note 53.

⁸⁸ See Fair in note 63 p. 24.

⁸⁹ Copenhagen Economics and The IPR Company, *Are IPR a barrier to the transfer of climate change technology?* Copenhagen, 2009. Available at: http://trade.ec.europa.eu/doclib/docs/2009/february/tradoc_142371.pdf

applies to patents in other fields as well.⁹⁰ As much as there seems to be possibilities to emit a compulsory license for a green technology patent under TRIPS, if the necessary means to use it does not exist, it seems to be complicated to access it. Many ideas regarding whether there is a real demand to access the technology, at least in LDC, points out that processes and products for the sake of the environment cannot be fully utilized there. Arguments such as lack of infrastructure, big initial investments and absence of FDI makes the case at least possible.

The emerging economies essentially lead by BIC, on the other hand seems to have a solid production line in a wide spectrum of industries and have demanded explicit inclusion of green technology under the TRIPS agreement. Environment should be considered “public good, just like health”. Therefore the transfer of green technology would be less of a grey area. We evaluate the opportunities for this being a viable option under TRIPS Article 31 (b), if the TRIPS agreement extends the compulsory license remedy beyond the Doha Declaration?

Let us start by pointing out again, that the Doha Declaration is a clarification of some parts of the TRIPS agreement, the reason for the declaration came out of insecurity regarding access to patented pharmaceuticals. It is explicit under the TRIPS agreement Article 31 (f) that patents produced under compulsory license shall be “authorized predominantly for the supply of the domestic market”. The interpretation of “predominantly” has caused endless debates. The clarification has been made with regards to pharmaceutical products. But a raising uncertainty regarding the environment might require additional clarifications.

Taking into account what the alarming current state of the environment, earlier defined in part 3, let us assume that a country rightfully manage to emit a compulsory license for a green technology patent. But the country cannot produce it; therefore it needs help from someone with the relevant skillset. But for green technology patents this seems to be rather complicated. The Doha Declaration is very pro-health, but paragraph 6, that explicitly discuss the topic of efficient transfer, has described what is considered a pharmaceutical product and it might be both farfetched and beyond the intended interpretation

⁹⁰ See *TRIPS and pharmaceutical patents*, Fact Sheet, World Trade Organization, 2006. Available at: http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf

to argue that at least the vast majority of green technology patents would be able to fit under that description. So therefore, there is no explicit inclusion of green technology, only for pharmaceutical products when it comes to the ability to access it, even without the necessary production means. The Doha Declaration is likely of no help here, unless the pharmaceutical product patent would have environmental friendly aspects. But that itself is not a green technology patent.

But while interpreting TRIPS there is no explicit distinction between green technology and medicine when it comes to the protection of public health. The main use has been related to pharmaceutical products and the clarifications that exist to improve access to public health has been in the pharmaceutical product field. The Doha Declaration does not seem to be able to support the transfer of green technology to countries without the necessary production facilities, the Doha Declaration is simply very explicit here and has defined very precisely what a pharmaceutical product is. So the compulsory license remedy of the TRIPS does not extend beyond the Doha Declaration, mainly because of the construction of the Doha Declaration itself. There might however be some “wobble room” under the current TRIPS agreement. Something that was of uncertainty before the Doha Declaration was the interpretation of “predominantly” that was mentioned above. Since predominantly does not equal “only” there is a possibility that similar discussions and eventually similar outcomes could lie ahead of the development. In that case, the next step might be an explicit inclusion of environmental health under the TRIPS agreement, perhaps concluded through a similar declaration.

