THE TRIPS AGREEMENT IN COMBATTING COVID-19 – COMPULSORY LICENCING AND TIMELY ACCESS TO VACCINES

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This thesis examines the role of the WTO TRIPS Agreement in combatting delays in pandemic-related vaccine distribution. The patent regulation of the TRIPS Agreement provides a limited number of exceptions to the patent holder's exclusive rights, the most relevant during pandemics being the combination of Art. 31 and 31 bis: compulsory licencing. This thesis focuses on investigating whether the compulsory licencing system manages to adequately respond to issues related to global timely access to vaccines.

The topic of the thesis was selected as after the outbreak of the Covid-19 pandemic, broad discussion on the role of the TRIPS regulation began. This thesis investigates the most relevant factors behind the unequal global distribution of vaccines during pandemics and provides an analysis on whether the TRIPS regulation may serve as a solution for these issues. The study is conducted by a legal dogmatic method, relying on economic argumentation from relevant parts. Primary sources are the Resource Book on TRIPS and Development by the WTO and WTO official documents regarding the compulsory licencing system and Covid-19 pandemic.

The key research findings are that although the compulsory licencing system is a flexible tool and may serve as an effective post-pandemic tool in keeping the prices of voluntary licences competitive, it does not offer a comprehensive solution to pandemic-related delays in vaccine distribution. The weakness of the system derives from the fact that one of the most significant factors behind the timely distribution of vaccines is the inadequate global manufacturing capacity, which is further aggravated by granting exclusive patent rights to vaccine developers. Furthermore, Art. 39 TRIPS prevents the efficient use of the compulsory licencing system by blocking the dissemination of know-how and technology.

The TRIPS Agreement has been drafted to protect private property rights and to support the dissemination of technology in the long term, whereas during pandemics, the balance should be more on global health considerations and on the dissemination of technology and know-how in a rapid timeframe. Thus, it is suggested that a new regulative framework should be mutually negotiated for future pandemics. This framework should be construed by taking into account the difficulties in global manufacturing capacity and the role of exclusive patent protection to these issues thereof. However, also the financial interests of pharmaceutical actors shall be considered to preserve the incentives for research and development.

Key words: TRIPS Agreement, compulsory licencing, pandemics, timely access to vaccines, manufacturing capacity, transfer of technology, dissemination of know-how

Pro gradu -tutkielma

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Tämä tutkielma käsittelee Maailmankauppajärjestön TRIPS sopimuksen roolia rokotteiden tasapuoliseen ja nopeaan saatavuuteen liittyvissä ongelmissa. TRIPS sopimuksen patenttisääntely tarjoaa rajallisesti poikkeuksia patentinhaltijoiden muuten eksklusiivisiin oikeuksiin. Pandemioiden kannalta poikkeuksista relevantein on sopimuksen artiklat 31 ja 31bis, jotka muodostavat yhdessä pohjan pakkolisensoinnille. Tässä tutkielmassa on keskitytty tutkimaan sitä, onko pakkolisensoinnilla mahdollista vastata pandemian aiheuttamiin rokotesaatavuuden haasteisiin, ja millä mittapuulla.

Tutkielman aihe valikoitui Covid-19 pandemian herättämän TRIPS sopimukseen liittyvän laajan keskustelun myötä. Keskustelun innoittamana tutkielmassa on paneuduttu niihin tekijöihin, jotka ovat keskeisessä roolissa rokotteiden tasapuolisen ja nopean saatavuuden kannalta, sekä otettu kantaa siihen, pystyykö TRIPS sopimus vastaamaan näiden tekijöiden asettamiin haasteisiin. Tutkimus on oikeusdogmaattinen, ja siinä hyödynnetään soveltuvin osin taloudellisia argumentteja sekä tukeudutaan yhteiskunnalliseen keskusteluun. Päälähteinä on käytetty Maailmankauppajärjestön tuottamaa kirjallisuutta TRIPS sopimuksen tulkintaan liittyen (Resource Book on TRIPS and Development) sekä Maailmankauppajärjestön virallislähteitä pakkolisensointiin sekä Covid-19 pandemiaan liittyen.

Tutkielman johtopäätös on, että artiklat on suunniteltu joustaviksi, ja pakkolisensoinnilla pystytään mahdollisesti pitämään pandemian jälkeiset lisenssihinnat matalina. Huolimatta näistä hyvistä puolista. pakkolisensoinnilla ei kuitenkaan pystytä kokonaisvaltaisesti vastaamaan pandemian asettamiin haasteisiin. Oikeudellisen kehikon heikkoudet ovat tulosta puutteellisesta globaalista rokotteiden valmistuskapasiteetista, jota TRIPS sopimuksen mukainen eksklusiivinen patenttien suoja vakavoittaa entisestään. Näitä ongelmia korostaa myös TRIPS sopimuksen 39 artikla, jonka vuoksi rokotteisiin liittyvän teknologian ja asiantuntijuuden levittäminen globaalisti on erittäin vaikeaa.

TRIPS sopimus on laadittu yksityisten toimijoiden omaisuudensuojan varmistamiseksi, tähdäten teknologian globaaliin levittämiseen pitkällä aikavälillä. Pandemiatilanteessa insentiivit ovat päinvastaiset: terveyshaittojen ratkaisemisen tulisi olla keskiössä, ja teknologian sekä osaamisen levittämisen tulisi tapahtua mahdollisimman nopealla aikavälillä. Tästä johtuen tutkielmassa ehdotetaan, että tulevia pandemioita varten neuvoteltaisiin täysin uusi lainsäädäntökehikko. Neuvotteluissa tulisi ottaa huomioon globaalissa rokotteiden valmistuskapasiteetissa havaitut ongelmat sekä patenttien suojan rooli kyseisissä ongelmissa. Erittäin tärkeää on myös huomioida yksityisten lääkeyritysten taloudelliset intressit, jotta insentiivit tehokkaaseen rokotteiden tutkimus- ja kehitystyöhön eivät heikkene.

Avainsanat: TRIPS sopimus, pakkolisensointi, pandemia, rokotesaatavuus, rokotteiden valmistuskapasiteetti, teknologian levittäminen, asiantuntijuuden levittäminen

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LIST OF ABBREVIATIONS

Art.	article
ACT-Accelerator	the Access to Covid-19 Tools Accelerator
BARDA	Biomedical Advanced Research and Development Authority (US)
C-TAP	Covid-19 Technology Access Pool
CEO	Chief Executive Officer
CEPI	the Coalition for Epidemic Preparedness Innovations
Communication	Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/669
COVAX	the vaccines pillar of the Access to Covid-19 Tools (ACT) Accelerator
Covenant	the Covenant on Economic, Social and Cultural Right
Covid-19	severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)
Declaration	Universal Declaration of Human Rights
Doha Declaration	Declaration on the TRIPS Agreement and public health
e.g.	exempli gratia (for example)
EMA	European Medicines Agency
etc.	et cetera (and so on)
EU	the European Union
EUL	Emergency Use Listing by World Health Organization
Facility	Covid-19 Vaccine Global Access Facility
H1N1	Influenza A, type H1N1; more commonly known as ‘Swine Flu’
i.e.	id est (that is)
ibid.	ibidem (in the same place)
IP	Intellectual Property
IPR	Intellectual Property Rights
LDC	least developed country
MFN	most favoured nation

p(p).	page(s)
para(s).	paragraph(s)
R&D	research and development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
Rev. Communication	Revised Waiver From Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19
UK	United Kingdom
US/A	United States of America
WIPO	World Intellectual Property Organization
WHO	World Health Organisation
WTO	World Trade Organization
WTO Agreement	the Marrakesh Agreement Establishing the World Trade Organization

1 INTRODUCTION

1.1 Background

At the beginning of 2020, the outbreak of severe acute respiratory syndrome coronavirus 2 ("**Covid-19**") shook the whole world. The disease started spreading insidiously from China, with around 6,000 confirmed cases worldwide on 29th February 2020 (excl. China with 142,000 suspected or confirmed cases).[1] A month later, on 27th March 2020, the total amount of confirmed cases amounted to 509,000.[2] On 1st December 2020, the number of confirmed cases reported to the World Health Organization ("**WHO**") rose up to 61.8 million, with reported deaths of 1.4 million individuals.[3] When finishing this study, the amount of confirmed cases worldwide stands at 229 million, and the number of death have reached 4,7 million.[4]

As it stands, the pandemic has affected societies around the world in a way not seen before in the modern era. The pandemic has forced the states to close their borders from people and commodities to protect their citizens from a spreading virus. Countries have even restricted the free movement of people within their borders. For example, in January 2020, China announced a lockdown of 9 million people in Wuhan to control the pandemic.[5] After the infectious wave of March 2020, this occurred also in multiple other countries such as India (82 different districts in 22 states), Italy (first Lombardia, then nationally), Ireland (three regions), and Finland (Helsinki).[6]

It is undisputed that societies around the world are suffering tremendous economic losses on a daily basis due to the lockdowns preventing individuals from engaging in business as usual. By 28th April 2020, 84 states had declared a state of emergency in response to the pandemic.[7] The urgent need for an effective vaccine has been driving the states, universities and private sector actors in their attempts to reach a solution for stopping the spread of the virus. In the course of one year, seven different vaccines had already been approved around the world, and more than

[1] World Health Organization 2020a. WHO COVID-19 Situation Report - 40.
[2] World Health Organization 2020b. WHO COVID-19 Situation Report - 67.
[3] World Health Organization 2021e. WHO Weekly epidemiological update - 1 December 2020.
[4] World Health Organization 2021b. WHO Coronavirus (COVID-19) Dashboard.
[5] Tian et al. 2020.
[6] Dunford et al. 2020. *Coronavirus: The world in lockdown in maps and charts.* BBC News.
[7] Fair Trials 2021. *Short Update: 84 countries have now declared a state of emergency in response to the COVID-19 pandemic.*

200 vaccines were still under development.[8] By the time of March 2021, the 'Coronavirus Global Response' initiated by the European Commission had collected nearly €16 billion for global distribution in combatting Covid-19.[9]

Though the global response to Covid-19 has been emphasized, the extremely tough and urgent situation has enticed other approaches as well. States have implemented export restrictions for Covid-19 related medical goods and devices, and by the end of 2020, 58 such prohibitions were in force.[10] In Israel, which paid the highest known price for vaccines,[11] already more than half of the population had received the first dose of vaccine at the beginning of March 2021,[12] meanwhile the vaccination rate of e.g. the European Union member states stayed approximately under 10 % regarding first dose uptake.[13]

The distribution of and timely access to essential medicines have been widely discussed topics during the 21st century, especially from the perspective of developing countries. That said, one of the greatest fears of the global community by the time of writing this research is the timely access to Covid-19 vaccination for developing countries, which once again, are under threat to gain access to medication well after the wealthier nations. Most of the invented Covid-19 vaccines are given in two doses, whereas some require only one vaccination. Still, e.g. Canada has preordered 9.6 vaccines per person, UK 5.5 vaccines per person and the US 3.7 vaccines per person. At the same time, the African Union and Latin America have a preorder rate of under 0.4 vaccines per person.[14]

The reasons for the delayed access to vaccines during pandemics are complex and in no way easily listable. One of the topics that has been intriguing to legal scholars is how the international patent regime affects the timely access to patented medication.[15] The core of the patent regulation resides within the World Trade Organization ("**WTO**"), which has been contributing to the harmonization of international intellectual property rights legislation.

[8] Wouters et al. 2021. p. 1025.
[9] European Union 2021. Coronavirus Global Response, Pledge.
[10] World Trade Organization 2020. Developing and Delivering Covid-19 Vaccines Around the World. p. 6.
[11] Dyer 2021. *Covid-19: Countries are learning what others paid for vaccines*. BMJ.
[12] Haaretz 2021. *COVID in Israel: How Many Have Already Been Vaccinated*.
[13] European Centre for Disease Prevention and Control. Covid-19 Vaccine Tracker.
[14] Kirk – Finbarr – Levett 2021. *Canada and UK among countries with most vaccine doses ordered per person.* The Guardian.
[15] See e.g. Pogge – Rimmer – Rubenstein eds. 2010. Incentives for Global Public Health: Patent Law and Access to Essential Medicines. Cambridge University Press.

Alongside its establishment under the Marrakesh Agreement in 1995, WTO provided its Member States[16] with Annex 1C, the Agreement on Trade-Related Aspects of Intellectual Property Rights ("**the TRIPS Agreement**").

The TRIPS Agreement is an inseparable part of the Marrakesh Agreement, and it provides a legal framework for international patent regulation, regulating the rights and obligations of the patent holder. During the Covid-19 pandemic, there have been rising concerns about whether the IP regime enforceable by private sector actors will have a negative effect on timely access to vaccines.[17] The concerns are related to the fact that when the product or process is patented, no other manufacturer may use the process for manufacturing the good nor distribute the product without the permission of the patent holder.[18] Several Covid-19 vaccines are patented, but no vaccine-related disputes had arisen by the time of finishing this study.

Though no patent rights have been enforced by pharmaceutical companies during Covid-19, and some have pledged not to enforce their patent related rights,[19] the question of whether the TRIPS Agreement is advanced enough to respond to a worldwide pandemic should be given more attention. The fact that the WTO Member States requested a waiver not to apply the patent-related regulation of the TRIPS Agreement during the Covid-19 pandemic speaks for itself:[20] the fear of pharmaceutical actors enforcing their rights during pandemic indicates that the patent regime is not adequate for responding to worldwide emergencies. Therefore, this research aims to investigate the emergency-specific exceptions of the TRIPS Agreement and whether they are of use during pandemics.

1.2 The scope of the study, research questions, and methodology

As described above, the TRIPS Agreement provides the legislative framework for patent regulation. The focus of the Agreement is on regulating patentability and rights during regular circumstances, and there is only a limited amount of emergency-specific regulation. Regarding health emergencies such as HIV/AIDS, Swine flu or by the time of writing, Covid-19, Art. 31

[16] By the time of writing, 164 countries are members of the WTO.
[17] See e.g. Eccleston-Turner – Upton 2021. pp. 426-449. and Radcliffe 2020. *Here's What Happened the Last Time We Had a Vaccine During a Pandemic.* Healthline.
[18] TRIPS Agreement Art. 28.
[19] See e.g. Santos – Fletcher 2020. *Moderna Makes Milestone Pledge To "Not Enforce Our Patents" On COVID-19 Vaccine Technologies During Pandemic & Issue Open Licenses Afterward.*
[20] India and South Africa for Council for TRIPS 2020. IP/C/W/669.

provides the relevant legislative framework. It provides the opportunity for 'other use without authorization of the right holder' of a patented good. This legal tool is called 'compulsory licencing', and it enables the use and manufacturing of patented pharmaceuticals without the consent of the patent holder. Accordingly, Art. 31bis allows exporting and importing of patented pharmaceuticals under certain conditions.

Compulsory licencing system is the only legal tool of the TRIPS Agreement that enables 'circumventing' patent-related rights. Thus, during pandemics, countries may use compulsory licencing to manufacture already invented vaccines if timely access to vaccines otherwise seems impossible. Compulsory licencing has invited several differing opinions. Some claim it is an inefficient tool in combatting delays in pharmaceutical distribution, and others claim the reasons for delayed timely access lie elsewhere.[21] The functioning of the system is also affected by other regulation of the TRIPS Agreement, which will be taken into account in the scope of this study. Accordingly, as the aim is to study the TRIPS Agreement's emergency-specific tools, the TRIPS Waiver (Art. IX(3-4) of the WTO Agreement) will be investigated as the last resource alternative.

The scope of the study is limited to widely spread infectious diseases, and the aim is to examine whether the TRIPS Agreement responds to the highly divergent conditions prevailing during a worldwide pandemic. Therefore, this study attempts to answer two research questions. First, what are the strengths and weaknesses of the compulsory licencing system in combatting pandemics? The aim is to create a deeper understanding of the legal tool and asses *why* it is not adequate for responding to pandemics, and on the other hand, whether there are some efficient aspects to it. By examining the reasons behind the claimed inefficiency of the tool, future responses to pandemics can be designed to better respond to the prevailing circumstances.

To fully understand the functionality of the tool, the legal context, that is, the TRIPS Agreement, must also be examined in its entirety, as also other TRIPS provisions may appear to be relevant to the first research question. Furthermore, there have been continuing discussions on waiving all the patent-related rights and obligations. Therefore, this alternative is also investigated as a solution to timely access to pandemics. Thus, the second research question is, how does the TRIPS Agreement as a whole respond to pandemics? To be precise,

[21] See e.g. Breuningen 2021. *Pfizer CEO opposes U.S. call to waive Covid vaccine patents, cites manufacturing and safety issues.* CNBC.

this study does not aim to find an overall solution for timely access to vaccines during pandemics but to investigate whether the TRIPS Agreement answers to the existing challenges in the best possible way.

To answer the research questions, multiple auxiliary questions will be addressed. First, the regulative framework for compulsory licencing will be investigated to outline the basis for the study. Second, the operability of the compulsory licencing system will be explored by defining in what kind of situations compulsory licences are usually effective and why. This examination is necessary to detect how the compulsory licencing system is intended to be used and what are the consequences of its use during regular circumstances.

Third, after having investigated the tool in regular circumstances, it is time to examine the circumstances compulsory licences should be addressing during pandemics. The idea is to assess the differences in circumstances prevailing during pandemics and, on the other hand, during regular times for which the tool has been designed for. When examining the characteristics of worldwide pandemics, the conditions during Covid-19 are emphasized due to their unparalleled nature. As a result, it will be possible to explore issues the system cannot (or can) provide an answer to within the operative framework. Lastly, the effects of other TRIPS regulation on the functioning of the compulsory licencing system will be investigated to comprehensively answer the two research questions.

The research is conducted by a legal dogmatic method. The method allows in-depth examination of the regulative framework, as the source of law-doctrine obliges the writer to examine the framework in the context of applicable legal sources.[22] Still, adopting a broader perspective to law is possible, as a legal dogmatic approach allows the examination of interconnection of society and law. [23] The prevailing issues ultimately derive from society, and norms and their interpretations are generally responses to these issues.[24] This study focuses precisely on a situation where norms are regulating matters they have not been created for, and the issues deriving thereof. The aim is to systemize the existing legal framework and investigate whether more efficient legal solutions could be adopted.

[22] Aarnio 1989. pp. 59-61.
[23] Ervasti 2017. pp. 11-12.
[24] Aarnio 1989. p. 304.

That said, the essence of this study is to examine the divergent conditions prevailing during pandemics. The study begins by systemizing the relevant articles of the TRIPS Agreement in light of case law, interpretational statements of official bodies, and scholarly writings. The idea is first to introduce why the legal framework exists and how the normative framework is currently functioning, so that later on the current framework and its usability to divergent conditions can be assessed. To be able to systemize the framework adequately, the socio-economic conditions affecting timely access to vaccines during pandemics are investigated in chapter 3. As a result, in chapter 4, the operability of the legal framework established in chapter 2 can be examined in light of the conditions that should be regulated.

Where applicable, this study emphasizes the economic perspective and approach to law. Thus, the core of the study is legal dogmatic, but economic conditions are investigated to map the prevailing circumstances more precisely. The economic approach has been selected as intellectual property rights strongly restrict competition, and thus affect the economic incentives of right holders.[25] The economic perspective of the study will enable the assessment of incentive structures and possible conflicts of interest during pandemics. It offers a perspective on whether the legal framework is functional, taking into account the socio-economic conditions of the pandemic.

1.3 Previous studies

The TRIPS Agreement is one of the most ambitious steps towards a unified international patent regime, and it has therefore been a widely researched agreement. One of the most investigated aspects of patent regulation has indeed been the relation of pharmaceutical patents to public health concerns. The research has heavily leaned towards the effects of the TRIPS Agreement on access to essential medication, which has been a concern especially for the developing country members. In this context, also the effectiveness of compulsory licences has been widely discussed.[26]

One ambitious study to mention is an edited collection of Thomas Pogge, Matthew Rimmer and Kim Rubenstein on 'Incentives of Global Public Health: Patent Law and Access to Essential Medicines', which consists of over 400 pages of scholarly articles on intellectual property rights

[25] Glader 2006. p. 8.
[26] See e.g. Beall – Kuhn 2012; Chung 2010.

and their relation to access to medicines, including suggestions for improving the legislative framework. The WTO has recognized the need to address public health concerns which have been on the table since the creation of the Agreement, and even more strongly after the Doha Declaration on the TRIPS Agreement and Public Health ("**Doha Declaration**"), which acknowledged public health values as guiding principles of pharmaceutical patenting in 2001.

Access to essential medicines is a prevailing concern that strongly raises its head each time an infectious disease starts spreading widely. This happened, for example, during the H1N1-virus (more commonly known as "swine flu") outbreak, which was declared a pandemic by WHO on 11th June 2009.[27] The concern has been the access of developing and low-income countries to the required vaccines to fight the pandemics, and as a rule, the developing countries have gained access far after western and wealthy states. [28] During the Covid-19 pandemic, the same concerns have arisen – again – as the distribution of vaccines seems once and for all to be concentrated to developed western countries.[29]

WHO has emphasized that timely access to vaccines for everyone should be the top priority during the pandemic while acknowledging it is one of the biggest challenges in combatting Covid-19. WHO e.g. founded a vaccine pillar named 'COVAX', which purpose is to enhance vaccine distribution amongst developing countries.[30] The issue seems to once again lie in the fact that however fast the distribution of vaccines would be, rich countries will still gain access to vaccines first.[31] This is problematic from the perspective of human rights, but also from the perspective of an efficient answer to the pandemic: each country should be supported in their rapid response in order to restrain the spread of disease worldwide. Accordingly, if the rapid response to pandemic is not available for every state, there will be even more long-lasting economic consequences globally.[32]

TRIPS patent regulation and the compulsory licencing system have been fiercely criticised in regular context. However, as the regulation also tend to have its bright sides, such as setting

[27] Doshi 2011. Bulletin of the World Health Organization: The elusive definition of pandemic influenza.
[28] Enserink 2009.
[29] See e.g. Beaumont 2021. *Vaccine inequality exposed by dire situation in world's poorest nations*. The Guardian.
[30] See e.g. Eccleston-Turner – Upton 2021.
[31] Kirk – Finbarr – Levett 2021. *Canada and UK among countries with most vaccine doses ordered per person*. The Guardian.
[32] Eurasia Group analyzed economic benefits of global equitable vaccine access, estimating that equitable vaccine solution would result in hundreds of billions dollars of savings merely for the investigated 10 countries. See World Health Organization 2020c.

incentives for research and development ("**R&D**") and transferring technology to third countries in the long term, its disadvantages have been tolerated this far.[33] The general discussion on the effectiveness of compulsory licences can be seen as parallel to this study: assessments lean heavily on the prevailing economic and social conditions, and are based on specific circumstances during regular times. On the contrary, the basis of this study consist of completely different socio-economic circumstances. However, the relevant arguments of general discussion are briefly introduced in chapter 2 in order to establish the differences between the framework of this study and the regular circumstances.

Indeed, the idea is not to take part in the already extensive discussion, but to assess the effectiveness of compulsory licences in different context. The legal tools have not been comprehensively assessed in the socio-economic context of the pandemics: the diversity in the conditions during pandemics has not been systematically investigated as such. There have been suggestions for amending the whole regulative framework, but the primary idea of this study is to examine the weaknesses and strengths of the current legislation to encourage conversation on possible solutions. As pandemics occur only once in a while (and seldom in this magnitude), the aim is to build a base for further steps for negotiating possible emergency-related legal solutions.

2 COMPULSORY LICENCING AND EMERGENCY REGULATION

This chapter focuses on introducing the patent-related aspects of the TRIPS Agreement by WTO. The idea is to examine the basics of patent regulation, including relevant principles. First, the regime for overall patent regulation is introduced, after which the exceptions to the patent holder's rights, i.e. compulsory licencing, will be addressed. The aim of this chapter is to introduce the regulation under which the Member States may pursue timely access to pharmaceutical products. Further, the chapter will build an understanding of the applicable legal framework, which will be useful when diving into the relevant pandemic-specific context in the next chapter.

Chapter 2 first (2.1) introduces the regime regulating patent holders' rights: what rights the TRIPS Agreement offers to an inventor of a pharmaceutical product? Second, the enforcement of the Agreement and related rights are discussed by introducing the implementation system of

[33] WTO General Council 2003. WT/L/540 and Corr. 1. para. 7.

the TRIPS Agreement, as it is of great relevance for the efficacy of available legal tools, though not in the centre of this research. Then (2.2) the legal aspects of the compulsory licencing system are introduced in more depth. Lastly, (2.3) the guiding principles of the Agreement and related public health considerations are discussed. In this context also some TRIPS-related other (emergency) tools are introduced.

2.1 Framework for patent regulation

2.1.1 Protection for inventions

The noble purpose of protecting inventions by patents stems from the fact that when one gains economic profit from innovation, one has an incentive for effective research and development.[34] In their study, Daron Acemoğlu and James A. Robinson found out that amongst other factors, poor incentives for individuals may lead to the economic inferiority of a society. When society poses adequate motivational incentives for individuals, socio-economic welfare increases.[35] The IP ("**Intellectual Property**") related economic growth is nowadays a recognized fact,[36] and the legal regime to protect inventions thus also reflects the state of development of a country somewhat well.

