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ALLEA STATEMENT ON VACCINATION BOTTLENECKS IN THE GLOBAL SOUTH AND A PATENT WAIVER FOR COVID-19 VACCINES

Summary

- The low level of Covid-19 vaccination in the Global South is not ethically acceptable and risks prolonging the pandemic.
- Additional and more robust measures with immediate effect should be undertaken to accelerate and improve the production, export and distribution/administration of vaccines.
- While it has given rise to a useful and legitimate debate, the patent waiver for Covid-19 vaccines supported by some countries within the World Trade Organization is not a silver bullet in the pursuit of vaccine equity. The focus on a patent waiver may distract attention from other measures that are of fundamental importance in striving towards this goal.
- Important adjustments to patents and trade secret protections should be adopted hic et nunc by the EU, its Member States and other countries. In particular, improved procedures and institutional design should help to streamline the process for the compulsory licensing on pharmaceutical products.
- Advance purchasing agreements for vaccines and the funding of research in the health sector should also be subject to additional scrutiny and to sharing obligations.
- More should be done to improve the transfer of technology and know-how relating to healthcare towards low- and middle-income countries.

Context

The announcement in April 2021 of the United States' support for a waiver on intellectual property (IP) for Covid-19 vaccines at the World Trade Organization (WTO), recently renewed with the crisis prompted by the Omicron variant¹, has sparked an intense debate on the adequacy of the measure. Some scientists have endorsed such a patent waiver. This is exemplified by an editorial in the journal *Nature* from 25 May 2021 that considers the measure "right and fair".² At the end of 2021, access to Covid-19 vaccines is still a priority³. Only 5.9 % of people in low-income countries have received at least one dose (on 29 November 2021, compared with 0.3% on 14 April), with numbers in Africa (except for Morocco) remaining very low.⁴ This situation is not acceptable. Furthermore, it appears with clarity today that the pandemic will not end until global vaccination reaches a sufficient level.⁵

Remedying this failure in global health requires addressing many complex issues (and sometimes very practical ones, such as the logistics for administering the vaccination in low-income countries). A change in the IP framework could only be one piece of the broader puzzle that decision-makers (and many operators on the ground) must solve to achieve global vaccine equity.

We first explain in legal terms what the WTO proposal for a patent waiver is and where the discussion stands. There is still much confusion surrounding this legal tool that arose in the 2021 public debate on the access to Covid-19 vaccines. For instance, the patent (or IP) waiver as initially proposed within the WTO is to be distinguished from the compulsory licensing of patents and from other "fixes" to patent/IP law. To highlight the legal issues, we firstly present the state of the WTO discussion, still ongoing at the end of 2021 and likely to continue well into 2022 (although the first proposal for a patent waiver dates back to October 2020). Secondly, we outline the measures that appear to be the most relevant and efficient ones for a rapid improvement of the state of vaccination in low- and middle-income countries (LMICs). Indeed, potential changes to the IP regime (in particular the WTO patent waiver) require decision-making processes that will only have effects in the medium- and long term. Thirdly, we highlight the shortcomings of the patent waiver

1 Statement by President Joe Biden on the Omicron COVID-19 Variant, 26 Nov. 2021 at <https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/26/statement-by-president-joe-biden-on-the-omicron-covid-19-variant/> : « I call on the nations [...] to meet the U.S. challenge to waive intellectual property protections for COVID vaccines, so these vaccines can be manufactured globally. I endorsed this position in April; this news today reiterates the importance of moving on this quickly. » All links in the footnotes were active and checked at the beginning of December 2021.

2 Editorial, A patent waiver on COVID vaccines is right and fair, *Nature*, 25 May 2021 (at: <https://www.nature.com/articles/d41586-021-01242-1>).

3 The fact that the vaccines do not ensure a full protection against the next (deadly) wave of Covid-19 is no excuse to abandon the objective of a satisfactory level of vaccination worldwide. With the discovery of the Omicron variant, the patent waiver issue came back in the press. It is otherwise still hotly debated in the relevant circles of decision makers, for instance between the Members, including the EU (represented by the DG Trade of the European Commission) within the WTO (TRIPS) Council. It also remains a hot political topic, sometimes reignited during a national political debate: for instance the candidate of the French Communist Party in the 2022 presidential election, Fabien Roussel, blames pharma giants like Pfizer which are still blocking access to vaccine patents for "crimes against humanity" (see the Nov. 9, 2021 article on https://www.euractiv.com/section/politics/short_news/communist-candidate-fabien-roussel-blames-big-pharma-for-crimes-against-humanity/).

4 See : https://ourworldindata.org/covid-vaccinations?country=OWID_WRL. Other sources are worth to be consulted: J. Holder, Tracking Coronavirus Vaccinations Around the World (regular updates by the New York Times) at <https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html> ; <https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/> . On the broader issue of vaccine equity, see: <https://data.undp.org/vaccine-equity/> .

