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**Compulsory licensing under the TRIPS-
Agreement: a tool for developing countries'
access to technology transfer**

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Summary

This bachelor thesis explores compulsory licensing under the TRIPS-Agreement as a tool for technology transfer to the developing world. After illustrating the relevant intellectual property rights, it highlights the relevant passages of the TRIPS-Agreement, the Doha Declaration, the August 30 Agreement and other relevant documents, in order to investigate all the relevant information and determine if compulsory licensing is, as intended, a good tool for technology transfer. The investigation focuses primarily on pharmaceuticals.

The conclusion reached from this investigation was chiefly that compulsory licensing under the TRIPS Agreement is indeed a useful tool for technology transfer to the developing world.

Abstract

In an era of globalization, international legal frameworks and vigorous international politics, we cannot refrain from hearing about the extensive health crisis of the developing world. HIV/AIDS, Malaria and drug resistant tuberculosis are only a few of the widespread disease which appear almost surreal to the citizens of the industrial world. The debates and discussions regarding the importance of aiding the developing nations inter alia through the international legal framework are persistent. The transfer of essential technology, such as pharmaceuticals, is vital if the crisis is to be eradicated, thus the need for an international legal framework which supports the needs of the developing world is indisputable.

Since the international legal framework is immense, and far too comprehensive to be analyzed in a bachelor thesis, the purpose of this essay is to analyze the TRIPS-Agreement of the WTO, i.e. the Agreement on Trade Related aspects of Intellectual Property rights, and investigate to what extent this legal framework is a useful tool for technology transfer to the developing nations. Particularly, focus will be on compulsory licensing as a tool for technology transfer.

The method employed was firstly a profound study of the TRIPS-Agreement and other relevant sources, followed by a research on compulsory licensing. Furthermore, due to the extent of the term “technology”, focus will be on pharmaceuticals.

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Abbreviations

Abbreviation	Explanation
AIDS	Acquired Immune-Deficiency Syndrome
AB	Appellate Body of the WTO
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes
EC	European Community
ECJ	European Court of Justice
EPO	European Patent Office in Munich
EU	European Union
FTA	Free Trade Agreement
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
IP	Intellectual Property
IPRs	Intellectual Property Rights
LDC	Least developed country
MNC	Multinational Corporation
NGO	Non-governmental organization
OECD	Organization for Economic Cooperation and Development
R&D	Research and Development
TRIPS Agreement	The Agreement on Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	United Nations
UNCTAD	United Nations Conference on Trade and Development
US	United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	The World Trade Organization

1. Introduction

1.1 Context

According to UNAIDS, the number of people infected with HIV in sub-Saharan Africa, were 25 million in 2003, and by that year more than 2 million had already died of AIDS.¹ By 2009, however, the number of people infected had fallen to 22.5 million, and although this number reflects a slight improvement, it is still far too great. Furthermore, this number makes up for 68% of global HIV burden,² reflecting the fact that the region is the most affected by HIV in the world. Despite the extensive international cooperation, only 7% of the infected people in developing countries in general had access to the pharmaceuticals required for treatment in 2003.³ This is to a great extent a result of the prices set by the pharmaceutical industry for its patented medicines; the prices are simply too high, making it impossible for developing countries to acquire the relevant pharmaceuticals.⁴ This is only one example of poor technology transfer, which is the topic of this essay.

As opposed to the 18th century when industrialization began in western Europe,⁵ we currently have the skills and knowledge of what is needed in order to attain economic growth and development. Today it is common knowledge that

¹ UNAID, Fact sheet, AIDS epidemic in sub-Saharan Africa, www.unaids.org, "Facilitating compulsory licensing under TRIPS in Response to the AIDS Crisis in Developing Countries", Lidgard., H., Atik., J., Loyola Law School Los Angeles, 2005, p.3

² UNAIDS, Fact sheet

³ UNAID, Fact sheet, see also Lidgard & Atik., p.3

⁴ "Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals", Lidgard., Hans, Atik, Jeff, Loyola Law School, Los Angeles, 2007, p. 1044

⁵ "Världens ekonomiska historia", Cameron, R., Neal, L., Studentlitteratur, 2006

technology is essential for growth.⁶ Therefore, it is vital that developing countries gain significant access to the acutely needed transfer of technology in order to experience an improvement of the public health crisis, subsequently resulting in a reduction of poverty levels.

There are many perspectives from which one could view technology transfer, however in the context of this thesis, the most useful perspective is that of the TRIPS Agreement, which is one of the three most essential international agreements of the WTO. The TRIPS Agreement, i.e. the “Agreement on Trade Related Aspects of Intellectual Property Rights”, was adopted in 1994 in Marrakech, and regulates intellectual property.⁷ Since all WTO member states are bound by, in principle, all the WTO Agreements, the TRIPS Agreement’s regulation of intellectual property rights is essential in the world today.

The notion in developing countries is typically that the comprehensive nature of intellectual property rights granted by the TRIPS Agreement is what causes a significant problem in accessing technology transfer. If vital technology, such as pharmaceuticals, were not patented, developing nations could legally produce the technology themselves without breaking any international laws or agreements, and the poorest nations lacking the resources to produce the medicines themselves could purchase them at a price which they find affordable. From this perspective, intellectual property rights actually work as a barrier to technology transfer, as opposed to a tool intended to promote it.⁸ Naturally, this view is not shared by the developed world, who argues that creators of e.g. new technology must be given the exclusive right to produce, utilize, offer for sale or sell the invention and prevent others from doing so.⁹ Intellectual property rights are viewed as vital for creating incentives to innovate,¹⁰ and are thus essential.

The international community has recognized the severe health crises in developing countries, and has therefore incorporated possibilities into the TRIPS Agreement, which are intended to help reduce this problem. One important

⁶ “Introduction to Economic Growth”, Jones, C., W.W. Northon & Company, Inc. 2002, page 96.

⁷ Wto.org

⁸ “Competition law in technology transfer under the TRIPS Agreement”, Nguyen, T., Manuscript for a Civil Law Licentiate Seminar, 2007, p.16-17

⁹ The TRIPS Agreement Art.8

¹⁰ Nguyen, p.16-17

opportunity given by the TRIPS Agreement to address the problem is that of compulsory licensing, a means of receiving a license from a patent holder without his or her consent.¹¹ This thesis investigates if and how compulsory licensing under the TRIPS Agreement facilitates the access to technology transfer from the developed nations to the developing world. The objective is to see if, from a legal perspective, compulsory licensing is a useful tool or not.