5.2. Explicit inclusion of environmental health

Strong emerging countries, essentially lead by BIC, are criticizing the US and other developed nations. This criticism is rooted in that they contribute to heavy pollution throughout the world, either locally or through outsourcing of production in countries where manufacturing is cheap and less environmentally strict. Additionally the technology to reduce pollution is

effectively being kept protected under patent in the developed nations and countries in need cannot obtain access.⁹¹

Further criticism points out the hypocrisy in developed nations demanding improved environmental conditions in developing nations. The argument here is that this current stage, of increased pollution, has been necessary for economic growth. Although this was true in the times around the industrial revolution and we therefore should not deny economic growth under such conditions in the developing nations now. It does not have to be that way and it should not either. A major difference between now and during the era of the industrial revolution is that improved technology exists and not using it to the fullest extent would be irresponsible, or at least hypocritical. It does not have to be a choice between environmental consciousness and economic growth.⁹²

Brazil, China and India proposed in 2008 that the TRIPS flexibility should be further formalized and that it should be extended to cover, not only medicines, but also green technology.⁹³ The argument presented for this is that the climate is “*public good, just like health*”. Although BIC might not be the countries in greatest need of technology transfer considering that they have funds, access to technology and the means to realize the production. China has in fact emerged as the largest producer of clean technology.⁹⁴ And this is not a small market, estimated to \$2.2 trillion worldwide by 2020.⁹⁵

However, one must take into account though that BIC can raise their voices for LDC and if the technology is not promoted and innovated it will and cannot be prioritized at all. Neither will pollution be combated, considering that the technology will be too expensive and that the companies cannot receive any licensing fees.

Others have suggested that the protection of green technology patent should be relaxed to the extent that all countries could gain free access, this was suggested by the President of Bolivia, he also received support in this idea

⁹¹ See Gupta, Rishi R, *Compulsory licensing in trips: chinese and indian comparative advantage in the manufacture and exportation of green technologies*, Sustainable Development Law & Policy, 2012.

⁹² Fair, in note 63 p. 21.

⁹³ See Copenhagen Economics and the IPR Company in note 93 p. 7. *Compare* p. 35.

⁹⁴ Green Growth and Developing Countries: A Summary for Policy Makers, OECD, 2012, p. 8. Available at: <http://www.oecd.org/dac/50526354.pdf>

⁹⁵ See United Nations, *The Road to Rio+20, For a development-led green economy*, Geneva and New York, 2011. p. 5. Available at: http://unctad.org/en/docs/ditcted2011d6_en.pdf.

from Nigeria, Indonesia, and even the European Parliament that have made similar statements. A relaxation would most likely discourage companies from investing more in research and development in the green technology area and therefore, if any solution to this idea would be possible, the initiative would have to come from the relevant governments. The governments must also be prepared to remunerate, or in anyway incentivize innovators in one way or another to stimulate further innovation.⁹⁶

It is therefore very important that the debate about technology access is taking place, and at least being pushed by BIC on the behalf of LDC.⁹⁷ Although since IP rights increase innovation of necessary green technology, the same rights may also prevent the ultimate purpose. Since most dangerous emission occurs in developing nations, it is also where it is needed the most.⁹⁸

Brazil, China, India, Mexico and South Africa has presented a joint statement, that access to relevant technology is crucial if developing countries are expected to successfully contribute to environmental issues.⁹⁹ The main concern among LDC are actually that strong IP protection effectively keeps them away from accessing green technology, considering the high prices set.¹⁰⁰ A serious agreement to make transfer of technology accessible to LDC has therefore been suggested, if LDC needs to use green technology - it has to be accessible, at the same time as innovation is being appreciated and remunerated.¹⁰¹

On the other hand, explicit inclusion may raise other issues that LDC have because they might lack manufacturing capacity, but this may not be as helpful for green technology because the cost of energy manufacturing is still a big barrier to entry that LDC needs to get by before they can start working with sustainable development.¹⁰² This is why some formal ratified modes of transfer are valuable and should be encouraged. In particular, effective agreements for establishing sustainable energy plants, especially where production processes are complex, will be valuable for improving the energy manufacturing base for LDC, and could potentially lead to greenhouse gas

⁹⁶ See Fair in note 63, p. 24

⁹⁷ See OECD in note 94, p. 8.

⁹⁸ See Fair in note 63, p. 22.

⁹⁹ See Fair in note 86, p. 23.

¹⁰⁰ See Copenhagen Economics and The IPR Company in note 89.

