

Covid-19 and the Role of Intellectual Property

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In a communication of 2 October 2020, India and South Africa proposed that members of the World Trade Organisation (WTO) should ‘work together to ensure that intellectual property [IP] rights such as patents, industrial designs, copyright and protection of undisclosed information do *not create barriers to the timely access to affordable medical products* including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19’.¹ Specifically, the document proposes a ‘waiver [that] should continue until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity’.² It states that ‘exceptional circumstances exist justifying waivers from the obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)’.³

There is no doubt that the communication of India and South Africa is well-intentioned. An effective response to the pandemic clearly requires ‘rapid access to affordable medical products’,⁴ and the world needs to stand together to achieve this. Yet, a waiver of all IP rights under the TRIPS Agreement is unlikely to be a necessary and suitable measure towards the pursued objectives. This Position Statement argues that IP rights might so far have played an enabling and facilitating rather than hindering role in overcoming Covid-19, and that the global community might not be better off by waiving IP rights, neither during nor after the pandemic.

1. Waiving IP rights will not scale or speed up vaccine manufacturing and distribution.

The holdups in vaccine manufacturing and distribution have been caused mainly by the shortage in raw materials,⁵ insufficient production capacity and highly complex manufacturing process (in the case of mRNA and vector vaccines).⁶ It is unlikely that a waiver of IP protection could solve these **factual problems**. The problems of insufficient production capacity and access to

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raw materials were already witnessed in the earlier days of the pandemic, e.g. with regard to masks and breathing equipment.⁷

Overall, IP holders have been rather actively entering into partnerships and granting manufacturing licences to capable licensees.⁸ One of the main manufacturers of mRNA vaccines, Moderna, pledged not to enforce their Covid-19-related patents against other manufacturers of vaccines to combat the pandemic.⁹

So far, cases where a patent holder (reportedly) refused to license IP appear to be a rare exception.¹⁰ If a refusal cannot be justified on the objective grounds (e.g. by quality and safety considerations), such cases should be resolved by means of the existing remedies (see below at 5) instead of burdening all right holders for the wrongdoings of a few. In any case, the pursuits to scale up manufacturing should not prioritise quantity at the expense of quality and safety of medicinal products.

2. IP rights are the basis for collaborations and contracts.

The product life cycle of the new mRNA and vector vaccines – from discovery to post-marketing authorisation safety studies – is highly complex.¹¹ Cooperation throughout the development, production and distribution of vaccines for Covid-19 has reached an unprecedented level. Examples include partnerships for joint development (e.g. BioNTech/Pfizer; CureVac/GSK) and production (e.g. BioNTech/Pfizer/Sanofi/Novartis; CureVac/Bayer; Moderna/Lonza).¹² This is remarkable given that the biopharmaceutical sector is traditionally characterised by fierce competition. Cooperation in the pharmaceutical sector is typically **based on IP rights**, which serve as the basis for contracts. Waiving IP rights may have detrimental consequences for the firms' willingness to cooperate.

Voluntary patent licences are usually accompanied by a contractual transfer of the know-how necessary to exploit a licensed technology. In the course of research and development (R&D), vaccine developers accumulate **considerable know-how** necessary for vaccine manufacturing.¹³ Such know-how is usually not disclosed in patents or patent applications, related scientific publications or assessment reports of drug authorities. When voluntary patent licences are concluded, know-how is transferred under non-disclosure agreements. A patent waiver, however, would remove an incentive of the developers of the original products to provide such information to manufacturers of biosimilars.¹⁴ It is highly unlikely that the waiver of trade secret protection could be effectively implemented and enforced to propel companies to disclose all relevant know-how.

3. A waiver of IP rights will not waive regulatory requirements for vaccine authorisation.

Any entity intending to place a medicinal product for human use on the market – whether an originator, generic or biosimilar product – needs to obtain marketing authorisation from drug authorities. Vaccines are biological medicinal products.¹⁵ Compared to generic versions of small-molecule drugs, biosimilar products are subject to more stringent regulatory requirements. Developers of biosimilars have to demonstrate through **comprehensive comparability studies** with the 'reference' biological product that, first, their biological product is 'highly similar to the reference medicine'¹⁶ and, second, that there are 'no clinically meaningful differences between the biosimilar and the reference medicine in terms of safety, quality and efficacy'.¹⁷ Regulatory requirements for biosimilars need to be complied with not only in the EU or US, but in developing countries, including India and South Africa,¹⁸ as well.

