Queen Mary Journal of Intellectual Property, Vol. 12 No. 4, pp. 441–469

COVID-19, vaccines and international knowledge governance on trial

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The production, distribution and availability of vaccines to combat the COVID-19 pandemic are all impacted by the international rules of knowledge governance. These rules include patents, trade secrets and health and efficacy regulatory approval processes. This article discusses how these intellectual property related mechanisms all interfered with vaccine availability. It analyses the international rules, related exceptions (including compulsory licensing and national security) and the possible waiver of the relevant rules found in the World Trade Organization TRIPS Agreement. Throughout the first two years of the pandemic, vaccines were not available widely enough. Although most of the developed world had enough vaccine doses by late 2021, that was not the position in much of the developing world, where the problem became the distribution of vaccines. Distribution may have always been difficult, but the failures in timely local supply exacerbated the problem of vaccine inequality between the developed and developing world. The inequality had several likely causes including intellectual property rules. The problem was not necessarily the existence of patents (or other rules) but the insufficiency of checks and balances that are necessary to address global public health needs. This resulted in private interests, whose primary goal is not public health, wielding too much power. The article concludes that collectively the effect of the international rules enacted in domestic laws supports a regime that was not fit for purpose to address the COVID-19 pandemic and is not fit to address future pandemics.

Keywords: *TRIPS Agreement, patents, regulatory approval, innovation incentives, COVID-19 vaccines, compulsory licensing, national security*

1 INTRODUCTION

Almost as soon as the COVID-19 pandemic began there emerged wide agreement that the long-term solution to the global public health crisis was the development and distribution of effective vaccines and ensuring that enough people are vaccinated to exercise some control over the pandemic. During 2021, vaccines were administered in some places following both fast-actioned clinical trials, fast-tracked regulatory approval processes and blanket legal immunity for pharmaceutical companies from liability for any possible side-effects or adverse medical consequences of the vaccines. Despite this progress in innovating vaccines, there were not enough doses to vaccinate everyone globally for most of 2021. There are different vaccines available in different parts of the world and their effectiveness varies both relative to each other and against different COVID-19 variants. When the vaccines first emerged there were not enough doses to simultaneously vaccinate everyone (or anything close to that). There were not enough vaccines administered in the developing world well into 2022. Later that year there were

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enough doses for all, but there was still a problem as vaccine distribution meant that there remain many parts of the world where not enough people are vaccinated. Pharmaceutical companies asserted that this means 'that the energy focused on undermining intellectual property could be channelled into collectively addressing vaccine equity'.[1] This statement wrongfully suggests that the intellectual property rights system is not and has never been part of the vaccine equity problem. This article shows how intellectual property has contributed to the initial delays in supply, ongoing delays in distribution and vaccine inequality.

The development and distribution of vaccines encounter knowledge governance issues that have a deep impact on the success, or otherwise, of those vaccines. The creation of vaccines requires research and development (R&D) involving many scientific and financial complexities. This includes private sector and government funded research. There has been a huge amount of government funding involved in COVID-19 vaccine development, accounting for at least 98 per cent of total funding in the United States and Europe.[2] The role that intellectual property plays in both the scientific and financial aspects of vaccine development and distribution is embedded in the international system of knowledge governance, which includes intellectual property. As a result of the pandemic, the use of patents, trade secrets and the regulatory approval systems to establish the safety and efficacy of any vaccine have been and continue to be on trial.

The pandemic has illustrated several challenges, weak spots and potential failures of the existing system which have contributed to delays in the manufacturing and distribution of vaccines. The inequality of distribution, with wealthy countries supplying themselves ahead of global distribution and ineffective distribution in the developing world when doses become available, points to both pharmaceutical company practice and government regulation that is unacceptable to those who support public health and access to medicines for all.

More generally than the COVID-19 pandemic, the effect of the patent and regulatory approval systems on the development of vaccines and access to medicines has been an issue for some time. Issues raised in this article may also be relevant to medicines other than vaccines, but this article focuses on vaccines. Vaccine development can be expensive and often not profitable because some of the vaccine market has been much smaller than the market for other pharmaceuticals.[3] This has, particularly, been the situation for what are known as neglected diseases.[4] Pharmaceutical companies are unlikely to invest

1. International Federation of Pharmaceutical Manufacturers and Associations, 'As COVID-19 Vaccine Output Estimated to Reach Over 12 Billion by Year End and 24 Billion by mid-2022, Innovative Vaccine Manufacturers Renew Commitment to Support G20 Efforts to Address Remaining Barriers to Equitable Access' (19 October 2021) <https://www.ifpma.org/resource-centre/as-covid-19-vaccine-output-estimated-to-reach-over-12-billion-by-year-end-and-24-billion-by-mid-2022-innovative-vaccine-manufacturers-renew-commitment-to-support-g20-efforts-to-address-remaining-barr/>.

2. RG Frank, L Dach and N Lurie, 'It Was the Government that Produced COVID-19 Vaccine Success' (*Health Affairs*, 14 May 2021) <https://www.healthaffairs.org/do/10.1377/hblog20210512.191448/full/>; N McCarthy, 'Which Companies Received the Most Covid-19 Vaccine R&D Funding?' (*Forbes*, 6 May 2021) <https://www.forbes.com/sites/niallmccarthy/2021/05/06/which-companies-received-the-most-covid-19-vaccine-rd-funding-infographic/?sh=5c84c7154333>.

3. PA Offit, 'Why Are Pharmaceutical Companies Gradually Abandoning Vaccines?' (2005) 24(3) Health Affairs 622.

4. The term neglected disease refers to diseases affecting primarily the world's poorest populations, World Health Organization, 'Neglected Tropical Diseases' <https://www.who.int/

in vaccine development for neglected diseases because there is no profit incentive to do so. Few would dispute that we need the invention of medicines and vaccines. The need for and benefits of innovation form the core rationale of patent law. However, as the history of vaccine development shows, it is not only the need for innovation but the profit that flows from the products of that innovation which lead to pharmaceutical companies deciding what areas to innovate in. The need to combat COVID-19 saw many pharmaceutical companies returning to, or being involved for the first time in, vaccine R&D because sales will undoubtedly generate extensive profits as there is an unprecedented global market for these vaccines.

In simple economic terms, there was no lack of demand and an immense supply shortage of COVID-19 vaccines. And while the pandemic raged in the developed world, demand outpaced global supply for some time.[5] Moreover, high levels of demand for better distribution continued while much of the world had not been vaccinated and some of those who were already vaccinated were having booster shots. At the same time, doses were wasted because they could not be distributed.[6] In the intervening period between the development of vaccines and their availability, vaccine hesitancy, perhaps alarmingly, blossomed.[7] Vaccine hesitancy seems to have several different causes, including the very difficult challenge of disinformation, but also concerns about side-effects for some vaccines.[8] One commentator suggested a connection between delays in availability and hesitancy.[9]

There is also the ongoing need for new vaccines to combat new variants. Almost simultaneously vaccinating everyone could have avoided the progress of variants, but such coordinated wide-scale vaccination has not happened and shows no sign of happening as further variants emerged late in 2021, in 2022 and in 2023. The infrastructure to vaccinate the globe almost simultaneously does not exist. This is a failure in which intellectual property has a significant, even if not exclusive, role.

This situation of limited supply and a failure to upscale manufacture and distribution fast enough to meet global demand is a symptom of a faulty international framework that

neglected_diseases/diseases/en/>. See also JM Bethony et al., 'Vaccines to Combat the Neglected Tropical Diseases' (2011) 239(1) Immunol Rev 237–70 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3438653/>.

