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ACCESS TO COVID-19 VACCINE: PATENTS VS. PEOPLE?

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Summary: The article is looking into the issue of global equitable access to Covid-19 vaccines from the perspective of intellectual property rights, in particular patents. The discussed topics include instruments that could potentially facilitate access to patent protected health technologies (Covid-19 vaccines). Some of them are non-voluntary in nature, like the compulsory licenses in accordance with the TRIPS Agreement and others rely on the voluntary participation of the pharmaceutical industry, such as the C-TAP and the Medicines Patent Pool. The article also explores the controversial initiative regarding an "intellectual property waiver" proposed by a number of WTO members.

Keywords: Covid-19, vaccine, intellectual property, patents, TRIPS Agreement, intellectual property waiver, compulsory licence, C-TAP, Medicines Patent Pool.

1 Introduction

On the day, the research for this article was concluded, the World Health Organisation (hereinafter: WHO) announced 115 289 961 confirmed cases of Covid-19 and 2 564 560 deaths in 223 countries, areas or territories around the world.[1] These figures are daunting then there hasn't even been a year since the WHO declared on 11 March 2020 the coronavirus disease 2019 (Covid-19) to be a pandemic[2]. However, not only our health and lives have been in constant jeopardy since 2020, but also the state of the global economy. The International Monetary Fund estimated in June 2020 that COVID-19 could cost the world economy $12 trillion up to the end of 2021.[3]

1 World Health Organization. Coronavirus disease (COVID-19) pandemic, 5 March 2021. [online]. Available at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019> Accessed: 05.03.2021.

2 World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19 – 11 March 2020, 11 March 2020. [online]. Available at: <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020> Accessed: 02.12.2020.

3 International Monetary Fund. Reopening from the Great Lockdown: Uneven and Uncer-

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However, in December 2020 a ray of light appeared on the horizon in form of the first Covid-19 vaccine being approved[4] and a number of others followed. Nevertheless, as the vaccine roll-out has begun, a brand new issue has emerged – the one of global equitable access to it (so-called "vaccine equity"). Oxfam International stated already in September 2020, based on the analysis of data on the deals that pharmaceutical companies and vaccine producers have made with nations around the world at that point for then five leading vaccine candidates, that wealthy nations (13 percent of the world's population) have already secured more than half (51 percent) of the promised doses.[5] Furthermore, this international agency also warned that same companies do not have the capacity to make sufficient vaccines for everyone who needs them.[6] An indicator for the issue of access to vaccines was already given in the WHO Draft Resolution on Covid-19 Response,[7] which didn't recognise the vaccines to be a "public health good", but instead acknowledged "the role of extensive immunisation against COVID-19 as a global public good for health in preventing, containing and stopping transmission in order to bring the pandemic to an end, once safe, quality, efficacious, effective, accessible and affordable vaccines are available". At the 148th WHO Executive Board held in January 2021, the Director-General, Dr Tedros Adhanom Ghebreyesus, strongly criticised the inequality of vaccine distribution in the world.[8] In his opening remarks,[9] he addressed the practice of some coun-

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tain Recovery, 24 June 2020. [online]. Available at: <https://blogs.imf.org/2020/06/24/reopening-from-the-great-lockdown-uneven-and-uncertain-recovery/> Accessed: 27.12.2020.

4 The Pfizer/BioNTech was the first Covid-19 vaccine that received authorisation for emergency use by the U.S. Food and Drug Administration on 11 December 2020, followed by the European Medicines Agency that recommended the grant of a conditional marketing authorisation for this vaccine on 21 December 2020. Currently, there are 74 vaccines in clinical trials on humans and 21 have reached the final stages of testing. See: ZIMMER, Carl, CORUM, Jonathan, WEE, Sui-Lee. Coronavirus Vaccine Tracker. The New York Times, 5 March 2021. [online]. <Available at: https://www.nytimes.com/interactive/2020/science/coronavirus-vaccine-tracker.html> Accessed: 06.03.2021.

5 Oxfam International. Small group of rich nations have bought up more than half the future supply of leading COVID-19 vaccine contenders, 17 September 2020. [online]. Available at: <https://www.oxfam.org/en/press-releases/small-group-rich-nations-have-bought-more-half-future-supply-leading-covid-19> Accessed: 21.12.2020.

6 Ibid.

7 World Health Organization. Seventy-third WHO Assembly. Agenda item 3, COVID-19 response. Draft resolution, 18 May 2020. [online]. Available at: <https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf> Accessed: 12.12.2020.

8 'T HOEN, Ellen. The elephant in the room at the WHO Executive Board, 22 January 2021. [online]. Available at: <https://medicineslawandpolicy.org/2021/01/the-elephant-in-the-room-at-the-who-executive-board/> Accessed: 25.01.2021.

9 World Health Organization. WHO Director-General's opening remarks at 148th session of the Executive Board, 18 January 2021. [online]. Available at: *<https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board>*. Accessed: 25.01.2021.

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tries and companies to prioritise bilateral deals and go around COVAX,[10] which results in driving up the prices and delays in COVAX deliveries. Furthermore, he pointed out that most manufacturers have opted for regulatory approval of the vaccines in high-income countries, rather than submitting full dossiers to WHO. Also, he urged the producers to allow countries with bilateral contracts to share doses with COVAX and to prioritise supplying COVAX rather than new bilateral deals. Also the Members of the European Parliament expressed during the plenary debate in January 2021,[11] on the EU's strategy on Covid-19 vaccinations, the need for more solidarity as well as transparency regarding vaccine contracts with pharmaceutical companies. Only a few days later, the EU Commissioner for Health and Food Safety issued a press statement[12] communicating, that the company AstraZeneca[13] unexpectedly informed the European Commission and the member states that it "intends to supply considerably fewer doses in the coming weeks than agreed and announced". And this is not the first vaccine manufacturer, that is delivering with delays.[14] The Commissioner stressed that the development with regard to AstraZeneca is unacceptable, since the EU prefinanced the development and production of the particular vaccine and expects ordered doses to be delivered and the contract to be fully fulfilled. Furthermore, she informed that an establishment of an "export transparency mechanism", providing that all vaccine manufactures in the EU will be obliged to give early notification on the intent to export vaccines to third countries (with the exception of humanitarian deliveries), has been proposed by the Commission to the 27 member states of the vaccine Steering Board.

10 COVAX represents the "vaccine pillar" of the Access to COVID-19 Tools (ACT) Accelerator, which was established by the WHO, the European Commission and France in April 2020. See: GAVI. COVAX explained, 3 September 2020. [online]. Available at: <https://www.gavi.org/vaccineswork/covax-explained> Accessed: 17.01.2021.

11 European Parliament. News. Covid-19 vaccinations: more solidarity and transparency needed, 19.01.2021. [online]. Available at: <https://www.europarl.europa.eu/news/en/headlines/society/20210114STO95642/covid-19-vaccinations-more-solidarity-and-transparency-needed> Accessed: 25.01.2021.

12 European Commission. Press statement by Commissioner Kyriakides on vaccine deliveries and on the vaccine export transparency scheme, 25 January 2021. [online]. Available at: <https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_211> Accessed: 26.01.2021.

13 COLLIS, Helen. AstraZeneca: Coronavirus vaccine deliveries to EU reduced. Politico, 22 January 2021. [online]. Available at: <https://www.politico.eu/article/astrazeneca-coronavirus-vaccine-deliveries-to-eu-reduced/> Accessed: 26.01.2021.

14 Also the deliveries of the Pfizer/BioNTech vaccine were cut, causing delays and halts of vaccination in some EU member states. See: BBC News. Coronavirus vaccine delays halt Pfizer jabs in parts of Europe, 23 January 2021. [online]. Available at: https://www.bbc.com/news/world-europe-55765556. Accessed: 26.01.2021. See also: DEUTSCH, Jillian, EDER, Florian, HERSZENHORN, David M. Enraged at AstraZeneca over shortfall, EU calls for vaccine export controls. Politico, 26 January 2021. [online]. Available at: <https://www.politico.eu/article/enraged-at-astrazeneca-over-shortfall-eu-calls-for-vaccine-export-controls/> Accessed: 26.01.2021.

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Apart from "hoarding of vaccines" or "vaccine nationalism" that have been detected as immense concerns regarding access to means for immunisation, also the intellectual property rights (hereinafter: IPR or IP), in particular patent rights, have been pinpointed as a major obstacle. This conclusion seems rather expected, since the story of antagonism between monopolistic patent rights, access to medicine (especially in low and middle-income countries) and public health is an old one. Hence, the question with this regards is, does the solution to Covid-19 crisis and the problem of easy, fast, equitable and affordable access to health products and technologies necessary for its prevention and treatment lie in unrestricted access for everyone to all drugs, vaccines, medical supplies, data etc. that would in other circumstances be undoubtably protected with one or a number of IPRs (patens, copyright, industrial design etc.)? At first glance and without further contemplation, the answer is a pretty straight-forward: "Yes!" But is it actually so simple? Or, are IPRs on said products and technologies enforced in the spirit of solidarity and in a flexible and responsible manner, which strongly takes into account not only the national, but global interests of public health, in fact the true and right path to master this worldwide medical crisis?

On that account, the aim of this article is to look into the relation between IPRs and the issue of access to, in particular, Covid-19 vaccines. While doing so, we will examine the current instruments of international trade law serving the purpose of creating balance between exclusive patent rights and interest of public health (compulsory licenses), already existent and newly established platforms for facilitating licensing of protected pharmaceutical inventions (C-TAP and Medicines Patent Pool), and the initiative on waiving IPRs within the World Trade Organization (hereinafter: WTO).