¹⁰¹ See Fair in note 63, p.23.

¹⁰² Pradhan, in note 64, p. 171.

emissions reductions. FDI needs to be encouraged as a tool for technology transfer since foreign investors will have to be involved in the strengthen of domestic manufacturing.¹⁰³

Creating solutions for the long-term benefit will require some kind of an amendment or another agreement to Supplement the TRIPS. If we are serious about introducing green technology in LDC incentives for corporations must be beneficial in the long-term and provide real economic growth, short-term profits will not help domestic growth. Developed states have typically not been very good in targeting LDC for transfer of their technology. Implying that TRIPS, as the driver for technology transfer and as a legal tool may not be enough to push the transfer of green technology patents. One suggestion could be an elaborate program or incentive to combine business in developed countries with sustainability projects in developing countries or LDC to push the development forward.¹⁰⁴

6. Brief on the situation in BIC

6.1 Access to health

One of the most serious issues that developing countries are struggling with today is access to patented pharmaceuticals. Ever since the ratification of the TRIPS this has been one of the major concerns in developing countries such as Brazil and India. This is where compulsory licensing could and have been a solution in several cases. Compulsory licensing constitutes one of the major flexibilities available under TRIPS to member countries of the WTO¹⁰⁵ and the threat of issuing a compulsory license has been used to negotiate the initial prices provided by the pharmaceutical firms to access patented medicines cheaper. Governments in the EU and the US have been less likely to issue compulsory licenses than Asian and African for instance, where it has been more frequently used to treat serious diseases. This slight reduction of IP rights benefits the public interest and the public health and is rooted in the

¹⁰³ Pradhan, in note 64, p. 173.

¹⁰⁴ Pradhan, in note 64, p. 175.

¹⁰⁵ See Bond *et al* in note 67, p. 2.

fundamental idea that everyone should have access to medicine to achieve some level of minimum health at least.¹⁰⁶

Developing countries in need for compulsory licensing of patented pharmaceuticals could benefit from the TRIPS by using the following. The waiver under Article 31 has been suggested to facilitate compulsory licensing in the interest of public health under articles 8 and 30 of the TRIPS instead of article 31.¹⁰⁷

6.1.1. Brazil

During the first meeting held with the Committee on Development and Intellectual Property, Brazil emphasized the importance of implementing a broad perspective when analyzing IP rights on one hand and economic development on the other. There is no simple policy that fits all developing countries.¹⁰⁸

The Brazilian patent act (Law No. 9279/96) today dates back to 1996. The patent act also provides for compulsory licensing in Article 68. A local working requirement exists in Brazil, as well as a requirement to satisfy the market. Article 71 states that: *“In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patent holder or his licensee does not fulfill such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio, without prejudice to the rights of the respective titleholder.”*

Not long after the enactment of the patent act Brazil also started to provide free ARV to the population as well as initiated local production in order to reduce medicine costs.¹⁰⁹ When it comes to price negotiation one must consider Brazil a very active country when it comes to threat of using compulsory license, mainly to receive the necessary drugs as a part of a nationwide anti HIV/AIDS campaign. It could be suggested that since the

¹⁰⁶ See Tudor in note 17, p. 226.

¹⁰⁷ Correa, Carlos Maria, Research Handbook on the Protection of Intellectual Property Under WTO Rules, 2010. p. 606.

¹⁰⁸ See Wetzler, Jennryn *et al*, *Timeline on Brazil's Compulsory Licensing*, Program on Information Justice and Intellectual Property, 2008. Available at:

<http://www.wcl.american.edu/pijip/download.cfm?downloadfile=33FC1E4B-0DF7-7EB8-69218ADA1C27DEBE&typename=dmFile&fieldname=filename>

¹⁰⁹ Wetzler in note 108.

