TALLINN UNIVERSITY OF TECHNOLOGY

School of Business and Governance

Department of Law

Joona Juhana Kirmula

COMPULSORY LICENSING AND PHARMACEUTICAL PRODUCTS: LESSONS FROM THE PAST AND THE NEED TO LEARN FROM THE FUTURE

Bachelor's thesis

Programme HAJB, specialisation: European Union and International Law

Supervisor: Pawan Kamar Dutt, Master of Arts in Law

Tallinn 2021

I hereby declare that I have compiled the thesis independently
and all works, important standpoints and data by other authors
have been properly referenced and the same paper
has not been previously presented for grading.
The document length is 12047 words from the introduction to the end of conclusion.

Joona Juhana Kirmula……

(signature, date)

Student code: 18908HAJB
Student e-mail address: Jokirm@ttu.ee

Supervisor: Pawan Kamar Dutt, Master of Arts in Law:
The paper conforms to requirements in force

……

(signature, date)

Chairman of the Defence Committee:
Permitted to the defence
……

(name, signature, date)

TABLE OF CONTENTS

ABSTRACT

The ultimate purpose of this research is to get a complete understanding on how compulsory licensing functions and how it can be used effectively under the Trade Related Aspects of Intellectual Property Rights agreement (TRIPS) to access patented pharmaceutical products. The fundamental goal of this research is to reach a conclusion whether compulsory licensing under the TRIPS agreement provides a solution that is adequate and efficient enough to access and afford patented pharmaceuticals. The viewpoint of accessibility and affordability must be studied from different perspectives due to wealth gaps between developed -and developing countries.

In order to reach a well-analyzed conclusion and understanding of compulsory licensing in its majority, the research will place its primary focus on three research questions. To guarantee that this research's standards, aims, and goals have been fulfilled, the research has been carried out by using qualitative empirical research methods.

In the next part of the thesis, the reader will be given a brief introduction to the research topic, and the research questions are presented. In the first chapter of the thesis, the reader will be given an overview of the TRIPS- agreement and its history, followed by a detailed analysis of TRIPS article 31, compulsory licensing. The second chapter analyses compulsory licensing in the light of past case studies, thus extending the issues of compulsory licensing to TRIPS article 31 BIS. The third chapter will highlight the present and future issues of compulsory licensing in in the age of COVID-19. Subsequent to this the fourth and final chapter will introduce the main findings and conclusions of this research.

Keywords: TRIPS-agreement, Compulsory Licensing, Patents, COVID-19

INTRODUCTION

"The patent system adds the fuel of interest to the fire of genius," were the words of wisdom by the former U.S president Abraham Lincoln.[1] In a world where intellectual property rights do not protect ideas and inventions lie a lack of incentive. All intellectual property rights, patents, copyrights, trademarks, and trade secrets confer new inventions. It is crucial for the incentive that the inventor of the idea receives a reward for his invention through having the exclusive right to the invention. This viewpoint also surfaces in the works of known philosophers John Stuart Mills and Jeremy Bentham. Bentham and Mills argued that exclusive rights to a specific patent are the pre-eminent and most effective way to promote the innovation of the inventors.[2] The protection of intellectual property rights versus incentives of the inventors has been a controversial topic for centuries.

Intellectual property rights have surfaced in the news feed and created much discussion due to the outbreak of the global pandemic COVID-19. It is unavoidable that patents surface in the discussion when the world faces a global pandemic as devastating as COVID-19. The ignorance of containing and eliminating the virus raises concerns for all governments worldwide. Naturally, governments, pharmaceutical companies, and non-profit organizations try their best to find a treatment for COVID-19. The invention of treatment for COVID-19 is the part where concerns arise. When Pharmaceutical companies invest hundreds of millions in research and development costs, the incentive is that the future treatment will be patent protected. Controversial to this, governments face the question of how to afford and access the treatment. In this context, it is crucial to acknowledge the wealth gap between developed – and developing countries. As we have learned from the past, global pandemics have affected developing countries in a much more severe way than developed countries. The lack of resources in the developing countries to afford or manufacture essential pharmaceuticals combined with the blocked accessibility due to patent protection is an issue that we must address.

[1] Lincoln, A. (1859). Second lecture on discoveries and inventions. *Collected Works of Abraham Lincoln*, *3*, 1953-55.
[2] Machlup, F., & Penrose, E. (1950). The Patent Controversy in the Nineteenth Century. *The Journal of Economic History, 10*(1), 1-29. 7-10

Multiple international treaties and conventions regarding the protection of intellectual property rights of the inventors have sought to balance the monopolistic right of the inventor versus the accessibility and affordability of the patented product. This research will place its main emphasis on the international legal agreement between the members of The World Trade Organization (WTO), The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS agreement provides a safeguard for the inventor of a product by granting an exclusive right over the product. However, TRIPS also provides additional" flexibilities" for others to acquire the right to manufacture or import the particular patented product. This research focuses on the use of TRIPS" flexibilities," placing its primary emphasis on compulsory licensing in the context of accessing and affording patented pharmaceutical products in both developed and developing countries, and how has this controversial provision evolved the accessibility and affordability of pharmaceutical products in the developing countries.

Thus the focal point of this research is to understand how the TRIPS" flexibilities" function and do these flexibilities provide an efficient solution when facing a global pandemic. This perspective will be studied by examining past cases on compulsory licensing during similar pandemics such as the HIV/AIDS crisis. The relevance of this research is to provide an overview of how compulsory licensing promotes the accessibility and affordability of patented pharmaceuticals during a global pandemic and to analyze whether these TRIPS flexibilities provide an adequate and efficient solution to questions of accessibility and affordability of patented pharmaceuticals. In order to get a complete understanding of the research, three research questions are listed below:

- How does compulsory licensing circumvent the negative social impact of patents when accessing essential pharmaceuticals?
- Does compulsory licensing create an effective enough solution to access pharmaceutical products in the developing countries?
- What will be the role of compulsory licensing during COVID-19?

1. THE TRIPS AGREEMENT AND COMPULSORY LICENSING

Patents and pharmaceutical products have been discussed a lot since the late 1990s during the HIV/AIDS crisis. Conversations concerning pharmaceutical products and patents tend to circle the same topics and issues, price and accessibility. This conversation and speculation have been going on in the shadows for decades. Both the developing and developed countries face an immediate need to access essential pharmaceutical products such as vaccines during global pandemics. However, developing countries face this need daily. The need for pharmaceutical products during a global pandemic can be illustrated by using the Southern African Development Community (SADC) as an example. SADC is a region in Southern Africa that consists of 16 countries. These 16 countries together had 7.1 Million reported HIV positive patients in 2016, making it the largest population of HIV positive patients in the world.[3]

To get a complete understanding of patent protection issues and the essential access to human health products, we must discuss history. The debate on exclusivity to inventors versus access to essential pharmaceutical products took a radical shift in 1995 when the international agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) became effective. TRIPS agreement established a set of minimum standards for the protection and enforcement of intellectual property rights. These minimum standards are binding for the members of the World Trade Organization (WTO). [4]

It is safe to acknowledge that when multiple competitors act as sellers, the product prices tend to be lower. However, the TRIPS agreement placed pharmaceutical companies on the pedestal since the TRIPS agreement gave inventors exclusivity, placing them in a monopolistic position. Once the TRIPS agreement became effective, it was unsure how the agreement will affect the accessibility of patented medicines. However, the fact that the prices of patented medicines would hike up was universally acknowledged. This lack of surety was due to the controversial nature of the agreement. On the other hand, TRIPS promoted market exclusivity, and on the other hand, also included various instruments, so-called "TRIPS flexibilities," which promoted

[3] FM't Hoen, E., Kujinga, T., & Boulet, P. (2018). Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region. *Journal of pharmaceutical policy and practice, 11*(1), 1-8.
[4] Yu, P. K. (2009). The objectives and principles of the trips agreement. *Houston Law Review, 46(4)*, 979-1046. 980-981

accessibility. The most critical instrument concerning accessibility in the TRIPS- agreement was compulsory licensing. [5]

As discussed previously, TRIPS provides the innovators of a particular product an exclusive marketing right by requiring WTO member states to guarantee patents. This "monopolistic" right of the patent owners creates an issue for developing countries to access pharmaceutical products which are high priced due to patent protection. Joseph Stiglitz, the former World Bank Chief Economist, outlines the issue in the most simple words through an example. A generic AIDS medicine costs $300 per year. However, this medicine costs will become $10300 due to the patent holder's brand name being the extra 10000$. Access to this particular AIDS medicine was reduced for the people living in developing countries due to not being able to pay 10000$ a year for only a brand name when the cost, in reality, could be 300$. According to Stiglitz, the TRIPS agreement was even designed to reduce access and described as a" death warrant" for people living in developing countries.[6] The controversy of TRIPS is undebatable since it creates a way for companies to set high prices on their patent-protected products, thus reducing the accessibility of a developing country to a particular medicine but at the same time providing flexibilities and options to access these particular patent-protected medicines.

