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„The WTO COVID-19 TRIPS waiver

An analysis of its role in the endeavour for equal access to COVID-19 vaccines“

verfasst von / submitted by

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List of abbreviations and acronyms

AB	Appellate Body
ACT-A	Access to COVID-19 tools Accelerator
COVAX	COVID-19 Vaccines Global Access
COVID-19	Coronavirus disease 2019
CoVDP	COVID-19 Vaccine Delivery Partnership
DC	Developing country
DG	Director-General (of the World Trade Organization)
DSB	Dispute Settlement Body
DSU	Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding)
EAC	East African Community
EU	European Union
GATT	General Agreement on Tariffs and Trade
IP	Intellectual property
IPR(s)	Intellectual property right(s)
LDC(s)	Least-developed country(s)
MC12	12th Ministerial Conference (of the World Trade Organization)
R&D	Research and development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom (of Great Britain and Northern Ireland)
US	United States (of America)
VJIL	Virginia Journal of International Law
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WTR	World Trade Review

1. Introduction

As for many other economic sectors, in the past decades medical technologies and the production of medical products have become an increasingly interconnected process. States can rarely rely exclusively on domestic production anymore but are dependent on well-functioning international supply chains for various precursors and components. For example, research and development activities might be taking place in a State where the scientific know-how and qualification of personnel is very high. Production facilities may be situated in another State, whereas a third State could be the centre of distribution and sales activities.

The trade-related dimension of these cross-border issues was recently demonstrated during the COVID-19 pandemic, that broke out in early 2020 and lead to a drastic increase in global demand for relevant medical supply and vaccines. Medical technology sectors were reminded of their reliance on a global infrastructure for trade in medical components and technologies as well as functioning production facilities abroad.

The WTO was quick on recognising these trade-related implications and took different measures aimed at alleviating the challenges for its Members in their fight against the COVID-19 pandemic.[1] A global effort for obtaining effective vaccination against the COVID-19 disease led to peaking research and testing activities in 2020. The developed countries of the global north headed this quest and their established and experienced vaccine developers, backed by governments and even military sectors,[2] were able to find promising vaccine candidates in less than one year after the outbreak of the pandemic.[3]

As production capacities were curbed up in order to supply the world with enough shots as fast as possible, before long an increasing inequality in the global distribution of the new vaccines became evident with populations of richer countries gaining better and faster access.[4] Consequently, a debate as old as the WTO's intellectual property ('IP') framework itself flared up again and it revolves around the question whether IP protection rules are *per se* an obstacle to equal access to medicines and treatment.[5] Critics of the international IPR rules argue that,

[1] See Ministerial Conference, 'Note by the Secretariat: WTO Secretariat's work in the context of the COVID-19 pandemic', WT/MIN(22)/34 (22 June 2022) 2.
[2] WIPO, *World Intellectual Property Report 2022: The Direction of Innovation* (2022) 62-63.
[3] Adam Mossoff and Amesh Adalja, 'Patents as a Driver of the Unprecedented Biomedical Response to COVID-19' (Policy Brief) [2022] INQUIRY: The Journal of Health Care Organization, Provision, and Financing <https://journals-sagepub-com.uaccess.univie.ac.at/doi/full/10.1177/00469580221124819> accessed on 3 December 2023.
[4] WHO, *Global vaccine market report 2022: a shared understanding for equitable access to vaccines* (2023) <www.who.int/publications/i/item/9789240062726> accessed on 3 December 2023.
[5] Bryan C Mercurio and Pratyush N Upreti, 'From Necessity to Flexibility: A Reflection on the Negotiations for a TRIPS Waiver for Covid-19 Vaccines and Treatments' [2022] WTR 633, 633.

besides a sharp increase in trade-restricting measures by WTO Members, especially the concentration of IP rights and production facilities with the big pharmaceutical companies in the developed countries is the main reason for the 'vaccine apartheid'[6]. In fact, most of the related patent applications were filed in the top 25 innovation economies, with 90% being first filed in the US or Europe.[7] In any case, vaccines were not only predominantly produced in Western developed countries but also seemed to remain there to be administered first to the domestic population. The EU, for example, notified the first export restrictions for vaccines produced within its territory in February 2021.[8]

Consequently, developing countries called for extraordinary trade liberalisation measures by the WTO to ensure a fairer global distribution of COVID-19-related medical supplies and vaccine shots. Along with a general revival of the debate about the field of tension between public health, human rights and the access to the medicines,[9] one proposal raised a lot of controversy within the WTO as well as the general public: a temporary waiver on the Members' obligations concerning the protection of intellectual property rights ('IPRs') under the Agreement on Trade-Related Aspects of Intellectual Property Rights ('TRIPS Agreement')[10].

In October 2020, shortly before the first COVID-19 vaccine was approved by health authorities in the US,[11] a proposal for an extensive waiver for the TRIPS obligations of the WTO Members was submitted. The measure was supported by low- and middle-income countries, spearheaded by India and South Africa and should become the subject to a lengthy controversy between the co-sponsors and their adversaries, especially the European Union, UK and Switzerland. By the time of the adoption of the waiver twenty months later, 78,2% of the population of high-income

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[6] Stéphane Paquin and Kristine Plouffe-Malette, 'The WTO and the Covid-19 "Vaccine apartheid": Big pharma and the minefield of patents' [2023] 1 Politics and Governance 261 <www.proquest.com/docview/2800736413?parentSessionId=7NxZ2yTRcrsJpGJdYNoqo1LhWwZ9BvaJO3S0hKU94bY%3D&pq-origsite=primo&accountid=14682> accessed on 3 December 2023.

[7] WTO, WIPO and WHO, *An Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic* (Second Update, May 2023), Extract from 'Promoting Access to Medical Technologies and Innovation' (Second Edition) 10-11.

[8] Committee on Market Access, 'Notification pursuant to the decision on notification procedures for quantitative restrictions (G/L/59/REV.1)', G/MA/QR/N/EU/5/Add.1 (5 February 2021); see also Caroline Glöckle, 'Exempting and Justifying Covid-19 Related Export Restrictions Under WTO Law' (2021) Legal issues of economic integration 201, 202.

[9] Isabel Feichtner, *The law and politics of WTO waivers: stability and flexibility in public international law* (CUP 2012) 126-27.

[10] Agreement on Trade-Related Aspects of Intellectual Property Rights, Annex 1C to the Marrakesh Agreement establishing the World Trade Organization (Marrakesh, 15 April 1994, entered into force on 1 January 1995) 1869 UNTS 299.

[11] Allison Inserro, 'FDA Advisory Panel Recommends Pfizer, BioNTech COVID-19 Vaccine', The American Journal of Managed Care (10 December 2020) <www.ajmc.com/view/fda-advisory-panel-recommends-pfizer-biontech-covid-19-vaccine> accessed on 3 December 2023.

countries had received at least one vaccine dose compared to 59.9% in lower-middle income countries and only 15.2% in low-income countries.[12]

While DC governments expected that a general waiver on their obligations to enforce IP rights would provide them and their population with better access to all relevant medical goods, WTO Members with respectable pharmaceutical industry sectors expressed doubt and refused to agree to the measure. Soon a debate erupted that should occupy the WTO, stakeholders and global public alike.[13] Not only did this controversy lead to a temporary deadlock of negotiations within the international organisation, but also to a significant delay of the adoption of the legal instrument as well as an outcome which expectedly had to consist in a compromise.

Because of the resistance of the opponents to the waiver, negotiations could be progressed successfully only in a (in terms of transparency not undisputed) small-group negotiation process of the main actors under the lead of DG Dr Ngozi Okonjo-Iweala.[14] Finally, a consensus was reached during the run-up to the twelfth Ministerial Conference on 17 June 2022 (the 'MC12') where the ministers of WTO Members adopted a decision containing a trimmed down version for a temporary TRIPS waiver.[15] However, almost immediately after the adoption discussions about its extension began but have not been concluded to this date.[16]

Since the proposal of the waiver, not only States were having a stand-off within the international organisation, but also an academic debate has erupted. While some authors advocated a quick adoption and watched the dragging negotiations with concern, others shared the opponents view that there was no necessity for a waiver and referred to the sufficiency of the existing flexibilities withing the legal regime of the TRIPS Agreement. Some deemed the waiving of IP rights even detrimental to the further development and improvement of COVID-19 vaccines and medication.

Against this backdrop, the present paper seeks to answer the question, in how far the COVID-19 TRIPS waiver provides additional legal flexibility to WTO Members regarding their

[12] Our World in Data, 'Share of people who received at least one dose of COVID-19 vaccine' (last updated 14 September 2023) <https://ourworldindata.org/grapher/share-people-vaccinated-covid?time=earliest..2022-06-17&country=High+income~Upper+middle+income~Lower+middle+income~Low+income> accessed on 3 December 2023.
[13] Ashutosh Pandey, 'India, South Africa bid to ban vaccine patents blocked' *Deutsche Welle* (2 April 2021) <www.dw.com/en/rich-countries-block-india-south-africas-bid-to-ban-covid-vaccine-patents/a-56460175> accessed on 3 December 2023.
[14] Ton Zuijdwijk, 'TRIPS and COVID-19 Vaccines: The New WTO TRIPS COVID-19 Waiver' (2022) 17 Global Trade and Customs Journal 452, 453.
[15] Ministerial Conference, 'Ministerial Decision on the TRIPS Agreement' (adopted on 17 June 2022) WT/MIN(22)/30 and WT/L/1141 (22 June 2022) ('TRIPS waiver').
[16] WTO, 'TRIPS Council welcomes MC12 TRIPS waiver decision, discusses possible extension', news item (6 July 2022) <www.wto.org/english/news_e/news22_e/trip_08jul22_e.htm> accessed on 3 December 2023.

obligations on patent rights under the TRIPS Agreement. In this context, it will be explored in how far the TRIPS waiver addressed the arguments brought forward by both sides during the negotiations.

Concerning the method used to answer these questions, a thorough analysis of the relevant legal framework of the TRIPS Agreement, of its built-in flexibilities and of the content of the waiver itself, is conducted. Additionally, the paper outlines the course of the WTO negotiations and reproduces the main arguments in the debate on the necessity of a waiver and contrasts them with the provisions of the waiver. The observations reflected in the present paper are to a large extent nourished by WTO documents available on the WTO Database such as notes, working documents, reports, minutes of meetings of WTO bodies and communications by WTO Members and organs. The discussion of the different arguments in favour and against the adoption of the waiver is based mainly on academic writings, studies, expert opinions and available international organisations' special reports on relevant topics. Lastly, any relevant 'case law' available, i.e. panel or AB reports that might offer valuable insight on certain aspects of the applicable provisions will be taken into consideration when discussing the respective aspects or legal questions.

The paper comprises of three main chapters. The first one outlines the fundamentals of the TRIPS Agreement, namely its structure, objectives and principles and the relevant provisions on IP protection (Articles 27 to 31bis TRIPS Agreement as well as the Annex to the TRIPS Agreement). It also contains an explanation of the concept of a waiver under the general WTO rules. Furthermore, the alternative means of technology transfer between Members and the existing (built-in) exceptions of the TRIPS Agreement will be discussed, considering the amendments giving effect to the Doha Declaration on TRIPS and Public Health 2001 ('Doha Declaration'). While predominantly being of a descriptive nature, this chapter also outlines the arguments of proponents as well as critics of the available flexibilities.

The next chapter focuses on the Ministerial Decision of 17 June 2022 ('2022 Ministerial Decision'). As will be seen, there is a difference between the Ministerial Decision and the TRIPS waiver it contains, thus it is useful to draw a distinction between the two. For this purpose, the most important steps in the negotiations on the Ministerial Decision will be traced back and the negotiating positions and proposals of the participating WTO Members reproduced. Then, scope, content and legal implications of the waiver will be scrutinised.

In the last main chapter, the legal implications of the waiver are discussed, taking into account the main arguments that have been brought forward in the discourse. The aim is to identify the

legal potential of the TRIPS waiver by analysing how it addresses the alleged insufficiencies of the TRIPS Agreement and its built-in flexibilities. Also, the different arguments in favour of and against the adoption of a TRIPS waiver will be contrasted against each other.

The analysis is concluded by a summary of the waiver's potential and the findings on its likely legal implications. Based on the preceding discussions of the different arguments and the thorough analysis of the waiver itself, it will be assessed whether the expectations of the proponents have been met. Lastly, a subjective judgement on the deficiencies that plague the current TRIPS flexibilities as well as the waiver's consequences in view of the WTO's role in future crises situations completes the analysis.

2. The fundamentals of the TRIPS Agreement

Like the majority of the WTO agreements, the TRIPS Agreement is a result of the Uruguay Round of Multilateral Trade Negotiations which took place between 1986 and 1994 and culminated in the signing of the Final Act[17] at the Marrakesh Ministerial Meeting on 15 April 1994. Consequently, the TRIPS Agreement was attached as Annex 1C to the Agreement Establishing the World Trade Organization ('WTO Agreement')[18] and has since become an integral part of the WTO Agreement and binding on all Members.[19]

With the TRIPS Agreement, a comprehensive regime for the protection of IP rights was introduced into the multilateral trading system for the first time. Before that, IP was covered by the fundamental principles of the General Agreement on Tariffs and Trade 1947 ('GATT 1947') like the non-discrimination rule in Article III:4, even though the GATT 1947 did not explicitly mention IP.[20] As part of the more extensive General Agreement on Tariffs and Trade 1994 ('GATT 1994'),[21] these general principles continue to apply.[22] However, as IP rights were among the areas that became increasingly important and were not sufficiently covered by the general rules on trade in goods, the TRIPS Agreement was designed in an attempt to 'narrow the gaps in the way these rights are protected and enforced around the world'.[23]

The administration of the Agreement and the Members' adherence of their obligations thereunder are the responsibility of the Council for Trade-Related Aspects of Intellectual Property Rights ('Council for TRIPS').[24] It is one of the three sectoral Councils operating under the General Council and annually reports to the General Council its findings on the functioning of the TRIPS system.[25] With regard to the treatment of disputes arising under the TRIPS Agreement, these should primarily be settled by amicable means between the parties.[26] In case no amicable solution can be found, the procedure before the Dispute Settlement Body ('DSB')

[17] Final Act embodying the Results of the Uruguay Round of Multilateral Trade Negotiations (Marrakesh, 15 April 1994) 1867 UNTS 14.
[18] Marrakesh Agreement establishing the World Trade Organization (Marrakesh, 15 April 1994, entered into force on 1 January 1995) 1867 UNTS 154 ('WTO Agreement').
[19] WTO Agreement, art II:2.
[20] General Agreement on Tariffs and Trade (Geneva, 30 October 1947, provisionally entered into force 1 January 1948) 55 UNTS 194 (GATT 1947); Hannu Wager, Jayashree Watal and Antony Taubman, *A Handbook on the WTO TRIPS Agreement* (CUP 2020) 5.
[21] General Agreement on Tariffs and Trade, Annex 1A to the Marrakesh Agreement establishing the World Trade Organization (Marrakesh, 15 April 1994, entered into force on 1 January 1995) 1867 UNTS 190 (GATT 1994).
[22] See TRIPS Agreement, Preamble, lit (a).
[23] See WTO, 'Intellectual property: protection and enforcement' <www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm> accessed on 3 December 2023.
[24] TRIPS Agreement, art 68.
[25] Annex to the TRIPS Agreement, para 7; Wager, Watal and Taubman (n 20) 10.
[26] See TRIPS Agreement, art 64.1 in conjunction with GATT 1994, arts XXII and XXIII.

under the procedures prescribed by the Dispute Settlement Understanding ('DSU') stands available to provide a binding decision in the matter.[27]

2.1. The objectives of the TRIPS Agreement

The objectives of the TRIPS Agreement are enshrined in its Preamble and in Article 7. Therefore, these parts should always be read in conjunction.[28] According to the Preamble, the Members wanted to promote the protection of IP rights whilst ensuring that enforcement measures themselves would not become barriers to trade. This twin-objective must be seen in the light of the WTO's principal objective of establishing mutually advantageous, non-discriminatory and wealth-fostering trade arrangements, as stipulated in the WTO Agreement.[29] Furthermore, Article 7 explains the prospects of the protection of IP to the promotion of technological innovation as well as the dissemination of technology in a manner beneficial to producers and users alike, and conducive to social and economic welfare.[30]

In this context, it is also noteworthy that Article 8, titled 'Principles', recognises that there are certain fundamental interests of the Members that may be taken into account when implementing their obligations under the TRIPS Agreement. For example, they may adopt measures necessary to protect public health and nutrition, as long as they are consistent with the provisions of the TRIPS Agreement.