The TRIPS Agreement came into effect on 1st January 1995, and it is the most comprehensive multilateral agreement related to intellectual property rights, including pharmaceutical patenting. In addition to rights associated with IPR ("**Intellectual Property Rights**"), the Agreement contains regulation on applicable principles, dispute resolution, enforcement of the rights concerned, and provisional measures. The relation of the TRIPS Agreement to Member States' domestic legislation will be introduced in the following subsection, whereas this subsection goes through the basics of patent regulation and the protection offered to inventions.

The core of the patent regulation is Part 2, Section 5 of the TRIPS Agreement, which consists of Articles from 27 to 34. TRIPS determines what can be patented, what rights the patent holder can achieve, how the rights can be enforced, and what exceptions there are for the rights the patent owner holds. According to Article 27, all inventions in any field of technology shall be patentable, whether the invention is a product or a process. Article 27 additionally lays down a

[34] Taubman – Wager – Watal 2012. p. 1.
[35] Acemoğlu – Robinson 2012. pp. 43-44; 73.
[36] Glader 2006. p. 8.

three-step test for an invention: it must be new, include an inventive step, and be industrially applicable. There are no further interpretational rules set by the TRIPS Agreement concerning the requirements of Art. 27, and the fulfilment of the test is considered on a case-by-case basis.

The patentability of vaccines differs from other patentable goods due to their complex nature. The vaccine itself might be a completely new, patentable product. Furthermore, vaccines may consist of different micro-organisms, new recombinants, new adjuvants etc., that might be patentable as such. Also the process of manufacturing the new vaccine in question is patentable.[37] As a consequence, one vaccine can include several different patents depending on the novelty of each component alone. The same curing result may also be achieved through several different processes and products, which means several patented products may cure the same disease.[38]

Article 28 provides the core of the patent regime: it introduces the rights the patent holder enjoys. Regarding products, making, using, offering for sale, selling, or importing of the product is forbidden without the patent holder's consent. Regarding patented processes, the acts of using the process and the acts of using, offering for sale, selling, or importing a product obtained by the patented process are forbidden. However, the patent holder may provide (usually by selling) a licence for a third party for a certain period, during which the licensee has the permission to engage in the act agreed between the parties. A licence given by the right holder is called a 'voluntary licence', whereas a licence issued without the right holder's authorization is a 'compulsory licence'. The following section addresses compulsory licencing in more detail.

According to the TRIPS Agreement, the eligible term of patent protection is at least 20 years from the date of filing.[39] Patents may also expire if the required patent renewal fees are not properly paid, which may be the case e.g. when the invention has lost its economic value.[40] As will be further discussed in the following subsection, Member States may grant more comprehensive protection for inventions, also regarding the protection term.

[37] Garrison 2004. p. 8.
[38] Ibid. p. 16
[39] TRIPS Agreement Art. 33.
[40] Garrison, Christopher 2004. p. 10.

Although the TRIPS Agreement sets a wide range of rules to protect the patent holder's rights, it also sets a requirement for the right holder to disclose a decent amount of information on the invention. Article 29 provides that for the patent application to be accepted, the applicant shall disclose the invention 'in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention'. This is to ascertain that relevant information on the new invention is disclosed to the public so that the competitors can use the information for further research and development.[41] As a result, individual research efforts benefit the whole scientific community and society's development, due to which the protection of IPRs is justified in the first place.

The obligation to disclose information, however, is restricted by Art. 39 of the TRIPS Agreement. The article in question protects undisclosed information, which in the case of vaccines may include test and other data or 'know-how' and related trade secrets.[42] Undisclosed information refers to for example trade secrets and data disclosed to governments in connection with marketing approval processes. Pursuant to Art. 39, unauthorized use and distribution of such data concludes a violation of patent holder's rights, and results in sanctions.

The role of Art. 39 and protection of undisclosed information may heavily affect the overall manufacturing capacity of vaccines. For example, the manufacturing of generic[43] vaccines is of an extremely low rate due to the complexity of the process.[44] Manufacturing requires expertise, know-how, and historical clinical data, all protected by Art. 39 of the TRIPS Agreement.[45] Whereas the protection of undisclosed information may not be problematic *per se*, it may constitute issues when interpreted in connection with compulsory licencing. These issues will be further analyzed in chapter 4.

[41] Taubman – Wager – Watal 2012. pp. 95-96.
[42] Garrison 2004. p. 2.
[43] A 'generic' pharmaceutical product refers to a non-patented variant of the product, of which price is usually much more competitive than the one of its patented counterpart. Pharmaceutical products produced under compulsory licence can be referred as generics, as they are produced without the authorization of the patent holder and often for the purpose of lower distribution price.
[44] see World Health Organization 2010a.
[45] Garrison. pp. 9-10.

2.1.2 Enforcement

As an international multilateral agreement, one essential aspect of TRIPS is how the Agreement is enforced. Accordingly, this subsection presents the central aspects of general obligations of the Member States in implementing and following the Agreement. In this regard, the process of drafting the TRIPS Agreement will be briefly introduced, as there are specific characteristics relating to the national implementation from the point of view of the developing countries. However, this study will not address the effects of different national implementation but instead examines the substantive aspects of the Agreement.

According to Art. 1 of the Agreement, Member States are required to give effect to all of the provisions of the TRIPS Agreement. There are no guidelines on how the effect shall be given, but the agreement must be fully implemented to the national legislation of each state. Pursuant to Art. 1, the method of implementing the legislation remains on the shoulders of each nation. Thus, the enforceability of the Agreement depends on how appropriately the Member States have implemented the regulation. Member States are required to provide the WTO with information on how the application of TRIPS is ensured in their national legislation and the possible delays with compliance thereof.[46]

According to Art. 1, TRIPS serves as a minimum standards agreement: Member States are required to implement at least the level of protection granted by the TRIPS Agreement, but they may also implement more protective legislation if they will. In this regard, however, the provisions and principles of the Agreement must be respected. Compliance with the principle of non-discrimination requires that if more comprehensive protection is granted, it must be available for all actors in the field, also for those operating in the other Member States. Thus, no state can favour its nationals.[47]

Drafting of the TRIPS Agreement started in April 1989 in the so-called ‘Uruguay round’, as the preparing negotiating group was given a full mandate to begin preparing a comprehensive set of international IPR rules. In its entirety, the drafting process lasted four years, during which multiple revision rounds by different committees were conducted. Finally, the negotiating

[46] Taubman – Wager – Watal 2012. p. 31.
[47] Ibid. p. 13-14.

group presented a Draft Final Act at the end of 1991, which became a Final Act at the end of 1993, after two years of intense consultation by groups consisting of Member States.[48]

The TRIPS Agreement came into force in 1995, and from developed country members, compliance was required starting from January 1996. The developing countries were granted a transition period of five years, and compliance was first required from the beginning of January 2000. In contrast, least developed countries ("**LDC**") were granted time until January 2006. Concerning pharmaceutical products, the transition period for developing countries was later extended until 2005 and for LDC's until 2016,[49] and further until 2033.[50]

The delays in implementing the TRIPS Agreement with respect to pharmaceutical products by developing countries reveal how tough it has been for developing country members to comply with the regulation. The issue lies in the lack of manufacturing capacity, and the patent-related cost rises: putting it simply, the developing countries do not profit from the legislation as they usually have an inadequate pharmaceutical infrastructure for developing new patentable products. Furthermore, they are forced to protect patented products manufactured by other states, which inevitably leads to price rises of pharmaceutical products.[51]

Notable is that the TRIPS Agreement is an integral part of the Marrakesh Agreement establishing the WTO ("**the WTO Agreement**"). When entering into the World Trade Organization, no option whether to enter into the TRIPS Agreement or not is available, making the implementation of the Agreement mandatory for states wanting to become part of the WTO.[52] When entering into the WTO, the TRIPS is accepted as such. Furthermore, before the TRIPS Agreement, patent protection for pharmaceutical products was not mandatory: the TRIPS Agreement is the first international agreement requiring the protection.

The perspective of developing countries can be reflected through the Indian example. Before 2005 (the year India was required to implement the TRIPS Agreement at the latest), a vast amount of generic pharmaceutical products were manufactured on Indian soil. India exported a significant amount of generic antiretroviral medicines to developing countries to fight against

[48] see Otten 2015.
[49] Taubman – Wager – Watal 2012. pp. 21-23.
[50] World Trade Organization 2015.
[51] see Anderson 2010. p. 166. After enforcement of the TRIPS Agreement, the prices of pharmaceutical products have verifiably risen especially in the developing countries.
[52] Taubman – Wager – Watal 2012. p. 8.

HIV/AIDS for the price of approximately $300 per patient for one year's treatment. After the implementation of the TRIPS Agreement, the price went up by 97%, to $12.000 per annum with a consequence of no LDC affording the medication anymore.[53]

As a final remark on enforcement, the TRIPS Agreement can be amended if need be. The amendment of the TRIPS Agreement requires the formal acceptance of two-thirds of the Member States. When the amendment affects the rights or obligations of Member States, it enters into force only for those states who have given their acceptance. Additionally, the amendments must be implemented into the national legislation to give them efficiency.[54] There has been only one amendment to the TRIPS Agreement, which concerns the importing and exporting of pharmaceutical products under the compulsory licence. This amendment will be addressed later in this study.

2.2 Compulsory licencing as an exception to patent holder's rights

2.2.1 Legal framework

As described in the section above, patents allow the developer of the invention to control the use and production of their invention. This right may result in a situation where the pharmaceutical actors optimize their profit by selling a licence for only a few manufacturers, thus keeping the competition low and the prices up. When a pharmaceutical product with high prices is needed to combat a health crisis, this may be extremely harmful. The same goes with pandemics, as the vaccine developers have the same rights during pandemics as any other time. As the adverse effects of patent regulation on the cost and timely access to pharmaceutical products are widely acknowledged,[55] the TRIPS Agreement has adopted tools for combatting these inefficiencies. This section introduces the most important (and basically the only one) of them, of which applicability to pandemics will be later assessed in chapter 4.

The tool is Art. 31 of the TRIPS Agreement, compulsory licencing. It is a method of interfering with the patent holder's right to fully command and benefit from her/his/its invention. The Agreement sets the legal framework for granting licences without the authorization of the right holder but also leaves a lot of discretion to the Member States regarding the conditions on which

[53] Garrison 2004. p. 16.
[54] Taubman – Wager – Watal 2012. p. 29.
[55] See e.g. Doha Declaration 2001.

these licences may be granted. The text of the TRIPS Agreement does not straightly refer to 'compulsory licence' but rather to 'other authorized use'. However, the term compulsory licence is used in this study to refer to the tool introduced in Art. 31, as the term was later used in this context by the Ministerial Conference of the WTO.

Pursuant to Art. 31 of the TRIPS Agreement, when specific criteria are fulfilled, the use of a patented product or process can be authorized by a government despite the right holder's authorization. In such cases, one is entitled e.g. to produce pharmaceutical products without the right holder's authorization. Compulsory licencing serves as a backup rule when the end-product is needed, but the patent prevents timely or cost-efficient access to the product.[56] During the first twelve years of the TRIPS Agreement, almost 30 pharmaceutical compulsory licences had been granted by nearly 20 countries.[57]

Compulsory licences may be granted on several conditions which are not always easily interpretable. When issuing a compulsory licence, prior negotiations with the right holder are required. Art. 31.1(b) requires that there must have been an attempt to negotiate a voluntary licence on reasonable commercial terms and conditions before issuing a compulsory license. Furthermore, when issuing a compulsory licence, the patent holder must be granted a reasonable remuneration, of which determination is a disputed issue under the TRIPS Agreement.[58]

Another indefinable condition is the purpose of compulsory licence. Art. 31.1(c) provides that the scope and duration of the authorized use under a compulsory licence shall be limited to the purpose of the authorization. The interpretation of this rule has been left open, and due to its vague nature, it is considerably hard to interpret. It seems that the intention is to enable the kind of acts under the licence that are *necessary* for achieving the purpose of the licence,[59] which poses a lot of pressure to the manufacturer of the products. However, it is acknowledged the investments and efforts of the licensee should also be taken into account in the assessment.[60]

The 'limited scope' requirement may occur as extremely difficult to interpret, especially regarding vaccines. As vaccines are used to fight infectious diseases continuously, the line where vaccines are no longer *necessary* may be hard to draw. Other significant issues are caused

[56] Anderson 2010. p. 169.
[57] Beall – Kuhn 2012. p. 1.
[58] Anderson 2010. pp. 176-177.
[59] Taubman – Wager – Watal 2012. p. 113.
[60] Ibid.

by Art. 31.1(f), according to which the authorized use must predominantly target the supply of the domestic market. This rule was found to discriminate against countries with lower manufacturing capacity, as no exportation under compulsory licencing was possible under the regulation. As a result, no Member State was allowed to manufacture patented pharmaceutical products for the exportation to countries where they were needed for the sake of public health crisis and where there were no resources to manufacture the necessary products.[61]

To address the problem, WTO Ministerial Meeting of 2001 in Doha gave a Declaration on the TRIPS Agreement and Public Health ("**Doha Declaration**"). Doha Declaration acknowledged the issue of compulsory licencing from the perspective of LDCs and delegated the solving of the issue to the Council of TRIPS.[62] The General Council came up with a decision of 2003 (referred to as "**Paragraph 6 system**"), according to which importing and exporting under compulsory licence would be enabled until further notice.[63] In 2005 the General Council decided to implement the decision to the TRIPS Agreement as an amendment. The amendment came into force twelve years later, in 2017, after two-thirds of the Member States had accepted the Protocol amending the TRIPS Agreement.[64]

The amendment is Art. 31bis, according to which a compulsory licence can be granted for exporting pharmaceutical products. Again, exporting must be necessary and targeted to 'an eligible importing Member'. An eligible importing Member has been described in section 2 of the Annex to the TRIPS Agreement, according to which the state in question must have established an insufficient capacity (or none at all) to manufacture the products in question. An LDC Member State automatically qualifies as an eligible importing Member.[65] When exporting pharmaceuticals under a compulsory licence, WTO must be notified of the precise amounts to be exported, to whom the products are exported, and the grounds under which the country may act as an eligible importing country. Exporting to multiple countries under compulsory licence is possible, but each export requires notification on behalf of the exporter and importer.[66]

[61] Correa 2002. pp. 19-20.
[62] Doha Declaration para. 6.
[63] WTO General Council 2003. WT/L/540 and Corr. 1.
[64] The decision of the General Council was first a waiver of its nature, which had to be accepted by each member state individually, after which it would be effective only by national implementation. In 2005 the decision of amending the TRIPS Agreement accordingly to the existing waiver was taken. It took twelve years to gain the needed two thirds of member state votes for the amendment. The states who have not ratified the amendment have no obligation to follow it.
[65] Annex to the TRIPS Agreement, Section 2(ii).
[66] Kampf 2015. pp. 11-12.

The exporting country will be the manufacturer under a compulsory licence and the one in charge of the remuneration for the right holder under Art. 31(h). Art. 31bis further restricts the right of the receiving country to re-export products to third states. To avoid illegal re-exporting, Art. 31bis imposes an obligation to label and package the products manufactured under Art. 31 distinctively from others. For the sake of public health, Art. 31bis contains a section according to which an importing country may further export the pharmaceutical product to a third country when they are both parties to a regional trade agreement, at least half of the member states of which are defined as LDCs on the UN list of least developed countries. This rule enhances the public health situation amongst the countries with no capacity to manufacture pharmaceutical products.

Despite the acceptance by two-thirds of Member States, the amendment also needs to be implemented into the national legislation to gain the desired effect, especially on behalf of the exporting states. Without national implementation, the country's IPR legislation may still prevent exporting of patented products. Furthermore, as a gesture of goodwill, multiple developed states gave an official waiver to refrain from acting as importers of pharmaceutical products (such as Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom, and the USA). Accordingly, some states pledged to act as importers merely in emergencies or circumstances of extreme urgency (Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Taipei, Turkey, United Arab Emirates).[67]

2.2.2 Compulsory licencing during national emergency and other extreme urgency

As presented above, Art. 31 (and 31bis) provides a broad set of conditions under which compulsory licence can be granted. However, as the compulsory licence may serve as a tool for a health crisis, Art. 31 provides some flexibility regarding the occurrence of a national emergency. According to Art. 31(b), when a state faces a 'national emergency or other circumstances of extreme urgency', it can waive its obligation first to try to negotiate a voluntary licence on reasonable commercial terms. The state is thus allowed to grant a compulsory licence without attempting to achieve a voluntary licence first. By avoiding

[67] WTO News 2003. *The General Council Chairperson's statement*.

burdensome negotiation proceedings, response to a national health emergency can be conducted more rapidly.

The TRIPS Agreement leaves the interpretation of 'national emergency or other circumstances of extreme urgency' for the discretion of each state. The fact that each country may individually set the criteria for 'national emergency' has gained critique as well as praise for providing flexibility.[68] The Doha Declaration provided some interpretational guidance to the issue, declaring that each state may indeed determine what constitutes a national emergency and that public health crises may fulfill this criterion. Furthermore, the Declaration listed HIV/AIDS, tuberculosis, malaria, and 'other epidemics' as examples of national emergency or other circumstances of extreme urgency,[69] thus confirming that long-lasting, unresolved national health problems can be classified as an emergency.

The exception withdrawing negotiating obligation provides the only emergency-related exception regarding compulsory licencing. All the other requirements of Art. 31 are applicable even during a national emergency, including decent remuneration for the right holder, notification to WTO, and the adequate labelling of the product. All the requirements are in force also regarding exporting under Art. 31bis. Notable is that even to this date, there has been only one case of exporting under compulsory licence: in 2007, Canada announced it will export antiretroviral medicines to Rwanda. In this case, the first shipment of products arrived in Rwanda 15 months after it first notified WTO of the intent of importing under a compulsory licence. The complexity of the procedure caused by bureaucratic and labelling obligations is interpreted to be one of the reasons why exporting under compulsory licence is extremely rare.[70]

Also other emergency opt-outs have been included in the TRIPS Agreement, one concerning Art. 39, protection of undisclosed information presented in subsection 2.1.1. In public emergency, governments are allowed to publish undisclosed test and other data. The operability of this exception will be further assessed in chapter 4. Be that as it may, even in a national public health emergency, patent holders are not required to disclose any information. Any barriers to access to information might be extremely harmful for low-income countries seeking timely access to vaccines, as the capacity to manufacture vaccines without support in know-

[68] Desai 2013. pp. 382-383.
[69] Doha Declaration Section 5(c).
[70] Anderson 2010. pp. 180-181.

how might be low. Furthermore, in the case of widely spread diseases, a lot of assets, time, and energy might be wasted in overlapping research.

2.2.3 Background for compulsory licencing system

The possibility to issue compulsory licences is the only measure of this scope available to third parties to independently derogate from the exclusive rights granted to the patent holder. As such, compulsory licencing provides a backdoor for situations where a well-founded need for cheaper pharmaceuticals with more rapid delivery occurs, such as during pandemics. Although this study aims to assess whether the compulsory licences can adequately respond to pandemics, it is first necessary to evaluate the effects of the legal tool in general. Therefore, this subsection introduces the socioeconomic and political arguments that lie behind the compulsory licencing system. The aim is to more profoundly understand what are thought to be the pros and cons of the tool in general in order to assess later whether these features are applicable in the context of the pandemic.

The scope of the compulsory licences has been widely discussed, and even its existence has faced questioning. Certain states have been promoting the private sector's right to innovation, stating that wide use of compulsory licences may deprive rights of patent holders as they will not be able to fully profit from their inventions, of which creation often requires a vast amount of resources.[71] From the point of view of pharmaceuticals, this may appear justified, as it is estimated that the costs of R&D for one new pharmaceutical product reach an average of $500 million.[72] However, the pharmaceutical industry tends also to be amongst the most profitable – according to Global 500 of 2020, seven pharmaceutical companies were amongst the hundred most profitable companies in the world.

The profitability rates raise concerns about whether the pricing of pharmaceutical products is always justified. It is acknowledged that patent protection raises product prices in the medical industry, which is recognized even by the Doha Declaration supplementing the interpretation of the TRIPS Agreement. However, the issue is not necessarily the patent regime *per se,* but the lack of competition it creates,[73] especially in connection with medical products requiring

[71] See e.g. The United States 1987. MTN.GNG/NG11/W/14 Suggestion by the United States for Achieving the Negotiating Objective.
[72] Anderson 2010. pp. 175-176.
[73] Garrison 2021. p. 19.

dedication to R&D, know-how on complex analysis, and manufacturing capacity. The lack of competition is well highlighted by the fact that in 2019 four manufacturers (GlaxoSmithKline, Pfizer, Merck, and Sanofi) dominated global vaccine markets with the value of 90 %, and 60 % of the world's vaccines were manufactured by only five actors (GlaxoSmithKline, Sanofi, Haffkine, Serum Institute of India and BBIL).[74]

The controversy in the discussion on compulsory licencing emerges as a consequence of two colliding arguments. On the other hand, compulsory licences are justified as they are a tool for a government to enable the manufacturing of cheaper, generic versions of pharmaceuticals when needed. This opportunity reflects the TRIPS principles on socioeconomic welfare and is said to enhance public health in general. On the other hand, exclusive pharmaceutical protection is also justified due to the excessive R&D costs linked with the industry. Pharmaceutical companies would not be willing to invest vast amounts in developing pharmaceutical products without a decent profit-risk rate. It is also a fact that several pharmaceutical products are easy to copy, which highlights the importance of legal protection.[75] It is thus suggested that the use of compulsory licences might result in the lack of incentives for developed companies to engage in the pharmaceutical field, thus negatively impacting global welfare.[76]

The highly polarised discussion also reflects the deep division between developed and developing country members. The ones with more secure access to pharmaceutical products wish to provide a more stringent framework for the use of compulsory licencing, whereas the ones with lower manufacturing capacity are standing behind a more accessible approach. Before the implementation of the TRIPS Agreement, the countries were heavily divided on whether the possibility to grant compulsory licences should exist at all.[77] Though it is known that the exclusive rights of patent holders (even monopolistic rights on some occasions) distort the economy, the distortion is often considered temporary and, in the end, to result in the adoption of new technologies and thus to development worldwide.[78]

The dividing opinions were actually one of the reasons why the TRIPS negotiations were initiated in the first place.[79] Before the TRIPS Agreement, the international legislative regime

[74] World Health Organization 2020. Global Vaccine Market Report 2019.
[75] Salazar in a panel discussion on Intellectual Property and Human Rights 1998. p. 70.
[76] UNCTAD-ICTSD 2005. p. 488.
[77] UNCTAD-ICTSD 2005. pp. 463-467.
[78] Salazar in a panel discussion on Intellectual Property and Human Rights 1998. p. 70.
[79] UNCTAD-ICTSD 2005. p. 463.

did not provide mandatory protection for pharmaceutical products. Hence, the compulsory licencing system established in the Paris Convention for the Protection of Industrial Property did not apply to pharmaceutical products, provided that member states had not implemented more protective measures to their national legislation. The global market for pharmaceuticals was thus unstable and unpredictable.

In the course of the 21st century, the US has persistently had a global market share of 50 % in the global pharmaceutical market, Europe and emerging markets arriving far behind with only 20 % market share each.[80] It is then no wonder that expressly the US pushed through the pre-TRIPS discussion on compulsory licencing and its yet undefined condition. The US strongly manifested for a narrow-scoped compulsory licencing system:[81] in its suggestion for the negotiating group of the TRIPS Agreement, the United States suggested the extension of patent protection to *'any technological field'* and stated that compulsory licences should not be generally granted, and when granted, only due to 'a legitimate reason for *not practicing the invention*' and only 'subject to agreed narrowly defined circumstances'.[82]

The abovementioned discussion on the general effects of compulsory licencing system is essential to this study, as the interests behind the system highlight its functionality. When examining whether the compulsory licencing system can adequately respond to pandemics, it is important to acknowledge why it is established in the first place and what are the considered socioeconomic consequences of using such a system. In addition, the relation of private-sector rights and public health will be of importance when assessing whether their equitable relation should be more appropriately balanced during worldwide pandemics. This discussion will take place in Chapter 4.

2.3 TRIPS legal framework for public health

2.3.1 TRIPS Principles

Since this research examines whether the rights and obligations of the TRIPS Agreement offer adequate tools for combatting worldwide pandemics, it is essential to understand the principles

[80] Global pharmaceutical sales share by market, last update 2021.
[81] UNCTAD-ICTSD 2005. p. 463.
[82] The United States 1987. MTN.GNG/NG11/W/14 Suggestion by the United States for Achieving the Negotiating Objective. p. 7.

and guidelines the Agreement is based on. This kind of broader contextual understanding of the TRIPS Agreement allows assessing whether the existing regulation is in balance with the fundamental principles and goals of the Agreement and whether the existing legal tools can be interpreted pro-health during pandemics. Therefore, this subsection introduces the basic principles of the TRIPS Agreement, whereas the following two subsections will first present the importance of the Doha Declaration and second the TRIPS Waiver of the WTO Agreement as a last resource response for emergencies.