5. G Finnegan, 'When will COVID-19 Vaccines be Available?' (*Vaccines Today*, 8 October 2020) <https://www.vaccinestoday.eu/stories/when-will-covid-19-vaccines-be-available/>.

6. L Barnéoud, 'The Huge Waste of Expired Covid-19 Vaccines' (*Le Monde*, 4 April 2022) <https://www.lemonde.fr/en/science/article/2022/04/04/the-huge-waste-of-expired-covid-19-vaccines_5979632_10.html> (indicating that the doses donated to COVAX could not be distributed before their use-by date. In other words, they were donated too late).

7. C Bateman, 'More than 7-million Expired Pfizer Covid-19 Vaccines could be Wasted by July' (*Mail & Guardian*, 1 April 2022) <https://mg.co.za/coronavirus-essentials/2022-04-01-more-than-7-million-expired-pfizer-covid-19-vaccines-could-be-wasted-by-july/> (citing misinformation and disinformation as the leading cause of vaccine hesitancy in South Africa); 'How Many COVID Vaccines Have Gone to Waste? Millions in the U.S. Alone—and the Total is Climbing' (*The Associated Press*, 7 March 2022) <https://fortune.com/2022/03/06/how-many-covid-vaccines-have-gone-to-waste-millions-in-the-u-s-alone-and-the-total-is-climbing/>.

8. Some countries never used the Astra Zeneca vaccine because of possible blood clots. Some countries have passed the vaccine that they do not want to use on to the developing world, see Barnéoud (n 6) and 60 million AstraZeneca shots might be thrown out, see '60 Million AstraZeneca Shots Might Be Thrown Out' (*The Asahi Shimbun*, 8 April 2022) <https://www.asahi.com/ajw/articles/14593642>.

9. Bateman (n 7) (referring to 'lack of access, apathy, anxiety and conspiracy as the four main drivers of hesitancy').

enables private control of vaccine availability to dominate the globe. This has resulted in some governments and international organizations repeatedly asking multinational pharmaceutical companies to address this issue more effectively.

One approach to ensuring a better and faster supply of vaccines, earlier in the pandemic, would have been to capacity build and voluntarily license others to be involved in vaccine manufacture and distribution, but this did not happen at the necessary speed and scale. This was not simply the result of the pandemic but was exacerbated by the international rules system and how the relevant knowledge is governed. The current structure of knowledge governance ensures that the pharmaceutical companies that invented the vaccines were in charge of innovation, supply and distribution, and pricing (and they remain so). Thus, a significant part of pandemic management was and remains under private control, with very few effective counterbalances that might give more weight to public health. The patent system, trade secrets and pharmaceutical regulatory approvals systems have framed a structure for innovation that is inadequate to address the needs of the pandemic and so needs reform if the current and future pandemics are to be more effectively addressed.

This does not necessarily mean that having patents is the problem and getting rid of them the solution. The problem is that patents operate without sufficient checks and balances stemming from public-regarding principles, such as public health. This may be true more broadly than in connection with the COVID-19 pandemic, but that is a separate point. The problem is particularly acute in the pandemic context and, consequently, needs addressing specifically in that setting regardless of the wider issues. Also, as a result of the pandemic and the dependence on vaccines, more people and policymakers are aware that the international intellectual property system has seemingly become part of the problem. Patents can be very strong exclusive rights with few exceptions permitted under international law. Those few exceptions include compulsory licensing (in limited circumstances) and exceptions based on national security interests. The rationales for the strength of patent law's exclusive rights, the limited exceptions to the rights and their application to COVID-19 vaccines are discussed in section 2.

Patents and trade secrets are not the only legal devices that are relevant to the availability of any vaccine. The safety and efficacy of any vaccine is a matter for the relevant national or regional regulatory body, such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the United Kingdom and the Food and Drug Administration (FDA) in the United States. These regulatory approval bodies are the gatekeepers to the marketing of pharmaceuticals. Any applicant for regulatory approval of a pharmaceutical must support their application with data. For innovative (first) medicines, including vaccines, this consists of clinical trials and their results. The regulatory bodies are subject to various rules about how they determine the efficacy and safety of pharmaceuticals, including provisions around the confidentiality and sometimes exclusivity of clinical data provided to them. Around the world regulatory bodies have used fast-track approval processes for COVID-19 vaccines.[10] Fast-tracking initially raised concerns about just how effective and safe the vaccines would be. In the United Kingdom, the United States and elsewhere pharmaceutical companies have been given immunity from any legal challenge about the safety of the vaccines.

Regulatory bodies are not able to share clinical data either with other such bodies or independent experts. The sharing of data, like the sharing of other information around

10. 'UK Moves to Fast-Track Coronavirus Vaccine if Safety Tests Passed' (*Reuters*, 29 August 2020) <https://www.reuters.com/article/us-health-coronavirus-britain-regulator-idUSKBN25O2FX>.

COVID-19 (such as gene sequences) might assist in, for example, a greater understanding of when and why the vaccines are effective and matters such as why some variants are resistant to some vaccines but not to others. Pharmaceutical companies are unwilling to share data but prefer confidentiality. Mandatory confidentiality and, in some instances, data exclusivity requirements that regulatory bodies must abide by, arise from national laws, some of which reflect trade agreement commitments. These confidentiality and exclusivity requirements function as barriers to data sharing and can, therefore, also adversely affect pandemic control, as part 3 of this article discusses.

An early response to the COVID- 19 vaccine shortage was a call for the waiver of intellectual property rights at the World Trade Organization (WTO).[11] The initial and continuing response of pharmaceutical companies to the waiver request was little more than the assertion that incentives for innovation are needed now more than ever.[12] Even though there was and is a need for innovation, that does not simply translate to accepting that the knowledge governance system is fit for purpose. The layers of rhetoric around patents, trade secrets and confidentiality being necessary for innovation mask a simple truth, which is that intellectual property rights alone were not the main incentive for COVID-19 vaccine development, rather the worldwide market provided that incentive because everyone who is medically able to be vaccinated should be.

The World Health Organization (WHO) has stated that access to vaccines should be possible for all and it has supported initiatives with that ultimate goal. One such initiative was COVAX, an alliance led by the WHO, the Global Alliance for Vaccines and Immunizations (GAVI) and the Coalition for Epidemic Preparedness Innovations (CEPI), which has committed to vaccine equality.[13] Its stated goal remains to 'facilitate the equitable access and distribution of these vaccines to protect people in all countries. People most at risk will be prioritized'.[14] Even this sort of public alliance must, however, rely on private pharmaceutical companies to supply it.[15] Only some pharmaceutical companies agreed to supply the alliance.[16] And some of those companies provided vaccines that were near their expiry date and therefore could not be

11. WTO 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). See also revised proposal, 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Communication from the African Group, the Plurilateral State of Bolivia, Egypt, Eswatini, Fiji, India, Indonesia, Kenya, LDC group, Maldives, Mozambique, Mongolia, Namibia, Pakistan, South Africa, Vanuatu, Bolivarian Republic of Venezuela, Zimbabwe, IP/C/W/669/Rev.1 (21 May 2021). For the final text of the waiver see, WTO Ministerial Conference Twelfth Session, Geneva, 12–15 June 2022, 'Ministerial Decision on the TRIPS Agreement', WT/MIN(22)/30, WT/L/1141 (17 June 2022).

12. E Farge, 'Backers of IP Waiver for COVID-19 Drugs Make Fresh Push at WTO' (*Reuters*, 20 Jan 2021) <https://www.reuters.com/article/us-health-coronavirus-wto-idUSKBN29O2DF>.