Current vaccine developers can either transfer their marketing authorisation licence¹⁹ (provided the safety and quality standards can be upheld) or assist their local partners in obtaining marketing authorisation (by sharing required data and know-how). Yet they may not be willing to cooperate in this regard as a result of the IP waiver. Thus, even if all related IP rights – including test data exclusivity – were waived, each new applicant for marketing authorisation would need to comply with safety, quality and efficacy requirements. All this suggests that, rather than speeding up vaccine supply, a waiver would likely cause a delay, if the current patent holders cease cooperating and/or supplying self-produced vaccines.

4. It is questionable whether a waiver of IP rights will significantly reduce prices for vaccines.

Concerns regarding vaccine prices are understandable, especially in view of inequalities among countries as far as access to healthcare is concerned. However, there are several reasons why a waiver of IP rights might **not result in a substantially lower price** for biosimilar versions compared to the currently supplied products.

First of all, some current vaccine developers and manufacturers have publicly announced ‘not-for-profit’ commitments.²⁰ Even though there might be concerns that such commitments will eventually be lifted, prices are likely to stay at a competitive level, given that there is an increasing number of actual and potential substitutes and therewith competition.²¹

Second, technological requirements for production of biosimilars result in higher costs of the development and manufacturing of biosimilars, compared to generic versions of small-molecule drugs. Setting the production for the new vector and mRNA vaccines therefore requires substantial investments. Biosimilar and generic companies, just like originators, usually operate as for-profit entities. The market prices for such products therefore might not be significantly lower than the current prices for vaccines, but the waiver would benefit the commercial interests of the generic manufacturers first of all because they would be exempt from paying royalties. Even if generic manufacturers were prepared to limit prices to their own production costs, it is questionable whether such prices would be substantially lower than the current prices for vaccines supplied under the not-for-profit commitments. Unless the manufacturers of biosimilars commit themselves to sell at cost price, a waiver might benefit their commercial interest more than it would serve the public interest in affordable vaccines.

Third, the cost of vaccine delivery alone – not including manufacturing – is considerable.²² In some cases, it can equal half of the vaccine market price.²³ Every entity along the complex supply chain needs to be paid for products and services, irrespective of whether vaccines are IP-protected or not.

In the abstract, there was certainly a risk of excessive prices when the vaccines were still under development. Such risk should have been addressed by governments in the framework of the contracts subsidising research on vaccines (see also below at 7), while affordability of vaccines should be approached as a matter of global solidarity (see also below at 10).

5. The TRIPS Agreement contains sufficient flexibilities to prevent negative effects of patents.

Before such an extreme measure as a waiver of all IP protection can be implemented, other policy options need to be considered and evaluated. According to the principle of proportionality, a waiver should only be implemented if there are no less restrictive - and equally effective - measures available to ensure equitable access to vaccines and treatments for Covid-19. Should private ordering mechanisms fail, it needs to be examined whether the flexibilities under Articles 30, 31 and 31*bis* of the TRIPS Agreement can increase the availability of necessary medicinal products.

Article 31 of the TRIPS Agreement allows the WTO members to provide for compulsory licences for patents, including use by the government or third parties authorised by the government. Such licences can be granted by the respective authorities based on national laws.²⁴ As a rule, a compulsory licence can be granted only after the negotiations with the rights holder to conclude a licensing agreement on 'reasonable commercial terms and conditions' have not succeeded within a reasonable period of time. However, this requirement can be waived by a WTO member 'in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use'.²⁵ The current pandemic clearly qualifies as such a case. Besides, the Doha Declaration affirms that the TRIPS Agreement should not 'prevent Members from taking measures to protect public health'.²⁶

It is the responsibility of a country to adjust its own legal framework to make use of the existing flexibilities. In this regard, the argument of the sponsors of the proposal for IP waiver that 'some WTO Members have carried out urgent legal amendments to their national patent laws to expedite the process of issuing compulsory/government use licences'²⁷ suggests that the problem is not caused by the TRIPS Agreement as such, but rather may arise at the level of domestic legislation.

Nevertheless, certain downsides of compulsory licences for patents should be recognised.

First, for compulsory licensing to be an effective instrument, a country – whether producing for its own consumption or for export under Article 31*bis* of the TRIPS Agreement – should have actual manufacturing capacity and facilities, as well as necessary expertise. For some vaccines – first and foremost, mRNA-based vaccines – this can be a challenge, even in industrialised countries.²⁸ Neither a compulsory licence nor the waiver of IP rights would resolve these factual hindrances (see also above at 1).