2 IPRs and access to essential health technologies

The subject matter of a number of IPRs is potentially the key to resolution of the Covid-19 crisis. For example, medical products (e.g. protection equipment, drugs and vaccines protected by patents), technologies (e.g. contact tracking software protected by copyright) and labelling (covered by trade marks that safeguard medical practitioners and patients against potential confusion)[15] play a crucial role in combating the pandemic. The question is, is the subject matter of IPRs a possible solution, but the IPRs themselves the barrier for accessing that solution? In June 2020, the perspective of the World Intellectual Property Organization (hereinafter: WIPO) on this topic was more then clear, since its, then, Director General explicitly stated, how there "does not appear to be any evidence that IP is a barrier to access to vital medical preventive measures, such

15 World Trade Organization. The TRIPS Agreement and COVID-19 Information Note, 15 October 2020, p. 2. [online]. Available at: <https://www.wto.org/english/tratop_e/covid19_e/trips_report_e.pdf> Accessed: 04.12.2020.

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as vaccines, or to treatments or cures"[16]. However, at that point, there were still no developed and approved vaccines for Covid-19, which is now the case.

It's evident that the pandemic directed a spotlight toward the IPRs, in particular patents. Perhaps even the strongest believers in their justification and necessity have been questioned in their faith in face of the pandemic and the current troubles with access to vaccines. But is there a reason for that? As a matter of fact, we haven't actually learned anything new last and this year, but only received a "front row" perspective and a reminder on the nature of IPRs. They don't have the goal to introduce walls or barriers per se. They are simply established as private rights by nature. Consequently, as a rule, they represent absolute, timely limited monopolies, which give their owners the exclusivity to decide how to manage and exploit them. As such, they create incentives for future innovation and research. However, in order to create a balance of interest, these private rights can actually be constrained by public interest and the instruments for that on the international level are already in place. The only particularity of the current situation is – the stakes of the global public health interest have never been so high.

The Covid-19 pandemic represents a game-changer on so many different levels. While historically research and development activities in the pharmaceutical sector in high-income countries were focused on the health priorities in those countries, the middle and low-income countries didn't have that privilege with regard to medicines relevant for their specific health priorities.[17] Today, we all sit in the same boat of lockdowns, increasing numbers of infections and deaths and all due to a common health threat – Covid-19. Regardless of the same health priority, the issue of restricted availability of essential medications and vaccines remains similar. But, are IPRs to blame for this current development, in particular the lack of equity when it comes to vaccine distribution?

If we take a closer look at patents, many argue that they result in high prices of health technologies and often unjustified so, since there is a misbalance between the necessary incentive for research and development (hereinafter: R&D) efforts and the actual (increased) drug prices.[18] The obvious solution to that is generic

16 GURRY, Francis. Intellectual property, innovation, access and COVID-19. WIPO Magazine, June 2020. [online]. Available at: <https://www.wipo.int/wipo_magazine/en/2020/02/article_0002.html> Accessed: 11.01.2021.

17 BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 231. [online]. Available at: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3123108#> Accessed: 13.12.2020.

18 'T HOEN, Ellen. Covid-19 and the comeback of compulsory licensing. Medicines Law and Policy, 23 March 2020. [online]. Available at: <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/>. Accessed: 11.12.2020. 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 5. [online]. Available at: <https://haiweb.org/wp-content/

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production, which decreases the prices and enables broader access, but patents, as timely limited monopoly rights, are a hurdle in the way until they expire, unless there is voluntary licensing. However, not only patents, but also the limited disclosure of technical information and their safeguarding by patent holders through trade-secret-protected "know-how", as well as data exclusivity disable the generic production.[19]

It is evident, that the barrier potential of patents for unimpeded and timely access to affordable vaccines is existent. But can this obstacle be circumvented, without simultaneously questioning the existence and the necessity of the patent system, as a backbone of research and innovation activities and in particular in the era of Covid-19? Can a balance be established with this regard between private and larger public interests, voluntary collaboration and government interventions? The current answers are different, depending on to whom this question is directed toward. Consequently, we shall revisit previously existent and inspect newly proposed initiatives and mechanism for facilitating equitable access to vaccines, predominantly in the context of patent law, in order to attempt to give an answer to that question.

3 Non-voluntary countermeasures

Although the pharmaceutical industry repeatedly stated since the beginning of the pandemic, that when it comes to sharing of health technologies they developed, its voluntary participation is critical,[20] when one thinks of protection of public (health) interests in the context of patent rights, compulsory licenses are the first instrument, that comes into ones mind. In particular, with regard to pharmaceutical patents. This traditional mechanism for limiting patent rights has also gained in popularity in the era of Covid-19. Somewhat in practice,[21] but

uploads/2016/07/Private-Patents-Public-Health.pdf> Accessed: 21.12.2020.

19 BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 237.

20 BRACHMANN, Steve. WHO's C-TAP Initiative Pushes for Non-Exclusive Global Licensing Amid Pharma Industry Concerns. IPWatchdog.com, 31 May 2020. [online]. Available at: <https://www.ipwatchdog.com/2020/05/31/whos-c-tap-initiative-pushes-non-exclusive-global-licensing-amid-pharmaceutical-industry-concerns/id=122041/> Accessed: 17.12.2020.

21 The mood toward issuing compulsory licensing for Covid-19 related health technologies has shifted in a number of countries (e.g. Chile, Israel, Ecuador) already very early on in the pandemic. See: 'T HOEN, Ellen. Covid-19 and the comeback of compulsory licensing. Medicines Law and Policy, 23 March 2020. E.g. Israel issued its first ever government-use licence for the generic version of the HIV/AIDS antiretroviral called Kaletra, although at that time the positive effect on Covid-19 patients was not even confirmed. See: URIAS, Eduardo, RAMANI, Shyma V. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. Journal of International Business Policy, 2020, no. 3, p. 379 et seq. [online]. Available at: <*https://link.springer.com/article/10.1057/s42214-020-00068-4*> Accessed: 04.01.2021.

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mostly in discussions on the topic of access to health technologies. Apart from compulsory licenses, also more restrictive, and one could say also rather invasive, non-voluntary measures have been proposed on the international level, to remove the potential obstacles to that access, caused by patent rights and IPRs in general.

3.1 Compulsory licenses

Compulsory license is an "umbrella term" for a number of non-voluntary authorisations to use a patent, including e.g. government use, mandatory licences and statutory licences.[22] If a compulsory license is invoked, the patent owner doesn't loose his rights over the patent and is entitled to a compensation for copies of the products made under such compulsory licence. The reasoning behind this instrument is predominantly twofold. On one hand, it's to motivate the effective use of the patented innovation. The latter in the sense, that a territory covered by patent protection is sufficiently supplied with the patented product.[23] On the other, it's to prevent the abuse of the monopoly position granted to the patentee in the sense of e.g. unfair licensing practices, or blocking the use of other patents. As a result, competition is encouraged, the local pharmaceutical industry is supported and access is provided to, often, life saving medication.[24] They also represent a powerful policy tool, since sometimes even a "threat" of issuing a compulsory license can have an effect on patent holder, in the sense of change of heart when it comes to voluntary licensing or price reduction.[25] The questions are, would the use of this mechanism have a positive influence on the access to Covid-19 vaccines and what are the preconditions for its invocation?

First of all, this instrument is not a novelty in the international patent system, but a measure as old, as that system itself, which has, however, evolved over time.[26] The latter was firstly introduced on an international level in Art. 5A of the Paris Convention.[27] However, compulsory licenses gained in impor-

22 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 50, fn. 83.

23 COHEN, Shlomo. Compulsory Licensing of Patents – The Paris Convention Model. IDEA: The Journal of Law and Technology, 1979, vol. 20, no. 2, p. 153, 156.

24 MURTHY, Divya. The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health. American University International Law Review, 2002, vol. 17, no. 6, p. 1307 et seq. [online]. Available at: <https://core.ac.uk/download/pdf/235401856.pdf> Accessed: 27.12.2020.

25 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 71.

26 COHEN, Shlomo. Compulsory Licensing of Patents – The Paris Convention Model. IDEA: The Journal of Law and Technology, 1979, vol. 20, no. 2, p. 153, 153 et seq.

27 Paris Convention for the Protection of Industrial Property of March 20, 1883, as revised at Brussels on December 14, 1900, at Washington on June 2, 1911, at The Hague on November 6, 1925, at London on June 2, 1934, at Lisbon on October 31, 1958, and at Stockholm on July 14, 1967 and as amended on September 28, 1979.