1.2 The purpose of the Thesis

The purpose of this bachelor thesis is to investigate compulsory licensing under the TRIPS Agreement regarding technology transfer from the industrialized world to the developing countries. The aim is to clarify how the TRIPS Agreement, through compulsory licensing, enables developing countries to have access to technology transfer, which is essential for their domestic economic growth and development. Is compulsory licensing under the TRIPS Agreement a useful tool for technology transfer to the developing world? This is the question I will attempt to answer. The starting points in this investigation are Art.7, Art.8, Art.27, Art.30 and Art.31 of the TRIPS Agreement.

1.3 Material and Method

Although there are substantial amounts of materials on the subject, the materials that were used first and foremost are the TRIPS-Agreement, the Doha Declaration, the August 30 Agreement and relevant articles in scientific journals. In order to get the most accurate information, the sources have thus mainly been official publications, scientific articles and documents from the WTO and other sources. Some sources have been used more than others, though. Two articles that have been particularly useful are “Facilitating compulsory licensing under TRIPS

¹¹ *TRIPs, Pharmaceuticals, Developing countries, and the Doha “Solution”*, Law School of The University of Chicago, John M. Olin law & economics working paper No. 140, Sykes, A., p.7

in Response to the AIDS Crisis in Developing Countries” and “Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals”, both by Hans Henrik Lidgard¹² and Jeffery Atik.¹³ These articles have been invaluable for understanding the relationship between compulsory licensing under the TRIPS Agreement and technology transfer to the developing world. Another useful article has been “TRIPs, Pharmaceuticals, Developing countries, and the Doha “Solution”, by Alan O. Sykes,¹⁴ which has been important for the investigation as a whole, as can be seen from the frequent references to it throughout the thesis. Moreover, the manuscript for the Civil Law Licentiate Seminar “Competition law in technology transfer under the TRIPS Agreement”, by Tu Thahn Nguyen¹⁵ has also been greatly helpful.

The method used was firstly a thorough investigation of the TRIPS Agreement, the Doha Declaration, the August 30 Agreement and the ACTA, followed by an acquiring of the relevant materials, which have been studied comprehensively. The language was intended to be clear, hopefully this objective has been satisfied.

1.4 Delimitation

In this investigation, no particular national laws on IPRs are considered, only the international intellectual property rights under the TRIPS Agreement relevant to the technology transfer from the industrialized world to the developing countries. This is due to the fact that, as briefly mentioned, all WTO member countries are bound by the TRIPS, and an investigation comprehensive enough to also comprise national laws on intellectual property rights is beyond the scope and means of this bachelor thesis.

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¹³ Professor of Law, Loyola Law School, Los Angeles, USA

¹⁴ Professor of Law, Chicago Law School, USA

¹⁵ Doctor of Law, Lund University, Sweden

Since there are many developing countries in the world, and the circumstances vary in different continents, focus will be on Sub-Saharan Africa, as the region is the poorest one in the world.

Furthermore, the term “technology” will in this case generally comprise all sorts of technology, such as software, patents, know-how, copyrights, etc. However, due to the fact that a bachelor thesis does not allow for an in-depth study of all important types of technology relevant to Sub-Saharan Africa, focus will be on one type of technology which is an essential, if not the most important, type of technology for the region, namely pharmaceuticals. Although the aim is to look on technology in general as well, I believe focusing on pharmaceuticals allows one to gain deeper knowledge and understanding of how compulsory licensing works.

1.5 Thesis disposition

The thesis begins with Chapter 1, which provides the introduction, briefly describing the current situation in developing countries (especially sub-Saharan Africa) regarding technology, the health crises, and the view on intellectual property rights, also portraying why technology transfer is such a vital necessity. Furthermore, the chapter states the purpose of the thesis, as well as the materials and methods used in the investigation. Lastly, it illustrates the delimitations that were made.

Chapter 2 describes intellectual property rights, mostly patents, and the economic implications of these, in order to give the reader the necessary background knowledge to understand the upcoming analysis. Furthermore, it discusses the relationship between intellectual property rights and technology transfer as well as the implications for pharmaceutical patents.

Chapter 3 explains the TRIPS-Agreement, providing some general information about the Agreement, along with facts regarding how the Agreement views patent protection and technology transfer. It also sheds light on some important

limitations of the TRIPS related to compulsory licensing and technology transfer, highlighting the need for other documents in order to clarify how some articles of the Agreement are intended to be interpreted.

Chapter 4 is devoted to compulsory licensing, which is the central concern of the investigation. This chapter discusses the important international agreements mentioned in the previous chapter, such as the Doha Declaration and the August 30 Agreement, which need to be considered when interpreting the TRIPS and attempting to find an answer to the introduction question. Finally, the chapter discusses the impact of these agreements on compulsory licensing, and subsequently on technology transfer, especially pharmaceuticals, in order to see whether compulsory licensing appears to be a good tool or not for technology transfer.

Finally, the thesis ends with a conclusion and a final statement, presenting the arguments found to support the claims.

2. Intellectual Property Rights

2.1 Introduction

Intellectual property rights are "instruments of public policy which confer economic privileges on individuals or institutions solely for the purposes of contributing to the greater public good."¹⁶ IPRs essentially give their holder an exclusive right (similar to a monopoly) of using the invention in question, and prevent others from using it without his or her consent for a certain time¹⁷.

The WIPO defines intellectual property, IP, as "creations of the mind,"¹⁸ e.g. images, symbols, designs and names used in commerce, inventions, as well as literary and artistic works. Intellectual property is thus related to the scientific, industrial, artistic and literary fields, and involves legal rights which governments attempt to protect both through national legislation and by means of international agreements such as the TRIPS Agreement.¹⁹ The reason for this is that nations wish to clearly define the rights of the creators as well as those of the public regarding the creations considered as IP. Furthermore, the scope is to contribute to long-run social and economic development by providing incentives to creators of intellectual property.²⁰

IP can be divided into copyright and industrial property. The latter refers to industrial designs, patents, geographical indications of source and trademarks,

¹⁶ www.wipo.org, "What is Intellectual Property?" www.wipo.int/about-ip/en/

¹⁷ The TRIPS Agreement, Art. 28.1.a

¹⁸ www.wipo.org

¹⁹ www.wipo.org

²⁰ www.wipo.org

while copyright incorporates artistic and literary works, inter alia musical works, and artistic works.