Second, the procedure of obtaining a compulsory licence can be cumbersome. However, the efficiency of the compulsory licensing mechanism ultimately depends on how it is implemented under the national laws. In this regard, different approaches and measures undertaken during the pandemic have been reported,²⁹ which suggest that compulsory licensing can serve its purpose under the current circumstances. Furthermore, it is advisable to provide for preliminary procedures that allow for fast decisions on the compulsory licence prior to the main proceeding.³⁰

Third, a compulsory licence for patent rights alone will not suffice without a comprehensive and effective transfer of know-how,³¹ which is essential to make use of a patented technology (see also above at 2). Accordingly, for medicinal products based on known methods, such as the use of small-molecule drugs or traditional vaccines using particles of a virus, a compulsory licence can provide a ready-to-deploy mechanism for production and distribution. In contrast,

in the case of vector-based or mRNA-based vaccines, replicating the technical teaching underlying a patent without access to the related know-how is by no means trivial.

Furthermore, to commercialise a medicinal product manufactured under a compulsory licence, a legal mechanism needs to be put in place to overcome the problem of test data exclusivity protection pursuant to Article 39 of the TRIPS Agreement.

Finally, it has to be mentioned that a compulsory licence requires a monetary compensation in the form of a licence fee. While this may be seen as a disadvantage compared to a waiver, national courts have the autonomy to set the fees for compulsory licences at a comparatively low level.

6. A comprehensive waiver of IP rights will likely have a detrimental effect on incentives for drug innovation.

It is important to consider potential effects of a comprehensive waiver of IP protection on **innovation incentives** in vaccine development (including emerging variants of Covid-19), as well as in *other* areas of medical research. As far as vaccine research is concerned, contrary to what was assumed at the beginning of the pandemic,³² recent studies demonstrate that coronaviruses can mutate significantly and at a fast rate.³³ Even though some of the existing vaccines have been proven effective, it cannot be excluded that extensive R&D will be required to tackle newly emerging virus variants. A waiver of IP protection could leave the society vulnerable to such emerging variants of Covid-19 if the current IP holders/vaccine developers abandoned research efforts as a result of such a waiver.

In this regard, a waiver of *all* IP protection related to research on coronaviruses appears to be highly disproportionate in its scope. There is a large number of ongoing research projects directed at the development of vaccines and therapeutics for Covid-19.³⁴ While IP rights resulting from such projects, including patent applications, do not pose an obstacle to the accessibility of the existing vaccines, a comprehensive waiver of IP rights can hinder such R&D.

Moreover, the disincentive effect could go beyond the research on vaccines. It should be emphasised that inventions underlying the first approved vaccines for Covid-19 were developed and filed for patents years before the outbreak (such as Moderna's mRNA-1273 technology and BioNTech and Pfizer's BNT162).³⁵ This implies that those inventions resulted from research that, as such, was not directed at vaccines that are currently being deployed as a response to the pandemic. Those platform technologies have a potential to yield numerous therapeutic applications in other medical areas, including cancer treatment.³⁶ A waiver of IP protection would not serve the interest of the society, as it would create a disincentive for companies to pursue research in those areas.

7. Concerns regarding profit maximisation by IP holders is not a valid reason for a waiver of IP rights.

It has been speculated that drug companies will thrive on the public health crisis,³⁷ and that governments – in the end, taxpayers – pay for Covid-19 vaccines twice: first, by subsidising vaccine development, and second, by purchasing vaccines.³⁸ Without knowing the real cost of vaccine development, manufacturing and distribution, it is impossible to verify such assumptions. The cause of concerns about 'excessive' prices for Covid-19 vaccines is not patent

rights as such, but **lack of transparency**. Both transparency and pricing issues should have been addressed by governments in the framework of the agreements that subsidised research.