13. World Health Organization, 'COVAX: Working for Global Equitable Access to COVID-19 Vaccines' <https://www.who.int/initiatives/act-accelerator/covax>.

14. ibid.

15. See explanation of how GAVI (a COVAX partner) secured a procurement deal with Sanofi GSK <https://www.gavi.org/news/media-room/gavi-signs-statement-intent-procure-200-million-doses-sanofi-gsk-covid-19-vaccine>.

16. Pfizer has agreed to supply 40 million doses to COVAX, see E Farge and M Blamont, 'WHO Says Pfizer Deal Could Allow Poor Countries to Start Vaccinating in Feb' (*Reuters*, 23 January 2021) <https://www.reuters.com/article/us-health-coronavirus-pfizer-covax-idUSKBN29R288>.

effectively used by those developing countries that were most in need.[17] By the end of 2022 there were questions about the viability of the programme because even though vaccination rates remain low in many developing countries demand for vaccines is also low.[18]

While cooperation of the COVAX kind seems heartening, the approach was, and is, not a shared goal of all, and there has been some considerable anti-equality behaviour, known as vaccine nationalism. This took several forms, including governments trying to gain exclusive access to potential vaccines[19] and vaccinating their own citizens first. Vaccine nationalism is also apparent in the European Union's use of export controls on some vaccines that it produced.[20] This would not be the first time that the world has witnessed nationalism around pharmaceuticals and the hoarding of products by wealthy countries. This occurred with oseltamivir (Tamiflu), in response to the flu epidemic earlier this century.[21] What has occurred before with some medicines does not necessarily tell us exactly what will happen with COVID-19 vaccines, but we can discern some considerable lessons about pharmaceutical company behaviour and government complicity with that behaviour from both this case study and what we have seen since the pandemic began. This has contributed to why some countries have sought a waiver of intellectual property rights at the WTO, which is discussed in section 4.

Finally, the article concludes that the invention, manufacture and distribution of COVID-19 vaccines shows how the defects of the patent and pharmaceutical regulatory system undermine its credibility and that the pandemic has placed the system on trial. The COVID-19 pandemic is a matter of global public health. Public health solutions should not play second fiddle to patents, trade secrets and regulatory secrecy in a worldwide pandemic. The extent to which such laws can interfere with public health is too great and, what is worse, significant parts of these laws rest on shaky policy rationales.

2 PATENT LAW AND COVID-19 VACCINES

From international intellectual property law's standpoint, vaccines are a subset of pharmaceuticals about which, more generally, there is an ongoing debate around the effect of patents (and trade secrets) on access to medicines. Even before COVID-19 emerged as a global problem, much of the international pharmaceutical debate has been framed around access to medicines for developing and least developed countries (LDCs) and

17. Barnéoud (n 6).
18. S Nolen, 'Global Partners May End Broad Covid Vaccination Effort in Developing Countries' (*New York Times*, 6 Dec 2022) <https://www.nytimes.com/2022/12/06/health/covid-vaccines-covax-gavi.htm>.
19. A McMahon, 'Patents, Private Governance and Access to Vaccines and Treatments for Covid-19' (*Journal of Medical Ethics blog*, 4 August 2020) <https://blogs.bmj.com/medical-ethics/2020/08/04/patents-private-governance-access-to-vaccines-and-treatments-for-covid-19/>; AS Rutschman, 'The Reemergence of Vaccine Nationalism' (2020) Georgetown Journal of International Affairs <https://gjia.georgetown.edu/2020/07/03/the-reemergence-of-vaccine-nationalism/>.
20. As the EU's ability to supply itself with vaccines dwindled, in February 2021 the EU limited export of vaccine doses, see JH Vela, 'EU Imposes Vaccine Export Controls on Rich Nations from Saturday' (*Politico*, 29 January 2021) <https://www.politico.eu/article/eu-imposes-export-controls-on-rich-nations-from-saturday/>.
21. Oseltamivir is the generic name for the active ingredient found in the brand Tamiflu manufactured by Roche; see the discussion in part 4.

the associated problems of access and availability at an affordable price.[22] Although pharmaceutical companies often charge prices beyond what is affordable in developing countries and LDCs, pricing issues are not only confined to those countries; such issues have also been central to debates in the developed world. Even though health systems may apportion the cost of pharmaceuticals among consumers, the public health system (where it exists) and insurance, and market conditions may temper that cost to some degree, the twentieth and early twenty-first centuries have generally seen very high prices for most pharmaceuticals. Prices might be lowered when the pharmaceuticals are off-patent and there is effective competition. Sometimes that competition comes from generic medicines, but sometimes there can also be only one generic producer or, worse, none. Because those who invent most pharmaceuticals can determine price, excessive pricing has continued apace. The effects of exclusive control over price were made stark in the pandemic where some countries could afford to pay the price direct to those selling vaccines and others could not. Unaffordability of medicines has been one of the prime reasons that many commentators doubt whether the patent system serves anything other than the profit-making goals of the pharmaceutical industry and, therefore, consider that it no longer serves the public good effectively.

Patent law and the property rights it enables should have explicable policy rationales because patents give strong exclusive rights and are a wholly legal construct; meaning that they do not exist without the law. Patents in effect regulate many aspects of uses of inventions. The law creates the property device of a patent that has an independent legal existence from the invention that it regulates. All property is regulated to some extent, and in different ways, depending on the relevant society and its political choices, but there is no society in which patents exist without regulation creating them, whereas real property (land) and personal property (such as violins and clothes) do so exist. Recognizing that patents are regulated property is not simply a matter of legal semantics, but doing so underscores why the exclusive rights that arise from patents and their scope should have detailed public policy rationales. The standard justification is that patents reward innovation and thus incentivize it. The pharmaceutical company response to the call for better access to vaccines (including more voluntary licences or waiver of rights) has mostly been the suggestion that those companies serve the public good by inventing medicines and that they need the incentive of intellectual property rights to do so. That is overly simplistic.

2.1 Incentive rationales and investment

The purpose of patent protection is often and simply described as encouraging innovation. In other words, patents are innovation incentives. Patent laws in national regimes of the common law tradition have historically been described as being based on a 'social contract', a bargain between the Crown (the state) and the inventor.[23] The essence of this social contract is a bargain where, in exchange for the exclusivity of a patent (a reward), society ultimately benefits from the disclosure of the invention in order for the exclusive right to be granted (disclosure takes place in the written form of the patent that enables

22. See for example, R Dreyfuss and C Rodríguez-Garavito (eds), *Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America* (Oxford University Press, 2014).
23. P Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge University Press, 2010) 27–32 and HL MacQueen, C Waelde and GT Laurie, *Contemporary Intellectual Property: Law and Policy* (Oxford University Press, 2008) 10.15–10.16.

the invention to be made by a person skilled in the relevant art).[24] The disclosure part of this rationale is reflected in modern trade agreements. The WTO's Agreement on Trade-Related Intellectual Property Rights[25] (TRIPS Agreement), mandates that national patent registration systems must require that patents disclose 'the invention in a manner sufficiently clear and complete'. Disclosing the 'best mode' of making the invention is optional.[26] The art of drafting a patent includes disclosing only as much as necessary and consequently disclosure is not always as fulsome as it should be, which in turn undermines the disclosure part of the incentive rationale.[27] Often, however, the patent does not provide the know-how to make the patented invention and there may also be trade secrets that prevent a competitor from using the patent to make the invention. Patent disclosure cannot fix this problem.