Intellectual property rights, IPRs, are established for things similar to public goods, which are nonexcludable and nonrival in consumption, e.g. sewage systems.²¹ If a sewage system is produced in a particular area to keep a river clean, it will have the same effect for all citizens in that area. The fact that it may benefit one person does not lead to it being consumed and thus no longer available to benefit others. Goods which are protected by intellectual property laws, such as a particular technology, work in the same way.²² If the developing world would have access to the same say, pharmaceuticals, as the developed world, it would not prevent citizens in developed nations from using pharmaceuticals as well. A problem is the prevalence of free rides, which often cannot be prevented from using the good in question.²³ This poses a problem because creating e.g. a masterpiece, a new software or a new pharmaceutical requires the investment of significant time, effort and money. In order for a person or corporation to invest all of this into a project, there are expectations of profits. Therefore, creating something which others can use freely without having to pay for it is discouraging for a producer, who would lose his or her incentive for innovation. For this reason, the existence of well defined property rights is essential for innovation of any kind.²⁴ One must keep in mind, though, that the real purpose of IPRs is more than the temporary protection of a particular producer's rights. The true purpose is to create incentives to innovate, in order to make development possible and thus encourage the progress of society.²⁵

²¹ Krugman, P., & Wells, R., 2005, *Microeconomics*, Worth Publishers, p.479

²² Nguyen, p.13

²³ Ibid

²⁴ Sykes, p.16

²⁵ www.wipo.org

2.2 Intellectual Property Rights and Technology Transfer

The relationship between IPRs and technology transfer is debatable. From the perspective of the developing world, IPRs can be viewed as an obstacle to technology transfer. This is due to the fact that higher levels of protection to patent holders and the need for e.g. compulsory licensing make it more difficult to import essential technology than in the markets which are freer, inter alia like the textile industry.²⁶ Simultaneously, patent holders have power similar to that of a monopolist,²⁷ being able to set high prices which developing countries cannot afford to pay. This way, strong IPRs can prevent developing countries from being able to acquire technology, and may thus be counterproductive considering their real purpose.

The developed world, however, finds IPRs to be an essential condition for innovation,²⁸ because without the guaranteed profits, producers would lose their incentives to make the necessary investments to develop innovations. From this perspective, the existence of IPRs, as mentioned, enables innovation and technology transfer.

2.3 Pharmaceutical Patents

One of the most important types of technology transfer needed in developing nations is the transfer of pharmaceuticals. As briefly mentioned, the developing world suffers from prominent, widespread disease such as HIV, but also Malaria and drug resistant tuberculosis,²⁹ and is in acute need of relevant pharmaceuticals.

Pharmaceuticals are also the type of technology for which patent protection is particularly strong.³⁰ In the production of pharmaceuticals, most of the costs are

²⁶ Sykes, p.15

²⁷ Lidgard & Atik, 2005, p.5

²⁸ Nguyen, p.13

²⁹ Sykes, p.3

³⁰ Sykes, p.16

related to R&D and in receiving regulatory approval.³¹ Hans Henrik Lidgard and Jeff Atik find that “a new chemical entity appears on average to require an investment far exceeding 100 million USD and requires more than ten years of systematic development and testing before the final product can be authorized.”³² The actual cost of producing the pharmaceuticals themselves is not very high once the R&D is finished, and the pharmaceutical has been approved. Having this in mind, it is easy to understand why patent holders in the pharmaceutical industry are so keen on securing their rights. Without satisfactory IPRs, the incentive to invest these monumental amounts of money and time would vanish, resulting in less production within the pharmaceutical sector, which could have disastrous effects on world health. Therefore, it is vital to realize that while most of us consider that the developing world is entitled to help, it is not to be forgotten that the pharmaceutical industry invests a lot in its goods, which ultimately benefit human health, and thus deserves to receive protection. Although the pharmaceuticals may not be distributed to the developing world to the same extent as in the developed countries, the medicines produced are essential to human life and health, and thus the serious need to protect these producers appears obvious.

2.3.1 Pharmaceutical patents, monopoly power & losses to society

As mentioned, an argument in favor of innovators is that IPRs are needed in order for innovation to occur. On the other hand, though, one cannot refrain from noting the monopolistic effect that a patent may imply. When holding a patent, an innovator has the power to prevent competition regarding products covered by the patent. The economic view on monopoly is that it creates deadweight losses,³³ since a monopolist has the power to charge higher prices than the cost of production, leading to higher prices than would exist if there were competition on the market.³⁴ This may not imply such a significant problem, if the patented

³¹ Lidgard & Atik, 2007, p.1056

³² Ibid

³³ A deadweight loss is defined as “the value of mutually beneficial transactions that do not occur because of monopoly behavior. Alan “Microeconomics”, Krugman & Wells, p. 348

³⁴ “Market Power in Antitrust cases”, Lander, William & Posner, Richard, Harvard Law Review, nr. 937, 1981

product would be one which is not truly needed, such as a luxury good. However, if the patented product happens to be an important one, inter alia HIV medicine, and is lacking close substitutes, the implications can be very severe for those in need of the medication but unable to pay the high price charged by the patent holder.

Therefore, it can be argued that despite the needs of patent holders to receive protection, the costs on society of this are exceedingly high, because the monopoly power of the patent holder can result in the loss of millions of lives. Consequently, it is not unreasonable to state that patent rights may be too strong in the case of pharmaceuticals.

Returning to monopoly power, one can find an additional view on this. Sykes goes as far as expressing that “monopolists may invest resources in obtaining monopoly, thereby dissipating monopoly profits *ex ante* and causing further deadweight losses.”³⁵ Excessive investments in the race to develop a new invention are predominantly common in the case of patents, leading to so called “patent races,”³⁶ causing dissipated monopoly rents. Consequently, the extent of monopoly power held by a patent holder determines the extent of the produced deadweight loss. Still, this loss is accepted due to the returns it generates to the patent holders and the investors, and is, as mentioned, considered necessary in order for these to find it worthwhile to strive for innovation.

However, what is interesting is that the level of patent protection is the same for all types of innovations, without taking account of the costs of developing the innovation that thus need to be recovered. As a result, some innovations are over-rewarded, while others are under-rewarded.³⁷ Therefore, in a case where a particular patent (usually pharmaceuticals) may be viewed as receiving excessive protection, one can argue that it is not filling the function of protecting incentives. Alan Sykes expresses it in the following manner: “If one had reason to believe that the patent protection afforded in a particular context was excessive, such a “property right” could not be defended as important to valuable incentives.”³⁸ In

³⁵ Sykes, p.11

³⁶ Sykes, p.12

³⁷ Sykes, p.13

³⁸ Ibid

fact, its existence would imply a level of deadweight loss that is unnecessarily high, while giving the patent holder a stronger monopoly right than needed for him/her to feel that the investments incurred in the innovation were worthwhile.