World Bank indicated that roughly 1.2 million people in Brazil would be infected by the year 2000, Brazil took the access to medicine very serious. Brazil initiated an effective campaign that was later recognized by UNESCO for its efficiency.¹¹⁰ One of the key components was said to be their aggressive price negotiation in order to access medicine for the necessary treatment.¹¹¹

One of the most famous cases, also known as the Merck case, was when Brazil issued a compulsory license under TRIPS Article for the HIV/AIDS medicine Efavirenz, up until that point they had just effectively used the threat of issuing a license to obtain the lower prices. During the negotiations with Merck price was actually one of the main concerns, but also the fact that the current production of relevant medicine held a low quality boosted the need for a compulsory license. Even though the license was issued, the major Brazilian pharmaceutical company lacked the knowledge to produce the drug and Brazil had to import from India during the first years.¹¹²

The Merck case has been heavily debated, partly because the US was everything besides happy about the compulsory license. The US Chamber called it a “*major step backward*” that sends “*a dangerous signal to the investment community*”.¹¹³

When analyzing whether the issuing of the license was in line with the TRIPS agreement, particularly article 31(b), it has to be ensured that Brazil, negotiated under reasonable commercial terms without a successful outcome. If this was considered to be a case that needed prior negotiation, there is also the possibility to waive prior negotiations. Either way, the negotiation with Merck had been going on for about two years before Brazil issued the license. Article 31(b) provides that negotiations must proceed over a reasonable amount of time, likely to avoid misuse and bad faith negotiations. Considering that the negotiations had been going on for two years, and that the question at stake was at such critical level that the country issued the compulsory license

¹¹⁰ The Contemporary Response of the Brazilian Government, the civil society and UNESCO. Available at: <http://unesdoc.unesco.org/images/0013/001362/136285e.pdf>

¹¹¹ Rutledge, Peter B, *TRIPS and BITs: An Essay on Compulsory Licenses, Expropriation and International Arbitration*, North Carolina Journal of Law and Technology, 2012. p. 1. Available at: http://digitalcommons.law.uga.edu/fac_artchop/827/

¹¹² See Bond *et al* in note 6 p. 5.

¹¹³ Christman, Daniel W, *Brazil Takes Major Step Backward on Intellectual Property Rights*, US Chamber of Commerce Press Statement, 2007. Available at: <http://lists.essential.org/pipermail/ip-health/2007-May/011111.html>

based on national emergency it was most likely a reasonable amount of time. A reasonable amount of time is not defined further by TRIPS.¹¹⁴

Using the threat to issue compulsory license to conduct negotiations might not be seen as negotiation under reasonable commercial terms and in fact, Brazil had several offers from Merck. None of them were considered pleasing enough and negotiations continued. On the other hand, all of them were priced well above another deal that Merck had made with Thailand; concerning the same medicine.

Additionally it would not have been the first time the tactic has been used to achieve the purpose. One must not forget that negotiation prior to compulsory license is something serious and more of a last resort, which could justify using it as a threat during negotiation but considering that it has not been determined by the WTO dispute settlement body, we cannot be sure.¹¹⁵

The likelihood of rightfully having waived the prior negotiation requirement is probably high. Considering that HIV/AIDS has been specifically mentioned under paragraph 5(c) as the kind of national emergencies that can justify waiving of the prior negotiation requirement under article 31(b) and that the intended use was for the governments campaign against HIV/AIDs. Probably means that Brazil would not have had to negotiate with Merck before the issuance of the compulsory license. On the other hand, if faced with the argument that there was in fact no national emergency or other circumstance of extreme urgency one must remember that this state is not defined by the TRIPS. Every member state has the right to determine this state considering their unique situation. Brazil might have had a low infection rate, but this was the result from effective negotiation with other pharmaceutical companies in the past to obtain access to medicine. It is unlikely that the dispute settlement would have required Brazil to be in terrible shape just to justify the epidemic state and therefore be allowed to qualify for the national emergency or other extreme urgency state in Article 31 (b).¹¹⁶

¹¹⁴ See Andrew in note 38, p. 415.

¹¹⁵ See Reichman in note 28 p. 18.

¹¹⁶ See Reichman in note 28 p. 3.