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tance with their introduction into the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter: TRIPS Agreement or TRIPS) as one of the flexibilities in the field of patent protection.[28] The TRIPS does not use the term "compulsory license" but instead in Art. 31 talks of "Other use without authorisation of the right holder", which can also mean a government use ("public non-commercial use").[29] Compulsory licenses use can be used by all World Trade Organization's (hereinafter: WTO) member states for patents in any field of technology, although there is a special interest in their application for pharmaceutical patents.[30] Hence, members may grant such licences for health technologies, such as medicines, vaccines and diagnostics, as well as any other product or technology needed to combat Covid-19,[31] provided that a set of prior conditions from Art. 31 is fulfilled. The developed WTO member states define the latter as liberal, while the developing and least-developed ones (hereinafter: LDC) consider them to be restrictive.[32] Furthermore, the TRIPS Agreement does not specifically list the reasons that might be used to justify compulsory licensing, hence the members are free to determine the grounds for granting them.[33] Depending on the member state, a variety of reasons can apply. Some countries include in their law "high prices of medicines", or a "lack of access to medicines" as grounds for compulsory licences. [34]

If a WTO member state does contain in its national law such possibility, conditions that need to be met in order to invoke a compulsory license, set forth in Art. 31, include a case-by-case grant,[35] prior efforts for obtaining authorisa-

28 World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights, in effect as of 1 January 1995. [online]. Available at: <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> Accessed: 02.12.2020.

29 World Trade Organization. TRIPS and pharmaceutical patents: fact sheet. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm00_e.htm> Accessed: 29.11.2021. See also: SAHA, Subhasis. Patent law and TRIPS: Compulsory licensing of patents and pharmaceuticals. Journal of the Patent and Trademark Office Society, 2009, vol. 91, no. 5, p. 369. See also: FORD, Sara M. Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents. American University of International Law Review, 2000, vol. 15, no. 4, p. 958.

30 World Trade Organization. Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Factsheet. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/tripsfacsheet_e.htm> Accessed: 14.12.2020. See also: World Trade Organization. TRIPS and pharmaceutical patents: fact sheet.

31 World Trade Organization. The TRIPS Agreement and COVID-19 Information Note, 15 October 2020, p. 9.

32 SAHA, Subhasis. Patent law and TRIPS: Compulsory licensing of patents and pharmaceuticals. Journal of the Patent and Trademark Office Society, 2009, vol. 91, no. 5, p. 369.

33 World Trade Organization. Compulsory licensing of pharmaceuticals and TRIPS. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> Accessed: 24.11.2020.

34 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 51.

35 SPERBACK, Ashley E. A Mathematical Solution to the Sine of Madness That Is Pharma-

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tion from the right holder on reasonable commercial terms and conditions and such efforts not beeing successful within a reasonable period of time and that such use is predominantly for the supply of the domestic market of the member state (Art. 31 (a), (b) and (f)). However, there is no requirement to first seek a voluntary licence in case of a national emergency or in other circumstances of extreme urgency or in cases of public non-commercial use (Art. 31 (b)). The TRIPS Agreement does not define the concept of "national emergency", which may lead to different interpretations by the WTO members.[36] The scope and duration of compulsory licenses is limited to the purpose for which they are authorised, they are non-exclusive, as a rule non-assignable and the right holder is entitled to an adequate remuneration in the circumstances of each case (Art. 31 (c), (d), (e) and (h)). Both the decision on the grant of a compulsory license and on the remuneration are subject to judicial review or other independent review by a distinct higher authority in the particular member state (Art. 31 (i) and (j)). Furthermore, compulsory licenses are liable to be terminated, if and when the circumstances which led to it cease to exist and are unlikely to recur (Art. 31 (g). Finally, the TRIPS Agreement also provides for licences to remedy anti-competitive practices (ARt. 31 (k) and for compulsory cross-licensing (Art. 31 (l)).

So far, this TRIPS flexibility has been predominantly used for the procurement of HIV medicines.[37] However, from 2008 onward, some governments have also started using them in order to gain access to affordable treatments for other diseases (e.g. cancer and hepatitis C), but have faced a certain amount of opposition from inside those countries (e.g. concerns about trade sanctions), as well as externally (e.g. pharmaceutical industry).[38] Notwithstanding their benefits, compulsory licenses also have to an extent (unproven) reputation of undermining R&D investments[39] and some countries refrain from invoking this mechanism out of precaution and, perhaps even, fear to discourage foreign investors and create an impression of not respecting IPRs.[40] Hence, although the use of com-

ceutical Compulsory Licensing under the TRIPS Agreement and the Doha Declaration. Marquette Intellectual Property Law Review, 2019, vol. 23, no. 1, p. 29.

36 MURTHY, Divya. The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health. American University International Law Review, 2002, vol. 17, no. 6, p. 1320.

37 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 63.

38 Ibid, p. 66 et seq.

39 URIAS, Eduardo, RAMANI, Shyma V. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. Journal of International Business Policy, 2020, no. 3, p. 372 et seq. and 380. See also: BACCHUS, James. An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines, 16 December 2020. [online]. Available at: <https://www.cato.org/publications/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid> Accessed: 28.12.2020.

40 SAHA, Subhasis. Patent law and TRIPS: Compulsory licensing of patents and pharma-

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pulsory licenses for limiting patent rights has the potential to enhance access to Covid-19 vaccines through generic manufacturing, the past "atmosphere" surrounding this instrument might hinder their invocation. Moreover, Art. 31 is mainly of use to the countries who have the necessary manufacturing capacities, since it predominantly serves for the supply of the domestic market (Art 31 (f)) and not for export to countries, which don't have those capacities (mostly developing and the LDCs), which is not beneficial in the current situation.[41]

However, this "flaw" in the system of TRIPS flexibilities in the field of patent rights has been detected much earlier, during the HIV/AIDS public health crisis, which led to the introduction of special compulsory licence system for export. In a simplified manner expressed, this system waived the condition in Article 31(f) that a compulsory licence needs to be predominantly used for the supply of the domestic market. The latter instrument could potentially also give its contribution to the ultimate goal of ensuring broad and equitable access to vaccines.

3.1.1 Special compulsory licensing system

The Declaration on TRIPS Agreement and public health (Doha Declaration)[42] of 14 November 2001 represented on one hand a clear response to the abovementioned public health concerns and its consequences on the developing countries and on the other, a tool to overcome patent barriers in this context.[43] Then, although the TRIPS Agreement already included flexibilities to patent rights, a number of questions were raised, whether they were sufficient to support also public health issues and promote affordable access to medicines.[44] This declaration has its relevance also in the light of the Covid-19 pandemic. A particular importance of its paragraph six manifests itself in the recognition, that countries with "insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under

ceuticals. Journal of the Patent and Trademark Office Society, 2009, vol. 91, no. 5, p. 372. See also: 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 66 et seq. See also: World Intellectual Property Organization. Draft reference document on the exception regarding compulsory licensing, 21 May 2019, p. 49 et seq. [online]. Available at: <https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf> Accessed: 24 January 2021.

41 SPERBACK, Ashley E. A Mathematical Solution to the Sine of Madness That Is Pharmaceutical Compulsory Licensing under the TRIPS Agreement and the Doha Declaration. Marquette Intellectual Property Law Review, 2019, vol. 23, no. 1, p. 29.

42 World Trade Organization. Declaration on the TRIPS agreement and public health adopted on 14 November 2001. WT/MIN(01)/DEC/2, 20 November 2001. [online]. Available at: <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> Accessed: 04.01.2021.

43 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 8.

44 World Trade Organization. The separate Doha Declaration explained. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm> Accessed: 04.01.2021.

TRIPS Agreement". In other words, the flaw in the flexibility offered by Art. 31 (in particular Art. 31 (f)) of TRIPS was acknowledged, since a number of countries rely on importation of medicines, because they don't have local manufacturing capacities[45]. Furthermore, paragraph 7 of the Doha Declaration removed the obligation of LDCs to implement and apply Section 5 (Patents) and Section 7 (Protection of Undisclosed Information) of Part II of TRIPS with regard to pharmaceutical products, which also includes the obligation to enforce rights under these sections, until 1 January 2016. This waiver was extended in 2015 until 1 January 2033, or until such a date on which they cease to be a LDC, whichever date is earlier.[46] In the current context of the pandemic, this transition period has been put to use, for example, by generic manufacturers in Bangladesh, who have begun producing a generic version of drug remdesivir, used for treatment of Covid-19.[47]

The first step in the implementation of the "paragraph 6" of the Doha Declaration was the Decision of the General Council of 30 August 2003 ("interim waiver").[48] The Decision (para. 1) defined the terms "pharmaceutical product",[49] "eligible importing member" and "exporting member" and waived the obligation of the exporting member under Art. 31 (f) to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing member(s). It is important to underline, that a number of non-LDC members of the WTO, such es e.g. Israel and Korea, have notified the TRIPS Council on the application of this flexibility only in cases of "national emergency" or "other circumstances of extreme urgency".[50] Others (e.g. EU and its mem-

45 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 35.

46 World Trade Organization. General Council Decision of 30 November 2015. Least developed country members – obligations under Article 70.8 and Article 70.9 of the TRIPS Agreement with respect to pharmaceutical products. [online]. Available at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/L/971.pdf&Open=True> Accessed: 11.01.2021.

47 World Trade Organization, World Health Organization, World Intellectual Property Organization. Promoting Access to Medical Technologies and Innovation. Second edition. Intersections between public health, intellectual property and trade, 2020, p. 2. [online]. Available at: <https://www.wto.org/english/res_e/booksp_e/extract_who-wipo-wto_2020_e.pdf> Accessed: 09.12.2020.

48 World Trade Organization. General Council. Decision of the General Council of 30 August 2003. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, 1 August 2003. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> Accessed: 05.01.2021.