Since it is generally the pharmaceutical patents that are viewed as “over-rewarded”, one can draw an important conclusion: In order to prevent the deadweight loss, which can be substantial considering that human lives are at stake, it is vital to have some form of Agreement or international legal framework which can act as a tool to prevent this loss. As will be noted in the following chapters, compulsory licensing under the TRIPS Agreement appears to be such a tool.

2.4 ACTA

The Anti-Counterfeiting Trade Agreement, ACTA, is still under negotiation, and as opposed to the other agreements that will be examined in this thesis, it is an international agreement attempting to “create improved international standards as to how to act against large-scale infringements of IPRs”³⁹ without taking too much consideration to the needs of the developing world.⁴⁰ The negotiations began in October 2007, between the United States, The European Community, Japan and Switzerland, however other countries such as Mexico, Singapore, Australia, New Zealand and Canada have joined the negotiations in the mean time. The ACTA deals with physical goods as well as information technology and internet distribution, its aim being the reduction, or rather, the prevention of inter alia “piracy”, and other violations of intellectual property laws, which have become a widespread problem. While aspiring to “address the problem of infringement of intellectual property rights, including that which takes place in the digital environment, and with respect to copyright or related rights in particular in a manner that balances the right and interests of the relevant right holders, service providers and users,”⁴¹ it is not intended to implement new IPRs.

³⁹ ACTA, Fact sheet, 2009, European Commission, <http://ec.eu.europa.org>

⁴⁰ Anti-Counterfeiting Trade Agreement, Electronic Frontier Foundation, www.eff.org/issues/acta

⁴¹ Consolidated text, Anti-Counterfeiting Trade Agreement, Informal Predecisional/Deliberative Draft: 2 October 2010, p.2

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It is to be noted, however, that the ACTA is not intended to contradict the TRIPS Agreement, which will be studied in the following chapter. The ACTA clearly stipulates that “Nothing in this Agreement shall derogate from any obligation of a Party with respect to any other Party under existing agreements, including the WTO Agreement on Trade Related Aspects of Intellectual Property Rights.”⁴²

⁴² Anti-Counterfeiting Trade Agreement, Art. 1.1

3. The TRIPS Agreement

3.1 Introduction

The Agreement on Trade Related Aspects of Intellectual Property Rights, the TRIPS Agreement, is, apart from the GATT and GATS, one of the three chief agreements of the WTO. It was adopted in 1994, with the aim of providing an international agreement determining IPRs, and thus providing protection for multinational corporations, MNCs,⁴³ largely due to the pressure perceived from the developed world. The Most Favored Nation Principle,⁴⁴ the National Treatment Principle,⁴⁵ and transparency requirements are cornerstones in the TRIPS Agreement, which also “provides basic substantive principles on the protection and enforcement of IPRs,”⁴⁶ The TRIPS Agreement was intended to serve as a very useful tool, since it had to be ratified by all member states of the WTO, also resulting in a more simple way of solving possible disputes between the members through the DSU,⁴⁷ the Dispute Settlement Understanding. This international Agreement has facilitated trade between nations by assuring a higher level of security due to the fact that all member states must comply with its rules. The international protection of IPRs that the TRIPS provides thus encourages trade, which is of high significance for the economies of the developing world. This implies, in theory, that goods and services, such as technology transfer in the form of R&D and pharmaceuticals, which are vital to development, were made more available through the implementation of the TRIPS agreement.

⁴³ Lidgard & Atik, 2005, p.4

⁴⁴ TRIPS Agreement Art.4

⁴⁵ TRIPS Agreement Art.3

⁴⁶ Nguyen, p.11

⁴⁷ “The Understanding on Rules and Procedures Governing the Settlement of Disputes”

Looking from this perspective, the TRIPS Agreement appears to be a useful tool for technology transfer to the developing world. Usually this view is held by WTO member states such as the EU, Japan and the US, who are the ones mostly requiring the protection of intellectual property, since these states are the ones developing most of the new technology due to their extensive investments in R&D.⁴⁸ This view, however, is not necessarily shared by developing countries, since extensive IPR protection generally makes it more difficult to acquire technology from the developed world. For this reason the developing countries have been given freer access to markets such as textiles and agriculture, on the condition that they respect the IPRs of other member states imposed by the TRIPS Agreement.⁴⁹ This, however, was not enough according to many countries in the developing world. Therefore, in order to aid the developing world in an increasingly comprehensive manner, the WTO produced the “Declaration on the TRIPS Agreement and Public Health,”⁵⁰ which will be examined in the following chapter.

3.2 Patent Protection under the TRIPS Agreement

The patent rules of the TRIPS Agreement are an extension of those of the Paris, Berne and Rome Conventions to all WTO members.⁵¹ The rules comprise three conditions which must be fulfilled in order for a patent to be granted,⁵² namely those of novelty, inventiveness and industrial applicability.

The TRIPS Agreement regulates patent protection in articles 27-34.⁵³ In article 27 we find that “patents must be made available for all inventions, whether products or processes, and must last for at least twenty years from the date of the filing of a patent application.”⁵⁴ Moreover, a patent holder has exclusive rights to produce,

⁴⁸ Nguyen, p.10

⁴⁹ Sykes, p.15

⁵⁰ The Doha Declaration

⁵¹ Lidgard & Atik, 2005, p.4

⁵² TRIPS Agreement Art. 27

⁵³ Sykes, p.5

⁵⁴ Sykes p.6, see also TRIPS Agreement Articles 27.1. and 33

utilize, offer for sale or sell both the patented product itself, as well as the product that may be produced from a patented process.⁵⁵ Moreover, according to the TRIPS Agreement “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not reasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner /.../.”⁵⁶

Furthermore, a patent holder has the exclusive right to import the product which is patented or created from the patented process. Nevertheless, member countries have the possibility to make a few exceptions, and refuse to issue patents in certain cases, even if they fulfill the required criteria.⁵⁷ For instance, a member can choose not to grant patents for an invention which may damage the morality or ordre public, i.e. the fundamental values behind the legislation of a nation. The same is valid if it is reasonable to believe that granting a patent would involve a risk to the life or health of humans, animals or plants, or if it could result in significant environmental degradation.⁵⁸ A member cannot, however, apply the right to make exceptions regarding innovations such as pharmaceuticals.