While Article 8 should not, by itself, be read as an exception to the obligations of the Members under the TRIPS Agreement, it expresses a principle that should be taken into account when interpreting and applying the other provisions of the treaty.[31] Accordingly, in *Canada – Pharmaceutical Patents* the panel shared Canada's opinion that Articles 7 and 8 'must obviously be borne in mind when [the conditions of Article 30] as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes [are examined]'.[32]

[27] Understanding on Rules and Procedures Governing the Settlement of Disputes, Annex 2 to the Marrakesh Agreement establishing the World Trade Organization (Marrakesh, 15 April 1994, entered into force on 1 January 1995) 1869 U.N.T.S. 401, art 1.1 in conjunction with Appendix, lit (B).
[28] Wager, Watal and Taubman (n 20) 14.
[29] WTO Agreement, Preamble.
[30] TRIPS Agreement, art 7.
[31] Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization: Text, Cases, and Materials* (5th edn, CUP 2022) 1085.
[32] *Canada – Patent Protection of Pharmaceutical Products—Report of the panel* (17 March 2000) WT/DS114/R [7.26].

2.2. The structure of the TRIPS Agreement

Advancing to the substantial provisions of the TRIPS Agreement, it can be noted that Part II covers the minimum standards that Members must ensure concerning availability, scope and use of the different types of IP rights. The provisions on patents can be found in Section 5 of Part II and cover the Articles 27 to 34. In view of the discussion of the waiver and its role in the distribution of patented COVID-19 vaccines, these provisions are clearly the most relevant. The main features covered in Section 5 are: the subject matter that is protected (Article 27), the rights to be conferred on the patent holders (Article 28), permissible exceptions (Article 30) and the minimum term of protection (Article 33). Except for the permissible exceptions, which will be addressed in Chapter 2.4.2, these features will be discussed briefly below.

2.2.1. The patentable subject matter

According to Article 27.1 TRIPS Agreement, any invention that involves an inventive step and can have an industrial application is eligible for a patent, regardless of the field of technology.[33] The term 'invention' is not defined in the TRIPS Agreement. In 1979 the WIPO published a model law for DCs on inventions, where it provided the following definition: An invention 'means an idea of an inventor which permits in practice the solution to a specific problem in the field of technology'.[34] Today, the organisation puts it in simpler words and describes an invention as 'a new solution to a technical problem'.[35]

For the terms 'inventive step' and 'capable of industrial application', however, the legal text itself suggests the synonyms 'non-obvious' respectively 'useful'.[36]

Members may exclude some inventions from patentability if it is necessary to prevent their commercial exploitation in order to protect certain values such as human life and health,[37] with diagnostic, therapeutical and surgical methods for the treatment of humans or animals explicitly mentioned.[38] This permissible exclusion from patentability is generally understood to apply to the method of treatment, such as an innovative way of performing a surgery.[39]

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[33] TRIPS Agreement, art 27.1.
[34] WIPO, 'Model Law for developing countries on inventions: Vol. I' (WIPO Publication No. 840 (E), 1979) <https://tind.wipo.int/record/28754> accessed on 3 December 2023> s 112(1).
[35] WIPO, 'Innovation and Intellectual Property' 105 <www.wipo.int/ip-outreach/en/ipday/2017/innovation_and_intellectual_property.html> accessed on 3 December 2023; Wager, Watal and Taubman (n 20).
[36] TRIPS Agreement, art 27.1. in conjunction with fn 5.
[37] TRIPS Agreement, art 27.2.
[38] TRIPS Agreement, art 27.3(a).
[39] WTO, 'Guide to the TRIPS Agreement', Module V, 96 <www.wto.org/english/tratop_e/trips_e/ta_modules_e.htm> accessed on 3 December 2023.

2.2.2. The rights conferred on the patent holder

If certain substantive and formal conditions are fulfilled,[40] an investor can apply for a patent and, according to the TRIPS Agreement, thereby acquire a set of exclusive rights. If the invention is a product, the patent should prevent any other party from making, using, selling (and offering for sale), or importing for these purposes that product without the patent owner's consent.[41] Where the invention consists in a process, a third party must not be allowed without the patent owner's consent to use this process or use, sell (or offer for sale), or import for these purposes the product that is directly obtained by this process.[42] If an invention is not patented in a country, any manufacturer can freely use or produce and market it within this country.[43]

The patent owner may always assign or transfer the right to use the invention to others – be it by succession or contract.[44] Of course, these rights and obligations also apply to medical products and health technology processes, such as COVID-19 treatments and vaccines as well as their industrial production procedures.[45]

In addition to a general non-discrimination clause,[46] the TRIPS Agreement contains a prohibition of discrimination especially for the treatment of patents. Article 27.1 provides that patents shall be made available and patent rights enjoyable without discrimination based on where the invention has been made, what the field of technology is and, in case of a product, whether it has been imported or locally produced.

2.2.3. Term of protection and exhaustion of rights

Article 33 of the TRIPS Agreement stipulates that the protection period of a patent shall last no less than 20 years from the filing date of the patent application. The period may, of course, be longer and extendable. Even the requirement to pay fees to uphold the protection period is admissible.[47]

A special problem in connection with the termination of the exclusive rights of the patent holder is the issue of 'exhaustion'. This term connotes the generally accepted principle in IP law that

[40] TRIPS Agreement, art 29; Wager, Watal and Taubman (n 20) 108.
[41] TRIPS Agreement, art 28.1(a).
[42] TRIPS Agreement, art 28.1(b).
[43] Bryan C. Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review' (2021) 62 VJIL Online 9, 20.
[44] TRIPS Agreement, art 28.2.
[45] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 11.
[46] TRIPS Agreement, art 4.
[47] See Wager, Watal and Taubman (n 20) 124.

the patent holder's exclusive right to sell and import the product lapses once it has been put on the market. This principle is being applied by many countries.[48] However, the question arises whether these exclusive rights are exhausted only when the product is placed on the domestic market (national exhaustion) or if it suffices that they enter the market of another State (international exhaustion). The question can also be put in simpler words: If a State applies the principle of exhaustion in its IP laws, are the patent holder's exclusive distribution rights in this State exhausted the moment the product is legally distributed in any other State? This problem was debated during the Uruguay Round negotiations and the solution can now be found in Article 6 TRIPS Agreement, which generously provides that Members have almost complete freedom to establish their own rules on exhaustion, only being subject to the non-discrimination rules of the Articles 3 and 4 TRIPS Agreement.[49]

As a practical consequence, it depends on a State's exhaustion regime whether it allows for parallel importation or not. Parallel importation is the importation and domestic sale of a product that is protected by a patent without authorisation of the patent holder, provided that this product was placed on the market of the exporting State by the patent holder or with their consent.[50] Thus, parallel importation is a relevant practice of States which do not have sufficient manufacturing capacities to acquire needed medicines.

2.3. The concept of waivers under the Marrakesh Agreement

As mentioned above, Members of the WTO are legally bound to comply with the rules of the Marrakesh Agreement as well as the Multilateral Trade Agreements annexed to it.[51] In practical terms, this means that Members must ensure that their national laws, regulations and administrative procedures are in conformity with their obligations under the agreements.[52]

However, situations may arise in which a Member may be facing difficulties to meet these obligations. In such a case, the Member can request the WTO to waive a specific obligation under the Marrakesh Agreement or one of the Multilateral Trade Agreements. Such a request will (eventually) be considered by the Ministerial Conference (or, on its behalf, the General Council). But a request for a waiver concerning an obligation under a Multilateral Trade Agreement has first to be submitted to the Council responsible for the administration of the

[48] See Wager, Watal and Taubman (n 20) 20.
[49] See TRIPS Agreement, art 6; Wager, Watal and Taubman (n 20) 21.
[50] Van den Bossche and Zdouc (n 31) 1100.
[51] WTO Agreement, art II:2.
[52] WTO Agreement, art XVI:4; Van den Bossche and Zdouc (n 31) 134.

Agreement concerned.[53] The Council – in the case of the TRIPS Agreement it is the Council for TRIPS – will consider the request within a period of 90 days and submit a report to the Ministerial Conference.[54]

A waiver can only be granted in exceptional circumstances and the Ministerial Conference must state these circumstances, the terms and conditions governing the application of the waiver and the date on which the waiver shall terminate in its decision. While the Ministerial Conference could adopt a waiver by a three-fourth majority of its Members,[55] the WTO customarily decides by consensus and has never abandoned this practice so far.[56]

If the waiver is granted for a period of more than one year, the Ministerial Conference must annually review whether the exceptional circumstances still exist, and the terms and conditions of the waiver have been met. It has been noted though that, in the recent past, these reviews have not amounted to more than a mere formality.[57] In any case, the Ministerial Conference can then decide to extend, modify or terminate the waiver.[58]

While a waiver can temporarily release a Member from its obligations under the WTO rules, its national legal IP legislation must also be adjusted in order to give effect to the waiver, at least if the Member represents the dualist tradition. Therefore, if TRIPS obligations are to be waived, it would be up to States to implement any measure promoting technology transfer.[59]

2.4. Technology transfer under the TRIPS regime

Under the TRIPS Agreement, the relationship between technology transfer and the protection of IP can be imagined double-stranded. The availability of technology for private actors is one issue, the dissemination of technology between States, from developed-country Members to DC Members specifically, another. These two strands will be illuminated in this chapter.

At first glance, it may seem as if the rules of the TRIPS Agreement preclude any transfer of technology between private actors once an invention has been patented. As IP rights are private rights,[60] one of the purposes of granting an inventor the benefits of a patent is indeed to create

[53] WTO Agreement, art IX:3(b); Feichtner (n 9) 61.
[54] WTO Agreement, art IX:3(b).
[55] WTO Agreement, art IX:3.
[56] Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 636 fn 30.
[57] Feichtner (n 9) 62.
[58] WTO Agreement, arts IX:4, IX:3.
[59] Gabrielle Marceau and Shivani Garg, 'The role of the WTO in the global response to the Covid-19 pandemic' [2021] International Organizations Law Review 335, 365-66.
[60] See WTO Agreement, Preamble.

an incentive for investments into research and development ('R&D'), thus promoting new inventions and technological progress.

But the promotion of R&D investment is not the only perk of the patent system. The IP protection rules of the TRIPS Agreement also state that Members need to require patent applicants to disclose information 'sufficiently clear and complete for the invention to be carried out by a person skilled in the art',[61] thereby enabling others to build on its technology to produce their own innovations. Hence, it can be noted that, besides the protection of the interests of the inventor, the disclosure, transfer and dissemination of technology for the benefit of society is also an inherent function of the patent system.[62] The IPR system tries to strike a balance between these two interests.

The use of synthetic mRNA, now highly acclaimed as the biotechnological basis for the development of the most effective COVID-19 vaccines, serves as a good example for both perspectives. On the one hand, it has been known and used for at least a decade before the COVID-19 pandemic, consequently, researchers could immediately focus their efforts to develop vaccine candidates based on this technology. Therefore, the patent-related disclosure of its functioning has helped immensely with the rapid development of the new vaccines.[63] Since the EU- or US-based pharmaceutical companies had to disclose their innovations on how they use mRNA technology for vaccine development, many other companies around the world, including developing countries, built on their ideas and began to use modified technologies to produce similarly promising COVID-19 vaccines,[64] thus proving that there is an inherent technology transfer effect within the patent system.

On the other hand, critics argued that the incentive for companies is sometimes based on the prospect that a patent will grant them a temporary monopoly on the use of the invention, thus allowing for determination of prices free from competitive pressure, and control of market access and productions.[65] While this cannot be denied, it is also true, that many groundbreaking inventions – and again, here the mRNA technology serves as a good example – were achieved

[61] TRIPS Agreement, art 29.1; Van den Bossche and Zdouc (n 31) 1128.
[62] Wager, Watal and Taubman (n 20) 106ff; WTO, WHO and WIPO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health*, *Intellectual Property and Trade* (2nd edn, 2020) 66.
[63] WIPO, *World Intellectual Property Report 2022* (n 2) 64.
[64] John Cohen, 'New Crop of Covid-19 mRNA vaccines could be easier to store, cheaper to use' [2022] Science 120-121.
[65] See, e.g. Sanath Wijesinghe, Chaminya Adikari and Ruwanthika Ariyaratna, 'The proposal for waiver of WTO's TRIPS Agreement to prevent, contain and treat COVID-19: investigating the benefits and challenges for low- and middle-income countries' [2022] 2 Journal of Intellectual Property Law & Practice 179, 180.

only after significant human and financial investment into R&D. And it must be acknowledged that it is more likely such investments will be made when there is a prospect of IP protection.[66]

Regarding the second strand, the TRIPS Agreement obliges developed-country Members to provide incentives to enterprises and institutions in their territory to promote technology transfer to LDC Members.[67] As instructed by the Ministerial Conference during the Doha Round,[68] the Council for TRIPS in 2001 adopted a decision introducing a new monitoring system for this obligation.[69] Developed-country Members have to submit annual reports on their actions taken or planned in order to comply with their commitment to technology transfer which are then discussed in the TRIPS Council, giving Members the opportunity to pose questions, request additional information and discuss the effectiveness of these actions.[70]

2.4.1. Voluntary licencing agreements

In terms of voluntary technology transfer, licence agreements are the most frequently used tool to transfer IP rights from the rights holder to a third party. In a standard licencing model, the licensor contractually authorises the third party, e.g. a company with production facilities, to use the invention whilst receiving a royalty fee in return.[71]

To highlight the role that voluntary licences have played in the negotiations on the TRIPS waiver, the criticism of the waiver's proponents, represented by India and South Africa, and the counterarguments by the opposition shall be briefly reproduced.