There are many difficulties with the social contract/bargain theories because they explain only some aspects of patent law. On their own these theories do not form either a sound normative or empirical basis for patent law, but their use for lobbying purposes is frequent. In particular it is often said, without any adornment or detail, that pharmaceutical companies need patents to incentivize innovation. This kind of claim when used without evidence has become more rhetorical than fit for purpose, yet it often persists without the necessary detailed evidence to support it. Rationales that are more substantive than rhetorical are necessary if patent law is to retain credibility. More problematically, patentees' exclusive rights have grown in scope and continue to do so, mostly because of bilateral and plurilateral trade agreements, whereas a concomitant flexibility that includes public-regarding checks and balances is not growing in the same way.

The problem of whether pharmaceutical patents motivate inventiveness or mostly excess profit (in the market where they are invented and/or export markets[28]) shows the need for better evidence and more detailed rationales for strengthening patent law than either the reward for disclosure bargain or social contract theories can provide. While innovation is undoubtedly a public good, whether patents are an appropriate reward or true incentive for innovation is a matter of some considerable division internationally. The ways in which the patent system does not serve the public good – such as when COVID-19 vaccines were limited in supply and unavailable and when they remain inaccessible for many – has caused that division to grow.

The pharmaceutical industry repeatedly uses this reward for innovation rationale in its lobbying, at both national and international level, for more extensive protection, and it has been remarkably successful in achieving many gains in protection, both

24. The disclosure must be made before the patent is granted, see RS Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) 56 Uni of Chicago LR 1017, 1022.

25. Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299; 33 ILM 1197 (adopted on 15 April 1994, entered into force 1 January 1995) ('TRIPS Agreement').

26. TRIPS Agreement (n 24) art 29.1 provides, 'Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application'.

27. For a discussion of how patent disclosure 'under performs', see J Fromer, 'Patent Disclosure' (2008–2009) 94 Iowa L Rev 539.

28. For a discussion of how the patent rationale for domestic and export markets differs see S Frankel, *Test Tubes for Global Intellectual Property Issues: The Small Market Economy* (Cambridge University Press, 2015).

domestically in some jurisdictions and through trade agreements. Particularly in trade agreement negotiations, the same rather simplistic claim that law reform is necessary to support innovation is made whatever the type of protection that the pharmaceutical industry seeks. Whether that protection is an extension of patent term, requiring new uses of various sorts to be patentable, increases in the conditions and terms of data exclusivity in the regulatory process, or any other matter, the same claim is made and is equally, as often as not, supported by evidence showing why any specific development in patent law would incentivise more innovation than the existing rules. Much patent law is devoid of a grounding in evidence-based policy of this kind,[29] although in some jurisdictions that has started to change, even if imperfectly.[30]

There is no doubt that vaccine development is highly sophisticated and expensive. It requires experts, extensive research and testing, none of which is possible without considerable investment. This investment may come from public funds and pharmaceutical private funding. Where private funding is involved, vaccine developers must try to recoup their losses through sales.[31] The reason that some vaccines are not researched is because there is too much business risk where there are not likely to be enough sales to recoup loss and make a profit. The patent incentive is supposedly able, at least sometimes, to fill that gap. The pandemic, however, created incentives that do not require patent exclusivity. First, given the volume of vaccines produced and sold initially, and orders for more to be made and delivered around the world, it seems likely that pharmaceutical companies have recouped any R&D costs within a few months (and then many times over) and made a considerable profit. Second, the global market is an incentive in its own right and there has been much gained for the first movers in the market. Finally, the global market when combined with government-funded research and immunity from liability meant that vaccine makers have not faced any real risk. In such a situation, the exclusivity of patents (and trade secrets) is not required as an incentive. Therefore, the owners of the patents should enable maximum voluntary licensing and technology transfer to increase the rate of supply. They should not use patents to reduce supply, but during 2021 this was what happened. It is inconsistent with patent-related justifications to not provide affordable licensing, enable capacity building and technology transfer so that others can make vaccine(s) in order to increase much needed supply, when there is a supply shortage. The failure to have manufacture more widely spread around the globe increased prices and thus unaffordability for some and may very well have increased the chances of variants emerging and even the growth of vaccine hesitancy.[32] Unnecessary intellectual property barriers are even more egregious when there is considerable public investment in the relevant research and a public health crisis.

Investment in vaccines comes from both public and private sources. The exact detail of any public and private investment overlap will vary depending on whether you are in Europe, China or the United States, for instance, but the framework of

29. For a discussion of what evidence-based policy might require see S Frankel, 'Intellectual Property as a Regulator of Behaviour' in S Frankel and D Gervais (eds), *Intellectual Property and the Regulation of the Internet* (Victoria University Press, 2017) 193–211 and see J de Beer, 'Evidence-Based Intellectual Property Policymaking: An Integrated Review of Methods and Conclusion' (2016) 19 JWIP 150.
30. In the EU the enactment of a waiver for the manufacturer of generic medicines for export during the term of a patent is an example of a patent reform where much evidence (both for and against) was gathered.
31. Offit (n 3).
32. Bateman (n 7).

the patent system leaves considerable power to the private sector to determine what to research and develop. Public–private partnerships are sometimes seen as ways to develop investment in areas of medical research that might not generate enough returns to merit private-only investment.[33] Such partnerships may also result in some form of public ownership of the invention. In relation to COVID-19 vaccine development, however, there has been considerable government investment in the research and there are many public private partnerships involved in R&D, but the private side of the equation seems to be predominantly involved in manufacturing and distribution. Private owners have ensured that the licensing of intellectual property rights is opaque and seemingly only in private hands. While public funds were used to develop a vaccine at Oxford University, for example, Oxford agreed to a commercialization partnership with Astra Zeneca where there is no public ownership of the intellectual property.[34] In the United States the Bayh-Dole Act allows for government ownership of patents that relate to publicly funded research in universities and some other entities, but the law's complexities are heavily critiqued and it has not changed the way the pharmaceutical industry operates, particularly during the pandemic.[35] Even if there are a few exceptions to the private ownership model, the behaviour of governments in having opaque supply deals with pharmaceutical companies undercuts the possibilities of public ownership allowing the technology being available for all to use in the making of vaccines.

Once the private sector develops a vaccine both governments and international organisations, such as the WHO, potentially have very little power to influence its distribution unless they buy large quantities so as to control some distribution, as both the COVAX alliance has done and some governments. By September 2021 the United States and EU had pledged to buy millions of doses of the Pfizer vaccine for middle- and low-income countries.[36] That was not a long-term solution to this kind of situation, which has arisen solely because private ownership is secured by patent ownership without any requirement to license the technology to others. And as vaccine distribution issues increased in 2022 that was underscored. Yet, the pharmaceutical system is structured on the contestable notion that patents ultimately serve the public good. In the pandemic the innovation of vaccines is unquestionably a public good, but their unequal distribution and the failure to license, on a voluntary basis, more entities to produce vaccines cannot be justified as a public good.