Regarding pharmaceuticals, Jeff Atik and Hans Henrik Lidgard state that “protection is granted for the chemical composition, production methods, and the ensuing product, as well as different modes of application.”⁵⁹

Because of the significant economic differences between developed and developing countries, though, the latter were permitted transitional provisions as stated in articles 65 and 66.⁶⁰ For instance, developing countries were allowed a five year delay of applying most of the provisions of the TRIPS Agreement after its entry into force, thus until January 1st 2000.⁶¹ LDCs were presented firstly with the possibility to comply with the obligations of the Agreement within six years,⁶² however, as will be explained shortly, the time frame was extended to January

⁵⁵ TRIPS Agreement Art.28, see also Sykes p.6

⁵⁶ TRIPS Agreement Art.30

⁵⁷ TRIPS Agreement Art.27

⁵⁸ TRIPS Agreement Art.27

⁵⁹ Lidgard & Atik, 2007, p.1057

⁶⁰ Länsisyrjä, p.39

⁶¹ TRIPS Agreement Art. 65.2-3

⁶² TRIPS Agreement Art.66.1

2016. Finally, there were developing nations which, prior to the ratification of the TRIPS Agreement, did not have any type of patent protection for e.g. pharmaceuticals (or some other particular field of technology). These countries had until January 2005 to “enforce patent rights in that area.”⁶³

As a final point, one should keep in mind that the TRIPS Agreements only provides minimum standards, and there is nothing preventing member states from developing their national laws further: “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement.”⁶⁴ The implications of this can be discussed. On the one hand, it can be considered that the WTO made a good choice by granting freedom to its members to decide for themselves how comprehensive national laws they wish to have on this topic. On the other hand, it can be argued, as Daniel Gervais does, that the TRIPS Agreement “did not achieve all that some countries wished.”⁶⁵

3.3 Limitations of articles 30 and 31 of the TRIPS Agreement

As mentioned, the provision of Article 30 is rather unclear, thus it is difficult to deduce exactly what is meant by “limited exceptions”. Also article 31 contains a number of uncertainties related to when and how compulsory licensing is to be regarded as appropriate.⁶⁶ Hans Lidgard and Jeff Atik have looked on the article and found four significant provisions which are unclear:⁶⁷

1. “When a situation of national emergency can be invoked
2. How much effort must be employed to reach a voluntary agreement with the patent holder before a failure has been established
3. What royalty compensation must be awarded to the rights holder
4. Whether least developed countries with no production capacity may rely on importation”

⁶³ TRIPS Agreement Art. 65(4)

⁶⁴ TRIPS Agreement Art. 1(1)

⁶⁵ Gervais, supra note 104, p. 86

⁶⁶ Lidgard & Atik, 2005, p.6

⁶⁷ Lidgard & Atik, 2007, p. 1049

The TRIPS Agreement allows importing member countries to decide for themselves how to interpret and decide on these uncertainties, as long as the decision is in accordance with TRIPS procedure. It is also useful to note the general security exemption of art. 73, which permits members “wide discretion to take any action it considers necessary in time of war or other emergency.”⁶⁸ Consequently, Lidgard and Atik find that “this provision relieves a party from virtually all of its substantial obligations under TRIPS.”⁶⁹

These uncertainties of the TRIPS Agreement were considered a rather significant problem, and it was the desire to solve it that led to the creation of the “Declaration on the TRIPS Agreement and Public Health,” which will be studied in the following chapter.

3.3 Technology Transfer under the TRIPS Agreement

The TRIPS Agreement states in Art.7 that the scope of the protection and enforcement of IPRs is to “contribute to the promotion of technological innovation and to the transfer and dissemination of technology”. Moreover, this is intended to benefit both the suppliers and consumers of the technology “in a manner conducive to social and economic welfare.”⁷⁰

Thus, from looking at this paragraph, it appears clear that the TRIPS Agreement recognizes the importance of and attempts to promote technology transfer, which is one significant factor “conductive to social and economic welfare.”⁷¹ It thus becomes clear that one of the purposes of the TRIPS Agreement is to work as a tool for contributing to technology transfer.

Since all members of the WTO are bound by the TRIPS Agreement, they are also obliged to comply with Art.7, which thus encourages us to consider the Agreement to be, at least in theory, a useful tool.

⁶⁸ TRIPS Agreement Art.73

⁶⁹ Lidgard & Atik, 2005, p.7

⁷⁰ TRIPS Agreement Art. 7

⁷¹ TRIPS Agreement Art. 7

Moreover, the Agreement stipulates that WTO member countries may “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development.”⁷² It is also stated that “appropriate measures /.../ may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”⁷³

The TRIPS Agreement appears to clearly indicate that its scope is, apart from protecting intellectual property rights, to promote technology transfer. However, despite this indication, if the Agreement is to truly benefit the developing countries then they must have the capacity to receive this transfer of technology and subsequently experience the social and economic development which that would result in. Unfortunately, this is not always the case, as the prices of technology are by far too high for them to afford. For this reason, there are conflicting views on this issue, between the desire of the developed world to promote and encourage innovation, and the strong need of the developing countries to acquire important technology such as pharmaceuticals. Sadly, a common view is that the TRIPS Agreement is in fact mostly benefitting the developed countries, intensifying their monopoly privileges and economic power. This is especially true for the pharmaceutical industry, which is one of the most desperately needed in developing countries. As a result, the transfer of technology to developing countries has not expanded very much, as can be seen in the extent of the HIV/AIDS crisis,⁷⁴ which is, unfortunately, still exceedingly extensive.