5 The recent focus on the Covid-19 vaccination should however not hide the broader vaccination issues in the LMICs ("As of 2018, 74 of 194 WHO member states had no adult vaccination programme for any disease; fewer than 11% of countries in Africa and South Asia reported having any such programme"; see Olivier J. Wouters et al., Challenges in ensuring global access to COVID-19 vaccines: production, affordability, allocation, and deployment", *The Lancet*, 2021, Vol. 397, Issue 10278, p. 1023-1034, at <https://pubmed.ncbi.nlm.nih.gov/33587887/>).

as the (urgent) solution to the vaccination gap while underlining the positive effects of the discussion it has prompted. To conclude, we make some proposals for adjusting the patent and trade secrets frameworks at national and EU level in order to solve some of the bottlenecks in the production and distribution of vaccines and medicines. Indeed, the assertion that the patent waiver is not the silver bullet heralded within certain circles does not mean that the patent system should continue to be applied as usual in the field of healthcare. Other reforms of the patent and IP framework are welcome and clearly needed.

A. State of the patent/TRIPS waiver in the WTO discussions

The call for a patent waiver first appeared in a communication from India and South Africa on the waiver of various chapters of the TRIPS⁶ Agreement on 2 October 2020.⁷ The India-South Africa proposal was later revised on 21 May 2021 and is now supported by a majority of LMICs within the WTO, with 63 WTO Members as co-sponsors (hereafter the “co-sponsored waiver”).⁸ These documents call on WTO Members to waive their IP rights relating to and having an impact on the “prevention, containment or treatment of COVID-19”.⁹ This indicates the broadness of the demand: It covers not only patent rights, but also copyright, industrial design and the protection of undisclosed information (trade secrets). Therefore, it would be better to refer to a “TRIPS (or IP) waiver” rather than, as it is usually presented, a “patent waiver”. The broadness of the proposal is also underlined by its three objectives: preventing, containing and treating Covid-19 illness and spreading.¹⁰ This shows that not only vaccination as a preventive measure is covered, but any means to fight Covid-19, including all “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture”.¹¹ Posterior WTO documents filed by the 63 WTO Members put forward that the co-sponsored waiver “allows companies the world over the freedom to operate and to produce covered COVID-19 health products” and that it is in line with the fundamental right to health and the United Nations’ 2030 Sustainable Development Goals (in particular SDG 3).¹²

While the EU (together with Canada, Australia, Norway, Switzerland and the UK) has consistently opposed the TRIPS waiver since the end of 2020, the United States reversed their initial position in a statement from May 2021.¹³ Underlining the Biden Administration’s aim “to get as many safe and effective vaccines to as many people as fast as possible” (but under the “nationalist” condition that “our vaccine supply for

6 The Trade-Related aspects of Intellectual Property Rights (TRIPS) Agreement was adopted in 1994 within the round of international trade negotiation that led to the creation of the WTO. It has been agreed by the 164 member countries of the WTO.

7 WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from India and South Africa, WTO Doc. IP/C/W/669, 2 October 2020.

8 WTO, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from the African Group, the Plurinational State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Jordan, Kenya, The LDC Group, Malaysia, Maldives, Mongolia, Mozambique, Namibia, Pakistan, South Africa, Vanuatu, The Bolivarian Republic of Venezuela and Zimbabwe, WTO Doc. IP/C/W/669/Rev.1, 21 May 2021.

9 Idem.

10 “Prevention refers to products and technologies to prevent the infection of COVID-19. Treatment refers to products and technologies to treat a patient who has been infected with COVID-19. Containment refers to products and technologies to control the spread of COVID-19” (Idem, WTO Doc. IP/C/W/684, 30 Sept. 2021, para. 30).

11 Idem, WTO Doc. IP/C/W/669/Rev.1, 21 May 2021, para. 1.

12 Idem, WTO Doc. IP/C/W/684, 30 Sept. 2021, para. 6, available at <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W684.pdf&Open=True> .

13 Office of the U.S. Trade Representative, Statement from Ambassador Katherine Tai on the Covid-19 TRIPS Waiver, 5 May 2021, available at <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver> .

the American people is secured”), the statement acknowledges that “[t]hose negotiations will take time given the consensus-based nature of the institution and the complexity of the issues involved”¹⁴. This is an implicit acknowledgement that the TRIPS solution to be negotiated (for example the exact scope of the waiver regarding the IP rights affected, the products/technologies covered, its duration, safeguards, etc.) will not respond to the urgency of the pandemic. While agreeing to participate in the WTO “text-based negotiations”, the U.S. do not support the co-sponsored waiver, but have not put an alternative text proposal on the table (as of 29 November 2021), hinting, however, that the future waiver should focus on vaccines. While opposing the TRIPS waiver, the EU advocates for a better use of the existing flexibility within TRIPS, in particular for facilitating the manufacturing and export of vaccines in favour of LMICs.¹⁵ Relying on the precedent of the TRIPS waiver adopted in the wake of the HIV/AIDS crisis in 2003, the European Commission pleads for lifting or simplifying some requirements for the exports of Covid-related pharmaceutical products (not only vaccines) produced under a compulsory license for at least three years.¹⁶ The TRIPS waiver remains on the agenda of the TRIPS Council meetings and will continue to be discussed in 2022.