Before the TRIPS agreement became effective, fair, and, affordable drug pricing was secured by excluding patent protection on pharmaceutical products. Without the patent holder's permission, countries that excluded patent protection could export low-price copies of particular drugs to international markets. Approximately 40 countries excluded patent protection for pharmaceutical products.[7] We can consider India a successful example of excluding patent protection on pharmaceutical products in its patent law from 1970. India managed to establish a permanent position in the drug market and became a world leader since they could replicate a drug that was still on a patent in a wealthier country. India was able to market a product legally because that particular product was not under local patent protection. Millions of people were supplied with low-cost generic medicines by India to cure life-threatening diseases. In 2005 India had to

[5] Urias, E., & Ramani, S. V. (2020). Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. *Journal of International Business Policy*, *3*(4), 367-384. 1-2
[6] Stiglitz, J. E. (2007). *Making globalization work*. WW Norton & Company. 105-106
[7] Urias, E., & Ramani, S. V. (2020). *supra nota 5*, 2-3

reintroduce pharmaceutical patents as they had to comply with the TRIPS agreement as a WTO member state. Many, at this point, saw it as an "international healthcare tragedy."[8]

The countries which had excluded patent protection on pharmaceutical products before were now facing a significant change in their patent regime. All the countries that had excluded patent protection on pharmaceutical products or processes had to ensure patents available for all inventions, regardless of the invention was a product or a process. TRIPS was not ensuring only patents on pharmaceutical products, but rather in all fields of technology for a set of 20 years being the minimum period for patent protection. [9]

1.1. Compulsory licensing and patented pharmaceuticals

As discussed, the challenge to provide access to the developing countries for the use of pharmaceutical products which are patented and high-priced has been a global problem for decades. Many scholars have argued of the TRIPS agreement being insufficient to provide a solution for developing countries.[10] The problem developing countries are facing urges from their resources. The expenditures used on drugs by a developing country may, and in most cases is, a relevant part of the resources spend only on drugs. This relevant part can be up to two-thirds of the total expenditures. It is clear that if a country is in a developing phase, it will not demolish the poor conditions when they have to use nearly two-thirds of the budget on drugs alone. Accessibility and affordability of drugs are problems that developing countries face daily.[11]

To evaluate whether TRIPS provides a solution for the developing countries to access patented pharmaceutical products, it is essential to fully understand the solutions TRIPS provides and how these solutions function. One of the main" flexibilities" in the TRIPS agreement, as discussed earlier, is compulsory licensing. Compulsory licensing is an essential flexibility in the TRIPS agreement in the context of accessing and affording patented pharmaceuticals.[12] Compulsory

[8] Mueller, J. M. (2007). The tiger awakens: The tumultuous transformation of india's patent system and the rise of indian pharmaceutical innovation. University of Pittsburgh Law Review, 68(3), 491-642. 495-496
[9] Urias, E., & Ramani, S. V. (2020). *supra nota 5*, 2-3
[10] Ooms, G., & Hanefeld, J. (2019). Threat of compulsory licences could increase access to essential medicines. *Bmj*, *365*. 1-2
[11] Watal, J. (2000). Access to essential medicines in developing countries: does the WTO TRIPS agreement hinder it?. *Science, Technology and Innovation Discussion Paper*, *8*, 1-3
[12] Ooms, G., & Hanefeld, J. (2019), *supra nota 10*, 1-2

licensing, in the most straightforward and pure form, means that a government issues a compulsory license to a manufacturer of a particular pharmaceutical product, which allows the Government to produce equivalent products without the consent of the manufacturer, who is the patent owner. Article 31 of the TRIPS agreement lays down the framework within which a compulsory license may be issued. According to Article 31, a compulsory license can be issued under circumstances that fall in the category of national emergencies, other circumstances of extreme urgency, public non-commercial use, and if used against anti-competitive practices.[13] Regardless of TRIPS article 31 providing a solution to manufacture patented products, it creates a problem for countries which does not have sufficient manufacturing capacity. This issue was also recognized in the declaration on the TRIPS Agreement and Public Health, here on after referred to as the Doha declaration.[14] As this issue was recognized, in 2003, the TRIPS council made a formal attempt to provide a solution where a developing country without the resources or sufficient manufacturing capacity would gain access to these products by exclusively exporting the drugs. This so-called "paragraph 6 problem" provided a solution for countries that lack the capabilities to manufacture a particular drug, here on after these countries were able to export an equivalent drug made under a compulsory license. The only example of the use of paragraph 6 of the Doha- declaration is the case of Rwanda in 2007. The case of Rwanda was the first attempt to make use of paragraph 6. The attempt was successful, and Rwanda became the first country to issue a compulsory license for exporting a generic drug to a third country. Equivalent drugs of Apo TriAvir were manufactured and later on shipped to Rwanda.[15] As discussed earlier, the process of issuing a compulsory license has three steps which include the issuance of the license, the licensee being the third-party that can manufacture, import, and sell equivalents of the drug which is patented, and lastly, the patentee who has the right to be compensated via royalties.[16]

To understand how compulsory licensing functions by improving access to drugs, the decision process involved is relevant. Firstly, before the issuance of a compulsory license, in most cases, the patented product is high-priced or unaffordable for the Government seeking access to that particular drug. Here, as this paper aims its primary focus on unaffordable drugs, we do not have

[13] World Trade Organization (WTO) (2006). *TRIPS and pharmaceutical patents: Obligations and exception*.
[14] Urias, E., & Ramani, S. V. (2020). *supra nota 5,* 2-3
[15] Stavropoulou, C., & Valletti, T. (2015). Compulsory licensing and access to drugs. *The European Journal of Health Economics*, *16*(1), 83-94. 84-85
[16] Urias, E., & Ramani, S. V. (2020). *supra nota 5,* 3-4

to evaluate whether the drug is unaffordable or not. When seeking access to a patented drug, specific questions must be asked and answered. Firstly, we must investigate whether the owner of the patented drug has granted a voluntary license on that particular product and whether the respective country is in the licensed territory. The decision process regarding compulsory licenses will not need to go further if the answer to this question is positive. However, if no voluntary license is granted, we need to determine whether the respective country is a so-called Least Developed Country (LDC) and a WTO member. In a case where the respective country falls in the category of being an LDC," LDC- waiver" may be used not to implement patent protection or enforce existing patents. The next step of the decision process is to search whether generic versions of the drug are available. If generic versions are available, the respective country may purchase these generic products. In a situation where the respective country is not an LDC, the next step is to solve whether there is a local capacity for developing and producing generic versions of the drug. If local capacity is not an issue, the respective country can issue a compulsory license for public non-commercial use or government use to gain access. However, suppose the situation is opposite and the respective country does not have the local capacity to develop and produce the drug. In that case, the next step is to search whether generic versions of the product are available to import. Incase where generic versions are available, a compulsory license can be issued. If no generic versions are available to import, the next step is to determine whether another country is willing to manufacture the product and issue a compulsory license for exports. Lastly, in a case where there is no country willing to issue a compulsory license for exports, local manufacturing capacity must be created. Whether a country is willing to issue the compulsory license for exports, the respective country may use TRIPS article 31.[17]

1.2. Hidden power of compulsory licensing in the age of a pandemic

We must place our emphasis on compulsory licensing now more than ever. The global HIV/AIDS crisis proved that compulsory licensing is an essential tool for accessing patented medicines. Compulsory licensing will most likely play a significant role globally in the near future due to the outbreak of the COVID-19 pandemic. The spread of COVID-19 is a severe threat to global health for both developing and developed countries. As in most cases, developed countries do not face significant problems in accessibility and affordability of medicines as the

[17] *Ibid. 4-5*

developing countries do, COVID-19 has already created a struggle in the United States. The U.S government has already faced a struggle with the affordability of COVID-19 treatment.[18] Even developed countries are struggling to afford and access treatment for the virus. The likelihood of the situation will be more devastating for the developing countries that already have under-resourced healthcare systems. Countries that fall in the category of being a developing country or an LDC should prepare necessary measures to battle against the spread of the virus. One of these measures is to prepare to issue a compulsory license on treatments proven to be effective. As pharmaceutical companies have produced potential vaccines for COVID-19, the distribution and access to these vaccines remain a question. From the past pandemics, we have learned that the most developed countries and countries with resources and capital will be the first to acquire treatment. COVID-19 is not an exception; The developing countries and LDC's will be the last ones on the list due to lack of resources and manufacturing capacity. As COVID-19 threatens health on a global scale, it is crucial to contain the virus globally. There must be no export restrictions placed on COVID-19 treatments to safeguard developing countries and LDC's supply. As the incentive for pharmaceutical companies to create a treatment for any virus is nonetheless profit, it is safe to conclude that Intellectual property (I.P.) rights will be involved, and patents will also protect vaccines in the battle against COVID-19. [19]

As discussed earlier, TRIPS provides a solution to situations where access to a specific treatment must be acquired. Governments can issue compulsory licenses when facing emergencies, such as the COVID-19 pandemic. Issuing a compulsory license or using it as a threat in price negotiations have shown success in the past. During the HIV/AIDS crisis, both Brazil and Thailand used compulsory license and the threat of compulsory license effectively and successfully.[20]

As mentioned, Compulsory licenseing contains a hidden power. The threat of issuing a compulsory license to access essential pharmaceutical products has been successful in multiple cases. Using a compulsory license as a threat means that a government notifies and warns the patent owner that they will issue a compulsory license on the product if necessary. Threats to using compulsory licenses in most cases lead to a situation where a voluntary license is

