Access patented vaccines in the time of COVID-19 pandemic

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Abstract

This thesis aims to describe and analyze three different solutions on how to make vaccines for COVID-19 available from a patent law perspective under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Under the TRIPS, patent law provides exclusive rights for vaccine inventors to prevent or stop others from commercially exploiting the patented invention for 20 years. During that time, the invention cannot be commercially made, used, distributed, imported, or sold by others without the patent owner's consent. Also, patents give inventors the rights to their discoveries and the means to be remunerated from them, and an incentive to encourage innovation. However, when a patent is licensed, an agreement is made between the patent owner and the person or company that wants to use and benefit from the patent. So a license is a permit to use something. There are various licenses, and it depends on what the parties have agreed. During the pandemic some pharmaceutical companies have made their patent available without any requirement of remuneration, but this has been shown not to be enough as the entire world requires the vaccines at the same time. The second option that might be used to access the vaccines is called compulsory licensing. However, at the time of writing, no Member States (MS) has used this, and it might be because it is difficult to implement through national legislation. Another reason is that some MSs cannot afford to transport and provide vaccines to their citizens, nor do they have the capacity to manufacture vaccines for themselves. Thus, they need to rely on other methods such as compulsory license or the waiver option. The third possibility to access the vaccines could be the recently proposed temporary waiver. The waiver option means that under the TRIPS and Doha Declaration, MSs can claim essential medicines without remuneration. However, the waiver is unsolved and MSs continued discussions on the role of intellectual property amid a pandemic. Between the MSs there are different views. The questions which have been raised around waiver are: does the current TRIPS flexibilities give enough possibilities to access COVID-19 vaccines or is the TRIPSs IP an obstacle to manufacturing

and access to vaccines? Or are the problems somewhere else than IP under TRIPS? This thesis concentrates especially on these questions with perspective of voluntary- and compulsory license and the current waiver.

Foreword

The author wants to dedicate her work to the late grandfather Lasse Antti Johan Wilhelm Vesterinen, a bank manager and Master of Law with court training. He has been a role model for the author. From the grandfather, the author has learned that one must always be interested in everything new. The author wants to dedicate her work to the late grandfather Lasse Antti Johan Wilhelm Vesterinen, a bank manager and Master of Law with court training. He has been a role model for the author. From the grandfather, the author has learned that one must always be interested in everything new. The author has promised her grandfather to start her legal studies and become a master of law. The author wants to thank her mother, Aila Vesterinen, and father, Jarmo Forstén and brother Jan Forstén, that they have supported through the author's path of legal studies. Thanks to her parents, the author has learned much determination and never gives up on her/his goal. The author wants to thank her fiance Tuomas Nylund for all the support and help he has given the author through her legal studies. In addition to this, the author wants to thank her dear friends Emmaleena Wenning, Mari Johnson, Erika Lindroos and Leena Haimilahti. They have supported her and taken care of her physical condition through her studies. Finally, the author wants to thank her supervisor, professor Johan Axhamn, for introducing more depth secrets of IPR. In addition to this, the author thanks her supervisor to fruital discussions and that he has been supportive, helpful throughout her research time.

Tiia Forsten, Lund, 2021

Abbreviations

APAs	Advanced Purchased Agreements
AIDS	Acquired immunodeficiency syndrome
EC	European Commission
EU	European Union
HIV	Human Immunodeficiency Virus
LDC	Least-developed country
DC	Developing countries
DVPC	Developed countries
OECD	The Organisation for Economic Co-operation and Development
PC	The pharmaceutical corporations
PHEIC	A public health emergency of international concern
R&D	Research and Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. Introduction

1.1. The state of vaccine distribution during the time of pandemic

At the time of writing, it has been over a year since WHO declared COVID-19 as a pandemic and provided a clear message to the world that the spread of the virus is very likely, and countries must prepare and act for quarantine plans and restrain public events. During this time, a COVID-19 has affected worldwide public health and the economy.[1] The WHO's declaration was triggered to accelerate the pharmacy companies' development of drugs and vaccines. At the same time, Member States (MS) planned together that vaccines should be accessed worldwide. Soon after this, we have found critical new tools to battle against disease, a COVID-19 vaccine. Creating a vaccine was recorded, thanks to unprecedented cooperation between pharmaceutical companies and between different countries. Later on, other vaccines against COVID-19 were created.[2][3]

After the vaccines were created, MSs realized that vaccines would play a crucial role in tackling this pandemic. During the pandemic, there has been a rising realization that no one is safe until everyone is safe.[4] Despite the common knowledge around these two subjects, there are conflicting interests in achieving the common good. In addition to this, unexpectedly, after COVID-19 vaccines were created, some MSs like the US and UK made Advance Vaccine Purchase Agreements (APAs) with PC's, and the joint will to have vaccines access

[1]James K. Jackson, 'Global Economic Effects of COVID-19' (2021) Congressional Research Service <https://fas.org/sgp/crs/row/R46270.pdf> accessed 5 May 2021

[2] WHO, 'R&D Blueprint and COVID-19' <https://www.who.int/teams/blueprint/covid-19> accessed 5 May 2021

[3] COVID-NMA, COVID-NMA vaccine mapping (2021) <https://covid-nma.com/vaccines/mapping> accessed 5 May 2021

[4] Andrea Shalal, 'WTO chief Ngozi Okonjo-Iweala on vaccine nationalism: No one is safe until everyone is safe' (*World Economic Forum,* 16 Feb 2021) <https://www.weforum.org/agenda/2021/02/world-trade-organisation-head-vaccine-nationalism-covid-19> accessed 29 April 2021

worldwide deviated. Soon after these first agreements, there began a race to attain the vaccines between MSs worldwide.[56]

Pharmaceutical professionals have declared that 2023 is the earliest date that everyone worldwide could receive a COVID-19 vaccine.[7] Some MSs have the capacity to manufacture huge volumes of vaccines themselves, and those enjoy the most significant advantage. On the other hand, developing countries (DC) can not afford to buy medicines or have the possibility to manufacture medicines. There is no formal definition of DCs in the WTO but in this thesis it has been pointed to those Member States (MS) who have been announcing themselves as developing countries.[8] Other problems include the difficulty in transporting vaccines. There may not be adequate facilities to properly hold the vaccines or those required to distribute the vaccines to the public.[9]

In addition to this, there have been rising problems with the distribution chain. The potential shortage of vaccines is likely to surface due to the lack of resources.[10] Instead, the problem would be the lack of MSs exclusive rights to the products.[11] This leads to a problem with the perspective of pharmaceutical companies, how they see what a current problem is and why the distribution does not work. Vaccines play a significant role in eradicating COVID-19, and it has become clear that the globally recognized patent laws are crucial in achieving effective and safe vaccines.[12] Without patents, the inventors and innovators can

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[5] United Nations UN General Assembly Resolutions: on Global solidarity to fight the coronavirus disease 2019 (COVID-19), UN Doc A/RES/74/270, (2020) <https://undocs.org/en/A/RES/74/270> accessed 29 April 2021

[6] Amnesty International (2020) <https://www.amnesty.org/download/Documents/IOR4033652020ENGLISH.PDF > access 29 April 2021

[7] Center for Global Development, COVID-19 Vaccine Predictions: Using Mathematical Modelling and Expert Opinions to Estimate Timelines and Probabilities of Success of COVID-19 Vaccines (2021) <https://www.cgdev.org/sites/default/files/COVID-19-Vaccine-Predictions-Full.pdf >access 20 April 2021

[8] WTO,Who are the developing countries in the WTO? Low<https://www.wto.org/english/tratop_e/devel_e/d1who_e.htm> accessed 20 May 2021

[9] WHO, The availability and affordability of selected essential medicines for chronic diseases in six low- and middle-income countries (2021) <https://www.who.int/bulletin/volumes/85/4/06-033647/en/ > accessed 5 May 2021

[10] PharmaExec, MAster of science of success(2021) Blockchain, COVID-a9 and the Pharmaceutical Supply Chain <https://www.pharmexec.com/view/blockchain-covid-19-and-the-pharmaceutical-supply-chain> accessed 20 May 2021

[11] Deutche Welle news,Access to COVID vaccine patents is not the same as access to vaccines <https://www.dw.com/en/access-to-covid-vaccine-patents-is-not-the-same-as-access-to-vaccines/a-57448750 > accessed 20 May 2021

[12] Benefits of Getting a COVID-19 Vaccine (2021) <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/vaccine-benefits.html> accessed 12 May 2021

neither be adequately compensated for their research costs nor be encouraged or motivated for further research to develop new and improved products.[13][14]

1.2. Patent law and pharmaceutical companies point of view

Vaccines for COVID-19 have made a record timeframe, and now several COVID-19 vaccines have created only 6-9 months.[15] Usually, it takes several years, even tens of years, to develop a successful and safe vaccine against viruses, and finally, only a tiny percentage of vaccines ever succeed. Before a successful vaccine, the inventors must invest substantial sums.[16] In other words, companies need to invest in the long, complex, risky, and costly process of providing new medicines to society. To be granted a patent with an exclusive right is slow, and it has to fulfill all the exact requirements as other inventions.[17] Early in the research, thousands of product compounds are screened and assessed in the development process, and only a few receive approval.[18] An IPR provides the right to have the exclusive right to exploit the patent. The drug companies that have manufactured the various COVID-19 vaccines own the patents and, therefore, the right to use (exploit) the patents. PCs' goal is to make a safe vaccine, but at the same time, it is also a complex business. Through licensing agreements, companies can have compensation for their complex and risky development.[19] PC's tend to give vaccines to the MSs that pay the best sum for the vaccine. However, the rapid spread of COVID-19 worldwide distinguishes the coronavirus from previous epidemics such as SARS, Ebola, and the swine flu. The coronavirus also is

[13]Pros and Cons of Compulsory Licensing: An Analysis of Arguments Muhammad Zaheer Abbas <http://www.ijssh.org/papers/239-D00013.pdf> accessed 14 April 2021

[14] IP/C/W/670, IP/C/W/671, IP/C/W/672, IP/C/W/673 and IP/C/W/674

[15] Medical News Today (2020) How did we develop a COVID-19 vaccine so quickly? <https://www.medicalnewstoday.com/articles/how-did-we-develop-a-covid-19-vaccine-so-quickly> accessed 15 May 2021

[16] World's Economic Forum; 5 charts that tell the story of vaccines today (2020) <https://www.weforum.org/agenda/2020/06/vaccine-development-barriers-coronavirus/> accessed 10 April 2021

[17] Statista, Research and development expenses of Moderna Inc. from 2016 to 2020 <https://www.statista.com/statistics/1108153/research-and-development-costs-moderna/> accessed 5 May 2021

[18] J. Postgrad; The clinical development process for a novel preventive vaccine: An overview (2016) doi: 10.4103/0022-3859.173187 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4944327/> accessed 10 April 2021

[19] WHO Outcome document Financing of R&D Preparedness and Response to Epidemic Emergencies (2015) <https://www.who.int/medicines/ebola-treatment/Outcome.pdf?ua=1> accessed 5 May 2021

affecting the whole world. The interest in curbing the pandemic is more significant than, for example, Ebola alone, which is considered a problem in Africa. Although the need for a vaccine is obvious, at the same time, specific steps in development and testing cannot be avoided.[20]

1.3. Three different options under TRIPS how to access patented COVID-19 vaccines

Some countries can not afford to transport and provide vaccines to their citizens, nor do they have the capacity to manufacture vaccines for themselves.[21] These DCs need to rely on other methods. This research provides three different options that might ensure that vaccines and treatments are shared more equitably across all countries in a perspective of patent law.