6.1.2. India

The Indian patent act section 84 states that a compulsory license may be granted if “*the reasonable requirements of the public with respect to the patented invention have not been satisfied...*” within three years from the granting of the patent. Compulsory license may also be granted if the invention is not reasonably priced, making it inaccessible to the public. The patent act also provides a local working requirement, saying that the patent must be worked in India. An application for a compulsory license is sent to the Controller and the Controller may then grant the license “*upon such terms as he may deem fit.*”

The first compulsory license granted in India occurred in 2012. The Indian generics producer Natco was granted a license to produce and sell the patented cancer medicine “*Nexavar*”. The reason for the granting was that the owner of the Patent, Bayer, had failed to make the medicine available in the market to an affordable price.¹¹⁷ Bayer had imported the drug during previous years but the Controller considered the quantity “grossly inadequate,” to a price inaccessible to most of the Indian population in need for the medicine.¹¹⁸ Bayer had essentially failed to comply with all of the conditions set forth in the Indian patent act.¹¹⁹

However, this ruling has been considered a bit odd due to the interpretation of the TRIPS Article 27(1).¹²⁰ In the Natco/Bayer case The Controller applied the standard, “worked to the fullest extent that is reasonably practicable” to Bayer's practices when analyzing the local working requirement. Section 84 together with Section 89 states that just the import of a product cannot fulfill the local working requirement. Considering that discrimination is not allowed under TRIPS regardless of whether the products are imported or locally produced, this makes an interesting use of the article. Article 30 would probably have been a better choice in combination with Article 31 that provides other opportunities for un-authorized use of patents.¹²¹

¹¹⁷ Bonadio, Enrico, *India Grants a Compulsory Licence of Bayer's Patented Cancer Drug: The Issue of Local Working Requirement*, European Journal of Risk Regulation, 2012, p. 247.

¹¹⁸ Barsoumian, Levon, *India's use it or lose it: Time to revisit TRIPS?* John Marshall Review of Intellectual Property Law, 2012, p. 806. Available at: <http://repository.jmls.edu/cgi/viewcontent.cgi?article=1293&context=ripl>

¹¹⁹ Naval Satarawala Chopra, Dinoo Muthappa, *The Curious Case of Compulsory Licensing in India*, Competition Law International, 2012, p.

¹²⁰ See Bonadio in note 117, p. 248.

¹²¹ See Barsoumian in note 118, p. 87.

6.1.3. China

Compulsory license of patents is allowed under Chinese law, and the patent law was extensively amended in 2008. China has also specifically implemented the outcome of the Doha Declaration. No compulsory license has ever been granted in China by SIPO. However, China has used compulsory license as a threat to obtain a voluntary license for Tamiflu in 2005.¹²²

The 2008 amendment added several new articles regarding compulsory license. Which indicates a policy change.¹²³ This will make legislation more clear to prepare for the use of it, as well as to comply with international agreement standards.

Article 48 of the Chinese patent act incorporates the local working requirement. If a patent has not been used at all, or at least not enough without an acceptable explanation, within three years from the granting of the patent, or four years from the filing date, a compulsory license could be granted. The promotion of active use of the protected patents will hopefully benefit the public interest in the end.¹²⁴

China has an emergency provision that allows for compulsory license in case of national emergency in Article 49. Then new Article 50 further complies with paragraph 6 of the Doha Declaration for public health purposes.¹²⁵ The Chinese government is likely to grant a compulsory license, in the case of a public health crisis, both for the local manufacturing and export. Article 50 further explains the requirements for export of such medicine, produced under compulsory license, which is allowed under Chinese law, as long as it is line with international treaties.¹²⁶ This could put China in an interesting situation, if considered to be against international treaties, they could wrongfully admit the export under national legislation. Used correctly it has been suggested that this could give China a very good

¹²² Stoianoff, Natalie P., *The Influence of the WTO Over China's Intellectual Property Regime*, The Sydney Law Review, Vol. 34, No. 1, pp. 65-89, 2012. Available at: <http://ssrn.com/abstract=2069697>

¹²³ Yang, Wei-Ning, Yen, Andrew Y, *The dragon gets new IP claws: The latest amendments to the Chinese patent law*, Intellectual Property & Technology Law Journal, 2009, p.4. Available at: <http://www.ipo.org/wp-content/uploads/2013/03/DragonGetsNewIPClaws.pdf>

¹²⁴ See Yang *et al* in note 123, p. 15.