49 Any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognised in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

50 HU, Weinian. Compulsory Licensing and Access to Future COVID-19 Vaccines. CEPS Research Report, no. 2020, 2 July 2020, p. 6. [online]. Available at: <https://www.ceps.eu/wp-content/uploads/2020/07/RR2020-2_Compulsory-licensing-and-access-to-future-

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ber states, Japan and Canada), have completely opted-out of this possibility.[51] The question at this point is, in case there is a political will and a necessity during the Covid-19 pandemic, would they be able to opt back in?[52] In addition, with regard to the notification that needs to be made by the importing (non-LDCs) member, it's relevant to clarify, that the latter is not for the purpose of approval by a WTO body.[53] The Decision also defines the conditions,[54] that the compulsory licence issued by the exporting member under the Decision must contain and stipulates that the exporting member must notify the Council for TRIPS of the grant of the license, including the latter conditions in specific. Considering the "adequate remuneration", pursuant to Art. 31 (h) of the TRIPS Agreement, the Decision stipulates that where a compulsory licence is granted by an exporting member under the Decision, that remuneration shall be paid in that member. Where a compulsory licence is granted for the same products in the eligible importing member, the obligation of that member under Article 31(h) shall be waived in respect of those products for which remuneration is paid in the exporting member in accordance with the Decision. Finally, para. 10 of the Decision explicitly states that members shall not challenge any measures taken in conformity with the provisions of the waivers contained in the Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

With regard to the assessment of the manufacturing capacities in the pharmaceutical sector the situation is different for LDCs and other eligible importing members. For the former, it is deemed that those capacities are insufficient

covid19-vaccines.pdf> Accessed: 04.12.2020.

51 SPERBACK, Ashley E. A Mathematical Solution to the Sine of Madness That Is Pharmaceutical Compulsory Licensing under the TRIPS Agreement and the Doha Declaration. Marquette Intellectual Property Law Review, 2019, vol. 23, no. 1, p. 38. See also: HU, Weinian. Compulsory Licensing and Access to Future COVID-19 Vaccines. CEPS Research Report, no. 2020, 2 July 2020, p. 6.

52 GROSSE RUSE-KHAN, Henning. Access to Covid-19 Treatment and International Intellectual Property Protection – Part I: Patent protection, voluntary access and compulsory licensing, 15 April 2020. [online]. Available at: <https://www.ejiltalk.org/access-to-covid19-treatment-and-international-intellectual-property-protection-part-i-patent-protection-voluntary-access-and-compulsory-licensing/> Accessed: 04.12.2020.

53 World Trade Organization. General Council. Decision of the General Council of 30 August 2003. Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, 1 August 2003, fn. 2.

54 Para. 2 (b): Only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production must be exported to the Member(s) which has notified its needs to the Council for TRIPS; products produced under the license must be clearly identified as being produced under the system set out in this Decision through specific labelling or marking (special packaging and/or special colouring/shaping of the products themselves), provided that such distinction is feasible and does not have a significant impact on price; and before shipment begins, the licensee shall post on a website the information on the quantities being supplied to each destination as referred to above and the distinguishing features of the product(s) referred to above.

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or non existent. For the latter, the provision of this criteria is established either in a way that the member in question has established that it has no manufacturing capacity, or after examining some manufacturing capacity, excluding any capacity owned or controlled by the patent owner, it has established that, it is currently insufficient for the purposes of meeting its needs. In other words, it is a matter of self-assessment of the individual country and neither subject to challenge by another member, nor to review or rejection by the TRIPS Council.[55] At this point, due to the global demand and only a hand full of approved Covid-19 vaccines, it is rather hard to find a country that has sufficient manufacturing capacities to do so.[56]

With the decision of the General Council from 6 December 2005 on the Amendment of the TRIPS Agreement[57] it was clearly expressed that the Decision of 2003 was supposed to become a permanent part of the TRIPS.[58] After two thirds of the WTO members accepted the Protocol amending TRIPS,[59] the first and so far the only amendment to TRIPS Agreement entered into force on 23 January 2017 consisting of new Art. 31bis and the Annex to the TRIPS Agreement after Art. 73. Furthermore, in order to be able to use this special compulsory licensing system for export, more than 50 WTO members, which are pharmaceutical exporting countries, have amended their national legislation accordingly.[60]

However, so far, the "paragraph 6 system" has only been used once by Rwanda as eligible importing and Canada as eligible exporting country in 2007[61] and the

55 HU, Weinian. Compulsory Licensing and Access to Future COVID-19 Vaccines. CEPS Research Report, no. 2020, 2 July 2020, p. 7.

56 GROSSE RUSE-KHAN, Henning. Access to Covid-19 Treatment and International Intellectual Property Protection – Part I: Patent protection, voluntary access and compulsory licensing, 15 April 2020.

57 World Trade Organization, General Council decision of 6 December 2005. Amendment of the TRIPS Agreement. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> Accessed: 14.12.2020.

58 SPERBACK, Ashley E. A Mathematical Solution to the Sine of Madness That Is Pharmaceutical Compulsory Licensing under the TRIPS Agreement and the Doha Declaration. Marquette Intellectual Property Law Review Marquette Intellectual Property Law Review, 2019, vol. 23, no. 1, p. 36.

59 World Trade Organization. Protocol Amending the TRIPS Agreement. Done at Geneva on 6 December 2005. Entry into force: 23 January 2017. Status of WTO Legal Instruments – 2021 edition. [online]. Available at: <https://www.wto.org/english/res_e/booksp_e/sli_e/20TRIPSAmendment.pdf> Accessed: 05.01.2021.

60 World Trade Organization. Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Factsheet.

61 See: World Trade Organization. Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Factsheet. See also: 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 45 et seq. See also: SPERBACK, Ashley E. A Mathematical Solution to the Sine of Madness That Is Pharmaceutical Compulsory Licensing under the TRIPS Agreement and the Doha Declaration. Marquette Intellectual Property Law Review, 2019, vol. 23, no. 1, p. 33 et seq.

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mechanism has been subject to criticism as being cumbersome and complex.[62] Furthermore, the above-mentioned reluctance with regard to issuing compulsory licences[63] in general applies also to this system. Notwithstanding the latter, a newly found approval and support of compulsory licenses in general seems to be developing on the international level and in particular among developed states, which could even lead to "tipping the scale" in favour of use of this instrument during the course of the pandemic.

3.1.2 Change of attitude toward compulsory licensing

For example, the European Commission is evidently very cautiously shifting its course with regard to issuing compulsory licenses, which is evident in its Communication "Making the most of the EU's innovative potential", even if only "as a means of last resort and a safety net, when all other efforts to make IP available have failed."[64] This comes as quite a surprise and highlights the urgency of the current situation, since the Commission has a previous track record of opposing the actual use of TRIPS-flexibilities internationally, even if it proclaims its support for the Doha Declaration.[65] Furthermore, a glimpse of this "new approach" was also given in the EU Statements at the WTO General Council from December 2020, when referring to compulsory licenses under TRIPS as "absolutely legitimate tools for members in need, and as we are in the midst of this pandemic"[66].

Since in the EU compulsory licensing is mainly governed by national law, with the exception of Regulation (EC) 816/2006,[67] and an EU-wide compulsory

62 'T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 45 et seq.

63 See Section: 3.1. Compulsory licenses.

64 European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience, Brussels, 25.11.2020, COM(2020) 760 final, p. 12. [online]. Available at: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52020DC0760> Accessed: 09.01.2021.

65 'T HOEN, Ellen. Some Surprises in the European Commission's New Intellectual Property Strategy. Medicines Law and Policy, 2 December 2020. [online]. Available at: <https://medicineslawandpolicy.org/2020/12/some-surprises-in-the-european-commissions-new-intellectual-property-strategy/> Accessed: 21.12.2020.

66 Permanent Mission of the European Union to the World Trade Organization (WTO). EU Statements at the WTO General Council, 18 December 2020. [online]. Available at: <https://eeas.europa.eu/delegations/world-trade-organization-wto_en/90872/EU%20Statements%20at%20the%20WTO%20General%20Council,%20on%2018%20December%202020> Accessed: 13.01.2021.

67 Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. Official Journal of the European Union L 157 of 9 June 2006.

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licence is not an available option, the Commission states, that if all EU countries have effective systems for the application of this mechanism (e.g. by putting in place fast-track procedures in emergency situations), the EU wide collaboration could nevertheless have the same effect. So far the relevant national legislation of every member state includes provisions on compulsory licensing, however there are differences with regard to grounds for authorisation and the procedural framework.[68] In general, the Commission sees a need for a stronger co-ordination and information sharing between member states, e.g. on the duration of and royalties on any such licenses and even aims to explore with member states the possibility of creating an emergency co-ordination mechanism, to be triggered at short notice when they consider issuing a compulsory license.[69] As 't Hoen accurately stated,[70] an obvious gap in the this new approach of the Commission is the fact that EU member states have opted out of TRIPS Article 31bis mechanism, disabling so with the importation into the EU of health products, which are produced in another country under a compulsory licence and that they would need to opt-in again.[71]

The pharmaceutical industry has already reacted to this new strategy of the Commission. The European Federation of Pharmaceutical Manufacturers (EFPIA), raised its concerns with regard to potential coordinating compulsory licensing in the EU and stated that this mechanism doesn't represent an effective policy tool to create access and puts at risk the incentives to invest in medical innovation in the time of global health crisis.[72]

3.2 Potential TRIPS IP waiver

Although compulsory licenses are limiting patent rights, they don't expropriate them. Furthermore, they provide rather strict preconditions for their grant and involve a remuneration for the patent holder. Nevertheless, the pharmaceutical industry is not looking favourable upon them, even in the current situation of impeded access to vaccines and other Covid-19 health technologies. However,

68 HU, Weinian. Compulsory Licensing and Access to Future COVID-19 Vaccines. CEPS Research Report, no. 2020, 2 July 2020, p. 6.