B. Need to focus on concrete measures for accelerating the production, export and distribution of vaccines

ALLEA fully supports any initiative that could accelerate and facilitate the manufacturing and distribution of the various types of Covid-19 vaccines all over the world, and in particular in low- and middle-income countries. Any solution to or improvement over the present situation and the imbalance between countries and regions where vaccination has been rapid (such as Israel, the U.S. and UK, as well as the EU) and the rest of the world should focus on factual measures with short-term and concrete effects such as:

» **Improving manufacturing capabilities in LMICs.** Massive investment in manufacturing capabilities and removal of the bottlenecks for mass-producing the more than 20 vaccines that have showed sufficient efficacy are needed. This would require adapting the existing plants for manufacturing the vaccines, ensuring that the raw materials (such as antigen) for producing vaccines are globally available, and incentivising the mobility of specialised staff towards countries with a manufacturing capacity, for example. Beyond the pharmaceutical companies in high-income countries, in particular in the EU and U.S., it appears that several companies in LMICs, such as the Serum Institute of India, Bio-Manguinhos in Brazil or the BioVac Institute in South Africa, are able to produce (mRNA) vaccines and are already engaged in testing and production.¹⁷ Such companies with existing experience in high-quality medicine production are potential candidates for Covid-19 vaccines and for RNA vaccine platforms which, according to some studies, could be set up rapidly and at a reasonable cost, and enable distributed manufacturing.¹⁸ The level of collaboration with pharmaceutical companies in the North seems to be low.¹⁹ The question here is whether the leading producers of Covid-19 vaccines are investing

14 Idem.

15 See WTO, Communication from the EU to the Council for TRIPS, WTO Doc. IP/C/W/681, 18 June 2021.

16 Some requirements of the TRIPS (Art. 31 ff) on compulsory licensing, such as the prior negotiations with patent holders (Art. 31(b)), the condition to supply predominantly the domestic market (Art. 31(f)), the remuneration (Art. 31(h)) or the mechanism for exports (Art. 31bis), could be waived under the European Commission proposal.

17 See the list of 10 strong candidates prepared by the New York Times (S. Nolen, Here’s Why Developing Countries Can Make mRNA Covid Vaccines, 22 Oct. 2021 at <https://www.nytimes.com/interactive/2021/10/22/science/developing-country-covid-vaccines.html>).

18 Zoltan Kis and al., Rapid development and deployment of high-volume vaccines for pandemic response, *Journal of Advanced Manufacturing and Processing*, vol. 2, issue 3, July 2020, at <https://aiche.onlinelibrary.wiley.com/doi/full/10.1002/amp2.10060>.

19 Sarah Wheaton and Ashleigh Furlong, The globe’s new public health strategy: Every country for itself, *Politico*, 9 Sept. 2021 (“Big Pharma is also resisting most Global South entreaties to cooperate. As yet, no company

as much effort into facilitating partnerships with potential producers in LMICs as they could be, and whether they are cooperating on the transfer of important technology. A mechanism to track the negotiations and shed light on efforts to transfer indispensable knowledge and technologies would be welcome. The design and implementation of such a framework for improving partnerships and licensing should be considered by international bodies like the WHO and the EU, and by national authorities. This does not require a change in IP rules.

» **Facilitating the export of vaccines from countries with manufacturing capabilities to other countries.** The COVAX mechanism²⁰, to which the WHO and its partners, including the World Bank²¹, contribute, was set up with a view to achieving this goal, but donations to this multilateral body have been rather slow and limited according to several observers²² – and countries have ignored the WHO’s various pleas, including a call for a moratorium on third doses until ten percent of every country’s population is vaccinated.²³ More donations should be made, but the volume of exports is determined by market conditions and by the policies adopted in high-income countries, which tend to privilege their own populations. This practice of what is called “vaccine nationalism”, albeit politically understandable, remains ethically indefensible and counterproductive as new variants develop in regions with lower vaccination rates and later disseminate everywhere. More transparency about donations from high-income countries and the deals for exporting the vaccines would be welcome to allow NGOs and the public to better assess which countries are not keeping their promises.