One solution might be a global vaccine distribution facility COVAX or The COVID-19 Vaccines Global Access Facility. It is a global multilateral initiative to develop, manufacture and deploy COVID-19 vaccines.[22] It is coordinated by the WHO in collaboration with the Vaccine Alliance (Gavi) and the Coalition for Innovations in Epidemic Preparedness (CEPI), COVAX is a part of a larger mechanism called the Access to COVID-19 Tools (ACT) Accelerator as a response to the COVID-19 pandemic.[23] About 190 nations have entered into agreements. Committed countries include 27 European Union countries plus Norway and Iceland, along with countries such as Australia, China, Japan, Singapore, Saudi Arabia, the UK, and The US.[24] The most of its funding has come

[20] Global Innovation policy center, Why Intellectual Property Protection Matters in the Time of Coronavirus <https://www.theglobalipcenter.com/why-intellectual-property-protection-matters-in-the-time-of-coronaviru> accessed 5 May 2021

[21]The Access to COVID-19 Tools (ACT) Accelerator (3.12.2020) <https://www.who.int/initiatives/act-accelerator> accessed 5 May 2021

[22] Gavi (2020) Gaci COVAX AMC Explained <https://www.gavi.org/vaccineswork/gavi-covax-amc-explained> accessed 20 may 2021

[23] WHO, Why do we need a COVAX <https://www.who.int/initiatives/act-accelerator/covax> accessed 20 May 2021

[24] Gavi, (2020) Commitment agreements <https://www.gavi.org/sites/default/files/covid/pr/COVAX_CA_COIP_List_COVAX_PR_15-12.pdf > accessed 4 April 2021

from high-income countries[25] and international organizations like the Bill & Melinda Gates Foundation.[26]

COVAX has an ambitious promise of providing global access to COVID-19 vaccines. COVAX has tried to enter into firm purchase agreements with vaccine manufacturers, but companies' slow or piecemeal submission of clinical trial data to WHO for emergency use listing posed delays. A COVAX target is to ensure that everyone can access COVID-19 vaccines as quickly, fairly and safely as possible.[27] COVAX is described to be "the world's best hope of bringing the acute phase of this pandemic to a swift end"."COVAX is a global collaboration created that would accelerate the development and manufacture of COVID-19 vaccines, as well as diagnostics and treatments, and guarantee rapid, fair and equitable access to them for people in all countries."[28] As a voluntary measure, COVAX tries to provide doses for at least 20% of countries' populations. Some argue that COVAX can be a solution for those countries who cannot access vaccines. Even though there are pharma companies to grant licenses voluntarily to other drug manufacturers, this is not enough to reach global markets. It "...is particularly important for vaccines to ensure timely production of a large number of doses needed…"[29] At the time of writing only a fraction has been reserved for the COVAX program[30] and it is known that they are not sufficient to tackle COVID in worldwidely. Thus, DCs know that they may be the last to gain the vaccines.

[25] Gavi, Annual Contributions and Proceeds <https://www.gavi.org/news-resources/document-library/annual-contributions-and-proceeds> accessed 20 May 2021

[26] Gavi (2020) The Bill and Melinda Gates Foundation<https://www.gavi.org/investing-gavi/funding/donor-profiles/bill-melinda-gates-foundation> accessed 20 May 2021

[27] Gavi (2020) COVAX explained < https://www.gavi.org/vaccineswork/covax-explained> accessed 20 May 2021

[28]Ibid

[29] OECD (2020) Treatments and a vaccine for COVID-19: The need for coordinating policies on R&D, manufacturing and access <https://www.oecd.org/coronavirus/policy-responses/treatments-and-a-vaccine-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/> accessed 20 May 2021

[30]The lancet, Souths Africa and India push for COVID-19 patents ban < https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext> accessed 20 May 2021

1.4. Aim and research question

The purpose of this thesis is to describe and analyze three different mechanisms for access to patent-protected vaccines of COVID-19; voluntary licensing (based on exclusivity – which could be combined with or without remuneration/royalty), compulsory licensing (set out in legislation), and a waive (exception from obligations to provide patent protection for inventions according to the TRIPS Agreement).

The thesis research questions are the following

1. How are patents for vaccines for COVID-19 protected at the international level according to the TRIPS Agreement?
2. Under which conditions does the TRIPS Agreement allow member states to introduce compulsory licensing for patents related to vaccines for COVID-19?
3. What is the content of the proposed waiver IP/C/W/669 related to the TRIPS Agreement regarding patent protection for vaccines for COVID-19?

1.5. Scope and constraints

This paper examines TRIPS Agreements Article 31 (compulsory licensing) and Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health as alternatives to voluntary licensing for access to future COVID-19 vaccines. Furthermore, the temporary waiver under TRIPS to suspend IP rights is examined. The analysis is restricted to the time of COVID-19 with the exception of a few earlier pandemic cases that are analysed in order to further understand the past use of the TRIPS flexibilities. It is worth mentioning that the subject of this research is new and dynamic. This is why it is legitimate that the primary sources of analysis that have been used are electronic sources via the internet. The electronic sources gathered include official documents/reports, relevant case law, the TRIPS Agreements, and legal literature. In addition to this reports and newspapers and articles are used to full extent since the nature of the pandemic: changes take place day by day and week by week.

1.6. Materials and method

1.6.1. Methodological approach

To fulfill the purpose of this thesis and to answer the research questions, a legal scientific dogmatic method will be applied. In this research *a legal dogmatic method* is mainly used. This method is considered to be the interpretation and systematization of legal provisions, the weighing of legal principles and the elucidation of existing law. Legal dogmatics is an interpretive science that studies legal texts. Thus, its *methods* are usually methods of interpretation. Legal dogmatics examines legal norms, their content of ideas, about which legal normative sentences provide information. Therefore, interpretation is the central method of legal dogmatic.[31]

The legal doctrine method used in this work has been defined well by professor Jan M Smits in his research paper What is Legal Doctrine? Regarding the aims and methods of legal dogmatic research, according Jan M Smits the legal doctrine provides three main goals which are description, prescription and justification. Description is explained to describe the existing law *the lex lata*. Prescription is the search for practical solutions, legal decision-makers such as legislatures and courts. Justification serves as a justification for the existing law.[32] These three approaches have been used in this research, because they provide a reasonable way to answer the research questions while not merely describing the relevant law and legalities, but also complementing a prescriptive approach in accounting the important practical aspects of implementing the law. The consideration of the practical implications is particularly important due to the focus of the research being COVID-19 pandemic.

A legal doctrine is research that aims to give a systematic exposition of the principles, rules and concepts governing a particular legal field or institution and analyses the relationship between these principles, rules and concepts with a view to solving unclarities and gaps in the existing law.

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[31] Ari Hirvonen `MItä metodit? Opas oikeustieteen metodologiaan´(2011) <https://www2.helsinki.fi/sites/default/files/atoms/files/hirvonen_mitka_metodit.pd> accessed 1 May 2021

[32] Jan M. Smith What is legal doctrine? On the aims and methods of legal-dogmatic research (2015) <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2644088> accessed 16 May 2021

It can be also said that a legal system is already justified by its own coherence that will have to be permanently readjusted on the basis of new judicial decisions and legislation. Possibility to describe and analyze the existing law, the author also comprises a search for practical solutions through main cases which reflect the state of the law, the *lex federa*. In this research *the historical interpretation* is used with the intent to examine the legislature and the preliminary work of the law.[33] In addition to this *the teleological interpretation* is used which gives a good way to explain the current state of law and regulation. First the objectives which the TRIPs Regulation seeks to promote are set and then the different interpretations and the actual consequences are assessed.[34]

1.6.2. Methodological constraints

About the scientific commitments and theoretical starting points, that during a pandemic the different methods i.e. research methods have been limited, because it has not been able to implement such extensive research material. For example libraries were not available due to pandemic restrictions. For this reason, the use of materials have also been limited during the pandemic and because of this most sources are internet sourced. In other words, most of the data that has been gathered are internet based (source of the material is mostly electrical books and internet based sources). In this research the scope of time and date is constrained to the pandemic due to the nature of research. This has been causing problems because the state of the pandemic is extremely dynamic and the situation changes rapidly from day to day. While the research aims to utilise official documents, reports, relevant case law, legal literature and newspaper articles as much as possible, there is no possibility to use *Qualitative studies* such as comprehensive interviews that could have enriched the perspective of the work.

1.7. Structure

The first chapter discusses the background of the research. The second chapter provides general background on the TRIPS Agreement and the general provisions of patent law under the TRIPS Agreement. The third chapter provides the main rule of the patent law and it gives a reader an understanding about the licensing.

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[33] Ari Hirvonen `MItä metodit? Opas oikeustieteen metodologiaan´(2011) <https://www2.helsinki.fi/sites/default/files/atoms/files/hirvonen_mitka_metodit.pd> et. seq. .35

[34] Peczenik, Aleksander, Juridikens teori och metod. Fritzes, Stockholm 1995. et seq. 56-59

The fourth chapter describes an exception for licensing the CL. A CL violates inventors exclusive rights and in certain circumstances the MS government can use this instrument. By using a CL the MS government can use the inventor´s patent but by the TRIPS Agreement it must give the inventor fair remuneration. The fifth chapter describes recent proposals for a temporary waiver which is unsolved at the time. The sixth chapter discusses the conclusion.

2. Provisions on patent protection in the TRIPS Agreement

2.1. Introduction

This chapter handles patents, innovations and TRIPS Agreement. Also, focus on what TRIPS Agreement can ensure that it can stimulate innovations. Intellectual Property Right has been seen as a reward after someone has greeted and innovated. Without IPRs, it has been seen that innovators do not have sufficient incentive to innovate and create. Under TRIPS Agreement article 7 stating that IPR "should contribute to the promotion of technological innovation,". The TRIPS provide standards for IPRs such as patents. In addition to this, it provides enforcement which includes procedures and remedies. In WTOs TRIPS Agreement obliged (under art.27.1) SMs to provide a patent for any invention that is new, includes an inventive step, and is capable of industrial application. Patents are an exclusive right to prevent others from exploiting an invention without the patent holder's permission (under art.28). The patent also provides a limited-term monopoly for the right holder (under art.33), it grants monopoly rights for at least 20 years from the date of filing the patent application. Licensing can be seen as a process where the patent owner permits another entity to extract benefits from the licensed patent. It permits the licensee to make or sell the product, design, or technology in the patent. The patent then creates income for both the licensee and the licensor through revenue and royalties for the duration of the licensing period.[35] However, the patentable subject matter can differ from MS to MS. When TRIPS was annexed to the Agreement Establishing the WTO in 1994, many DCs resisted it because they were afraid that this might obstruct access to essential medicines. However, later they were constrained to accept the whole TRIPS backpage.[36] However, TRIPS Agreement provides flexibility for MSs as a result

[35] Simon Lester, Bryan Mercurio and Arwel Davies, World Trade Law, Text, materials and commentary, third edition, 2018 et. seq.829

[36]WHO, Using TRIPS flexibilities to facilitate access to medicines <https://www.who.int/bulletin/volumes/91/7/12-115865/en/> accessed 20 May 2021

of the language of art. 1.1 of the TRIPS Agreement. TRIPS Agreement enunciates, not defines the provisions.[37]

2.2. TRIPS Agreement background about patents

2.2.1. Introduction

On 15 April was signed The Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS. However, before and after this, there have been long and complicated negotiations between the MSs. DCs did not want to include the IP regime into the WTO system, they were afraid that this decision might set barriers for their own development and also for the access to important goods, like medicines. Although, DCs were forced to take TRIPS as a whole package. After this DCs have pointed out several times that IP has been violating DCs public health and development. At the same time, the TRIPS Agreement has included more flexibilities and highlighted Public Health importance. Same time, into IP protection has been put at higher minimum standards levels.