The TRIPS Agreement is a multilateral agreement regulating the patent regime of more than 150 Member States, and it is therefore heavily guided by principles to create interpretational space and, consequently, flexibility. In its preamble, the Agreement emphasizes the importance of 'taking into account differences in national legal systems.' Furthermore, the preamble recognizes the divergent needs of LDCs regarding their capability of implementing the TRIPS Agreement while the infrastructure in multiple technology areas still lags behind.

Part I of the TRIPS Agreement provides the basic principles the Agreement is built on. Art. 8, titled as 'Principles', includes explicit reference to public health issues by stating that the Member States are allowed to take into account the protection of public health and nutrition in their national implementation of the Agreement, as long as the measures are 'consistent with the provisions of this Agreement'. Art. 7, headed as 'Objectives', emphasizes public health issues by stating that the protection of intellectual property rights 'should contribute to the promotion of technological innovation … in a manner conducive to social and economic welfare, and to a balance of right and obligations'.

Art. 7 is interpreted to present the purpose of the TRIPS Agreement:[83] protecting intellectual property rights simultaneously contributing to the overall accessibility of technology enhancing socio-economic welfare. Together with Art. 8, it establishes the context for interpreting the TRIPS provisions,[84] which, as a consequence, is somewhat based on social welfare and equality. These principles were further enforced by the Doha Declaration in 2001, which will be addressed in the following subsection.

[83] Mitchell – Voon 2010. pp. 57-58.
[84] Ibid. p. 58.

The equality approach is enforced by articles 3 and 4, which establish the principle of non-discrimination through components of national treatment and Most-Favored-Nation ("**MFN**"). Under Art. 3, Member States are not allowed to establish more protective intellectual property regulation towards its nationals than to third-country nationals. According to this national treatment principle, Member States must provide equal protection to other states as they provide domestically. This ensures non-discrimination by not allowing too protective measures against the other Member States, also resulting in a situation where too protective legislation is not profitable, as the protection should be granted to foreign nationals too.

The national treatment principle provides some exceptions to the rule,[85] but it efficiently prevents discrimination amongst states. Yet, during the TRIPS negotiations, a concern regarding bilateral and multilateral agreements where more favourable protection would be granted to the other Member States in respect to others arose.[86] As a result, Art. 4 introduces the MFN principle: any privilege given to a third Member State regarding intellectual property rights will be immediately granted to all other Member States with equal conditions. However, e.g. general procedural agreements, exceptions provided by the Berne Convention or the Rome Convention, and obligations arising from other international IPR agreements in force prior to the TRIPS Agreement are exempted from this obligation.[87]

2.3.2 Doha Declaration

The Declaration on the TRIPS Agreement and Public Health was concluded in Doha, Qatar, on 14th November 2001 by the Ministerial Conference consisting of government representatives.[88] The Declaration was adopted by consensus, and it aimed to clarify the somewhat contradictory relationship between intellectual property rights and public health considerations.[89] Doha Declaration is not a binding legal document *per se,* but it provides guidelines for the implementation and interpretation of the TRIPS Agreement from the point of view of public health considerations. It is, however, a subsequent agreement of the TRIPS Agreement and close to having a status of formal agreement on the interpretation of TRIPS.[90]

[85] The exceptions are mostly related to copyrights and judicial procedures, the reason for which they are not more profoundly introduced here.
[86] Taubman – Wager – Watal 2012. p. 17.
[87] TRIPS Agreement Art. 4(a-d); 5.
[88] Law 2009. p. 29. Ministerial Conference is the highest decision-making body of the WTO.
[89] Ibid. pp. 156; 161.
[90] Ibid. pp. 161-163.

The Doha Ministerial Conference was preceded by a division between developed and developing -country members. The developing country members were facing issues in implementing the TRIPS Agreement in a manner simultaneously respecting socio-economic welfare.[91] The South African example well demonstrates the struggles. South Africa suffered from tremendous HIV/AIDS episode in the late '90s and started amending its laws to allow the importation of pharmaceuticals under a compulsory licence,[92] as the patented antiretrovirals were too costly for combatting the disease. South Africa faced fierce resistance also in the form of a legal challenge by pharmaceutical actors (and by the international field e.g. by the United States).[93] The lawsuit was withdrawn in 2001 as a consequence of non-governmental organizations efforts and the Doha Declaration.[94]

The struggles of emerging countries resulted from the fact that developing country members could not participate in the TRIPS negotiations as efficiently as developed countries due to the lack of financial resources and technical knowledge. As a consequence, the developing countries started to demand a formal acknowledgement regarding the connection of intellectual property rights and socio-economic considerations later on. The countries were of the opinion that the TRIPS Agreement was not being implemented in a manner respecting the objectives and purposes established in Articles 7 and 8 of the Agreement.[95]

Indeed, Doha Declaration states that the public health problems affecting developing countries and LDCs are acknowledged and that the effects of intellectual property rights on the costs of pharmaceutical products are recognized.[96] Furthermore, paragraph 5(a) specifically lays down that the TRIPS Agreement and all of its rights and obligations should be read in light of objectives and principles, thus straightly referring to Articles 7 and 8. The public health dimension is further emphasized by paragraph 4 of the Declaration, according to which TRIPS should not prevent the Member States from protecting public health. Instead, the Agreement should be implemented and interpreted in a manner supporting the Member States to protect public health. In this context, the Declaration particularly refers to access to medicines.

[91] Ibid. p. 29.
[92] By the time importing/exporting under compulsory licence was yet not allowed.
[93] Law 2009. p. 39.
[94] Young 2010. pp. 364-371.
[95] Law 2009. pp. 39; 164.
[96] Doha Declaration paras. 1; 3.

In paragraph 5, Doha Declaration also addressed few issues in a more detailed manner. For example, paragraph 5(b) provides that compulsory licencing is a right belonging to each Member State, and each Member State also has the freedom to determine the grounds based on which compulsory licences can be granted. Moreover, paragraph 5 confirmed that defining 'national emergency' or 'other extreme urgency', based on which the requirement of primary negotiations regarding compulsory licencing can be waived, can be determined by each state independently. In this regard also explicit references to HIV/AIDS, tuberculosis, and malaria were made.

One of the most notable achievements of the Declaration by the time was its paragraph 6, which gave the authorization to the General Council to start preparing a solution for the issue of the compulsory licences not allowing other than domestic distribution. As already addressed in subsection 2.2.1, this authorization led later to the amendment of the TRIPS Agreement and the implementation of Art. 31bis (the Paragraph 6 system) allowing eligible states to import pharmaceutical products under compulsory licences.

Another achievement worth mentioning was the extension of the transition period of LDCs until 2016 regarding patent protection of pharmaceutical products. In practice, the LDCs were freed from implementing Sections 5 and 7 of Part II of the TRIPS Agreement concerning pharmaceutical products. As a result, the countries did not have to offer patent protection to any medical products invented. Furthermore, the LDCs did not have to protect undisclosed information either for the sake of enhancing the transfer of know-how resources to least-developed countries. However, it remains questionable whether the last exception was relevant since undisclosed information is not publicly available in those countries where the patent regime is enforced.

The Declaration does not alter the obligations or rights granted by the TRIPS Agreement[97] but merely clarifies the relation of the regulation to public health considerations, which tended to be left aside in the early years of implementation. It also emphasizes some available rights and offers guidance for the use of compulsory licencing as a tool. Though the Declaration did not bring anything mind-blowing to the table, it seems to have been a necessary policy tool during the time being. The growing gap between developing and developed countries and the fierce

[97] Law 2009. p. 167.

promotion of intellectual property rights even at the expense of health considerations got to be formally addressed. Furthermore, the interpretational guidance offered by the Declaration will be of use when assessing whether the current regulation can answer the challenges of pandemics, taking into account the emphasised public health considerations (chapter 4).

2.3.3 TRIPS Waiver as the last resource

As described above, compulsory licencing serves as a tool for accessing pharmaceutical products protected by patents when certain preconditions are met. As this research focuses on studying the regulation from the perspective of worldwide emergencies, other available exceptions (mainly the TRIPS Waiver) are briefly described here. During the Covid-19 pandemic, the TRIPS Waiver was largely in the centre of attention, and its usefulness as a legal tool in combatting pandemics is assessed in chapter 4.

Any obligation of the TRIPS Agreement may be waived during exceptional circumstances. This possibility is provided by Article IX of the WTO Agreement, according to which an obligation imposed by any Multilateral Trade Agreement (annexed to the WTO Agreement) may be waived by a decision of the Member States. There is no clear framework for what concludes exceptional circumstances, but waivers' exceptional nature and strict discipline have been emphasized – the profound idea of Art. IX(3) is to provide a limited exception to one's obligations, and the interpretation of waivers must be conducted with due care and on a case-by-case basis.[98]

To comply with Art. IX(3) requirement of strict discipline, the waiver must, first of all, be limited from its timely scope. Art. IX(4), therefore, provides that if the waiver has been granted for more than one year, it shall be annually reviewed to assess whether the circumstances that led to the granting of the waiver still exist. Art. IX(4) further provides that when pursuing a waiver, the policy objective and the need to state 'exceptional circumstances' must be clearly stated, and the application of the waiver must be subject to clear terms and conditions.

Suggested waivers are dealt with by the Ministerial Conference, which strives for acceptance by consensus of the Members. The Ministerial Conference may set up a deadline of a maximum of 90 days for reaching the consensus, after which the waiver may be imposed by a three-fourths

[98] World Trade Organization 2021. WTO Analytical Index: WTO Agreement - Article IX. p. 6.

majority of Members to the WTO Agreement (Art. IX(3)). In addition to the strict discipline of waivers, the Appellate Body found in the *EC – Bananas III* that waivers can merely release a Member State from its obligations.[99] Furthermore, the Appellate Body Report states explicitly that the 'purpose is not to modify existing provisions in the agreements, let alone create new law …'.[100]

Hundreds of waivers have been accepted under Art. IX of the Marrakesh Agreement, of which only two have concerned the TRIPS Agreement. One of these is the Paragraph 6 decision implementing the possibility to export pharmaceuticals under compulsory licences. For instance, this waiver did create new law (as indicated in section 2.2.1), though it did not add to Member States obligations but rather enabled new rights. The *EC – Bananas III* Appellate Body Report, according to which waivers should not provide new regulation, was published in 2008, whereas the Paragraph 6 system was introduced in 2003.[101] Therefore, it seems that the interpretation of waivers has tightened, and it is probable that regulation similar to the Paragraph 6 system could not be established today.

During the Covid-19 pandemic, the third TRIPS waiver was brought to the table, gaining a lot of attention and multiple different opinions. The discussion on the waiver and the pandemic will be introduced in chapter 4. However, before the discussion on the applicability and adequacy of the legal framework introduced in this chapter can take place, the context must be fully understood. That is why chapter 3 will dive deep into the prevailing circumstances of the Covid-19 pandemic from the perspective of vaccine distribution.

3 PANDEMICS AND TIMELY ACCESS TO VACCINES

This chapter is to establish the context for this research. The compulsory licencing system has been implemented in the TRIPS Agreement as it may provide access to necessary medical treatment in a cost-efficient and timely manner. During pandemics, the need for vaccines is worldwide, and the faster, the better. The compulsory licencing system is initially designed for *national* emergencies, not for global ones; however, it is the only concrete legal tool available for states in reaching out for timely access to patented pharmaceuticals. This is highly worrying

[99] The WTO Apellate Body. EC - Bananas III 1997. WT/DS27/AB/R.
[100] The WTO Apellate Body 2008. WT/DS27/AB/RW2/ECU para. 382.
[101] WTO General Council 2003. WT/L/540 and Corr. 1.

as global emergencies also invite political disputes and protective attitudes, partly avoidable by more clear regulation.

As this study aims to investigate the pros and cons of the available legal options under TRIPS in pursuing timely (global) access to vaccines during pandemics, this chapter explores the nature of vaccine distribution during pandemics. The chapter establishes the framework in which the existing legislative framework should be functioning. The idea is to investigate how fast the vaccines have been distributed around the world and what have been the major factors affecting timely access. The examination allows the further investigation of how these major factors are taken into account in the relevant legislation in the next chapter.

The first section will focus on (3.1) possible distribution delays related to the research and development phase. In this context also the funding mechanisms and their implications to timely access are assessed. The second section introduces (3.2) factors related to manufacturing and distribution of the vaccines, and the third section is dedicated to (3.3) other relevant factors. The examination is conducted by heavily leaning on experiences of the Covid-19 pandemic, the scope of which has not been seen before in the modern era.

3.1 Vaccine development

3.1.1 Research and development

During two recent pandemics, H1N1 (2009) and Covid-19 (2019), timely access to vaccines has been widely discussed from different perspectives. Viewing the statistics, the response to pandemics seems hugely efficient: for H1N1-virus, the first doses of vaccines were distributed after only five months from the identification of the pandemic virus[102], and for Covid-19, WHO issued its first emergency use validation within nine months from the declaration of the pandemic.[103] As the development of a vaccine generally takes more than ten years,[104] the response time is astonishing.

[102] World Health Organization 2009. Transcript of virtual press conference with Gregory Hartl, Spokesperson for H1N1, and Dr Marie-Paule Kieny, WHO Director of the Initiative for Vaccine Research. p. 1.
[103] World Health Organization 2020d. *WHO issues its first emergency use validation for a COVID-19 vaccine and emphasizes need for equitable global access.*
[104] Eccleston-Turner – Upton 2021. p. 430; Gray et al. 2021. p. 89.

Indeed, R&D itself does not seem to be the bottleneck regarding vaccine distribution. However, vaccines tend to be established by private manufacturers functioning in high-income states, a set-up that somewhat reflects distribution rates of vaccines. It is thus worth investigating whether the very beginning of the vaccine development process during pandemics comprise features that may reflect the distortion in vaccine distribution later on. This subsection focuses on the R&D process itself, whereas the following subsection introduces the funding mechanisms.

In April 2020, only a few months after the breakout of the pandemic, already 115 vaccine candidates under development were reported to WHO. The vaccine candidates presented a wide range of different and even new technologies. Of the 115 candidates, 72 percent were launched by private and industry developers and 28 percent by academic and public sector actors and non-profit organizations. Interestingly, almost half of the reported developers were situated in North America (46 %). China and Europe were represented by 18 percent share each, and Asia and Australia together had a share of 18 percent. Latin America and Africa had no reported vaccine developers in April 2020, and all the reported developers represented only 19 countries worldwide.[105]

By the time of February 2021, the number of reported vaccine candidates was already 289.[106] In June 2021, six vaccines had received the emergency use listing ("**EUL**") status by WHO: Comirnaty by Pfizer/BioNTech (US/Germany), AstraZeneca/Oxford (UK/Sweden), Johnson & Johnson by Janssen (US), Sinopharm by Beijing Bio-Institute of Biological Products Co Ltd. (CH), Moderna by ModernaTX Inc. (US) and Sinovac by Sinovac Biotech Ltd. (CH). EUL is used as an indicator of globally usable vaccines here, as it is based on evaluation and approval conducted by WHO.[107] It must be noted that the states are not bound by EUL, and they may thus grant approvals to any vaccine they wish.[108] In fact, five other vaccines had received approval from other regulatory authorities by June 2021.[109]

[105] Le et al. 2020. pp. 1-2.
[106] Wouters et al. 2021. p. 1025.
[107] World Health Organization 2021a. *WHO validates Sinovac COVID-19 vaccine for emergency use and issues interim policy recommendations.*
[108] However, only the vaccines approved by WHO or other stringent authorities can be purchased through COVAX (later explained in this study).
[109] Wouters et al. 2021. p. 1025.

When assessing the vaccines which have received the EUL status, the success of developed countries is remarkable. There is no direct explanation for this phenomenon, however, the reasons may lie in the long R&D tradition and capacity of companies that have been situated in developed countries. Understandably, the resources developed countries are able to offer have increased the ability of companies to conduct rapid R&D processes. Furthermore, successful and large companies tend to situate in more developed states, as the IP regime may be more favourable for the private sector in developed countries. This is as in the pharmaceutical industry, R&D processes are usually long-lasting and expensive from their nature, due to which a higher level of patent protection is more profitable.

It is indeed understandable that without patent rights, the incentives for extensive research would also be diminished. Accordingly, if one does not patent their innovation, they have no binding obligation to disclose any information associated with a pharmaceutical product. As a result, societies would not benefit from innovation, as other experts in the field would not gain any information related to other's discoveries. Due to patent protection, when the product or process is patented, a certain amount of information must be disclosed to the public, although the TRIPS Agreement does not specify the amount of information to be disclosed. Understandably, some level of protection to the disclosed information must be provided in order to encourage patenting. Therefore, disclosing information regarding pharmaceutical products and information related to their manufacturing processes is typically forbidden by third parties in accordance with Art. 39 of the TRIPS Agreement.

The issue is that pandemics require rapid solutions, which cannot be achieved without transparent cooperation and data sharing. Therefore, WHO launched the Covid-19 Technology Access Pool ("**C-TAP**"), the intention of which was to urge pharmaceutical industry actors to share knowledge on Covid-19 related technology and, for example, information on clinical test data of Covid-19 vaccine candidates. It has been stated that C-TAP was not a success, as the most vital vaccine candidate developers disregarded it.[110] However, some contribution to the dissemination of know-how by successful Covid-19 vaccine developers has been evidenced during the pandemic.

[110] Wouters et al. 2021. p. 1031.

In connection with its authorisation granted by Health Canada and European Medicines Agency ("**EMA**"), Moderna allowed publication of the entire clinical data related to the development of the vaccine. The disclosure of information took place in March 2021.[111] In a way, the act can be considered hugely important. This is as Moderna uses the kind of technology (mRNA) that is still relatively unfamiliar for most of the actors in the pharmaceutical field. For other actors to be able to manufacture and distribute the vaccine, it is essential that clinical data is extensively shared.

It is, however, disputable how much the clinical data disclosure benefits the (timely) R&D processes if the data is shared only in connection with the authorisation, not already when the process is still pending. It is also noteworthy that Moderna patented parts of the used mRNA - process already before the pandemic, and the end-product, in other words, the Covid-19 vaccine, in July 2020.[112] Despite the patents, Moderna pledged not to enforce its patent-related rights during the pandemic in the name of international cooperation and announced it will not initiate any proceedings against actors who will be manufacturing the Covid-19 vaccine as the pandemic is still ongoing.[113]

Moderna's acts being exemplary, they also create a post-pandemic market for the company itself. As Moderna owns the patent rights, it can enforce the patent rights post-pandemic. Furthermore, due to the current rarity of existing mRNA technology in the field, Moderna may succeed in adding mRNA technology by freeing its use during the pandemic, after which it has potential clients for buying voluntary licences as the technology has already been implemented.[114] There is nothing wrong with this: on the contrary, the post-pandemic opportunities might have boosted the company's openness. However, this reminds us that private actors do act based on market-driven values, which should be remembered when designing responses to pandemics.

Concerning R&D, it is hard to assess how much faster the process could still be. The vaccine developers seem to have already done an almost impossible job creating functioning vaccines (not only one but six) in less than a year. Though every credit should be given from these efforts,

[111] European Medicines Agency 2021a. *EMA and Health Canada publish clinical data used to support their authorisations of the Moderna COVID-19 vaccine*.
[112] De Fougerolles – Guild 2020. Modified polynucleotides for the production of secreted proteins. ModernaTX Inc. assignee. Patent no US10953089.
[113] Shores 2020. *Breaking Down Moderna's COVID-19 Patent Pledge: Why Did They Do It?* IP Watchdog.
[114] Ibid.

it seems that cooperation in the name of transparency and data disclosure could still be enhanced. The circumstances prevailing during the Covid-19 pandemic require a response of which delay even by days results in significant economic losses and a large number of deaths. Better coordination and data sharing could result in even faster response, be it days, weeks, or even months. Furthermore, the observation that R&D capacity seems to be unbalanced and leaning towards developed states requires a closer look, which will be done next.

3.1.2 Development funding

Though the pharmaceutical industry receives financial support during regular times, the amount is nothing in respect to the cash flow directed to pharmaceutical actors during pandemics. To speed up the R&D process and promote transparency and cooperation, significant investments have been made in the development of a functioning vaccine during Covid-19. In addition to direct government funding to pharmaceutical companies, universities, and other actors, international funding methods have also been adopted.

To efficiently combat the pandemic, WHO launched the Access to Covid-19 Tools (ACT) Accelerator ("**the ACT-Accelerator**") containing four pillars which aims are to strengthen diagnostics, therapeutics, vaccine development and distribution and health systems. One pillar of the ACT-Accelerator is COVAX, administrated by Gavi (the Vaccine Alliance), the Coalition for Epidemic Preparedness Innovations ("**CEPI**") and WHO. Regarding R&D, the objective of COVAX was to gather funds for the most promising vaccine candidate developers in order to speed up the process.[115]

It is estimated that COVAX funded vaccine candidate developers' research and development by 2.4 billion dollars. COVAX funding is gathered from external investors and up-front payments from the participating states, and it is based on 'pull financing' and 'push financing', due to which the incentives for pharmaceutical companies to develop a vaccine are high. Push financing consists of at-risk investments, which in regular circumstances would rarely if ever be offered. At-risk investment signifies that the manufacturing capacity (facilities and technologies) is scaled up before the (promising) vaccine candidates have proven to be usable, even though there is a risk that the vaccine will never be manufactured. Without at-risk investments, the timeline for vaccine distribution would be much longer, as investments enable

[115] Eccleston-Turner – Upton 2021. p. 430.

manufacturers to build up the manufacturing capacity prior to the regulatory approval of vaccines.[116] Push financing is granted for pharmaceuticals with auspicious results.

Pull financing, on the other hand, is implemented in the form of advance purchase agreements. In other words, COVAX made pledges for vaccine developers to purchase significant amounts of vaccines, were they proven efficient. By pull financing, vaccine developers can ensure their investments in research and development will be compensated by a significant demand. The funding strategy of COVAX is rather incentivising, as when a successful vaccine is created, the profit rate climbs high, but when the trial fails, the financial risk is covered by others. Furthermore, even when failing in creating a successful vaccine, the investments already made in manufacturing capacity (funded by COVAX) remain in the use of the developer and may thus be commercialised for future use.[117]

One significant international funder for development has been CEPI, receiving donations of around 1,4 billion dollars to be distributed for vaccine developers. CEPI funded around ten vaccine candidates, of which AstraZeneca, Moderna and Novavax successfully gained the EUL status. CEPI funded vaccine developers are obligated to participate in COVAX Facility, a facility under COVAX promoting equal distribution of vaccines (of COVAX Facility more in section 3.2). CEPI has informed that the agreements with successful vaccine developers obligate the developers to provide COVAX with the number of vaccines corresponding to CEPI funding. The agreements, however, remain secret.[118]

In total, it has been (conservatively) estimated that vaccine developers worldwide have received from the public and non-profit actors more than 10 billion dollars for the development of the Covid-19 vaccine.[119] In light of the gathered data, the most prominent financiers of already Emergency Use Listed vaccines have been the relevant states and Biomedical Advanced Research and Development Authority ("**BARDA**"), US. BARDA has been involved in financing the research of AstraZeneca, Johnson & Johnson and Moderna by approximately 3,7 billion dollars in total.[120]

[116] Ibid. p. 432.
[117] Eccleston-Turner – Upton 2021. p. 432-433.
[118] Usher 2021. *CEPI criticised for lack of transparency*. The Lancet 397(10271).
[119] Wouters et al. 2021. p. 1025.
[120] See Appendix 2 in Wouters et al. 2021.

The monetary efforts put into R&D during the pandemic have been extraordinary, and the back-up given to pharmaceutical companies has, without questioning, expedited the access to vaccines. The interesting question is, has it done so for everyone. It is very common that the home state of a pharmaceutical company or the manufacturing facility reaches access to vaccines first, many times also with the most considerable quantities. Similar to COVAX, States tend to use bilateral or multilateral advance purchase agreements. Though the terms of the agreements remain mostly secret, it seems to be common that the more close you reside the manufacturer, the faster you receive the delivery.

This is due to two reasons: the commercial relationship between the parties (and the possibly secret agreement) and export restrictions/pressure put on the manufacturer. Accordingly, in spring 2021, AstraZeneca struggled with manufacturing capacity issues in its Belgian factory and could not provide the EU with promised amount of vaccines. Even though the factory in Great Britain was mentioned in the agreement between AstraZeneca and the EU, it prioritized deliveries to Great Britain.[121] The reasons for this remain unclear due to the secrecy of the agreements. Similar occurrences have also emerged due to state vaccine export bans, which force the manufacturer to provide vaccines first for the enacting state (more in subsection 3.2.3). As it stands, it is worth taking a closer look at which actors have gained most of the international funding, as the location of manufacturing facilities may affect the timely access to vaccines.