Concerning the current voluntary licencing practices of multilateral pharmaceutical companies, the proponents of the waiver have criticised that patent holding companies were choosing their contracting partners in a selective and exclusive manner and their licences were often restrictive and non-transparent.[72] In that sense, they argued that voluntary licences were usually confidential and lacking transparency while, at the same time, being too restrictive by limiting their scope to only certain geographic regions, thereby excluding many DCs, especially most

[66] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 17.
[67] TRIPS Agreement, art 67.2.
[68] Ministerial Conference, 'Implementation-Related Issues and Concerns', Decision of 14 November 2001, WT/MIN(01)/17 (20 November 2001) [11.2].
[69] Council for TRIPS, 'Implementation of Article 66.2 of the TRIPS Agreement', Decision of the Council for TRIPS of 19 February 2003, IP/C/28 (20 February 2003).
[70] ibid, para 2.
[71] Jhon Carmona and Edward Harris, 'Improving access to COVID-19 treatments: how IP makes it possible', [2021] 4 WIPO Magazine 10, 12.
[72] Council for TRIPS, 'Response to Questions on Intellectual-Property Challenges experienced by Members in Relation to COVID-19 in Document IP/C/W/671', Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/673 (15 January 2021) ('Response to Questions') paras 17-20.

South American countries.[73] This alleged 'pickiness' of licensors also includes detailed contract terms on sources and production of active pharmaceutical ingredients for the generic medicines.[74]

Other critics of the current practice of voluntary technology transfer have even suggested that multinational pharmaceutical corporations have strategically used voluntary licences to divide and control markets, to polish their image or dissuade governments from resorting to compulsory licences.[75]

Consequently, critics argue that *de-facto* voluntary licencing represents an obstacle to equal access to health and cannot be relied upon for maximising global vaccine production.

The defence of the opponents of the waiver was based on the notion that the TRIPS IP regime in itself was not a barrier to scaling up the global production capacities and distribution of COVID-19 vaccines and that, in any case, a combination of voluntary and compulsory licencing is an adequate tool to address any concerns and shortcomings.

To underpin their position, they referred to the historically continuously increasing access to medicines and defended their coverage as being sufficient. In comparison to compulsory licences, which adhere to a country-by-country approach, especially the benefit of being able to cover many countries with one voluntary licence was highlighted.[76]

On the same note, it was pointed out that the compulsory licencing system might have beneficial effects on voluntary technology transfer: If a State announces its intent to grant a compulsory licence to a third party, the patent holder is encouraged to step into a licencing agreement with domestic producers, because only then can he participate in the determination of its terms.[77]

If, on the other hand, a compulsory licence is actually used for importation or domestic production of a pharmaceutical product, the State might be confronted with the issue of ensuring safety and efficacy of the product, implying its responsibility to put in place the legislation, infrastructure and enforcement for this task. This might be a huge burden for countries with

[73] ibid, paras 7(2), 17; see also Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 10-11 March 2021', IP/C/M/98/Add.1 (30 July 2021) paras 231, 280-82.
[74] Council for TRIPS, 'Minutes of Meeting (n 73) para 282.
[75] Anand Grover, 'India: Pharmaceutical Patents and Evergreen Battle for Access to Medicines', in Srividhya Ragavan and Amaka Vanni (eds), *Intellectual Property Law and Access to Medicines: TRIPS Agreement, Health, and Pharmaceuticals* (Law, Development and Globalization Series, Routledge/Taylor and Francis 2021) 231.
[76] ibid 232.
[77] Paquin and Plouffe-Malette (n 6) 268.

little resources and capacities. For example, in 2018 the East African Community ('EAC')[78] acknowledged that the surveillance and testing systems for substandard and falsified medical and health technologies in the East African region was in a poor state.[79] Hence, the combination of IP protection and voluntary technology transfer plays a crucial role in ensuring the safety of medical products, especially vaccines.[80]

Additionally, in defence of the positive impact of voluntary licencing agreements, a number of incidents have been brought up where pharmaceutical companies have enabled producers in DC Members to manufacture COVID-19 medicines and vaccines.[81] Instead of a defective IPR regime, it was claimed that problems along the supply chains, limited manufacturing capacities and demand shocks were the real reasons hampering access to vaccines.[82]

In other words, proponents of voluntary licencing have disputed that the current practice poses a barrier to equal access to medicines and have instead highlighted their positive effects not only on the proliferation of knowledge but also on the scaling-up of manufacturing safe medicines and vaccines. Thus, they argued that a waiver was not necessary to ensure equal access to COVID-19 medicines and vaccines.[83]

However, there are other ways for third parties to benefit from the inventions of others despite their patent status. The different forms of these *built-in* exceptions to the exclusive rights that the patent protection purports according to Article 28 of the TRIPS Agreement shall be discussed below.

2.4.2. Limited exceptions to patent rights (Article 30)

One way of allowing technology transfer under the patent protection regime is provided by Article 30 of the TRIPS Agreement. It stipulates that Members may provide 'limited exceptions' to the exclusive rights conferred by a patent if they do not 'unreasonably conflict

[78] The EAC is a regional intergovernmental organisation that today comprises of seven States, namely the Democratic Republic of the Congo, Burundi, Kenya, Rwanda, South Sudan, Uganda and the United Republic of Tanzania, all of which are LDCs except for Kenya.
[79] EAC, 'East African Community Medicines and Health Technologies Strategic Plan (2018-2022)' (February 2018) 18, available at <www.eac.int/documents> accessed on 3 December 2023.
[80] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments (n 43) 28.
[81] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments (n 43) 21.
[82] Jillian Kohler, Anna Wong and Lauren Tailor, 'Improving Access to COVID-19 Vaccines: An Analysis of TRIPS Waiver Discourse among WTO Members, Civil Society Organizations, and Pharmaceutical Industry Stakeholders' [2022] 24(2) Health and Human Rights 159, 164 <www-jstor-org.uaccess.univie.ac.at/stable/48718218> accessed on 3 December 2023.
[83] See also Wijesinghe, Adikari and Ariyaratna (n 65) 184-85.

with a normal exploitation' of the patent nor 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'.

Due to the rather vague language of this provision, the conditions under which Members can make use of this exception are hardly self-explanatory. In practice, a 'three-step test' has emerged that requires the individual examination but also cumulative presence of all three elements.[84] The cases in which the DSB had to deal with Article 30 of the TRIPS Agreement are scarce. However, in *Canada – Pharmaceutical Patents* the panel concerned itself with all three elements required by this exception and provided some clarification of their meaning.

In this case Canada was allowing for a practice known as the 'Bolar' exemption, whereby patented pharmaceuticals are being produced by third parties during the term of protection solely for the purpose of obtaining regulatory approval of their own generics as soon as the term of protection ends. [85] The panel ruled that the Canadian legislation was covered by Article 30 TRIPS Agreement, as it was a limited exception that still allowed for a normal exploitation of the patent without prejudice to the legitimate interests of the patent owner.[86] In contrast, regarding the production and 'stockpiling' of such generics during the final six months of the protection term, the panel missed any limitation to this authorisation by the Canadian law in relation to the patent owner's exclusive right to manufacture for commercial sale of the patented product.[87]

The panel explained that the first condition of Article 30, namely that the exception be 'limited', means that the exception must make 'only a narrow curtailment of the legal rights which Article 28.1 requires to be granted to patent owners'.[88] (see 2.2.2).

As for the second condition, which requires that the exception does not unreasonably conflict with a 'normal exploitation' of the patent, the panel in *Canada – Pharmaceutical Patents* found that 'exploitation' means the 'commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent'. For the determination of the word 'normal' it relied on the dictionary definition.[89] Combining these two elements, the panel concluded that the normal practice of exploitation by patent owners is to 'exclude all forms of competition that could detract significantly from the economic returns anticipated form

[84] Wager, Watal and Taubman (n 20) 118.
[85] ibid 118.
[86] *Canada – Pharmaceutical Patents* (n 32) [7.50], [7.59], [7.83]-[7.84].
[87] ibid [7.36].
[88] ibid [7.44].
[89] ibid [7.54].

a patent's grant of market exclusivity'.[90] As it did not find that preventing submissions for regulatory authorisation could be seen as such an anticipated economic return of market exclusivity, it did not consider the regulatory review exception to conflict with a normal exploitation of a patent.[91]

Lastly, the panel sought to answer the question what 'legitimate interests' means, as Article 30 also requires that a possible exception needs to strike a balance between the legitimate interests of the patent owner on the one hand, and the legitimate interests of third parties on the other.

Research exceptions are a very common way to make use of the exception under Article 30. They allow examination and/or use of the invention for scientific purposes, without infringement of the patent. While a majority of WTO Members provides for research exceptions in their domestic legislation, their extent differs, and some Members only allow for use with non-commercial intent.[92]

2.4.3. Compulsory licensing (Article 31)

Article 31 of the TRIPS Agreement covers a form of governmental interference with the rights of patent owners that is known as 'compulsory licencing'. It is titled 'Other Use Without Authorization of the Right Holder' implying that it deals with additional cases than those already envisaged by Article 30.[93] It is designed to allow for governments to authorise, in a situation where they find it necessary to do so, the use of a patented invention without the right holder's permission. It expressly allows for authorisation of use for the government itself or for a third party.[94]

In contrast to Article 30, Article 31 contains a catalogue of requirements that a lawful 'compulsory licence' needs to fulfil. In the present context the most important condition actually represents an exception from a general rule. Principally, before an authorisation can be granted by a government, the proposed user must have tried first to directly obtain, on reasonable commercial terms and conditions, authorisation from the patent owner. Only if this attempt has not been successful within a reasonable period of time a compulsory licence can be issued by the government. However, a Member can waive this requirement in the case of a national emergency or other circumstances of extreme urgency or where it intends to non-commercially use the invention. In these cases, it suffices that, after the authorisation, the patent

[90] ibid [7.55].
[91] ibid [7.59]; Van den Bossche and Zdouc (n 31) 1130.
[92] WTO, WHO and WIPO, *Promoting Access to Medical Technologies and Innovation* (n 62) 176.
[93] See TRIPS Agreement, art 31, fn 7.
[94] Wager, Watal and Taubman (n 20) 121.

holder is informed of this authorisation.[95] In a public health crisis, such as the COVID-19 pandemic, the issuance of a compulsory licence could be qualified as a measure to ensure affordable access to critical medicines.[96] This has been confirmed by the Ministerial Conference, as will be discussed later.

Every compulsory licence must limit scope and duration of the use of the relevant invention to the specific purpose for which it is authorised.[97] For example, the use of a certain pharmaceutical technology, necessary to produce a specific drug, could be limited to the production of a fixed amount of that drug within one year. Also, the licence must only authorise the use of the invention to the extent necessary to achieve this purpose but nothing beyond it.[98] Article 31 TRIPS Agreement further provides that Members should put in place regulations so that the compulsory licence is terminated when the circumstances no longer justify its existence.[99]

Furthermore, the authorised use must be non-exclusive and non-assignable, so that the patent-holder can continue to produce whilst the holder of the compulsory licence cannot pass on the licence to others.[100] Every application for authorisation must be considered on its individual merits and the governments cannot issue compulsory licences for whole economic sectors.[101] And finally, of course the patent holder must be compensated for the interference with his normally exclusive right to use the invention. It must be ensured that he is paid adequate remuneration, taking into account the economic value of the licence.[102]

One more condition which has led to significant debate especially in the context of the production of pharmaceuticals is that the authorisation must be granted predominantly for the supply of the domestic market of the respective Member.[103] Therefore, the export of obtained products must be of subordinate significance in relation to the quantity placed on the domestic market. This restriction turned out to be of great concern to DC Members and consequently was addressed during the earlier years of the Doha Negotiation Round. The solution that was negotiated will be discussed in the following chapters.

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[95] TRIPS Agreement, art 31(b).
[96] Van den Bossche and Zdouc (n 31) 1132.
[97] TRIPS Agreement, art 31(c).
[98] Wager, Watal and Taubman (n 20) 122.
[99] TRIPS Agreement, art 31(g).
[100] TRIPS Agreement, art 31(d) and (e); WTO, 'Compulsory licensing of pharmaceuticals and TRIPS', TRIPS and Health: Frequently asked Questions <www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed on 3 December 2023.
[101] TRIPS Agreement, art 31(a); Wager, Watal and Taubman (n 20) 122.
[102] TRIPS Agreement, art 31(h).
[103] TRIPS Agreement, art 31(f).

2.4.4. The 2001 Doha Declaration on the TRIPS Agreement and Public Health

In 2001, the Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health ('Doha Declaration'),[104] addressing growing concerns of some WTO Members, especially DCs and LDCs, regarding the interpretation of the patent rules of the TRIPS Agreement and Members' leeway to respond to contemporary threats to public health.[105] Accordingly, in the Doha Declaration the Ministerial Conference acknowledged the challenges that pandemics such as HIV/AIDS, tuberculosis or malaria posed to the public health systems of these Members and confirmed the WTO Members' right to protect public health and promote access to medicines for all,[106] whereas the protection of IP rights as a driver for the development of new medicines is mentioned only in terms of its criticised effects on the price-making of medicines.[107]

Most importantly, the Doha Declaration specifically sought to address the concrete concerns of the DC and LDC Members by clarifying that the TRIPS Agreement should not prevent Members from taking measures necessary to protect public health but should rather be interpreted in a way supportive of such efforts.[108] As the panel in *Australia – Tobacco Plain Packaging* noted,[109] this is emphasised by a reference to the customary rules of interpretation as codified in the Vienna Convention on the Law of Treaties ('Vienna Convention')[110] which requires that each provision of a treaty shall be read in the light of object and purpose of the treaty.[111] Accordingly, the Doha Declaration is to be read as indirectly referring to Articles 7 (titled 'Objectives') and 8 (titled 'Principles') of the TRIPS Agreement, the latter expressly mentioning that Members may 'adopt measures necessary to protect public health …, provided that such measures are consistent with the provisions of [the TRIPS Agreement]'.[112] Moreover, the panel in *Australia – Tobacco Plain Packaging* was of the view that the relevant paragraph of the Doha Declaration constitutes a subsequent agreement among the WTO Members to

[104] Ministerial Conference, 'Declaration on the TRIPS Agreement and Public Health' (adopted on 14 November 2001) WT/MIN(01)/DEC/2 (20 November 2001) ('Doha Declaration').
[105] Wager, Watal and Taubman (n 20) 199-200.
[106] Doha Declaration, paras 1, 4.
[107] ibid, para 3.
[108] ibid, para 4; Wager, Watal and Taubman (n 20) 200.
[109] *Australia – Tobacco Plain Packaging—Reports of the panels* (28 June 2018) WT/DS435/R, WT/DS441/R WT/DS458/R and WT/DS467/R [7.2588].
[110] Vienna Convention on the Law of Treaties (Vienna, 23 May 1969, entered into force on 27 January 1980) 1155 UNTS 331, Art 31(1) ('Vienna Convention').
[111] Doha Declaration, para 5(a); Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments (n 43) 23.
[112] TRIPS Agreement, art 8.1.

interpret each provision of the TRIPS Agreement in the light of its Articles 7 and 8.[113] In other words, to a certain extent the Doha Declaration could even be binding on the Members.