2.2.2. Background

The target of the TRIPS Agreement was to build a worldwide system of protection that could support the markets when trading technology. Before the TRIPS Agreement, Intellectual Property was only partly secured through the World Intellectual Property Organization (WIPO) and most notably by the Paris and Berne Conventions. “The Paris Convention, adopted in 1883, applies to industrial property in the widest sense, including patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications, and the repression of unfair competition.[38] This international agreement was the first major step taken to help creators ensure that their intellectual works were protected in other countries.”[39] Three years later, in 1886, the Berne Convention was adopted, and it concerns authors rights about works. The Berne Convention provides “...with the means to control how their works are used, by whom, and on

[37]WIPO, Advice on Flexibilities under the TRIPS Agreement <https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html> accessed 20 May 2021

[38] Summaries of Conventions, Treaties ans Agremeents Administered by WIPO <https://www.wipo.int/edocs/pubdocs/en/intproperty/442/wipo_pub_442.pdf> accessed 20 May 2021

[39] WIPO, Paris Convention for the protection of Industrial Property <https://www.wipo.int/treaties/en/ip/paris/> accessed 20 may 2021

what terms. It is based on three basic principles and contains a series of provisions determining the minimum protection to be granted, as well as special provisions available to developing countries that want to make use of them."[40] The WIPO Convention, the constituent instrument of the World Intellectual Property Organization (WIPO), entered force in 1970 and amended in 1979. The WIPO describes itself as "Our mission is to lead the development of a balanced and effective international IP system that enables innovation and creativity for the benefit of all."[41] So, it tries to create an accessible international system, which stimulates innovation, rewards creativity, and contributes to economic development while safeguarding public interests.[42] WIPO has 193 members, and it is a self-funding agency of the United Nations.[43]

After this, the TRIPS Agreement enforced the agreed aspects as obligations for all of the member countries taking part in TRIPS. For example, history is seen in Articles 2.1 and 9.1 of the TRIPS Agreement related to the Paris Convention and the Berne Convention. Therefore the TRIPS agreement can also be referred to as the Paris+ and Berne+ agreement.[44] The Marrakesh Agreement defines the WTO's scope, functions, and structure. All previous agreements under GATT and all the previous TRIPS negotiations were included in Marrakesh Agreement Annexes. All these agreements are later on considered WTO agreements. In this research, all WTO agreements have been cited as treaties.[45]

TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) was signed on 15.4.1994.[46] The result of

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[40] WIPO, Berne Convention For the Protection of Literary and Artistic Works <https://www.wipo.int/treaties/en/ip/berne/> accessed 20 may 2021

[41] WIPO, Inside WIPO <https://www.wipo.int/about-wipo/en/#:~:text=Inside%20WIPO-,What%20is%20WIPO%3F,%2C%20policy%2C%20information%20and%20cooperation.&text=Our%20mission%20is%20to%20lead,for%20the%20benefit%20of%20all.> accessed 20 May 2021

[42] WIPO,Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention) (1967) <https://www.wipo.int/treaties/en/convention/summary_wipo_convention.html> accessed 20 May 2021

[43] WIPO, Countries <https://www.wipo.int/dcea/en/cooperating_countries.html> accesed 20 May 2021

[44] WTO, TRIPS : A MORE DETAILED OVERVIEW OF THE TRIPS AGREEMENT <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> accessed 9 May 2021

[45] WTO legal text <https://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs> accessed 16 May 2021

[46]* The Uruguay Round was the multilateral trade negotiations conducted within the framework of the GATT. The Round led to the creation of the World Trade Organization, with GATT remaining as an integral part of the WTO agreements. The Doha Development Round was the next trade round, beginning in 2001. <https://www.wto.org/english/thewto_e/whatis_e/tif_e/fact5_e.htm> accessed 20 May 2021

negotiations between 1986-1994 was a majority agreement, and they signed at the Marrakesh meeting in 1994 April.[47] The Marrakesh Agreement was developed out of GATT. It also established dispute resolution.[48] During the negotiations of TRIPS, the US began unilaterally enforcing IPR under the United States Trade Representative authority under Sec. 301. This Section on the Trade Act had an important role in defeating competing policy positions that DCs favored. In doing so, the US created that IPR can be linked to international trade.[49] Later on, the Doha Declaration on the TRIPS Agreement and Public Health was adopted 14.11.2001. It clarified the flexibility of TRIPS MSs in circumventing patent rights for better access to essential medicines. However, during the Uruguay Round, all countries did not see it the same way, especially DCs whose markets were more robust but at the same time, weak innovative capacities resisted. In contrast to DCs, the high-income countries have smaller national markets but more vital innovation capacity that favors robust protection. After lengthy negotiations between WTO MSs, they agreed to set minimum intellectual property (IP) protection standards.[50]

2.3. General provisions

2.3.1. Introduction

This chapter provides a general overview on patent protection under the TRIPS agreement. The TRIPS Agreement establishes a set of universal intellectual property norms that all WTO MSs must respect in their domestic laws. It recognizes minimum standards for the enforcement of intellectual property rights within MSs national systems, defines the main aspects of protection as well as permissible exceptions to those rights. For example, it gives the minimum duration of protection. The DCs have in some cases materialized the all standards which have been given via TRIPS and thus, TRIPS also provides some balance and flexibility like in TRIPS Article 1.1 ”Members may, but shall not be obliged

[47] WTO legal text <https://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs >access14 May 2021
[48] Marrakesh Declaration of 15 April 1994
<https://www.wto.org/english/docs_e/legal_e/marrakesh_decl_e.htm> accessed 14 May 2021
[49] S.Sell, Private Power, Public Law -The Globalization on Intellectual Property Rights, 2003 (pp. 60-74) ISBN:9780511491665
[50] Anna Maria Pacon, Ph.D. (1996) What will TRIPS do for developing countries? In: Beier F, Schricker G, editors. From GATT to TRIPS – the Agreement on Trade-Related Aspects of Intellectual Property Rights, studies in industrial property and copyright law. Munich: VCH Verlagsgesellschaft mbH.

to, implementing their law more extensive protection than is required by this agreement, provided that such protection does not contravene the provisions of this agreement". Also, in 2001 MSs adopted Doha Declaration "...to clarify ambiguities between the need for governments to apply the principles of public health and the terms of the Agreement on..."[51] TRIPS. Doha Declaration has provided flexibility of TRIPS MSs to circumvent patent rights to get more easily access to essential medicines. "The Doha Declaration states that each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[52]

2.3.2. General provisions

The minimum standards of the intellectual property regulations among the World Trade Organisation (WTO) member states (MSs) are established in the TRIPS Agreement.[53] The TRIPS Agreement aims to bring balance between the short-term objective of providing access to life-saving medicines and the long-term objective of encouraging and providing incentives to the pharmaceutical industry to develop new medicines. The TRIPS Agreement also includes the possibility of patenting an invention, and after that, it gives exclusivity for invention.[54] Under the TRIPS Agreement, every WTO MS must provide patents to protect for new inventions, involve an inventive step, and possibly industrial applications. However, defining what is patentable can differ from country to country among WTO MSs. The TRIPS Agreement requires that after an inventor has filed a patent application for an invention, a pharmaceutical product or process must be protected by a minimum MS term of 20 years.[55] Along with the set minimum standards of intellectual property regulations for the WTO MSs, there is a range of considered aspects, including the enforcement procedures and remedies and dispute resolution procedures. An important notion is an objective to promote technological innovation. There are mutual advantages towards the producers and

[51] WHO, The Doha Declaration on the TRIPS Agreement and public health <https://www.who.int/medicines/areas/policy/doha_declaration/en/> accessed 20 May 2021
[52] Ibid
[53] The TRIPS Agreement <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf > accessed 1 April 2021
[54] TRIPS, Patents, and Access To Life-Saving Drugs In The Developing World Bryan C. Mercurio <https://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1040&context=iplr> accessed 1 April 2021
[55] The TRIPS Agreement < https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 1 April 2021

users of technological knowledge for the social and economic common good while retaining the balance between rights and obligations.[56]

The most pertinent parts of the TRIPS Agreement in terms of patent protection are Articles 27-34. These articles require MS to provide a minimal standard of protection for inventors for twenty years and require the MS to protect inventions like the patent of vaccines. Under the TRIPS Agreement, MS must provide patent protection for the processes of products. Patent rights provide for absolute protection of the product and process and provide security of the technology, the process, or method of manufacture.[57]

Article 28 gives inventors the exclusive right to prohibit third parties from making, using, offering, selling, or importing inventions. The same article provides the inventor the right to make a license contract.[58] The TRIPS is not a unilateral system of IPR, so members might not always recognize other Member patents, which is why inventors should apply for protection in each MS separately, and usually, like medicine's invention, they do so. One of the crucial aspects that the TRIPS Art 3 and 4 provide is the non-discrimination rule or known as most-favored-nation treatment; MSs must give the same level of protection to other MSs citizens and their citizens. In addition to this, the TRIPS prohibits the MS from discriminating against other members.[59]

Shy (1995) notes that the patent system encourages innovation by granting those who create new, and this also encourages public knowledge as fast as possible. A *patent* is a temporary legal monopoly granted to an inventor. The rapid dissemination of knowledge is vital for the development of society. It reduces the cost of research and development (R&D) by preventing the development of the same inventions more than once.[60]

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[56] Ibid

[57] WHO, Access to Medicines <https://www.who.int/medicines/areas/policy/AccesstoMedicinesIPP.pdf?ua=1> access 1 April 2021

[58] The TRIPS Agreements arts. 3, 4, 27-34

[59]WTO, Procedures for notifying and sharing information: most-favoured nation <https://www.wto.org/english/tratop_e/trips_e/trips_notif4_art4d_e.htm#:~:text=The%20TRIPS%20Agreement%20allows%20WTO,holders%20from%20different%20trading%20partners.> access 16 May 2021

[60] Shy, O. (1995). Industrial Organization: Theory and Applications. Cambridge, Mass.: The MIT Press.

2.3.3. Issues regarding intellectual property rights

It should be noted that initially, there have been strong arguments for and against whether the IP in the WTO system prevents access to essential medicines. Even though TRIPS made a harmonized system, it did not create standard patent policies or levels of patent protection. In contrast, it allows countries to exercise flexibility in their IP systems. However, TRIPS classifies property rights as the highest priority, and DCs have criticized that TRIPS-related IPR registration and enforcement systems are too expensive for them. From the point of view of DCs, the agreement is problematic, as most patents are held by Western and international companies, and on the other hand, the agreement makes it difficult for all new technologies to be introduced voluntarily in DCs. During the COVID-19 pandemic, TRIPS have also been criticized for obstructing the free movement of goods and ideas, contrary to the core principle and idea of the WTO.[61]

2.3.4. TRIPS and Developing Countries flexibilities

In November 2001 was adopted the Doha Declaration on the TRIPS agreement and Public Health. It dressed up the public health problem policies around the intellectual property system. In this declaration open options to address public health needs, which are also called "flexibilities."[62] In addition to this, Doha Declaration paragraph 4 affirms that MSs has a right to use the provisions of the TRIPS Agreement, which provides flexibility.[63] Also, WIPO has four different groups. First, flexibilities as to the method of implementing TRIPS obligations. Second, flexibilities to substantive standards of protection. Third, flexibilities as to mechanisms of enforcement; And finally Flexibilities as to areas not covered by the TRIPS Agreement.[64] In addition to this, TRIPS Agreement Article 1.1 provides that MS are not obliged to implement their law wider protection than is required by Agreement.

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[61] Juhani Koponen, Jari Lanki ja Anna Kervinen: "WTOn toimivalta ja pyrkimykset", Kehitysmaatutkimus, johdatus perusteisiin, s. 142. Helsinki: Gummerrus, 2007. ISBN 978-952-495-004-6.

[62] WTO,TRIPS and public health<https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed 20 May 2021

[63]WTO, Declaration on the TRIPS agreement and public health <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> access 20 may 2021

[64] WIPO, Advice on Flexibilities under the TRIPS Agreement <https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html> accessed 20 May 2020

Under the TRIPS Agreement give minimum standards of protection and these protections must be given under MS the IP of other MSs. However, TRIPS provides certain flexibility. These flexibilities "aim to permit developing and least-developed countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development." This means that DCs have the possibility to in certain circumstances to access for example COVID-19 pharmaceutical products like vaccines. The final decision of using flexibilities and the choice of legislative option are exclusively each MSs. First flexibility is flexibility to implement TRIPS obligations provides TRIPS Agreement Article 1.1. Examples of those according to this article are flexibilities include concepts such as situations of extreme urgency for the purposes of using compulsory licenses. Second flexibility is flexibility to substantive standards of protection. This means that flexibility may permit measures that limit the rights conferred by the TRIPS Agreement. For example advertisements for alcohol. Alcohol is considered to be prejudicial to health. Flexibility can also raise the level of protection over the minimum standards by the TRIPS Agreement. For example the extension of scope of patentability beyond the minimum standards of TRIPS Agreements patentable subject matters Which are in article 15 and 27. Third flexibility is mechanisms of enforcement which are provided by the TRIPS Agreements Pat III. Identifies the mechanisms that MSs must adopt to give enforcement rights available to IP owners. However, MSs can use their own legal system and their own practices to implement enforcement obligations. Fourth flexibility handles flexibilities as to areas not covered by the TRIPS Agreement such as many different Ip subject matters.[65]

Under the TRIPS Agreement, there were added later on in 2001 exceptions with a Doha Declaration, which gave primacy to public health over private intellectual property and clarified WTO Members' rights to use the TRIPS safeguards. Some

[65]WIPO, Advice on Flexibilities under the TRIPS Agreement <https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html> accessed 20 May 2020

have argued that property law might sometimes go to the head of Human rights.[66] Patent laws, exceptions, and limitations can be different in every MS because of the flexibility of TRIPS. Nevertheless, two similarities are meaningful for this research. First is private and non-commercial use, and second is compulsory licensing and MS use.[67]

2.4. Licensing

2.4.1. Introduction

Patent right is an exclusive right and it prohibits others from using the invention, this is a big carrot for inventors, especially pharmaceutical companies (PC) when they consider to research and develop (R&D) a new invention-vaccine. Pharmaceutical R&D is a risky business because they have a very high failure rate. PCs must invest enormous sums of money for advantage to invent a vaccine, and only a small percent of drugs really end up on the market. With licensing the PC can reduce the monetary risks.[68] Patent law under the TRIPS Agreement (art. 28.2) also provides inventors with license possibilities. Licenses give rights for others to use the inventor's invention. There can be different licensing agreements and it depends what parties have agreed upon. Licensing is a process where the patent owner gives permission to another entity who can extract benefit from the licensed patent. It permits the licensee to make or sell the product, design, or technology in the patent. The patent then creates income for both the licensee and the licensor through revenue and royalties for the duration of the licensing period. However, there is no legal provision given under the TRIPS Agreement as voluntary license access is done through a mutual contractual agreement. A voluntary license is a voluntary agreement between the patent holder and the licensee. Terms and conditions of such a license can be agreed between the patent holder and licensee and can specify in which countries a medicine can be sold and what the royalty will be.