» **Set up massive vaccination campaigns in LMICs.** This may require, for example, huge investments in logistics (for the transport and conservation of vaccines doses as many vaccines require ultra-cold chains and have short shelf-lives), setting up call centres, and the immediate launch of awareness campaigns through various media. Even if the vaccine doses are available, whether shipped or locally produced, administering the doses presents major challenges for some LMICs (vaccine hesitancy is also present in low-income countries, and disinformation plays a role in all regions²⁴). More could be done by the WHO and other organisations to

has signed on to share knowledge with either the South African mRNA hub or the Senegalese factory for coronavirus vaccines — though BioNTech is working with Rwanda and Senegal in a European Commission-backed deal to produce experimental tuberculosis and malaria shots.”) at <https://www.politico.eu/article/the-globes-new-public-health-strategy-every-country-for-itself/>; Ashleigh Furlong, Africa wants to produce a coronavirus vaccine – and Big Pharma’s not happy, Politico, 26 July 2021. See also the access campaign of MSF: <https://msfaccess.org/4-reasons-why-pfizer-biontech-and-moderna-must-share-covid-19-mrna-vaccine-technology-now>

20 See: <https://www.who.int/initiatives/act-accelerator/covax>. The COVAX mechanism is the vaccines pillar of the Access to Covid-19 Tools (ACT) Accelerator which is a larger global coalition to accelerate the development, production, and equitable access to COVID-19 tests, treatments, and vaccines and which brings together governments, scientists, businesses, civil society and philanthropists. (see <https://www.who.int/initiatives/act-accelerator/about>). See also: Armin von Bogdandy and Pedro Villarreal, “The Role of International Law in Vaccinating Against COVID-19: Appraising the COVAX Initiative”, MPIL, 81 Heidelberg Journal of International Law, 2021, p. 89-116 (<https://ssrn.com/abstract=3733454>).

21 See <https://www.worldbank.org/en/news/press-release/2021/07/26/covax-and-world-bank-to-accelerate-vaccine-access-for-developing-countries>.

22 However, on October 18, 2021, the EU has exported over 1 billion vaccine doses worldwide, to more than 150 countries, with around 87 million doses to LMICs through COVAX. The president of the Commission stresses that the EU is the largest exporter of Covid-19 vaccines (see https://ec.europa.eu/commission/presscorner/detail/en/statement_21_5341).

23 See Sarah Wheaton and Ashleigh Furlong, op. cit.

24 See Olivier J. Wouters and al., op. cit. Some press articles (Politico, Brussels Playbook, 1/12/2021) have highlighted this issue in harsh terms: “The problem isn’t always a lack of vaccines: South Africa, where Omicron was first detected, says it has enough vaccines to last for the next five months — the problem is people are refusing to get jabbed amid high rates of vaccine skepticism. The government has [asked vaccine manufacturers](#) to delay shipments over fears doses will expire. Money talks: So South Africa’s [leadership of a global campaign](#) to scrap patents on COVID vaccines at the World

avoid fiascos in the local distribution of the doses. Of course, the readiness of local authorities and medical staff to support the campaigns will also play a leading role, and there is no quick solution at this level.

These various initiatives and supporting measures (which should be determined by experts in various fields, including global health experts and health economists) require substantial public funding and support, and more should be done at an international level to coordinate these practical measures.

C. While it has given rise to a useful and legitimate debate, the patent waiver is not a silver bullet in the pursuit of vaccine equity

The possible issues relating to IP appear very marginal compared to the impact the measures focussing on production, export and distribution/administration (under B above) could have in the short-term. This is not to say that we do not consider that adjustments to the patent system are not necessary – as explained below under D, we propose several measures to improve the patent/IP framework, but we do not share the view that the patent waiver proposed within the WTO will make a real difference, and even less so in the short or medium term.

The patent waiver is not an adequate solution to the urgent need to facilitate access to Covid-19 vaccines in the LMICs

Our view is justified among others by the following reasons:

- Any proposal on the WTO table, such as the one initiated in October 2020 by India and South Africa and the subsequent proposals of modified waivers, or the alternative proposals by other members of the WTO²⁵, would in practice require unanimity between the 164 WTO Members to be adopted²⁶, which means that its possible effects are likely to be delayed beyond the public health crisis. The fact that the discussion is still nowhere close to an agreement within the WTO at the end of 2021 shows the gap between the urgency of the situation and the lengthy duration of international negotiations between sovereign states.
- The co-sponsored waiver is not well-tailored to the vaccine problem as it aims to facilitate access to many other medical products, such as diagnostics kits, medical masks, ventilators, personal protective equipment, medicines for treating patients in need, etc. (see A above). In addition, the proposed waiver applies to nearly all IP rights. There may be important supply issues with some of the medical products, but a blanket suspension of the international obligations regarding IP rights, including copyright and design, is not a silver bullet, and might even have no practical effect on vaccine supply issues. The many national laws providing for those IP rights will in any case remain in place for a long time, even if WTO Members are no longer subject to the TRIPS obligations. Indeed, a waiver at WTO level would only remove an obligation for the countries to guarantee IP protection to the many medical products that could help in the fight against Covid-19; it will not remove possible reliance by private parties on their acquired IP protection. To remove the possibility for private parties to rely on their existing IP rights, the adoption of the waiver at WTO level would have to

Trade Organization [probably has more to do](#) with its industry's appetite for mRNA technology, than an acute need for more doses for its populace." See also: Chad de Guzman, Africa's COVID-19 Vaccine Problem is More Than Just a Shortage of Doses, Time, 1 Dec. 2021 at <https://time.com/6124974/omicron-africa-vaccines/>.