As of February 2021, of all leading vaccine candidates, the most funded were Sanofi ($2.1 bln, France), Novavax ($2.1 bln, US), AstraZeneca ($1.7 bln, UK), Johnson & Johnson ($1.5 bln, US) and Moderna ($957 mln, US). The data was not available for Sinovac or Sinopharm by the Beijing Institute. The companies situated in the United States seem to be overrepresented in the statistics, whereas the absence of Latin America, Africa and even Asia is notable. The US government has actively funded the development of successful vaccine candidates during Covid-19, also those residing outside the US. Accordingly, the UK has financed AstraZeneca extensively. This indicates that direct state funding does play a significant role in creating successful vaccines during pandemics, which might in its part lead to high-income states gaining access to vaccines first. It must be noted that also CEPI funded promising vaccine

[121] Halminen 2021. *Mitä AstraZeneca lupasi EU:lle? Juristin mukaan "kahdella yhtiön asiakkaalla on nyt päteviä perusteluja pitää rokotteista kiinni"*. Helsingin Sanomat.

candidates around the world.[122] This indicates that to achieve equal and timely access to vaccines, international funding is desperately required.

The fact that funding is mainly directed to western pharmaceutical actors might also indicate that the companies with the most prominent manufacturing capacity are emphasized already in the R&D phase. Though this seems natural, it could be questioned whether the patent regulation has something to do with this unequal distribution of R&D funding – the risk of patent holder enforcing patent rights during pandemic could in its worse lead to a complete shortage of vaccines if the patent holder does not have the capacity to manufacture the vaccine itself, and is not willing to share the know-how to other manufacturers. In fear of a vaccine shortage, the funds may be directed to actors that would be able to manufacture the patent protected vaccine at least to some extent by themselves.

As it stands out, the R&D process itself does not hugely affect the timely access to vaccines; however, the abovementioned information disclosure could be enhanced. Be that as it may, the imbalance in capabilities to fund vaccine development may lead to unequal timely access to vaccines in the form of national protectionism. It indeed seems that the effects of R&D on timely access to vaccines emerge mostly after the R&D process itself, as the residency of the vaccine developer or manufacturer may affect the equal distribution of vaccines. These challenges will be assessed in chapter 4 in more detail and in connection with the applicable legislation.

[122] Halminen 2021. Appendix 2.

3.2 Manufacturing capacity and vaccine distribution

3.2.1 Vaccine developers' manufacturing capacity, external manufacturing contracts and international patent regime

The challenges to timely access seem to arrive within manufacturing and distribution. During the H1N1 pandemic, vaccine manufacturing was extremely slow due to somewhat outdated manufacturing methods,[123] which fortunately is not the case in the current pandemic. On the other hand, Covid-19 raises the concern whether the modern technologies required in some vaccines can be adopted rapidly enough by a decent amount of manufacturers. The remains of H1N1 also indicate that low- and middle-income countries gained access to vaccines in a less timely manner than others, which in its part raises concerns regarding timely access during Covid-19.

In this section, the factors related to manufacturing capacity and the distribution of vaccines are examined in general. It is assessed (3.2.1) whether the timely access to vaccines could be restricted by the limited manufacturing capacity of the vaccine developers. It is also examined to what extent external actors manufacture vaccines and on what basis, and whether intellectual property rights play a role in these arrangements. Furthermore, (3.2.2) the effects of vaccine purchase agreements will be assessed: how are the purchase agreements negotiated and who gains the access first? Lastly, (3.2.3) the impacts of protective acts by the states will be examined.

According to WHO, in 2019 four manufacturers (GlaxoSmithKline, Pfizer, Merck and Sanofi) dominated global vaccine markets with a value of 90 %. Accordingly, 60 % of the world's vaccines were manufactured by five actors (GlaxoSmithKline, Sanofi, Haffkine, Serum Institute of India and BBIL).[124] The numbers well reflect the potential of the pharmaceutical industry to produce Covid-19 vaccines globally: manufacturing capacity is extremely unequally divided. Moreover, as most of the manufacturing capacity lies in high-income states (and India), the vaccine supply tends to reach those states first. This has been predominantly the case also during Covid-19, as delays in manufacturing have led to a shortage of vaccines in low- and middle-income countries.[125]

[123] Radcliffe 2020.
[124] World Health Organization 2020. Global Vaccine Market Report 2019.
[125] Imran Khan – Ikram – Bin Hamza 2021.

In 2021, the world population is around 7.9 billion, and most of the Covid-19 vaccines are two dose course vaccines. Therefore, the pharmaceutical industry should be able to produce approximately 15.8 billion vaccines in the shortest time possible. In August 2020, the CEPI survey suggested that by the end of 2021, around 2 billion people could be fully vaccinated when estimating the manufacturing capacity of the potential vaccine candidate developers. On the contrary, the manufacturers whose vaccine had received EUL -status by July 2021[126] estimated that by the end of 2021, they would be able to fully vaccinate 6 billion people.[127]

The global manufacturing capacity of Covid-19 vaccines is one aspect of the timely access that could easily be limited by international patent regulation. The patent regime protects the developers right to produce vaccines exclusively, and even during pandemics, this right can be enforced. However, when examining Covid-19 related patents, it must be remembered that vaccines are extraordinarily complex of their nature. As a result, one can patent vaccines in different levels: the end product may be patented, as well as the foundational technology (such as mRNA) or parts of the end-product (such as particular vectors and other particles fatal to the end product). Followingly, several Covid-19 related patents had already been applied and accepted before the outbreak of the pandemic, as some of the foundational technologies had already been invented and were then applied for the development of the Covid-19 vaccine.[128]

Also many of the Emergency Use Listed vaccines are patent protected to some extent. For example, as indicated in section 3.1.1, Moderna holds multiple patents related to Covid-19 vaccines. Two of these have been accepted after the pandemic outbreak: the first patent was applied for already in 2019, and the Covid-19 vaccine was patented by a follow-up application to the initial one, due to which its approval was significantly faster.[129] Accordingly, AstraZeneca has a patent that covers novel adenoviral vectors. The patent was applied for already in 2011 and accepted in 2012,[130] and the same vector is used in AstraZeneca's Covid-

[126] This estimation includes also the contribution of Novavax Inc. (US) of which Covid-19 vaccine was not yet Emergency Use Listed by WHO by the time, but which is used in several countries and was waiting for the approval. Novavax alone estimated its manufacturing capacity until the end of 2021 would be to produce full vaccination for around 1 billion people, reason for which it is included in this estimation.
[127] So – Woo 2020. p. 5.
[128] See e.g. Gaviria 2021.
[129] De Fougerolles – Guild 2020; Claramella – Himansu 2020. US10953089.
[130] Dicks – Cottingham – Hill – Gilbert 2012. WO2012172277. This international patent application accepted by WIPO resulted at least in the following granted patents: EP2714916 (Europe), US9714435 (United States), CN103930551 (China) and IN318021 (India). See Garrison 2021. p. 18.

19 vaccine. AstraZeneca further applied for a new patent including the same vector in April 2020, which indicates that it intends to patent its Covid-19 vaccine.[131]

Accordingly, BioNTech possesses a patent related to the Covid-19 vaccine, as their vaccine is based on technology (RNA decorated particles) that received patent protection in March 2020, though the protection was applied already in 2018.[132] Also BioNTech filed a patent application in 2020.[133] Novavax -vaccine has been patented in March 2021 after the application filed by Novavax Inc. in August 2020 was approved.[134] Lastly, Johnsson & Johnsson has manufactured vaccines based on the AD26 adenoviral vector for several years. Vaccines based on this vector are patented, however, excluding the Covid-19 vaccine, which is expected to have been applied for, though there is no publicly available data regarding the assumed application. Be that as it may, due to the previous patents, Johnsson & Johnsson holds the right to manufacture AD26 -based vaccines, which also its Covid-19 vaccine is.[135] At the time of writing this research, information regarding Sinovac nor Sinopharm was available.

Despite the Covid-19 related patent rights, they have been fully enforced by none of the abovementioned companies during the pandemic. In the context of manufacturing capacity, none of the companies, even their capacity put together, would be able to manufacture all the required doses in a rapid timeframe. That is also why significant efforts towards cooperation in the manufacturing field have been necessary, and it goes without saying that waiving one's patent-related rights to a certain extent is part of effective cooperation.

To satisfy the global vaccine demand, companies have been conducting manufacturing agreements globally. This is quite uncommon, and before the pandemic, the leading manufacturers of the Covid-19 vaccine did not have comprehensive networks with other manufacturers but instead played within their own domain.[136] *Figure 1* presents statistics from 18th August 2021, showing how many manufacturing agreements had been conducted by each vaccine candidate developer and the global whereabouts of the facilities. AstraZeneca had 16 manufacturing contracts in nine different countries, Pfizer/BioNTech 15 contracts in 8

[131] Silbersher 2020. The information regarding the most recent application remains secret until the application has been processed.
[132] Sahin – Haas – Kreiter – Husemann – Diken – Reuter – Hefesha 2020. Patent US10576146B2.
[133] Sahin – Haas – Kreiter – Husemann – Diken – Reuter – Hefesha US20200166671A1. Application pending.
[134] Smith – Massare – Tian 2021. US10953089.
[135] Silbersher 2020.
[136] Wouters et al. 2021. p. 1025.

countries, Moderna 10 contracts in 7 countries, Janssen Pharmaceuticals 8 contracts in 6 countries and Novavax 8 contracts in 5 countries.

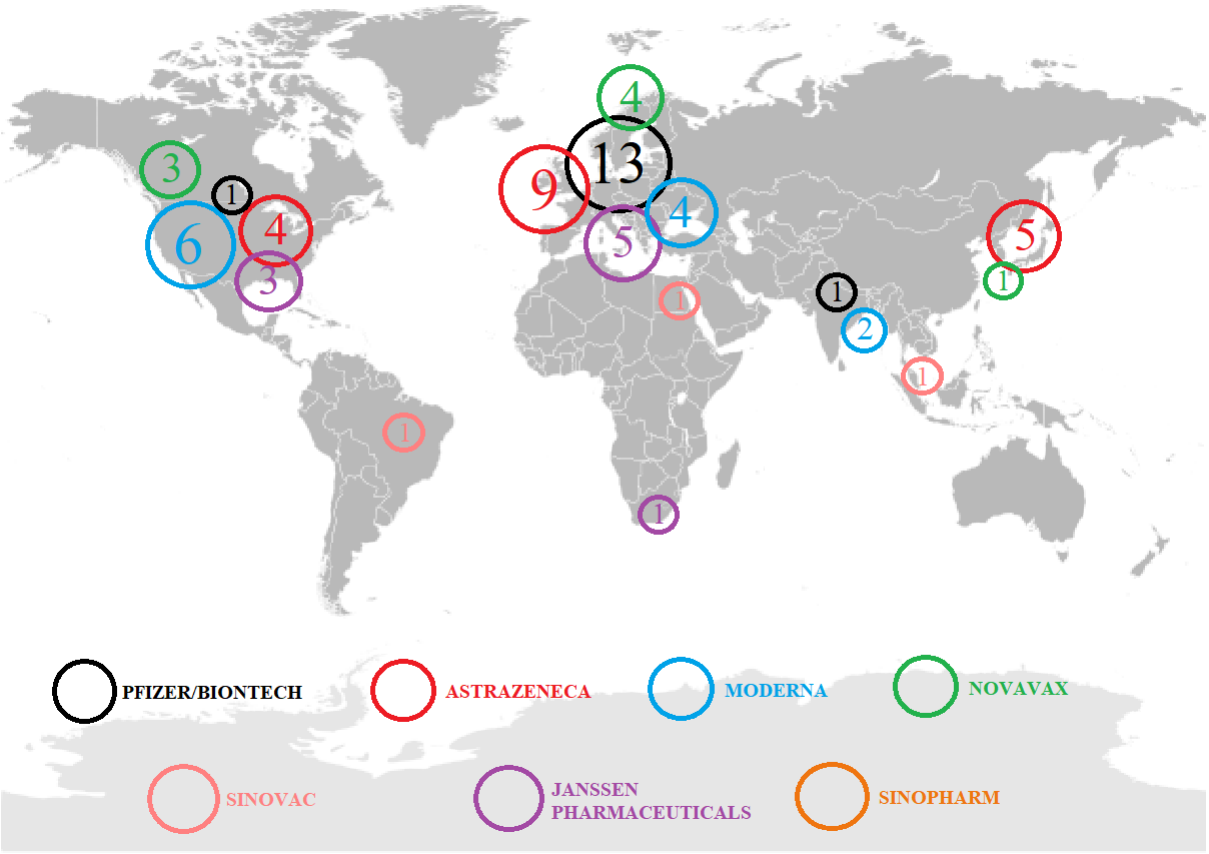

Figure 1 **Covid-19 vaccine manufacturing contracts**

The figure presents all reported manufacturing contracts entered into by vaccine developers per continent (as of 18th August 2021) of which vaccines had been Emergency Use Listed (plus Novavax). The figure does not contain manufacturing facilities of Serum Institute of India nor contracts under which no vaccines had yet been manufactured. Sources: Sources: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard; Bridge Beijing 2021. China COVID-19 Vaccine Tracker. Accessed 18 Aug 2021.

When examining the existing manufacturing contracts more closely, it can be noted that most of the manufacturing contracts are made with companies situated in high-income states (*figure 1*). Africa, Latin America and Asia are highly underrepresented what comes to the manufacturing of vaccines, taking into account the population. This phenomenon is to further the dilemma introduced already in subsection 3.1.2: the distribution of vaccines closely relates to the place of manufacturing.

The fact that manufacturing contracts are mostly made with companies in high-income states does not necessarily reflect the companies' attitudes but rather the poor technological capability to produce vaccines globally. Several Covid-19 vaccines are based on extremely sophisticated

techniques that are new to the pharmaceutical industry. In addition to the developers and a few high-income states, the needed technology does not necessarily exist,[137] and large technology transfers are required. The ability to rapidly grow one's technological capacity to produce millions of doses of Covid-19 vaccines does not necessarily exist around the globe but is centralized in high-income states. The following figure will show to what extent technology transfers have been made by the leading Covid-19 vaccine developers.

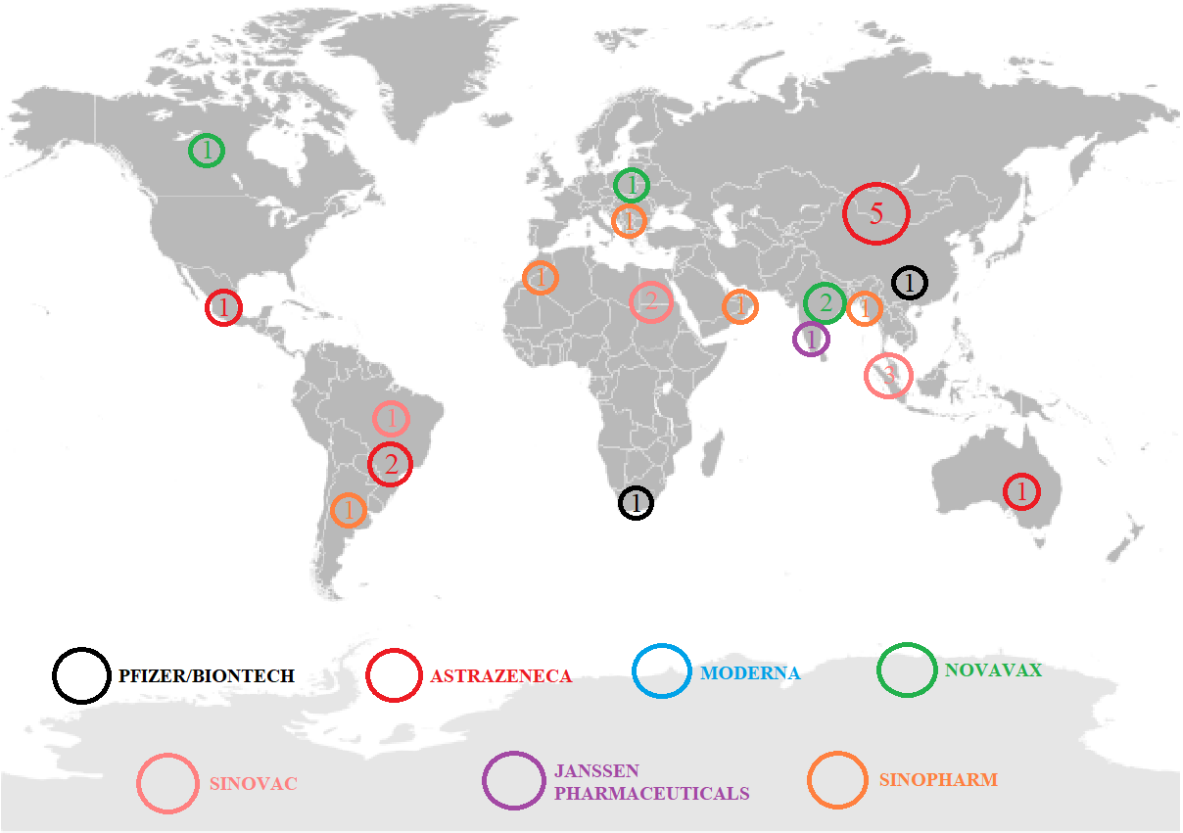

Figure 2 **Technology transfer agreements by Covid-19 vaccine developers**

Reported technology transfer agreements entered into by vaccine developers (as of 18th August 2021) of which vaccines had been Emergency Use Listed. The figure presents the number of contracts of vaccine developers per continent. Sources: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard; Bridge Beijing 2021. China COVID-19 Vaccine Tracker. Accessed 18 Aug 2021.

AstraZeneca seems to have been quite active in pursuing technology transfer to Asia and Latin America, conducting agreements with companies situated e.g. in Mexico, Brazil, Japan, Thailand and India.[138] On the other hand, the vaccine developers using new and highly

[137] Eccleston-Turner – Upton 2021. p. 434.
[138] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Manufacturing Agreements.

sophisticated mRNA-technology, Pfizer/BioNTech and Moderna, are seemingly less active in their efforts, at least in light of publicly available data.[139] Accordingly, though Sinovac and Sinopharm appear to have very few manufacturing contracts, they still actively distribute their technical capability amongst developing nations. The efforts to upbuild the technical capacity in developing states will lead to increased manufacturing capacity and further to manufacturing contracts.

Sinopharm and Sinovac have also been actively contributing to the distribution of vaccines for developing and low- and middle-income states. By August 2021, Sinovac had donated 5.4 million doses to Asia Pacific, Africa and Latin America and sold additional 261 million doses to Asia and 222 million doses to Latin America. Accordingly, Sinopharm's donations added up to 23 million to Asia and 6,5 million to Africa, whereas sales for Asia were almost 190 million, for Latin America 98 million and for Africa 59 million doses.[140] This contribution reflects the importance of manufacturers existing in different parts of the world.

The global manufacturing capacity thus depends on several different, large scale issues. It must be noted that though the leading companies have emphasized they are not going to invoke their patent-related rights during Covid-19, the intellectual property rights may play a role what comes to the distribution of vaccines. First of all, publicly available data on the manufacturing process is limited and, also, protected by the TRIPS Agreement. Without the support of the vaccine developers, it is extremely tough if not impossible to develop the infrastructure for Covid-19 vaccine manufacturing. For example, even though Moderna has published its clinical trial data,[141] the information sharing can in the end be rendered meaningless due to lack of Moderna's inactivity in technology transfer (see *figure 2*). Thus, the activity of the vaccine developers in the field of technology transfer is of crucial importance during pandemics.

Additionally, the creation of such infrastructure without the support of the vaccine developers may appear extremely unattractive to pharmaceutical companies and governments with low manufacturing capacity, as patents may be invoked after the pandemic. As a result, the technology may become useless due to expensive licences and the simultaneous crash in the demand rate of the vaccines. Also, with small inner markets and minor pharmaceutical

[139] E.g. Pfizer/BioNTech and Moderna have not joined a technology transfer hub (founded by WHO) aiming to expand the manufacturing capacity of LMICs regarding mRNA-vaccines. See Correa 2021. p. 2.
[140] Bridge Beijing 2021. China COVID-19 Vaccine Tracker.
[141] European Medicines Agency 2021a.

exportation, in addition to limited research and development capacity, some states struggle to find an economically viable resolution what comes to adopting brand new technologies that could be used only to produce Covid-19 vaccines.

The Covid-19 vaccine developers seem to support the existence of a strong patent regime. Due to Covid-19, the US government endorsed a waiver that exhausts all the patent-related rights for the pandemic.[142] The endorsement invoked reaction from the US company Pfizer, according to which the freedom to manufacture Covid-19 vaccines may lead to high competition on raw materials. According to the CEO of Pfizer, Albert Bourla, freedom to manufacture Covid-19 vaccine may cause a situation where raw materials are purchased by pharmaceutical companies which have inadequate quantitative and qualitative capability to produce vaccines, thus threatening the rapid distribution of vaccines and 'putting the safety and security of all at risk'. Bourla also suggested that manufacturing capacity is not the issue regarding the distribution, but the lack of raw materials is.[143]

In conclusion, the equal and rapid distribution of vaccines seems to be influenced by multiple factors, all of which significantly affect the timely access to Covid-19 vaccines. These factors include the manufacturing capacity of the vaccine developers, their activity in sharing knowledge and transferring technology, the technological capability of the industry altogether, the individual manufacturing contracts made with third-party manufacturers and the location of these facilities, the existence of patent rights and their use, the complexity of the vaccines and the raw materials used for them. It must be noted that a significant share of these factors seems to be left as the responsibility of the private manufacturing companies, which have a lot on their plates even without the heavy burden of technology transfer. Chapter 4 is dedicated to the assessment of the TRIPS Agreement and whether it has the required potential in answering these obstacles.

3.2.2 Vaccine purchase agreements

In June 2021, as the world was still struggling in the middle of the Covid-19 pandemic, the distribution of vaccines seemed somewhat imbalanced in respect to the world's needs. 51 percent of the existing vaccine supply was preordered by states populated by only 13 percent

[142] A TRIPS Waiver which will be further discussed in chapter 4.
[143] Breuningen 2021.

of the world's human population.[144] In Africa, under 2 percent of the population had received the vaccine in June 2021. In Europe, over 40 doses of vaccines had been distributed per 100 persons, and in the US, almost 90 doses per 100 persons, whilst in Africa the number was 2.3 single doses per 100 persons. Surprisingly, also India was amongst the states with the lowest vaccination rates, with less than 20 distributed doses per 100 persons.[145]

One of the factors affecting timely access to vaccines is the purchase agreements. During Covid-19, and also during the H1N1 pandemic, purchase agreements were conducted between the patent (or licence) holder and the procuring party (basically the governments or coalitions such as the EU). The agreements are negotiated individually between the parties, and the vaccine prices differ from an agreement to another. During pandemics, the agreements are most commonly conducted as advance purchase agreements, i.e. the vaccine doses are reserved before the manufacturing process has started. During H1N1, these advance purchase agreements were taken advantage of by developed nations that could afford significantly higher prices than developing ones. This lead to a situation where developing countries were the last to receive vaccines against the disease.[146]

The purpose of this subsection is to examine whether the vaccine purchase agreements have possibly affected the equal and timely distribution of vaccines during the Covid-19 pandemic. The examination includes investigating the number of agreements, the number of vaccines included in the agreements, prices and differences in them and whether the advance purchase agreements have been fulfilled and in which order. Also the international tools to combat possible problems will be introduced. Due to the secrecy of agreements, some details cannot be taken into account.

In August 2021, Pfizer/BioNTech was the most prominent vaccine supplier what comes to the vaccine supply agreements and the number of doses they cover (*figure 3*). Reportedly, over five billion doses had been reserved by advance purchase agreements from Pfizer/BioNTech, of which the European Commission had secured access to over two billion. When examining all the vaccine developers together, the USA and the Commission seem to have reserved a significant amount of doses via advance purchase agreements.

[144] Gray et al. 2021. p. 90.
[145] Beaumont 2021.
[146] Eccleston-Turner – Upton 2021. p. 428.