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[66] Juhani Koponen, Jari Lanki ja Anna Kervinen: ”WTOn toimivalta ja pyrkimykset”, Kehitysmaatutkimus, johdatus perusteisiin, s. 142. Helsinki: Gummerrus, 2007. ISBN 978-952-495-004-6.

[67] WIPO Exceptions and Limitations to Patent Rights <https://www.wipo.int/patents/en/topics/exceptions_limitations.html#:~:text=Nevertheless%2C%20the%20SCP%20has%20identified,prior%20use%3B%20(v)%20use> accessed 19 May 2021

[68] Catenion Academy, Risky business <https://catenion-academy.com/courses/risky-business/> accessed 20 May 2021

2.4.2. Licensing

Article 29 grants that patent holders can prevent third parties from using, offering for sale, selling, or importing. The patent holder has the right to assign, or transfer by succession, the patent and conclude licensing contracts. The TRIPS establishes a set of conditions that should be met in granting compulsory licenses, but how these conditions are operationalized in MSs national patent systems is left to be determined locally. Licensing can be seen as a process where the owner of the patent gives permission to another entity that can extract benefit from the licensed patent. It permits the licensee to make or sell the product, design, or technology in the patent. The patent then creates income for both the licensee and the licensor through revenue and royalties for the duration of the licensing period.[69]

2.4.3. Voluntary licensing

During the current pandemic, some pharmaceutical companies were already sharing technology on a voluntary basis and it means that they give patents voluntarily. Under the TRIPS Agreement, patent law provides exclusive rights for vaccine inventors to prevent or stop others from commercially exploiting the patented invention, as described in the previous chapter. In addition to this, a patent inventor can grant rights to another firm to produce and/or sell a product by a license agreement. When a patent is licensed, an agreement is made between the patent owner and, for example, the MS that wants to use and benefit from the patent. There are various licenses, and it depends on what the parties have agreed into a contract. This thesis paper has focussed on the classic definition of voluntary licensing, which permits a third party to manufacture, distribute and market a patented product.[70] Typically, a voluntary license is where a PC that holds patents on a product (patentee) offers on his own accord a license to a third party (usually a generic producer) to produce, market, and distribute the patented product. Licensing is a process where the patent owner gives permission to another entity who can extract benefit from the licensed patent. It permits the licensee to make or sell the product, design, or technology in the patent. The patent then creates income for both the licensee and the licensor through revenue

[69] Simon Lester, Bryan Mercurio and Arwel Davies, World Trade Law, Text, materials and commentary, third edition, 2018 et. seq.829

[70]Springer (2020) Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence <https://link.springer.com/article/10.1057/s42214-020-00068-4> accessed 8 May 2021

and royalties for the duration of the licensing period. However, there is no legal provision given under the TRIPS Agreement as voluntary license access is done through a mutual contractual agreement. A preliminary survey of voluntary licenses all globally reveals that only a handful of inventions have undergone voluntary licensing. Voluntary licensing is rarely offered as really voluntary rather, mostly as a result of litigation and civil society pressure or in the wake of the outbreak of pandemics such as HIV.[71] Sometimes a mere public announcement or discussion of potentially issuing a CL for a drug has led the patent holder to offer a discount or a voluntary license for the drug.

A voluntary license is a voluntary agreement between the patent holder and the licensee. Terms and conditions of such a license can be agreed between the patent holder and licensee and can specify in which countries a medicine can be sold and what the royalty will be. One example of a voluntary license is a drug whose name is Remdesivir. Patent holder Gilead signed an agreement which is a non-exclusive voluntary licensing agreement. A non-Exclusive license agreement means that a license can be granted to multiple entities. Gilead gave a license to drug makers of India and Pakistan to expand the supply of an experimental drug used on COVID-19 patients, but later on, it turned out that it was not effective enough to cure a COVID-19.[72][73]

Another example is AstraZeneca's which have agreed to transfer its know-how to a mass vaccine manufacturer in India, and the Republic of Korea[74] and AstraZeneca is producing AstraZeneca vaccines for COVAX. This voluntary license provides bilateral technology transfer from a company which owns the

[71] Reuters, Natco Pharma ties up with Gilead on hepatitis C drugs (2015) <https://donttradeourlivesaway.wordpress.com/2015/03/02/natco-pharma-ties-up-with-gilead-on-hepatitis-c-drugs/> accessed 8 May 2021

[72] Mondaq (2021), Voluntary Licensing Agreements For Remdesivir <https://www.mondaq.com/india/patent/945086/voluntary-licensing-agreements-for-remdesivir> accessed 8 May 2021

[73] The Strange Story Of Remdesivir, A Covid Drug That Doesn't Work (2021) <https://www.forbes.com/sites/jvchamary/2021/01/31/remdesivir-covid-coronavirus/> accessed 8 May 2021

[74] WHO (2021) WHO Director-General's opening remarks at the media briefing on COVID-19 – 5 March 2021 <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-5-march-2021> accessed 8 May 2021

patents on a vaccine to another company which can produce them.[75] In other words, AstraZeneca has transferred the technology for its vaccine to the Republic of Korea and India, which is producing AstraZeneca vaccines for COVAX.[76] AstraZeneca has made agreements with the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance, and the Serum Institute of India (SII), especially AstraZeneca agreed a voluntary licensing agreement with SII to supply one billion doses for DCs with a commitment to provide 400 million before the end of 2020.[77] A COVAX target is to ensure that everyone around the world has access to COVID-19 vaccines quickly, fairly, and safely guaranteeing to accelerate the development and manufacture of COVID-19 vaccines.[78] As a voluntary measure, COVAX seeks to provide two billion vaccine doses to be equally shared by DCs by the end of 2021. In the longer term, the goal is to provide funded countries with enough doses to cover 20% of their whole population. At the moment, COVAX is playing a big role in ensuring equitable allocation of vaccines. At the time of writing, there are 88 different COVID -19 candidates who are undergoing clinical trials and 184 vaccine candidates having a pre-clinical development.[79] After this, they have three different phase trials, and only a few manage to pass all the tests until phase 3. A COVAX also has the final stage, which is phase 4 trials, and it means that the vaccine needs monitoring over a longer period after it has national regulatory approval. However, it's not certain whether the COVAX will be able to carry out its promise fully before some of the DVPC that are donating supplies have fully vaccinated their own population.[80]

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[75] WHO, (2021)<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-5-march-2021> accessed 8 may 2021

[76] WHO, (2021) <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-5-march-2021> accessed 8 May 2021

[77] AstraZeneca, AstraZeneca takes next steps towards broad and equitable access to Oxford University's potential COVID-19 vaccine (2020) <https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-covid-19-vaccine.html> access 5 May 2021

[78] Gavi, COVAX explained <https://www.gavi.org/vaccineswork/covax-explained> accessed 30 December 2020

[79] GAVI, The COVID-19 vaccine race – weekly update <https://www.gavi.org/vaccineswork/covid-19-vaccine-race> accessed 21 April 2021

[80]Launchandscale Speedometer, TRACKING COVID-19 VACCINE PURCHASES ACROSS THE GLOBE (2021) <https://launchandscalefaster.org/covid-19/vaccineprocurement> accessed 20 April 2021

On the other hand, at the time of writing, only a fraction worldwide has been reserved for the program.[81] A few companies such as AstraZeneca and Moderna have announced giving some of their IP rights to the COVID-19 vaccine. Moderna has said that it would not enforce its patents in relation to the vaccine.[82] However, while Moderna has pledged not to enforce patents, the trade secrets would not necessarily be shared.

AstraZeneca has made a deal by voluntary licensing with India to transfer its know-how to a mass vaccine manufacturer in India.[83] AstraZeneca will provide the vaccine "on a cost basis until the pandemic is over".[84] They say that the cost applies only until July 31, 2021. AstraZeneca recognizes the essential incentive in all medicine innovations as their chief executive; Pascal Soriot said, "if you do not protect IP then essentially there is no incentive for anyone to innovate."[85] Also, Both of these companies, Moderna and AstraZeneca, have made bilateral agreements with countries, and these agreements say Advance market commitments (AMCs). These AMCs agreements guarantee priority access to the COVID-19 vaccine and manufacturing capacity. These contracts have also been "...criticized on ethical and medical effectiveness grounds for skewing distribution of vaccines on the basis of the ability to pay, rather than medical need".[86] These AMCs reduce global countries' cooperation, and it also raises inequality and keeps the time frame of the pandemic.[87][88][89]

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[81]The Lancet, South Africa and India push for COVID-19 patents ban, Ann Danaiya Usher <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext> accessed 30 December 2020

[82]Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward,Raisa Santos and Elaine R. Fletcher(2020) <https://healthpolicy-watch.news/77521-2/> accessed 30 December 2020

[83]BBC News,Covid vaccine manufacturers should work with poorer countries, says WTO chief (2021) <https://www.bbc.com/news/business-56598612> accessed 13 April 2021

[84] Financial Times; AstraZeneca vaccine document shows limit of non-profit pledge (2021) <https://www.ft.com/content/c474f9e1-8807-4e57-9c79-6f4af145b686> accessed 22 April 2021

[85] Financial Times; Pandemic reopens wounds on IP rights (2020) <https://www.ft.com/content/9ed5ca5e-9360-11ea-899a-f62a20d54625> accessed 22 April 2021

[86]WTO, DEVELOPING AND DELIVERING COVID-19 VACCINES AROUND THE WORLD <https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf> accessed 2 January 2021

[87] COVID-19 Vaccine Advance Purchases Explained, The Petrie-Flom Center Staff, Nicholson Price, Rachel Sachs, Jakob S Sherkow and Lisa L Squelette (2020) <https://blog.petrieflom.law.harvard.edu/2020/08/11/covid19-vaccine-advance-purchases-explained/> accessed 2 January 2021

[88]WTO, DEVELOPING AND DELIVERING COVID-19 VACCINES AROUND THE WORLD <https://www.wto.org/english/tratop_e/covid19_e/vaccine_report_e.pdf> accessed 2 January 2021

[89]Nature, How COVID vaccines are being divvied up around the world, Asher Mullad (2020) <https://www.nature.com/articles/d41586-020-03370-6> accessed 2 January 2021

In relation to MSs governmental subsidies towards COVID-19 vaccine research, Ellen `t Hoen, director of research group Medicines Law & Policy, says that the IP monopoly model has benefited big pharma. However, this time it should be recognized that the benefit of COVID-19 vaccine research has already been given upfront in the form of MS governmental support.[90] A different route is taken by Eli Lilly and Company, an American pharmaceutical company that has come to an agreement with the Bill & Gates Foundation to supply COVID-19 drugs to DCs without royalties.[91] It is worth pointing out that these are one-of arrangements between private operators. Until time of writing, no drug company has enjoyed the WHO COVID-19 Technology Access Pool (C-TAP) C-TAP "...encourages industry-wide contributions of IP, technologies, and data to allow global sharing and manufacturing scale-up of all COVID-19 health products".[92]

Even though there are pharma companies to grant licenses voluntarily to other drug manufacturers, this is not enough to reach global markets. It "...is particularly important for vaccines to ensure timely production of a large number of doses needed…"[93] Thus, during the writing, there are now more than 140 world leaders who have called for a COVID-19 vaccine to be made available free to everyone.[94] [95]

2.4.4. Issues relating voluntary licensing and equal distribution

What comes to distribution, if the Center for Global Development calculation will be realized, then equal access worldwide to medicines plays a crucial role. This

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[90]Financial Times;Pandemic reopens wounds on IP rights (2020) <https://www.ft.com/content/9ed5ca5e-9360-11ea-899a-f62a20d546125> accessed 22 April 2021

[91] Reuters, Eli Lilly in deal to supply COVID-19 drugs to low-income countries (2020) <https://uk.reuters.com/article/health-coronavirus-lilly-antibody/eli-lilly-in-deal-to-supply-covid-19-drugs-to-low-income-countries-idUSKBN26T26H> accessed 30 December 2020

[92] The conversation,COVID-19 drug and vaccine patents are putting profit before people (2020) <https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270> accessed 30 December 2020

[93]OECD, Treatments and a vaccine for COVID-19: The need for coordinating policies on R&D, manufacturing and access (2020) <https://www.oecd.org/coronavirus/policy-responses/treatments-and-a-vaccine-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/> accessed 5 January 2021

[94] UnAids, Uniting behind a people's vaccine against COVID-19 (2020) <https://www.unaids.org/en/resources/presscentre/featurestories/2020/may/20200514_covid19-vaccine-open-letter> accessed 5 January 2021

[95] WHO, A global pandemic requires a world effort to end it – none of us will be safe until everyone is safe (2020) <https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe> accessed 5 January 2021

means vaccine distribution race. Who gets the first vaccine, and who will be on the tail of the queue.