⁷² TRIPS Agreement Art. 8(1)

⁷³ TRIPS Agreement Art. 8(2)

⁷⁴ Lidgard & Atik, 2005 p.5

4. Compulsory Licensing

4.1 Introduction

Due to the pressing needs for technology transfer in the developing world, compulsory licensing has become an option offered by both national laws and the TRIPS Agreements. As will be described in more detail below, compulsory licensing allows a legitimate authority to issue licenses to others than the holder of the intellectual property rights of a particular good or process, without the consent of the latter. Although this can only take place under certain conditions, it is intended to offer an opportunity in the attempt to facilitate, among other things, the transfer of technology to the developing world. If e.g. a Kenyan corporation would receive a compulsory license to produce the HIV drug flucanazole,⁷⁵ the drug could be produced at a much lower cost than by the corporation holding the patent, since the latter was obligated to pay large amounts of money on R&D and on regulatory approval,⁷⁶ resulting in the need to require high prices for the produced pharmaceuticals in order to receive revenues higher than the total costs of production. This, however, is not something the holder of a compulsory license is forced to do, since the R&D has already been completed, as well as the gaining of the regulatory approval. Therefore, the holder of a compulsory license could set a significantly lower price, which could literally mean the difference between life and death to the domestic population, without violating international standards of patent protection. For instance, the price of 150 Mg of flucanazole in India is 55 USD,⁷⁷ because it is not protected by a patent, while in the Philippines, where

⁷⁵ Sykes, p.1

⁷⁶ Sykes, p.16

⁷⁷ Sykes p.1

patent protection occurs for the drug, the price is as high as 817 USD,⁷⁸ which of course implies a monumental difference in opportunities for the populations in question to purchase the drug. Thus, if compulsory licensing can result in prices being such that a larger part of the population could afford to purchase essential pharmaceuticals, it would indeed be a successful result of technology transfer, and therefore, it would also reflect the success of our current international laws and agreements on intellectual property rights and compulsory licenses.

Compulsory licensing may thus be regarded as a helpful tool in technology transfer, because the possibility it brings allows companies to produce crucial technologies such as pharmaceuticals at acceptable prices, resulting in the possibility of setting a price which consumers can afford. Consequently, compulsory licensing can bring help to the poor without breaking international laws or agreements. From this perspective, compulsory licensing appears to be not only a good tool, but rather an excellent one.

4.2 Compulsory Licensing under the TRIPS Agreement

Compulsory licensing is allowed under the TRIPS-Agreement article 31, and implies a right to produce or import a patented item without the actual consent of the patent holder.⁷⁹ In order for a compulsory license to be issued, however, there are certain requirements that must be satisfied.⁸⁰ Firstly, compulsory licenses are only granted if the purpose is for them to be used “predominantly for the supply of the domestic market,”⁸¹ and a license is “limited to the purpose for which it was authorized.”⁸² Secondly, one must during a “reasonable period of time”⁸³ attempt to negotiate with the holder of the right, striving to convince him or her

⁷⁸ Sykes, p.1. See also the United Nations Commission on Human Rights, Report of the High Commissioner, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights §44, E/CN.4/Sub.2/2001/13 (June 2001)

⁷⁹ Sykes, p.7

⁸⁰ TRIPS Agreement Art. 31

⁸¹ TRIPS Agreement Art. 31(f)

⁸² TRIPS Agreement Art. 31(c)

⁸³ TRIPS Agreement Art. 31(b)

to willingly grant a license. One is also required to offer commercial terms that are reasonable for both parties. When granted a compulsory license, one is required to pay adequate remunerations to the right holder,⁸⁴ “taking into account the economic value of the authorization.”⁸⁵ Compulsory licenses may also be granted in the face of a national emergency.⁸⁶

Today we find that the developing nations are undoubtedly affected by epidemic diseases to the extent that they are undoubtedly considered to fall into the category of “emergency situations,”⁸⁷ which entitle them to the use of compulsory licenses.

This has not always been the case, though. If one is to look on the development of the TRIPS, one can find that there was a problem. There were originally quite obvious limitations to the TRIPS Agreement, because the solutions offered by the Agreement were long-term, while the needs in the developing world were urgent. In order to acquire and distribute the required pharmaceuticals, a nation must have know-how, technology and education to be able to produce the pharmaceuticals in question, as well as functioning institutions and an infrastructure that is capable of distributing the medicine to those in need. The reality is, however, that the developing countries did not, and still do not have these resources. For this reason, the Africa Group found a need to slightly clarify the conditions offered by TRIPS Agreement, and this began at the Ministerial Conference meeting in Doha, 2001.⁸⁸

4.3 The Doha Declaration

Due to the limitations of the TRIPS Agreement regarding the health crisis in the developing world, WTO member countries recognized the need for change, and discussed the issue during the Ministerial conference in Doha, Qatar, in

⁸⁴ TRIPS Agreement Art. 31(h), Sykes, p.7

⁸⁵ TRIPS Agreement Art. 31(h)

⁸⁶ Sykes, p. 7

⁸⁷ TRIPS Agreement Art. 31

⁸⁸ Lidgard & Atik, 2005, p. 10

November 2001, forming “The Declaration on the TRIPS Agreement and Public Health”, more frequently referred to as “the Doha Declaration.”⁸⁹ The reason for the Doha Declaration was not only the will of the developing world to clarify some articles of the TRIPS, but also the desire of some developed countries, prominently e.g. the US and Switzerland, to protect their interpretation of the Agreement.⁹⁰ It should be noted, however, that the Doha Declaration did not alter the TRIPS Agreement, it is merely a ministerial interpretation of the Agreement intended to clarify the uncertainties. During the meeting, members reached the conclusion that “TRIPS can and should be interpreted in a manner supportive of WTO members’ right to protect public health and, in particular to promote access to medicines for all.”⁹¹ Theoretically, this implied a right of WTO members to grant compulsory licenses freely and “decide on the grounds therefore.”⁹² With the implementation of the Doha Declaration, compulsory licensing came to be viewed as an acceptable tool for making pharmaceuticals more accessible in developing countries.⁹³ The implementation of this decision was intended to provide the developing world with necessary pharmaceuticals, giving the region a chance to improve the health of its populations and thus relieve the countries to some extent from the pressing health crisis.

Another identified goal was that of providing relief for countries with no production capacity in the pharmaceutical sector. However the decision to find an effective, short term solution to this problem turned out to be quite difficult. This was due to the rather selfish nature of some of the member countries involved; often nations targeted their own self-interest as opposed to that of the developing world, who’s problems were in fact the reason for discussion.⁹⁴ The United States, for instance, was such a member. Hans Henrik Lidgard and Jeffrey Atik find that the US suggested to “limit the types of products that would be available for compulsory licensing to medicines to combat epidemic diseases and to reduce the

⁸⁹ Lidgard & Atik, 2005, p.10

⁹⁰ Sykes, p.2

⁹¹ Lidgard & Atik, 2005, p.11

⁹² Lidgard & Atik, 2007, p. 1051

⁹³ Länsisyrjä, p. 45

⁹⁴ Lidgard & Atik, 2005, p. 11

number of countries that would be eligible as both importers and exporters of these products.”⁹⁵

Similar views were held by other members, and despite the compromise suggested by the European Union, no final decision was made until August 30, 2003, referred to as “the August 30 Agreement”.