25 We underline here that although the U.S. President made an announcement on the patent waiver in May 2021, the U.S. administration, at the end of November 2021, has not yet put a proposal on the WTO table. This seems to indicate that the political momentum created by the public announcement was the primary goal of the U.S. policy move.

26 In principle, Article IX(3) of the WTO Agreement would allow Members, "in exceptional circumstances", to vote on any proposal with a three-fourths majority for a waiver to any WTO obligation, but in practice, as is the case with other international fora comprising sovereign States, the WTO has never abandoned "consensus decision-making", meaning that every Member of the WTO has a veto over all organizational decisions. See Simon Lester, Bryan Mercurio and Arwel Davies, *World Trade Law*, Bloomsbury, 2018, p. 74-77.

be followed by adequate national legislation in the relevant WTO states, meaning that the legal effects of a waiver (between WTO states) for the private actors would be delayed in any case.²⁷

- There is arguably, at least in Europe, no existing patent yet in force on the Covid-19 vaccines themselves since the pandemic was declared at the end of 2019 and the vaccine race started in 2020.²⁸ To ask today for a waiver of patents that do not yet exist thus seems inadequate and not aligned with the need to find solutions for today's sanitary situation. While recognising in a WTO waiver document from September 2021 that "the patent landscape remains quite uncertain" (because of the 18-month delay to patent applications being made public), the 63 countries co-sponsoring the WTO waiver quote a study showing "a rapid increase in human coronavirus patents, especially COVID-19 patents".²⁹ But this study is based on patent documents and not on granted patents. Interestingly, it reveals that most patent applications come from academia and public institutions in China and the United States (AstraZeneca appears in the top 10 list of patent assignees, but not the mRNA vaccine producers). However, some patents on the new (RNA) platforms that are used to develop the last generation vaccines might indeed be in force and those patents might have a blocking effect.³⁰ Some valid patents could thus (indirectly) affect the production of (some) Covid-19 vaccines. But those granted patents cannot be put on hold just by introducing a waiver at WTO level without a change in national laws. This is not to say that measures should not be considered and adapted to ensure patents do not prevent the production and dissemination of vaccines in the future (see below under D).

- The IP problem, if it can be established and not just presumed (as it is sometimes on political or ideological grounds), probably has less to do with the (possible) patents and more with the transfer of know-how and trade secrets on the development and production of Covid vaccines. However, a waiver (in the sense of the co-sponsored proposals at the WTO) of IP protection, including trade secrets, would never make this know-how publicly accessible, but only remove the possibility for companies enjoying confidentiality protection to sue for trade secret infringement (if the trade secret protection is removed by the waiver and its subsequent national implementation). To force the disclosure of such confidential information, such as that contained in the (not yet published) patent applications, is a measure that public authorities might possibly take. But to implement such disclosure obligation is full of pitfalls, and to remove the protection of commercial confidentiality might even be counter-productive in certain cases, as companies with the know-how might refrain from entering into licensing agreements. That being said, we consider that more should be done to improve the transfer of technology and know-how relating to healthcare towards LMICs, and this should be a priority for the future. But it is not dependent on a suspension of trade secret protection, and less still of patent-related obligations as proposed in the co-sponsored waiver.

27 As IP rights are, as other forms of property, protected as fundamental rights (for instance under Article 17(2) of the EU Charter on fundamental rights), severely cutting into those rights and removing them altogether might be considered as excessive and disproportionate in some instances where the legitimate expectations of the right holders are jeopardized.

28 When a new vaccine is developed, a company can file a patent; the demand is published 18 months after the date of the first filing (thus taking into account that the first vaccines were developed around March 2020, the patent applications should only be known at the end of 2021); more importantly, the granting of a European patent by the European Patent Office usually takes between 3 to 5 years, which means that the first patents on an invention developed since the sanitary crisis started will be in force around 2023, not before.

29 Liu Kunmeng et al., "Global landscape of patents related to human coronaviruses." 2021; 17(6), p. 1588–1599 [published online 2021 Apr] <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8071764/> quoted in WTO Doc. IP/C/W/684, 30 Sept. 2021, para. 33.

30 This seems to be the case with the mRNA vaccines, but it is less likely for the older (viral-vector- or protein-based) technologies. See M. Gaviria and B. Kilic, A network analysis of COVID-19 mRNA vaccine patents, *Nature Biotechnology*, vol. 39, May 2021, p. 546-549 (<https://doi.org/10.1038/s41587-021-00912-9>).