In principle, companies need to earn returns on R&D to have incentives to innovate. As pointed out above, basic molecular technologies underlying some vaccines currently deployed for Covid-19 were developed and covered by patent applications prior to the outbreak.³⁹ If patent protection had not been available, those technologies, without which the vaccines could not have been made available in such a short time, might not have been developed in the first place.⁴⁰

The question is rather how much profit is justified. The patent system underlies an inherent trade-off between innovation incentives and access to affordable medicines, which has been subject to a long-standing debate as to how innovation and affordability – both of which are in the public interest – should be balanced. The proposed waiver will not resolve this fundamental challenge of the patent system. Besides, companies need to fulfil all pre-existing obligations under the agreements that were concluded on the basis of IP rights, such as paying back loans.⁴¹

8. Accountability for the use of public funds invested in vaccine development requires transparency.

Drug discovery and development are often financed by both private and **public money**. While basic research is mostly funded by governments and undertaken by public institutions, including universities and research institutes, late stages of the development process are typically financed and carried out by the private sector, namely pharmaceutical companies. In between lies the ‘valley of death’ in which basic discoveries need to be translated into marketable drugs.

The fact that public money is invested in drug discovery and development creates an issue of **accountability**. Since the investments are ultimately paid for by the citizens, they should have the possibility to assess the appropriate and efficient use of public funds. This necessitates **transparency** in terms of the amounts invested and the agreement concluded with regard to the exploitation and distribution of a drug or vaccine developed with public funds. At the same time, it requires the recipient of the funds to disclose the cost and pricing structures of the products and/or services that are developed with them, including the risks and opportunity costs.

9. The scope of the waiver is not clear.

The proposal states that all categories of IP rights protected under the TRIPS Agreement ‘shall be waived in relation to prevention, containment or treatment of Covid-19’.⁴² The clause ‘in relation to’ can be interpreted extremely broadly as to encompass any remotely related subject matter. On the one hand, this appears problematic in view of the principles of necessity and proportionality. On the other hand, it is also problematic given that multiple patent-protected technologies, compounds and products are involved in research, development, manufacturing and distribution of vaccines. This can include precursor components such as lipids,⁴³ or syringes required for the administration of the vaccines, or refrigerators needed to keep the currently available mRNA vaccines at very low temperatures during transport and storage. The proposed waiver consequently could have sweeping effects on innovation in other areas (see above at 6).

10. Global governance could provide better support to developing countries.

Global herd immunity within a reasonable time can only be achieved through ensuring **global equitable access** to Covid-19 vaccines. Since no country is fully independent with the development, production and supply of Covid-19-related vaccines and therapeutics, it is a matter of international solidarity to improve adequate access to them.⁴⁴ This calls for the need for **global governance**, which requires safety, transparency, accountability⁴⁵ and legal compliance control to achieve a comprehensive vaccinations and medical products coverage around the world.⁴⁶ In the case of vaccines, the price of the doses is likely to remain one of the relevant obstacles to faster and widespread access by most developing, lower-income and non-producing countries, even if compulsory licences or IP waivers are granted.⁴⁷

The promotion of equitable opportunity and fair access to vaccines at the global level presupposes, directly or indirectly, financial and institutional support from high-income countries, including by directly supplying vaccines to developing countries, especially doses that were pre-ordered in excess of their own population needs.⁴⁸ It is impermissible that developing countries, in some cases, had to pay for a vaccine more than developed countries, because they had not invested in the R&D.⁴⁹ Through immunization in developing areas, the virus incidence and the emergence of virus variants⁵⁰ could be better controlled. Consequently, the developed countries' commerce and freedoms would be less affected, while the risks of civil and political crises that could affect global economic stability and growth would be reduced. Some **international initiatives** (e.g. ACT-A,⁵¹ COVAX⁵²) have already contributed to achieving those objectives. However, scaling up production and broader distribution coverage are still needed. An international pandemic treaty as advocated by more than 25 global leaders of different countries and institutions, including France, Germany, Italy, the UK and the WHO,⁵³ is an example of what can be done. If properly designed, it could offer an appropriate framework to address relevant issues, such as trade, distribution, access and innovation in the vaccine and therapeutics sector.⁵⁴ In view of the inability of the proposed waiver to achieve its goals, it remains a task for the countries to adopt effective emergency solutions to deal with the unresolved problems of access to medicinal products against Covid-19 and a global governance framework to address future pandemics.

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Endnotes

¹ Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19. Communication from India and South Africa (2 Oct 2020) IP/C/W/669 <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W/669.pdf&Open=True> (accessed 6 May 2021) (hereinafter Communication from India and South Africa) para 3 (emphasis added).

² *ibid* para 13.

³ Communication from India and South Africa (n 1), Annex 'Draft decision text. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19'.

⁴ Communication from India and South Africa (n 1) para 5.