Even though the Doha Declaration, by and large, reaffirms the sufficiency of the existing flexibilities of the TRIPS Agreement for the protection of public health, and the option to grant compulsory licences in particular, it also emphasises that the grounds upon which such licences may be granted, as well as the decision of what constitutes a national emergency or other circumstances of extreme urgency in the sense of Article 31 (see 2.4.3), is at the discretion of each Member.[114]

The TRIPS Agreement granted original WTO Members transition periods to bring their legislation into compliance with the WTO rules, differing according to their stage of development.[115] The Doha Declaration reproduces the Members' agreement to extend the transitional period for LDC Members to implement, with respect to pharmaceutical products, the TRIPS rules on patents and the protection of undisclosed information.[116]

Lastly, by reference to Article 66.2 of the TRIPS Agreement, the Doha Declaration concludes with a reaffirmation of the developed-country Members' commitment to promote technology transfer to LDCs by providing appropriate incentives to their enterprises and institutions.[117]

To summarise the political relevance of the Doha Declaration, it can be noted that it incorporates the Ministerial Conference's effort to assure a concerned group of WTO Members that they need not fear to declare their public health problems a national emergency (or other circumstances of extreme urgency) in order to put themselves in a position to lawfully grant compulsory licences without having to seek prior authorisation of the patent holders.

However, the Doha Declaration also addressed a more concrete deficiency of the TRIPS Agreement. Firstly, as explained above, Article 31(f) generally restricts the issuance of compulsory licences to the purpose of supplying the domestic market with the patented product, thus making it difficult for Members with insufficient or no capacities to manufacture the product to make effective use of this exception. This is extremely relevant in the context of the production of vaccines because the production process of vaccines is not a trivial process and only few States have the capacities to produce COVID-19 vaccines, most of them being

[113] In the sense of the Vienna Convention, art 31(3)(a); *Australia – Tobacco Plain Packaging—Reports of the panels* (28 June 2018) WT/DS435/R, WT/DS441/R, WT/DS458/R and WT/DS467/R [7.2409]-[7.2410]; Wager, Watal and Taubman (n 20) 201; Van den Bossche and Zdouc (n 31) 1086.
[114] See Doha Declaration, paras 5(b) and (c).
[115] TRIPS Agreement, arts 65 and 66; Wager, Watal and Taubman (n 20) 22-23.
[116] Doha Declaration, para 7.
[117] ibid, para 7.

developed countries although some DC Members such as China, India, Thailand and Vietnam have also built strong pharmaceutical sectors by now.[118] All other Members have to rely on importation from the producing Members. But if pharmaceutical companies in the producing Members eligible for exportation were to produce on the basis of a compulsory licence, the exportation quantities of these Members would be severely restricted by this condition.

Recalling that DC Members have benefitted from a prolonged transitional period for the implementation of the rules of the TRIPS Agreement on patent protection, it becomes evident why this issue became urgent at the time of the adoption of the Doha Declaration. This transitional period expired in 2005,[119] forcing these Members to fully implement the patent protection rules pursuant to Section 5 of Part II of the TRIPS Agreement. This included, of course, the conditions of Article 31 and, specifically the requirement to grant compulsory licences 'predominantly for the supply of the domestic market'.[120] As those DCs with pharmaceutical capacities, especially India, had built up significant generic industries by this time, they had become important exporting candidates for other DC and LDC countries. However, due to the expiring transition period, they had to implement an IP legislation that threatened to severely restrict their export potential for generic medicines to import-dependent DCs and LDCs.[121] Acknowledging this issue, the Doha Declaration instructed the TRIPS Council 'to find an expeditious solution to this problem'.[122]

The measures taken by the WTO following-up on the Doha Declaration were designed to mitigate the burdens of the obligations of the TRIPS Agreement on DC Members.[123] They will be the subject of the following chapters.

2.4.4.1. The special compulsory licensing system

The first problem identified in the Doha Declaration concerned the trade of generic pharmaceuticals between producing DCs and DCs with insufficient or no manufacturing capacities in the pharmaceutical sector which were dependent on importation of medicines. Since the importation of a product is among the exclusive rights conferred on the owner of a

[118] Paquin and Plouffe-Malette (n 6) 266; Tahir Amin and Aaron S. Kesselheim, 'A Global Intellectual Property Waiver is Still Needed to Address the Inequities of COVID-19 and Future Pandemic Preparedness' [2022] INQUIRY: The Journal of Health Care Organization, Provision, and Financing 4 <https://journals-sagepub-com.uaccess.univie.ac.at/doi/10.1177/00469580221124821> accessed on 3 December 2023.
[119] TRIPS Agreement, art 65(4); Wager, Watal and Taubman (n 20) 23.
[120] TRIPS Agreement, art 31(f); Wager, Watal and Taubman (n 20) 204.
[121] Van den Bossche and Zdouc (n 31) 1133.
[122] Doha Declaration, para 6.
[123] Feichtner (n 9) 126.

patent (see 2.2.2),[124] DC Members would have to rely on compulsory licences to import patented pharmaceutical products. The same is true for exporting Members.

In line with the mandate accorded to it by the Doha Declaration, on 30 August 2003 the General Council adopted the Decision on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ('2003 General Council Decision')[125] which introduced the so-called 'special compulsory licencing system' or 'Paragraph 6 system'. This system is available for any patented pharmaceutical product and basically consists of a two-fold waiver.[126]

The first strand of the waiver releases WTO Members of the obligations to produce predominantly for the supply of their domestic market, as set out in Article 31(f) of the TRIPS Agreement, with respect to the grant of a compulsory licence for the sole purpose of producing a pharmaceutical product and exporting it to one or more eligible Member(s).[127] While LDC Members automatically qualify as eligible Members, other Members first have to determine the insufficiency of their pharmaceutical manufacturing capacities and notify the TRIPS Council accordingly, if they intend to make use of the compulsory licencing system as an importer.[128] The purpose of these notifications are information and transparency for the WTO community and do not require approval by the WTO.

The second easement is that the obligation of the importing Members to pay patent holders adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement is waived, provided that such remuneration, compensating for a compulsory licence, has been paid already in the exporting Member.[129]

In summary, the special compulsory system enabled developed Members and DC Members with adequate production capacities to produce a certain pharmaceutical for the purpose of supplying another Member which itself is lacking sufficient production capacities for the relevant pharmaceutical. Naturally, the use of this option is subject to several formal conditions in the exporting and the importing Member, such as timely notification to the TRIPS Council, specific labelling of the product(s) and publication of quantities and destinations.[130] But in

[124] TRIPS Agreement, art 28.1(a).
[125] General Council, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', Decision of 30 August 2003, WT/L/540 and WT/L/540 Corr.1 (2 September 2003) ('2003 General Council Decision').
[126] WTO, WHO and WIPO, *Promoting Access to Medical Technologies and Innovation* (n 62) 304.
[127] 2003 General Council Decision, para 2.
[128] 2003 General Council Decision, paras 1(b) and 2(a)(ii).
[129] 2003 General Council Decision, para 3.
[130] See 2003 General Council Decision, para 2.

principle, a flexibility designed specifically for the solidary proliferation of (generic) pharmaceuticals been introduced. However, the 2003 Decision was not designed to remain in force indefinitely.

2.4.4.2. The TRIPS Amendment 2017: Solidifying flexibilities

The system established by the 2003 General Council Decision was meant to be a temporary one and was supposed to be replaced by a permanent amendment to the TRIPS Agreement. Consequently, attached to the General Council Decision of 6 December 2005, the Protocol Amending the TRIPS Agreement ('2005 Protocol')[131] was submitted to Members for acceptance. It entered into force on 23 January 2017,[132] after two-thirds of the WTO Members had accepted it and continues to be open for acceptance.[133]

For those 133 Members that have accepted the amendment so far, the 2003 General Council Decision has terminated and been replaced by the provisions of the Protocol.[134] Other Members continue to benefit from the Decision but will have to accept the amendment until 31 December 2023.[135]

The Protocol added a new Article 31bis, an Annex as well as an Appendix to the TRIPS Agreement and extended the treaty by a set of clauses that is by and large identical to the special compulsory licensing system introduced by the 2003 General Council Decision.[136] But there is one additional paragraph containing a safeguard against the diversion of products to third markets. It is designed to ensure that Members importing under a special compulsory licence take measures to prevent re-exportation of these products from their territories.[137]

Thus, as of January 2017, the legal basis for the special compulsory licensing system is permanently enshrined in Articles 31 and 31bis, the Annex and the Appendix of the TRIPS Agreement. While currently only 22 Members have formally notified patent legislation

[131] General Council, 'Amendment of the TRIPS Agreement', Decision of 6 December 2005, WT/L/641 (8 December 2005) 2 ('2005 Protocol').
[132] WTO, 'Protocol Amending the TRIPS Agreement done at Geneva on 6 December 2005', Notification of entry into force, WT/LET/1236 (30 January 2017).
[133] See General Council, 'Amendment of the TRIPS Agreement – Eighth Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement', Decision of 22 November 2021, WT/L/1122 (23 November 2021).
[134] 2003 General Council Decision, para 11; WTO, *Annual Report* (WTO Secretariat 2022) 117.
[135] WTO, *Annual Report* (WTO Secretariat 2022) 117.
[136] TRIPS Agreement, art 31(f); Wager, Watal and Taubman (n 20) 205.
[137] Annex to the TRIPS Agreement, para 3; Wager, Watal and Taubman (n 20) 206.

implementing the system, a number of Members have also taken implementation measures but have not yet notified them to the TRIPS Council.[138]

The first incident of the use of the Paragraph 6 system was registered in 2007, when Canada and Rwanda notified their first authorisations issued under the system to the TRIPS Council. It concerned the generic production of an HIV/AIDS drug by a Canadian company and the subsequent shipment to Rwanda.[139]

During the COVID-19 pandemic, very few Members issued a compulsory licence. In 2020, only Hungary and Russia granted licences for the local production of the drug remdesivir while Israel issued a government-use licence for the import for generic lopinavir/ritonavir.[140] In the following year, the Plurinational State of Bolivia as well as Antigua and Barbuda notified to the WTO their intention to make use of the special compulsory system as importers.[141] However, due to a general reluctancy of Members to notify implementing measures to the WTO in time,[142] it is difficult to reliably keep track of Members' implementation and use of the special licensing system.

2.4.4.3. Least-Developed Country Members

The second issue addressed by the Doha Declaration concerned the transitional periods for the implementation of the TRIPS Agreement by LDC Members. Pursuant to the Doha Declaration, the general transitional period for LDC Members was extended by the TRIPS Council in 2005

[138] See WTO, 'Members' laws implementing the 'Paragraph 6' system' (last updated on 24 January 2022) <www.wto.org/english/tratop_e/trips_e/par6laws_e.htm> accessed on 3 December 2023.
[139] Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 2 March 2010', IP/C/M/62 (1 June 2010) paras 185-195; Council for TRIPS, 'Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', Report to the General Council, IP/C/57 (10 December 2010) paras 5-8.
[140] See WTO, 'COVID-19: Measures regarding trade-related intellectual property rights', List compiled by the WTO Secretariat (last updated on 30 June 2023) <www.wto.org/english/tratop_e/covid19_e/trade_related_ip_measure_e.htm> accessed on 3 December 2023; for Hungary's notification see Council for TRIPS, 'Notification of laws and regulations under Article 63.2 of the TRIPS Agreement – Hungary: Government Decree 212/2020 (16 May) on public health compulsory licences for exploitation within Hungary', IP/N/1/HUN/3 and IP/N/1/HUN/P/3 (4 June 2020); WTO, WIPO and WHO, *An Integrated Health, Trade and IP Approach to Respond to the COVID-19 Pandemic* (n 7) 12.
[141] Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 9-10 March, 6 May and 1 June 2022', IP/C/M/104/Add.1 (28 June 2022) para 77; WTO, *Annual Report* (WTO Secretariat 2022) 118. In contrast to Antigua and Barbuda, Bolivia also notified its concrete intention to import an estimated 15 million doses of COVID-19 vaccines, cf Council for TRIPS, 'Notification under the amended TRIPS Agreement – Notification of intention to use the special compulsory licensing system as an importing Member', IP/N/8/ATG/1 (17 May 2021); 'Notification under the amended TRIPS Agreement – Notification of intention to use the special compulsory licensing system as an importing Member, IP/N/8/BOL/1 (19 February 2021) and IP/N/9/BOL/1 (11 May 2021).
[142] See Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 16-17 March 2023', IP/C/M/107 (17 April 2023) paras 8-9.

and 2013,[143] resulting in an expiration date of 1 July 2021 or whenever a member ceases to be an LDC. Recently, a further extension until 1 July 2034 was agreed.[144]

Taking up on the Ministerial Conference's promise of the Doha Declaration, the General Council in July 2002 adopted a second decision ('2002 General Council Decision') containing a waiver of LDC Members' obligations under Article 70.9 of the TRIPS Agreement.[145] This provision requires a Member which has not yet implemented patent protection for pharmaceutical products to grant exclusive marketing rights to such products, if a patent application has been filed and a patent as well as market approval has already been obtained in another Member.[146] Correspondingly, Members also have to accept patent applications according to Article 70.8 TRIPS Agreement, even during the transitional period.[147] In other words, according to this so-called 'mailbox provision', a Member exploiting its transitional period nevertheless has to accept patent applications and store them for posterior processing. Additionally, it must grant a minimum of IP protection within its domestic market for pharmaceutical products patented in another State. According to the 2002 General Council Decision, LDC Members were released from the 'mailbox provision' until 1 January 2016.

2.5. The security exception in Article 73

As a rule, WTO Agreements contain provisions on security exceptions for Members to ensure that their obligations under the WTO framework do not interfere with their security policies. The TRIPS Agreement is no exception. According to Article 73, the TRIPS Agreement cannot be construed to require Members to reveal information against their essential security interests or, in certain situations, prevent them from taking action which they consider necessary for the protection of their security interests.[148] Occasionally, it is argued that the COVID-19 pandemic qualified as one of the situations listed, [149] namely that there is an emergency in international

[143] WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation* (2nd edn, 2020) 65.
[144] Council for TRIPS, 'Extension of the transition period under article 66.1 for least developed country Members', Decision of 29 June 2021, IP/C/88 (29 June 2021) para 1; WTO, *Annual Report* (WTO Secretariat 2022) 119.
[145] General Council, 'Least-Developed Country Members – Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products', Decision of 8 July 2002, WT/L/478 (12 July 2002) para 1.
[146] TRIPS Agreement, art 70.9; Feichtner (n 9) 126.
[147] TRIPS Agreement, art 70.8.
[148] TRIPS Agreement, art 73(a) and (b); Wager, Watal and Taubman (n 20) 28.
[149] Vijay Kumar Chattu and others, 'COVID-19 Vaccine, TRIPS, and Global Health Diplomacy: India's Role at the WTO Platform' [2021] BioMed Research International 1, 4; Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments (n 43) 26-27.

relations other than war.[150] If this is the case, Article 73 could provide a further flexibility for Members to relax their patent legislation or temporarily intervene with individual patent rights.