69 European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience, Brussels, 25. 11. 2020, COM(2020) 760 final, p. 12.

70 'T HOEN, Ellen. Some Surprises in the European Commission's New Intellectual Property Strategy. Medicines Law and Policy, 2 December 2020.

71 See more detailed in Section: 3.1.1. Special compulsory licensing system.

72 BYRNE, Jane. Compulsory licensing is not an effective policy tool, warns EU biopharma group as it reacts to European IP action plan, 26 November 2020. [online]. Available at: <https://www.biopharma-reporter.com/Article/2020/11/26/Compulsory-licensing-is-not-an-effective-policy-tool-warns-EU-biopharma-group-as-it-reacts-to-European-IP-action-plan> Accessed: 22.12.2020.

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presently there are also other initiatives for facilitating access, which are way more invasive on patents and other IPRs, then this mechanism.

Namely, an interesting, but at the same time very controversial, strategy for enabling access was put forward by India and South Africa in the meeting of the Council for TRIPS in October 2020.[73] This initiative suggests that the Council for TRIPS recommends to the WTO General Council a waiver[74] from the implementation, application and enforcement of Sections 1 (copyright and related rights), 4 (industrial design), 5 (patents), and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of Covid-19.[75]

The initiative paper draw attention to the risk, that IPRs might create barriers for the timely access to affordable medical products (e.g. diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and drugs for the prevention and treatment).[76] Furthermore, whilst referring to some reports about IPRs hindering or potentially hindering timely provisioning of affordable medical products to the patients, it was pointed out, that there are significant concerns, how, in particular future vaccines and drugs, will be made available rapidly, in sufficient quantities and at affordable prices to meet global demand.[77] The initiative document also contains an Annex including the draft decision on the waiver.[78] The latter specifies that it shall not apply to the protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organisations under Article 14 of the TRIPS Agreement and that it's without prejudice to the right of LDC from paragraph 1 of Article 66[79] of

73 See Medecins Sans Frontieres (Access Campaign). Press Release supporting this initiative. [online]. Available at: <https://msfaccess.org/landmark-move-india-and-south-africa-propose-no-patents-covid-19-medicines-tools-during-pandemic> Accessed: 08.12.2020. See also: Medecins Sans Frontieres. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 1. [online]. Available at: <https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf> Accessed: 09.12.2020.

74 The possibility of waiver from obligations under the TRIPS Agreement in "exceptional circumstances" is regulated in Art. IX (3) and (4) of the Marrakesh Agreement Establishing the World Trade Organization of 15 April 1994. [online]. Available at: <https://www.wto.org/english/docs_e/legal_e/04-wto.pdf> Accessed: 02.12.2020.

75 World Trade Organisation. Council for Trade-Related Aspects of Intellectual Property Rights. 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, p. 2. [online]. Available at: <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> Accessed: 07.12.2020.

76 Ibid, p. 1.

77 Ibid, p. 1 et seq.

78 Ibid, p. 3 et seq.

79 In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create

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the TRIPS Agreement. Furthermore, according to the draft decision, the waiver should be reviewed by the General Council not later than one year after it is granted, and thereafter annually until the waiver terminates, in accordance with the provisions of paragraph 4 of Article IX of the WTO Agreement. Finally, it provides that the members shall not challenge any measures taken in conformity with the provision of the waiver contained in that decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism.

In other words, the latter proposed initiative is limited strictly to the circumstances and duration of the Covid-19 pandemic.[80] The consequence of this waiver would be that WTO members could choose to neither grant, nor enforce patents and other IPRs related to products, technologies and procedures related to Covid-19 (e.g. drugs, vaccines, diagnostics, masks, ventilators etc.).[81] The initiative was discussed during the TRIPS Council meeting[82] on 15–16 October 2020 and didn't experience support among the developed and some developing countries, but also some emerging markets.[83] However, over 370 intergovernmental and international civil society and other organisations, such as e.g. WHO and UNAID, expressed their support for the waiver.[84]

The countries, who opposed the waiver pointed out that there is no indication that IPRs constitute a barrier to accessing Covid-19 related medicines and

a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period (Art. 66 (1) TRIPS Agreement).

80 Medecins Sans Frontiers. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 2.

81 Ibid.

82 World Trade Organization. Members discuss intellectual property response to the COVID-19 pandemic. [online]. Available at: <https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm> Accessed: 28.11.2020.

83 In full support of the TRIPS waiver proposal, as of 16 October, are: Argentina, Bangladesh, Egypt, Indonesia, Mali, Mauritius, Mozambique, Nepal, Nicaragua, Pakistan, Sri Lanka, Tunisia, Venezuela and Holy See, whilst the Members of WTO, which opposed or did not support the proposal were: Australia, Brazil, Canada, EU, Japan, Norway, Switzerland, United Kingdom and United States. A number of states also welcomed and supported the general need for further discussions (e.g. China and Turkey). Furthermore, multiple intergovernmental and international civil society and other organisations, such as e.g. WHO and UNAID, expressed their support for the waiver. See Medecins Sans Frontieres. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 2.

84 Third World Network. Civil society letter supporting proposal by India and South Africa on waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19. [online]. Available at: <https://www.twn.my/title2/health.info/2020/hi201007.htm> Accessed: 02.12.2020.

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technologies.[85] Furthermore, they observed that the issues with rapid access to health products during the Covid-19 are more likely related to nonefficient and underfunded health care and procurement systems, as well as rising demand and lack of manufacturing capacity. Finally, they expressed the position, that even a limited suspension of IPRs would undermine the already taken collaborative steps in fighting the pandemic and that the existing IP system under TRIPS offers enough tools and flexibilities (Art. 30, Art. 31bis and Art 73(b)) for members to take measures to protect public health.[86]

On the other hand, the proponents of the waiver pointed out at, alleged, IP barriers created with regard to health products necessary for therapy, diagnostics and prevention of Covid-19.[87] Criticism is directed toward the pharmaceutical industry, claiming that since the beginning of the crisis it continued with the "business – as usual" practice, in the sense of meticulous safeguarding their IPRs, or by pursuing "secretive and monopolistic commercial deals" and excluding countries heavily affected by Covid-19".[88] Furthermore, the supporters of the TRIPS IPR-waiver underline, that "the pharmaceutical industry as a whole" isn't involved in the WHO Covid-19 Technology Access Pool (C-TAP)[89] initiative.[90]

85 World Trade Organization. Members discuss intellectual property response to the COVID-19 pandemic.

86 Ibid.

87 Medecins Sans Frontiers. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 6 et seq.

88 This statement in particular refers to the bilateral deals that the pharmaceutical corporation Gilead Sciences signed with a number of generic companies, which the advocates criticise due to generous public funding of the development of remdesivir (one of the candidate drugs for COVID-19 treatments) and to those agreements having the effect of excluding "nearly half of the world's population from its licensed territories". See: Medecins Sans Frontieres. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 4. According to information from Gilead Science, the voluntary licensing agreements have been signed with generic pharmaceutical manufacturers based in Egypt, India and Pakistan to manufacture remdesivir for distribution in 127 countries (nearly all low-income and lower-middle income countries, as well as a number of upper-middle- and high-income countries). Gilead also promised to donate the first 1.5 million doses. See: Gilead Sciences. Voluntary Licensing Agreements for Remdesivir. [online]. Available at: https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir. Accessed: 05.12.2020. See also: See: THRASHER, Rachel. TRIPS agreement: A waiver makes the COVID-19 vaccine more accessible. Open Access Government, 25 November 2020. [online]. Available at: <https://www.openaccessgovernment.org/covid-19-vaccine-3/98561/> Accessed: 08.12.2020.

89 See Section: 4.1. Covid-19 Technology Access Pool (C-TAP).

90 Medecins Sans Frontiers. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 4. [online]. Available at: <https://msfaccess.org/sites/default/files/2020-11/COVID_Brief_WTO_WaiverProposal_ENG_v2_18Nov2020.pdf> Accessed: 09.12.2020.

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Apart from that, the advocates of the waiver don't consider the waiver to be mutually exclusive with the existing TRIPS flexibilities. However, they think that the "case by case" / "product by product" approach required when using the instruments of Art. 31 and 31bis of TRIPS could be limiting during the pandemic.[91] Namely, the latter involve complex, long and costly administrative procedures, which results in slowing down the process of scaling up the production.[92] In the context of vaccines, the parallel has been drawn to the limitations, which, according to studies,[93] patents created to access to PCV13 and HPV vaccines. Furthermore, attention has been raised to a very intense patenting activity with regard to vaccine background IP (e.g. more than 100 patents on mRNA platform technologies that are used for COVID-19 vaccines), the fact that some vaccine companies (e.g. Pfizer/BioNTech) have shown no interest in licensing IPR-s to enable global manufacturing, whist others (e.g. AstraZeneca) insist on commercial secrecy when it comes to making the terms and conditions on IP licensing public. [94]

This trend of divided standpoints continued during the further informal meetings of the TRIPS Council on 20 November and 3 December,[95] as well as during its formal meeting on 10 December[96]. However, a consensus has been reached by the WTO members to continue discussion on the waiver proposal and that a status report will be submitted to the General Council meeting on 16–18 December.[97] The General Council ratified on December 18 the decision of

91 Ibid, p. 5.

92 THRASHER, Rachel. TRIPS agreement: A waiver makes the COVID-19 vaccine more accessible. Open Access Government, 25 November 2020. See also: LABONTE, Ronald, JOHRI, Mira. COVID-19 drug and vaccine patents are putting profit before people. The Conversation, 5 November 2020. [online]. Available at: <https://theconversation.com/covid-19-drug-and-vaccine-patents-are-putting-profit-before-people-149270> Accessed: 09.12.2020.