⁵ See e.g. Jonathan Dakin, Supply Chain Challenges Creating Hurdles to COVID-19 Vaccine Production (2 Apr 2021) PharmTech <https://www.pharmtech.com/view/supply-chain-challenges-creating-hurdles-to-covid-19-vaccine-production> (accessed 6 May 2021); Shruti Menon, India coronavirus: Can it make enough vaccines to meet demand? BBC News <https://www.bbc.com/news/world-asia-india-55571793> (accessed 6 May 2021); Costad Paris, Supply-Chain Obstacles Led to Last Month's Cut to Pfizer's Covid-19 Vaccine-Rollout Target (3 Dec 2020) The Wall Street Journal <https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787> (accessed 6 May 2021).

⁶ For instance, mRNA or vector-based vaccines are manufactured in bio-reactors and require a high degree of sophistication and technology. For a discussion, see e.g. Jim Geraghty, The Vaccine-Distribution Bottleneck (3 Feb 2021) <https://www.nationalreview.com/the-morning-jolt/the-vaccine-distribution-bottleneck/> National Review (accessed 6 May 2021); Derek Lowe, Myths of Vaccine Manufacturing (2 Feb 2021) <https://blogs.sciencemag.org/pipeline/archives/2021/02/02/myths-of-vaccine-manufacturing> (accessed 6 May 2021); Edward Segal, New Vaccine Supply And Distribution Problems Slow Fight Against Covid – And Provide More Crisis Management Lessons (26 Jan 2021) <https://www.forbes.com/sites/edwardsegal/2021/01/26/new-vaccine-supply-and-distribution-problems-slow-fight-against-covid---and-provide-more-crisis-management-lessons/> (accessed 6 May 2021); COVID-19 vaccine manufacturing bottlenecks – troubling issues (14 Dec 2020) <https://www.skepticalraptor.com/skepticalraptorblog.php/covid-19-vaccine-manufacturing-bottlenecks-troubling-issues/> (accessed 6 May 2021).

⁷ OECD, The face mask global value chain in the COVID-19 outbreak: Evidence and policy lessons (4 May 2020) <https://www.oecd.org/coronavirus/policy-responses/the-face-mask-global-value-chain-in-the-covid-19-outbreak-evidence-and-policy-lessons-a4df866d/> (accessed 6 May 2021); Abirami Kirubarajan et al., Mask shortage during epidemics and pandemics: a scoping review of interventions to overcome limited supply (2020) *BMJ Open* 2020;10:e040547. doi:10.1136/bmjopen-2020-040547; Megan L. Ranney et al., Critical supply shortages – the need for ventilators and personal protective equipment during the Covid-19 Pandemic (30 Apr 2020) *N Engl J Med* 382:e41 DOI: 10.1056/NEJMp2006141; Huai-liang Wu et al., Facemask shortage and the novel coronavirus disease (COVID-19) outbreak: Reflections on public health measures (2 Apr 2020) 21(100329) DOI:<https://doi.org/10.1016/j.eclinm.2020.100329>.

⁸ Bojan Pancevski, BioNTech recruits rivals to boost Covid-19 vaccine production (March 13 2021) Wall Street Journal <https://www.wsj.com/articles/biontech-recruits-rivals-to-boost-covid-19-vaccine-production-11615640401> (accessed 6 May 2021) (reporting that 'BioNTech SE, a German company that joined with Pfizer Inc. to manufacture and distribute its vaccine, has marshaled an alliance of 13 companies, including Novartis AG, Merck KGaA and Sanofi SA, in an effort to meet – and perhaps exceed – an ambitious target of making two billion doses of vaccine this year').

See also Marcelo Rochabrun, Brazil signs agreement to produce AstraZeneca's experimental COVID-19 vaccine (27 Jun 2020) <https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB>; AstraZeneca's China partner expects to be able to make 400 million COVID-19 vaccine doses a year (2 Feb 2021) <https://www.reuters.com/article/us-health-coronavirus-kangtai-astrazenec-idUSKBN2A20VB>; Abhirup Roy and Euan Rocha, AstraZeneca partner sticks with two full dose regimen in COVID trials in India (1 Dec 2020); Serum Institute of India obtains emergency use authorisation in India for AstraZeneca's COVID-19 vaccine (6 Jan 2021) <https://www.astrazeneca.com/media-centre/press-releases/2021/serum-institute-of-india-obtains-emergency-use-authorisation-in-india-for-astrazenecas-covid-19-vaccine.html>; Holly Ellyatt, 2021 will see 'vaccine cooperation, not competition,' Russian official says after AstraZeneca tie-up (17 Dec 2020) <https://www.cnn.com/2020/12/17/russia-covid-vaccine-cooperation-with-astrazeneca-a-great-example.html> (accessed 6 May 2021).