33. See A Krattiger, T Bombelles and A Jedrusik, 'Driving Innovation for Global Health through Multi-stakeholder Partnerships' in M Chon, P Roffe and A Abdel-Latif (eds), *The Cambridge Handbook of Public-Private Partnerships, Intellectual Property Governance, and Sustainable Development* (Cambridge University Press, 2018).
34. 'Coronavirus: How Countries Aim to Get the Vaccine First by Cutting Opaque Supply Deals' (*The Conversation*, 27 July 2020) <https://theconversation.com/coronavirus-how-countries-aim-to-get-the-vaccine-first-by-cutting-opaque-supply-deals-143366>.
35. AK Rai et al., 'Is Bayh-Dole Good for Developing Countries? Lessons from the US Experience' (2008) 6 PLoS Biology 2078–84; DC Mowery and BN Sampat, 'The Bayh-Dole Act of 1980 and University–Industry Technology Transfer: A Model for Other OECD Governments?' (2004) 30 Jour of Tech Transfer 115.
36. K Cullinan, 'US Will Give 500 Million More Pfizer Jabs to Poor Countries, Joins EU in Launching New COVID Financing Fund' (*Health Policy Watch*, 22 Sept 2021) <https://healthpolicy-watch.org/us-will-give-500-million-more-pfizer-jabs-to-poor-countries-joins-eu-in-launching-new-covid-financing-fund/>.

2.2 The exclusive rights of patentees

A patent includes claims that delineate the scope of the patent that frame the exclusive rights of the patentee. A single vaccine may involve several separate patents and claims relating to either or both the process of making the subject vaccine and the vaccine as a product.[37] Vaccines vary in type and scope (some are biologics[38] and others are chemical[39]) and, consequently, so do the patents that relate to them. The development of some vaccines will rely on the application of new knowledge that is patentable and the development of others might only utilize existing or fundamental knowledge that is not novel and, therefore, not patentable. All new vaccines, however, have the potential to be patented and the pharmaceutical companies developing such vaccines tend to patent all aspects of them.

The existence of a patent(s) is not on its own the main concern. After all there are good arguments for inventors to patent their inventions, such as the need to recoup R&D expenses. Although, the exact details of such expenses are often kept as commercial secrets.[40] As noted above in connection with innovation incentives, a worldwide market for COVID-19 vaccines means that these expenses seem likely to have been relatively quickly recouped. When this is combined with massive amounts of public funding and liability waivers there is very little risk to most pharmaceutical companies. In such circumstances, inflexible exclusivity cannot be justified and affordable access and licensing opportunities should be possible, but there are not enough levers to ensure such access and licensing takes place and so it has not happened. The issues of access are a combination of supply and affordable price. The price that the developed world can play, and the infrastructure that developed countries have, cannot be matched by much of the developing world.

Attempts by the United Nations to change the pricing of pharmaceuticals, based on decoupling the price of them from R&D expenditure,[41] have been vehemently opposed by pharmaceutical companies. Indeed, some such companies would go as far as to say that the obligations of companies to their shareholders requires that they seek patents (and other protections) and enforce them.[42] The real issue is not so much the existence of patents but is rather the latitude given to patent owners to determine price and licensing arrangements without appropriate checks and balances within either the patent or regulatory systems. Trade secrets also have an important role and act to shore up protection rather than offer a counterbalance to it. Consequently, how the inventors of vaccines may choose to exploit their intellectual property, and particularly patents, is critical. There are several possibilities. Vaccine inventors may choose to be the only manufacturer and distributor of the vaccine. They may license others to either manufacture or distribute the vaccine, or to do both in a particular country or region.

37. The scope of a patent is governed by the claims in the patent specification.
38. A biologic is a pharmaceutical that is derived from human, animal or microorganism material.
39. Chemical pharmaceuticals are mostly small molecules.
40. The pharmaceutical industry does not reveal how much it spends on R&D on a per drug basis. It claims that it needs to recoup costs on failed drugs as well as successful drugs, see The United Nations Secretary-General's High-Level Panel on Access to Medicines Report <http://www.unsgaccessmeds.org/final-report/>.
41. ibid.
42. See E Silverman, 'UN Panel Urges Wider Access to Medicines, but Pharma Slams the Report' (*Stat Pharmalot*, 14 September 2016) <https://www.statnews.com/pharmalot/2016/09/14/united-nations-drug-prices-patents/>.

The ability for others to obtain a licence might arise from an existing relationship with the manufacturer (such as one arising from investment in the R&D process) or it might be something that can be purchased for a considerable price. Another, but sadly as time has proven, unlikely, option is that the patent(s) and related knowledge for COVID-19 vaccines are made available for licensing to anyone to make them and distribute them, at an affordable price.

2.3 Distribution problems and compulsory licensing exceptions to patentees' exclusive rights

The first two years of the COVID-19 pandemic demonstrated that there are considerable practical issues around the ability of any, or indeed several, manufacturers to make enough of any vaccine and have the capacity to distribute it widely and in a timely manner. In addition, there were supply chain challenges of various kinds, including some shortages in materials required to make, for example, the phials for the vaccine.[43] While in 2022 there was more supply, distribution remains problematic. This may also be why countries have not taken advantage of compulsory licensing. The ideal way for intellectual property law to contribute to the upscaling of manufacture and distribution would be non-exclusive voluntary licensing of the relevant patents and trade secrets. This coupled with capacity building should create effective technology transfer. But this is not something that the private interests involved have been willing to do to address COVID-19 and many governments have not been prepared to force the issue with compulsion. This behaviour seems likely to continue.

Vaccinations have been administered at different speeds in different places, but there has been little evidence that those making the vaccine are willing to license others to also do so. In early 2021 one pharmaceutical company (Sanofi) appears to have agreed to manufacture the Pfizer BioNTech vaccine, but the terms of this agreement do not seem to be publicly available.[44] This kind of cooperation needed to happen on a much wider and global scale so as to effectively address the global public health crisis and need for vaccines as fast as possible. There were also reports of the Astra Zeneca vaccine being licensed more widely, particularly in developing countries.[45] The Serum Institute in India is one place that is licensed to make vaccines but its ability to meet supply requirements particularly in Africa has been controversial.[46] And capacity building to address this is coming too late.

It has also been unclear if there was spare capability and capacity to make the vaccine earlier in the pandemic. This remains an issue. If there was idle capacity, as some

43. 'Covid-19 Vaccine Rollout Calls for Supply-Chain Collaboration, Logistics Chief Says' (*The Wall Street Journal*, 26 October 2020) <https://www.wsj.com/articles/covid-19-vaccine-rollout-calls-for-supply-chain-collaboration-logistics-chief-says-11603713612>.
44. A Charlton, 'France's Sanofi to Help Rival Pfizer-BioNTech Make Vaccines' (*AP News*, 28 January 2021) <https://apnews.com/article/coronavirus-pandemic-france-germany-coronavirus-vaccine-frankfurt-df5e622611a52bd706a5171c5047688a>.
45. M Rochabrun, 'Brazil Signs Agreement to Produce AstraZeneca's Experimental COVID-19 Vaccine' (*Reuters*, 28 June 2020) <https://www.reuters.com/article/us-health-coronavirus-brazil-vaccine-idUSKBN23Y0NB>.
46. J Macharia, 'India's Serum Institute Let Africa Down on Vaccines, Says Africa CDC' (*Reuters*, 10 December 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/indias-serum-institute-let-africa-down-vaccines-says-africa-cdc-2021-12-09/>.

news reports suggested,[47] then it should have been used, not blocked because of a failure to transfer the relevant technology. It takes time to capacity build in an area as complex as vaccines, but when the pandemic had been raging for several months (let alone over two years) there ought to have been substantial capacity building and perhaps even retooling or building places to produce enough vaccine earlier, which after all would be duplicating existing technology. An unwillingness to license intellectual property rights (patents, trade secrets and any relevant know-how) to do this apace was and is unacceptable in a pandemic. If there was no spare manufacturing capacity or the ability to upscale to vaccinate everyone within a reasonable time (perhaps even to stop more variants of the virus developing and spreading), then the existing knowledge governance system that has supported this outcome needs to be reformed.