[18] Wong, H. (2020). The case for compulsory licensing during COVID-19. *Journal of Global Health*, *10*(1). 1-2
[19] Parliamentary questions for the European parliament on 23 December 2020, E-005595/2020
[20] Wong, H. (2020), *supra nota 18*

granted.[21] A well-executed example of the usage of a compulsory license as a threat is from the United States. In 2001 the U.S faced a possibility of a terrorist attack suspected to be carried out by using anthrax.[22] The U.S government tried to prepare for this possible attack by obtaining stockpiles of ciprofloxacin medicine as this medicine was the best available cure against anthrax. During negotiations, Bayer, which was the patent owner of ciprofloxacin, would not reduce their price. After this, both the U.S government and the Canadian Government threatened to issue a compulsory license to access ciprofloxacin. The threats of issuing a compulsory license were successful, and Bayer reduced the price of ciprofloxacin. [23]

To observe whether TRIPS flexibilities, mainly compulsory licensing, and the threat of issuing a compulsory license improves access to patented pharmaceutical products, further research must be conducted. The most known cases regarding compulsory licensing and access to patented pharmaceutical products concern antiretroviral treatment as the TRIPS agreement was formed when the first treatments for HIV/AIDS were developed.[24] As antiretroviral treatment was available and provided a solution to battle against the HIV/AIDS crisis, the treatment cost was high-priced. Countries that did not fall in the category of a developing country or a country with minimal wealth could subsidize the treatment cost. At this point, the price of antiretroviral treatment was approximately $10 000 a year for one patient, thus eliminating low-income and developing countries' access to this cure. As discussed later, the most well-known cases concerning TRIPS agreement and compulsory licensing are cases which concern the accessibility to antiretroviral treatment, as TRIPS flexibilities were first demonstrated in cases involving the aspect of accessing antiretroviral treatment.[25]

[21] Ooms, G., & Hanefeld, J. (2019), *supra nota 10*, 3-4
[22] Love, J. P. (2007). Recent examples of the use of compulsory licenses on patents. *Knowledge Ecology International*, *8*. 3-4
[23] *Ibid. 6-7*
[24] Ooms, G., & Hanefeld, J. (2019), *supra nota 10*, 2-4
[25] *Ibid.*

2. CASE STUDY: PAST PANDEMICS AND THE FUTURE OF COMPULSORY LICENSING

In the next chapter of the thesis, the paper introduces the reader to the legal responses of three countries and the response of the European Union on the HIV crisis. These countries have their separate chapters and observe how they effectively used compulsory licensing under the TRIPS-agreement to broaden their access to patented pharmaceutical products. The case studies provide successful examples on the use of compulsory licensing and the use of compulsory license as a threat in price negotiations. The countries and cases observed are from Brazil, Thailand, South Africa, and the response of the European Union. The reasoning behind why these countries were chosen to be a part of the research is the nature being most severely affected by the HIV/AIDS crisis. All three countries pursued a similar yet different approach to access patented pharmaceuticals by using compulsory licensing under the TRIPS- agreement. Lastly, we discuss the future and analyze whether compulsory licensing provides an efficient enough solution for the developing countries in the age of the current pandemic COVID-19.

2.1. Brazil

As it is known, still to this day, many developing countries struggle to gain access to life-saving treatments for HIV/AIDS, for example. However, we can observe progress, and a few low-income countries have set an example for other developing countries. The progress can be shown by simple statistical data. In 2003 approximately 300,000 people received treatment for HIV/AIDS. By 2009 the number of recipients was 4 million. A relevant part of this progress is due to the successful promoting of global HIV/AIDS treatment. Brazil is one of the countries to set an example and provide precedents for developing countries to take advantage of when challenging drug companies to gain access to medicines to treat life-threatening diseases.[26] Brazil has provided precedents and examples for other countries to access and reduce the price of antiretroviral medicines by using price negotiations associated with the threat of issuing a compulsory license as their primary strategy. [27]

[26] Nunn, A. S., da Fonseca, E. M., Bastos, F. I., & Gruskin, S. (2009). AIDS treatment in Brazil: impacts and challenges. *Health affairs*, *28*(4), 1103-1113. 3-4

[27] Ford, N., Wilson, D., Chaves, G. C., Lotrowska, M., & Kijtiwatchakul, K. (2007). Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. *Aids*, *21*, S21-S29. 21-24

In 1996 the congress of Brazil passed a law concerning free, universal access to antiretroviral treatment. Alongside this law, Industrial property law was also passed in the congress and forced Brazil to adopt the WTO rules. These rules consisted of introducing patent rights for pharmaceutical products as well. As Brazil was required to comply with the WTO rules, the production of generic medicines was limited. As WTO rules gave market exclusivity for patent owners, all pharmaceutical products introduced after 1996 were protected by patent, resulting in higher prices. The combination of new antiretroviral treatments, which enjoyed patent protection and the rising amount of patients seeking treatment, caused a spike in the cost of HIV/AIDS treatment in the late 1990s.[28]

As Brazil was fighting against the HIV crisis, the constitution of Brazil created a moral and legal basis for a treatment plan for people suffering from HIV. As mentioned, one of the major shifts during the HIV crisis was when the Government of Brazil guaranteed free universal access to antiretroviral treatment. Despite the majority of countries recognizing health care as a human right, none of the legal responses on pandemics or crisis such as the HIV crisis has been as successful as the legal response of Brazil. The Government did not make the initial response to expanding services for people living with HIV of Brazil. The Government only took action on the matter after several AIDS advocacy groups filed successful class-action suits on problematic issues such as free viral-resistance testing and expanded drug formulary. [29]

After the Government faced pressure to address issues concerning HIV treatment, Brazil's Congress passed the law in 1996, which created free universal access to antiretroviral treatment possible. The passed law combined with accelerating pressure to respond to the HIV crisis created a sudden price shift in offering free antiretroviral treatment. In response to the rising costs of antiretroviral treatment, The Government of Brazil was forced to take action and seek additional options on how to access affordable antiretroviral treatment. The Health Minister of

[28] Nunn, A. S., da Fonseca, E. M., Bastos, F. I., & Gruskin, S. (2009), *supra nota 25,* 1-2
[29] Berkman, A., Garcia, J., Muñoz-Laboy, M., Paiva, V., & Parker, R. (2005). A critical analysis of the Brazilian response to HIV/AIDS: lessons learned for controlling and mitigating the epidemic in developing countries. *American journal of public health*, *95*(7), 1162-1172.

Brazil, Jose Serra, started implementing strategies to keep the program alive and to address the rising costs that came alongside.[30]

In 2001 the Health Minister of Brazil took action and threatened to issue a compulsory license for manufacturing an antiretroviral drug called nelfinavir. Roche sold this drug under the brand name Viracept. Shortly after the threat of issuing a compulsory license on nelfinavir, Roche agreed to sell the drug in Brazil with an additional 40% discount, provided that the Government of Brazil does not issue the compulsory license.[31]

The Government of Brazil has had multiple successful attempts by using the threat of issuing a compulsory license to drive down the prices of antiretroviral treatments. In 2005 the Brazilian Government used the threat of issuing a compulsory license as a negotiation tactic and reduced the price of Viread by approximately 50%.[32] The same year Brazil government announced a possibility to break patent protection on Lopinavir/Ritonavir. According to the former Health Minister of Brazil, Humberto Costa, Brazil had the resources and capabilities to produce an equivalent for Lopinavir/Ritonavir with significantly lower costs than Abbott Laboratories, the patent owner of Lopinavir/Ritonavir.[33] The Brazilian Government was able to reduce the price by using a compulsory license as a threat in the price negotiations. The threat was credible enough for Abbott to reduce the price of the drug from $3241 per patient/year to $1380 for an older version of the drug and $1518 for a heat-stable version.[34]

In 2007, rather than using a compulsory license as a threat, Brazil issued its first compulsory license to import a drug called Efavirenz. Efavirenz, at this point, was under patent protection in Brazil.[35] The owner of Efavirenz was Merck, who sold it under the brand name Sustiva. Before Brazil had issued the compulsory license to import Efavirenz, Merck had offered to sell the drug for a price of $760 per patient a year. The compulsory license issued by the Brazilian Government drove the price down, and Brazil was able to import a generic version of Efavirenz

[30] Nunn, A., Dickman, S., Nattrass, N., Cornwall, A., & Gruskin, S. (2012). The impacts of AIDS movements on the policy responses to HIV/AIDS in Brazil and South Africa: a comparative analysis. *Global public health, 7*(10), 1031-1044.
[31] Love, J. P. (2007), *supra nota 22,* 14-15
[32] *Ibid.*
[33] Marques, U. R. Q., Guimarães, V. S., & Sternberg, C. (2005). Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing. *Food & Drug LJ*, *60*, 471. 475-476
[34] Wong, H. (2020). *supra nota 18,* 2-3
[35] Love, J. P. (2007, *supra nota 22,* 14-15

for $170 per patient a year.[36] This case demonstrates a successful issuance of a compulsory license. As Brazil issued a compulsory license on Efavirenz in 2007, they could import Efavirenz with a significant discount. The mean price variation after issuing a compulsory license on Efavirenz was approximately -71 %.[37]