There are also legal reasons, as elucidated in a statement by the Max Planck Institute for Innovation and Competition³¹, that we endorse in support of our view that a patent waiver is not the right legal solution. At the same time, we hold that the debate prompted by the waiver highlights some real issues with the use of patents and trade secrets to control the manufacturing chain in the pharmaceutical sector.

The discussion on the patent waiver sheds light on some real issues of pharmaceutical manufacturing, and could prompt positive changes to industry practices

While, as such, the legal fix resulting from the adoption of the patent/TRIPS waiver within the WTO is not a silver bullet and might miss its target, the debate on the waiver is definitely helpful in offering a unique opportunity to improve the situation in the manufacturing and distribution chain of vaccines (and of medicinal products in general). The proposal for a waiver must also be seen as a “tactical position designed to start a debate”.³² Another attentive observer, Jayashree Watal, India’s negotiator to the TRIPS Agreement, sees the waiver proposal as an “indirect attempt to put pressure on the original manufacturers to cooperate”.³³ If the waiver proposal helps to facilitate the licensing of technologies and the transfer of know-how, then it is to be welcomed, independently from its intrinsic (de)merit as a legal response to the vaccination problem. The co-sponsored waiver can thus be read as a bargaining chip for LMICs and for their local producers to better negotiate over technology and know-how transfers. That being said, other legal and accompanying measures, including compulsory licensing of IP, should be examined so as to remedy the situation.

D. Other legal fixes and the design of a working cooperation framework for healthcare products must be put in place by public authorities, including the EU

The “vaccine nationalism” exemplified by pre-orders of vaccines by many wealthy states (including the U.S., UK and EU) has been blamed for reducing the availability of vaccines in LMICs and criticised for offering too generous terms to the existing vaccine manufacturers.

A missed opportunity: the contracts between the public purchasers of vaccines and the producers.

Anticipating the criticisms, the European Commission’s advance purchase agreements (APAs) negotiating mandate, as agreed between the Commission and the EU Member States, included a broader message on vaccines as a “global public good” and a promise for an IP reform:

“In the negotiations with the pharmaceutical industry under the present Agreement, the Commission will promote a Covid-19 vaccine as a global public good. This promotion will include access for low- and middle-income countries to these vaccines in sufficient quantity and at low prices. *The Commission will seek to promote related questions with the pharmaceutical industry regarding intellectual property sharing, especially when such IP has been developed with public support*, in order to [meet] these objectives. Any vaccines available for purchase under the APAs concluded but not needed and purchased by Participating Member States can be made available to the global solidarity effort”.³⁴

31 Position Statement of the Max Planck Institute for Innovation and Competition, Covid-19 and the Role of Intellectual Property, 7 May 2021 (hereafter MPI Statement) available at https://www.ip.mpg.de/fileadmin/ipmpg/content/stellungnahmen/2021_05_07_Position_statement_Covid_IP_waiver.pdf.

32 See Alan Beattie, Katherine Tai springs a surprise on Covid vaccine patents, Financial Times, 6 May 2021 (quoted by Bryan Mercurio, The IP Waiver for COVID-19: Bad Policy, Bad Precedent, IIC (2021) 52, p. 986).

33 Interviewed by Maximilien Steinbeis and Evin Dalkilic, “Three Crises and One Waiver”, Verfassungsblog. On Matters Constitutional, 7 May 2021 (at <https://verfassungsblog.de/three-crises-and-one-waiver/>). In her interview, J. Watal adds: « “Vaccine equity is not happening. With the best of intentions or efforts, but it’s not happening.” But will a waiver of intellectual property rights, in and of itself, improve vaccine equity? „No. It won’t. That’s clear.”».

34 Excerpt of the annex (p. 50-51) to the Commission’s mandate to negotiate APAs. This document is annexed to the agreed APAs with vaccine producers such as the one with CureVac available at https://ec.europa.eu/info/sites/default/files/curevac_-_redacted_advance_purchase_agreement_0.pdf.

It is time to ask the EU Commission to stand with its promise on “IP sharing”. The APAs concluded by the Commission should have included obligations for vaccine manufacturers to facilitate the licensing of their IP rights and know-how (including access to the clinical test data generated by the advanced EC purchase/funding.)³⁵ When the research and development, and sometimes the production itself, are supported by public funding, more IP sharing should be organised.³⁶ More transparency on the importance of the various public support measures (direct funding, but also tax breaks for researchers and other forms of state aid such as pre-sale agreements) and on the pricing schemes and the supply contracts for vaccines should in any case be promoted to the benefit of all. Health authorities should have broader access to such information. This is badly needed if we want to avoid that the costs of developing vaccines are covered by the public authorities and citizens while the profits are solely appropriated by private companies.