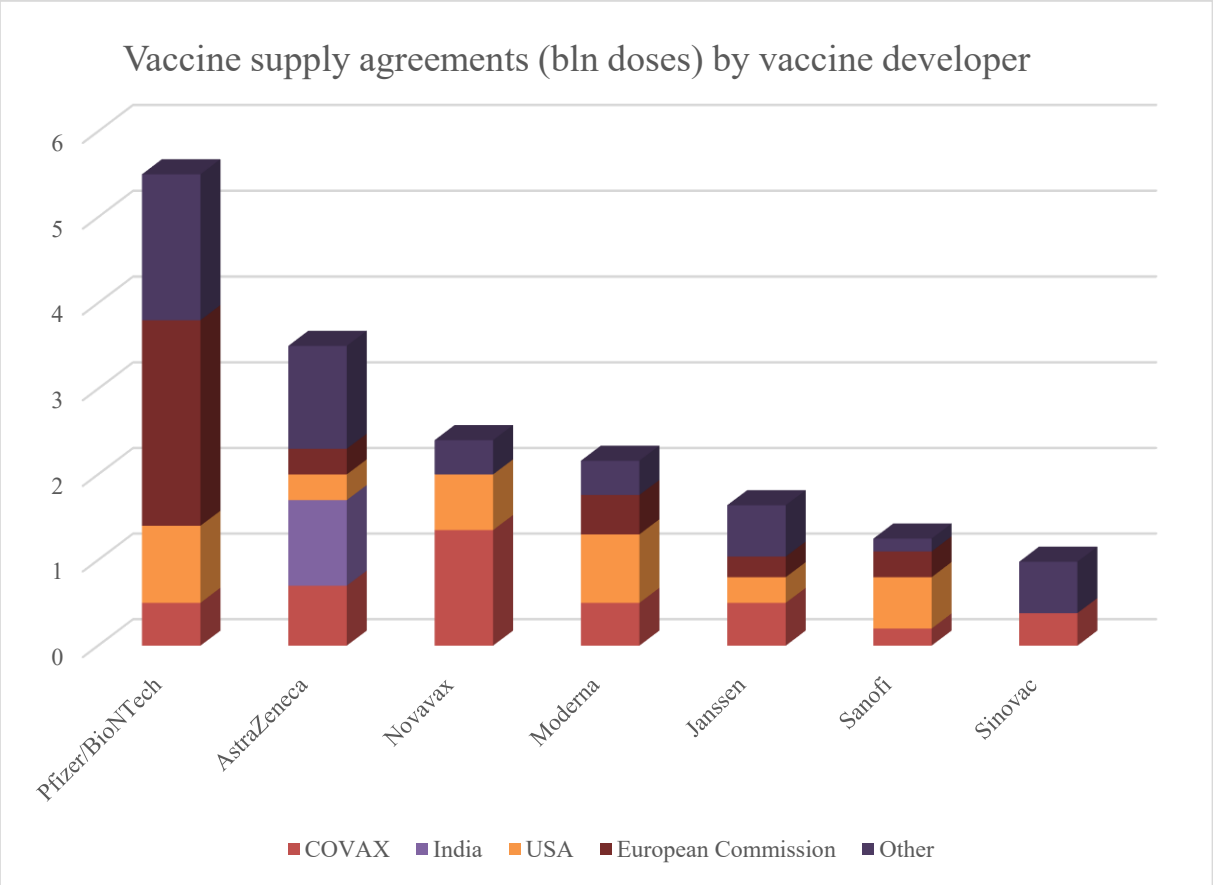

Figure 3 **Vaccine supply agreements (bln) doses by vaccine developer**

Source: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Accessed 11 Aug 2021.

The same trend is noticeable when examining purely country or region based purchase agreements and the number of vaccine doses they reportedly contain (*figure 4*). When comparing the purchased amounts to population, the European Commission and the USA seem to have reserved significant amounts of vaccines with respect to their needs. In contrast, India is struggling to meet the vaccine demand, and the African Union is far from granting even at least one vaccine for each individual.

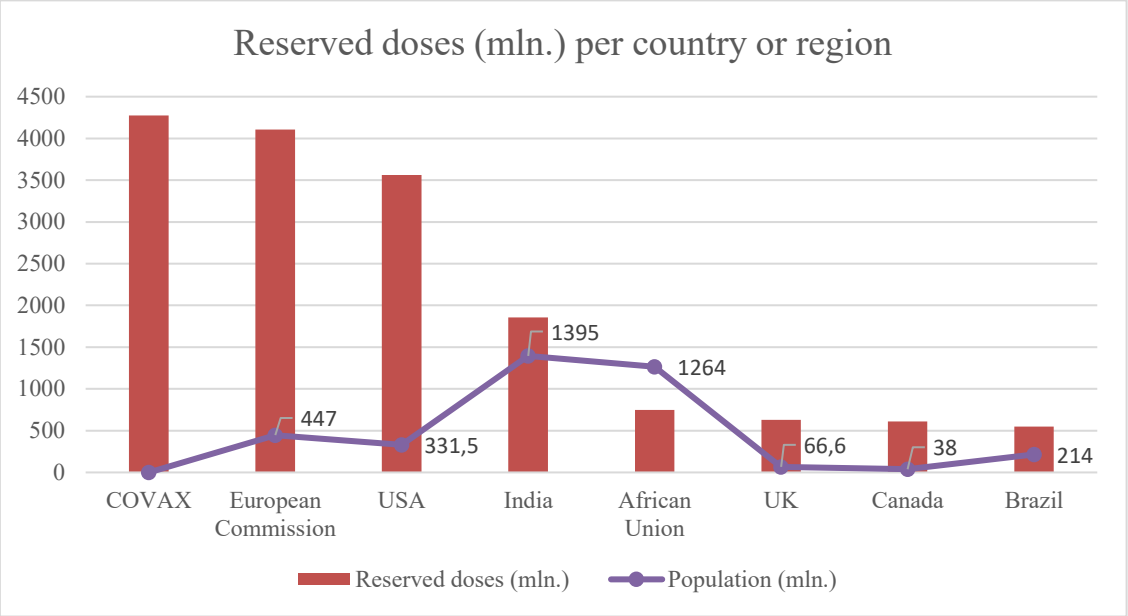

Figure 4 **Reserved Covid-19 vaccine doses (mln) per country or region**

Most of the developed vaccines are two-dose course vaccines, meaning each state might need vaccines double the amount of the population. This figure includes eight regions/countries with the highest number of reserved doses, excluding the USA for Covax. Source: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Accessed 11 Aug 2021.

When examining the statistics more closely, by the middle of August 2021, 48 countries had succeeded in reserving enough doses (and predominantly considerably more) in respect to their population. Of those countries, two were lower-middle-income countries (Bolivia and Morocco), seven upper-middle-income countries, and the rest high income, mostly European Union countries.[147] The trend familiar from the times of the H1N1 pandemic seems to prevail also during Covid-19: hoarding of advance purchase agreements by developed nations.

This may appear as advantageous from two perspectives. As described earlier, the vaccine developers are willing to fund their rapid R&D process and make at-risk investments in manufacturing technology partly due to the purchase commitments made by states, regions and organizations. Thus, there are also globally positive impacts what comes to the advance purchase agreements. On the other hand, there is no guarantee that a particular vaccine candidate won't cause side effects that would render it unusable nor that the manufacturing proceeds as rapidly as planned. From the perspective of one state or region alone, the more agreements you enter into with different vaccine manufacturers, the closer you are to receive the promised vaccines rapidly.

[147] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Vaccine Purchase Agreements.

However, there are also severe downsides to this hoarding. As can be detected from *figure 4*, COVAX Facility has been able to conduct a decent amount of advance purchase agreements. As described earlier, COVAX funded several of the successful vaccine candidate developers. COVAX pillar also includes 'COVAX Facility', which aims to contribute to the equal and timely distribution of vaccines through procurement and donations.[148] In March 2021, 92 low- and middle-income countries were listed as 'funded countries', and 69 countries plus the EU had formally joined as 'self-funded' countries, with 86 having expressed their interest in joining the Facility.[149]

The COVAX Facility aims to distribute vaccines to funded countries with extremely low prices and as rapidly as possible. Its function is based on assets gathered from self-funded countries: the states are required to pay an up-front payment, which is not required from funded states. The Facility uses these assets to purchase vaccines. Additionally, self-funded countries pledge to purchase all the vaccines assigned to them through COVAX Facility. To allure self-funded countries to participate, the Facility has guaranteed to provide them with a number of vaccines enough to immunise 20 percent of each state's population.[150] The price of one dose for a self-funded state is approximately 11 dollars, whereas the funded states receive vaccines with 1.6-2.0 dollars per dose.[151]

There are some significant absentees, such as China, Russia, the US and UK.[152] The greatest issue tends to be the abovementioned fact that self-funded (and other high-income states) have entered into advance purchase agreements that give them recourse to a vast amount of vaccines beyond their factual needs. The states have given monetary aid to COVAX and pledged to donate leftover doses, simultaneously being reluctant to actually join the Facility. As indicated above, several countries have submitted an expression of interest to enter the Facility, however never doing so.[153]

The hesitancy appears to derive from the fact that there is mistrust in the capability of COVAX to distribute vaccines more rapidly than the countries can manage themselves.[154] The most

[148] Eccleston-Turner – Upton 2021. p. 434.
[149] Ibid. p. 437.
[150] Eccleston-Turner – Upton 2021 p. 436.
[151] Wouters et al. 2021. p. 1028.
[152] Eccleston-Turner – Upton 2021. p. 437.
[153] Ibid. pp. 437-439.
[154] Eccleston-Turner – Upton 2021. p. 439.

prominent and strong countries are able to conduct and finance (and finally, enforce) their own bilateral agreements and thus, receive vaccines before COVAX. If countries were to join COVAX, they would have to fulfil their obligation to purchase the vaccines assigned to them, even though they would have already received the amount needed to immunise the whole population. Accordingly, they would gain access to vaccines *simultaneously* with 'weaker' states, thus losing their privilege. To highlight the issue of equal distribution, *figure 5* presents the statistics from 12th August 2021, revealing which 20 countries/regions had received the most vaccines in proportion to their population.

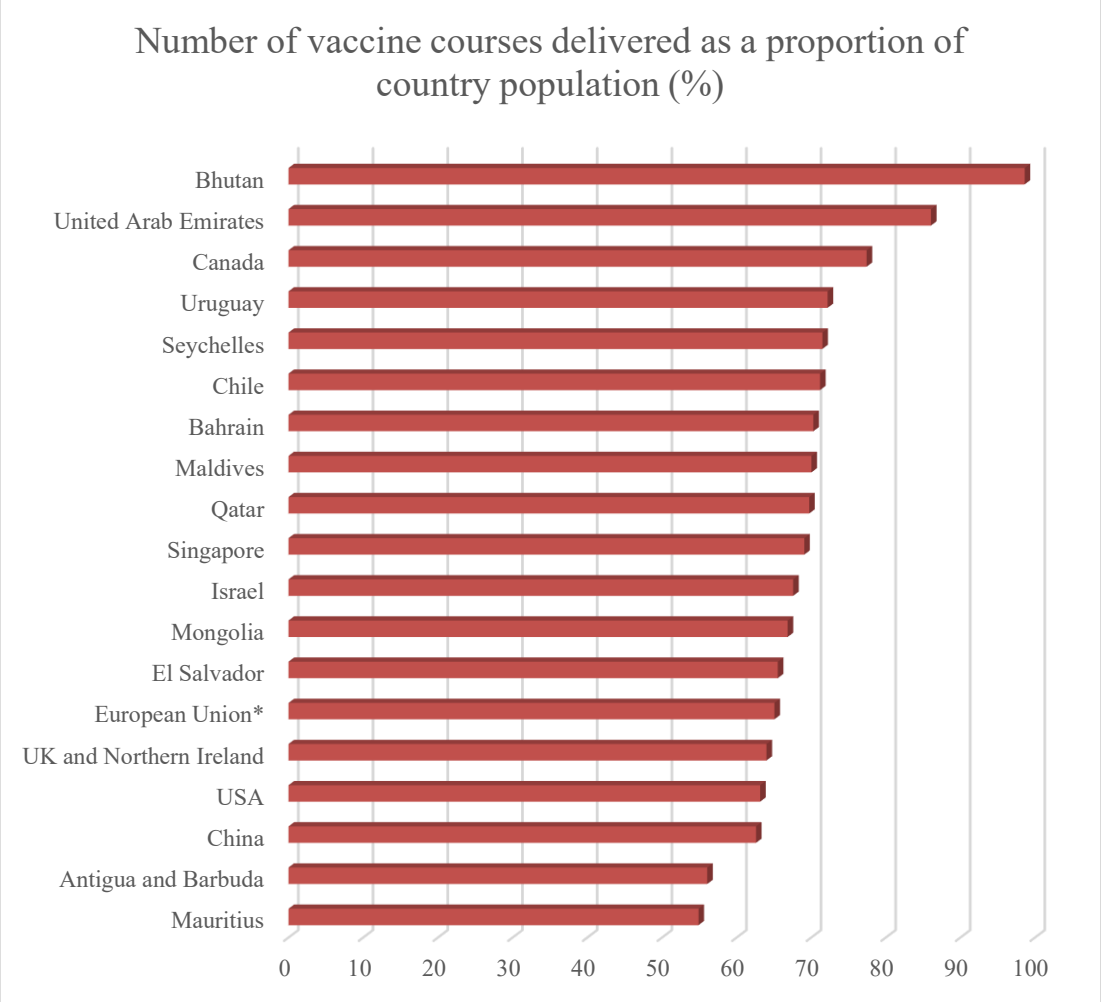

Figure 5 **Number of vaccine courses delivered as a proportion of country population (%)**

The figure is based on reported data on how many full vaccine courses each country has received. The source remarks that some states may have followed a policy according to which every vaccination is only given once (even two-dose course vaccines). Therefore, the amount of total deliveries does not fully indicate the precise amount of vaccines received. *approximate delivery rate of all European Union countries together. Source: Source: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Accessed 12 Aug 2021.

On 12th August, 4 870 million doses had been delivered around the world, of which only 192 million had been distributed by COVAX Facility, of which target was to allocate 2 billion vaccines by the end of 2021. In contrast, 1 831 million doses were distributed based on bilateral or multilateral agreements.[155] However, in Africa, multiple states had not received a single dose of vaccine through bilateral or multilateral agreements[156] (e.g. Mauritania, Zambia, Eswatini, Cameroon, Somalia, Sudan, Chad, Niger, Nigeria, South-Sudan, Tanzania, Kenya, Somalia, Mali, Burkina Faso, Sierra Leone, Gambia, and the list goes on).[157] Also, though the administration rate of vaccines is not entirely comparable to the proportionate delivery rates due to possible inadequacies in countries' health care infrastructure, it is still worth noting that merely 1.2 % of low-income states' population had received at least one dose of vaccine, whilst the administration rate globally was simultaneously 30.4 %.[158]

The reasons behind unequal delivery rates are rather complex and not necessarily detectable in light of public information. It is beyond the remit of this study to investigate each advance purchase agreement separately, partly due to the lack of public information and partly due to the limited resources and space. However, some founded speculation on the prevailing reasons behind the imbalanced timely access to vaccines can be done. One of these reasons would be the pricing. Too costly vaccines may result in a situation where a nation cannot afford the vaccine and is thus left without. On the other hand, international bidding competition also offers a fast lane for states that offer the highest price for vaccines.

Multiple factors may affect the pricing. The most obvious factors include the cost of raw materials, the costs of manufacturing and R&D, and the received funding. Also the company's overall profit-making strategy may affect the prices, such as the political pressure to offer reasonable prices during pandemics.[159] Notable is that AstraZeneca and Janssen Pharmaceuticals received significant amounts of public funding (also through COVAX), due to which they made a public commitment to sell their Covid-19 vaccines at affordable prices.[160] Also Moderna was funded by COVAX,[161] still making no such commitment.

[155] Over 2 400 million deliveries were reported as 'unknown', indicating they have not been made through COVAX Facility, but possibly due to unreported donations and bilateral agreements.
[156] And no deliveries were reported as 'unknown', see footnote 154.
[157] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard.
[158] Ibid.
[159] Wouters et al. 2021. p. 1026.
[160] Wouters et al. 2021.p. 1026.
[161] Eccleston-Turner – Upton 2021. p. 431.

The location of manufacturing facilities might also affect prices due to longer distances and more expensive transportation costs, which furthers the issue of certain states getting access more rapidly (see section 3.1.2). The size of the state itself might indicate lower prices: understandably, larger deliveries are prioritized and excused in prices since transport is also more cost-efficient. Being commercially justified, at the same time, minor nations without strong regional back-up and thus probably also with low manufacturing capacity are left in a weak position what comes to the prices. For example, Moderna announced it had priced its small deliveries with a price range of $32-37 dollars per dose,[162] whilst the larger deliveries are significantly cheaper (e.g. the US $15, European Commission $18 and Argentina $21,50).[163]

The pricing during Covid-19 has been rather interesting. Having a chance to negotiate each bilateral and multilateral agreement individually, the vaccine developers have an opportunity to take advantage of different negotiation positions and capabilities (such as those mentioned above). The highest known price paid based on a bilateral agreement during Covid-19 has been by Hungary for Sinopharm vaccine with a $36 per dose, whilst the European Commission succeeded in negotiating the lowest known price for AstraZeneca, merely $2,19 per dose. Simultaneously, AstraZeneca's purchase agreement with the United States offered the price of $4 per dose and with South Africa $5,45 per dose.[164]

The negotiation powers seem to have some effect on the vaccine prices indeed, were they due to the size of the state, the purchasing power of the state or other details of the agreement between the parties. This is as some of the seven successful vaccine developers seem to have quite a big range in their vaccine prices (*figure 6*). For example, the mean for Moderna's vaccine price is $25,41, but the highest agreed price is $37 and the lowest $10,69. The price range of all vaccine developers is not as great as it is with Moderna, Pfizer/BioNTech and Sinovac. Janssen Pharmaceuticals and AstraZeneca are great examples: Astra-Zeneca has sold its vaccine with a price range of $2,19-5,45 per dose[165] and Janssen Pharmaceuticals with a respectful price range of $8.50-10.[166]

[162] Banerjee – O'Donnell 2020. *Moderna prices COVID-19 vaccine at $32-$37 per dose for smaller volume deals.* Reuters.
[163] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard.
[164] Ibid.
[165] Excluding prices for Indian private market ($7.95) and Bangladesh private market ($13,27).
[166] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard.

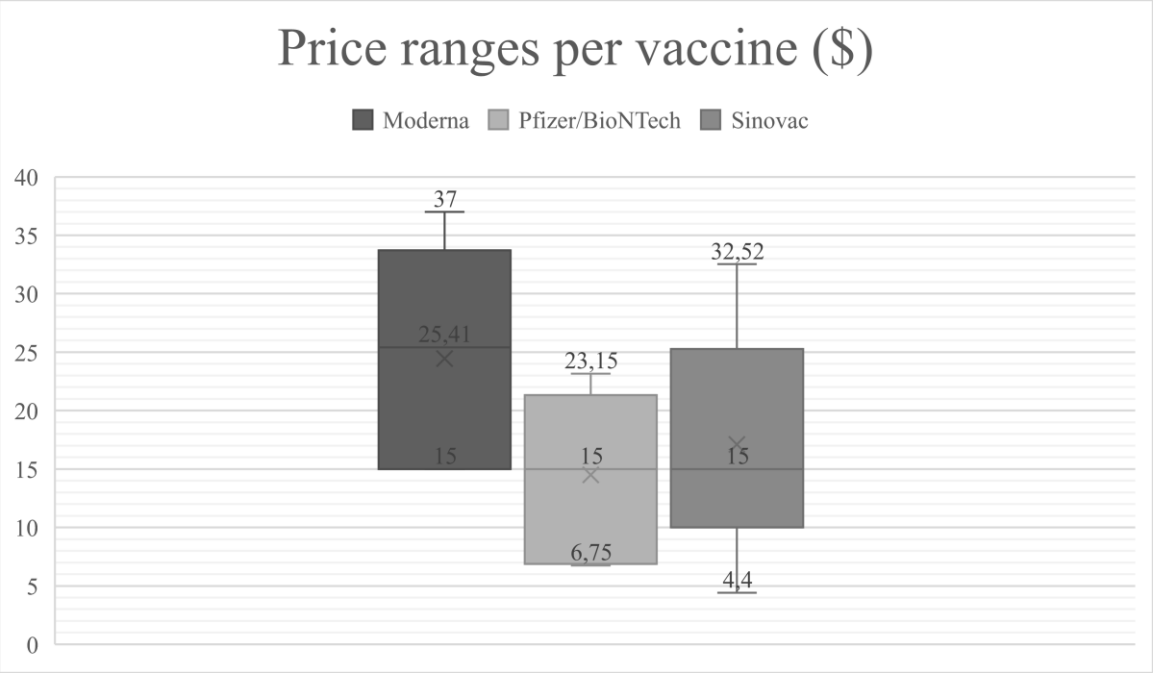

Figure 6 **Price ranges per Covid-19 vaccine ($)**

Source: UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Accessed 12 Aug 2021.

Though the price differences between vaccines by different vaccine developers and manufacturers might be justifiable due to differing expenses, the fact that the price range of one vaccine is significantly higher than those of the others indicates there is more to the price differences. One reason is probably agreement-based details that are individually negotiated. However, these details cannot be investigated due to the lack of publicly available information. These details may include, *inter alia,* upfront payments used to secure a certain amount of doses right when the manufacturing starts.[167]

The theory of 'who pays the most, gets fast' is somewhat impossible to establish in the light of available data. For example, of those countries or regions that have received proportionally most vaccines (see *figure 5*), only three has established publicly available data on paid prices.[168] Moreover, most agreements are confidential, and pharmaceutical companies may appear rather unwilling to reveal details regarding prices for not being accused of pursuing a mere economic

[167] For example, a leaked agreement of the European Commission and Pfizer/BioNTech includes commitments of an upfront payment (€700 000 000). See <https://www.barrons.com/news/european-commission-embarrassed-by-vaccine-price-leak-01608300609>. Retrieved 13 Aug 2021.

[168] Willingly or unwillingly: for example, the European Commission did not want to publish the information on paid prices, nor were they allowed to, but the information was leaked to the public. See for example <https://www.theguardian.com/world/2020/dec/18/belgian-minister-accidentally-tweets-eus-covid-vaccine-price-list>. Retrieved 13 Aug 2021.

interest in the middle of a pandemic. Nevertheless, some indication on straight effects of prices to timely access exists, though only speculation.

One is example is the fact that EU paid a low price for AstraZeneca, which may have led to delays in deliveries when AstraZeneca had manufacturing problems at the beginning (see section 3.1.2). Accordingly, at the beginning of the pandemic, Israel was the first to succeed in rapid vaccination of its population (excluding the Palestinian population, which is why Israel is presumably not present in the statistics presenting proportional vaccination rates). At the time, Israel had paid the highest known price for the vaccines ($23.5 per dose).[169] It thus seems that the capacity to offer higher prices also leads to more rapid access to vaccines, which inevitably leads to unequal timely access to them.

While this fact is in line with modern capitalist ideology, it can be questioned whether the outcome during pandemics is justified. Even more so, as the pharmaceutical field is highly protected by patents and the competition is extremely limited, which further may raise the prices far above the production costs. The pandemics are rare occurrences, and pharmaceutical industry is comprehensively funded by public actors in these occurrences, which should be taken into account in the scope of property protection. While during regular times the balance of right to property and right to health and life are balanced, the balance seems to be somewhat shifted to right to property during pandemics due to lack of inadequate regulation. Deeper analysis on this balance will take place in chapter 4.3.

As a result of the examination of the vaccine delivery rates and available data on agreements and prices, a straightforward reason for unequal timely distribution of vaccines is hard to conclude. It appears that during pandemics, all means can be used by nations in pursuing timely access to vaccines, and most of those means are protected by confidentiality regulation. The lack of transparency causes doubts and even international mistrust, of which presence during worldwide emergencies should be minimized. Of course, the companies and governments cannot be deprived of their rights to act as independent legal persons conducting agreements based on pure mutual understanding. However, the system seems to set an unbearable burden for market-driven, commercially thinking entities to act for the best of all the existing states

[169] Dyer 2021. The Isreali deal with Pfizer/BioNTech, however, also well concretize the importance of other details of the agreement: allegedly, Israel had promised to provide the company with health data of all the Covid-19 vaccine recipients, which has been cited as a ‘real-world testing ground’ and ‘Phase 4 study’. See also Gurwitz 2021.

with no regulative framework for pandemics, even though no international consensus on how such a goal could be reached exists.

3.2.3 Protectionism

Though the international atmosphere on combatting Covid-19 has been mainly positive and cooperative, some exceptions have occurred. Somewhat nationalist acts during worldwide emergencies are, to some extent, forgivable and understandable, but solidarity would be strongly needed. This subsection briefly examines some protectionist acts that have occurred during the Covid-19 pandemic and their effect on timely access to vaccines.