Alongside producing non-patented antiretroviral medicines, we can observe that the strategies of Brazil mainly consisted of using domestic manufacturing capabilities to their advantage by threatening to produce patented medicines under a compulsory license locally. Using this strategy, Brazil was able to drive down the prices of antiretroviral treatment in price negotiations. Both of these legal strategies, manufacturing patented medicines and using compulsory licensing as a threat on patented medicines, culminated in 1.2 billion U.S. dollars in cost savings. Thus Brazil was able to reduce the costs of offering this highly-priced program.[38]

Thus we can observe that Brazil's manufacturing capacity strengthened its position in negotiations with big pharmaceutical companies and eventually created a way for Brazil to fight against pharmaceutical companies abusing their patents by setting too high prices for the Brazilian Government to reach.[39] The knowledge of Brazil's domestic pharmaceutical industry created the opportunity for Brazil to manufacture generic versions of products registered before the TRIPS agreement in 1996. As of 2006, 8 out of 16 drugs purchased by the Government of Brazil were locally manufactured in Brazil. [40]

The legal strategy of demanding antiretroviral treatment from the Government by filing class-action suits was pursued in other countries also after being successful in Brazil's case. Court rulings created a legal standing to the claims of Brazil's AIDS movement. They layed the ground for the state to start providing free antiretroviral treatment as an obligation of the state.[41]

However, other countries have not had such remarkable success as Brazil when demanding antiretroviral treatment through court orders. The problem facing other countries such as South Africa and countries within Latin America and the Caribbean has been the fact that even in a

[36] Wong, H. (2020). *supra nota 18,* 2-3
[37] Urias, E., & Ramani, S. V. (2020). *supra nota 5,* 12-13
[38] Nunn, A., Dickman, S., Nattrass, N., Cornwall, A., & Gruskin, S. (2012), *supra nota 30.*
[39] Berkman, A., Garcia, J., Muñoz-Laboy, M., Paiva, V., & Parker, R. (2005), *supra nota 29.*
[40] Okie, S. (2006). Fighting HIV—lessons from Brazil. *New England journal of medicine*, *354*(19), 1977-1981.
[41] [41] Nunn, A., Dickman, S., Nattrass, N., Cornwall, A., & Gruskin, S. (2012), *supra nota 30.*

case where the court had ruled in favor of the plaintiff, the court has no authority to force the Government to comply with its decision. Even the strategies of these countries being similar, the execution is dissimilar. Where the Government of Brazil was able to implement court rulings in a timely and appropriate way, other countries were impeded to reach a successful outcome.[42]

2.2. Thailand

The response of Thailand on managing the HIV crisis circles around the same phases as Brazil's case. The Thai Government responded to HIV in a relatively quick manner, such as Brazil did. The first step to combat the HIV crisis was when the Multi-sectoral AIDS Prevention Strategy (MAPS) was introduced in 1991. This program created a way for inclusive policy formulation by engaging non-governmental organizations and civil society to respond to the HIV crisis nationally. The Social Security Law of Thailand obliged the Government to provide basic health care for its citizens. This law played a significant role in response to HIV in Thailand due to creating a legal groundwork for the antiretroviral treatment (ARV) provision. This provision was the backbone for the successful efforts made by Thailand to prevent the spread of HIV. A successful example that was possible due to this provision is the 100% Condom Programme in Thailand.[43]

One notable success point in the fight against HIV in Thailand is the Thai Network for People Living with HIV/AIDS (TNP+). Increased access to ARV's has been brought through the legal and political advocacy of this network. TNP+ also plays a significant role in the ARV provision in Thailand.[44]

Non-Governmental Organizations have also played a central role in accessing antiretroviral treatment in Thailand. Different civil society groups in Thailand have developed different legal routes to access medicines. A successful case example of this is the case by the AIDS Access Foundation. In this particular case, two HIV patients challenged a Didanosine patent application.

[42] Berkman, A., Garcia, J., Muñoz-Laboy, M., Paiva, V., & Parker, R. (2005), *supra nota 29.*
[43] Mauchline, K. (2008). Official government justifications and public ARV provision: a comparison of Brazil, Thailand and South Africa. 11-13
[44] Lyttleton, C., Beesey, A., & Sitthikriengkrai, M. (2007). Expanding community through ARV provision in Thailand. *AIDS care*, *19*(sup1), 44-53.

In this case, the court ruled that patients are allowed to challenge patents that may restrict access to their own health.[45]

As the Brazil Government pursued to threaten pharmaceutical companies by using their manufacturing capabilities to produce patented medicines, the response has been different on the part of the Thai Government. While the Thai Government engaged in negotiations regarding the access to patented ARV medication, Thailand instituted legal challenges to patents, which meant that the Thai Government tried to force pharmaceutical companies to reduce their prices or withdraw their patent applications. [46]

Alongside Brazil, Thailand has had notable success in accessing and reducing the price of essential medicines, such as the accessibility and price of antiretroviral treatment. Even though achieving success by threats of compulsory license and successful price negotiations, a difference can be observed between these two countries. Multiple price negotiations between drug companies and the Thai Government have resulted in situations where Thailand rejects the offered price due to the price being unaffordable. As Brazil used price negotiations and threats of issuing a compulsory license successfully, the result in this area for Thailand is mixed. Despite the result being mixed, Thailand has still been able to access affordable medicines by issuing a compulsory license.[47]

As Brazil, the Government of Thailand faced issues concerning the affordability and accessibility of Efavirenz. The issues to access Efavirenz resulted in hospital stocks running out. The main issue with accessing Efavirenz was the price. As the generic drug manufacturers in India were supplying Efavirenz for $216 per patient/year, the price of Merck was over double, resulting in the price of Efavirenz at $468 per patient/year.[48] The Government of Thailand tried to negotiate with Merck to achieve a lower price for Efavirenz, but without success. In 2006 the Government of Thailand informed Merck that they would issue a compulsory license on Efavirenz. The threat of compulsory license forced Merck to reduce the price of Efavirenz down to $288 per patient/year. However, even with partial success in the price negotiations, The

[45] Mauchline, K. (2008), *supra nota 43*, 13-23
[46] *ibid.*
[47] Ford, N., Wilson, D., Chaves, G. C., Lotrowska, M., & Kijtiwatchakul, K. (2007), *supra nota 26*, 26-27
[48] *Ibid.*

Government of Thailand proceeded to issue a compulsory license on Efavirenz and was able to import generic Efavirenz even at a more affordable price.[49]

Another successful case of issuing a compulsory license by the Government of Thailand was in January 2007 on patents for an antiretroviral drug Kaletra (Lopinavir and Ritonavir). [50] The Government of Thailand went through extensive price negotiations in 2004-2006 to gain access to Kaletra at an affordable price, but without success.[51] During the extensive price negotiations between Abbott Laboratories and the Government of Thailand, Abbott faced pressure from multiple activist groups and resulted in Abbott reducing the price of Kaletra on multiple occasions. During the start of the negotiations, Abbott had offered Kaletra for $2967 per patient/year. The publicity of the negotiations and the pressure by certain activist groups forced Abbott to reduce the price to $2200. During this time, the average annual wage in Thailand was $1600 per year, and thus too expensive for Thailand to accept the offer. Thailand proceeded to pursue more affordable prices by issuing a compulsory license for Lopinavir/Ritonavir in 2007. By issuing the compulsory license, Abbott reduced the price by an additional $200, making the final price $2000 per patient/year.[52] Thailand rejected multiple offers made by Abbott and pursued by issuing a compulsory license on Lopinavir/Ritonavir, resulting in Thailand being able to import generic versions of this particular drug for $676 per patient/year from India.[53] Unlike Brazil, In the case of Lopinavir/Ritonavir, Thailand proceeded to acquire this particular drug by issuing a compulsory license rather than using it as a threat in price negotiations. Despite being successful, these different approaches and strategies between the two countries had a notable difference. Thailand could import generic versions of the drug from India for $676 per patient/year by acquiring a compulsory license to import Lopinavir/Ritonavir. Using a compulsory license as a threat in price negotiations, Brazil set out the price of Lopinavir/Ritonavir at $1380 per patient/year for an old version of the drug and $1518 for a heat-stable version.[54] As a comparison, despite both strategies being successful, In this particular case, the issuance of a compulsory license resulted in a significantly lower price than merely using a compulsory license as a threat in price negotiations.