⁹ Statement by Moderna on Intellectual Property Matters during the COVID-19 Pandemic (8 Oct 2020) <https://investors.modernatx.com/node/10066/pdf> (accessed 6 May 2021). It should be noted that the development of Moderna's vaccine was, to a considerable extent, funded by the U.S. Government. See Allie Clouse, 'Fact check: Moderna vaccine funded by government spending, with notable private donation' <https://eu.usatoday.com/story/news/factcheck/2020/11/24/fact-check-donations-research-grants-helped-fund-moderna-vaccine/6398486002> (accessed 6 May 2021).

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¹¹ Anthony King, Why manufacturing Covid vaccines at scale is hard (23 Mar 2021) https://www.chemistryworld.com/news/why-manufacturing-covid-vaccines-at-scale-is-hard/4013429.article# (accessed 6 May 2021).

¹² Mark Terry, With Supply Lagging, COVID-19 Vaccine Manufacturers Pledge to Ramp Up (24 Feb 2021) BioSpace <https://www.biospace.com/article/covid-19-vaccine-bottleneck-scaling-up-manufacturing/>; Derek Lowe, A rough guide to pharma partnership deals (9 Feb 2021) Chemistry World <https://www.chemistryworld.com/opinion/a-rough-guide-to-pharma-partnership-deals/4013179.article>; Bojan Pancevski, BioNTech Recruits Rivals to Boost Covid-19 Vaccine Production (13 Mar 2021) <https://www.wsj.com/articles/biontech-recruits-rivals-to-boost-covid-19-vaccine-production-11615640401?page=1> (accessed 6 May 2021).

¹³ See e.g. Sara Eve Crager, Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways (2014) *Am J Public Health* 104(11): e85–e91. doi: 10.2105/AJPH.2014.302236; W. Nicholson Price II, Arti K. Rai and Timo Minssen, Knowledge transfer for large-scale vaccine manufacturing (13 Aug 2020) *Science* doi: 10.1126/science.abc9588.

¹⁴ There is no universally accepted definition of 'biosimilar' medicine. According to the European Medicines Agency, a biosimilar is 'a biological medicine highly similar to another biological medicine already approved in the EU (called 'reference medicine') in terms of structure, biological activity and efficacy, safety and immunogenicity profile (the intrinsic ability of proteins and other biological medicines to cause an immune response)'. EMA, Biosimilar medicines: Overview <https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview> (accessed 6 May 2021).

¹⁵ See e.g. EMA, European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal products applications (19 Aug 2019) EMA/940451/2011, p. 5; U.S. FDA, Biosimilar and Interchangeable Products <https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products> (accessed 6 May 2021).

¹⁶ EMA, Biosimilar medicines: Overview <https://www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview> (accessed 6 May 2021).

¹⁷ *ibid.*

¹⁸ Ministry of Science & Technology, Ministry of Health & Family Welfare of the Government of India, Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India (15 Aug 2016) http://dbtindia.gov.in/sites/default/files/uploadfiles/Guidelines_on_Similar_Biologics%2C2016.pdf; South African Health Products Regulatory Authority, Biosimilar Medicines Quality, Non-Clinical and Clinical Requirements (14 Aug 2014) <https://www.sahpra.org.za/biological-medicines-evaluation-and-research-unit-bmeru-guidelines/> (accessed 6 May 2021).

¹⁹ For the situation at the EMA, see EMA, Transfer of marketing authorisation: questions and answers <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/transfer-marketing-authorisation-questions-answers> (accessed 6 May 2021).

²⁰ Pascal Soriot, At AstraZeneca, we know that until everyone is safe from Covid, no one is safe (10 Mar 2021) <https://covid19.astrazeneca.com/en/latest-news/until-everyone-is-safe-from-covid.html> (accessed 6 May 2021); Johnson & Johnson COVID-19 Vaccine Authorized by U.S. FDA For Emergency Use - First Single-Shot Vaccine in Fight Against Global Pandemic (27 Feb 2021) <https://www.jnj.com/johnson-johnson-covid-19-vaccine-authorized-by-u-s-fda-for-emergency-use-first-single-shot-vaccine-in-fight-against-global-pandemic> (accessed 6 May 2021).