¹²⁵ See Yang *et al* in note 123, p. 16.

¹²⁶ See Yang *et al* in note 123, p. 15.

reputation in developing countries and LDC that cannot produce necessary medicine themselves.¹²⁷

Some limitations have been implemented as well, for reasons that seems to be pro-commercial, but still to benefit the country in certain cases. Compulsory licensing of semi-conductor technology is allowed as long as it is granted mainly to benefit the public interest. China has a considerable amount of foreign companies in the semi-conductor industry and would probably not want to risk upsetting them.¹²⁸

The TRIPS and Doha Declaration complaint legislation in combination with China's enormous production capacity provides for an interesting and strong future for China and the other developing nations.¹²⁹

6.2. BIC Outlook

Both Brazil and India has been involved in some of the most interesting cases of compulsory licensing during the last decade. The Nexavar case is of particular interest because it is one of few medicines that are outside of the ARV category. This by itself indicates that there is a development, perhaps as a result from the Doha Declaration, but also for what is included in the public health definition. China has yet not been involved in any cases, but the new provisions under their national legislation opens up the possible for them to engage in that in the future. An interesting aspect is that these countries are likely to drive the development in this area. Both Brazil and India, as already mentioned, has been very active in the arena of granting compulsory license to protect public health, they keep pushing and building the arena for what is possible under the TRIPS agreement today. Introducing medicines outside of the "classic" ARV scope opens up for a very interesting future in the area of compulsory licensing.

¹²⁷ See Yang *et al* in note 123, p. 16.

¹²⁸ See Yang *et al* in note 123, p. 17.

¹²⁹ See Stoianoff in note 122, p. 65-89.

7. Conclusion

The Doha Declaration defines the scope very powerfully in paragraph 1: “We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.” It is further emphasized that the TRIPS agreement is necessary to address public health problems and that IP protection is important for the development of new medicines. The scope also points out that the TRIPS agreement does not prevent any member country from taking necessary action to protect public health.

Based on many findings from the WHO, one cannot deny that there is a correlation between our environment and public health. However, it is important to point out some key differences. The Doha Declaration addressed the access to medicine, which in general has a strong, direct and quick effect on public health crisis compared to green technology. The access to green technology is part of long-term visions among many nations desires to improve the environment. Yet, WHO has expressed strong concern for the impact air pollution has on the world’s population today.

Both disease and climate change posses a real threat to public health. The difference here has been pointed out as the very “precise” use of medicine for instance and the rather loose definition of green technology when it comes to its impact on public health. Yet, one of the main focuses of the Doha Declaration was to address issues related to public health, to reaffirm the member states commitment to the TRIPS agreement and to promote access to medicines. Further, the Doha Declaration specifically points at that Article 31 of the TRIPS agreement does not limit the base for the subject to a compulsory license. It is every member states right to determine what is to be considered a state.

So simply put a compulsory license for a green technology patent is justified if a country considers it to be so. Of course that is in theory and the reality would probably look a lot more complicated. The TRIPS agreement does not define what measures that are allowed to use in order to achieve public health. Health is something that is of importance and should be both promoted and facilitated under the TRIPS agreement.

So far there are no known cases where a compulsory license for a green technology patent has been emitted to protect public health, neither as a reaction to a current situation nor as a precautionary measure. But according to TRIPS there is no explicit difference between green technology and medicine in the context of public health. However, defining the threat, an extreme urgency or a national emergency about to affect public health will be different from the way one would justify a compulsory license for a pharmaceutical patent. Some development in the area of compulsory licensing has been seen in cases involving India and Thailand, where “less urgent” diseases, has been granted compulsory licenses. This is a development in the sense that the typical medicine for compulsory license has been related to HIV/AIDS, which is a condition that evolves more rapidly. The recent conditions that were granted compulsory licenses for in India and Thailand suggest that the development in the area is expanding to conditions that are evolving slower. This could potentially be in favor when seeking to justify a compulsory license for green technology patents; when trying to define the threat to public health. There is also and always the explicit right in the TRIPS agreement that allows every member state to determine what constitutes such risk that requires a compulsory license.