Will equal access to the vaccine be realized? Another problem around this is that Moderna and AstraZeneca cost and data are secret, even though all or most of their R&D is publicly financed for the MSs. How can we make sure that the distribution is fair if the availability of the information is also secret? It would be reasonable to require cost and data information sharing to be transparent.[96] For example, European Commission (EC) struggled with a transparent issue with AstraZeneca when it announced that vaccine dose delivery would be badly delayed but at the same time, the PC delivered in UK doses. The EC acted to protect its position by implementing Regulation (2021/111) which contains provisions mandating information disclosure by COVID-19 vaccine producers that have APAs with the EC, as well as establishing an export authorization scheme. The EC said its export controls are needed to tackle "the current lack of transparency"[97] over vaccine exports outside the EU, with exports made "subject to an authorisation"[98] over vaccine exports outside the EU, with exports made "subject to an authorization" by MSs. The vaccine companies will now have to seek permission before supplying doses beyond the EU, with its 27 MSs that can vet those export applications. The EU controls will impact approximately 100 countries worldwide, including the UK, the US, Canada, and Australia, though there are also 92 exemptions.[99][100]

[96] Medecins Sans Frontieres, non-governmental organization; Governments must demand pharma make all COVID-19 vaccine deals public (2021) <https://www.msf.org/governments-must-demand-all-coronavirus-covid-19-vaccine-deals-are-made-public> accessed 22 April 2021

[97] Vaccine export -Temporary transparency and authorisation (2021) <https://trade.ec.europa.eu/doclib/docs/2021/february/tradoc_159437.pdf> accessed 22 April 2021

[98] iNews: EU says priority is 'protection of our citizens' as export controls are imposed on vaccines (2021) <https://inews.co.uk/news/eu-says-priority-is-protection-of-our-citizens-as-export-controls-are-imposed-on-vaccines-851422> accessed 22 April 2021

[99] European council on foreign relations; The EU's misguided export regulation on vaccines (2021) <https://ecfr.eu/article/the-eus-misguided-export-regulation-on-vaccines/> accessed 22 April 2021

[100] United Nations Office for the Coordination of Human Affairs (OCHA) provides Relief Web; MSF: Governments must demand pharma make all COVID-19 vaccine licensing deals public(2020) <https://reliefweb.int/report/world/msf-governments-must-demand-pharma-make-all-covid-19-vaccine-licensing-deals-public> accessed 22 April 2021

2.5. Summary

The TRIPS establishes minimum standards for the protection of intellectual property rights by members of the World Trade Organization (WTO). It includes many flexibilities that allow members to define their policies and standards on various matters. Still, at times like pandemic, there appear problems even though property law in normal times works very well. The economic view of prospective innovation is costly and very risky. It must be pointed out that pharmaceutical companies invest heavily in drug development with no guarantee of success. Suppose other pharmaceutical companies could freely copy a newly discovered treatment. In that case, it can cause the scenario that inventions price would quickly fall to the marginal cost of production, which leads to the situation that the innovator cannot cover the costs of development. This is why a short-term monopoly on production granted to innovating pharmaceutical companies is needed to make the upfront investments economically worthwhile. Patents provide this protection.[101]

The TRIPS Agreement provides a patent right which is an exclusive right and prohibits others from using, selling, offering, selling, importing or making the patented invention. In addition to this patent law provides inventors even 20 years from the filing date. However, the right is a limited property right which MS gives a reward when the inventor shares for everyone his/her/ patented innovations details.[102] Thus, property rights, as normally any property rights, can be licensed. Patent licensing agreement is a contract where inventors allow the other party to use, sell, make and import and in return the inventor has some compensation. There are different kinds of patent license agreements and it depends what parties have agreed.[103] For example during the pandemic some have given patent protected COVID-19 vaccines with voluntary license for COVAX. One might ask can voluntary licenses be then available for everyone, especially during a

[101] The economist (2021) How to think about vaccines and patents in a pandemic <https://www.economist.com/finance-and-economics/2021/04/22/how-to-think-about-vaccines-and-patents-in-a-pandemic> accessed 13 May 2021

[102] OECD library, Patent Systems and Procedures (2009) <https://www.oecd-ilibrary.org/docserver/9789264056442-4-en.pdf?expires=1621850431&id=id&accname=guest&checksum=0A46F0230930E5B35B8E1DFB6EBD86B6> accessed 20 May 2021

[103] The European Union, Licensing and selling intellectual property (2021) <https://europa.eu/youreurope/business/running-business/intellectual-property/licensing-selling/index_en.htm> accessed 20 May 2021

pandemic. Future will tell this because at the time of writing the patent applications are not yet 18 months old and usually the patent is published 18 months after filing date.[104] One argues that the PCs got remuneration from some MS government in advance to create a vaccine against COVID-19 and thus, they need to make a patent available for free. But then another issue raised because getting the actual know-how is a barrier. Even MSs could access patented protected vaccines, for example how to make vaccines might be a problem. There is a new technology based on COVID-19 vaccines.[105]

After the WHO declared the COVID-19 virus a worldwide pandemic, pharmaceutical companies have started to develop a vaccine against the virus. At the same time, this has caused fear among some MSs that other MSs or companies could protect COVID-19 vaccines under patents. Many DCs resist the inclusion of an IP regime in the WTO system because they fear preventing development goals and necessary access to essential medicines. These same concerns have arisen in the past at the starting point of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and when there were issues whether they should include IP protection or not. In 1994 the TRIPS was annexed to the Agreement Establishing the World Trade Organisation (WTO).

[104]Ibid

[105] IFPMA, COVID-19 vaccine industry cautions immediate action needed to remove manufacturing supply barriers to meet production targets and keep on course to equitable and fair access to COVID-19 vaccines <https://www.ifpma.org/resource-centre/covid-19-vaccine-industry-cautions-immediate-action-needed-to-remove-manufacturing-supply-barriers-to-meet-production-targets-and-keep-on-course-to-equitable-and-fair-access-to-covid-19-vaccines/> accessed 20 May 2021

3. Compulsory licensing according to the TRIPS Agreement

3.1. Introduction

The TRIPS Agreement provides that MSs must protect innovation, and it should do so for the sake of public health. The TRIPS also gives flexibility to MSs to decide their ways on how to approach under article 28 innovations protection. However, it also says that the MS does not need to tolerate abuse of monopoly power when it affects the public interest.

When a country approves a patent, it gives the patent holder a monopoly, usually for 20 years, for new and highly inventive ideas. Article 28 of the TRIPS provides for conferring exclusive rights to patent holders, and this ensures that without the patent holders' permission, others cannot make, use, offer for sale or import a patented process or product. Article 7 of the TRIPS states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to transfer dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." The article says that it encourages innovation, and innovations give social welfare to MSs. In addition to this, article 8(1) of the TRIPS gives MSs the freedom to achieve public health so that it does not threaten their socio-economic and technological development. However, article 8(2) provides that "Appropriate measures, provided that they are consistent with the provisions of this Agreement, 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." So this article says that abuse of the power of monopoly cannot be acceptable when it affects public health interests like a pandemic.

3.2. How is compulsory license defined under the TRIPS

3.2.1. Introduction

The TRIPS Agreement Art. 31 b) initially allowed every MSs to allow patented drugs without the patent holder's consent in unlikely circumstances that could be considered a national emergency or a similar state of extreme urgency, and The TRIPS Agreements Art.31 f) says that mainly for the supply of the domestic market. However, the weakness of the feature was that those MSs that lack the domestic manufacturing capacity in the pharmaceutical sector would have great difficulties in using this flexibility. In 2001 WTO members considered these issues mentioned above in the Doha meeting and after this MSs enshrined principles in the Doha Declaration.Thus, Doha Declaration Paragraph 4 affirmed "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and this paragraph enhance better access to medicines for poor countries. The amendments included the possibility for the WTO members to import and export generic versions of patented drugs.

3.2.2. Compulsory licensing defined under TRIPS

The TRIPS Agreement allows a non-voluntary license which is more commonly defined as a compulsory license (CL). A compulsory license (CL) is under the TRIPS to check misuse of monopoly rights and to deal with situations of public health crisis.[106] A MS can allow the production of a patented medicine or the process of medicines without the patent holder's acceptance.[107] A CL is under the TRIPS Agreement in Article 31, and it has been phrased as "other use without authorization of the right holder." So, the term "compulsory licensing" does not appear in the TRIPS Agreement, it is only part of this since "other use" includes use by MSs for their own purposes. The CL for medicines is defined by WTO: "Compulsory licensing is when MS allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."[108] In addition to this, according to Article 70

[106] Voluntary Licensing of Pharmaceuticals: The Strategy Against Compulsory Licensing p.76 <https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1111&context=ipbrief> accessed 11 May 2021

[107]WTO, obligations and exceptions <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#compulsorylicensing> accessed 20 May 2021

[108]Compulsory licensing of pharmaceuticals and TRIPS <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 29 April 2021

paragraph 4 the MS must remunerate innovators when it uses innovations like vaccine patents. The CL option has existed before the TRIPS, and it has been before the official ratification of the WTO agreement, most countries had the option to CL a patent. Article 31 provides certain provisions of how the MS can grant a CL for the patent. According to Article 31 paragraph f), it must be granted mainly to supply the domestic market. In addition to this, article 31 permits the practice of MSs to engage in compulsory licensing if there is a "case of a national emergency or other circumstances of extreme urgency" or in cases of "public non-commercial use."

3.3. Compulsory licensing and Doha Declaration

3.3.1. Introduction

After the TRIPS Agreement entered into force as a part of the WTO in 1995, its MSs soon recognized that the agreement had gaps between patent protection and life-saving drugs in DCs. The South Africa case was important because it led to a worldwide dialogue on how IPR can negatively affect regarding public health and later on culminated in the Doha declaration on the TRIPS and *Public Health.* Later on 14 November 2001, The TRIPS Agreement adopted the Doha Declaration. For the first time, because of the declaration, health and development were handled in WTO governance and at the same time declaration was a victory for DCs because in the declaration, finally, the public health issues can take precedence over the IPR.[109] In 2001, The Doha Declaration on the TRIPS Agreement and Public Health was adopted to clarify ambiguities between the need for MSs to apply the principles of public health and the terms of the TRIPS. With this declaration the MS are able to provide a compulsory grant to export patented generic versions of the medicine to countries that have insufficient manufacturing capabilities of their own.[110] Although there have been several improvements regarding the agreement, DCs have stated that there are still gaps and the most considerable harm shown during the pandemic.[111]

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[109] WTO, Doha Work programme; Ministerial Declaration (2005) <https://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#public_health> accessed 10 May 2021

[110] International journal for legal research&analysis(2020) COMPULSORY LICENSING, PUBLIC HEALTH AND ACCESS TO MEDICINES AMID COVID -19 <https://ijlra.com/wp-content/uploads/2020/12/Volume-1-Issue-7-Aisha-Bilal.pdf> accessed 24 May 2021

[111] WTO,Trade finance, gaps and the covid-19 pandemic: a review of events and policy responses to date

3.3.2. Compulsory licensing and Doha Declaration

A CL is neither novel nor radical, since 1994, scores of such licenses have been granted worldwide. The first time the CL came to a discussion in the 1990s when Human Immunodeficiency Virus (HIV) and Acquired Immune Deficiency Syndrome (AIDS) came, especially in Africa. It was a global problem about public health. A CL is under the TRIPS Agreement in Article 31, and it has been phrased as "other use without authorization of the right holder."