[49] *Ibid.*
[50] Love, J. P. (2007, *supra nota 21,* 13-14
[51] Ford, N., Wilson, D., Chaves, G. C., Lotrowska, M., & Kijtiwatchakul, K. (2007), *supra nota 26,* 27-28
[52] *Ibid.* 25-26
[53] Wong, H. (2020). *supra nota 18, 2-3*
[54] *Ibid.*

To sum up, why the actions and efforts of Thailand were favorable and prosperous towards promoting and accessing antiretroviral treatment, intense domestic advocacy played a crucial role. Scholars have suggested that the most crucial element in the policy change was the radical shift in the prices of antiretroviral treatment. The price reductions in the case of Thailand were mainly achieved through domestic production efforts and price negotiations combined with compulsory licensing. Even when the price reductions achieved with compulsory licensing in most cases were not as fruitful as in the case of Brazil, Thailand used compulsory licensing and domestic production efforts in a manner that is relatively similar to the efforts and actions of Brazil.[55]

2.3. South Africa and the evolving of the TRIPS agreement

Brazil, Thailand, and South Africa share mostly similar issues when accessing affordable medicines such as antiretroviral treatment. However, South Africa is different for the reason of being a Least developed country (LDC). As discussed previously, even Thailand and Brazil have an ongoing battle against gaining access to essential medicines, and both countries are still considered "Middle countries."[56] Next, we will conclude an overview of how and what options LDC's have when it comes to accessing antiretroviral treatment and looking into previous case law regarding LDC's on this particular matter. In the case of South Africa, we can observe a significant difference between the actions of Brazil and South Africa.

The first significant response by South Africa to the global AIDS/HIV crisis was in 1997 when the South African parliament proposed the South African medicines and related substances control amendment Act, here on after called the act. The act's goal was to drive down the prices of antiretroviral treatment to make them affordable to the population.[57]

Despite the similarity of Brazil and South Africa both having a local drug manufacturing capacity, the outcome was reasonably different. As introduced, the act of 1997 was supposed to accelerate and enhance access to generic HIV medicines. The legislation itself was a massive

[55] Mauchline, K. (2008), *supra nota 43*, 14-15.
[56] Ford, N., Wilson, D., Chaves, G. C., Lotrowska, M., & Kijtiwatchakul, K. (2007), *supra nota 26*, 27-28
[57] Harris, D. (2010). TRIPS after fifteen years: Success or failure, as measured by compulsory licensing. *J. Intell. Prop. L.*, *18*, 367. 384-386

success on the part of South Africa to combat HIV by importing and producing generic equivalents.[58] With this act, local antiretroviral medicine producers were able to manufacture AIDS drugs through compulsory licensing and import equivalent drugs that were more affordable than the patent owners' ones.[59]

The act, however, faced criticism and objection from multiple parties, mainly the patent owners. Multiple pharmaceutical companies objected throughout Europe and United States that the act violated TRIPS and several other international patent laws.[60] The view of the pharmaceutical companies around Europe and the U.S were more or less in line with a statement made by the U.S Trade Representative Charlene Barshefsky:" South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights."[61] All lawsuits combined, South Africa was facing 39 suits from pharmaceutical companies over Europe and the U.S. Even when the suits were dropped, the actions from the pharmaceutical companies pointed to a direction where antiretroviral treatment would not be accessible and affordable for millions of patients struggling with HIV/AIDS.[62]

As a result of these events, members of the WTO gathered in Doha in November 2001 (The Doha declaration) for a ministerial conference to improve access to essential medicines. A mutual understanding between the member states of WTO that clarification towards the issues at hand was needed and thus TRIPS flexibilities in connection with public health was the main agenda of the conference.[63]

As the TRIPS Agreement in its original form had limitations in cases where the license was to serve the domestic market, The declaration explicitly pointed out that restrictions of this type could hinder the effective use of a compulsory license, especially in developing countries with insufficient or no manufacturing capacities to produce essential medicines. The declaration

[58] Nattrass N. Mortal combat: AIDS denialism and the struggle for antiretrovirals in South Africa. Scottsville: University of KwaZulu-Natal Press; 2007
[59] Harris, D. (2010). *supra nota 56*, 386-387
[60] *Ibid.* 384-385
[61] Bond, P. (1999). Globalization, pharmaceutical pricing, and South African health policy: managing confrontation with US firms and politicians. *International Journal of Health Services*, *29*(4), 765-792.
[62] Harris, D. (2010). *supra nota 44*, 384-386
[63] Beall, R., & Kuhn, R. (2012). Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis. *PLoS Med*, *9*(1), 1-2

outlined that the TRIPS Council must form a solution to the issue. The aim was to amend the TRIPS agreement by creating a so-called" tailored" compulsory licensing provision for the possibility to export essential medicines to the countries which lack the capacity to produce the medicines themselves.[64] Later on, in 2003, the TRIPS Council found a solution regarding the issues on compulsory licensing for developing countries and countries with insufficient or no manufacturing capacities to produce essential medicines. This solution by the TRIPS Council was called the amendment- Article 31 BIS. Article 31 BIS was adopted by member states of The WTO later on December 6, 2005.[65]

2.3.1. TRIPS Article 31 BIS and LDC's

The solution found by the TRIPS council provided countries with insufficient or no manufacturing capabilities with a new option to access affordable drugs such as antiretroviral treatment. The TRIPS article 31 BIS allowed countries with manufacturing capabilities to issue a compulsory license to export a drug to a country that lacks sufficient manufacturing capabilities to manufacture the drug on their own.[66] This resulted in a situation where a developing country or an LDC could import equivalents from the other country without the interference of the patent owner. As Article 31 BIS provided a new alternative for developing countries and LDC's to battle against multiple diseases such as HIV/AIDS, the WTO encouraged member states to benefit from article 31 BIS. WTO promoted the use of Article 31 BIS to improve health in developing countries by setting up multiple WTO workshops and joint operations between the World Health Organization (WHO) and WTO.[67] However, despite the efforts by the WTO to promote LDC's and developing countries to make use of TRIPS article 31 BIS, it has only been used on one occasion. According to multiple scholars and public interest organizations, the battle against patented drugs by Thailand and Brazil with the successful use of compulsory licensing under TRIPS article 31 was hoped to change the perspective for the use of Article 31 BIS towards a more favorable one. The only case where TRIPS article 31 BIS was used was between Rwanda and Canada.[68]

---

[64] Amendment of the TRIPS Agreement, World Trade Organization (WTO), 2005 8 December.
[65] Harris, D. (2010). *supra nota 44*, 386-387
[66] Beall, R., & Kuhn, R. (2012). *supra nota 48*, 2-3
[67] *Ibid.*
[68] Harris, D. (2010). *supra nota 44*, 389-391

In the case of Rwanda and Canada, Rwanda had the intention to import an antiretroviral drug called Apo TriAvir from a Canadian generic pharmaceutical manufacturer Apotex.[69] The delegation of Rwanda informed the TRIPS council as follows: "Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine, and Nevirapine (hereinafter referred to as the 'Product') manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate. Pursuant to Paragraph 7 of the Doha Declaration and implementation thereof by the TRIPS Council (Decision of the Council for TRIPS of June 27, 2002), we have decided that we will not enforce rights provided under Part II Section 5 of the TRIPS Agreement that may have been granted within Rwanda's territory with respect to the Product (Rwanda, 2007)." [70]

The process of issuing a compulsory license as an LDC under TRIPS article 31 BIS was lengthy and challenging in the case of Rwanda since it was and is the only case where compulsory licensing has been used under TRIPS 31 BIS. However, despite the process faced multiple difficulties and was not efficient, Apotex was granted a compulsory license for the export of Apo TriAvir and was able to export three batches of the drug to Rwanda between 2008 and 2010.[71] As stated above, the use of TRIPS article 31 BIS is not effortless and fast. The use has been described as a process too cumbersome and complicated. According to Apotex, the use of Article 31 BIS did not provide enough incentive for the company compared to the benefits. Apotex even stated that from experience in the case of Rwanda and Canada, they would not use the system that comes with Article 31 BIS again in the future if there will be no amendments to the legislation. During the process to manufacture and export TriAvir to Rwanda, Apotex had to negotiate between patent holders for two years. Another alarming aspect of the use of Article 31 BIS was that the compulsory license, which was issued and granted, could, in reality, be limited to a fixed term that is not long enough to profit on.[72]

[69] Stavropoulou, C., & Valletti, T. (2015). *supra nota 15*, 84-85
[70] Notification under paragraph 2(a) of the decision of 30 august 2003 on the implementation of paragraph 6 of the doha declaration on the trips agreement and public health, World Trade Organization (WTO) 2007.
[71] Ooms, G., & Hanefeld, J. (2019), *supra nota 10*, 2-3
[72] Harris, D. (2010). *supra nota 44*, 390-391

It can be argued whether article 31 BIS provides actual possibilities to solve the issue of LDC's and developing countries to get easy access to essential medicines. The wording of the article indicates that there is a possibility to increase the use of compulsory licensing in LDC's and developing countries. However, article 31 BIS has been used only once. As the case of Rwanda and Canada implicates, the process was long and cumbersome and did not provide enough incentives for the exporting country to go through the long-lasting process. It is safe to say that with only one single application of article 31 BIS this far, the solution provided in the Doha declaration for LDC's and developing countries to access essential medicines is not efficient and does not provide an actual answer for the accessibility and affordability of medicines in the developing countries. The goal of article 31 BIS was to answer questions concerning the accessibility and affordability of medicines in developing countries and provide a working solution for this matter. The problem, still over a decade later, remains the same: developing countries struggle to maintain public health due to not being able to gain access or afford essential medicines.[73]