Notably, there is case law on the use of this security exception. In *Saudi Arabia–IPRs* the panel found that it may assess:

a) whether the existence of a 'war or other emergency in international relations' has been established in the sense of subparagraph (iii) to Article 73(b);
b) whether the relevant actions were 'taken in time of' that war or other emergency in international relations;
c) whether the invoking Member has articulated its relevant 'essential security interests' sufficiently to enable an assessment of whether there is any link between those actions and the protection of its essential security interests; and
d) whether the relevant actions are so remote from, or unrelated to, the 'emergency in international relations' as to make it implausible that the invoking Member considers those actions to be necessary for the protection of its essential security interests arising out of the emergency.[151]

Even though it is uncertain whether the COVID-19 pandemic constitutes an emergency in international relations in the sense of Article 73, it is unlikely that any Member would challenge the invocation of Article 73 by a DC Member.[152] However, as no WTO Member invoked Article 73 during the pandemic to justify their non-conformance with the TRIPS Agreement, the discussion on this issue remains academic.

[150] TRIPS Agreement, art 73(b)(iii).
[151] *Saudi Arabia – Measures Concerning the Protection of Intellectual Property Rights—Report of the panel* (16 June 2020) WT/DS567/R [7.242.] (underscore added).
[152] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 27.

3. The 2022 COVID-19 TRIPS waiver

3.1. The negotiations within the TRIPS Council

The waiver was proposed by India and South Africa on 2 October 2020.[153] The initial draft amounts to only one page but contains the text for a waiver covering virtually every obligation of the Members under the TRIPS Agreement in relation to the protection of IP rights significant to health-related, medical, or pharmaceutical technologies. It covered the Sections 1, 4, 5 and 7 of Part II and the enforcement of these Sections under Part III of the TRIPS Agreement for a number of years left open to negotiation.[154] Meeting serious resistance from a number of WTO Members, this proposal was not adopted right away but became subject to extensive discussion within the WTO.

On 25 May 2021 the first revised draft was circulated among the Members.[155] The proposal was now co-sponsored by additional Members, mainly from the African group[156] and the LDC group[157] which together amounted to a total of 65 Members in support of a waiver.[158] Only shortly before, the US had given up their initial opposition and were now open to discussions.[159] The main changes of the revised draft concerned the reference to the emergence of new variants of the COVID-19 virus, the emphasis on an urgent need to diversify and scale-up the production of health products and technologies and the recognition of the fact that there was a field of tension between the preservation of incentives for (private) research and innovation and the

[153] Council for TRIPS, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19', Communication from India and South Africa, IP/C/W/669 (2 October 2020).
[154] ibid, para 1.
[155] Council for TRIPS, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text', Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/669/Rev.1 (25 May 2021). In the following months, Jordan, Malaysia and Argentina joined the co-sponsors. Council for TRIPS, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text – Addendum', IP/C/W/669/Rev.1/Add.1 (9 August 2021), IP/C/W/669/Rev.1/Add.2 (9 August 2021), IP/C/W/669/Rev.1/Add.3 (15 December 2021).
[156] For a list of the Member States of the regional group see UN, 'Regional groups of Member States: African States', <www.un.org/dgacm/en/content/regional-groups> accessed on 3 December 2023.
[157] For a list of the LDC Member States see UN Committee of Development Policy, 'List of Least Developed Countries (as of 25 August 2023)' <www.un.org/development/desa/dpad/wp-content/uploads/sites/45/publication/ldc_list.pdf> accessed on 3 December 2023.
[158] Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 9-10 March 2022', IP/C/M/104 (8 April 2022) para 61.
[159] Office of the United States Trade Representative, 'Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver', Press Release (5 May 2021) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> accessed on 3 December 2023; Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 634.

public health interest. In the operative part, the most important change was a further limitation of the waiver to 'health products and technologies'.[160]

These changes must be seen as partial concessions to the adversaries to the proposal, who were concerned that by depriving the health technology industries of the prospect of obtaining new patents, such a waiver would spoil any incentives for their research and innovation in the long run.[161]

Furthermore, according to this revised draft, the waiver was supposed to stay in force for at least three years, without a definite expiration date but until terminated by the General Council.[162] It has been noted that, due to the decision-making within the WTO in practice being consensus-based, this would have meant that even a single Member's objection would have kept the waiver in force.[163] Moreover, it is doubtful whether such a provision would have satisfied the principal requirement that a decision by the Ministerial Conference to grant a waiver must 'state … the date on which the waiver shall terminate'.[164]

However, this proposal was still too extensive for the EU which in June 2021 advanced its own position by submitting a new proposal for a General Council Declaration to the TRIPS Council to clarify that the pandemic constituted a 'national emergency or other circumstances of extreme urgency' in the sense of Article 31(b) of the TRIPS Agreement (see 2.4.3).[165] Recalling the 2001 Doha Declaration, the EU emphasised its point that, in the context of the pandemic, each Member had the right to grant compulsory licences to domestic producers under the conditions it thought appropriate and could waive the requirement to negotiate with the right holder before a compulsory licence is granted. Concerning the obligation to provide for 'adequate remuneration' of the right holder according to Article 31(h) of the TRIPS Agreement,

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[160] See Draft Decision Text in Council for TRIPS, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text', Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/669/Rev.1 (25 May 2021) Annex, para 1.

[161] Kohler, Wong and Tailor (n 82) 165.

[162] See Draft Decision Text in Council for TRIPS, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19: Revised Decision Text', Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, the LDC Group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe, IP/C/W/669/Rev.1 (25 May 2021) Annex, para 2.

[163] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments (n 43) 13.

[164] See WTO Agreement, art IX:4.

[165] Council for TRIPS, 'Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic', Communication from the European Union to the Council for TRIPS, IP/C/W/681 (18 June 2021) Annex 3, para (a); see also Council for TRIPS, 'Urgent Trade Policy Responses to the COVID-19 Crisis: Intellectual Property', Communication from the European Union to the Council for TRIPS, IP/C/W/680 (4 June 2021) para 9(a).

it proposed that this remuneration may reflect the price charged by the manufacturer of the vaccine or pharmaceutical.[166] Apart from that, it recalled that LDCs were already temporarily exempted from the obligations under Sections 5 (Patents) and 7 (Protection of undisclosed information) of the TRIPS Agreement, concerning pharmaceutical products.[167] However, the EU acknowledged that the Paragraph 6 system required quite some administrative effort of Members and proposed vast simplifications to the notification requirement of an exporting Member.[168]

Overall, these clarifications and proposals of the EU express the bloc's efforts to maintain the Council position determined by the Doha Declaration of 2001 according to which the exceptions available in the TRIPS Agreement are, theoretically, already sufficient to facilitate the diversification of vaccine and pharmaceutical production. This is evidenced by the fact that it still promoted the adoption of a Declaration rather than a Decision with potential binding legal effect. Also, the EU stressed the incentivising effects of the existing IP protection by highlighting the rapid development of COVID-19 vaccines (within one year) and the already tremendous scale of global production.[169] Following this argument, not only would a waiver be unnecessary but also detrimental to the pharmaceutical research and innovation that was necessary in the context of emerging variants of the Coronavirus.

Despite the official proposals from both sides, the formal proceedings could never really advance to the stage of text-based negotiations and finally became deadlocked in autumn 2021. However, work continued through informal quadrilateral discussions between India, South Africa, the EU and the US (the 'Quad') under the auspices of DG Okonjo-Iweala. Apparently, this process was not conducted in a very transparent manner, so that the General-Director felt obliged to assure the Chair of the Council for TRIPS as well as the rest of the Members that the outcome would be put forward 'transparently to the full Membership for discussion in the TRIPS Council'.[170]

It is noteworthy how China reacted to this draft document at the following meeting of the General Council: China rejected a clause that aimed at excluding DC Members who had exported 'more than 10% of world exports of COVID-19 vaccine doses in 2021'[171] from the scope of the Ministerial Declaration and, in the same breath, unambiguously declared to 'opt-

[166] Ibid, para 11.
[167] Ibid, para 8.
[168] ibid, para 12.
[169] ibid, para 6.
[170] Council for TRIPS, 'Communication from the Chairperson', IP/C/W/688 (3 May 2022) 2 ('Quad Draft').
[171] Quad Draft, fn 1.

out' of the waiver.[172] Indeed, this clause had been introduced on demand of the US seeking to exclude specifically China.[173]

It was only one and a half months before the twelfth Ministerial Conference ('MC12') was scheduled that the draft text developed behind closed doors was first circulated among all Members. Yet, on its basis and almost 20 months after the initial proposal by India and South Africa had been tabled, the negotiations culminated in the adoption of the TRIPS waiver by the MC12. And, consequently, the WTO was quick to record China's earlier statement as a manifest of its 'binding commitment' to continue respecting its TRIPS obligations.[174]

To sum up, the examination of the different proposals and communications tabled during the negotiations has revealed following positions of the two parties: The overall stance of the opponents of the waiver is very clear and comprises of two core arguments. The first one goes that the TRIPS regime already provides sufficient tools for the diversification of the vaccine and pharmaceutical production; the second one stresses that the IP protection regime must be maintained to keep further development of COVID-19 vaccines and pharmaceuticals attractive. The proponents of the waiver were mainly relying on the argument that there is an urgent need to diversify and scale-up the production of health products and technologies for the treatment of COVID-19 in order to meet the global demand; and that this diversification and scaling-up requires an adjustment of the legal framework that determines the balance between the public health interests and the preservation of incentives for R&D.

3.2. Examination of content and extent of the waiver

As the Ministerial Decision of 17 June 2022 is the centrepiece of the present paper, to be able to properly assess its potential and implications, a closer examination of the waiver is necessary. For clarity, for the purpose of this chapter, it is to be understood that the 'Ministerial Decision' refers to the document as a whole, while the 'TRIPS waiver' only refers to a specific part of the text, namely paragraph 3 including its subparagraphs.

Firstly, it is striking that the 2022 Ministerial Decision, in comparison to the official proposals tabled in 2020 and 2021, has changed quite considerably. In contrast, in substantial parts it is identical to the draft prepared by the Quad.[175] This means that the Ministerial Council,

[172] General Council, 'Minutes of the Meeting held in the Centre William Rappard and in the virtual format on 9-10 May 2022', WT/GC/M/198 (21 July 2022) para 5.9.
[173] Amin and Kesselheim (n 118) 4.
[174] Council for TRIPS, 'Record in Accordance with Footnote 1 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022 (WT/L/1141)', IP/C/W/690 (22 June 2022).
[175] Cf TRIPS waiver, paras 1-8; Quad Draft, paras 1-8.

consisting of representatives of all 164 WTO Members, adopted the outcome of the backroom Quad negotiations virtually without change. What is most remarkable though, is that it remains heavily committed to the fundamentals of Article 31 TRIPS Agreement. This is evident from many parts of the text which seem to have been drafted closely after the provisions of the special compulsory licensing system in the TRIPS Agreement.

For example, the first paragraph reiterates that an eligible Member may, in accordance with Article 31, limit patent holders' rights by authorising the use of the subject matter of the patent if it is required for the production and supply of COVID-19 vaccines and only necessary to the extent to address the COVID-19 pandemic.[176] The text is basically paraphrasing Article 31 TRIPS Agreement, with the additional part on the restriction to the necessary extent being derived from Article 31bis.[177] Insofar, the main text of the Declaration does not provide any substantial changes.

However, important information can be found in the footnotes of the 2022 Ministerial Declaration, namely the definitions of 'eligible Member' and of 'subject matter of a patent'. Firstly, contrary to the definition of 'eligible importing Member' in the TRIPS Agreement which automatically encompasses LDC Members and generally excludes (other) DC Members unless they make a notification to the Council for TRIPS,[178] according to the 2022 Ministerial Decision, all DC Members are eligible.[179] Also, DC Members with the capacity to manufacture COVID-19 vaccines – i.e. especially Brazil, Russia, India, China and South Africa – are encouraged to make a binding declaration not to make use of the waiver.[180] As mentioned above, this clause had been part of the Quad draft already, rendering it a very odd clause considering that the waiver was not only proposed and negotiated by the generic exporters India and South Africa but would also be useless if all generic producing DC Members were to opt-out of it. Subsequently bound by its oral statement in the meeting of the General Council in May 2022, China is the only Member that has been excluded of the waiver thus far.

The second important footnote states that with 'subject matter of a patent' the Ministerial Decision means, *inter alia*, ingredients and processes necessary for the manufacture of the COVID-19 vaccine.[181] This provision clarifies that for vaccines which are produced with a lot

[176] TRIPS waiver, para 1.
[177] See TRIPS Agreement, art 31bis para 1.
[178] See Annex to the TRIPS Agreement, para 1(b).
[179] TRIPS waiver 1, fn 1.
[180] TRIPS waiver 1, fn 1.
[181] TRIPS waiver 1, fn 2.

of components and intermediate products a compulsory licence may cover all patented products of processes along the whole manufacturing process.

Finally, the 2022 Ministerial Decision waives the above-mentioned obligations only in regard to COVID-19 vaccines and to the extent necessary to address the COVID-19 pandemic.[182] Therefore, for the time being, the inclusion of other medical products as initially demanded by the waivers proponents has been spared.

This being said, these fundamental provisions define the general scope of the TRIPS waiver and should be kept in mind during the reflections on the following provisions.

3.2.1. The waiver on Article 31(b)

Paragraph 2 of the 2022 Ministerial Declaration contains a clarification that Members may grant compulsory licences under Article 31 TRIPS Agreement through any instrument available in their law. It also provides a demonstrative list of instruments with different administrative acts, presumably to emphasise that Members do not need to set in motion the parliamentary process to adopt new legislation or have a dedicated compulsory licence regime in place.[183] In other words, it is made clear that Members have full discretion on how to implement the 2022 Ministerial Declaration respectively the existing Article 31 TRIPS Agreement.

Advancing to Paragraph 3 of the 2022 Ministerial Decision, this is where the alleged TRIPS waiver is incorporated. However, it has been cut back to cover only some elements of the compulsory licensing system under the TRIPS Agreement. As the *chapeau* of Paragraph 3 speaks of 'the following clarifications and waiver',[184] it already takes away that only some of the items listed below amount to a real waiver, whereas others are merely declaratory.