93 Medecins Sans Frontiers. A Fair Shot for Vaccine Affordability – Understanding and addressing the effects of patents on access to newer vaccines, September 2017. [online]. Available at: <https://msfaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf> Accessed: 10.12.2020.

94 Medecins Sans Frontiers. India and South Africa proposal for WTO waiver from intellectual property protections for COVID-19-related medical technologies. Briefing Document, updated 18 November 2020, p. 7.

95 World Trade Organization. TRIPS: Council Work. [online]. Available at: <https://www.wto.org/english/tratop_e/trips_e/intel6_e.htm> Accessed: 12.12.2020. See also: THRASHER, Rachel. TRIPS agreement: A waiver makes the COVID-19 vaccine more accessible. Open Access Government, 25 November 2020. See also: PATNAIK, Priti. TRIPS Council informal meeting on TRIPS Waiver proposal. Geneva Health Files, 3 December 2020. [online]. Available at: <https://genevahealthfiles.wordpress.com/2020/12/03/trips-council-informal-meeting-on-trips-waiver-proposal/> Accessed: 08.12.2020.

96 World Trade Organization. Members to continue discussion on proposal for temporary IP waiver in response to COVID-19, 10 December 2020. [online]. Available at: <https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm> Accessed: 14.12.2020.

97 Ibid.

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the TRIPS Council to continue discussions on this initiative in early 2021.[98] The next formal meeting of the TRIPS Council is scheduled for 10–11 March 2021 when some more information on this topic will be available.

4 Voluntary measures for facilitating access

Apart from limitations to patent rights established with norms of international trade law and national patent legislation (compulsory licenses), as well as, to an extent, radical proposals on facilitating access to Covid-19 vaccines and other health technologies through waiver on IPRs, which both seem to antagonise the pharmaceutical industry, there is also the obvious solution of voluntary collaboration and participation of the latter. However, currently, there doesn't seem to be a sufficient sense of solidarity on their part, although initiatives in this direction have also been put forward during 2020 and certain mechanisms for such collaboration are already at place for years.

4.1 Covid-19 Technology Access Pool (C-TAP)

Voluntary pooling of IPRs gained increased attention during the Covid-19 pandemic.[99] In March 2020 the President of Costa Rica, addressed the Director-General of the WHO to "undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the Covid-19 pandemic" and as a result, on 29 May 2020, the Covid-19 Technology Access Pool (hereinafter: C-TAP) was formally launched by President Carlos Alvarado Quesada and Dr Tedros Adhanom Ghebreyesus with the Solidarity Call to Action.[100]

It was clear from the start, that the success of C-TAP would depend on the political support it will receive. The endorsement in particular needs to come from governments and institutions that spend public resources on the development of new health products required to prevent and treat Covid-19, by demanding from their recipients the sharing of the IP and know-how they create with those funds with the C-TAP.[101] However, only 40 WHO Members so far

98 ENGELHARDT, Jordan, NADIPURAM, Joyce. WTO to Discuss Member Proposal to Waive IP Rights for COVID-19 Technologies. JDSUPRA, 7 January 2021. [online]. Available at: <https://www.jdsupra.com/legalnews/wto-to-discuss-member-proposal-to-waive-3456081/> Accessed: 04.01.2021.

99 World Trade Organization. The TRIPS Agreement and COVID-19 Information Note, 15 October 2020, p. 5.

100 World Health Organisation. Operationalising the COVID-19 Technology Access Pool (C-TAP): A concept paper. [online]. Available at: <https://www.who.int/publications/m/item/c-tap-a-concept-paper> Accessed: 07.12.2020. See also: World Trade Organization, World Health Organization, World Intellectual Property Organization. Promoting Access to Medical Technologies and Innovation. Second edition. Intersections between public health, intellectual property and trade, 2020, p. 5 et seq.

101 'T HOEN, Ellen. The Indian/South African Proposal For a WTO Waiver On IP For COVID-19 Related Health Products – What It Means? 14 October 2020. [online]. Available at: <https://healthpolicy-watch.news/77719-2/> Accessed: 27.11.2020.

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joined this call and endorsed the initiative, only three of which are European countries (Norway, Belgium Portugal) and only two of which are EU member states (Portugal and Belgium).[102] Furthermore, up to the moment this paper is being written, the C-TAP has remained empty and there are reasons for that. Firstly, the concept of this newly introduced mechanism is very ambitious and there is nothing wrong with that. Namely, the key elements of this initiative aiming toward transparency of Covid-19 related date, know-how and technologies as well as facilitation of access to treatments, vaccines and other health products are, among others, transparency around the publication of all clinical trial results, licensing of health technologies and products to the Medicines Patent Pool and promotion of open innovation models and technology transfer.[103] Furthermore, the activities of C-TAP are envisaged to be built around existing institutions,[104] such as the Tech Access Partnership (TAP), the Medicines Patent Pool,[105] the Open Covid Pledge, the Global Initiative on Sharing All Influenza Data (GISAID) and the WHO Global Observatory on Health R&D. The plan is also to create a WHO C-TAP database as a repository for data and know-how on key Covid-19 health technologies and for the submission of member states' pledges to support C-TAP.[106] It is obvious, that the goal of this initiative is to include as many current players in the "Covid-19 arena" as possible in joined action, which, however, makes this mechanism rather complex, somewhat scattered and perhaps even inefficient.

Notwithstanding the above, the biggest issue is, that there is quite a clear indication, that the C-TAP has been launched without the coordination with and input from the driving stakeholders of this program – the pharmaceutical companies.[107] Their reactions demonstrate that WHO has been "counting its chickens before they were hatched". Even before its official launch, The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) trade body pointed out that is hasn't been included in discussions and has limited understanding of what exactly is being proposed and how it is different from the various existing facilitating mechanism, whilst specifically underlining that

102 World Health Organisation. Endorsements of the Solidarity Call to Action. [online]. Available at: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action> Accessed: 19.12.2020.

103 World Health Organization. International community rallies to support open research and science to fight COVID-19, 29 May 2020. [online]. Available at: <https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19> Accessed: 16 December 2020.

104 World Health Organisation. Operationalising the COVID-19 Technology Access Pool (C-TAP): A concept paper, 4 et seq.

105 See Section: 4.2. Medicines Patent Pool.

106 World Health Organisation. Operationalising the COVID-19 Technology Access Pool (C-TAP): A concept paper, 4 et seq.

107 BRACHMANN, Steve. WHO's C-TAP Initiative Pushes for Non-Exclusive Global Licensing Amid Pharma Industry Concerns. IPWatchdog.com, 31 May 2020.

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voluntary patent pools already exist (Medicines Patent Pool) and that it is questionable, whether additional platforms are needed.[108] Furthermore, the Concept paper for the pool is not making a very strong case to the industry to join and it is obvious that an operating model for C-TAP is yet to be established.[109] Given all of these circumstances, it doesn't surprise that the voices around this mechanism have become silent, which hasn't gone unnoticed. In late January 2021, the WHO has been addressed by Oxfam acting on behalf the People's Vaccine Alliance and Health Action International expressing their concern about the lack of political support and the reported progress on C-TAP.[110] They have requested answers from WHO regarding, among others, following urgent recommendations: clarification of the strategy for C-TAP, who is providing political leadership, and who is providing the necessary technical leadership; the publication of clear guidelines and model agreements that C-TAP is seeking and publish current financial support for C-TAP and required funding for the pool to operate speedily and effectively. Generally speaking, WHO is called upon to be more transparent about its activities and proactive with regard to its leadership of and advocacy for C-TAP.[111] Unfortunately, the Director General of the WHO hasn't mentioned the C-TAP with a single word in his opening remarks at the 148th session of the WHO Executive Board.[112] Another topic that was left out, was the circumstance, that most pharmaceutical companies are still not sharing their know-how and technology needed for mass-production of vaccines.[113] Perhaps the recent, unofficial and verbal endorsement of Dr. Anthony Fauci for the C-TAP might move things for this platform in the right direction.[114]

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108 Ibid. See also: The Guardian. US and UK 'lead push against global patent pool for Covid-19 drugs. Available, 17 May 2020. [online]. Available at: <https://www.theguardian.com/world/2020/may/17/us-and-uk-lead-push-against-global-patent-pool-for-covid-19-drugs> Accessed: 20.12.2020. See also: REN, Grace. Progress On COVID-19 Technology Pool Inches Along As Sister Initiative To Pool Vaccine Procurement Accelerates, 25 September 2020. [online]. Available at: <https://healthpolicy-watch.news/progress-on-covid-19-technology-pool-inches-along-as-sister-initiative-to-pool-vaccine-procurement-accelerates/> Accessed: 20.12.2020. See also: SILVERMAN, Ed. Pharma leaders shoot down WHO voluntary pool for patent rights on Covid-19 products, 28 May 2020. [online]. Available at: <https://www.statnews.com/pharmalot/2020/05/28/who-voluntary-pool-patents-pfizer/> Accessed: 21.12.2020.