In 1995 WTO came into effect but at the same time also the emergency of HIV and AIDS. During that time, DCs could manufacture medicines, but they could not access medicines if they did not break patent rules. In other words, DVPC could not afford to buy patents to manufacture the medicines. Instead of buying patents, for example, South Africa's government used a CL in a matter of emergency. Using a CL means that the MS pays a lower sum for the inventor. From the company's perspective, it must pay for a drug patent much cheaper. The background of CL comes from the human rights aspects: how can we ensure human rights in all cases.[112] The first time in WTO, the CL came to a discussion in the 1990s when HIV and AIDS came, especially in Africa, even though it was a global problem about public health.[113][114] There was a case when the US pharmaceutical industry sued Nelson Mandela and the South-Africa government to try to prevent CL, *High Court of South Africa (Transvaal Provincial Division)* Case No. 4183/98[115]. Because of civil society pressure, the US did not bring further a WTO case against South Africa. Later, MSs came together and made the 2001 Doha Declaration. This affects that MSs can decide when it is an emergency, and after that, they can grant CLs.[116] For MSs to use CL for COVID-19 and related purposes, it needs to have its own domestic law procedures to authorize such kind of government actions. The Doha Declaration clause 5 again affirmed

<https://www.wto.org/english/res_e/reser_e/ersd202105_e.htm> accessed 10 May 2021

[112] M. Z. Abbas, "Pros and Cons of Compulsory Licensing: An Analysis of Arguments", International Journal of Social Science and Humanity, Vol. 3, No. 3 (2013)

[113] R. Bird and D. R. Cahoy, "The Impact of compulsory licensing on foreign direct investment: a collective bargaining approach," American Business Law Journal, vol. 45, no. 2, et. seq. 286, 2008.

[114] WTO,Compulsory licensing of pharmaceuticals and TRIPS <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 29 April 2021

[115]*Pharm. Mfrs.' Ass'n of S. Afr. v. President of the Republic of S. Afr.*, [1998]Case no. 4183/98, *High Court of South Africa (Transvaal Provincial Division)*[1998]

[116]Prof. William W. Fisher III Dr. Cyrill P. Rigamonti ,The South Africa AIDS Controversy A Case Study in Patent Law and Policy (2005) <https://core.ac.uk/download/pdf/33087557.pdf> accessed 12 May 2021

that “each WTO member has the right to grant CLs and the freedom to determine on which grounds upon which such licenses are granted.” Also, Clause 5(c) clarified that: “public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics,” can constitute “a national emergency or other circumstances of extreme urgency.” [117]

The TRIPS Agreement has not formally defined the exact meaning of the term “flexible”. The TRIPS Agreement makes only limited use of the term. The term became part of the TRIPS system at the conclusion of The Doha Declaration negotiations. However, the term "flexibility" is explicitly pointed out here in relation to the specific requirements of the least DVPC to establish a sound and workable technological base.[118] The Doha Declaration establishes “the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility” to protect public health. The Declaration also lists a number of flexibilities related to a CL and exhaustion. The final decision on the choice of legislative options rests with each individual MS, but they may, if necessary, seek the assistance of WIPO on how to exercise jurisdiction in their own country. Patents give patent holders exclusive rights to manufacture, sell and import a product, leading to overpricing of patented products and this leads to the situation that some countries do not have affordable access to medicines. Moreover, this causes side effects patents need to be violated to make generic copies of the needed drugs. For example piracy can ensure access to needed goods and services for a low price, and the local counterfeit industry provides jobs to the residents.[119] At the same time, it must be acknowledged that, especially now in COVI-19, we need Intellectual property (IP) in particular that all efforts are placed by the inventors to create vaccines and IP gives this encouragement.[120] Many DCs tend to avoid using CL even though they could reduce prices of medicines this way.

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[117] The case for compulsory licensing during COVID-19 (2020) Hillary Wong <http://www.jogh.org/documents/issue202001/jogh-10-010358.pdf> accessed 24 May 2021

[118] WTO, Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade, 2nd edition: <https://www.wto.org/english/res_e/booksp_e/who-wipo-wto_2020_e/chapter_2_who-wipo-wto_2020_e.pdf#page=59> accessed 27 April 2021

[119] Pros and Cons of Compulsory Licensing: An Analysis of Arguments Muhammad Zaheer Abbas <http://www.ijssh.org/papers/239-D00013.pdf> accessed 14 April 2021

[120] Why Intellectual Property Protection Matters in the Time of Coronavirus <https://www.theglobalipcenter.com/why-intellectual-property-protection-matters-in-the-time-of-coronavirus/> accessed 16 April 2021

Some MSs are bound by restrictions in bilateral relations, like, for example, free-trade agreements with provisions limiting the use of compulsory licenses. However, most DCs avoid CL because they fear trade retaliation. Also, they avoid CL because using CL might seem very complicated and time-consuming. MSs should take a legal and legislative step to establish a framework for using CLs in time when it is necessary.[121] In addition to this, during a pandemic, Bolivia has applied a compulsory license to Canadian PC Johnson & Johnson to use patent-protected vaccines. However, it can take a long time; amending the Canadian Patent Act can take even 15 months.[122]

3.4. On what basis can a compulsory license be used?

3.4.1. Introduction

The main rule is to protect patents, but under the TRIPS Agreement one of the flexibility is the CL. This flexibility has been since the TRIPS Agreement took effect 1995. In 2001 WTO clarified TRIPS Agreements flexibilities for MSs with Doha Ministerial Declaration on TRIPS and Public Health. That MS could have a possibility to grant CL, but they must meet some criterias.

3.4.2. Conditions which TRIPS allow to use CL

The TRIPS Agreement does not say specific grounds for justifying CL. However, Art 31 mentions national emergencies, other circumstances of extreme urgency and anti-competitive practices. A COVID-19 pandemic can be considered to fulfil the requirements mentioned above. In addition to this, to grant CL MS should meet certain criterias as well as. The first CL must be taken for a public purpose and this criteria is under TRIPS Agreement 31 f). The second criteria is that CL must accept on a non-discriminatory basis and this criteria is under TRIPS Agreement art. 4 d). The third criteria, the MS must pay adequate remuneration for patent holders under TRIPS Agreement Art. 31 h).

[121]The case of compulsory licensing during COVID-19. HIllar Wong (2020) <http://www.jogh.org/documents/issue202001/jogh-10-010358.pdf> accessed 24 May 2021

[122]GlobalNews, Bolivia signs deal to import J&J vaccine from Canadian company, pending patent issue <https://globalnews.ca/news/7851500/bolivia-biolyse-covid-19-vaccine-patent-johnson-and-johnson/> accessed 24 May 2021

3.5. Issues relating compulsory licensing

3.5.1. Introduction

Especially in the current situation where voluntary license does not give a proper solution, some countries have made APAs and estimated time to get vaccines worldwide is 2033. In addition to this DCs cannot afford high price medicine can be seen as restricting DCs to access vaccines. There is an urgent need to find balance for the right to have a healthy and safe life and the individual monopoly on IPRs. One solution could be a compulsory license.

3.5.2. Barriers relating compulsory license

To ensure vaccines for all MSs, compulsory license can be one solution. However, there can be some barriers. Most patent inventors have benefited from public money to invent vaccines, but still CLs are not royalty free licenses. The MS must pay a reasonable royalty to the patent holder, by TRIPS MS can consider the sum of compensation the TRIPS Agreement says "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization", and it does not define "adequate remuneration" or "economic value". Some might see this as an unfair situation. Another barrier is that vaccines have new technology and the know-how transfer can be complicated. Thus, the crucial question would be, does the patents contain all the necessary information that DCs could manufacture vaccines. At the time of writing patents have not been published yet. Patents are usually published 18 months after an inventor filing a patent application. Also, CLs have not been used in general so much and it is not so familiar for all countries.[123] MSs should review their ability to use their CL powers so that they could have practically effective CL powers ready if they need to use them.[124] Other issues can be raised that the inventor may not receive a reasonable benefit when CL is in use and it may create uncertainty about whether the use of CL threatens future inventions or product

[123] Trends in compulsory licensing of pharmaceuticals since the Doha Declaration: a database analysis (2012) <https://pubmed.ncbi.nlm.nih.gov/22253577/> accessed 29 April 2021

[124] Medicines law policy (2020) Never say never – Why the High Income Countries that opted-out from the Art. 31bis WTO TRIPS system must urgently reconsider their decision in the face of the Covid-19 pandemic<https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/> accessed 13 may 2021

development.[125] DCs may need to be creative in invoking other provisions of the TRIPS that could ensure affordable medicines for their citizens. Patent know-how transfer can be complicated and the crucial question would be, does the patents contain all the necessary information that DCs could manufacture vaccines. At the time of writing patents have not been published yet. On one hand by using this CL MS can protect human rights and health. Also, DC considerations about access drugs for hard patent law can be somehow solved.[126][127] On the other hand CL can offend inventors exclusive rights. In addition to the known practical problems in producing and distributing a vaccine of this kind in such a short notice, there are also issues that relate to the lack of administrative maturity of the beneficiary MS in question. This in particular holds true in relation to the use of the CL where the issues include the lack of existing legal framework around the use of non-voluntary license.

3.6. Summary

Before Doha Declaration TRIPS Art 31 f) said that a compulsory license can be used mostly to supply the domestic markets and the Doha Declaration and Public Health after in 2001 did not make big changes on the rules. However, two changes happened. First, if the country does not have production capacity, they can obtain cheaper copies produced elsewhere. Second, changes gaved a possibility to MS to export to one or more countries vaccines, but first ms need to amend its laws that such production is permissible under compulsory license. DCs can delay to provide a patent protection until January 2033. Thus, DCs does not have to issue a compulsory license to import vaccines, it needs to make a compulsory license for the supplying country.[128] TRIPS does not determine the reason when MS can use compulsory license. Also, the implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health gives a power for MS to determine the grounds for granting CL and also determine what means a national

[125] M. Z. Abbas, “Pros and Cons of Compulsory Licensing: An Analysis of Arguments”, International Journal of Social Science and Humanity, Vol. 3, No. 3 (2013)

[126] BBC news (2020) <https://www.bbc.com/news/world-55325450> accessed 29 April 2021

[127] R. P. Rozek, “The effects of compulsory licensing on innovation and access to health care,” Journal of World Intellectual Property, vol. 3, no. 6, et.seq. 897.