²¹ Milken Institute, COVID-19 Treatment and Vaccine Tracker https://covid-19tracker.milkeninstitute.org/#vaccines_intro (accessed 6 May 2021).

²² See COVAX Working Group on delivery costs, Costs of delivering COVID-19 vaccine in 92 AMC countries (8 Feb 2021) section 5.2, table 9 <https://www.who.int/publications/m/item/costs-of-delivering-covid-19-vaccine-in-92-amc-countries> (accessed 6 May 2021) (estimating that the total, country-level costs of delivering (not

including manufacturing) 1,219 million doses equals USD 1,722 billion, which is equivalent to USD 1.41 per dose supplied and USD 3.15 per person vaccinated with two doses).

²³ In India, for instance, the price cap is Rs 250 per dose (about 3.5 USD). See COVID-19 vaccine: Govt caps price at Rs 250 per dose in private hospitals (28 Feb 2021) <https://economictimes.indiatimes.com/news/politics-and-nation/covid-19-vaccine-govt-caps-price-at-rs-250-per-dose-in-private-hospitals/videoshow/81253391.cms> (accessed 6 May 2021).

²⁴ See e.g. the *Raltegravir* decision by the German Federal Supreme Court of 11 July 2017 (X ZB 2/17).

²⁵ Article 31(b) of the TRIPS Agreement.

²⁶ World Trade Organization, Declaration on the TRIPS Agreement and public health (14 Nov 2001) WT/MIN(01)/DEC/2, para 4.

²⁷ Communication from India and South Africa (n 1) para 9.

²⁸ The recent incident at Emergent BioSolutions in Baltimore is a case in point. See Sheryl Gay Stolberg, Emergent BioSolutions halts operations at its Baltimore plant, where J.&J. doses were ruined, at the F.D.A.'s request (19 Apr 2021) <https://www.nytimes.com/2021/04/19/us/emergent-johnson-covid-vaccine.html> (accessed 6 May 2021).

²⁹ For an overview, see Ellen't Hoen, Covid-19 and the comeback of compulsory licensing (23 Mar 2020) Medicines Law & Policy <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/> (accessed 6 May 2021); Hilary Wong, The case for compulsory licensing during COVID-19 J Glob Health 10(1) doi: 10.7189/jogh.10.010358.

³⁰ For instance, preliminary decisions on compulsory licences are possible in Germany according to Sec. 85 of the German Patent Act.

³¹ Cormac O'Sullivan, Paul Rutten, and Caspar Schatz, Why tech transfer may be critical to beating COVID-19 (23 Jul 2020) <https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/why-tech-transfer-may-be-critical-to-beating-covid-19> (accessed 6 May 2021).

³² Joel Achenbach, The coronavirus isn't mutating quickly, suggesting a vaccine would offer lasting protection (24 Mar 2020) Washington Post https://www.washingtonpost.com/health/the-coronavirus-isnt-mutating-quickly-suggesting-a-vaccine-would-offer-lasting-protection/2020/03/24/406522d6-6dfd-11ea-b148-e4ce3fbd85b5_story.html (accessed 6 May 2021).

³³ Steven A. Kemp et al., SARS-CoV-2 evolution during treatment of chronic infection (5 Feb 2021) Nature 592, 277–282 doi: 10.1038/s41586-021-03291-y.

³⁴ Milken Institute, COVID-19 Treatment and Vaccine Tracker https://covid-19tracker.milkeninstitute.org/#vaccines_intro (accessed 6 May 2021).

³⁵ For Moderna's patents, see: <https://www.modernatx.com/patents>. See also Mario Gaviria and Burcu Kilic, BioNTech and Pfizer's BNT162 Vaccine Patent Landscape (16 Nov 2020) https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/#_ftnref3 (accessed 6 May 2021).

³⁶ Elie Dolgin, Unlocking the potential of vaccines built on messenger RNA. The technology could help to boost immunity against cancer, influenza and much more (16 Oct 2019) <https://www.nature.com/articles/d41586-019-03072-8> (accessed 6 May 2021).

³⁷ Julia Kollewe, From Pfizer to Moderna: who's making billions from Covid-19 vaccines? The Guardian (6 Mar 2021) <https://www.theguardian.com/business/2021/mar/06/from-pfizer-to-moderna-whos-making-billions-from-covid-vaccines>; Matt Egan, Pfizer and Moderna could score \$32 billion in Covid-19 vaccine sales – in 2021 alone CNN (11 Dec 2020) <https://edition.cnn.com/2020/12/11/business/pfizer-vaccine-covid-moderna-revenue/index.html> (accessed 6 May 2021).