109 World Health Organisation. Operationalising the COVID-19 Technology Access Pool (C-TAP): A concept paper, p. 6.

110 BUCHER, Gabriela, REED, Tim. Letter to Dr Tedros: Leadership and Advocacy for C-TAP, 21 January 2021. [online]. Available at: <https://haiweb.org/publication/c-tap/> Accessed: 22.01.2021. See also: 'T HOEN, Ellen. The elephant in the room at the WHO Executive Board, 22 January 2021.

111 BUCHER, Gabriela, REED, Tim. Letter to Dr Tedros: Leadership and Advocacy for C-TAP, 21 January 2021.

112 World Health Organization. WHO Director-General's opening remarks at 148th session of the Executive Board, 18 January 2021.

113 'T HOEN, Ellen. The elephant in the room at the WHO Executive Board, 22 January 2021.

114 Ibid.

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4.2 Medicines Patent Pool

Another option for voluntary collaboration of the pharmaceutical industry is the Medicines Patent Pool (hereinafter: MPP), that started as a "crazy concept"[115] proposed in 2002 at an International AIDS Conference and became reality in 2010 as the first patent pool with a public health mandate, which is a United Nations-backed public health organisation.[116] The MPP was founded[117] by UNITAID and its primary mandate and mission was not only to increase, simplify and expedite the access to affordable quality treatments for HIV, hepatitis C and tuberculosis patients, as well as patients living with HIV-associated co-morbidities, but also to facilitate the development of those treatments.[118] Since 2019, the activities of MPP also cover other treatments on the WHO's Essential Medicines List.[119] Finally, given the urgent circumstances of the pandemic, the MPP temporarily expended its mandate in March 2020 to also include any health technology that could contribute to the global response to Covid-19 and where licensing could support innovation and enable access.[120] It is of importance to underline, that the activities of MPP are in particular significant and beneficial for the low and middle-income countries (hereinafter: LMIC), which are predominantly affected by the economic, legal and administrative obstacles when accessing life-saving health technologies.

Basically, how MPP works is that it represents a mechanism of public-private partnership where the public health mandate holder is the MPP and the private partners are the patent right holders/originators (e.g. innovative pharmaceuticals companies), generic drug manufacturers as well as developing companies. One of its most evident benefits for the involved parties is that it eliminates the negative effects of individual negotiating of multiple licenses, which reduces time and transaction costs. Then, the entire system is based on the principle of one-stop-shop voluntary licensing, where MPP negotiates those licences with patent holders and concludes sub-licensing agreements with generic companies, but also product developers. However, the true beneficiaries of this mechanism

115 'T HOEN, Ellen. The Medicines Patent Pool at 10: from crazy concept to real results. Medicines Patent Pool, 10 December 2020. [online]. Available at: <https://medicinespatentpool.org/story-post/mpp-10-years-ellen-t-hoen-story/> Accessed: 12.01.2021.

116 See more detailed: T HOEN, Ellen. Private patents and public health. Changing intellectual property rules for access to medicines, 2016, p. 73 et seq.

117 Medicines Patent Pool. Founders. [online]. Available at: <https://medicinespatentpool.org/partners/funders/> Accessed: 09.01.2021.

118 'T HOEN, Ellen. The Medicines Patent Pool at 10: from crazy concept to real results. Medicines Patent Pool, 10 December 2020.

119 Ibid.

120 Medicines Patent Pool. The Medicines Patent Pool and Unitaid respond to access efforts for COVID-19 treatments and technologies, 31 March 2020. [online]. Available at: <https://medicinespatentpool.org/news-publications-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-covid-19-treatments-and-technologies/> Accessed: 19.12.2020.

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are the LMICs, which gain access to quality and low-cost generic drugs. The particularities of the MPP licensing system include the transparency of licenses (full-text publication), waiver on data exclusivity, wide geographical scope (up to 131 LMICs),[121] the requirement of disclosure of patent information, royalty cap of usually up to 5% of revenue,[122] non-exclusivity, as well as pro-competitiveness, which is coupled with flexibilities allowing for further development of treatments (e.g. paediatric formulations and fixed-dose combinations[123]).[124] So with, the MPP supports competition and follow-on innovation, whilst performing quality management of the sublicensees' development projects.[125] MPP also aims to accelerate the access to generics by negotiating licenses with patent holders sometimes even before regulatory approval of drugs.[126]

Notwithstanding the latter, the originators also benefit from MPP mechanism. The latter in a way that the process of licensing and royalty negotiation with numerous generic companies is being simplified, expedited and made cost-effective,[127] grant-back provisions enable them to use the improvements

121 Nevertheless, criticism has been addressed that those middle-income countries, which are perceived by the patent holders as commercially valuable, are not included in the licenses. However, due to the compatibility of MPP licenses with the TRIPS flexibilities, this issue can be overcome by compulsory licenses granted by the governments of the countries in question. See BURRONE, Esteban. Patent Pooling in Public Health. The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development (Chapter 5), last revised 25 April 2019. [online]. Available at: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3358839> Accessed: 04.01.2021. See also: COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 319 et seq. [online]. Available at: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2076717> Accessed: 15.12.2020. See also in general: BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 240 and 283 et seq.

122 WANG, Lucy Xiaolu. Global Drug Diffusion and Innovation with the Medicines Patent Pool, 29 December 2020, p. 7, Fn. 10. [online]. Available at: <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3426554> Accessed: 12.01.2021.

123 Medicines Patent Pool. Medicines Patent Pool – Frequently Asked Questions (FAQs), 1 June 2018, p. 1. [online]. Available at: <https://medicinespatentpool.org/uploads/2020/04/Frequently-Asked-Questions-about-the-MPP.pdf> Accessed: 29.12.2020. See also: BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 254.

124 Medicines Patent Pool. Licenses. [online]. Available at: <https://medicinespatentpool.org/progress-achievements/licences/> Accessed: 05.01.2021. See also: BURRONE, Esteban. Patent Pooling in Public Health, 25 April 2019, p. 96 et seq.

125 Medicines Patent Pool. Medicines Patent Pool – Frequently Asked Questions (FAQs), 1 June 2018, p. 4.

126 BURRONE, Esteban. Patent Pooling in Public Health. The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development (Chapter 5), last revised 25 April 2019, p. 101.

127 COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-

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on medications developed by the licensees, but also the increased profit plays a significant role, due to access to under-developed markets without the need to establish sales networks.[128] MPP collaborates with (LMICs') governments with regard to collecting data on treatment needs, prices and procurement obstacles, as well as with national patent offices in order to obtain patent data[129] for its Medicines Patents and Licensing Database (MedsPal)[130]. Finally, the MPP licences are compliant with the TRIPS flexibilities (Arts. 30, 31 and 31 bis) and the majority of them includes provisions, which allow generic manufacturers to sell outside the agreed territory, if they are not infringing on a patent.[131] However, although compatible with those instruments, the MPP actually also aims to avoid compulsory licensing.[132] Notwithstanding the latter, when the territorial scope of MPP license prevents access to medications on territories where the latter is required, some countries have in the past made use of these flexibilities.[133]

In regard to Covid-19, MPP was no stranger to scepticism that the C-TAP is facing at this point.[134] Not before the US National Institutes of Health decided to share its patents for HIV medication with MPP in late 2010 and even royalty-free, which was followed up by the support of the US government for this decision,[135] did the initial reluctance vanish and make room for additional originators and generic companies to join the game. In the meantime, according to

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Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 299.

128 WANG, Lucy Xiaolu. Global Drug Diffusion and Innovation with the Medicines Patent Pool, 29 December 2020, p. 8. See also: COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 316 et seq.

129 BURRONE, Esteban. Patent Pooling in Public Health. The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development (Chapter 5), last revised 25 April 2019, p. 100.

130 MedsPal. Medicines Patent Pool. [online]. Available at: <https://www.medspal.org/?disease_areas%5B%5D=COVID-19&page=1> Accessed: 13.01.2021.

131 Medicines Patent Pool. Medicines Patent Pool – Frequently Asked Questions (FAQs), 1 June 2018, p. 4. See also the example of the first MPP/Gilead license in: COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 314 et seq.

132 WANG, Lucy Xiaolu. Global Drug Diffusion and Innovation with the Medicines Patent Pool, 29 December 2020, p. 6.

133 For example, Indonesia and Ecuador have taken these measures in 2012. BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 291 et seq.

134 See Section: 4.1. Covid-19 Technology Access Pool (C-TAP).

135 'T HOEN, Ellen. The Medicines Patent Pool at 10: from crazy concept to real results. Medicines Patent Pool, 10 December 2020. See also: COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 300.

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latest data from June 2020,[136] the MPP has signed licenses with ten patent holders for 13 HIV antiretrovirals, one HIV technology platform, a tuberculosis treatment and three hepatitis C direct-acting antivirals. Also, it signed sub-licensing agreements with 22 generic manufacturers and product developers. Given this data, the question is – do we really need a new patent pool (C-TAP) for Covid-19 health technologies, when there is already an existent one (MPP) that has the mandate, but even more important, ten-years of experience in facilitating access to essential medications?