[128] WTO,Compulsory licenseing of pharmaceuticals and TRIPS <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 20 May 2021

emergency.[129] All MSs are allowed to use a compulsory license for the purpose of local manufacturing or import under as TRIPS art. 31 provides. The TRIPS Agreements 31 bis provides addition to compulsory licences if to produce medicines for exporting.[130]

At the time of the pandemic, the importance of innovations has emphasized and it has been a big victory for society that COVID-19 vaccines has created in record time. The current pandemic time has shown that only with vaccines we can tackle COVID-19 and thus, CL can offend inventors exclusive rights. However, there is a need to find balance between human right health and individual monopoly IPR. To access lifesaving medicines must be a fundamental right and thus human right to have a healthy and safe life. There is an urgent need to find balance for the right to have a healthy and safe life and the individual monopoly on IPRs. One solution could be a compulsory license. A compulsory license is an economical way to manufacture reasonably priced medicines and patent holders could have reasonable remuneration by using their patent. However, after granting a compulsory license there can be some barriers. One barrier might be that DC must still pay an adequate remuneration for inventions even though most inventors have benefited from public money in advantage. Another issue is that some vaccines are new technology and know-how transfer can be an obstacle even if DC could access patents via CL. And finally, MSs should review their ability to use their CL powers so that they could have practically effective CL powers ready if they need to use them. However, in 2021 India had granted a CL by Bayer which helped to access drugs for liver and kidney cancer.[131] This case states that India's Patent Act can provide a CL patented medicines when it comes to a national emergency and the drugs use is a public non-commercial.[132]

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[129]WHO,WTOdesicion on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health <https://www.who.int/medicines/areas/policy/wto_impl_para6/en/> accessed 24 May 2021

[130] WTO,Compulsory licenseing of pharmaceuticals and TRIPS <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 20 May 2021

[131] Application for compulsory license No. 1 2011 <http://www.gnaipr.com/CaseLaws/Controller%20Order%20-%2012032012.pdf> accessed 20 May 2021

[132] The Wire, Shambhavi Sinha (2021) <https://thewire.in/health/india-patent-law-compulsory-licenses-covid-19-vaccines> accessed 20 May 2021

4. The proposed waiver

4.1. Introduction

In October 2020 at the first state India and South Africa proposed a temporary waiver (IP/C669) from specific provisions of the TRIPS Agreement contrary to a CL, the waiver asks that MSs be exempt from the provision of the TRIPS that require MSs to access without no remuneration to all medical drugs and equipments until the pandemic is over. Thus, the proposed waiver concerns the role of intellectual property during the pandemic. DVPC strongly resists while DCs supports the proposal. The question that MSs are arguing with the waiver is that does the current TRIPS flexibilities not give enough possibilities to access COVID-19 vaccines and is the IP an obstacle to manufacturing and access to vaccines? Or whether the TRIPS Agreement already provides enough different flexibility to access COVID-19 vaccines, and the problems are somewhere else?

4.2. Legal basis and process

4.2.1. Introduction

In normal times, the decision making regarding a waiver is decided by consensus, however, it is important to note that during exceptional times such as the one we are enduring as of writing, it is possible to adopt the use of a waiver if a minimum of three quarters of WTO MSs adopt the waiver.[133] John Zarocostas [134]

4.2.2. Legal basis and process

An Article IX.3 of the Marrakesh Agreement establishing the WTO provides that in “exceptional circumstances”, the Ministerial Conference may waive an obligation imposed on a WTO member country by the WTO Agreement or any

[133] Simon Lester, Bryan Mercurio and Arwel Davies,World Trade Law, Third edition(2018) pp.74-83

[134] John Zarocostas, What next for a COVID-19 intellectual property waiver? The Lancet, (2021) <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)01151-X/fulltext> accessed 22 May 2021

other multilateral trade agreement.[135] At the same time it provides that a waiver must first try to decide by consensus. If there is no possibility to reach a consensus, then the matter must be decided by the three-quarters majority Decision Making Procedures under Article IX and XII of the WTO Agreement.[136] Article IX.3 (b) says that "A request for a waiver concerning the Multilateral Trade Agreements in Annexes 1A or 1B or 1C and their annexes shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or the Council for TRIPS, respectively, for consideration during a time-period which shall not exceed 90 days. At the end of the time-period, the relevant Council shall submit a report to the Ministerial Conference."[137] The article says that if a wave concerns Annexes above, then the request correspondingly should be first submitted to the Council for Trade in Goods, Council for Trade in Services, and Council for TRIPS.[138]

The TRIPS Council has jurisdiction to handle the waiver under the TRIPS Agreement. In addition to this, Article IX.4 of the WTO Agreement states that granting the waiver should state the "exceptional circumstances" justifying the decision and the terms and conditions that shall govern the working of the waiver, and the waiver should have an end date. Current waiver has stated a time until the pandemic is over. In the WTO Agreement, there has not been a defined term "exceptional circumstances." However, articles IX.3 and IX.4 recognize that there may be certain demanding situations causing hardship to MS, and compliance with the WTO norms is impossible.[139] There is, for example, a decision in *case WT/L/540 in* 2003 the WTO system provided a collective waiver. In this case, was the need to implement the Doha Declaration Paragraph 6 on the TRIPS Agreement and Public Health to find a rapid solution to help DCs because they did not have the manufacturing capacity for medicines and the General Council

[135] Isabel Feichtner, The Waiver Power of the WTO: Opening the WTO for Political Deliberation on the Reconciliation of Public Interests (2008) <https://jeanmonnetprogram.org/wp-content/uploads/2014/12/081101.pdf> accessed 9 May 2021

[136] WTO,DECISION-MAKING PROCEDURES UNDER ARTICLES IX AND XII OF THE WTO AGREEMENT<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/93.pdf&Open=True > accessed 24 May 2021

[137] Marrakesh Agreement <https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleXI> accessed 9 May 2021

[138] World Trade Law,Simon Lester, Bryan Mercurio and Arwel Davies, third edition (2018) et. seq.83-84

[139] World Trade Law,third edition, Simon Lester, Bryan Mercurio and Arwel Davies (2018) ISBN:9781509915989 et.seq.82

waived the obligations contained in Article 31 f) and article 31 h) of the TRIPS Agreement.[140] The current COVID-19 pandemic materialized the term "exceptional circumstances" under the WTO Agreements article IX.3 and article IX.4 terms. Decisions determining on a waiver, applying to one MSs, require a three‑fourths majority. This has been specified in the WTO Agreement, Article IX.3. Note 4 to the Agreement Establishing the WTO specifies that if a MS requests an extension of its transition period with less obligations imposed, the decision must be taken by consensus. A request for a waiver "shall be submitted initially to the Council for Trade in Goods, the Council for Trade in Services or the Council for TRIPS, respectively, for consideration during a time period which shall not exceed 90 days."[141] The most critical issues are decided jointly by the MSs. The ministers themselves or their ambassadors or delegations are involved in the decision-making itself.[142] Consensus-based decision-making is inherited from GATT times, as we handle it in chapter 2.5 WTO decision making process, but the WTO agreement also allows voting if consensus is not possible. In the vote, each MS shall have one vote.[143] Waiver decisions constitute acts of secondary law that are binding on all WTO members, but it also binds all dispute settlement organs too. The waiver power provides a possibility of political debate, and this result can lead to a legally binding decision.[144] The WTO members have already had eight different meetings about the waiver, but they have not agreed yet. For the waiver to be accepted, it needs 164 MSs to accept, proposals need backing by a consensus of the WTO's MSs to pass. The next TRIPS Council meeting is on June 8-9.[145]

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[140] General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision, WT/L/540 (WTO, 30 August, 2003).

[141] WTO Agreement -Article IX
<https://www.wto.org/english/res_e/publications_e/ai17_e/wto_agree_art9_oth.pdf >

[142] WTO, Understanding the WTO:The Organization
<https://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm> accessed 14 May 2021

[143] World Trade Law Text, materials and Commentary, third edition, 2018, Simon Lester, Bryan Mercurio and Arwel Davies. et.seq. 74-76

[144] Isabel Feichtner (2009) The Waiver Power of the WTO: Opening the WTO for Political Debate on the Reconciliation of Competing Interests, European Journal of International Law, Volume 20, Issue 3, pp.633, https://doi.org/10.1093/ejil/chp039

[145] WTO, Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic
<https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm> accessed 20 May 2021

4.3. The waiver

4.3.1. Introduction

In this chapter it describes the open possible legal instrument the waiver and handles pros and cons. In addition to this, argues that current TRIPS flexibility such as CL is already enough to access life saving medicine such as COVID-19 vaccines. Also, race the question: is the waiver necessary? And conclude that waiver might underlying much wider issues than IP.

4.3.2. The waiver

At the time of writing South Africas and India's proposals have been submitted for 60 WTO MS. [146] For example Kenya, Eswatini, Mozambique, Pakistan, Bolivia, Venezuela, Mongolia, Zimbabwe, Egypt, the African Group, DCs, and most recently Maldives, Fiji and Namibia have supported this.[147]

If the proposal could be accepted, the proposal would allow MSs to waive "implementation, application, and enforcement" of IPR related to the "prevention, containment, or treatment of COVID-19". Such a change would effectively allow MSs to freely use COVID-19 related patents without obtaining a CL or ever paying the patent owner. However, this proposal would be only temporary. This means that the implementation of waiver would be until the majority of the hoal population has developed herd immunity or the whole population has a possibility of widespread vaccination.[148] Contrary to CL, IP waivers ask that countries be exempt from the TRIPS provisions that require countries to protect and also enforce patent rights to COVID-19 vaccines and other treatments. However, this proposal was met with strong resistance from DVPC while DCs were accepting it. The proposal failed to pass a resolution at the WTO in March 2021.

The MSs have been divided with their opinions about the impact of IP protection in ensuring fast and safe access to COVID-19 vaccine and other medical products. Some MSs view is that current pandemic issues cannot tackle current regulations,

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[146] WTO, TRIPS Council to continue to discuss temporary IP waiver, revised proposal expected in May (30 April 2021) <https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm> accessed 4 May 2021

[147]WTO, general council ;DG Okonjo-Iweala underlines urgent need to address equitable access to vaccines 5 May 2021 <https://www.wto.org/english/news_e/news21_e/gc_05may21_e.htm > accessed 4 May 2021

[148] WHO, COVID and what is a herd immunity? <https://www.who.int/news-room/q-a-detail/herd-immunity-lockdowns-and-covid-19?gclid=Cj0KCQjwwLKFBhDPARIsAPzPi-J-lCzuXeVjdwGYxKL6Cy4LQ1ZT0oFDjqJxjo-5E95DcYy1pQc_nokaAvhAEALw_wcB# > accessed 24 May 2021

thus the only way is to by waiving certain TRIPS obligations. However, the majority of MSs view is that it is necessary to waive at the international level. Some countries have even added concerns that waive could be harmful and diminish current co-operations efforts which have been successfully made. The chair commented that "without a minimum of common understanding of the nature of the challenge, it is difficult to see how a consensual approach to the waiver request could be established."[149] A Director-General at the WTO Ngozi Okonjo-Iweala in 21 May 2021 general meeting with G20 leaders and the heads of international organizations said, that MSs addition the waiver from WTO IP rules for vaccines and other pandemic-related medicines "must address issues related to technology transfer, knowhow and intellectual property."[150]

4.3.3. Which kind of problems the wave might face of and is the waive a viable alternative

Difference between the waiver and compulsory licensing is that the waiver calls for certain provisions of the TRIPS Agreement in relation to the "prevention, containment or treatment"[151] of pandemic. The purpose of a waiver is to eliminate the barriers for the benefit of timely access to affordable medicines, vaccines or other essential medical products.[152] In addition to this, all concerned IP rights would be freely accessed instead of a compulsory licensing would give inventors a reasonable compensation by the MS. So, the waiver IP right scale is very wide and patent holders could not have any compensation during temporary pandemic time. Addition to this, if we take a look COVID-19 vaccines accessibility and compare these two different options the waive and the compulsory licensing, do they differ from each other in IP perspective? Because at the moment TRIPS Agreements 31 provide for compulsory licensing for vaccines for domestic use. In addition to this 31bis provides the possibility to access patented vaccines for those countries who do not have their own manufacturing capacity, and thus allows exports to countries of vaccines. Does the published patent application

[149]WTO, TRIPS Council to continue to discuss temporary IP waiver, revised proposal expected in May <https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm> accessed 4 May 2021

[150] WTO, Director-general Ngozi Okonzi Okonjo-Iweala (21May 2021) <https://www.wto.org/english/news_e/news21_e/dgno_21may21_e.htm > access 21 May 2021

[151] IP/C/W/669 (2020) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True >

[152] WTO, (2021)TRIPS Council to continue to discuss temporary IP waiver, revised proposal expected in May <https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm > accessed 30 April 2021

include all necessary information that all MS could manufacture medicines. In addition to this, at the moment there is unused capacity which could manufacture vaccines as in the previous chapter Compulsory licensing summary section discussed. And the TRIPS Council should discuss that these could be used.

4.4. Summary

The waiver is an important call for the time of pandemic. It offers MSs like Dr Christos Christou, MSF International President[153] has said "opportunities to take action for better collaboration in development, production and supply of COVID medical tools without being restricted by private industry's interests and actions, and crucially would give MSs all available tools to ensure global access."[154] The waiver would be an effective way to end COVID-19 pandemic.[155] It would allow MSs to suspend the protection of IP for COVID-19 products during the pandemic. It tries to give help to fight against the pandemic by taking away any potential IP barriers. But the decision is open with the role of IP amid pandemic and discussions continue and the next regular meeting of the WTO´s Council is 8-9 June 2021.[156] However, MSs have an alternative possibility to use a compulsory license.