Other measures within the IP toolbox as medium-term solutions. We have already highlighted some important policy measures *outside* the IP field (see B), for instance the need to put in place a transparency mechanism to track negotiations and shed light on the efforts of pharmaceutical companies to transfer indispensable knowledge and technologies to the LMICs directly – or to partners in the countries of the North that could help to solve the manufacturing gap in the South. For instance, some drug companies in various countries (e.g. Israel, Canada, South Africa and Denmark) have claimed they have unused vaccine manufacturing capacities that could quickly be harnessed if they received the necessary resources and knowledge.³⁷ This should be further investigated by various authorities, including in the health sector, to incentivise the conclusion of licensing agreements.

Within the IP toolkit, other measures should also be considered, and we hope that the debate on these issues will continue independently from the sanitary situation:

- **Compulsory patent licenses.** Cases in which a patent holder refuses to grant a license on a vaccine technology are probably rare. The mRNA vaccine manufacturer Moderna even pledged not to enforce the patents they might rely on against other manufacturers, at least during the health crisis.³⁸ Yet the same company is at the same time involved in several patent disputes relating to the Covid patents³⁹, including one with the U.S. government on the allocation of inventorship for one of its vaccine patents (see below). This indicates that the vaccines producers, at least when the urgency of the crisis is over, would be prepared to invoke their patents to at least delay the licensing deals and to impose restrictive conditions. It is thus not possible to prevent technologies from being locked up by relying on patents and, more importantly, on

35 See also Ellen't Hoen and Pascale Boulet, The European Commission says Covid-19 vaccines should be global public goods, but do their agreements with pharma reflect this?, 28 Jan. 2021 at <https://medicineslawandpolicy.org/2021/01/the-european-commission-says-covid-19-vaccines-should-be-global-public-goods-but-do-their-agreements-with-pharma-reflect-this/> : “The fact that such IP sharing is not part of the agreement with CureVac is particularly noteworthy because the [CEO of the company has publicly stated](#) in December [2020] that patents related to Covid-19 vaccines should be temporarily suspended and has called for much closer international collaboration in research & development of the new vaccines.” In addition, the Member States are not allowed to resell, export, distribute or donate for free to a country outside the EU/EEA, including via NGOs and the WHO, without the prior consent of CureVac (Art. I.10.2).

36 It appears that the mRNA and Johnson & Johnson vaccines rely on a technology that was invented in a U.S. government lab, the National Institute of Allergy and Infectious Diseases, and that other vaccines were partly developed in universities (see C. Morten and M. Herder, We Can't Trust Big Pharma to Make Enough Vaccines, The Nation, 31 May 2021 (available at: <https://www.thenation.com/article/world/covid-vaccines-pharma/>).

37 C. Morten and M. Herder, op. cit.

38 See the MPI Statement (op. cit.) as well as the quoted sources: Priti Patnaik, Views from a vaccine manufacturer: Q&A – Abdul Mukhtar, Incepta Pharmaceuticals (1 April 2021) Health Policy Watch <https://healthpolicy-watch.news/views-from-a-vaccine-manufacturer-qa-abdul-mukhtar-incepta-pharmaceuticals/> ; Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (8 Oct 2020) <https://investors.modernatx.com/node/10066/pdf> .

39 See Moderna Therapeutics v. Arbutus BioPharma (Fed. Cir. 2021) ([20-1184 Decision](#)) ([20-2329 Decision](#)) discussed by D. Crouch, COVID Patents at the Federal Circuit (Moderna Loses), 2 Dec. 2021 on <https://patentlyo.com/patent/2021/12/patents-federal-circuit.html> .

confidential information, as well as on restrictive contractual practices. The existing provisions of TRIPS (Art. 30, 31 and 31 bis) and their implementation in national laws ensure in principle that compulsory licenses can be imposed, including for exporting patented products. However, domestic laws do not necessarily offer expedited and easy ways to obtain those compulsory licenses; a cause for complaint for many LMICs and NGOs. With this in mind, the EU Commission has been pushing within the WTO for the adoption of a “Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic”.⁴⁰ The draft text recognises that the response to the Covid-19 crisis must “ensur[e] that the intellectual property system supports efforts to enhance production and supply of vaccines and medicines”. It declares the right of WTO Members to use the flexibility for compulsory licenses (under Art. 31 and 31 bis) and aims to remove the requirement, before the issuance of a compulsory license, of making efforts to obtain authorisation from the right holder (under Art. 31(b)) and at reducing the remuneration (in exchange for the compulsory license). This could improve the situation but it is too early to assess the potentialities of the EU draft proposal.

What is clear is that more should be done to streamline the process for obtaining compulsory patent licenses, and that this should include initiatives to share the associated know-how. There is no need to wait for a possible change of the TRIPS framework to facilitate the export of vaccines produced under compulsory licenses.