The first element concerns the obligation set out in Article 31(b) TRIPS Agreement requiring the licensee to make efforts to obtain authorisation from the patent holder prior to applying for a compulsory licence. Here, the document states that 'an eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder'.[185] What *prima facie* seems to be a waiver according to Article IX:3 WTO Agreement, technically is not a waiver but a clarification. This is due to the fact that Article 31(b) already offers the option to any Member to refrain from requiring this condition within its jurisdiction in a situation of national emergency or other circumstances of extreme urgency.

[182] See TRIPS waiver, para 3 in conjunction with para 1.
[183] TRIPS waiver, para 2.
[184] See TRIPS waiver, para 3.
[185] TRIPS waiver, para 3(a).

This means that the Members have already been released from their obligation to enforce Article 31(b) in their jurisdiction and a waiver would be devoid of purpose – presuming of course, that the COVID-19 pandemic constitutes such a national emergency.[186]

In this context it may be recalled that the Doha Declaration emphasised the Members' discretion to determine what constitutes an emergency in the sense of Article 31(b) TRIPS Agreement,[187] shifting the burden of proof to refute a state of emergency to any potential complainants.[188]

3.2.2. The waiver on Article 31(f)

Turning to the second element of the TRIPS waiver, it should first be recalled that the notorious Article 31(f) TRIPS Agreement requires that compulsory licences authorise licensees to produce predominantly for the domestic market and therefore severely restrict export. As already pointed out above (see 2.4.4), this provision has been deemed to be a huge obstacle for DC Members with production capacity wanting to export, even before the COVID-19 pandemic. The TRIPS waiver suspends this restriction and allows for exportation of 'any proportion of the products manufactured under the authorization'.[189]

As the waiver generally applies to all DC Members automatically, it may seem as if it goes beyond the similar provision in Article 31bis TRIPS Agreement which allows exportation only to 'eligible importing Members(s)'.[190] However, as explained, after the implementation of the Doha Decision, Article 31(f) is merely a formal and administrative restriction as a notification to the TRIPS Council suffices to qualify any DC Member as an eligible destination for the export of pharmaceutical products.[191] Thus, what is actually waived is this notification requirement for importing Members. Additionally, as will be explained below (see 3.2.5), the Ministerial Decision does not completely renounce the notification requirement but rather modifies it.

3.2.3. Best effort to prevent re-exportation

The next provision of the TRIPS waiver obliges Members that have imported into their territory a product manufactured under the Ministerial Declaration to undertake 'all reasonable efforts' to prevent the re-exportation of this product from their territory.[192] Furthermore, Members

[186] Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 639.
[187] Doha Declaration, para 5(b).
[188] Van den Bossche and Zdouc (n 31) 1132.
[189] TRIPS waiver, para 3(b).
[190] TRIPS Agreement, art 31bis para 1.
[191] Annex to the TRIPS Agreement, para 1(b).
[192] TRIPS waiver, para 3(c).

which are neither the exporter nor the importer of the product must provide in their legislation effective legal means to prevent the unlawful importation of the product into their territory. [193] Both of these provisions are reflecting the *status quo* of the existing special compulsory licensing system and therefore don't provide any new conditions or flexibilities compared to the relevant provisions of the TRIPS Agreement.[194] However, the TRIPS waiver adds a new exception to the re-exportation limitation so that eligible Members 'may re-export COVID-19 vaccines to another eligible Member for humanitarian and not-for-profit purposes'.[195] Therefore, this clause does not constitute a real waiver but rather amends an existing obligation and possibly adds another exception.

3.2.4. Adequate remuneration

The last provision of the TRIPS waiver concerns the calculation of the remuneration the patent holder must be paid to compensate for the compulsory authorisation of the substance matter of the patent. It stipulates that '[d]etermination of the adequate remuneration under Article 31(h) TRIPS Agreement may take account of the humanitarian and not-for-profit purpose of specific vaccine distribution programs'.[196] As Article 31(h) already provides that the remuneration shall be paid 'in the circumstances of each case, taking into account the economic value of the authorization', this point of the waiver is hardly more than clarifying and explicitly referencing to the specific circumstances of the COVID-19 pandemic. Furthermore, it is drafted in form of a permission rather than an obligation, thus leaving it up to the producing Member to determine an adequate remuneration. Consequently, this provision does not provide any additional flexibilities in comparison to the present system but rather offers guidance for Members to setting national standards for remuneration that could potentially ease the financial burden on generic manufacturers.[197]

3.2.5. Miscellaneous provisions

The 2022 Ministerial Decision required the Members to decide within six months from the date of its adoption on its extension to also cover the production and supply of COVID-19 diagnostics and therapeutics.[198] Even though the negotiations on the extension began immediately after the MC12, it appears that Members have replicated their stances during the

[193] TRIPS waiver, para 3(c).
[194] See Annex to the TRIPS Agreement, paras 3-4.
[195] TRIPS waiver 2, fn 3.
[196] TRIPS waiver, para 3(d).
[197] See TRIPS waiver 2, fn 4; Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 639-40.
[198] TRIPS waiver, para 8.

preceding waiver negotiations and still struggle to find a compromise.[199] Thus, no agreement could be reached within that timeframe and the TRIPS Council in December 2022 decided that it should be recommended to the General Council to extend the deadline for the decision.[200] The discussions on the extension of the TRIPS waiver are still ongoing at this point.

The TRIPS waiver is designed to stay in force for five years and can be extended by the General Council if the pandemic situation so requires. According to the general conditions of Article IX:4 WTO Agreement, it also must be reviewed by the General Council annually.[201]

Finally, if Members decide to make use of the waiver, it requires them to communicate to the TRIPS Council any measure related to the implementation of the 2022 Ministerial Decision, as soon as possible after the adoption of the measures.[202] While the terms of the special compulsory licensing system require an importing Member to make a notification to the Council for TRIPS before it takes action,[203] the waiver allows for a subsequent notification. The content of the notification mostly remains the same, namely the product(s) for which the authorisation is granted and the quantities that ought to be exported, the countries to which the product is exported and the duration of the authorisation.[204] However, the Ministerial Declaration does not require the exporting Member to set up a website with other information or to specifically label or mark the products.[205] As of now, no Member has notified to the WTO its intention to invoke the new TRIPS waiver.

Lastly, for the sake of comprehensiveness, it should be mentioned that the TRIPS waiver was accompanied by a Ministerial Declaration dealing with the WTO response to the COVID-19 pandemic in a general way and also highlighting areas that had proven critical.[206] The Declaration recalls the Doha Declaration of 2001 and reaffirms the Members' right to utilise the existing flexibilities of the TRIPS Agreement to protect public health.[207] Furthermore, it arranges for a yearly stocktaking of the work of WTO bodies involved during the COVID-19

[199] Cf the statements of South Africa, India, Switzerland and the UK, Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 16-17 March 2023 – Addendum', IP/C/M/107/Add.1 (25 May 2023) paras 222-33, 255-56, 261-63 and 268-73.
[200] Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 12-13 October and 15-16 December 2022', IP/C/M/106 (17 January 2023) paras 81-82.
[201] TRIPS waiver, para 6.
[202] TRIPS waiver, para 5.
[203] See Annex to the TRIPS Agreement, para 2(a).
[204] See Annex to the TRIPS Agreement, para 2(c); TRIPS waiver, para 5 and fn 5.
[205] See, in contrast, Annex to the TRIPS Agreement, para 2(b)(ii)-(iii).
[206] Ministerial Conference, 'Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics' (adopted on 17 June 2022), WT/MIN(22)/31 and WT/L/1142 (22 June 2022) ('2022 Ministerial Declaration').
[207] ibid, paras 12-14.

pandemic until 2024 in order to be prepared better for future challenges.[208] For clarity, it should be emphasised that, unlike the 2022 Ministerial Decision, the Ministerial Declaration does not entail any binding provisions for WTO Members.[209]

[208] ibid, paras 23-24.
[209] ibid, para 29.

4. Expectations (un)met: Can the waiver keep its promise?

After examining the main components of the TRIPS waiver and the changes it underwent during the negotiations, the most prominent arguments of both parties involved shall be reproduced to allow a better understanding of what were the proponents' expectations and whether the waiver could be expected to satisfy them. For this purpose, the main issues that were highlighted in regard with the flexibilities of the TRIPS Agreement will be discussed and it will be assessed whether they are actually addressed by the TRIPS waiver.

A comprehensive study of the WTO Members submissions related to the COVID-19 TRIPS waiver identified the main arguments of both sides. They can be summarised as follows: The current IP regime is a barrier to access to COVID-19 vaccines and medicines because it prevents mass manufacture, and the existing flexibilities are inadequate to address this problem. Especially civil society organisations highlighted that in the past developed-country Members and pharmaceutical corporations have pressured DC Members into not using compulsory licensing.[210] India opined that the waiver would allow the production of COVID-19 vaccines by many manufacturers simultaneously.[211] Overall, a human rights-based position was taken, arguing that a broad TRIPS waiver that covered all relevant health technologies was a legitimate trade policy tool under the WTO rules rather than an exception and suitable to promote the human right to health.[212]

The opponents, on the other hand, contested the notion that the TRIPS obligations by themselves were a barrier to the access to medical products and any issues in this regard could be addressed through minor modifications of the compulsory licensing rules. A waiver, on the other hand, would do more harm than good by undermining existing voluntary licensing partnerships and development of local pharmaceutical industries.[213]

In the following chapters, these arguments shall be addressed one by one and contrasted with the counterarguments of the opponents.

4.1. The IPR regime is a barrier to access to health

Shortly after the waiver had been tabled in October 2020, the proponents were confronted with a set of concrete questions raised by Australia, Canada, Chile and Mexico, who wanted to know what concrete obstacles to the procurement and production of COVID-19 diagnostics,

[210] Kohler, Wong and Tailor (n 82) 166.
[211] Council for TRIPS, 'Minutes of meeting (n 73) para 232.
[212] Kohler, Wong and Tailor (n 82) 162-64.
[213] ibid 164-165.

equipment, therapeutics or vaccines Members had experienced or identified in the current IP regime.[214] India and South Africa argued that a TRIPS waiver was necessary to overcome the barriers posed by the existing IP regime, a task for which voluntary and compulsory licences were not sufficient.[215] The most critical issues brought forward will be outlined hereafter.

4.1.1. Issues regarding voluntary technology transfer

The proponent's criticism of voluntary licencing and licencing agreements has already been portrayed above (see 2.4.1). As the analysis of the TRIPS waiver has shown, most of the obligations under the TRIPS Agreement concerning patent protection were not altered. WTO Members are, in general, still bound to maintain a minimum standard of IP protection in accordance with the TRIPS Agreement. Particularly, neither does the waiver address issues in connection with the negotiation or acquirement nor does it deal with the transparency or inclusiveness of licensing agreements.[216] While a real waiver on these obligations would have eliminated the burden of generic pharmaceutical companies to pay licence fees or royalties to licensors in other countries,[217] the reality is that Members are still bound to issue compulsory licences in accordance with the TRIPS Agreement and the 2022 Ministerial Decision if they want to achieve this outcome.

In summary, the waivers implications on the current voluntary licensing practice are limited to the potential indirect effects that more flexible national legislation on compulsory licensing might have, provided that Members find ways to implement the TRIPS waiver.

4.1.2. Issues regarding (special) compulsory licencing

In order to determine in how far the alleged issues of the compulsory licensing system have been addressed by the waiver, a closer look at the concrete arguments is due. Firstly, it can be noted that the criticism relied mainly on the complexities and administrative hurdles of the implementation of Article 31 and 31bis TRIPS Agreement. Accordingly, it has been claimed that the provisions of Article 31 TRIPS Agreement were too complex to apply for States with little resources and in particular not suitable for a quick reaction in case of emergencies like a pandemic.[218] In support of this argument, it was claimed that Article 31bis TRIPS Agreement

[214] See Council for TRIPS, 'Questions on Intellectual-Property Challenges experienced by Members in Relation to COVID-19', Communication from Australia, Canada, Chile and Mexico, IP/C/W/671 (27 November 2020).
[215] Kohler, Wong and Tailor (n 82) 162.
[216] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 19.
[217] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 20.
[218] See, e.g., Chattu and others (n 149) 5; Kohler, Wong and Tailor (n 82) 162-63.

had only rarely been used due to the procedural complexities it holds and therefore could not be considered to provide an effective remedy to the barriers the WTO IP regime represents to equal access to medicines in a public health emergency.[219]

In view of the often very limited overall capacities of DC Members and, all the more, LDC Members, this argument is reasonable and to a certain point surely valid. The WTO has acknowledged this fact and tweaked the notification requirements on several points. Generally, the TRIPS Agreement states that a notification of an importing Member, announcing the Member's intention to grant a compulsory licence, only needs to state the names and the expected quantities of the product and a confirmation that the importing Members lack sufficient production capacities for this product.[220] Arguably, an importing State will have to make such assessments anyway and they should only be a formality. For LDC Members the conditions are even less demanding.

On the exporting Members' side, the products need to be marked as having been produced under the compulsory licence (an issue foremost of packaging and labelling), if this is feasible and does not significantly increase the price of the product, and the quantities intended for exportation including their destination need to be publicised on a website.[221] Furthermore, the exporting Member needs to notify to the TRIPS Council about the grant of the compulsory licence including the obvious formalities like who is the licensee, what is the product in question and who is the importing Member, as well as the conditions attached to the licence.[222]

While a judgement on the practical complexity of these formal requirements would fall beyond the scope of the present paper, it should be noted that they reflect the desire of transparency in trade issues which is one of the principles of the WTO.[223] Thus, neither does it seem desirable nor in line with the WTO framework to entirely omit the requirement to notify such exceptional measures as compulsory licences to the WTO so that other Members are aware of them.

The WTO provides options and has taken different steps to facilitate the implementation of the TRIPS Agreement and the compulsory licencing system for Members. For example, in a trilateral cooperation with WIPO and the WHO, the WTO offers technical assistance to help with the implementation of an IP regime that can be tailored to Members' individual

[219] Response to Questions (n 72) para 44; Wijesinghe, Adikari and Ariyaratna (n 65) 186.
[220] Annex to the TRIPS Agreement, para 2(a)(i)-(iii).
[221] Annex to the TRIPS Agreement, para 2(b)(ii)-(iii).
[222] Annex to the TRIPS Agreement, para 2(c).
[223] See, especially, GATT 1994, art X.

developmental needs.[224] It also provides an online tool for the submission of TRIPS-related notifications as well as guidelines and information on how to make the different types of notifications.[225] Additionally, the TRIPS Agreement obliges developed-country Members, upon request, to help DC and LDC Members with the implementation of the Agreement through technical and financial cooperation, including assistance with the preparation of laws and regulations and training of personnel to properly enforce them.[226] Also, a structural alleviation may be recalled in this context, namely that LDC Members are always eligible Members in the sense of Article 31bis TRIPS Agreement and are not required to make a notification of their intent to make use of the special compulsory system, thus facilitating and accelerating the procedure for them.