2.4. Shifting responses from the E.U. and western countries

In order to get a complete understanding of the impacts of the HIV crisis and to research the potential responses on COVID-19, it is crucial to observe the response of the European Union and the member states of the E.U. The European response to HIV bases its grassroots on the European Convention on Human Rights and the European Social Charter; both recognize the right to health. Countries inside the E.U. were the first countries to first respond to mitigating HIV infections. The European countries have in multiple other ways also been leaders in both human rights and in the responses concerning HIV. The E.U. is committed to ensuring the right to health as a human right, but has shifted in the light of the HIV pandemic from a rights-based response to a response dealing with risk management. As E.U. shifted from a right-based approach to a risk management approach, on a global level, the E.U. backtracked on its commitments on global health and prioritized the rights of pharmaceutical companies. As prioritizing the intellectual property rights of drug companies, the people affected with HIV were left in the shadows.[74]

The response of E.U. has shifted its priorities during the HIV crisis, for example, towards an approach that emphasizes intellectual property rights over human rights such as the right to health. During the HIV crisis, the E.U. had promoted intellectual property law flexibilities such

[73] *Ibid. 389-400*
[74] Smith, J. (2016). Europe's shifting response to HIV/AIDS: from human rights to risk management. *Health and human rights*, *18*(2), 145-156.

as the TRIPS agreement to improve access to generic medications, for example, in developing countries. However, E.U. backtracked on this statement and claimed that they simply referred to strengthening the medicines patent pool and thus creating improved access. Previous to this statement, E.U. had been supporting and promoting increased access to antiretrovirals. Prioritizing intellectual property rights rather than promoting and supporting access to medicines is the view that the E.U. has shown during different price negotiations. A good example illustrating this is the case of 2014 negotiations between India and the E.U. In this case, E.U. was negotiating with India on generic HIV medication manufacturing but then pushed for a data exclusivity provision that significantly reduced the production of generic HIV medicines in India. During the negotiations, E.U. also proposed a provision that would have allowed companies within the E.U. member states to take legal actions against India as the actions of India was a threat to the profits of these E.U. companies.[75]

Prioritizing intellectual property rights over supporting and promoting access to essential pharmaceuticals has become even more topical due to COVID-19. As the paper will introduce later, multiple low-income and middle-income countries have proposed a waiver to suspend intellectual property rights temporarily. This proposal is more or less only supported by middle-income and low-income countries. For example, Norway and Switzerland, being countries within the European Economic Area (EEA), has firmly rejected the proposal. Countries that are blocking or delaying the proposal are countries that have already secured the majority of the vaccines available.[76]

Blocking and delaying such a proposal that would provide a more expedited solution for governments at the international level to gain access to essential pharmaceuticals such as the COVID-19 vaccine highlights the approach of the E.U. and high-income countries prioritizing intellectual property rights. Countries obstructing and blocking the proposal argue that the I.P. system is required to create an incentive for pharmaceutical companies to research and develop medicines such as vaccines. These countries have dismissed the fact that I.P. is one of the significant barriers to access.[77]

[75] *ibid.*
[76] Christou, C. (2021), Countries obstructing COVID-19 patent waiver must allow negotiations to start. *Medecines Sans Frontieres.*
[77] *Ibid.*

3. COMPULSORY LICENSING IN THE AGE OF COVID-19

The outbreak of COVID-19 has and will have an enormous impact in the future on all the countries around the world. However, the developing countries will most likely be the ones to struggle the most due to not being able to access and afford patented treatments for the virus. The future will show how the battle against accessing and affording essential medicines in developing countries will play out during the COVID-19 crisis. COVID-19 provides the perfect opportunity for developing countries and LDC's to step up and show precedent for other countries in the same situation on how to access and afford patented medicines. Whether the solution is article 31 BIS of the TRIPS agreement, it is crucial to develop an efficient and working solution for LDC's and developing countries to access and afford medicines.

South Africa and India have already taken action by proposing a ban for patents concerning COVID-19 vaccines, medicines, and technologies that will contain the virus from spreading. The main agenda behind placing a ban on COVID-19 related treatments is that the products would be accessible and affordable for developing countries. According to the proposal, in the age of the COVID-19 pandemic, I.P. rights create a barrier to access and afford these medical products. Multiple low-income and middle-income countries have supported the proposal when pharmaceutical companies, High-income countries, and the E.U. rejected the proposal by emphasizing the importance of patents to incentivize new inventions. The rejection of this proposal was justified by claiming that voluntary licenses and technology transfer arrangements will guarantee equitable access to medicines in all countries. A statement made by the Indian Government regarding this matter sums up the controversial aspect of this matter in a perfect way. According to the statement, countries that rejected the proposal are also the countries that are purchasing most of the vaccines supplied, so that there are no left for the low-income countries.[78]

As for the current situation, some high-income countries and the E.U. have indicated a more supportive approach on the patent waiver proposal. The U.S. Government alongside the current president Joe Biden expressed their support on the waiver to drop patent protection on COVID-19 vaccines. Subsequent to this, on the next day the European Commission President Ursula von

[78] Usher, A. D. (2020). South Africa and India push for COVID-19 patents ban. *The Lancet*, *396*(10265), 1790-1791.

der Leyen expressed the view of the E.U. by stating their willingness to discuss the patent waiver proposal. However, there are still a significant amount of countries objecting the patent waiver proposal. Countries objecting the patent waiver proposal such as Germany, base their argument on the grounds of vaccine shortages are due to limited production capacity, not patent protection issues.[79]

The refusal of the proposal taken by high-income countries indicates a risk of drifting to a situation where high-income countries monopolize the global supply of COVID-19 vaccines. Past pandemics have shown that high-income countries tend to drain out the supply of vaccines before developing countries get the opportunity to access and afford the medicine. This can be demonstrated by using a case example of Influenza A/H1N1 from 2009. In 2009, high-income countries negotiated and placed large orders on the vaccine against A/H1N1 influenza during the influenza pandemic, thus leaving the developing countries without treatment.[80] While influenza A was spreading around the world in 2009, questions regarding equitable access to vaccines emerged. As high-income countries placed large orders for the influenza A vaccine leaving the developing countries without supply, WHO initiated negotiations with vaccine manufacturers and with the governments of high-income countries. The goal of these negotiations was to provide developing countries with access to the treatment against influenza A. WHO and the United Nations (U.N.) appealed for monetary donations to provide treatment for the developing countries. The effort by WHO and U.N. was successful, and donations made it possible for developing countries to gain access to the treatment. However, in reality, the situation did not change radically. Developing countries were still left with limited supplies to battle against the pandemic.[81]

As the world is battling against a severe pandemic having the potential for one of the most devastating outcomes in the history of pandemics, governments should take reasonable actions against COVID-19. One of the actions is compulsory licensing under the TRIPS agreement. Even when preparing to issue a compulsory license under TRIPS agreement against COVID-19

[79] Blenkinsop, P., O'donnell, C. (2021, May 7), EU supports COVID vaccine patent waiver talks, but critics say won't solve scarcity. *Reuters.* Retrieved from: https://www.reuters.com/world/europe/eu-willing-discuss-covid-19-vaccine-patent-waiver-eus-von-der-leyen-2021-05-06/

[80] Yamey, G., Schäferhoff, M., Hatchett, R., Pate, M., Zhao, F., & McDade, K. K. (2020). Ensuring global access to COVID-19 vaccines. *The Lancet*, *395*(10234), 1405-1406.

[81] Fidler, D. P. (2012). Negotiating equitable access to influenza vaccines: global health diplomacy and the controversies surrounding avian influenza H5N1 and pandemic influenza H1N1. In *Negotiating and Navigating Global Health: Case Studies in Global Health Diplomacy* (pp. 161-172). 1-3

is reasonable, it comes with consequences. The possibility of compulsory licensing may affect the incentive of pharmaceutical companies to invest in their research and development costs.[82] As compulsory licensing is an effective tool provided in the TRIPS agreement, countries must, in the age of COVID-19, modify their domestic laws to have procedures to issue a compulsory license effectively. Multiple countries, as observed, have already started to prepare themselves for a situation where the battle against the COVID-19 pandemic needs legislative measures and compulsory licensing.[83]

Countries within the E.U. have learned from the past pandemics and have started to pass legislation that prevents future issues during a pandemic, such as COVID-19. Relevant to this study, provisions that concern compulsory licensing have been passed in the past to ensure access to vaccines when E.U. and the world face a new pandemic in the future. While the TRIPS agreement does not provide an exhaustive list for the requirements for a country to be granted a compulsory license in the light of a pandemic or an emergency, the Doha declaration states that a country has the right to determine independently what are the requirements. The fact that the grounds of justifying the use of compulsory licensing in the age of a pandemic is not defined in these treaties gives the countries free hands to amend their legislation what they see fit. There is a relevant difference in the light of domestic legislation when a compulsory license can be granted within the E.U. countries. [84]

In order to fully understand the differences in legislation between E.U. countries when it comes to granting a compulsory license, we must observe a few example countries. Even though The United Kingdom is no longer a part of the E.U., but as being a part of the western world, it is crucial to investigate its compulsory licensing provisions, especially now in the age of COVID-19. The U.K. is an interesting country when talking about its compulsory licensing provisions. The right to grant a compulsory license in case of emergency in the U.K. bases its legal grounds on the U.K. Patent Act of 1977. According to the act, any department in the U.K. government or any person that the Government authorizes may ensure compulsory licenses for the services of the crown when there is an emergency. As the U.K. legislation does not provide any list of the