As licensing of relevant intellectual property was not made widely available for COVID-19 vaccines, then compulsory licensing could be an option for some countries. Canada, for example, passed legislation entertaining the possibility of compulsory licensing of vaccines and medicines.[48] The TRIPS Agreement provides rules for compulsory licences of patents.[49] A compulsory licence that complies with those rules requires that first efforts have been made 'to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time'.[50] Consultation can be dispensed with in cases of a national emergency.[51]

The TRIPS Agreement does not define 'national emergency' and members of the WTO have disputed what it means. The Doha Declaration on Public Health[52] clarified that members of the WTO can each determine, as a matter of national autonomy, what amounts to a national emergency.[53] On the face of it, one might expect that this condition was met for COVID-19 as the WHO declared a global pandemic and that countries would be readily using this option.[54] However, that has for the most part not been the case. First, many countries have not utilised this exception, but rather called for a waiver of rights. Second, the relevant provision allows WTO members to waive the requirement to consult the patent owner, based on its own declaration of a national

47. M Kapur, 'How Many Covid-19 Vaccine Doses Is India Producing? Modi Government Has Many Answers to This' (*Scroll.in*, 12 September 2021) <https://scroll.in/article/1001057/how-many-covid-19-vaccine-doses-is-india-producing-modi-government-has-many-answers-to-this>.

48. Statutes of Canada (25 March 2020) Bill C-13 part 12 temporarily amended section 19 of the Patent Act (until September 2020), adding section 19.4 to authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to a public health emergency that is a matter of national concern. This now seems to have lapsed, see K Cullinan, 'Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine' (*Health Policy Watch*, 11 May 2021) <https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/>.

49. TRIPS Agreement (n 25) arts 31 and 31bis.

50. ibid art 31(b).

51. ibid.

52. The Doha Declaration on the TRIPS Agreement and Public Health, World Trade Organization (20 November 2001), WT/MIN(01)/DEC/2 ('Doha Declaration').

53. ibid para 5(c).

54. WHO Director-General's opening remarks at the media briefing on COVID-19 (*WHO*, 11 March 2020) <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/events-as-they-happen>.

emergency.[55] For a WTO member to do so might be relatively straightforward given the WHO declaration of a pandemic, however, this requirement shows that the TRIPS Agreement compulsory licensing provisions were not created with global pandemics in mind, but rather localised epidemics. That does not mean that the rules are not relevant to pandemics, but they are ill-fitting and give rise to opportunities for legalistic arguments about the availability and scope of compulsory licensing options. Even if such arguments are unsustainable in the longer term, they may in the shorter term gain some traction. A counter to such a restrictive approach to interpretation is that properly applying the Vienna Convention rules on the interpretation of treaties would see that the object and purpose of the treaty was to provide a compulsory licensing framework for all health emergencies, including pandemics.[56] Even if one was to accept that the compulsory licensing provisions apply because any distinction between a global pandemic and epidemic is not warranted, a fear of this sort of litigation contributed to the lack of use of this flexibility. Developing countries have often faced threats of litigation or trade threats when trying to utilize compulsory licences.[57] A related political restraint on the use of compulsory licences is the broader controversy around them.

Compulsory licensing under the TRIPS Agreement was controversial when it was first negotiated because developed countries, seeking to protect their intellectual property globally, regarded flexible compulsory licensing as difficult to limit to particular places or for particular purposes and overall likely to ruin their gains in global protection. Ironically, developed countries have very effectively used compulsory licensing when it suits them.[58] When the rules came into force there was more controversy because the places that most needed compulsory licences (LDCs) were entirely unable to utilize the rules as they had no relevant manufacturing capacity. Others could not assume this role for them because the rules required that any compulsory licensing arrangement must be for the supply of the domestic market.[59] The ability to manufacture pharmaceuticals requires local capacity, technology and skills that are absent in LDCs and in some developing countries.[60] This led to the amendment of the TRIPS Agreement to allow one country to manufacture pharmaceuticals under a compulsory

55. TRIPS Agreement (n 25) art 31(b).
56. Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force 27 January 1980) 1115 UNTS 331 (VCLT) art 31.
57. D Halbert, 'Moralized Discourses: South Africa's Intellectual Property Fight for Access to AIDS Drugs' (2002) 1 Seattle Jour Social Justice 257. Even with developed countries assisting, compulsory licences are difficult to make effective, see H Hestermeyer, 'Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines' (2007) 11(28) ASIL Insights <https://www.asil.org/insights/volume/11/issue/28/canadian-made-drugs-rwanda-first-application-wto-waiver-patents>.
58. When threatened with the Anthrax virus in 2001 the United States threatened Bayer with a compulsory licence for the manufacture of ciprofloxacin, see JH Reichman, 'Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options' (2009) 37(2) J Law Med Ethics 247, 262.
59. ibid; TRIPS Agreement (n 25) art 31(f).
60. It is precisely because some developing countries can manufacture pharmaceuticals that TRIPS narrowed the scope of compulsory licensing or what is known as local working of a patent. For a discussion of the arguments on whether local working remains possible under the TRIPS Agreement see R Dreyfuss and S Frankel, 'From Incentive to Commodity to Asset: How International Law Is Reconceptualizing Intellectual Property' (2015) 36 Mich J Int'l L 557.

licence so as to export those products to another country also subject to the licence.[61] That amendment also enabled some economies of scale, thereby allowing one country to manufacture not just for one other country but also for a regional emergency.[62] The system has been little used and where it has been the requirements of the rules (including special labelling, packaging and notifications) are so administratively difficult as to make such exercises not worthwhile.[63]

The structure of the TRIPS rules, however, anticipate predominantly bilateral compulsory licensing arrangements. A global compulsory licensing system would in fact be a series of mostly bilateral arrangements which will almost certainly introduce inefficiencies. This would arise because the system requires that each licence is considered individually: a 'case-by-case and product-by-product' approach.[64] To apply this approach to meet the needs of vaccine supply chains would create an enormously complex coordination process.[65] The manufacture and distribution of COVID-19 vaccines have not been based on compulsory licensing because it is apparently not effective to do so. The move from the requirement of wholly domestic compulsory licensing to bilateral cross-border and regional licensing points towards compulsory licensing on a global scale. This regional compulsory licensing mechanism was not, however, used to manufacture COVID-19 vaccines because it too was not effective to do so.