Difference between the waiver and compulsory licensing is that the waiver calls for certain provisions of the TRIPS Agreement in relation to the "prevention, containment or treatment"[157] of pandemic. The purpose of a waiver is to eliminate the barriers for the benefit of timely access to affordable medicines, vaccines or other essential medical products.[158] In addition to this, all concerned IP rights

[153]*MFS is an international, independent medical humanitarian organisation who provide medical assistance to people affected by conflict, epidemics, disasters, or exclusion from healthcare. More; an international, independent medical humanitarian organisation <https://www.msf.org/ > access 24 may 2021

[154]Medicins sans frontieres, Countries obstructing COVID-19 patent waiver must allow negotiations to start (2021) <https://www.msf.org/countries-obstructing-covid-19-patent-waiver-must-allow-negotiations> accessed 23 May 2021

[155] SQUIRE Patton Boggs, (2021) When Compulsory licenses Apparently Just Won´t Do: The US Backs Waiver of Rights to IP Relating to COVID-19 <https://www.iptechblog.com/2021/05/when-compulsory-licenses-apparently-just-wont-do-the-us-backs-waiver-of-rights-to-ip-relating-to-covid-19/> accessed 6 May 2021

[156]WTO, Members discussion TRIPS waiver request, exchange views on IP role amid a pandemic <https://www.wto.org/english/news_e/news21_e/trip_23feb21_e.htm> accessed 23 May 2021

[157] IP/C/W/669 (2020) <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True >

[158] WTO, (2021)TRIPS Council to continue to discuss temporary IP waiver, revised proposal expected in May <https://www.wto.org/english/news_e/news21_e/trip_30apr21_e.htm > accessed 30 April 2021

would be freely accessed instead of a compulsory licensing would give inventors a reasonable compensation by the MS. So, the waiver IP right scale is very wide and patent holders could not have any compensation during temporary pandemic time. Addition to this, if we take a look COVID-19 vaccines accessibility and compare these two different options the waive and the compulsory licensing, do they differ from each other in IP perspective? Because at the moment TRIPS Agreements 31 provide for compulsory licensing for vaccines for domestic use. In addition to this 31bis provides possibility to acce patented vaccines for those countries who does not have own manufacturing capacity, and thus allows exports to countries vaccines. Does the published patent application include all necessary information that all MS could manufacture medicines. In addition to this, at the moment there is unused capacity which could manufacture vaccines as in the previous chapter Compulsory licensing summary section discussed. And the TRIPS Council should discuss that these could be used. There are many open questions around the waiver. At the moment the waiver has not answered three different questions, which rights are coming to waived; for which purpose these can be used and lastly, what really is a timeframe. Some have said that the waiver is not about COVID-19 pandemic at all, it is against IPR. And this is continuous at the time of the doha declaration discussion time. DCs are trying as possible to access IP protected medicines.[159] For example Bolivia tries to have a compulsory license to Canada so that they could manufacture Johnsons & Johnsons COVID-19 vaccines. [160]

The waiver does not precisely handle future IP problems, but it can be a sign of conflicts more than just conflict between TRIPS IP and public health. It can be an expression of underlying conflicts of interests. While the research has ended the question, is the DCs IP waive about pandemic or is the waiver something more?[161] Perhaps, DCs want to raise the IP issues as in the starting point 1994 when TRIPS

[159]Global news, Bolivia signs deal to import J&J vaccine from Canadian company, pending patent issues (2021) <https://globalnews.ca/news/7851500/bolivia-biolyse-covid-19-vaccine-patent-johnson-and-johnson/> accessed 25 May 2021

[160]CISION (2021) Bolivia and Biolyse sign landmark agreement for export of COVID-19 vaccines <https://www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmark-agreement-for-export-of-covid-19-vaccines-832670191.html> accessed 25 May 2021

[161]Daniel Gervais, The TRIPS Agreement, Drafting History and Analysis, 5th edition (2021) <https://www.sweetandmaxwell.co.uk/Product/Intellectual-Property/TRIPS-Agreement-The/Hardback/30804050 > accessed 20 May 2021

was annexed to the Agreement Establishing the WTO. Many DCs resisted it because they were afraid that this might obstruct access to important goods like essential drugs.[162] Maybe the waiver is about more than just COVID-19 vaccines, maybe something else and wider issues.

[162]WHO, Using TRIPS flexibilities to facilitate access to medicines <https://www.who.int/bulletin/volumes/91/7/12-115865/en/> accessed 20 May 2021

5. Conclusion

Countries around the world have the common goal to end COVID-19 and the most effective way is to vaccinate people as fast as possible. This means that we must be increasing the production of vaccines and also ensuring equitable access globally. Voluntary options like COVAX which aim is to accelerate the development and production of vaccines are shown to be not enough on the scale that is required. While some countries have the manufacturing capability, they cannot use the TRIPS flexibilities like a CL. The same possibility cannot be used if the countries suffer the lack of capacity, especially DCs like South Africa.[163] In addition to this, if IP would be waived for everyone, it does not solve all the problems.[164] In contrast to all the potential benefits in the transfer of the knowledge and know-how of the vaccines under patents, there can be great risks involved as well. The notable risks include the uncertainty in the production of such vaccines which require very high level technological skill and existing infrastructure in order to produce the product safely as well as with the expected effect. There is a risk that the good will and the public health interest may very well backfire. In addition to the known practical problems in producing and distributing a vaccine of this kind in such a short notice, there are also issues that relate to the lack of administrative maturity of the beneficiary MS in question. This in particular holds true in relation to the use of the waiver where the issues include the lack of existing legal framework around the use of non-voluntary license. One of the distinctive differences between the two flexibilities, the CL, and the Waiver, is the difference in compensation for the patent holder.

[163]Devex (2021) Is COVAX part of the problem or the solution? <https://www.devex.com/news/is-covax-part-of-the-problem-or-the-solution-99334> accessed 16 May 2021
[164]Health Policy Watch, Independent Global Health Reporting (2021) Sustainable COVAX Vaccine Funding and Voluntary Manufacturing Licenses are Better Solutions than IP Waiver, Says IFPMA Head <https://healthpolicy-watch.news/sustainable-covax-funding-voluntary-manufacturing-alliances-are-better-solutions-than-ip-waiver-pharma-industry-leader/> accessed 6 May 2021

In terms of CL, while being a non-voluntary measure, the patent holder still is compensated for the use of the licenses in question. On the other hand, when the patents are waived, the patent holders are in a difficult position in receiving any compensation for the use of their licenses. A notable aspect of the Waiver is the fact that once one COVID-19 patent is waived, the waiver also applies to all other medicines for the time of the crisis. One of the distinctive differences between the two flexibilities, the CL and the waiver, is the difference in compensation for the patent holder. In terms of CL, while being a non-voluntary measure, the patent holder still is compensated for the use of the license.[165] However, PCs have received public money and public grants for their advantage in the development of COVID-19 vaccines. Thus PCs should make the patents available for everyone. Thus it is legitimated that everyone should benefit from the result of the research.[166] On the other hand now more than ever we need to encourage inventors to invent vaccines especially if there are further mutations of COVID-19 to appear.[167] As WHO has said; no one is safe until everyone is safe.[168] The TRIPS waiver could be an important step forward to tackle COVID-19, but in addition to this MS globally should cooperate more so that we could tackle the pandemic.

DCs argues that patents obstruct reasonably priced COVID-19 medical products. A temporary waiver could help to start manufacturing vaccines sooner and more manufacturing capacity could be used worldwide.[169] However, there are no legal obstacles in using TRIPS flexibilities such as CL. TRIPS Articles 31 and 31bis provide the possibility to use CL. Art. 31 gives a possibility to use CL if MS has a

[165]The conversation (2021) How to get COVID-19 vaccines to poor countries-and still keep patent bevefits for drugmakers
<https://theconversation.com/how-to-get-covid-19-vaccines-to-poor-countries-and-still-keep-patent-benefits-for-drugmakers-158384> accessed 16 May 2021
[166]Forbes (2020) The People´s Vaccine-Moderna´s Coronavirus Vaccine Was Largely Funded By Taxpayer Dollars
<https://www.forbes.com/sites/judystone/2020/12/03/the-peoples-vaccine-modernas-coronavirus-vaccine-was-largely-funded-by-taxpayer-dollars/?sh=3a5587446303> accessed 16 May 2021
[167]The global innovation policy center, Why Intellectual Property Protection Matters in the Time of Coronavirus
<https://www.theglobalipcenter.com/why-intellectual-property-protection-matters-in-the-time-of-coronaviru> accessed 16 May 2021
[168]WHO, (2020) A global pandemic requires a world effort to end it – none of us will be safe until everyone is safe
<https://www.who.int/news-room/commentaries/detail/a-global-pandemic-requires-a-world-effort-to-end-it-none-of-us-will-be-safe-until-everyone-is-safe> accessed 14 May 2021
[169]IP/C/W/669<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>

domestic manufacturing capacity and the use is mainly domestic use. Art. 31bis allows the export of vaccines for those countries who do not have manufacturing capacities. The risk is that the use of CL and accessing COVID-19 vaccines may take longer than expected because of the possible lack of existing legal framework within the MS government. Also, many cases in WTO jurisprudence have interpreted WTO rules flexibly[170] when public health measures like for example in *Australia-Tobacco Plain Packaging* (DS435)[171]case and *EC-Asbestos (*DS135)[172] case. On the other hand, John-Arne Røttingen, who chairs the WHO Solidarity Trial of COVID-19 treatments pointed out that the waiver might not solve the problem, because COVID-19 vaccines include new tech and the transfer of know-how is a more relevant obstacle.[173] The same problem might be faced with the CL option, this can be a solution only for those countries who have the know-how (presume that they have manufacturing capacity). Patent applications have not been published yet, patents published 18 months after filling date.[174] However, Modernas former director of chemistry Suhaib Siddiqi stated that modern factories could start new manufacturing in three to four months when they access the technical advice.[175] With CL the patent holder can have remuneration, the waiver does to include such. Conclusion in this research is that the waiver cannot achieve any additional benefit compared to CL.

During the analysis, further questions have risen: Is the DCs motivation in utilising the IP waiver about the pandemic or are there other reasons to push for the waiver as well?[176] Perhaps, DCs want to raise the IP issues as in the starting point 1994 when TRIPS was annexed to the Agreement Establishing the WTO.

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[170]*Honduras v AustraliaAustralia* [2012] Case no. DS435, *Tobacco Plain Packaging* [2020]

[171]WTO,Declaration on the TRIPS Agreemetn and public health <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 20 May 2021

[172] *Canada v European Communities* [1998] Case no. DS135, *EC-Asbestos* [2001]

[173]The Lancet, Ann Danaiya Usher (2020) South Africa and India push for COVID-19 patent ban <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext > accessed 20 May 2021

[174]OECD, <https://www.oecd.org/coronavirus/policy-responses/access-to-covid-19-vaccines-global-approaches-in-a-global-crisis-c6a18370/ > access 20 May 2021

[175]AP, Countries urge drug companies to share vaccine know-how (2021) Maria Cheng and Lori Hinnant <https://apnews.com/article/drug-companies-called-share-vaccine-info-22d92afbc3ea9ed519be007f8887bcf> access 20 May 2021

[176]Daniel Gervais, The TRIPS Agreement, Drafting History and Analysis, 5th edition (2021) <https://www.sweetandmaxwell.co.uk/Product/Intellectual-Property/TRIPS-Agreement-The/Hardback/30804050 > accessed 20 May 2021

Many DCs resisted it because they were afraid that this might obstruct access to important goods like essential drugs.[177] The push for the waiver may hold alternative agendas past the COVID-19 vaccines.

[177]WHO, Using TRIPS flexibilities to facilitate access to medicines <https://www.who.int/bulletin/volumes/91/7/12-115865/en/> accessed 20 May 2021

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ne-for-covid-19-the-need-for-coordinating-policies-on-r-d-manufacturing-and-access-6e7669a9/> accessed 20 May 2021

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Bryan C. Mercurio
<https://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1040&context=iplr> accessed 1 April 2021

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<https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 1 April 2021

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