Returning to the Doha Declaration, however, it is essential to recognize that it has thoroughly clarified some parts of the TRIPS Agreement which were quite unclear.⁹⁶ One such vagueness is found in TRIPS art. 31, regarding compulsory licensing, where the Agreement refers to “other use”, while the Doha Declaration clarifies the meaning of the expression by referring to it explicitly as “compulsory licenses”. This specification in the Doha Declaration may be viewed as a means to highlight the existence and importance of compulsory licenses.⁹⁷ Furthermore, apart from stipulating that members have the right to grant compulsory licenses, the Doha Declaration also specifies under what conditions they may be granted.⁹⁸ It is also stated that members are entitled to determine themselves exactly what is to be considered a “national or extreme emergency”, under which TRIPS allows compulsory licensing. What is particularly encouraging is that the Declaration overtly specifies that the widespread health concerns of the developing world, namely HIV/AIDS, may unmistakably be viewed as an emergency of the sort.⁹⁹

Another vagueness of the TRIPS Agreement which the Doha Declaration clarifies is that when interpreting and applying the TRIPS, members must always recognize that they have an apparent right to protect public health. The interpretation of the TRIPS should not be such that it in any way goes in opposition to this objective. Moreover, the Doha Declaration stipulates that the TRIPS is not in any way intended to be implemented in a way which would imply a prevention of access to medicines, on the contrary!¹⁰⁰ The ministers creating the Declaration “agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health,”, adding that it “can and

⁹⁵ Lidgard & Atik, 2005, p.11

⁹⁶ Länsisyrjä, p. 45

⁹⁷ Länsisyrjä, p. 45

⁹⁸ The Doha Declaration, §5

⁹⁹ The Doha Declaration, §5

¹⁰⁰ The Doha Declaration, §4.

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."¹⁰¹ It should also be highlighted that the Doha Declaration recognizes 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."¹⁰²

To conclude, the Doha declaration clarifies the uncertainties of the TRIPS related to compulsory licensing in the following way:¹⁰³

- a) "In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
- b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.
- c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN¹⁰⁴ and national treatment provisions of articles 3 and 4."¹⁰⁵

What is important to note in this paragraph of the Doha Declaration is firstly the implications of §a), which stipulates that the interpretation of the TRIPS should occur in agreement with the core objectives and principles of the Agreement. A prominent principle in this case is the one found in TRIPS article 8, stating that

¹⁰¹ The Doha Declaration, §4

¹⁰² The Doha Declaration, §1

¹⁰³ The Doha Declaration, §5

¹⁰⁴ MFN is short for the "Most Favored Nation" principle.

¹⁰⁵ The Doha Declaration §5

“Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health.”¹⁰⁶ Another important thing to note is found in §c, which clarifies that the public health crisis occurring in many developing countries falls within the category “national emergency.” This implies that there is no need for the relevant countries to negotiate with the right holders in order to receive compulsory licenses.¹⁰⁷

Additionally, the Doha Declaration specifies that the transitional period of LDCs regarding the implementation of patent protection on pharmaceuticals is to be extended to January 2016.¹⁰⁸

However, one should keep in mind that the Doha Declaration is a ministerial declaration, and is thus not a legally binding document. Nevertheless, since the Doha Declaration is an interpretation of the uncertainties under the TRIPS Agreement, and not in any way a contradiction to it, it is reasonable to believe that it will serve as a powerful tool when interpreting the TRIPS Agreement. This is likely to be true also in the case of possible disputes between WTO members.¹⁰⁹

In conclusion, the very prevalence of the Doha Declaration can be considered to make a powerful statement; the fact that the WTO has bothered to develop an entire declaration on public health issues in the developing world relating to IPRs, reflects an increased acknowledgement of the strong correlation between the two, and the high importance of improving the crisis in the developing world. There are many contradicting views on to what extent this is true, however, Amit Gupta interpreted the declaration as the first time the WTO “openly acknowledged that the public health problems in many countries were in part a result of the intellectual property regime under the TRIPS Agreement.”¹¹⁰ In any case, the Doha Declaration has served as a useful tool for specifying the uncertainties of the TRIPS Agreement, and is a framework which offers support to the needs of the developing world. Thus the Doha Declaration has, through the clarifications

¹⁰⁶ The TRIPS Agreement Art. 8.1

¹⁰⁷ Sykes, p.9

¹⁰⁸ Doha Declaration, §7

¹⁰⁹ Sykes, p.9-10

¹¹⁰ Gupta, A., “Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?”, *Buffalo Intellectual Property Law Journal* (2004), p. 146. See also Länsisyrjä, p. 47

provided, turned the TRIPS Agreement into a more useful tool than it was initially.

4.3.1 The August 30 Agreement

This Agreement “refers merely to pharmaceutical products needed to address a public health problem with a reference to the Doha Declaration.”¹¹¹ Furthermore, in the statement of the chairman, it is stipulated that the August 30 Agreement is not in any way intended to be used as a tool for pursuing commercial or industrial policy objectives, but for protecting public health.¹¹² The August 30 Agreement sheds light on some issues which might appear unclear in the TRIPS Agreement that were not clarified in the Doha Declaration. For instance, the August 30 Agreement stipulates that although the developing countries are the ones expected to seek compulsory licenses, they are not the only ones entitled to receive them. A developed nation can invoke the right to obtain a compulsory license as well, however, as opposed to a developing country, the developed one must demonstrate that an urgent situation occurs in the country. The prerequisite of domestic production found in TRIPS art. 31(f) is ignored under the August 30 Agreement if the following requirements are met:¹¹³

1. An importing country must make an application to the WTO
2. Should an exporting country receives a compulsory license, it is obliged to give notice to the WTO. Additionally, the license must be restricted to the amount needed to meet the requests of the importing country.
3. Moreover, by means of unmistakable marking and labeling, products must be discernible. Also, one is required to publish relevant information regarding this on the internet.¹¹⁴

As a result, when reading the requirements under the August 30 Agreement and article 31 of the TRIPS Agreements, it becomes clear that before a WTO member

¹¹¹ Lidgard & Atik, 2005, p. 12, see also “The August 30 Agreement”, §1,

¹¹² The statement of the chairperson of the General Council, the August 30 Agreement, 2003, www.wto.org

¹¹³ Lidgard & Atik, 2005, p. 12

¹¹⁴ See previous footnote

may receive a compulsory license, there are several requirements that must be fulfilled.