The most restrictive measures adopted by a vast amount of states have been export prohibitions. Already by December 2020, before the vaccine distribution had prominently started, 43 different WTO Member States had imposed export restrictions to Covid-19 related medical products and equipment.[170] The scope of export restrictions has also affected the manufacturing capacity of vaccines. For example, the United States restricted the export of raw materials used to manufacture Covid-19 vaccines based on its Defense Production Act. The regulation obligates producers of key raw materials to provide materials primarily to domestic production.[171]

Consequently, the European Union regulation 2021/111 of 29 January 2021 making the exportation of certain products subject to the production of an export authorisation exposes a requirement of export authorisation for 'vaccines against SARS-related coronaviruses' and 'active substances … used for the manufacture of such vaccines'. According to the regulation, exports to COVAX listed low- and middle-income countries are not exposed to such authorisation.[172] In its preamble, the regulation expressly notes that the Union has financed vaccine developers of which manufacturing facilities reside in the Union, and that 'certain vaccine manufacturers have already announced that they would not be in a position to supply the quantities of vaccine destined to the Union that they have pledged'. A European Commission paper concerning the regulation also straightly states that the regulation 'aims at

[170] World Trade Organization 2020. Developing and Delivering Covid-19 Vaccines Around the World. p. 6.
[171] The Hindu 2021. *U.S. defends restrictions on export of COVID-19 vaccine raw materials amid India's request to lift ban.*
[172] Commission Implementing Regulation (EU) 2021/111 of 29 January 2021 Making the Exportation of Certain Products Subject to the Production of an Export Authorisation. Art. 1.

preventing exports from companies with whom the EU has concluded Advance Purchase Agreements (APAs), where they threaten the execution of those APAs … '.[173]

The EU regulation was applied by Italy in March 2021, when it blocked a shipment of 250.700 doses of AstraZeneca vaccines to Australia. The export was backed up by the European Commission, according to which AstraZeneca had failed to provide the agreed number of vaccines to the Union. Also, as Australia was a developed country, the ban was acceptable.[174] No other export restrictions based on the EC regulation had been made by the time of writing. However, the EU has been accused of 'forcing' European based Covid-19 vaccine manufacturers to guide the vaccine shipments to the Union, due to which Australia was missing out on AstraZeneca's vaccine shipments for more than two months.[175] Accordingly, due to the deathly Covid-19 wave that hit India in spring 2021, also India resorted to export bans, thus restricting the export of one of the biggest Covid-19 manufacturers, Serum Institute of India (AstraZeneca vaccine).[176]

The list of countries enacting export bans is interesting when comparing to the international manufacturing capacity of vaccines. OECD conducted a study on global vaccine manufacturing capacity, in which the stances before Covid-19 were assessed. According to the study, 93 % of the global vaccine export value and 80 % of its volume resides in ten countries, in the following order: Ireland, Belgium, France, Great Britain, USA, Netherlands, Italy, India, Germany, and Canada. Furthermore, the European Union seems to be accountable for two-thirds of all vaccine exports made to South Asia and Sub-Saharan Africa. The OECD also (carefully) listed China, Netherlands, United States, Germany, and France as leading producers and exporters of items needed in production, manufacturing, and administering vaccines.[177]

Though Covid-19 vaccines are produced globally, the technological assets to manufacture bulks of vaccines is strongly concentrated. EU has stated it is the leading provider of Covid-19 vaccines and reported it was providing vaccines for 31 countries worldwide of the amount of

[173] European Commission 2021b. Export Requirements for COVID-19 Vaccines: Frequently Asked Questions. p. 1.
[174] Cursano – Ovidi – Carlet 2021. *Italy blocks shipment of 250,700 doses of COVID-19 vaccine to Australia.* Baker McKenzie.
[175] Vela – Heath 2021. *Brussels blocks vaccine exports in all but name*. Politico.
[176] Arora – Das – Jain 2021. *India unlikely to resume sizable COVID-19 vaccine exports until October.* Reuters.
[177] Organization for Economic Cooperation and Development 2021. OECD Policy Responses to Coronavirus (COVID-19). Using trade to fight COVID-19: Manufacturing and distributing vaccines.

34 million doses already in March 2021.[178] This is highlighted by the fact that most of the AstraZeneca Covid-19 vaccines are manufactured in Europe (Belgium, Great Britain, Netherlands, Germany, Spain and Italy). Also Pfizer/BioNTech vaccine is produced in more than ten manufacturing facilities in Europe, Moderna and Novavax also having part of their production in different European countries.[179]

The division of manufacturing capacity as such combined with enacted export restrictions inevitably cause harm. Following the US export restrictions on raw materials, India got in trouble with its already struggling manufacturing capacity of Covid-19 vaccines.[180] India's incapacity to manufacture enough vaccines appeared to be fatal expressly to developing countries, as India is the leading exporter of Covid-19 vaccines to Africa and several emerging countries.[181] Furthermore, US raw material restrictions have caused problems also to European manufacturers, some of which rely on materials produced only in the US.[182] Restrictions on exports and stockpiling of vaccines may, in addition to affecting equal distribution, also cause spoilage of vaccines due to the vulnerable supply chains of some of the Covid-19 vaccines (primarily those based on mRNA technology and those needing extremely low storage temperatures).

The list of export bans introduced here is not exhaustive. However, the introduced restrictions highlight the effects of protectionist measures on timely and equal access to vaccines. Whereas a significant amount of export bans related to e.g. protective masks and other equipment were enacted worldwide, the vaccine-related export bans have been the privilege of countries owning vaccine manufacturing capacity. It is extremely worrying that a government may impose export restrictions on vaccines, although each nation desperately needs them, and pharmaceutical companies have agreed to produce them for another state. Though the TRIPS Agreement does not straightly address the issues regarding international trade in general, the WTO Agreement does have a role to play what comes to export restrictions. However, the regulation of the WTO Agreement falls outside the scope of this research.

[178] European Commission 2021a. Commission extends transparency and authorisation mechanism for export of COVID-19 vaccines.
[179] UNICEF 2021. UNICEF Covid-19 Vaccine Market Dashboard. Manufacturing Agreements.
[180] The Hindu 2021. *U.S. defends restrictions on export of COVID-19 vaccine raw materials amid India's request to lift ban.*
[181] Ibrahim 2021.
[182] Burger – Guarascio 2021. *EU persuades U.S. to ease COVID export restrictions for CureVac -sources*. Reuters.

Before moving on to the next section, the findings made so far are presented below in the form of a list of factors affecting the timely access to vaccines by category:

1. **Global factors**
    a. divided R&D and manufacturing capacity
    b. distribution of global R&D funding
    c. raw material production and distribution
    d. political atmosphere and applicable legal regime

2. **State-related factors**
    a. capability to conduct bilateral agreements (size, trade relations)
    b. developing stage and the number of vaccine developers and manufacturers
    c. protectionist measures

3. **Factors related to vaccine developer**
    a. received R&D funds
    b. IP enforcement
    c. profiting strategy
    d. activity in technology transfer
    e. manufacturing capacity and the aims to enlarge it
    f. transparency of agreements

4. **Factors related to the vaccine manufacturer**
    a. location of the facility
    b. ability to distribute know-how

As can be detected from the list above, many of the affecting factors are interconnected. For example, the global funding rates affect vaccine developers, and the international legal regime affects the transparency of vaccine purchase agreements etc. Accordingly, the contextual framework that should be adequately regulated seems extremely complex and somewhat different from the regular context for which patent regime and compulsory licences have been designed for. It is also alarming how many factors behind the timely access to vaccines are actually in the hands of private sector actors, although reasonable expectation would be that the emergencies are controlled and managed by states.

3.3 Other factors

In addition to those already introduced, several other factors affect timely access to vaccines during pandemics. These factors are state-related factors that may affect the purchasing, import and dissemination of vaccines. The emphasis of this study being on global issues regarding vaccine distribution, state-related factors are only briefly introduced. It is, however, essential to acknowledge managing timely access to vaccines may sometimes be out of reach of international efforts.

The lack or inadequacy of healthcare infrastructure in some states is one of the most discussed issues. WHO assessed that at the end of April 2021, some African states had failed to efficiently administer the vaccines they had been provided with. Apparently, 15 states had administered less than half of the doses, and nine states less than a quarter.[183] Similar issues were faced during the H1N1 pandemic, and a deployment plan requirement for prioritizing vaccine deliveries was used to solve the problem. However, the system had its downsides, as creating an adequate deployment plan turned out to be too burdensome for some states, leaving them far behind in the vaccine distribution line.[184]

The issue of delivering a vast number of vaccines to states incapable of efficiently administering them is that thousands of vaccine doses may be wasted. This may result from passing expiry dates as in Malawi[185] or from inadequate storage conditions and lack of cold-chain infrastructure. During Covid-19 the logistics play a crucial role, as one of the vaccines require storage and transport temperature of -70 degrees Celsius. Accordingly, some of the vaccines require temperatures below 0 degrees Celsius. The infrastructure to sustain an unbroken cold chain cannot be readily found from all the developing countries, causing problems with the timely distribution of vaccines.

During Covid-19, it has become, once again, apparent that the prevailing attitudes and political atmosphere are huge determinants of what comes to the successful dissemination of vaccines. The lack of trust towards the state leaders may trigger vaccine hesitancy, such as can a strong leader with strong anti-vaccine opinions. Deep in the middle of the Covid-19 pandemic, some state leaders denied the severity of the disease, refusing to initiate adequate measures to vaccine

[183] Beaumont 2021. *Vaccine inequality exposed by dire situation in world's poorest nations.* The Guardian.
[184] Eccleston-Turner – Upton 2021. p. 442.
[185] Beaumont 2021. *Vaccine inequality exposed by dire situation in world's poorest nations.* The Guardian.

the country population.[186] As a result of such conduct, the national approvals for vaccines may be delayed, and active pursuit of bilateral and multilateral vaccine purchase agreements can be disregarded, resulting in a high death toll and the need for extremely rapid actions.

Vaccine hesitancy is also affected by the fact that the timeline of vaccine development has been extremely fast during Covid-19, and people doubt some side-effects have not been detected during the process.[187] For example, after AstraZeneca vaccines had been largely administered, cases of unusual blood clots were associated with the vaccine.[188] Though the occurrence of this side-effect was extremely low (lower than in many other widely used medicines), many countries, for example in the European Union, halted using AstraZeneca vaccines. In addition, multiple EU countries decided to administer AstraZeneca vaccines only to the elderly, as they were detected to be less affected by the side-effect.[189]

The major purely state-related factors behind state-specific vaccination rates seem to in fact include healthcare infrastructure, logistical capabilities and political atmosphere. The list is, however, not exhausting. It must also be noted that one of the aims of the TRIPS Agreement was and is to foster the transfer of technology to developing countries. This is required by Art. 66 of the Agreement, pursuant to which developed states must set incentives to enterprises and institutions for promoting and encouraging technology transfer to least-developed countries. The lack of adequate healthcare infrastructure is thus an international concern to be solved in the long run, but rather complex of an issue to be sorted out in the course of a pandemic.

As this study focuses on legislation offering more rapid solutions to timely access to vaccines during pandemics, the long-term incentives set by the TRIPS Agreement are not investigated as such. Additionally, the topic has already been subject to intensive discussion and keeps on doing so. Thus, the emphasis of the next chapter shall be in the assessment of legal solutions provided by the TRIPS Agreement to the barriers of timely access to vaccines examined in this chapter, excluding the purely state-related factors introduced in this subsection.

[186] These include for example Brazil and Tanzania. See e.g. Nugent 2021 <https://time.com/5946401/brazil-covid-19-vaccines-bolsonaro/> and Barivo – Steinhauser 2021 <https://www.wsj.com/articles/after-a-year-of-denying-covid-19-tanzania-orders-vaccines-11623938431>
[187] Wouters et al. 2021. p. 1030.
[188] European Medicines Agency 2021b.
[189] BBC News 2021. *AstraZeneca vaccine: Denmark stops rollout completely.*

4 TRIPS IN COMBATTING PANDEMICS

Having examined the most relevant factors behind timely access to vaccines during the Covid-19 pandemic, it is time to assess how effectively the current TRIPS framework answers the existing challenges. This chapter provides an answer to the research question and thus examines whether the IPR framework can adjust to the prevailing, distorted market situation. The objective is to discover the possible strengths and weaknesses of the current legislative framework and pay attention to those important details affecting the timely access that have been left unregulated (or have been overregulated) or otherwise without attention.

In the first section (4.1), the compulsory licencing system will be examined more closely by analysing the effects of its possible use on the timely access of vaccines. The analysis will include reflection of Art. 31 and Art. 31*bis*, the Paragraph 6 system. The second section is dedicated to (4.2) other legal details provided by the TRIPS Agreement, including the effects of the TRIPS Waiver and protection of disclosed information. The idea is to examine whether the latter legal tools are sufficient enough to compensate for the weaknesses found in section 4.1. Lastly, (4.3) the factors that have been left without attention will be introduced. Consequently, the overall operability of the TRIPS Agreement and possible future solutions are assessed.

4.1 Compulsory licencing in managing timely access to vaccines

4.1.1 General applicability during pandemics

Intellectual property rights, especially patents, are recognized to provide inventors with the possibility to economically profit from creations of their mind, which again foster inventive actions and thus socioeconomic development,[190] especially in the form of disclosed information. As the patent rights provide exclusive rights for the patent holder and accordingly grant the patent holder power to control the market over the invented product, tools to interfere with these exclusive rights have been created. It has been stated that the most efficient tool in controlling sometimes even monopolistic patent rights is compulsory licencing,[191] which is also the only applicable tool of such nature usable during pandemics.

[190] See e.g. TRIPS Preamble para. (e).
[191] Penrose 1951. p. 487.

In this subsection, the general applicability of the compulsory licencing system of the TRIPS Agreement to pandemics is assessed, whereas the following subsection (4.1.2) presents the concrete effects and implications of the system to factors presented in chapter 3. Finally, the last subsection (4.1.3) provides an analysis of exporting under compulsory licencing. The general applicability of compulsory licences to a situation such as pandemic is questionable already *per se*, as during Covid-19, the patent right holders have pledged not to enforce their patent-related rights. This, however, does not automatically mean compulsory licencing system would be rendered meaningless and inoperative as a result.

Despite pledges not to enforce patent rights, the rights still exist as described in subsection 3.2.1. IPRs have an established and remarkable role in the international trading community, of which presence has been supported by a great deal of countries. During Covid-19, the messages from pharmaceutical companies and, accordingly, states, have been mixed: are IPRs enforceable and will that happen? Despite the pledges, all the actors are still playing by the TRIPS book. It is no wonder, as patent rights have stretched the limits of amicable relations multiple times before. As a result, there is no incentive to start manufacturing Covid-19 vaccines without securing one complies with the TRIPS Agreement, as there is no certainty of the consequences. Thus, in theory, compulsory licences do present an opt-out from a situation where the country is not receiving adequate amounts of vaccines.

During pandemics, an optimal situation (in light of the existing legal framework) would emerge if the vaccine candidate developers would grant a significant amount of voluntary licences to manufacturers worldwide and support them in initiating the manufacturing process. Unfortunately, this has not been the case – multiple voluntary licences have not been granted despite initiated negotiations. This occurred for example with Janssen Pharmaceuticals, which, after negotiations, did not grant a voluntary licence to the Canadian company Biolyse.[192] In these cases, the possibility for a compulsory licence could provide an exit.

When examining the factors affecting timely access to vaccines (represented in section 3.2.3) more closely, the division between vaccine developer-related, vaccine manufacturer-related, state-related and global factors demonstrates to what extent the patent regime may be of use during pandemics. Representing private rights, patent rights may serve as a tool in combatting

[192] Medecins Sans Frontieres 2021. pp. 8-9.

timely delays emerging from private sector actors. The TRIPS, being an agreement between the states, also imposes obligations to states and has political implications. However, the global factors (divided R&D and manufacturing capacity, distribution of R&D funding and raw material production and distribution) may fall outside the reach of the TRIPS what comes to a short timeframe.

The issues with the applicability of the compulsory licencing system, however, lie in the global factors as well. Compulsory licences are not designed to be used by one manufacturer to provide the licenced product globally but rather to provide the product for the state of residence or one state with a limited manufacturing capacity. It is thus questionable to what extent compulsory licences may serve as a solution, as most of the states around the globe are incapable of building up the manufacturing capacity necessary to produce complex vaccines without the support of the vaccine developer. Furthermore, the tool has not been designed to be used in a situation where the whole globe is in rapid need of one product, but rather to a situation where one state needs a product produced elsewhere in great volumes.

During the pandemic, patent rights have been mainly applied for by the successful vaccine developers in those states where the manufacturing capacity lies. This indicates that, to some extent, compulsory licences may serve as a tool for expediting the distribution of vaccines. This is as the patent rights can be enforced in exactly those states where the manufacturing of vaccines would be capacity-vice possible, and thus granting a compulsory licence would be necessary not to infringe the TRIPS Agreement. Further, the threat of compulsory licences may incentivise vaccine developers to obtain voluntary licenses and support manufacturers in their capacity building, as voluntary licences are usually more valuable than compulsory ones.

The role of compulsory licences during pandemics seems to appear questionable at most, a reason for which its use is investigated in more depth in the following subsections. The specific features of the system are examined in light of the hypothetical assumption that a compulsory licence would be issued to provide the Covid-19 vaccine to reveal the functional components of the tool. There have been indications that steps towards international cooperation in developing the legal framework will be taken after the pandemic. Thus, it is essential to review the strengths and weaknesses of the tool in the proper context.

4.1.2 Effects on vaccine distribution

The effectiveness of a compulsory licencing system to combat delays in vaccine distribution during pandemics has been fiercely questioned. Certainly, one legal tool will not address all the issues affecting the timely access to vaccines. Still, it remains questionable whether the tool is usable during pandemics at all and how its effectiveness could be enhanced. This subsection examines Art. 31 of the TRIPS Agreement more closely in light of the context set out in chapter 3. Each subparagraph of the Article is reviewed in more depth, after which it is assessed as a whole. Consequently, the following subsection will examine Art. 31bis, exporting under compulsory licences, as Art. 31 merely provides the opportunity for domestic production.

(a) authorization of compulsory licences shall be considered on its individual merits

According to Art. 31(a), a compulsory licence can be granted merely based on an individual assessment of each licence. The requirement establishes that no compulsory licence can be granted to certain types of technologies or enterprises, but must concern the production of a single product. It has been interpreted that Art. 31(a) does not prevent the establishment of rules allowing the use of compulsory licences in the occurrence of certain conditions, such as the national shortage of a particular product.[193] The Article does not seem to – at least *per se* – impose requirements that would negatively impact different pandemic-related approaches. On the contrary, it provides flexibility that can be an advance.

However, it must be noted that the TRIPS Agreement leaves a vast amount of discretion to the Member States in the implementation of the agreement, especially regarding compulsory licencing. The Doha Declaration in 2001 made clear that each state may decide on what basis compulsory licences are granted,[194] and it is acknowledged that the national legal regimes vary significantly in this regard. To ensure Art. 31 has been implemented in a pro-pandemic manner, the TRIPS Council could take a stance on how to implement Art. 31(a) so that it adequately and efficiently covers the pandemics.

(b) obligation to make efforts to obtain a voluntary licence before the issuance of compulsory licence (can be waived in certain circumstances)

[193] UNCTAD-ICTSD 2005. p. 468.
[194] WTO General Council 2003. WT/L/540 and Corr. 1. para. 5(c).

As described earlier, Art. 31(b) obliges that efforts must have been made to obtain a voluntary licence with commercially reasonable terms before a compulsory licence can be issued. In case of a pandemic, this obligation is not an issue, as it can be waived due to a national emergency or other circumstances of extreme urgency. Though nations can freely decide what constitutes a national emergency,[195] most Member States assumably have included the pandemic spread of disease in this category. However, there tend to be some other far-reaching issues that seem to be currently solvable only by reaching voluntary licences. To highlight them more efficiently, some examples are discussed below.

Compulsory licences are primarily used for gaining access to pharmaceutical products at more affordable prices. Since the establishment of the TRIPS Agreement until 2012, 24 confirmed cases involving compulsory licencing or its threat in connection with pharmaceuticals have been identified. Of these occurrences, 13 resulted in the issuance of a compulsory licence, three in the issuance of a voluntary licence, nine in discount, and two remained without any mentionable result.[196] Some successful cases of compulsory licencing are introduced here to demonstrate their socioeconomic impacts.

In 2006, Thailand issued a compulsory licence for treating HIV/AIDS with Efavirenz and Kaletra, manufactured by different producers. During the time being, Thailand had nearly one million patients requiring medical treatment for HIV/AIDS, of which only 5 % had access to medication. Efavirenz was accessed by around 4500 people and Kaletra by only 150 individuals. The company producing Kaletra offered a discount of 50 % for the product, but Thailand maintained its decision to issue the compulsory licence.[197]

After the establishment of the compulsory licence, the prices dropped drastically: Kaletra could now be accessed with 71 percent lower cost, whereas the price drop for Efavirenz was more than 80 percent. Between 2006 and 2016, the number of treated people rose from 4,500 to 100.000 and from 150 to 30.000 respectively.[198] The price drop can be considered as tremendous, and the amount of treated people indicates a massive advancement to public health. Besides the international pressure not to issue the compulsory licence, other issues were faced as well.

[195] WTO General Council 2003. WT/L/540 and Corr. 1. para. 5(b).
[196] Beall – Kuhn 2012. p. 1.
[197] Guennif 2017. pp. 96-97.
[198] Ibid. pp. 97-98.

Before issuing the compulsory licence, concerns about whether Thailand's manufacturing capacity was at an adequate level arose. Thailand was still incapable of producing pharmaceuticals following international standards, and it also lacked the overall manufacturing capacity. The manufacturing process of Kaletra was initiated in 2011, and of Efavirenz only in 2014, eight years after issuing the licence. During the process, generics from India were imported due to the lack of manufacturing capacity.[199]

The story of Brazil follows the same tracks. Before issuing its first compulsory licence, Brazil was able to negotiate substantial discounts by the mere threat of compulsory licencing. In 2001, Brazil negotiated a discount of 40 % and in 2005 a discount of 50 % by notifying it will issue a compulsory licence for the products, after which the private companies returned to the negotiation table.[200] In 2007, however, Brazil issued a compulsory licence for the same Efavirenz antiretroviral as Thailand did in 2006.[201] The price of the generic version of Efavirenz remained under half of the original one, and by 2015 it had been used for medicating more than 75.000 people.[202]

Brazil faced the same kind of issues related to manufacturing capacity as Thailand. Though the delay in distribution was not as lengthy, it, however, lasted from 2007 until 2010 for Brazil to start manufacturing the licenced pharmaceutical. Once again, the Indian generic was used as a substitute for ensuring access to medicines. Even though the Brazilian generic was half of the price of the original pharmaceutical, the price was still 66 % higher than its Indian counterparty's.[203] These two examples well reflect the manufacturing capacity and long history of Indian IPR policy.

Now, as the examples highlight, compulsory licences can at best be tools to combat the high price affecting accessibility during pandemics. As described in chapter 3, price is one of the factors affecting the timely access of vaccines. Emerging states may access the vaccines way after others since they are not able to conduct bilateral vaccine purchase agreements offering high prices enough. In theory, a compulsory licence may provide a solution for the price dilemma: as established above, the price drop of pharmaceuticals tends to be significant when

[199] Guennif 2017. p. 99.
[200] Deere 2008. pp. 230-231.
[201] Saroha – Kaushik – Nanda 2015. p. 63.
[202] Guennif 2017. p. 97.
[203] Ibid. p. 97.

generics versions are produced. When vaccines could not be obtained at a low cost, they could be licenced without the right holder's authorisation. The fact that vaccines would be manufactured domestically would also reduce any expenses related to transport and could facilitate the efficient administration of vaccines.

However, it remains rather questionable whether this would work in practice. As established in section 3.2.1, the manufacturing capacity of vaccines is globally divided, and even more so what comes to pandemics and rapid solutions. In the examples above, the manufacturing of the licenced pharmaceuticals took several years to start due to inadequate manufacturing capacity. This was although the relevant medication had already existed for years, during which the pharmaceutical field had the chance to research the pharmaceutical further and gain know-how on its manufacturing. It thus seems that compulsory licencing might not be able to offer a required rapid solution for the shortage of vaccines.

What comes to the manufacturing of a brand new vaccine without the support of the patent holder, it may reveal to be impossible in a rapid timeframe due to the lack of any developed expertise in the field. Mere patent applications (which are not necessarily even published during the crucial moments of the pandemic)[204] are not providing enough information to allow the practical exploitation of the technology. The trade secrets, clinical test data and know-how necessary for the exploitation of compulsory licence remain in the hands of the patent holder.[205] There is no obligation to disclose such data; on the contrary, there are third party obligations to protect it. The only feasible solution might thus be trying to obtain a voluntary licence, after which the patent holder would make investments in technology and information transfer.

This incapability is also acknowledged by the pharmaceutical companies negotiating bilateral vaccine purchase agreements. As a result, the threat of issuing a compulsory licence does not play the same role in negotiations as it might play otherwise. Consequently, manufacturers have not been resorting to developing countries what comes to the manufacturing of vaccines during the pandemic: there have been only a few technology transfer agreements with third-world countries. Moreover, some successful vaccine developers have shown zero effort to transfer technology equally throughout the world during the pandemic (see section 3.2.1). Thus, the aims to solve a state’s inability to afford high prices with compulsory licences is made

[204] Medecins Sans Frontieres 2021. p. 7.
[205] UNCTAD-ICTSD 2005. p. 470.

somewhat empty by (1.) the state's developing stage and inadequate manufacturing capacity, (2.) the general (lack of) aims of vaccine developers to voluntarily engage in technology transfer, and (3.) the legal regime enabling the protection of information and property.