The EU and US are having a more strict and firm position towards the flexibility of allowing for this kind of “new” compulsory license, especially the US. Even though there are domestic initiatives to promote development of green technology, the US position in the international compulsory licensing debate is fairly negative. The EU has chosen to add several goal-oriented sections of the TEU that points out their environmental and sustainable responsibility towards others. This also seems to be in line with domestic legislation in several EU member states. The US position as firm and slightly reluctant to compulsory licensing is shown both under national legislation, there is no one really, and in the few cases we have examined the outcome has just been similar to a compulsory license, although for the sake of the public interest.

However, Article 31(b) states that a compulsory license may be granted to benefit health, if the current state of a nation constitutes a national emergency or other extreme circumstance. It has been concluded that the environmental problems are in fact causing more casualties annually than

HIV/AIDS, furthermore WHO has called air pollution the major environment-related health threat of today. This together could justify that air pollution is a threat to public health and it does not seem to exist a theoretical problem to justify a compulsory license for a green technology patent based on Article 31(b).

The need for green technology is part of the global agenda lead by strong emerging nations and the developed nations. However, they do not agree always regarding the means to achieve a more sustainable planet.

The Doha Declaration does not seem to be able to support the transfer of green technology to countries without the necessary production facilities, the Doha Declaration is simply very explicit here and has defined very precise what a pharmaceutical product is. Considering that the events that eventually lead to the Doha Declaration were rooted in the urging need to access medicine, the current state of the environment seems at least a bit similar to those conditions. Insecurity and urging need to ensure public health, without knowing exactly what tools that could justify the access to the relevant innovations. However, even though the Doha Declaration is very pro-health and that paragraph 6, which explicitly discusses the topic of efficient technology transfer, it is limited to pharmaceutical products. It might be quite farfetched to argue that at least the vast majority of green technology patents could fit in that description. “Public health” under TRIPS could be interpreted extensively but it is probably necessary to add a separate clarification to TRIPS regarding how to access green technology. It is by no means clear and there is a demand for clarity as far as the thesis shows. The BIC countries demanded already in 2008 that the TRIPS flexibilities should be further formalized and that it should extend to cover green technology, based on that the climate is public good, just like health.

After pointing out that the Doha Declaration is a clarification for some parts of the TRIPS agreement, we know that it was made with regards to pharmaceutical products. Furthermore, the Doha Declaration does not seem to be able to support the transfer of green technology to countries without the necessary production facilities. So the compulsory license remedy of the TRIPS does not extend beyond the Doha Declaration, mainly because of the construction of the Doha Declaration itself. There might be some possibilities to extend the possibility to transfer technology under the current TRIPS

agreement. The uncertainties regarding the interpretation of “predominantly” before the Doha Declaration might be the only room for discussion here. Since predominantly does not equal “only” there is a possibility that similar discussions and eventually similar outcomes could lie ahead of the development in the green technology field. In that case, the next step might be an explicit inclusion of environmental health under the TRIPS agreement, perhaps concluded through a similar declaration.

The last reflections and conclusions from this thesis come from the BIC countries. Brazil and India has been involved in some of the most interesting cases of compulsory licensing. An interesting aspect is that these countries are likely to drive the development in this area. Both Brazil and India, have been very active in granting compulsory license to protect public health, they keep pushing and building the arena for what is possible under the TRIPS agreement today. Future solutions for protection of public health might come from efficient negotiation like in the case of Brazil or effectively exercised local working requirements for patents like in India could be a solution. BIC are in one way leading the development in this area, they are the ones pushing to access necessary innovations to protect public health. In that sense they are setting the standard for the future development in the area.

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