[82] Urias, E., & Ramani, S. V. (2020). *supra nota 5,* 11-14
[83] Wong, H. (2020). *supra nota 18,* 3-4
[84] World Trade Organization (WTO) (2006). *TRIPS and pharmaceutical patents: Compulsory licensing of pharmaceuticals and TRIPS.*

situations where a compulsory license may be used, it can be viewed as one of the broadest concepts of compulsory licensing in the western world.[85]

Opposite to the U.K., Belgium does not have a broad concept when it comes to compulsory licensing. The Belgian legislation grants compulsory licenses only in specific situations. According to the code of economic law (BCEL), compulsory licenses can only be granted in cases where there is interest of public health.[86]

The Netherlands is a mix of the U.K. and Belgium. The Dutch legislation has a broader concept of granting a compulsory license than Belgium does, but not as abstract as the one in the U.K. The Dutch Patent Act (DPA) provides a list of grounds for a compulsory license. The list consists, for example, the Euratom Treaty, ownership of dependent patents, national defense, and public interests.[87] The respective countries have taken measures to prevent the crisis that come with global pandemics, yet very few compulsory licenses have been issued. This topic gains relevance while COVID-19 affects all countries globally, and the time will show if any of these countries will rely on their legislation to grant a compulsory license to fight this pandemic.

As compulsory licensing in the age of COVID-19 has been a discussed topic amongst several countries, only one documented case of a compulsory license on COVID-19 treatment has been issued. On March 24, 2020, The Israelian government issued a compulsory license to import equivalents of Lopinavir/Ritonavir, branded as Kaletra. As discussed earlier, this medication provided treatment during the HIV crisis. However, research had shown that this medication could be a possible treatment for COVID-19 patients as well. However, as in most previous cases, compulsory licensing has been used to drive down the price of a particular drug. However, in the case of Israel, a compulsory license was issued to provide sufficient supplies of the medication.[88] As stated, the only documented compulsory license issued on COVID-19 treatment this far has been the case of Israel. However, similar to issuing a compulsory license, the Canadian Government enacted an emergency response act against COVID-19 on March 25, 2020. This act allowed the production, sales, and use of an invention that was already patent protected in Canada. As it can be observed, this act provided Canada with the same possibilities

[85] The United Kingdom Intellectual Property Office (2016), Manual of patent practice, *section 55: use of patented inventions for services of the crown.*
[86] Reichman, J. H. (2009). Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options. *The Journal of Law, Medicine & Ethics*, *37*(2), 247-263.

[87] Rijksoctrooiwet 1995
[88] Wong, H. (2020). *supra nota 18,* 2-3

that a compulsory license would have. Under this act, a production license could be issued without carrying out negotiations with the patent owner.

As for the behalf of developing countries, some precedent has surfaced. The Committee of the National Assembly in Ecuador passed a resolution where the President and the Health Minister of Ecuador must ensure accessible and affordable access to COVID-19 related treatments via compulsory license. The case of Ecuador provides a precedent for other developing countries to establish a framework where compulsory licensing could be used if needed. [89] On top of the countries mentioned before, Chile and Germany have also taken steps to adapt their national legislation so that compulsory licensing can be used to access different technologies and treatments for COVID-19.[90]

As discussed earlier, TRIPS article 31bis can provide a solution to gain access for some countries during COVID-19. Article 31bis provides a solution for catastrophic situations, which sadly, many countries around the world find themselves during the current pandemic. As COVID-19 has affected all countries globally, multiple countries certainly experience significant shortages on treatments for this virus. As countries are infected by this pandemic more or less severe, all countries share the same concern, the urgent need for medication. As a considerable proportion of the countries affected do not have sufficient domestic manufacturing capacities to provide treatment, these countries could use article 31bis to allow for a cooperative strategy on importing and exporting life-saving COVID-19 generic treatment. However, the use of article 31bis imposes a legal complication for the developed countries and most countries within the E.U. As article 31bis was introduced, many of these countries opted out from the article 31bis system, which meant the refusal of using this provision to import generic pharmaceuticals. Some of the countries that opted out from the use of the system provided by article 31bis even ruled out the possibility of ever using the provision, even in situations of national emergency or other types of extreme urgencies. This does not rule out the possibility to gain access by using article 31bis for the countries that did not opt-out on the use of this article. Even countries that did opt-out, it is suggested that as a matter of justice and fairness when global justice requires, that they

[89] *Ibid.*
[90] Bassi, L. L., & Hwenda, L. (2020). COVID-19: time to plan for prompt universal access to diagnostics and treatments. *The Lancet Global Health*, *8*(6), 1-2

could be permitted back in the circle of article 31bis. COVID-19, without a doubt, creates an urgent emergency where these sorts of aspects should be taken into consideration.[91]

[91] De Campos-Rudinsky, T. C. (2021). Intellectual property and essential medicines in the COVID-19 pandemic. *International Affairs*, *97*(2), 523-537.

4. CONCLUSION

As concluded in the research, there have been various approaches to how crises that affect global health are handled. The countries' legal responses in the scope of this research had similar elements on approach, but the results on affordability and accessing patented pharmaceuticals varied. As pharmaceutical companies are trying to gain profit from their innovations, high prices create barriers to access and afford treatment in developing – and middle-income countries.

" How does compulsory licensing circumvent the negative social impact of patents when accessing essential pharmaceuticals?".

The majority of the countries affected severely by life-threatening diseases are either developing countries or middle-income countries. The health services in these countries are overwhelmed by the costs that, for example providing antiretroviral treatment creates. Issuing a compulsory license on a patented drug or using a compulsory license as a threat in price negotiations can and has been used to drive down the price of patented pharmaceuticals. Both solutions have been proven successful in the past and thus have created a way for middle-income -and developing countries to access pharmaceutical products at a more affordable price.

However, issuing a compulsory license creates a situation that can be referred to as being a double-sided coin. The other side consists of the fact that these countries are unable to pay high prices for pharmaceutical companies for a treatment. The other side is the ability to produce generic medicines locally. However, if done so, these countries will face pressure from the pharmaceutical companies and, for example, the U.S. Government to increase their protection of intellectual property rights or face the possibility of legal actions.

When a compulsory license is issued, the rights of the patent holder are violated. As the protection of intellectual property rights is the incentive for pharmaceutical companies to invest in research and development costs, a compulsory license has an undesired social effect on behalf of pharmaceutical companies. However, strong patent protection tends to create competition between pharmaceutical companies to a race for possible treatment and thus affects prices positively due to competition.

" Does compulsory licensing create an effective enough solution to access pharmaceutical products in the developing countries?".

Strong intellectual property protection provides pharmaceutical companies incentive for innovation. This incentive is achieved through profits from high-priced patented pharmaceuticals. As compulsory licensing is a powerful tool to access or drive the price down of a pharmaceutical product, it comes with its difficulties. As in the presented cases, compulsory licensing was proven effective by using the threat of issuing a compulsory license in price negotiations. Brazil was able to use compulsory licensing effectively to reduce the price of patented medicines. Thailand, however, pursued issuing compulsory licenses, which also resulted in price reductions. Despite being successful, these processes are long and cumbersome and might limit the access of patients.

Countries seeking to issue a compulsory license are usually under a significant trade pressure from pharmaceutical companies and governments such as the U.S. This pressure may lead to a situation where a country is forced to implement even more strict rules on the protection of intellectual property than the international agreements imposes. The pressure itself creates a barrier to the effective use of compulsory licensing in developing countries as it creates fear of retaliation in the form of trade sanctions.

Domestic legislations play a significant role in the effectiveness of a compulsory license. Legal challenges aimed at the domestic legislation of a country pursuing a compulsory license hinder the effective use of a compulsory license, as in South Africa. While pharmaceutical companies and governments legally challenge the domestic implementation of compulsory licensing provisions in the country seeking to access pharmaceutical products via compulsory licensing, it creates delays to access and unnecessary expenses.

Additionally, article 31bis in the TRIPS agreement was found to provide developing countries with no manufacturing capabilities with an option to gain access to more affordable drugs. However, the use of article 31bis has not implicated itself for being an efficient solution for developing countries. Due to the nature of article 31bis, it has only been used once with questionable success when compared to the efforts, length, and procedural requirements that the use of this article requires. With only one single application of article 31bis and the nature of this

article, it is safe to conclude that it has not created an efficient enough solution in the past for the developing countries.

" What will be the role of compulsory licensing during COVID-19?"

Compulsory licensing in the age of COVID-19 is a discussed topic while countries seek options on how to access and afford potential treatment options. The current pandemic gives legal ground in many countries to issue a compulsory license on patented pharmaceuticals.

There is evidence that several countries have taken legislative steps to ensure that they can issue a compulsory license on a treatment efficiently in case needed. These similar responses to the COVID-19 crisis have implicated that compulsory licensing might play a relevant role when accessing potential vaccines, notably in developing countries. While it is crucial to protect pharmaceutical companies' incentive in the age of an unseen crisis, countries severely affected will do what it takes to fight the pandemic.