- **Compulsory trade secret licenses.** As we have underlined, the facilitation of patent licensing will not suffice, as the know-how is often the real ingredient that is needed for technology transfer to be successful. Neither the TRIPS Agreement nor other international instruments provide for rules on compulsory trade secret licenses. A scheme for facilitating and imposing the licensing of know-how, under strict conditions and limited to the transfer of technologies such as vaccines and medicines in the case of a pandemic, might have to be designed to complement the IP landscape.⁴¹
- **Linkage with the marketing authorisation procedure.** Vaccines, even if copied from original ones, require marketing authorisations (MAs) to check the safety, quality and efficacy standards. This also applies in LMICs. It is important that the original manufacturers assist the local manufacturers to get the acquisition of MAs, which is why (voluntary or mandatory) licensing agreements that provide for data and know-how sharing while relying on IP rights could accelerate the acquisition of the MAs. If IP rights are suspended (as a consequence of a waiver), one might expect less cooperation and further delays. But international cooperation among the agencies in charge of the MAs should be fostered, and this could be part of a positive regulatory agenda for enhancing the global production and administration of vaccines. It is essential that the best quality controls are in place all over the world, and bodies in charge of MA should be actively involved in the process to facilitate the licensing and manufacturing of vaccines.
- **Clarification of the patent ownership rules for public-private innovation.** Many inventions are co-developed over a long period by public and private laboratories working together. The Moderna vaccine, for instance, grew out of a four-year collaboration between Moderna and the U.S. National Institutes of Health (NIH). Yet Moderna’s patent application does not name the employees of the NIH as inventors of a crucial component of its Covid vaccine.⁴² This has led to a bitter dispute, which remains unsolved today.⁴³ Its resolution could have some implications for access to the Moderna vaccine globally: If the U.S. government/NIH is a co-inventor, it could have a say regarding the technology transfer to third parties, and even decide to license the technology

40 See WTO, Communication from the EU to the Council for TRIPS, WTO Doc. IP/C/W/681, 18 June 2021.

41 For a first attempt to design such as scheme, see Olga Gurgula and John Hull, Compulsory licensing of trade secrets: ensuring access to Covid-19 vaccines via involuntary technology transfer, Queen Mary Law Research paper No. 363/2021, forthcoming in JIPLP, 2021 (at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3872796).

42 Sheryl Gay Stolberg and Rebecca Robbins, Moderna and U.S. at Odds Over Vaccine Patent Rights, New York Times, 9/11 Nov. 2021 (<https://www.nytimes.com/2021/11/09/us/moderna-vaccine-patent.html>).

43 This issue could lead to the invalidation of the patent, in case Moderna deliberately names the wrong inventors (see <https://law.stanford.edu/2021/11/11/stanfords-mark-lemley-on-the-moderna-ip-dispute-with-us-government/>).

to third parties. The correct allocation of patent rights should be established in advance⁴⁴, especially when the private party receives substantial funding from public authorities to develop and test the product (in this case Moderna obtained about \$10 billion). Rules for better determining who are the inventors should at least be included in the funding schemes for vaccines (and medicines), including some clearer “march-in rights” that would allow the public funder to license the patent to third parties (including producers in LMICs).

Conclusions

Advocating for vaccines to become a “global common good”, although an attractive idea, remains extremely vague and largely disconnected from the existing legal framework and practices that cannot – and should not – be ignored. The related debate on the patent waiver, as prompted by the U.S. announcement in April 2021 (yet to be followed by a concrete proposal), risks detracting attention from the real problem: the need to produce more vaccine doses at a faster pace and to administer the vaccines to large populations in all countries, including LMICs.

Rather than advocating that the European Union and the UK “follow suit” with the U.S. on the patent waiver, as urged by the above-mentioned editorial in *Nature*,⁴⁵ we uphold that the focus should be on i) the many practical measures that could accelerate the production, export and administration of vaccines worldwide and ii) on an international mechanism affording additional scrutiny of the manufacturing bottlenecks combined with new measures in the IP framework, such as new flexibility for the compulsory licensing of patents.

44 It is worth noting that the co-inventorship rules, requiring a substantive contribution to the inventive part of a patent claim, are stricter than the co-authorship practices for scientific publications, as many heads of labs who co-sign scientific articles without being directly involved in the research (a common practice) would not qualify as co-inventors under patent rules. On this, the IP rules are to be preferred to some practices regarding authorship in the scientific community.

45 Editorial, A patent waiver on COVID vaccines is right and fair, op. cit. (<https://www.nature.com/articles/d41586-021-01242-1>).

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This ALLEA statement has been prepared by ALLEA’s Permanent Working Group Intellectual Property Rights (PWGIPR) with Professor Alain Strowel as principal author. Through its Working Groups, ALLEA provides input on behalf of European academies to pressing societal, scientific and science-policy debates and their underlying legislations. With its work, ALLEA seeks to ensure that science and research in Europe can excel and serve the interests of society.

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