In this regard, it must be noted that the first issue concerning the receiving state's manufacturing capacity may be fixed by Art. 31bis of the TRIPS Agreement allowing the exportation under compulsory licences. This opportunity will be discussed in the following subsection. However, the second and the third issue are providing a considerable disadvantage during pandemics requiring immediate solutions. The transfer of know-how seems to be one of the factors impeding the effective use of compulsory licences during pandemics, an issue that will be discussed in the next section.

(c) the scope and duration shall be limited to the purpose for which the licence was authorized and; (g) the licence shall be liable to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur

Though states can freely determine the grounds of compulsory licences, they are bound to certain limitations. Art. 31(c) requires that the scope and duration of the licence are limited, whereas subparagraph (g) lays down that the licence shall be liable to be terminated when the circumstances which led to it cease to exist and are unlikely to recur. The latter requirement is subject to adequate protection of the legitimate interests of the persons who have been granted the compulsory licence. The limited scope of licences established in these subparagraphs has not been assessed in more depth to date, leaving the possible boundaries undefined. To a certain extent, this freedom or rather, uncertainty, may impose barriers for using compulsory licences.

If there was a state with adequate national manufacturing capacity, beating thus all the odds described above, the manufacturing of generic vaccines should, however, be limited to some extent. Unfortunately, there is no straightforward interpretation of what would fulfil the requirement of Art. 31(c). Regarding pandemics, the question is when do the rights of the licensee expire. If the Article is interpreted too strictly, it would deprive the licensee of any economically viable solution. After investing considerable sums in manufacturing capacity, the manufacturer would have to eventually cut down the production or acquire a voluntary licence, of which future prices are uncertain and thus intimidating. On the other hand, allowing compulsory licences to continue without limitation would deprive the intellectual property rights of the patent holder and render their research efforts economically meaningless.

Although the assessment is always made on a case-by-case basis, some guidelines are necessary to a) provide the licensees' safety and thus courage to initiate the manufacturing process, and b) make sure that also the intellectual property rights of the patent holder are protected so that incentives to fight against using compulsory licences would be limited. Further, suppose the 'purpose' of the compulsory licence according to 31(c) is considered to be only fighting the pandemic. As a result, the concept of purpose remains shallow, and the licence should end straight when the pandemic has settled. As the pandemic would slowly globally settle, termination could be applied by the right holder, even though the disease would still be raging in several countries.

The TRIPS Agreement does provide interpretative tools which may be of help when balancing the rights and obligations. As might be clear, subparagraphs (c) and (g) walk hand in hand, indicating that the intention has not been to limit the use of compulsory licence without protecting the justifiable economic interests of the licensee. Generally, it has been interpreted that the scope of compulsory licences must justify the investment made by the licensee, and thus the licence should last sufficiently enough to provide an incentive for the production.[206] Member States also have the freedom to decide whether national law poses a minimum term necessary for the licence to provide adequate incentives and how the licence's termination – or continuation – can be applied for.[207] Thus, once again, one of the most significant restrictions might be the national implementation itself.

Be that as it may, in the absence of any further guidelines, what should be of relevance when interpreting the 'limited scope' -issue are Articles 7 and 8 of the TRIPS Agreement; thus, the objectives and principles of the Agreement (section 2.3.1). Art. 7 provides insight into the core objectives of the Agreement, that is, not the mere promotion of private property rights but the balancing of rights and obligations so that it leads to the mutual advantage of producers and users, also in a manner conducive to social and economic welfare. Also, Art. 8 suggests that public health considerations may be taken into account in the implementation of the Agreement.

Assessing how to balance the rights and obligations of the licensee and patent holder, also taking into account the social welfare and public health aspects, is far from simple. Taking that nations may need vaccines years to come even after the pandemic, it seems somewhat against

[206] UNCTAD-ICTSD 2005. p. 473.
[207] Ibid. p. 475.

the TRIPS objectives to let the manufacturing continue when the influenza phase has emerged and been going on for a while. However, the most viable solution regarding social and health impacts would be letting multiple local factors combat the accessibility issues described in chapter 3, deriving from distant manufacturing and price-related issues. Thus, it would be necessary to provide potential licensees with incentives to invest in manufacturing capacity. It is also arguable that during pandemics, to rapidly answer to a global health emergency, these incentives should perhaps be more substantial than those allowed otherwise, meaning that the length of the licence term could be assessed with more freedom.

In addition to the absence of any guidelines to the issue, there is also no obligation to provide voluntary licence in economically justified price after the term of compulsory licence has ended. There is actually no obligation to offer a voluntary licence at all, and it may well be that the patent holder has the right to step in and supply the market in place of the licensee by paying adequate remuneration for the investments already made.[208] It might be of the state's interest to retain the manufacturing capacity after the pandemic to provide the population with adequately priced vaccines after the emergency. This could also serve as an additional incentive for building up the manufacturing capacity during pandemics if an option to obtain an affordable voluntary licence (or no licence at all) afterwards would not be only a big question mark.

However, the opportunity to use Art. 31 as a post-pandemic tool might give recourse to reasonable prices and, therefore, remedy the flaws deriving from uncertainty. As established, both Thailand and Brazil (amongst others) have used compulsory licencing in order to cut the prices of pharmaceuticals. As the state practice is relevant in interpreting the TRIPS, the case of Thailand might indicate what is allowed under Art. 31. After the alleged negotiations to achieve a voluntary licence[209] failed, Thailand issued a compulsory licence for Plavix (pharmaceutical comparable to aspirin).[210] Plavix was not on the WHO list of essential medicines and has no curing or preventive function.[211] Though Thailand's action was politically challenged, there has been no indication that it would not have been TRIPS-compliant.

Thus, even though the limitation of Art. 31(c) would create an insecure atmosphere, the licensee could potentially issue an additional post-pandemic compulsory licence if it would not be able

[208] UNCTAD-ICTSD 2005. p. 475.
[209] The sincerity of the negotiations was afterwards questioned.
[210] See e.g. Burton Macleod 2010.
[211] Burton Macleod 2010. p. 417.

to negotiate a voluntary licence with reasonable terms as provided in Art. 31(b). As a consequence, Art. 31(c) does not seem to impose legislative restrictions for using compulsory licences during pandemics. Another question is, once again, the amount of international debate and pressure arising from interpreting Art. 31 broadly. The normally useful flexibility of the TRIPS Agreement might serve as a deterrent to politically more invisible states not to establish a too broad interpretation of the agreement, which during pandemics is not the best alternative.

(d) a compulsory licence shall be non-exclusive and (e) non-assignable

The requirement of non-exclusivity might provide the needed silver lining to the applicability of Art. 31. Many voluntary licences are exclusive in the sense that they are providing exclusive marketing rights of the licenced product to one licensee only.[212] Compulsory licences cannot include this kind of exclusive rights, and thus, other manufacturers are allowed to operate simultaneously in the same areas. From the perspective of timely distribution of vaccines, this is a welcomed thing.

Non-assignability does not appear to restrict the recourse to timely access either. The provision is built to prevent a differentiated market for compulsory licences where they would have own value. Thus, each actor who wishes to manufacture under a compulsory licence must issue the licence themselves. As the non-assignability rule does not extend to businesses that have obtained compulsory licences, there is no risk of losing the investments made to be able to manufacture under the licence.[213] Under this interpretation, it also seems that all the tangible assets acquired for the production would be assignable to a third party who wishes to obtain a compulsory licence and acquire the manufacturing capacity.

(h) the right holder shall be paid adequate remuneration

As described in chapter 2, the right to remuneration by the right holder has remained as an undefined obligation without any existing precedents. Art. 31(h) obliges that the remuneration is assessed by the circumstances of each case, taking into account the economic value of the authorization. The remedy might as well be based on the right holder's sales marginal or other specific data regarding the development costs, total global market, average rate of return and so forth. It has also been validly suggested that the rationale for issuing the licence must be

[212] UNCTAD-ICTSD 2005. p. 473.
[213] Ibid. p. 473.

taken into account in assessing adequate remuneration. Thus, if generics are manufactured to combat a national emergency by a low-income state, the compensation should be the lowest acceptable royalty.[214]

During the Covid-19 pandemic, many of the pharmaceutical companies have pledged to sell their vaccines at minimum prices (section 3.2.2). As a result, it might as well be that the remuneration would be marginal if it would even exist, as it is also assumable that the returns for the generic manufacturer would not be significant. Accordingly, when assessing the balance under the TRIPS Agreement objectives and principles, the approach that global pandemic where vaccine developers have received a substantial amount of R&D funds would entitle the vaccine developer to significant remunerations by generic producers seems unjustifiable. Also, though the general rate of return of the vaccine developers would remain extremely low, there would be no excuse to try to recover them from generic manufacturers.

However, as established in chapter 3, there seem to be differing stances between the companies. The price ranges of some companies indicate that the rate of return is not the lowest possible for all the patent holders. Given the current level of transparency of the companies in question, it is questionable whether remunerations would be demanded by appealing to sales figures. In any case, when assessing the compensation, not only should the value of the licence for the patent holder but also for the licensee be taken into account. As a result, the obligation for remuneration does not seem to impose barriers to timely access in the form of an overwhelming economic burden. It is, however, arguable whether such remuneration should exist at all.

Art. 31(f) will be examined in the following subsection, whereas Articles 31 (i)-(l) will be left without further attention in this research due to their irrelevant nature regarding the research questions. In conclusion, the compulsory licencing system does not seem to be as restrictive as indicated by some when it comes to pandemics. The tool has some strengths which could be applied when negotiating possible amendments, one being the non-exclusivity of the licences. Accordingly, compulsory licencing may be used post-pandemic to pressure the prices down in case patent holders would start raising their prices to recoup possible economic ‘losses’, or rather to eventually profit from the pharmaceutical. This alternative thus serves as a ‘backup’

[214] UNCTAD-ICTSD 2005. p. 476.

incentive for manufacturing capacity building, as there is no fear of losing one's investments completely after the pandemic has settled.

However, as the inadequate global manufacturing capacity cannot be solved by legal means, it remains questionable whether compulsory licencing would serve any kind of role during pandemics. Despite its bright sides, there is not much to be done if the tool cannot be used in the first place. In this regard, Art. 31bis allowing the export under compulsory licence might serve as the needed escape from a dead-end, allowing capable manufacturers to export generic vaccines. However, as indicated at the beginning of this section, the greatest obstacle seems to be the lack of know-how, which should be transferred willingly by the vaccine developers and manufacturers. These issues will be addressed next.

4.1.3 Exporting under compulsory licences

Art. 31bis represents itself as an opportunity to solve one of the most significant issues of Art. 31: lack of manufacturing capacity. The legal tool is still far from simple, and it poses several different restrictions that may prevent or set unwanted obstacles to its use. The know-how dilemma described in the previous section also concerns the usage of Art. 31bis, but this issue is more comprehensively addressed in section 4.2: this subsection will assess the elements of the TRIPS Paragraph 6 system and how they function in worldwide emergencies. To demonstrate the functioning of the tool, a case study will be conducted.

As a brief reminder, the Paragraph 6 system waives the restriction of Art. 31 (f) to manufacture pharmaceuticals mainly for domestic distribution. In addition, it waives the importing country's obligation for remuneration. As a result, only the exporting state is obligated to grant a decent remuneration for the patent holder when issuing a compulsory licence. Furthermore, the system obligates both the exporter and importer to notify the WTO on importing under the compulsory licence. The notification must include the grounds for import (indication of inadequate manufacturing capacity) and the rationale for importing (the terms and duration of the export licence and the quantities to be supplied).[215]

Even though the Paragraph 6 system has been available for over a decade, there has been only one materialized case of importing under a compulsory licence to this date. This import

[215] UNCTAD-ICTSD 2005. pp. 484-485.

occurred in 2008 when Canada imported HIV/AIDS-related pharmaceutical TriAvir to Rwanda.[216] The import was preceded by Rwanda's notification in July 2007 and Canada's respective notification in October 2007. According to the notifications, a Canadian pharmaceutical manufacturer Apotex Inc. was authorized to manufacture and distribute 15.600.000 tablets of TriAvir to Rwanda.[217]

The first export took place over a year later, in September 2008.[218] Though the process was somewhat slow, the price gap between Canadian generic and the original pharmaceutical was, once again, incredibly significant. TriAvir was distributed to Rwanda with a price of $295 per person for one year's treatment, whereas the cost of the corresponding pharmaceutical in the US was $14.600. Considering that Rwanda's GDP per capita was $1000 a year, and most of the population had earnings of under $200 a year, the price-drop undisputedly saved lives.[219]

The Canada-Rwanda case gives some important perspective on the functionality of the Paragraph 6 system during pandemics. Four observations can be made from the tool. First, the absence of incentives for the exporting manufacturer during regular times is remarkable. The notification requirements have been assessed to place an unnecessary burden on manufacturers, as no exporter can precisely predict the number of pharmaceuticals that will be exported.[220] Furthermore, the notification may be done only for one pharmaceutical component at a time for the use of one country alone. Apotex Inc. straightly criticized the system for creating an uncertain atmosphere for generic producers, as at the beginning, manufacturing can be directed only to one customer, without any guarantee on further contracts or other customers.[221]

During pandemics, achieving enough customers might not be such a significant issue as it is during regular times. As the vaccine is needed worldwide, the lack of clients is not a probable scenario. Additionally, when observing the notifications of Canada and Rwanda to the WTO, they do not seem to contain very specific information on the amounts to be manufactured. In its notification, Rwanda reserved the right to modify its estimate on the amount of needed pharmaceuticals 'as necessary or appropriate'.[222] In connection with the pandemic, the number

[216] Council for Trade-Related Aspects of Intellectual Property Rights 2018. Annual Review of the Special Compulsory Licensing System IP/C/82. p. 7.
[217] Canada for Council for TRIPS 2007. IP/N/10/CAN/1; Rwanda for Council for TRIPS 2007. IP/N/9/RWA/1.
[218] Mitchell – Voon 2010. p. 59.
[219] Chung 2010. p. 154.
[220] Mitchell – Voon 2010. p. 71.
[221] Chung 2010. pp. 167-168.
[222] Rwanda for Council for TRIPS 2007. IP/N/9/RWA/1.

of needed pharmaceuticals is also easily assessable, considering the whole population of each country is in need of a vaccine. Thus, the notification process does not seem to provide significant barriers for the use of the Paragraph 6 system.

Though some of the barriers existing during regular times are set aside, the pandemic has a way of construing its own. The pandemic requires rapid measures, which are seldom provided by the legislation of Member States. The second observation is that the national implementation of the Paragraph 6 system might well deprive its efficiency by limiting the timely access to vaccines. The whole process of getting a licenced product to Rwanda took three years from the perspective of the exporting company. Apotex initially applied for permission to act as an exporter already in 2005, and the approval was granted six months later (before Rwanda was even identified as a potential customer).[223] It has indeed been argued that the national implementation of Canada led to the delay in distribution, as it places burdensome regulatory approval processes on the manufacturer.[224]

Somewhat ironically, by the time of writing, Canada is the only state that has initiated a procedure to allow a pharmaceutical company to manufacture and export the Covid-19 vaccine under a compulsory licence. On February 17th 2021, Bolivia notified the TRIPS Council of its intent to import pharmaceuticals under Art. 31bis.[225] In March, a Canadian company Biolyse informed that it had sought to conclude a voluntary licence with Janssen Pharmaceuticals with poor success. Subsequently, Biolyse decided to apply for a compulsory licence to contribute to the vaccine distribution, as it obtains the manufacturing capacity required for the Johnson&Johnson vaccine. On 10th May, Biolyse and Bolivia conducted an advance purchase agreement, according to which Biolyse was to provide Bolivia with 15 million doses of vaccines.[226]

Followingly, Bolivia notified the TRIPS Council of the arrangement on 11th May.[227] By the end of August, there had not yet been any notification on behalf of the Canadian government. It thus seems that the national implementation of the Paragraph 6 system should be paid more attention to: though the Art. 31*bis* would not *per se* restrict the possibilities to export, national

[223] Chung 2010. pp. 170-171.
[224] Novogrodsky 2010. p. 350-351.
[225] Bolivia for Council for TRIPS 2021a. IP/N/8/BOL/1.
[226] Medecins Sans Frontieres 26 May 2021. p. 8-9.
[227] Bolivia for Council for TRIPS 2021b. IP/N/9/BOL/1.

implementation with disregard to worldwide emergencies might. Accordingly, the national implementation may deprive manufacturers of any incentives. If the issuing of a compulsory licence is an insecure and burdensome process of which results are beyond clear, the manufacturers will be hesitant to start the upbuilding of manufacturing capacity, which again leads to further distribution delays.

When negotiating possible new pandemic-related legal responses, the incentives of generic manufacturers should be taken into account. A good example is COVAX, which invests in the manufacturing capacity upbuilding even before the vaccine candidate has proven successful. If the licencing procedure is lengthy, and there is no security on whether the application will be accepted, there are no incentives to prepare for the manufacturing as the investments might be lost entirely. In this regard, the mechanism of applying for compulsory licences during pandemics should be significantly faster or provide other incentives for capacity building.

Additionally, one issue regarding national implementation is the enforceability of Art. 31bis in general. By April 2021, 20 countries plus the European Union had implemented the Paragraph 6 system to some extent in their national legislation.[228] Some states have reported that their legal regime already allows importing or exporting pharmaceuticals, and thus no national implementation measures are needed. This goes with only a few states, such as Japan and Ecuador.[229] Furthermore, several states have given a waiver not to use Art. 31bis for importing under any circumstances (see section 2.2.1). However, these states are mainly the European Union countries and high-income countries that have succeeded in securing timely access to vaccines during the Covid-19 pandemic via other means. This indicates that the given waivers are not the most significant concern, especially as they are completely voluntary and can therefore be pulled back or altered at any time.[230]

Returning to the Canadian case: the president of Biolyse pushed the Canadian government to accept the compulsory licence for the Covid-19 vaccine, without any reactions from the government whatsoever. In his open letter, John Fulton addressed the issue of the government being afraid of the reactions of Canadian citizens if vaccines are exported in the middle of the pandemic.[231] The situation well reflects the effects of politics on the distribution of vaccines

[228] World Trade Organization. Member's laws implementing the 'Paragraph 6' system.
[229] Kampf 2015. p. 7.
[230] Correa 2004. p. 15.
[231] Fulton to Minister of Innovation, Science and Industry of Canada 2021.

and brings us to the third observation: the use of Art. 31bis has been restricted by national and international political aspirations during the Covid-19 pandemic.

Canadian example being a reflection on the national attitudes, Russian example will serve as an example of international barriers. Russia issued a compulsory licence for Gilead's Remedesivir in 2020, as it had (by the time) proved to shorten the recovery time of Covid-19. Gilead filed a lawsuit against the Russian government claiming infringement of intellectual property rights.[232] By manufacturing Remedesivir, Russia intended to support India, which was struggling with a high number of Covid-19 infections and diseased thereof. Due to the political pressure, Russia eventually withdrew from exporting 300.000-400.000 injections of the pharmaceutical.[233]

The issues seem to arrive as the legal tools of the TRIPS Agreement are not mutually intended to cover and concern worldwide pandemics. The Articles are flexible and are designed to be used also in national emergencies, but they do not take into account a situation where each state is suffering from a public health emergency simultaneously. The lack of consensus on how to use the available legal tools is crucial in the middle of an emergency and might significantly restrict the attempts of private sector actors in fighting against the Covid-19. The states have not been able to maintain the level of needed certainty what comes to the effects of the TRIPS Agreement, resulting in a situation where political desires can comprehensively make the regulation redundant. This kind of uncertainty could be avoided (at least to some extent) by creating legal tools designed explicitly for responding to global emergencies.

The fourth and the last observation regarding Art. 31bis concerns its restriction regarding re-exporting. As described in section 2.2.2, pharmaceuticals exported under a compulsory licence cannot be re-exported by the importing state (excluding LDC FTA's). Though this requirement is not necessarily the most crucial one, it is worth considering whether re-exporting should be allowed in certain circumstances. Exceptions could be allowed, for example, in situations where the country would already have satisfied its vaccine needs (unlikely if generics are imported) or in the more likely case the country is incapable of administering the received vaccines before their expiration. As a result, the vaccines produced under compulsory licence could be distributed before their spoilage.

[232] Nikolskaya 2021. *Russian firm awaits government approval to ship remedesivir to India*. Reuters.
[233] Haidar 2021. *22 tonnes of COVID-19 supplies from Russia arrive in India.* The Hindu.

It is also questionable whether re-exporting should be allowed only to the FTAs currently provided in the Article, or should the opportunity be reserved to all Member States. This is as any export barriers during pandemics may prevent the timely and efficient response to the situation. However, in light of the fact that yet no exports have occurred during the Covid-19 pandemic, it is clear that there are more significant issues related to the use of the Paragraph 6 system.

In conclusion, the issues circle the lack of incentives set for the generic manufacturers, especially due to inadequate national implementation of the legislation. Accordingly, the uncertainty deriving from the legislation is undermining its operability, also due to the political aspirations that are given a vast amount of space in an insecure situation, where nationalism is easily supportable. By intervening in these impediments, Art. 31bis could serve as an efficient legal tool in combatting the inefficiencies deriving from Art. 31. A functional combination of these articles could provide a partial answer to the issue of bilaterally negotiated advance purchase agreements and the timely access of vaccines from the point of view of the emerging world. However, before the efficacy of these articles can be praised, the issue of undisclosed information must be addressed.

4.2 The effects of other TRIPS provisions on timely access to vaccines

As a result of examining the effectiveness of compulsory licences, the importance of know-how and technology transfer has become evident. In order to adequately respond to pandemics, the legal system should be able to take into account the challenges behind the timely access to vaccines. As established in section 3.2.1, one of the most significant factors behind unequal vaccine distribution is the imbalanced division of manufacturing capacity. Currently, the compulsory licencing system is not providing solutions to the issue. Despite its potential, the system remains rather unusable as it has not been designed for worldwide emergencies.

Therefore, the question is: does the other TRIPS legal regime support the use of compulsory licences by perhaps supplementing its inefficiencies? This section examines first (4.2.1) the role of Art. 39 in the battle against pandemics. The subsection will introduce the content of the Article and the obligations deriving thereof, and briefly assess its effects on balanced sharing of know-how. Also, its connection to the functionality of the compulsory licencing system is estimated. Lastly, (4.2.2) the Covid-19 TRIPS Waiver will be examined as a last resource

solution. The idea is to investigate whether the waiver of obligations serves as an expedient solution to the timely access issues when the legal regime itself does not.

4.2.1 Protection of undisclosed information

As indicated earlier, the manufacturing of vaccines is strongly dependent on know-how, as vaccines tend to be complex pharmaceutical products requiring years of expertise in the field.[234] It has been assessed that factors related to the dissemination of know-how may significantly impact how effectively tools such as compulsory licencing can function. Accordingly, it has been noted that not all the relevant know-how is disclosed in connection with public patent applications as required by Art. 29 TRIPS. As a result, compulsory licencing might not serve as an efficient tool for transferring vaccine manufacturing capacity.[235] As the manufacturing capacity transfer plays a significant role in the effectiveness of the compulsory licences during pandemics, the know-how related TRIPS regulation is presented below.

In the TRIPS Agreement, undisclosed information is protected by Art. 39. The Article sets two requirements for the Member States to protect data from unfair competition: 1. protection of data from being disclosed in a manner contrary to honest practices (31.2) and; 2. protection of data disclosed to national authorities in connection with pursuing a marketing (or other) approval (Art. 31.3). The first requirement concerns information that can be classified as (a.) secret, (b.) possessing commercial value, and (c.) having been subject to reasonable steps by the person lawfully in control of the information to keep it secret.[236] Instead, the requirement to protect data specifically disclosed to the government covers 'undisclosed test or other data, the origination of which involves a considerable effort' (Art. 39.3). Both forms of protection are relevant to this study.

It must be noted that by the time of writing, there were no legally binding WTO decisions regarding the interpretation of Art. 39, due to which the assessment will be based on scholarly writings.[237] Focusing first on Art. 31.2: due to the absence of enforceable interpretation, there are no binding limits on what constitutes 'secret, commercially valuable' information that has

[234] Garrison 2004. pp. 9-10.
[235] Ibid. p. 10.
[236] TRIPS Agreement Art. 39.2 (a-c).
[237] Few complaints have been issued, but the processes are still pending. See e.g. The WTO Dispute Settlement Body. WT/DS549 China v. European Communities; WT/DS583 Turkey v European Union; WT/DS171 United States, complaint withdrawn.

been subject to attempts of keeping the information secret.[238] If assessed in connection with the Covid-19 vaccines, the vaccine-related data seem to fulfil these criteria. The data behind the vaccines is not generally known or readily accessible to persons typically dealing with the information in question, and the data certainly has commercial value as it is used to establish a product needed worldwide.