Pharmaceutical companies, through their governments, have resisted compulsory licensing. The long-fought changes to the compulsory licensing system and its resulting complexities, discussed above, are illustrative of known behaviours of those companies and reflect the fact that they prioritize market control ahead of epidemic control, and the first three years of the COVID-19 pandemic have witnessed those companies placing profits ahead of pandemic control. Another example of this profit-oriented behaviour was revealed by Australian scholars who undertook a case study relating to the medicine that was used to treat the influenza outbreak in the early twenty-first century.[66] During that time the best treatment available was oseltamivir (marketed

61. TRIPS Agreement (n 25) art 31bis (1).
62. ibid art 31(3) provides, 'With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.'
63. World Health Organization, 'Country Experiences in Using TRIPS Safeguards: Part I' <https://apps.who.int/iris/rest/bitstreams/1140143/retrieve>.
64. MSF Briefing Document, 'Compulsory Licenses, the TRIPS Waiver and Access to Covid-19 Medical Technologies' (MSF Briefing Document, May 2021) <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>.
65. M Gaviria and B Kilic, 'A Network Analysis of COVID-19 mRNA Vaccine Patents' (2021) 39 Nature Biotechnol 546–8 <https://doi.org/10.1038/s41587-021-00912-9>.
66. B Lokuge, P Drahos and W Neville, 'Pandemics, Antiviral Stockpiles and Biosecurity in Australia: What About the Generic Option?' (2006) 184(1) Med J Aust 16.

as Tamiflu). The patent owners, Gilead, had licensed Roche to manufacture and distribute Tamiflu worldwide. Gilead then tried to terminate that licence because of fear that its patents would be overridden by compulsory licences because Roche had failed to supply many markets.[67] Roche had not supplied Tamiflu to over 40 countries including China. There were also problems in quality and manufacturing was expensive. The manufacturing of pharmaceuticals is generally expensive, but large-scale manufacturing can introduce efficiencies that could reduce costs. Gilead was reported to have concluded that the manner of Roche's control over the pharmaceutical meant that Tamiflu would not 'achieve its full potential in protecting the public health from the threat of influenza'.[68] Roche sought to change that outcome rather than have its patents made subject to compulsory licences. At the time, this led to calls for governments to manufacture their own medicines and not to wait for Roche.[69] The countries that indicated they would manufacture oseltamivir included India, Taiwan, Argentina, the Philippines and the United States. This apparent threat led to Roche negotiating for US-based generic manufacture.[70] It seemed there was nothing quite like threatening a compulsory licence to get the pharmaceutical companies on board with better terms.[71]

There are several defects with the patent-driven approach which enables pharmaceutical companies to act in ways that hinder public health. The result of the Tamiflu race was that wealthy countries stockpiled the medicine and demanded more be manufactured for them, and so poorer countries were unable to access the medicine.[72] From a health strategy standpoint this was very foolish as the best way to contain the epidemic would have been to have the most treatment available in the places where there were, or looked likely to be, a serious number of cases. Perhaps the greatest tragedy of this experience was that a more effective product was ultimately found, not without some delay because of the way the patents were deployed to make this kind of competition difficult.[73]

Compulsory licensing is necessary when voluntary licensing fails either because the products are not made available or are not realistically available at an affordable price. It would be possible, however, to dispute the need for any licence (compulsory or voluntary) if an argument can be maintained that patent infringement (and thus local manufacturing of a patented vaccine) is justified on the grounds of national security.

67. YK Gupta, M Meenu and P Mohan, 'The Tamiflu Fiasco and Lessons Learnt' (2015) 47(1) Indian J Pharmacol 11.
68. 'Don't Wait for Tamiflu – Make Our Own' (*Financial Times*, 15 November 2005) <https://www.afr.com/companies/healthcare-and-fitness/dont-wait-for-tamiflu-make-our-own-20051115-jejw4>.
69. ibid.
70. ibid.
71. When Brazil won a dispute at the WTO against the United States and was authorized through the arbitration compliance process to take cross-retaliation under the TRIPS Agreement, including suspending patents against the United States for its failure to comply with losing rulings, the United States quickly negotiated a solution. See S Frankel, 'The TRIPS Agreement and Cross-Retaliation' in S Frankel and MK Lewis (eds), *Trade Agreements at the Crossroads* (Routledge 2013) 208. Regarding TRIPS and cross-retaliation see also Shamnad Basheer, 'Turning TRIPS on Its Head: An "IP Cross Retaliation Model" for Developing Countries' (2010) 3 Law and Development Review 141.
72. Gupta et al. (n 67).
73. Lokuge et al. (n 66).

2.4 The TRIPS security exception

At the time of writing, the most recent dispute at the WTO Dispute Settlement Body, under the TRIPS Agreement, concerned the security exception.[74] The facts of the dispute are very far removed from anything relating to vaccines (or indeed pharmaceuticals more broadly), but an understanding of the dispute and approaches to security exceptions in WTO agreements is telling for its application to vaccine patents. The dispute was about a Qatari global sports and entertainment company that was licensed to broadcast major sports events in Saudi Arabia. In 2017 Saudi Arabia, United Arab Emirates, Bahrain and Egypt had all imposed a blockade against Qatar, which meant the Qatari sports company could not operate in Saudi Arabia. Instead, a Saudi-based business embarked on unauthorized streaming and distribution of the copyrighted broadcast content in Saudi Arabia that the Qatari company was licensed to do. The Qatari company could not enforce its copyright rights because of the blockade, which included a bar on lawyers in Saudi Arabia from providing services to Qatari nationals or Qatar.[75] Qatar brought the matter to the WTO and Saudi Arabia invoked the security exception in the TRIPS Agreement, which provides that nothing in the TRIPS Agreement shall prevent a WTO Member from taking any action which it considers 'necessary for the protection of its essential security interests taken in the time of war or other emergency in international relations'.[76]

Recent years have seen the United States make some rather excessive claims that imposing high tariffs, particularly on steel, are matters of national security.[77] The national security exception in the General Agreement on Tariffs and Trade (GATT)[78] cannot be invoked simply for the purpose of preferring domestic industry over imports and 'political or economic differences between Members are not sufficient, of themselves, to constitute an emergency in international relations'.[79] The United States has consistently taken the position that the security exception is not something the WTO can scrutinize, but is a self-determining exercise of national sovereignty. It supported Russia's invocation of the security exception when Russia used it against the Ukraine.[80] The EU and many others take the position that any WTO Members' application of the security exemption can be objectively reviewed.

In its analysis, the Dispute Settlement Panel, in the Qatari dispute, adopted the approach taken in the dispute that the Ukraine brought against Russia regarding goods in transit. In sum, the WTO concluded that the circumstances in which the exception could be invoked (an emergency in international relations) is justiciable. Within that frame, whether there is an essential security interest and whether the measure is necessary to meet that interest are left to the Member relying on the exception to determine, but these are subject to an

74. WTO, *Saudi Arabia: Measures Concerning the Protection of Intellectual Property Rights – Panel Report* (16 June 2020) WT/DS567/R (*Saudi – IP*).
75. ibid para 7.245.
76. TRIPS Agreement (n 25) art 73(b)(iii).
77. G Gertz, 'Did Trump's Tariffs Benefit American Workers and National Security?' (Brookings Institute, 10 September 2020) <https://www.brookings.edu/policy2020/votervital/did-trumps-tariffs-benefit-american-workers-and-national-security/>.
78. General Agreement on Tariffs and Trade 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A (adopted 15 April 1994, in force 1 January 1995) 1867 UNTS 187 (GATT).
79. WTO, *Russia: Measures Concerning Traffic in Transit – Panel Report* (26 April 2019) WT/DS512/7 (*Russia – Transit*).
80. ibid, third party submissions.

objective plausibility test. The Panel said that for an application of the exception to be plausible, and, thus, withstand scrutiny the following had to be demonstrated:[81]

(i) whether there was a 'war or other emergency in international relations';
(ii) whether the actions were 'taken in time of' that war or other emergency;
(iii) whether the Member has articulated its relevant 'essential security interests'. This must be done to assess whether there is any link between those actions and the protection of its essential security interests; and
(iv) whether actions were too remote from the 'emergency in international relations', making it implausible that those actions were necessary for that purpose.

On the first factor the panel adopted the GATT test that an emergency in international relations involves 'a situation of armed conflict, or of latent armed conflict, or of heightened tension or crisis, or of general instability engulfing or surrounding a state'.[82] The panel did not analyse if there was any TRIPS-Agreement-related context of relevance in interpreting this provision.