4.5 Implications for the Pharmaceutical industry

The authorization of compulsory licensing has had important implications for the pharmaceutical industry of the industrialized world, in favor of the developing countries. The pharmaceutical industry is not too contented with the possibility of compulsory licensing, and thus feels threatened by developing countries, fearing they may request these licenses. Consequently, the pharmaceutical industry has agreed to supply the developing world with HIV/AIDS medicines, at prices significantly lower than in the developed world.¹¹⁵ Thus the clarifications of the TRIPS Agreement have given the pharmaceutical industry a choice: to accept compulsory licenses for their pharmaceuticals, or providing the necessitating countries with pharmaceuticals at a price level they can afford. Evidently, it appears that the path of choice is that of supplying needed medicines to developing countries. This, however, leads to price discrimination,¹¹⁶ which has certain implications. When prices are low in LDCs and high in developed countries, there is high risk of arbitration, i.e. the possibility of purchasing the drugs in LDCs where they are cheap, and offer them for sale in developed countries, though at lower prices than those set by the pharmaceutical industry. That way, the drugs would flow back to the developed countries, resulting in an economic loss to the patent holders, and a loss of the very needed supply of drugs in the developing nations. Therefore, controls in the form of suitable legal regulations are required, otherwise the system would backfire.

In conclusion, the evidence at hand reflects that, although in a different way than intended, compulsory licenses are useful tools for technology transfer. The provisions of the TRIPS, including the clarifications made through the Doha Declaration and the August 30 Agreement, have resulted in price discrimination, which, ultimately, fulfill the intended aspiration of providing access of

¹¹⁵ Lidgard & Atik, 2007, p.1044

¹¹⁶ Low prices for markets in developing countries and significantly higher ones in the markets of the industrialized world, see Lidgard & Atik, 2007, p.1045

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pharmaceuticals to developing countries. One may also note the goodwill of the WTO for developing both the Doha Declaration and the August 30 Agreement for the sole purpose of clarifying the TRIPS agreement, thus aiding the international community in understanding the intention behind compulsory licensing as well as the conditions under which these are to be granted and used.

5. Conclusion

Today, it is difficult to question the fact that the developing world is in acute need of technology transfer. The health crisis in the developing world, with HIV/AIDS at the front, is one important and highly debated example of the need for technology transfer, in which compulsory licensing is significant. The making of the TRIPS Agreement, but perhaps even more so the formation of the Doha Declaration and the August 30 Agreement, reflects that not only the WTO but also the world as a whole appears to recognize the severity of the problem, and the importance to overcome it. It is evident, that the solution to this problem lies in international cooperation, implying a responsibility of the international community to apply international laws and conventions in a manner which supports the developing world in receiving essential technology transfer. The TRIPS Agreement is one tool which is to be interpreted and implemented in such a way. With the creation of the Doha Declaration and the August 30 Agreement, which have explained and clarified the ambiguous elements of the TRIPS, the WTO member countries have attempted to strengthen this tool further, and this appears to have been successful.

The question is then, if compulsory licensing is a useful tool in this aim of supporting and increasing the extent of technology transfer to the developing world? From this investigation, the answer appears to be yes, due to several reasons.

Firstly, the very possibility to receive a compulsory license makes it possible for developing countries to produce e.g. essential medicines, and sell them at a price level that the domestic population could afford, thus enabling more people in need of the drugs to acquire them. One could argue that the presence of a compulsory license does not guarantee that the ones in need will receive the looked-for

medicines, due to weaknesses in domestic infrastructure, poor institutions, high levels of corruption, etc, which all influence to what extent the needed medicines can reach the recipients. It is true that the mentioned factors are important, and indeed, if those are lacking in quality, the medicines may not be distributed to all who need them, however the prevalence of compulsory licensing enables what would otherwise not be possible. Indeed it is true, that due to social and economic problems in a particular developing country, the effects of a particular compulsory license may not be as great as they could be if the social and economic conditions were increasingly developed. However, this is not in reality a valid argument, since it is obvious that developing countries are not at the same social and economic levels as the developed world and are thus unable to use and distribute resources as well- that is why they are referred to as “developing” countries. It is vital to note that although compulsory licensing may not benefit all in need, if it benefits more people than was the case before the introduction of the license, then it is to be viewed as useful for the particular developing country.

Secondly, compulsory licensing is a useful tool because it causes prices of pharmaceuticals to fall considerably by “threatening” the pharmaceutical industry. The latter has, due to the rules on compulsory licensing, an incentive to supply developing markets with needed pharmaceuticals at low prices, because if not, “generic producers holding compulsory licenses could undertake activities which could ultimately be launched in the markets of the industrialized world.”¹¹⁷ The provisions of the TRIPS Agreement allowing for compulsory licensing have thus resulted in the fact that the pharmaceutical industry now supplies escalating amounts of required medicines to developing countries, at considerably lower prices than beforehand. Additionally, the possibility to invoke compulsory licenses reduces the extent of monopoly power enjoyed by some patent holders, and thus results in more competition on the market.

It was mentioned at the end of chapter 3 that the HIV/AIDS epidemic is still widespread in the developing countries, particularly in sub-Saharan Africa, hinting perhaps that compulsory licensing has not been an all too successful tool for increasing technology transfer to developing nations. This, however, would

¹¹⁷ Lidgard & Atik, 2005, p.17

not in actual fact be a reasonable conclusion, because the prevalence of the epidemic does not only depend on the provisions of the TRIPS Agreement. There are countless social and economic factors which play a part in the HIV epidemic, and it is possible that compulsory licensing in itself, as a legal tool, is successful, however there are other factors intervening, inter alia corruption and poor infrastructure, which may reduce the positive effects of the licenses or even prevent them from occurring. Therefore, this argument is built on speculations and not reliable facts, as it would require an investigation far beyond the means of a bachelor thesis to truly find the correct answer to exactly how compulsory licensing has affected inter alia the HIV/AIDS epidemic from an economic, legal and social perspective. From the legal perspective, however, which is the only one of real significance in this thesis, compulsory licensing under the TRIPS Agreement has proved to be successful.

The conclusion is thus, that by surveying the evidence at hand, it is unambiguous that the provisions of the TRIPS Agreement regarding compulsory licensing have made countless patent holders within the pharmaceutical industry willing to provide patented medicines at low prices in developing countries, which is unmistakably a considerable accomplishment. Accordingly, compulsory licensing under the TRIPS Agreement is a useful tool for technology transfer.

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