As described in section 3.1.1, Moderna has rather interestingly disclosed the test data of its Covid-19 mRNA vaccine.[239] This disclosure waives the protection of Art. 39, as the requirement of 39.2(c) is not fulfilled. Naturally, if the company (or another actor) decides to disclose the information willingly, it becomes publicly available information accessible by everyone. Other Covid-19 vaccine producers have not taken similar steps, and accordingly, their vaccine-related data remain under the scope of Art. 39.2. The protected data may include technical know-how such as processes, formulas and other knowledge often resulting from experience.[240]

Art. 39.2 protects the disclosed data against unfair competition by forbidding the disclosure of information in a manner *contrary to honest commercial practices*. According to footnote 10 to the TRIPS Agreement, this shall mean 'at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition'. Furthermore, 'unfair competition' has generally been defined as 'any act that a competitor or another market participant undertakes with the intention of directly exploiting another person's industrial or commercial achievement for his own business purposes without substantially departing from the original achievement'.[241]

Consequently, any violation of a patent holder's rights would result in significant sanctions for the violator. Assessed in the context of a pandemic, the requirement to protect data concerns e.g. the licensees of the Covid-19 vaccines established in *figure 1*, section 3.2.1. Though the agreements between the Covid-19 vaccine patent holders and the manufacturers are not publicly available, the assumption that they include a non-disclosure clause is made. There is no

[238] UNCTAD-ICTSD 2005. p. 521.
[239] European Medicines Agency 2021a.
[240] UNCTAD-ICTSD 2005. p. 521.
[241] WIPO 2004. p. 153; UNCTAD-ICTSD 2005 p. 521.

indication of any licensee contributing to the dissemination of know-how and technology in the Covid-19 vaccine field, strongly pointing to the direction of non-disclosure clauses.

The requirement of preserving data appears to be problematic for the effective use of compulsory licencing. Without achieving a voluntary licence from the patent holder, the know-how may remain inaccessible. Even though there would be multiple actors possessing the know-how, they are obligated to non-disclosure by the threat of sanctions. Without restrictions, the dissemination of know-how could be significantly expedited, as local licensees could distribute their experience to their specific business partners and areas nearby. This would also ease the burden of patent holders in engaging in multiple simultaneous technology transfer processes around the world. As a consequence, the issuance of compulsory licence could show up as a solution for significantly more actors than it currently does.

While Art. 39.2 TRIPS does not contain any exceptions to the protection, Art. 39.3 does. As explained above, Art. 39.3 covers the protection of test and other data provided for the government for the marketing approval and other processes. However, Member States are not obliged to protect any data 'where necessary to protect the public'. Thus, in practice, a government may impose a compulsory licence to protect public health and disclose all the relevant test data and know-how for the licensee.[242] This is particularly important, as Art. 39.3 covers all the data necessary to obtain marketing approval, which oftentimes includes manufacturing and conservation methods.[243]

However, there are at least three reasons why Art. 39.3 exception might be deprived of its usefulness. First, the national implementation of the Article must be successfully done. If Member State has not implemented the public protection -exemption, compulsory licences will still be issued without access to required data. Second, even the national implementation may not be enough to gain access to relevant data. It is possible to apply for marketing approval based on marketing approval already granted by a national authority of another Member State. When doing so, it is not necessary to submit data in connection with the second marketing application.[244]

[242] UNCTAD-ICTSD 2005. p. 532.
[243] Ibid. p. 530.
[244] Ibid. p. 530.

As established in section 3.1.1, the Covid-19 vaccine patent holders primarily reside in the US and the EU. As a result, the first marketing approvals, in connection with which the vast amount of data is submitted, will be applied for in the exact territories which already possess the know-how of vaccine manufacturing. Art. 39 poses no obligation for the Member States to share the disclosed data with the other Member States wishing to grant a compulsory licence. As a result, the third Member States wishing to grant the compulsory licence may simply not have access to the required data, due to which the manufacturing may reveal to be impossible.

Third, if the national implementation would be in place, and the data would be in possession of the relevant state, the last issue remains. Suppose a company is granted a compulsory licence under which it also gains access to all the submitted data. However, it still remains questionable whether access to such data would suddenly create the ability to utilize the know-how and produce the vaccines. Due to the significant differences in technical sophistication and expertise, emerging suppliers cannot necessarily build manufacturing capacity up without the assistance of another supplier.[245] Thus, some support could still be required by the patent holder or by other licensees to set up a functional manufacturing facility. It may be assumed that the patent holder is not necessarily willing to provide its assistance, which leaves the manufacturer dependent on other licensees.

In this regard, the relation of Art. 39.2 and 39.3 is far from clear. There is no indication that the private contractual obligations referred to in Art. 39.2 would be waived if Art. 39.3 public protection -exemption is invoked. Thus, the licensees who have possessed their manufacturing capacity by voluntary licences are still obligated not to disclose the data protected by the voluntary licencing agreements. As a consequence, the compulsory licence might remain redundant, as there are no parties that could or would support the company in its manufacturing capacity building process.

In conclusion, Art. 39 does not seem to support the TRIPS compulsory licencing system in the manner required. Due to the combination of the Art. 31/Art. 31bis and Art. 39, it is extremely difficult for a Member State to overcome all the challenges mentioned in chapter 3. Also the statistics speak for the difficulties: by the time of writing, only one company worldwide has indicated that it would have the capacity to manufacture Covid-19 vaccines under a compulsory

[245] Garrison 2004. p. 26.

licence.[246] As a result of the examination, the flexibilities under the TRIPS Agreement do not seem to take into account the pandemic-specific conditions. Therefore, they do not adequately respond to the issues related to timely access to vaccines.

4.2.2 The Covid-19 TRIPS Waiver

As established in section 2.3.3, the WTO Agreement presents a chance to waive obligations set by any WTO Treaty by consensus or a majority vote of Member States. In October 2021, India and South Africa addressed a communication for the Council of TRIPS to start preparing a waiver from specific TRIPS provisions as a global response to the Covid-19 pandemic ("**the Communication**"). The Communication emphasized the need for a global response to 'scale up the research, development, manufacturing and supply of medical products essential to combat Covid-19', and pointed out that intellectual property rights have been deemed hindering timely access to pharmaceuticals by many actors due to which a waiver from certain obligations is required.[247]

The Communication included a detailed draft decision text for the waiver, according to which Sections 1, 4, 5 and 7 of Part II (thus comprising patents and protection of undisclosed information) of the TRIPS Agreement would be waived for combating Covid-19 for the time to be determined.[248] The Communication was circulated and extensively discussed, after which a revised version by multiple Member States was established ("**the Revised Communication**"). The Revised Communication amended the first paragraph of the draft decision by limiting the scope of the waiver to 'health products and technologies including therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of Covid-19'.[249]

The TRIPS Covid-19 Waiver invited a large number of opinions and extensive discussion amongst the Member States. There have been some fundamental differences in the stances, as the states disagree on the underlying issues of timely access to vaccines.[250] The timeline has

[246] Medecins Sans Frontieres 2021. pp. 8-9.
[247] India and South Africa for Council for TRIPS 2020. IP/C/W/669. paras. 3, 8-9.
[248] Ibid. p. 3-4.
[249] The African Group, et al. for the Council for TRIPS 2021. IP/C/W/669/Rev.1. para. 4, pp. 3-4 para 1 of the draft decision.
[250] IP/C/M/100 Minutes of Meeting 8-9 and 29 June 2021. p. 8.

been postponed during the process: the aim was to deliver a revised TRIPS Waiver to the General Council for its meeting on 21-22 July 2021,[251] but due to the lack of consensus, the negotiations were extended until the next formal TRIPS Council meeting scheduled for 13-14 October 2021.[252] Unfortunately, by the time of writing, the July meeting minutes were not published, and the stances of Member States could not have been investigated in more depth.

Enforcement of the Covid-19 TRIPS Waiver would waive the obligation to protect patent-protected products and processes, as well as the undisclosed information under Art. 39. As a result, the manufacturers would be exempted from any obligations regarding patent-related rights. They would thus gain an immunization against any remedies usually resulting from infringements of using and adopting patent-protected technologies or importation of protected products.[253] Accordingly, the manufacturers would be freed from the obligation of Art. 39, and they could thus participate more actively in the dissemination of technology.

Some questions remain in connection with the effectiveness of the Waiver. For example, as the private contractual relationships are also regulated by other international treaties and by national legislation, it might be that private-sector manufacturers would be hesitant to break any existing contractual obligations despite the Covid-19 TRIPS Waiver. As a result, contractual clauses of non-disclosure could still prevent the efficient use of the compulsory licencing system. All the states would be free to publish test data, but it remains questionable whether states would publish any data without the consent of a profiting pharmaceutical company. This kind of action could undermine the state's role as a private rights protector, which is the state's primary function.

The process of enacting the Waiver does not convince either. The vaccine roll-out has been ongoing since the beginning of 2021, yet no solutions regarding the Waiver had been made by September 2021. Moreover, in September 2021 the pandemic had proceeded to a phase where more infectious variants were threatening human lives,[254] and some states had already vaccinated a significant amount of their population (see *figure 5*, section 3.2.2). As indicated multiple times in this study, the uncertainty related to the regulation is a crucial factor, as private

[251] IP/C/M/100 Minutes of Meeting 8-9 and 29 June 2021. p. 8.
[252] World Trade Organization 2021. TRIPS Council agrees to continue discussions on IP response to COVID-19.
[253] Correa 2021. p. 2.
[254] The African Group et al. for the Council for TRIPS 2021. IP/C/W/669/Rev.1. para. 3.

sector actors are not willing to take their chances on the international legal, and more precisely, political field.

If enforced, the Covid-19 Waiver would not facilitate the interpretation of international obligations. Waiving all the obligations and thus, also all the rights, creates a complex interpretational web. Would the waiver signify that no issuing of compulsory licences would be needed, and one could initiate manufacturing without any restrictions if capable of doing so? Would any actor engage in such an action in fear of consequences? The relationship between patent holders and licensees would not be regulated at the international level anymore, which invokes a question: What are the minimum rules applicable then? Accordingly, as the national implementation of the TRIPS Agreement is not always straightforward and is perhaps nationally fragmented under several laws, the Waiver may create even more uncertainty.

It must be noted that waiving certain obligations of the TRIPS Agreement might by the time of writing be one of the only globally effective measures that could be done what comes to fixing legislative barriers to timely access to vaccines. However, the timeline and the void the waiver might create indicate that the TRIPS Waiver should not be trusted as a permanent resolution to future pandemics and other emergencies. It is necessary to create a legal framework where the pandemic-specific circumstances are taken into account and where functional incentives for private sector actors to act on behalf of the global community are set.

4.3 Remarks for the future: clarifying the regulation and balancing of rights

As a result of examining the available TRIPS tools, it must be concluded that they are not designed for providing a comprehensive response to timely access to vaccines. Despite some exemplary aspects of the compulsory licencing system, the TRIPS Agreement fails to take into account the bigger picture and the economic circumstances prevailing during pandemics. During pandemics, the TRIPS regulation allows the private sector actors to operate in a manner equal to any other circumstances. Furthermore, it leaves the possible responses on the shoulder of one legal tool only, which accordingly should be taken advantage of by private sector actors. Though this is understandable as the Agreement is drafted to provide patent protection in regular circumstances, the need for future responses is inevitable.

When assessing the TRIPS response to pandemics, many factors affecting timely access to vaccines are left unresolved. The most significant factor behind timely access being the lack of

manufacturing capacity, the possible future resolutions should circle the issues related to the concentrated technical capacity of the pharmaceutical sector. In this regard, it would be advisable to pay attention to all the factors that serve as barriers to the dissemination of manufacturing capacity in a rapid time frame. This, in turn, would require a reassessment of the private sector's exclusive recourse to protect their inventions and thus almost entirely determine the amount and prices of voluntary licenses and the velocity of the dissemination of know-how. It is also questionable whether bilateral private actor/state vaccine purchase agreements are the best alternative from the perspective of equal distribution of vaccines, at least as the level of transparency is currently non-existent.

The study suggests that multiple issues relating to timely access to vaccines are closely related to the fact that during pandemics, private-sector pharmaceutical actors' rights remain unchanged compared to regular circumstances. Thus, private sector actors are left with a lot of freedom to operate, putting them under a lot of political pressure during worldwide emergencies. The current system does not support coherent and predictable responses to pandemics, nor does it allow effective international cooperation by different levels of actors. This study suggests that some pressure should be removed from the shoulders of private vaccine developers, simultaneously meaning part of intellectual property protection must be lifted.

The legal justification for this approach can be found in human rights norms and, more precisely, from balancing the right to property with regard to right to life and health. The discussion on access to medicines as a right to health and its relation to IPR protection as a right to property has been taking place for decades.[255] One supported argument has been that access to pharmaceuticals is a human right by virtue of the right to health, and thus the protection of pharmaceutical patents should be aligned with health interests of societies.[256] This study is not aiming to take part in the general discussion but is merely reflecting on some key points and addressing why the balance of rights should be reassessed in the context of pandemics.

The right to life is protected by Art. 3 of the Universal Declaration of Human Rights ("**the Declaration**"), and it has on certain occasions been regarded as *jus cogens* of international law.[257] Accordingly, the right to life has been interpreted to allude to other human rights,

[255] See e.g. Hein – Moon – Poku 2013.
[256] Matthews 2015. p. 499.
[257] Nowak 1993. p. 105.

principally to the right to health.[258] The right to health is protected by Art. 25 of the Declaration and by Art. 12 of the International Covenant on Economic, Social and Cultural Rights ("**the Covenant**"). Right to health is a broad concept of which protection has been implemented widely to national and regional legal regimes, thus signifying it has a firm status almost comparable to international customary law.[259]

Lastly, Art. 17 of the Declaration establishes the right to property. In this regard, the Declaration and the Covenant also both grant right to enjoy the benefits (or material interests) resulting from any scientific production the individual is an author of.[260] The protection of intellectual property rights has been interpreted to belong to the scope of protection of property as a human right. However, there is a lack of consensus on whether these rights may be regarded as fundamental.[261] As property rights are still protected by international human rights norms, the question is can those rights be exempted from, and what kind of restrictions to property rights would be justified during pandemics.

One justification to human rights restrictions is a collision of two human rights, where both rights cannot be realized in full.[262] During pandemics, the right to health and even to life might be strongly endangered, as can be detected from the death toll of the Covid-19 pandemic. As established in this study, the patent protection and its scope aggravate the issues related to global manufacturing capacity, thus affecting timely access to vaccines. Thus, in case of pandemics, the question is whether the patent protection could be to some extent restricted in respect to regular circumstances, as the upholding of those rights are somewhat interfering with the right to health.

It must be noted that even the wording of the Declaration and Convention strongly points to the direction of effective responses to pandemics. Art. 25 Declaration provides that 'everyone has the right to a standard of living adequate for the health … including … medical care', referring to access to pharmaceuticals. Moreover, Art. 12 of the Convention straightly states that the actions of states to protect the right to health shall include steps '*necessary* for … the prevention, treatment and control of epidemic, endemic, occupational and other diseases [emphasis added]'.

[258] Xiong 2012. p. 50.
[259] Ibid. p. 23.
[260] Universal Declaration of Human Rights Art. 27; International Covenant on Economic, Social and Cultural Rights Art. 15.
[261] Xiong 2012. pp. 51-53.
[262] Hallberg, et al. 2005. Section II.3.

The word ‘necessary’ brings us to the principle of proportionality, which is oftentimes used for balancing the scope of two interfering human rights. The idea of the proportionality test is to assess how the link between a given measure and its impact on the pursued aim is measured: the measure should be necessary and in proportion regarding the legitimate purpose.[263] However, the substantive content of the proportionality test is arguable and criticized as being too vague of an indicator to such measurement.[264] Nevertheless, in the context of pandemics, some interpretational sources can be of help when assessing the balance of rights.

First, the UN Committee on Economic, Social and Cultural Rights published a statement in response to evolving discussion on the right to health and the right to property to address the issues that arose after the establishment of the TRIPS Agreement. In the statement, the Committee established that human rights should be regarded as timeless expressions of fundamental entitlements of the human person, whereas intellectual property rights are tradable and, above all, limited in time.[265] Accordingly, the Committee emphasized that any failure to protect the right to health due to reasons deriving from patent protection would render Member State in breach of the Convention.[266]

The statement generally refers to intellectual property rights and the right to health, not in any specific context. However, it is evident from the statement that the right to health should not be interfered with by patent protection, let alone during pandemics, while the health considerations are extremely pronounced. As chapter 3 suggests, there are multiple factors affecting timely access to vaccines that are also linked to private actors' patent protection. As a consequence, there seems to be an imbalance between the right to property protection and the right to health deriving from the regulation of the TRIPS Agreement.

The Committee also made an explicit reference to the 2001 Doha Declaration, implying that when reviewing the balance of concurrent Covenant provisions, the text of the Doha Declaration may serve as guidance. The Committee referred to Art. 3 of the Doha Declaration, which strikes a balance between property rights and human health by recognizing the need for adequate intellectual property protection for the development of new medicines. However, it

[263] Christoffersen 2021. p. 28.
[264] Ibid. pp. 19-20.
[265] Committee on Economic Social and Cultural Rights. E/C.12/2001/15. p. 3 para 6.
[266] Ibid. p. 3 para 6.

also identifies the concerns of its effects on pharmaceutical prices.[267] The second relevant tool for interpreting the adequate level of balance is indeed the Doha Declaration, as well as Article 7 of the TRIPS Agreement itself.

The relation of intellectual property rights affecting the access to medicines established in paragraph 3 of the Doha Declaration offers a standing point for balancing property and health-related rights. Furthermore, Art. 7 of the TRIPS Agreement provides that the protection of IP rights should contribute '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'. When assessing the TRIPS Agreement in light of pandemics, no balancing of rights has been conducted since the TRIPS is not designed to respond to pandemics. The lack of this kind of assessment and discussion during the drafting of the Agreement is now reflected by the fact that timely access to vaccines could be more rapid without exclusive patent rights.

Currently, there are no functioning legal tools to counterbalance the negative effects of regular patent protection during pandemics. Moreover, paragraph 2 of the Doha Declaration suggests that not only should the regulation receive neutrality in the eyes of health considerations, but also 'be part of the wider national and international action to address these [health] problems'. The wording of Doha Declaration and Art. 7 of the TRIPS Agreement together suggest that the current TRIPS framework is not adequately balanced what comes to pandemics and the relation of the right to property and the right to health.

As a result, a new, more comprehensive and balanced legal framework should be adopted for pandemics. When assessing what should be considered when negotiating possible new solutions, one of the most significant issues to tackle is balancing state and private actor responsibilities. With responsibility also comes the ability to control the situation, which currently seems to reside more on the private actor side: private actors are responsible for providing the whole world with vaccines, and they are also granted all the rights to their inventions and their dissemination thereof. This kind of responsibility should lie on the shoulders of states, which at the moment seem more like instruments than players.

In this regard, the details to be taken into account would be first to assess how exclusively the private sector actors can exploit their inventions. As the technology transfer and dissemination

[267] Committee on Economic Social and Cultural Rights. E/C.12/2001/15. p. 3 para 6.

of know-how appear to be one of the most significant factors behind the timely access, it should be assessed whether there should be an obligation to contribute to the global manufacturing capacity upbuilding. That said, the suggestion is not to obligate private sector actors to give up on their market-driven principles, but there should be attempts to negotiate a completely new alternative to the patent regime what comes to pandemics. This alternative should ensure the economic incentives of private sector actors to still engage in R&D, however taking into account that the invention perhaps should not be exclusively managed by one actor in order to preserve the right to health.

It can be argued that there are also several factors affecting the timely and equal distribution of vaccines that are not related to private sector actors, and thus, private property rights should not be restricted. However, this argument fails to recognize the need for an overall approach, which requires also taking into account the private-sector-related considerations. Accordingly, the suggestion is not to establish a framework where no economic incentives are protected, but on the contrary, to negotiate an alternative where both financial incentives and human health are preserved. A good example of such an attempt would be COVAX (see section 3.2.2); however, the issues of COVAX are related to the fact that in the absence of any previously agreed, binding international response models to pandemics, the states cannot risk their status in the eyes of their own population, and are thus fiercely pursuing bilateral agreements at the expense of other states.

The resolution would be a mutually negotiated, clarified legal regime to be applied during pandemics. Furthermore, the framework should move responsibility from private sector actor to states and possibly, to the international field. This would enhance the political coherency during worldwide emergencies and thus enable private sector actors to function more efficiently in a more clear and economically predictable environment. Accordingly, protectionist measures by states could be decreased when the response would be more cooperative. Future responses should also take into account the need for more transparent processes regarding purchasing of vaccines and the fact that currently the negotiations are bilateral, causing evident competitive advantage to wealthy states. In this regard, also the R&D funding incentives of the states should be considered, as states are the most significant funders of vaccine R&D processes during pandemics.

5 CONCLUSIONS

The compulsory licencing system under the TRIPS Agreement does not adequately take into account the divergent circumstances prevailing during pandemics. The system has been drafted to be used in national emergencies, but not bearing in mind that the same emergency could concern the whole world simultaneously. The examination also revealed that the other relevant articles under the TRIPS Agreement fail to support the compulsory licencing system. As a result, compulsory licences might be meaningless for those states that would need them the most.

The research questions of this study were to examine the strengths and weaknesses of the compulsory licencing system in the context of the pandemic and further to assess whether the TRIPS Agreement as a whole responds to pandemic-specific issues related to timely access to vaccines. The factors behind timely access to vaccines during pandemics revealed to be the opposite of straightforward. Many of the reasons behind unequal timely access are a heritage of already existing issues, which only materialize during pandemics. However, some factors stood out from the mass: the most remarkable factor behind the unequal access relates to the concentration of manufacturing capacity to certain areas of the world. The manufacturing capacity-related issues, on the other hand, are further highlighted by exclusive patent protection, making the dissemination of technology and know-how dependent on the patent right holders.

The complex web of factors poses issues also to the use of compulsory licences. When assessing each feature of the system alone, some of the legislative choices seem justified. For example, the system offers interpretational flexibility in public health emergencies what comes to the remedy for the patent right holder. Accordingly, the system has the potential to serve as a post-pandemic tool if the rising vaccine prices must be controlled. Generic manufacturers have the possibility to obtain a compulsory licence if the post-pandemic prices for voluntary licences are too high, which in turn creates security during pandemics: manufacturers may have the courage to build up the manufacturing capacity as they will have an economically viable solution waiting also after the pandemic.

The system, however, seems to disregard the bigger picture. During a pandemic, the key is cooperation, information sharing, technology transfer and global support. The fact that pandemic-specific responses are left in the hands of one system, which is created to be used by individual (private) manufacturers only, is indefensible. Moreover, during pandemics, the

political uncertainty circulating patent-related rights create an unbearable situation for private sector actors, which on the other hand, are the ones that should be able to utilize the compulsory licencing system. From the perspective of an operational business environment, on which the distribution of vaccines is currently dependent, political predictability and unambiguousness around applicable legal tools are essential. Therefore, the TRIPS Waiver waiving all the rights and obligations, and which is still under negotiation by the time of finishing this study, does not seem to be a viable and sustainable solution for future pandemics either.

Further, as the number of pharmaceutical actors with adequate expertise is limited, the compulsory licencing system is practically meaningless due to the lack of potential users. Art. 39 TRIPS does not facilitate the situation, as it poses severe restrictions to the access of know-how. Art. 39 serves as a deterrent to capable voluntary licence holders to engage in any activity related to the transfer of technology or know-how, as it restricts the sharing of relevant information to third parties. Art. 39 provides the Member States with the possibility of being exempt from non-disclosure obligations under public health emergency, however, failing to assure the efficiency of this exception: the test and other data is required to be submitted for marketing approval only once, after which the approval can be applied for in other states without disclosing the relevant information. As a result, only a few developed states will gain access to crucial know-how, and the information is thus unlikely to be disclosed to the public.

The system's effectiveness is deprived by the fact that there are no obligations of global co-operation during worldwide emergencies whatsoever. The TRIPS Agreement is focused on protecting private rights, simultaneously trying to contribute to the dissemination of technology in the long term. The approach during pandemics should be the opposite: protecting global needs, focusing on disseminating technology and know-how as rapidly as possible. Unfortunately, the incentives necessary for the private sector have not been created, and the political atmosphere around patent rights has been casting its shadows above rapid responses.

The next step towards managing timely access to vaccines in the following emergencies would be to form an entirely different legislative framework. The approach must be changed, and the weaknesses and a few strengths of the current legislation should be kept in mind. When negotiating new solutions, important would be not to forget the market principles according to which essential private actors are operating. However, to be able to better respond to future pandemics, the manufacturing capacity issues related to the dissemination of technology and know-how must be taken seriously. In this context, it would be crucial to reflect the role of

patent protection and investigate whether the R&D incentives could be upheld by other means during worldwide emergencies.

That said, the process, of course, needs the support of all the Member States of the WTO. As the states also tend to be the most significant funders of pandemic-related vaccine development, the incentives for this funding must be balanced as well. However, there certainly is hope for a better future: if the states have been able to draft and accept the TRIPS Agreement, why not a pandemic response where everyone has the same goal – getting access to needed pharmaceuticals as soon as possible.