However, a major concern of the proponents was that compulsory licences of both importing Member and exporting Member might be necessary for each component or ingredient required for the production of the desired vaccine.[227] To address this concern, the EU had suggested that a uniform emergency notification mechanism could alleviate this 'country-by-country' and 'product-by-product' approach.[228] This issue seems to have been cleared out partially by the waiver, as it expressly regards all necessary ingredients and processes as included in the patent for a COVID-19. Also, the requirement that a single authorisation for multiple patents will have to list all the patents covered was omitted after it had still appeared in the outcome document of the Quad negotiations.[229] Hence, in this respect the TRIPS waiver indeed alleviates Members' administrative burdens in connection with the issuance of compulsory licences.

However, the legislative effort that comes with the implementation of a waiver should not be left unmentioned. The waiver itself is not automatically effective but needs to be transposed through the amendment of national legislation of the States that intend to take advantage of it. But many Members have not yet put in place the necessary legal framework to make use of the existing flexibilities, thus making it questionable if they can be expected to be in a position to

[224] See WTO, 'WTO technical assistance on the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)' <www.wto.org/english/tratop_e/trips_e/intel9_e.htm> accessed on 3 December 2023.
[225] See WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation* (2nd edn, 2020) 305.
[226] TRIPS Agreement, art 67.
[227] Response to Questions (n 72) para 50.
[228] Council for TRIPS, 'Draft General Council Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic', Communication from the European Union to the Council for TRIPS, IP/C/W/681 (18 June 2021) Annex 3, para (c); Kohler, Wong and Tailor (n 82) 165.
[229] See Council for TRIPS, 'Communication from the Chairperson', IP/C/W/688 (3 May 2022) para 3(a); Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 638 fn 38.

rapidly implement the waiver.[230] Sometimes the domestic legislation might exist, but be overly complicated, thus making it difficult in practice for a Member to efficiently use the TRIPS flexibilities.[231]

On the same note, early in the negotiation process, the question was raised how the proponents of the waiver planned to give effect to the waiver on a national level. In reply, the proponents merely pointed out that each country had its individual political and constitutional arrangement and choice of modality of implementing the waiver, although 'emergency and disaster management legislations or any other legislative methodology may be relied upon'.[232] Even though this notion has been incorporated into the TRIPS waiver,[233] it is obviously a truism and does not change the fact that the implementation of the waiver – just as issuance of a compulsory licence – comes with a certain amount of administrative and legislative burden.

Even though the waivers proponents wanted to see the fact that, early in the pandemic, developed country Members also had amended their legislation to enable quicker and easier compulsory licensing as evidence for the deficiencies of the IP system,[234] this is actually not true. If WTO Members, in preparation of an emergency, improve the domestic legal framework to better make use of their flexibilities under the TRIPS Agreement, if anything this is a sign of awareness and willingness to exhaust the available options. It can only be asserted in hindsight, whether these options were insufficient – provided, of course, that they had actually been made optimal use of.

Lastly, regarding the effective utilisation of compulsory licensing pre-dating the pandemic, a WHO study found that, between 2011 and 2016, there were 176 instances of the possible use of TRIPS facilities by 89 countries aiming to lower the prices of generic medicines. 99 (56.3%) measures were introduced by DC and 46 (26.1%) by LDC Members.[235] The 176 measures comprised of: 48 (27.3%) compulsory licences and 52 (29.5%) public non-commercial use licences, 40 (22.7%) LDC transitional measures, 1 (0.6%) parallel importation and 3 (1.7%) research exceptions.[236] The study also found that the majority of invoked flexibilities was

[230] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 27-28.
[231] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 25-26.
[232] Response to Questions (n 72) paras 71-72.
[233] See TRIPS waiver, para 2.
[234] Response to Questions (n 72) paras 9-10.
[235] 't Hoen and others (n 228) 186-87. These calculations were conducted by the author based on the given figures.
[236] 't Hoen and others (n 228) 186-87; Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 24-25.

successfully implemented and has proven effective for the procurement of generic versions of essential medicines.[237] Therefore, it seems that, after an initial slow start, the Paragraph 6 system was used quite frequently indeed already before the COVID-19 pandemic.

It was further criticised that the compulsory licences can only be issued for pharmaceutical products but not for medical devices.[238] While this is true for the special compulsory licences under Article 31bis, this restriction does not apply to general authorisations according to Article 31 TRIPS Agreement which does not contain any such restriction. Furthermore, the TRIPS waiver is confined to ingredients and processes necessary for the manufacture of a COVID-19 vaccine and thus even more restrictive.[239] Therefore, this issue has only been taken into account in so far as the 2022 Ministerial Decision foresees the possibility of an extension of the waiver to cover production and supply of COVID-19 diagnostics and therapeutics as well.[240] For the time being though, it must be concluded that the TRIPS waiver does not adequately remedy the situation that compulsory licences may only cover pharmaceuticals. Also, it must be kept in mind that pharmaceutical production is likely to rely not only on patented procedures and components but also on other IPRs such as trade secrets which are not protected by patents and therefore cannot be made subject to a compulsory licensing.[241]

To sum up the main arguments discussed in this chapter, it can be said that the proponents of the TRIPS waiver criticised the complexity and administrative burden of the compulsory licensing system according to Article 31 and 31bis TRIPS Agreement and expected the waiver to remedy this insufficiency. While the TRIPS waiver seems to provide some improvement in this regard, the necessity to implement the waiver on the national level might pose an additional, possibly even bigger challenge for those Members that already struggle with the effective utilisation of compulsory licences.

4.2. Legal uncertainties and risk of litigation

Another argument put forward in favour of the adoption of the waiver goes that the use of the compulsory licensing system under Article 31bis creates legal uncertainties and comes with the

[237] The demand especially concerned new generic HIV medicines, ‘t Hoen and others (n 228) 189-90.
[238] Chattu and others (n 149) 5.
[239] TRIPS waiver 1, fn 2.
[240] TRIPS waiver, para 8.
[241] Amin and Kesselheim (n 118) 3.

risk of 'Big Pharma' and developed countries taking legal action or exercising political and economic pressure against the respective Member.[242]

Firstly, the proponents have highlighted the role of background and foreground IP on key vaccine technologies and the disputes that have arisen in this regard already during the pandemic.[243] It is ironic but true that the three big EU- or US-based pharmaceutical companies that first used the mRNA technology to produce innovative COVID-19 vaccines in 2020/21, BioNTech-Pfizer, Moderna and CureVAC, were soon involved in a multitude of lawsuits in which they accused each other of violation of the patents for the mRNA technology. CureVac and Moderna, claiming that they had been holding the patents for the use of mRNA for vaccine production since at least 2016, sued BioNTech in 2022 for breach of their exclusive IP rights. BioNTech, in return, demanded that the patents be annulled, arguing that mRNA technology had not been a new invention even back then.[244] It is clear that such circumstances can only be frightening and repelling to other, often smaller, producers around the world because no one wants to risk getting in the crosshair of such behemoths. The myriad of patentable components and processes involved in the development of vaccines exacerbates these risks.[245] Even though the mentioned lawsuits had nothing to do with compulsory licencing, the argument of possible legal uncertainties regarding the 'real' patent holder remains reasonable.

Whether it is true that certain developed WTO Members or multinational pharmaceutical corporations have pressured DC Members into refraining from using the TRIPS flexibilities,[246] requires an investigation that would go beyond the scope of this paper. What can be said though, is that the Doha Declaration (see 2.4.4) was drafted for the very reason to give concerned WTO Members reassurance on their rights to restrict IP rights regarding their public health challenges. Given the fact that the Ministerial Conference is the highest organ of the WTO, the Doha Declaration, the 2022 Ministerial Declaration and the TRIPS waiver should have enough authority to give Members a good argument at hand, should they have to justify any national measures targeted at the protection of public health, but also restricting IP rights. The finding

[242] See, especially, the Statement of South Africa in Council for TRIPS, 'Minutes of Meeting held in the Centre William Rappard on 10-11 March 2021', IP/C/M/98/Add.1 (30 July 2021) paras 287-89; see also Wijesinghe, Adikari and Ariyaratna (n 65) 186; Paquin and Plouffe-Malette (n 6) 267-68; Amin and Kesselheim (n 118) 3.
[243] Response to Questions (n 72) para 15.
[244] Bundespatentgericht, 'Impfstoffentwickler streiten um ein mRNA-Grundlagenpatent', Press Release (11 January 2023) <www.bundespatentgericht.de/SharedDocs/Pressemitteilungen/DE/11012023.html> accessed on 3 December 2023; 'Biontech-Pfizer klagt Moderna: Der Patentstreit der mRNA-Vorreiter' *Die Presse* (Vienna 7 December 2022) <www.diepresse.com/6224744/biontech-pfizer-klagt-moderna-der-patentstreit-der-mrna-vorreiter> accessed on 3 December 2023.
[245] See Response to Questions (n 72) para 26.
[246] See, e.g., 't Hoen and others (n 228) 189-90.

of the DSB that the Doha Declaration qualifies as a subsequent agreement in the sense of the rules of treaty interpretation (see 2.4.4) can only advance the importance of these Ministerial Declarations as a basis for the legitimate application of the TRIPS flexibilities.

On the same note, it may be just an indication for the success of the Doha Declaration, but it is a fact that a stark increase in the use of TRIPS flexibilities could be observed after the implementation of the Doha Declaration in 2003 which, incidentally, also correlated with a rise of funding for HIV treatment, thus creating generic competition and reducing the prices for HIV medicines.[247]

While issues of legal uncertainties can rarely be disposed of for good as long as they have not been dealt with by a judicial body, it might be said that the 2022 Ministerial Decision in combination with the accompanying Ministerial Declaration and the Doha Declaration all reaffirm Members' rights to take measures to protect public health and should provide a solid basis for the independent use of the TRIPS flexibilities by Members. Concerning the alleged economic or political pressure from developed country Members to prevent other Members from granting compulsory licences, this is an issue unsuited for the primary legal approach of this work and would require further investigation.

4.3. Detrimental effects on local industries and R&D

It has already been noted that one objective of IP protection is to incentivise innovation (see 2.4). The logic of the economic utilitarianism dictates that investors will more readily invest funds into research and development if the prospect of patent protection promises profit, or at least, amortisation.[248] Hence, it has been one of the most prominent arguments against softening IP protection through a TRIPS waiver that this would impair the climate for investments in research and development and therefore be detrimental to innovation overall.[249] The very fact that effective COVID-19 vaccines had been developed in record speed was brought up as an argument to emphasise the importance of maintaining investments in R&D profitable.[250] This is true especially in view of new variants of the virus that require adaption of existing vaccines. However, as these questions are of economic or public health rather than a legal character, to find the appropriate answers will be left a privilege of other scholars. However, a few arguments

[247] ibid 188.
[248] Olufemi Soyeju and Joshua Wabwire, 'The WTO–TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework' (2018) 17 WTR 145, 148.
[249] Kohler, Wong and Tailor (n 82) 165-66.
[250] Mercurio, 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments' (n 43) 17-18.

are worth mentioning to put in perspective the interplay of IPRs, investment in manufacturing capacities and R&D.

The efforts of the EAC to promote access to health by way of IPR-related policies may serve as an example of the inconsistent approaches that States have taken in this regard. In 2013, the EAC adopted a policy with recommendations to its Partner States, of which five out of six were LDCs,[251] on how to best adjust their national IPR legislation to fully utilise the flexibilities of the TRIPS Agreement and settle on 'the lowest common denominator of IP legislation that can be approximated across all the EAC Partner States'.[252] The expected outcome was better access to health-related products and services for the population as well as the promotion of the regional pharmaceutical innovation and manufacturing industry.[253] But in July 2022, the month after the TRIPS-waiver was adopted, the EAC found that, even though the pharmaceutical manufacturing landscape in the region was rapidly growing, EAC Partner States still had to import 70% of pharmaceutical requirements and were completely dependent on imports of vaccines and active pharmaceutical ingredients.[254]

The EAC's policy has been criticised for its one-dimensional approach focusing mainly on the reduction of the prices of medicines while neglecting the adverse effects of the measures on the domestic economic climate for investments in the development and production of the required medicines.[255] In line with this criticism, the EAC, somewhat ironically, identified weak intellectual property regimes as well as inadequate frameworks to support innovation and technology transfer as main factors for the regions limited progress in the health technologies R&D sector.[256]

Initially it was mentioned that COVID-19 medicines and vaccines were developed and produced primarily by the pharmaceutical industry of the developed countries and exported to the rest of the world. In the light of the facts discussed above, it is highly unlikely that the TRIPS waiver, even if it had been adopted in October 2020 when the first proposal was tabled,

[251] The DRC, also an LDC, acceded to the EAC Treaty on 8 April 2022 and became a full member on 11 July 2022; EAC, 'About the EAC: EAC Partner States' <www.eac.int/eac-partner-states/drcongo> accessed on 3 December 2023.
[252] EAC, 'Regional Intellectual Property Policy on the Utilisation of Public Health-Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation' (February 2013) 11 <https://ipaccessmeds.southcentre.int/wp-content/uploads/2019/12/EACTRIPSPolicy.pdf> accessed on 3 December 2023.
[253] ibid 11.
[254] EAC, 'EAC Pharmaceutical Manufacturing', Policy Brief (July 2022) available at <www.eac.int/documents> accessed on 3 December 2023.
[255] Soyeju and Wabwire (n 248) 167-68.
[256] AC, 'East African Community Medicines and Health Technologies Strategic Plan (2018-2022)' (February 2018) 19, available at <www.eac.int/documents> accessed on 3 December 2023.

would have allowed LDC Members, such as the EAC Partner States, for the production of new, technologically sophisticated COVID-19 vaccines such as the MRNA-types from Moderna and Pfizer/BioNTech. Even if it were true that other, more traditional vaccine technologies could be easily reproduced,[257] as building-up pharmaceutical production capacities requires time, resources and expertise, Members without manufacturing capacities could probably not have built them in short time.[258] Thus, only those Members with established generic producers could ramp up vaccine production. Among the waivers proponents were Members with big generic drug industries, especially India,[259] thus it is not surprising that incentivising R&D was not a main concern for them and the prospect of making available the patent protected manufacturing processes and components for vaccine production was a strong incentive for the adoption of a broad TRIPS waiver.

Against this backdrop, it becomes evident that a waiver on IPR protection can only lead to a higher global production of vaccines and lower prices for a certain period of time, but it is doubtful that it would be beneficial for the development of regional pharmaceutical sectors in DCs.