Interestingly, the idea of patent pooling in the context of coronavirus was not brought up for the first time in 2020, but already during the outbreak of severe acute respiratory syndrome (hereinafter: SARS) that began in 2002,[137] way before MPP even came to life. This initiative was even supported by the WHO SARS Consultation Group and National Institutes of Health Office of Technology Transfer in the USA.[138] However, when the outbreak ended in 2003, the existence of a market for a potential vaccine was in question, putting its development and the need for patent pooling on hold.[139] The initial idea was to use this, or similar mechanism, to overcome multiple overlapping patent applications on either parts, or the whole of the genomic sequence of the coronavirus causing SARS (key building block for vaccines) filed by different institutions, as well as many additional patent applications on SARS (over 160 by 2005)[140] by means of facilitating the issuing of non-exclusive licences on essential patents and promotion of developing the vaccines.[141]

There is no reason to believe that patent pooling is not also a potential solution for broader and affordable access to vaccines and other Covid-19 health technologies. For example, Gilead Sciences joined the MPP already in 2011 by licensing four HIV drugs and a fixed-dose combination of these drugs covering up to 112 countries and with time licensed all of its HIV drugs to MPP,[142] so why wouldn't it do it again for Covid-19 related medicines (e.g. remdesivir).

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136 Medicines Patent Pool. Access to Medicines Tracker. [online]. Available at: <https://medicinespatentpool.org/progress-achievements/access-to-medicines-tracker/> Accessed: 19.11.2020.

137 BURRONE, Esteban. Patent Pooling in Public Health. The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development (Chapter 5), last revised 25 April 2019, p. 94.

138 SIMON, James H. M., CLAASSEN, Eric, CORREA, Carmen E. and OSTERHAUS, Albert. Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling. Bulletin of the World Health Organization, September 2005, vol. 83, no. 9, p. 708.

139 Ibid.

140 Ibid, p. 707 et seq.

141 Ibid, p. 709. See also: BURRONE, Esteban. Patent Pooling in Public Health. The Cambridge Handbook on Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development (Chapter 5), last revised 25 April 2019, p. 94.

142 'T HOEN, Ellen. The Medicines Patent Pool at 10: from crazy concept to real results, 10

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Mid January 2021, another development in direction of exploring models for potential voluntary licensing and patent pooling with regard to treatments for Covid-19 has emerged.[143] Namely, the MPP and the Joint Research Centre of the European Commission (JRC)[144] signed a Memorandum of Understanding with the goal to lay foundation for establishing a partnership in exploring together how management of IP can bring about access to health technologies for prevention and treatments of Covid-19. In particular, the two organisations will, among others, work together to identify mechanisms and incentives to encourage the beneficiaries of EU funding to make available their IP through MPP.[145] This partnering does not come as a surprise and it follows the path, that the European Commission has already defined in its Communication from November 2020 "Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience"[146]. Namely, the Commission supports voluntary pooling and licensing of IP related to COVID-19 therapeutics and vaccines, in line with the resolution of the World Health Assembly.[147] However, it is clear from this Communication that the Commission does not support the idea of any type of IP-waiver, as e.g. suggested by

December 2020. See also: WANG, Lucy Xiaolu. Global Drug Diffusion and Innovation with the Medicines Patent Pool, 29 December 2020, p. 6, Fn. 9. See also: COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 304 et seq.

143 Medicines Patent Pool. MPP and the Joint Research Centre of the European Commission partner in the field of intellectual property for COVID-19 and beyond, 18 January 2021. [online]. Available at: <https://medicinespatentpool.org/news-publications-post/mpp-eu-commission-mou-covid19-ip/> Accessed: 18.01.2021.

144 JSR is the science and knowledge service of the European Commission, consists of a number of Competence Centres including the European Commission's Central Intellectual Property Service (CIPS) and the Centre of Competence for Technology Transfer (CCTT). More on JRC: Joint Research Centre. [online]. Available at: <https://ec.europa.eu/info/departments/joint-research-centre_en> Accessed: 19.01.2021.

145 Medicines Patent Pool. MPP and the Joint Research Centre of the European Commission partner in the field of intellectual property for COVID-19 and beyond, 18 January 2021.

146 European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience, Brussels, 25.11.2020, COM(2020) 760 final.

147 WHO calls international organisations and other stakeholders to "work collaboratively at all levels to develop, test, and scale-up production of safe, effective, quality, affordable diagnostics, therapeutics, medicines and vaccines for the COVID-19 response, including, existing mechanisms for voluntary pooling and licensing of patents to facilitate timely, equitable and affordable access to them, consistent with the provisions of relevant international treaties including the provisions of the TRIPS agreement and the flexibilities as confirmed by the Doha Declaration on the TRIPS Agreement and Public Health". See: World Health Organization. World Health Organization Assembly Resolution 73, 18 May 2020, OP8.2. [online]. Available at: <https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_CONF1Rev1-en.pdf> Accessed: 29.11.2020.

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the above-discussed initiative.[148] Then, while it stresses the importance of ensuring broad and equitable access, it also underlines that these schemes should be of voluntary nature and allow the IP owners to recoup investments in a balanced way.[149] The Commission has also taken steps to ensure that the results of publicly-funded R&D programs in the EU and its member states are made available and is exploring ways to incentivise the rapid pooling of critical IP e.g. through a novel licensing system making such IP available in a controlled manner and on a temporary basis.[150]

5 Conclusion

It is rather obvious, that there is no clear answer to the question, which one of the above-elaborated mechanisms would generate the best results with regard to unimpeded, fast, equitable and affordable access to Covid-19 vaccines, but also other health technologies of importance to fight the pandemic. Every one of the access options is incomplete and exhibits a number of flaws, which means they should be used complementary and strategically.[151] The ultimate goal should be, to achieve a balance act between the fostering of generic competition and equitable access on one hand and honouring the interests of patent (and other IP) holders on the other. Its fulfilment requires political will of national governments, but also the manifestation of corporate social responsibility, which pharmaceutical companies claim to exercise,[152] but don't necessarily do.

With respect to compulsory licenses, both for the supply of domestic market and for export, in the light of the pandemic there is a clear shift in the attitude of developed countries, when it comes to their invocation. They don't seem to be as much frowned upon any more, as a potential mechanism for facilitating access to health technologies, even if they are considered "the last resort". Hence, the political will for their grant, if the situation requires such a step, might be present.

148 See Section: 3.2. Potential TRIPS IP waiver.

149 European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience, Brussels, 25.11.2020, COM(2020) 760 final, p. 11. See also: 'T HOEN, Ellen. Some Surprises in the European Commission's New Intellectual Property Strategy, 2 December 2020.

150 European Commission. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Making the most of the EU's innovative potential. An intellectual property action plan to support the EU's recovery and resilience, Brussels, 25.11.2020, COM(2020) 760 final, p. 11 et seq.

151 BAKER, Brook K. A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines. Northeastern University Law Review, 2018, vol. 10, no. 2, p. 314.

152 COX, Krista L. The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses. Hastings Science and Technology Law Journal, 2012, vol. 4, no. 2, p. 303.

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However, the application of this instrument is limited by complex, costly and potentially long administrative procedures, which are not compatible with the request for urgent action, when it comes to enabling broader access to vaccines. Furthermore, the success of a compulsory licence, in particular in developing and least-developed countries, often heavily depends on the readiness of the patent holder to actively participate in this process and to transfer also the skills and technical knowledge essential to the working of the patented technology.[153] However, let's not forget, that even an announcement of a compulsory licensing event could have an impact on the patent holders' attitude toward voluntary licensing but also pricing.

Of course, voluntary collaboration of the pharmaceutical industry would be the best solution. But what platform should they use – C-TAP or MPP? The launch of C-TAP, without consultations with the industry, when there was already a successful patent pool with ten-year experience record in facilitating access, which expended its mandate also to Covid-19, potentially undermined the readiness of that same industry to enter into voluntary licensing. In a way, the MPPs' hands are tied to act completely autonomously with this regard, since the C-TAP relies on it and this circumstance probably also makes the representative of the industry reluctant to share their protected health technologies through this platform. Hopefully this is not a deadlock situation, since the combination of the characteristic MPP license and compulsory licenses, in countries that are not covered by that license, would represent a very good access solution. The destiny of C-TAP, on the other hand, is rather unclear and not very optimistically looking.

Considering the proposed IP waiver, it seems like this option is the least advisable one for facilitating access. First of all, before a suspension of rights from the TRIPS Agreement is introduced, one must be sure that the flexibilities, in particular to patent rights, offered by it, are insufficient or inadequate, which is not proven. Another reason why this proposal is rather far from reality is, that many health technologies would not even be available, if there weren't IP rights and the incentives they offer.[154] Furthermore, suspending IP rights from the TRIPS Agreement would also send the wrong message to pharmaceutical industry that has taken many risks during 2020 and achieved groundbreaking results in record time, when it comes to vaccine development. However, bypassing patent rights with a waiver cannot in general represent a solution. Then the access through generic production requires the collaboration of the originators with regard to sharing/transfer of technology, data and know-how with the generic

153 COHEN, Shlomo. Compulsory Licensing of Patents – The Paris Convention Model. IDEA: The Journal of Law and Technology, 1979, vol. 20, no. 2, p. 153, 188.

154 BACCHUS, James. An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines, 16 December 2020.

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producers, the cooperation of governments,[155] and of course, the existence of developed manufacturing capacities.

Potentially, the source of the problem of global equitable access to Covid-19 vaccine does not even lie with patent rights at all, but with the answer to the question, whether there is a sufficient number of countries with adequate production facilities to manufacture drugs and vaccines for us all[156].

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