³⁸ Is the U.S. government paying twice for coronavirus vaccine? (17 Sep 2020) <https://www.pbs.org/newshour/show/is-the-u-s-government-paying-twice-for-coronavirus-vaccine> (accessed 6 May 2021).

³⁹ Above (n 35).

⁴⁰ On this point, see also Bryan Mercurio, WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review (forthcoming) Virginia Journal of International Law https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820 (accessed 6 May 2021).

⁴¹ See e.g. the agreement between the European Investment Bank and BioNTech available at <https://www.keionline.org/misc-docs/EuropeanInvestmentBank-BioNTech-Finance-Contract-10June2020.pdf> (accessed 6 May 2021). Article 2.1 of the agreement ('Amount of Credit') states: 'By this Contract, the Bank establishes in favour of the Borrower, and the Borrower accepts, a credit [...] in an aggregate amount of up to EUR 100,000,000 (one hundred million euro) for the financing of the Investment (the "Credit")'.

⁴² Communication from India and South Africa (n 1), Annex ‘Draft decision text. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19’, para 1.

⁴³ Anthony King, Why manufacturing Covid vaccines at scale is hard (23 Mar 2021) <https://www.chemistryworld.com/news/why-manufacturing-covid-vaccines-at-scale-is-hard/4013429.article/> (accessed 6 May 2021).

⁴⁴ Joint Declaration of the Alliance for Multilateralism (25 May 2020) <https://www.auswaertiges-amt.de/en/newsroom/news/alliance-multilateralism-covid19/2333394> (accessed 6 May 2021).

⁴⁵ United Nations Office on Drugs and Crime, Covid-19 vaccines and corruption risks: Preventing corruption in the manufacture, allocation and distribution of vaccines https://www.unodc.org/documents/corruption/COVID-19/Policy_paper_on_COVID-19_vaccines_and_corruption_risks.pdf (accessed 6 May 2021).

⁴⁶ Vinay Bhargava, Ensuring good governance in COVID-19 vaccination (18 Feb 2021) <https://blogs.worldbank.org/governance/ensuring-good-governance-covid-19-vaccination> (accessed 6 May 2021).

⁴⁷ Above at 4.

⁴⁸ OECD, Coronavirus (COVID-19) vaccines for developing countries: An equal shot at recovery (4 Feb 2021) <https://www.oecd.org/coronavirus/policy-responses/coronavirus-covid-19-vaccines-for-developing-countries-an-equal-shot-at-recovery-6b0771e6/> (accessed 6 May 2021).

⁴⁹ Owen Dyer, Covid-19: Countries are learning what others paid for vaccines (29 Jan 2021) BMJ doi: <https://doi.org/10.1136/bmj.n281>.

⁵⁰ On higher risks caused by variants of Covid-19 that have emerged in Brazil, South Africa and the UK, see e.g. Michelle Roberts, What are the India, Brazil, South Africa and UK variants? BBC News <https://www.bbc.com/news/health-55659820> (accessed 6 May 2021).

⁵¹ WHO, The Access to COVID-19 Tools (ACT) Accelerator <https://www.who.int/initiatives/act-accelerator> (accessed 6 May 2021).

⁵² Seth Berkley, COVAX explained (3 Sep 2020) <https://www.gavi.org/vaccineswork/covax-explained> (accessed 6 May 2021).

⁵³ WHO, Global leaders unite in urgent call for international pandemic treaty (30 Mar 2021) <https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-international-pandemic-treaty> (accessed 6 May 2021).

⁵⁴ See e.g. Haik Nikogosian, The case for an international pandemic treaty BMJ 2021, 372 www.bmj.com/content/372/bmj.n527 (accessed 6 May 2021); EFPIA, Vaccines Europe response to global leaders urgent call for international pandemic treaty (30 Mar 2021) <https://efpia.eu/news-events/the-efpia-view/statements-press-releases/efpia-vaccines-europe-response-to-global-leaders-urgent-call-for-international-pandemic-treaty/> (accessed 6 May 2021).

⁵⁵ In section 5 of this version, the paragraph on Article 31bis TRIPS is removed because this provision - contrary to what was stated in the previous version - applies not only to the least-developed countries. The current law thus already addresses the concern initially expressed. We thank the careful readers for pointing this out.