4.4. IPRs are no barrier to the access to vaccines

Finally, the opponents of the TRIPS waiver have denied that the TRIPS Agreement in its current form posed an obstacle to equal and fair distribution to medicines and vaccines. In addition to fostering R&D, they have highlighted their own donations of medical supply and vaccines as well as the multitude of solidarity initiatives that have emerged on the international level.[260] Early in the pandemic, international organisations and private charitable organisations began to form alliances to support the development of COVID-19 vaccines, raised enormous sums and eventually introduced the WHO COVAX facility to raise vaccine shots for global distribution.[261] For example, the Access to COVID-19 tools Accelerator ('ACT-A')[262] has been very successful in raising and distributing diagnostics, therapeutics and vaccines. To this date, 1.96 billion doses of vaccine were delivered to 146 countries through COVID-19 Vaccines

[257] Rachel Thrasher, 'Why Innovation Would Survive a COVID-19 TRIPS Waiver' (IPWatchdog.com, 24 March 2021) <www.ipwatchdog.com/2021/03/24/innovation-survive-covid-19-trips-waiver/id=131194/> accessed 3 December 2023.
[258] Paquin and Plouffe-Malette (n 6) 266.
[259] Mossoff and Adalja (n 3) 2.
[260] General Council, 'Urgent Trade Policy Responses to the COVID-19 Crisis', Communication from the European Union to the WTO General Council, WT/GC/231 (4 June 2021) para 1.2; Council for TRIPS, 'Minutes of Meeting (n 73) paras 353-355.
[261] Chattu and others (n 149) 3.
[262] WHO, 'ACT-Accelerator: Areas of Work' <www.act-a.org/areas-of-work> accessed on 3 December 2023.

Global Access ('COVAX'), the famous vaccine branch of ACT-A.[263] The overwhelming majority of the donations came from Northern American and European countries.[264] Notably, although they all publicly opposed the TRIPS waiver, the five major pharmaceutical companies AstraZeneca, BioNTech, Janssen, Pfizer and Sanofi all partnered with COVAX.[265]

As mass production of COVID-19 gradually but rapidly increased, eventually it was argued that supplies were even exceeding demands, therefore the barrier to access to vaccination in some countries were no longer supply shortages but rather logistic bottlenecks, regulatory or trade barriers or even vaccine hesitancy.[266]

For example, in April 2021, it was reported that the Democratic Republic of the Congo had to re-deploy about half a million of COVID-19 vaccine doses to other African countries because national authorities were not able to administer them before their expiration date.[267] While this was at the peak of the pandemic, when vaccine supply was limited and the negotiations of the TRIPS waiver were in full progress, it is obvious that problems like these are not IP related and therefore could not have been solved through waiving Members' TRIPS obligations.

However, issues of this kind have not gone unnoticed by the international community. Initiatives designed to support countries facing non-supply related problems to reach their national vaccination targets have been established. The COVID-19 Vaccine Delivery Partnership ('CoVDP') was launched in January 2022 and is aiming at accelerating COVID-19 vaccination rates in those countries with the lowest vaccination rates thereby contributing to closing the vaccination gap between high- and low-income countries.[268]

In any case, the question of equal distribution of and access to COVID-19 vaccines cannot be viewed only through the narrow lens of the exclusiveness of patents stipulated by the international IPR rules. The barriers to effective vaccine administration to a population can be

[263] WHO, 'Global COVID-19 Access tracker' (updated on 3 May 2023) <www.covid19globaltracker.org/> accessed on 3 December 2023.
[264] Our World in Data, 'COVID-19 vaccine doses donated to COVAX' (as of 23 March 2022) <https://ourworldindata.org/grapher/covax-donations> accessed on 3 December 2023.
[265] Kohler, Wong and Tailor (n 82) 166-67.
[266] See statements of EU and UK in General Council, 'Minutes of the Meeting held in the Centre William Rappard and in the virtual format on 9-10 May 2022', WT/GC/M/198 (21 July 2022) paras 5.38-39, 5.57-58; see also Mossoff and Adalja (n 3) 6.
[267] Hereward Holland, 'Congo starts re-deployment of expiring COVID-19 vaccines to other African countries', *Reuters* (29 April 2021) <www.reuters.com/world/africa/congo-starts-re-deployment-expiring-covid-19-vaccines-other-african-countries-2021-04-29/> accessed on 3 December 2023.
[268] WHO, 'COVID-19 Vaccine Delivery Partnership: Frequently Asked Questions' (last updated in March 2023) <www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines/covid-19-vaccine-delivery-partnership/faq> accessed on 3 December 2023.

manifold. Initiatives like CoVDP could help to identify a countries specific situation and provide tailor-made support.

5. Conclusions

As has become evident by now, the relationship between IP rights, public health policies and the access to vaccines and medicines is a complex matter. In promotion of the desirable goal of equitable access to health products many arguments in favour of softening international IP protection have been broad forward. The counterarguments, favouring the protection and retention of the current system may seem overly pragmatic and even unethical sometimes. Even though it has become apparent that there are still some issues when it comes to the effective implementation of the special compulsory licencing system, it has never been the intention of the present paper to take on the seemingly Herculean task to finally determine whether a TRIPS waiver was necessary from a public health perspective or not. Now that the proponents have pushed through the adoption of the waiver, the new question arises what practical advantages in a legal sense they have gained.

As the analysis of the content of the 2022 Ministerial Decision has shown, the so-called TRIPS waiver is hardly a real waiver of any substantive obligation of WTO Members under the TRIPS Agreement.[269] The most important conditions of Article 31 TRIPS Agreement, namely the prerequisite to make efforts to obtain an authorisation from the right holder before a compulsory licence is granted and the restriction to supply only the domestic market, are substantially duplicated by the TRIPS waiver. While it does modify the formalities required by the (special) compulsory licencing system such as notification, packaging and labelling or publication requirements, it does not entirely discard of them. Thus, administrative burden is alleviated but not eliminated. Consequently, during the duration the Decision is in force Members will continue to be bound by the substantial provisions of the TRIPS Agreement and rely on the special compulsory licensing system according to Article 31bis. In other words, it must be doubted that the proponents of the TRIPS waiver have achieved what they desired, namely, to not be dependent on the rules of the existing TRIPS system in public health crises. The fundamental rule of the protection of IPRs, in contrast, has been affirmed.

The question whether the use of the TRIPS flexibilities is too complex for DC and LDC Members, one of the arguments brought forward by the waivers' proponents, would require further investigation. On the one hand, it is obvious that DC and LDC countries possess fewer resources and capacities to deal with the administrative requirements involved; on the other, these flexibilities have been used by DC and LDC Members for at least one decade now and in

[269] Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 637-38.

a significant number as well. Also, the Paragraph 6 system has been in place for almost two decades now, giving WTO Members a lot of time to put in place appropriate legislative frameworks and protocols to make efficient use of them. As the policy actions of the EAC have shown, the awareness of the system and its inherent potential as well as the willingness to make best use of it are certainly existing.

The waiver, in contrast, must now be implemented swiftly to be of benefit during the sustained challenges that COVID-19 might pose. And, unfortunately, for most Members this must happen in a state of national distress. In view of future pandemics, it is hard to see how this is preferable to a well-designed and efficient national framework for the issuance of compulsory licences in accordance with the TRIPS Agreement. Due to this fact and the experience of a painstakingly long negotiation process during the hight of the pandemic it seems that a waiver is not the instrument of choice for the WTO to tackle future crises.

The special compulsory licence system as introduced by the Doha Decision and its subsequent implementation measures was specifically designed to provide a way for generic producers to export to countries in need that lack manufacturing capacity.[270] It seems illogical to put aside this system the moment the situation, that it was designed to deal with, arises. Instead, a foresighted approach would be for all Members to carefully design and implement effective and quickly deployable national legal frameworks for the use of the existing flexibilities of the TRIPS Agreement. But due to limited resources, capacities and expertise, DC Members will need support to achieve this. Developed Members should assist them in line with their commitment to technical cooperation under the TRIPS Agreement.

Furthermore, the flexibilities under Articles 31 and 31bis TRIPS Agreement are certainly not perfect and require further tweaking to streamline the necessary formal requirements and facilitate the application of the system for Members. Alas, the negotiations on the waiver have revealed the WTO's ineptness for quick crises reaction as were demanded by some Members, NGOs and the global public in the course of the COVID-19 pandemic.[271] But instead of rapid crisis response, the WTO is the right multilateral forum for the development of such permanent adjustments on the basis of inclusive and well-grounded negotiations and with a medium- to long-term horizon for the implementation. In short, the WTO should focus on the improvement of the multilateral trade framework and the elimination of any obstacles it poses to the

[270] Paquin and Plouffe-Malette (n 6) 264.
[271] Mercurio and Upreti, 'From Necessity to Flexibility' (n 5) 641.

fulfilment of its underlying principles, as it cannot be expected to find quick solutions in emergency situations.

Instead, the international initiatives that were forged especially under the auspices of the WHO seemed to have proven effective in providing a quick public health response and disseminating COVID-19 medicines and vaccines to countries in need. They should be strengthened and established on a permanent basis because having such schemes in place already they might prove invaluable in view of future public health crises. Especially, if additionally, they can provide technical support and help struggling countries with administration of vaccines and medicines. The negotiations on an agreement on pandemic prevention, preparedness and response launched under the auspices of the WHO will raise great expectations in this regard.[272]

While the topic of voluntary licences or licensing agreements was not directly addressed by the TRIPS waiver, voluntary technology transfer also plays its role in the proliferation of knowledge and the access to health. The discussion has highlighted a synergetic interplay of licencing agreements and compulsory licencing suggesting that a combination of both will remain important in the future. However, an investigation into current practice of concluding licencing agreements with pharmaceutical partners in DCs should be conducted in order to find out more about any alleged abuse.

To conclude with a final observation, the debate about the necessity and the effectiveness of the TRIPS waiver has abated with the moment of its adoption, only leaving behind the questions of what to do with it and what to learn from it. Unfortunately, a new and similar debate is already in progress, revolving around the extension of the TRIPS waiver to diagnostics and therapeutics and it threatens to become another apple of discord.

[272] WHO, 'Countries begin negotiations on global agreement to protect world from future pandemic emergencies', Press Release (3 March 2023) <www.who.int/news/item/03-03-2023-countries-begin-negotiations-on-global-agreement-to-protect-world-from-future-pandemic-emergencies> accessed on 3 December 2023.

Abstract

This paper critically examines the role of the WTO Ministerial Decision of 17 June 2022, known commonly as the COVID-19 TRIPS waiver, in furthering the global effort to ensure equal and just access to COVID-19 vaccines. It approaches the topic primarily from a legal point of view and focusses on scrutinising the actual legal flexibility the COVID-19 TRIPS waiver provides to WTO Members. Investigating into the available WTO and other international organisations' documents, legal instruments and scholarly writings on the subject of COVID-19 and IPRs, this issue is tackled in three parts.

In the first part, those provisions of the TRIPS Agreement that form the relevant international legal framework for the protection of vaccine patents are thoroughly analysed. Furthermore, the paper explains what permanent built-in flexibilities of the TRIPS Agreement exist that enable WTO Members to allow for the use of patented inventions in their territory – with and without the patent holder's consent.

The second part deals with the Ministerial Decision of 17 June 2022 itself by first tracing the major steps during the negotiations within the WTO and then discussing its scope, content and legal implications in detail. The paper finds that the TRIPS waiver is technically not a real waiver in the sense of the WTO legal foundations and that the additional leeway it provides to WTO Members is limited. Nonetheless, it highlights those flexibilities that WTO Members actually gained.

Finally, a third and last part outlines the main arguments brought forward during the negotiations by proponents as well as opponents of the TRIPS waiver and compares them with each other. Also, these arguments are confronted with other facts and research on the debate on IPRs and public health in general, and the role of the WTO in the COVID-19 pandemic specifically.

Concluding the research on the COVID-19 TRIPS waiver, the paper finds that the arguments brought forward in support of a TRIPS waiver have only been addressed to a very limited extent, especially concerning the alleged insufficiencies of the TRIPS Agreement and the complexities of applying the flexibilities it contains. Instead, the Ministerial Decision of 17 June 2022 has reaffirmed the WTO's commitment to the protection of IPRs and the principles of the TRIPS Agreement.

Kurzbeschreibung

Diese Arbeit untersucht die Rolle des WTO-Ministerbeschlusses vom 17. Juni 2022, allgemein bekannt als *COVID-19 TRIPS waiver*, bei der Umsetzung eines fairen Zugangs aller Staaten zu COVID-19-Impfstoffen. Sie konzentriert sich dabei auf die Untersuchung des zusätzlichen rechtlichen Spielraums, den der *TRIPS waiver* den WTO-Mitgliedern einräumt. Das Thema wird in drei Teilen behandelt und stützt sich auf die Untersuchung der verfügbaren Dokumente der WTO und anderer internationaler Organisationen, der relevanten WTO-Rechtsgrundlagen und wissenschaftlicher Schriften zum Thema COVID-19 und geistige Eigentumsrechte.

Im ersten Teil werden die Bestimmungen des TRIPS-Abkommens, die den internationalen Rechtsrahmen für den Schutz von Impfstoffpatenten bilden, eingehend analysiert. Darüber hinaus wird erläutert, welche dauerhaften Flexibilitäten das TRIPS-Abkommen bereits enthält, um den WTO-Mitgliedern zu ermöglichen, die Nutzung patentierter Erfindungen – mit und ohne Zustimmung des Patentinhabers – in ihrem Hoheitsgebiet zuzulassen.

Der zweite Teil befasst sich mit dem Ministerbeschluss vom 17. Juni 2022, indem zunächst die wichtigsten Schritte während der Verhandlungen innerhalb der WTO dargelegt werden und dann Geltungsbereich, Inhalt und rechtliche Auswirkungen des Instruments im Detail erörtert werden. Dabei kommt die Arbeit zum Schluss, dass der *TRIPS-waiver* technisch gesehen kein echter *waiver* im Sinne der WTO-Rechtsgrundlagen ist, und dass der zusätzliche Spielraum, den er den WTO-Mitgliedern bietet, begrenzt ist. Nichtsdestotrotz werden jene Flexibilitäten hervorgehoben, die die WTO-Mitglieder dennoch dazugewinnen.

In einem dritten und letzten Teil werden schließlich die wichtigsten Argumente, die während der Verhandlungen von den Befürwortern, einerseits, und den Gegnern des *TRIPS waivers*, andererseits, vorgebracht wurden, dargelegt und einander gegenübergestellt. Außerdem werden sie anhand von Fakten und Forschungsergebnissen im Rahmen der Debatte über geistige Eigentumsrechte und öffentliche Gesundheit im Allgemeinen, sowie die Rolle der WTO in der COVID-19-Pandemie im Besonderen, überprüft.

Die Arbeit kommt zu dem Ergebnis, dass die Argumente, die zur Unterstützung eines *TRIPS waivers* vorgebracht wurden, nur in begrenztem Maße berücksichtigt wurden, insbesondere im Hinblick auf die angeblichen Unzulänglichkeiten des TRIPS-Abkommens und der Komplexität der darin enthaltenen Flexibilitäten. Tatsächlich bestätigte der Ministerbeschluss vom 17. Juni 2022 das Bekenntnis der WTO zum Schutz der Rechte des geistigen Eigentums und zu den Grundsätzen des TRIPS-Übereinkommens.

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