In case history repeats itself, middle-income -and developing countries face difficulties accessing and affording treatment for COVID-19. The legal solution for these countries will be compulsory licensing. COVID-19 re-opens the door for developing -and middle-income countries to show precedent for other countries fighting the same battle as Brazil did against the HIV crisis. Precedent on this matter has already surfaced in the case of Ecuador. It is crucial that developing countries to follow these steps and establish a framework in their legislation where compulsory licensing can be used to battle COVID-19. Time will show whether the solution to battle COVID-19 for middle-income -and developing countries is compulsory licensing under TRIPS article 31 or 31bis. Even though the use of article 31bis is unlikely due to the complicated nature of this provision, it is possible that some countries would re-open the door for the use of this provision since it has the potential to be an efficient solution for developing countries even when proven otherwise. Looking into the future of COVID-19, an efficient and working solution must be created to access affordable medicines in developing countries.

Considering the history of compulsory licensing and past cases, compulsory licensing can be somewhat seen as a double-edged sword. The issuance of a compulsory license does not positively serve both parties. Either a country must pay the prices that a pharmaceutical company

has set, or the innovation of the patent holder is violated. All the issues and controversies that surface in using a compulsory license are eventually tied to the roots of this controversial provision, the effort to try to balance the rights of the patent holder and the country issuing the compulsory license. Time will show us the role and relevancy of the patent waiver proposal during this pandemic, and how the controversial aspects of compulsory licensing will evolve and in which ways compulsory licensing will be used, especially now in the age of COVID-19.

LIST OF REFERENCES

Scientific books:

1. Fidler, D. P. (2012). Negotiating equitable access to influenza vaccines: global health diplomacy and the controversies surrounding avian influenza H5N1 and pandemic influenza H1N1. In *Negotiating and Navigating Global Health: Case Studies in Global Health Diplomacy*.

2. Harris, D. (2010). TRIPS after fifteen years: Success or failure, as measured by compulsory licensing. *J. Intell. Prop. L.*, *18*.

3. Lincoln, A. (1859). Second lecture on discoveries and inventions. *Collected Works of Abraham Lincoln*, *3*.

4. Marques, U. R. Q., Guimarães, V. S., & Sternberg, C. (2005). Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing. *Food & Drug LJ*, *60*.

5. Mueller, J. M. (2006). The tiger awakens: the tumultuous transformation of India's patent system and the rise of Indian pharmaceutical innovation. *U. Pitt. l. reV.*, *68*.

6. Nattrass, N. (2007). *Mortal combat: AIDS denialism and the struggle for antiretrovirals in South Africa*. University of KwaZulu-Natal Press.

7. Stiglitz, J. E. (2007). *Making globalization work*. WW Norton & Company.

Scientific articles:

8. Bassi, L. L., & Hwenda, L. (2020). COVID-19: time to plan for prompt universal access to diagnostics and treatments. *The Lancet Global Health*, *8*(6), e756-e757.

9. Beall, R., & Kuhn, R. (2012). Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis. *PLoS Med*, *9*(1), e1001154.

10. Berkman, A., Garcia, J., Muñoz-Laboy, M., Paiva, V., & Parker, R. (2005). A critical analysis of the Brazilian response to HIV/AIDS: lessons learned for controlling and mitigating the epidemic in developing countries. *American journal of public health*, *95*(7), 1162-1172.

11. Bond, P. (1999). Globalization, pharmaceutical pricing, and South African health policy: managing confrontation with US firms and politicians. *International Journal of Health Services*, *29*(4), 765-792.

12. Christou, C. (2021), Countries obstructing COVID-19 patent waiver must allow negotiations to start. *Medecines Sans Frontieres.*

13. De Campos-Rudinsky, T. C. (2021). Intellectual property and essential medicines in the COVID-19 pandemic. *International Affairs*, *97*(2), 523-537.

14. FM't Hoen, E., Kujinga, T., & Boulet, P. (2018). Patent challenges in the procurement and supply of generic new essential medicines and lessons from HIV in the southern African development community (SADC) region. *Journal of pharmaceutical policy and practice*, *11*(1), 1-8.

15. Ford, N., Wilson, D., Chaves, G. C., Lotrowska, M., & Kijtiwatchakul, K. (2007). Sustaining access to antiretroviral therapy in the less-developed world: lessons from Brazil and Thailand. *Aids*, *21*, 21-29.

16. Love, J. P. (2007). Recent examples of the use of compulsory licenses on patents. *Knowledge Ecology International*, *8*. 1-18

17. Lyttleton, C., Beesey, A., & Sitthikriengkrai, M. (2007). Expanding community through ARV provision in Thailand. *AIDS care*, *19*(sup1), 44-53.

18. Machlup, F., & Penrose, E. (1950). The Patent Controversy in the Nineteenth Century. *The Journal of Economic History*, *10*(1), 1-29. 7-10

19. Nunn, A. S., da Fonseca, E. M., Bastos, F. I., & Gruskin, S. (2009). AIDS treatment in Brazil: impacts and challenges. *Health affairs*, *28*(4), 1103-1113.

20. Nunn, A., Dickman, S., Nattrass, N., Cornwall, A., & Gruskin, S. (2012). The impacts of AIDS movements on the policy responses to HIV/AIDS in Brazil and South Africa: a comparative analysis. *Global public health*, *7*(10), 1031-1044.

21. Okie, S. (2006). Fighting HIV—lessons from Brazil. *New England journal of medicine*, *354*(19), 1977-1981.

22. Ooms, G., & Hanefeld, J. (2019). Threat of compulsory licences could increase access to essential medicines. *Bmj*, *365*.

23. Reichman, J. H. (2009). Comment: compulsory licensing of patented pharmaceutical inventions: evaluating the options. *The Journal of Law, Medicine & Ethics*, *37*(2), 247-263.

24. Smith, J. (2016). Europe's shifting response to HIV/AIDS: from human rights to risk management. *Health and human rights*, *18*(2), 145-156.

25. Stavropoulou, C., & Valletti, T. (2015). Compulsory licensing and access to drugs. *The European Journal of Health Economics*, *16*(1), 83-94.

26. Urias, E., & Ramani, S. V. (2020). Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. *Journal of International Business Policy*, *3*(4), 367-384.

27. Usher, A. D. (2020). South Africa and India push for COVID-19 patents ban. *The Lancet*, *396*(10265), 1790-1791.

28. Watal, J. (2000). Access to essential medicines in developing countries: does the WTO TRIPS agreement hinder it?. *Science, Technology and Innovation Discussion Paper*, *8*.

29. Wong, H. (2020). The case for compulsory licensing during COVID-19. *Journal of Global Health*, *10*(1).

30. Yamey, G., Schäferhoff, M., Hatchett, R., Pate, M., Zhao, F., & McDade, K. K. (2020). Ensuring global access to COVID-19 vaccines. *The Lancet*, *395*(10234), 1405-1406.

E.U Legislation:

31. Parliamentary questions for the European parliament on 23 December 2020, E-005595/2020

International Legislation:

32. Amendment of the TRIPS Agreement, World Trade Organization (WTO), 2005 8 December.

33. Notification under paragraph 2(a) of the decision of 30 august 2003 on the implementation of paragraph 6 of the doha declaration on the trips agreement and public health, World Trade Organization (WTO) 2007.

34. World Trade Organization (WTO) (2006). *TRIPS and pharmaceutical patents: Compulsory licensing of pharmaceuticals and TRIPS.*

35. World Trade Organization (WTO) (2006). *TRIPS and pharmaceutical patents: Obligations and exception*

Other sources:

36. Blenkinsop, P., O'donnell, C. (2021, May 7), EU supports COVID vaccine patent waiver talks, but critics say won't solve scarcity. *Reuters.* Retrieved from: https://www.reuters.com/world/europe/eu-willing-discuss-covid-19-vaccine-patent-waiver-eus-von-der-leyen-2021-05-06/

37. Mauchline, K. (2008). Official government justifications and public ARV provision: a comparison of Brazil, Thailand and South Africa.

38. The United Kingdom Intellectual Property Office (2016), Manual of patent practice, *section 55: use of patented inventions for services of the crown.*

39. Rijksoctrooiwet (1995)

Appendix 1. Non-exclusive licence

A non-exclusive licence for reproduction and for granting public access to the graduation thesis[1]

I Joona Juhana Kirmula

1. Give Tallinn University of Technology a permission (non-exclusive licence) to use free of charge my creation

Compulsory Licensing And Pharmaceutical Products: Lessons From The Past And The Need To Learn From The Future,

supervised by Pawan Kumar Dutt,

1.1. to reproduce with the purpose of keeping and publishing electronically, including for the purpose of supplementing the digital collection of TalTech library until the copyright expires;

1.2. to make available to the public through the web environment of Tallinn University of Technology, including through the digital collection of TalTech library until the copyright expires.

2. I am aware that the author will also retain the rights provided in Section 1.

3. I confirm that by granting the non-exclusive licence no infringement is committed to the third persons' intellectual property rights or to the rights arising from the personal data protection act and other legislation.

[1] The non-exclusive licence is not valid during the access restriction period with the exception of the right of the university to reproduce the graduation thesis only for the purposes of preservation.