The second step of the above test was met as the timing of the measures was during the 'emergency in international relations'. The panel again adopted the approach in the *Russia-Transit* dispute to the third step of the test and said that 'essential security interests' refer to functions of the state 'namely, the protection of its territory and its population from external threats, and the maintenance of law and public order internally'.[83] Saudi Arabia said it was protecting itself from terrorism and extremism and so the Panel found that step was met.[84] As Saudi Arabia had imposed a travel ban on all Qatari nationals from entering Saudi territory, it in effect took measures preventing Qatari nationals from accessing Saudi Arabia's courts and tribunals. This was significant because part of the Panel's report included a finding that the absence of application of criminal procedures and penalties was 'remote from, or unrelated to the "emergency in international relations"'.[85] This meant that it was not plausible that the measure was enacted to protect Saudi Arabia's essential security interests.[86] Consequently, that aspect of the measures was unrelated to the emergency in international relations and could not be justified as an essential security interest.

Given the facts before the Panel (and no doubt the submissions of counsel) it is not surprising that the Panel adopted the test from the GATT Agreement. GATT decisions are, according to the TRIPS preamble, relevant to its interpretation.[87] GATT jurisprudence is not, however, decisive of an interpretation of TRIPS but is a relevant part of the context for the purposes of interpretation.[88] The Panel seemed to ignore the contextual interpretation and rather accepted that as the TRIPS exception is 'identical' wording to the GATT the same test applies to both. This was particularly disappointing

81. *Saudi – IP* (n 74) para 7.242.
82. ibid para 7.245.
83. ibid para 7.286.
84. ibid para 7.289.
85. ibid para 7.293.
86. ibid.
87. The preamble acknowledges, 'the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions'.
88. Using the VCLT (n 56) rules of treaty interpretation found in Article 31, the context to the TRIPS Agreement (n 25) includes other WTO Agreements, see S Frankel, 'WTO Application of "the Customary Rules of Interpretation of Public International Law" to Intellectual Property' (2006) 46 Va J Int'l L 365.

as the Panel was not blind to the notions of context when interpreting other provisions of the TRIPS Agreement and, in fact, explicitly refers to it. The Panel stated, in regard to the criminal enforcement provision of TRIPS, 'it is important to consider Article 61 in the context of the whole of the TRIPS Agreement'.[89] Article 61 was the provision found to have been violated and, as discussed above, that the security exception could not cure. The same contextual approach, however, was not applied to the provision proffered as the reason for the violation, the security exception.

For future disputes, relating perhaps to vaccines or other pharmaceuticals, a TRIPS Agreement interpretation that fully utilizes the Vienna Convention requirements of interpretation of ordinary meaning in context and in light of the TRIPS Agreement object and purpose will be important.[90] If a WTO member chooses to apply the security exception to the potential violation of patents or the sharing of regulatory information, the health threat to the nation and its economic stability will also be relevant.

As a WTO member can determine for itself: (a) whether COVID-19 and its consequences give rise to 'an essential security interest' and (b) whether any measure that enables using others' intellectual property interests is necessary to meet that interest, the remaining issue is whether any measure taken meets the objective plausibility test. Manufacturing vaccines which might otherwise infringe patent or other intellectual property rights would not be an activity that was too remote from the emergency in international relations that is a pandemic. It would be more than plausible (almost certain) to have been done for the purpose of addressing the vaccine needs related to the pandemic. Whether the effects of the COVID-19 pandemic give rise to an emergency in international relations is perhaps the most contentious point.

The Panel in the dispute between Saudi Arabia and Qatar said:[91]

> while 'political' and 'economic' conflicts could sometimes be considered 'urgent' and 'serious' in a political sense, such conflicts would not be 'emergencies in international relations … unless they give rise to defence and military interests, or a maintenance of law and public order interests'.[92]

As both the WTO panels had similar armed conflict/war interests in mind, their focus was on that kind of problem. The reference to public order is important because it hints at other types of national security interests which in the twenty-first century may not be confined to matters of armed conflict.[93]

The WTO Appellate Body's most detailed consideration of public order was in the context of the GATS Agreement[94] in the dispute brought by Antigua against the United States for its blocking of online gambling.[95] That Panel acknowledged the 'sensitivities' associated with these concepts and concluded that 'Members should be given some scope to define and apply for themselves the concepts of "public morals" and

89. *Saudi – IP* (n 74) para 7.209.
90. VCLT (n 56).
91. *Saudi – IP* (n 74) para 7.245 referencing *Russia – Transit* (n 79) para 7.75–7.76.
92. ibid.
93. NF Diebold, 'The Morals and Order Exceptions in WTO Law: Balancing the Toothless Tiger and the Undermining Mole' (2008) 11 JIEL 43.
94. General Agreement on Trade in Services (GATS), Marrakesh Agreement Establishing the World Trade Organization, Annex 1B (adopted 15 April 1994, in force 1 January 1995) 1869 UNTS 183 (GATS).
95. WTO, *United States: Measures Affecting the Cross-Border Supply of Gambling and Betting Services – Appellate Body Report* (7 April 2005) WT/DS285/ABR (*US – Gambling*).

"public order" in their respective territories, according to their own systems and scales of values'.[96]

These statements about public order are in relation to exceptions other than the security exception and it is arguable that as the security exception (including in TRIPS) does not use the express words 'public order' that the notion is inapplicable. The Qatari dispute is an armed conflict context that happens to involve copyright law. It does not consider what the TRIPS-related intellectual property context brings to a proper interpretation of the national security exception. That leaves the question of what amounts to an emergency in international relations in a TRIPS Agreement context to a future case.

The pandemic has created not only health but serious political and economic situations which are emergencies.[97] In addition, an 'emergency in international relations' could arise from the non-availability of vaccines for some in a global pandemic and, in particular, the refusal of vaccine-supplying countries to follow the WHO declaration about access to vaccines for all. The WHO stated: 'if safe and effective vaccines for COVID-19 are developed, WHO believes that everyone, everywhere who could benefit from these vaccines should have access as quickly as possible, starting with those at highest risk'.[98]

One difficulty that countries would have faced if relying on the WHO's call for equal vaccine access or the declaration of a public health emergency is that the WHO has no rule-making power and so its declaration cannot force patent owners to change their behaviour. The power to share patents lies with private businesses whose property rights have been granted by the state. Although, the WHO rules include that:[99]

> States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies.

One commentator has suggested a different path, arguing that because the WHO Director-General declared a Public Health Emergency of International Concern[100] this could trigger the security exception as an 'emergency in international relations' because the disruption of trade and travel could lead to hostilities.[101]

The countries that may have wanted to, or possibly still want to, apply the security exception in the TRIPS Agreement context to manufacture COVID-19 vaccines, may

96. ibid para 6.461.
97. See discussion M Svicevic, 'COVID-19 as a Threat to International Peace and Security: What Place for the UN Security Council?' (*EJIL Talk!*, 27 March 2020) <https://www.ejiltalk.org/covid-19-as-a-threat-to-international-peace-and-security-what-place-for-the-un-security-council/?utm_source=mailpoet&utm_medium=email&utm_campaign=ejil-talk-newsletter-post-title_2>.
98. 'Coronavirus Disease (COVID-19): Vaccine Access and Allocation' (*WHO*, updated 6 August 2021) <https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccine-access-and-allocation>.
99. WHO International Health Regulations (2005), Article 3, Principle 4.
100. 'WHO Director-General's Statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV), (*WHO*, 30 January 2020) <https://www.who.int/director-general/speeches/detail/who-director-general-s-statement-on-ihremergency-committee-on-novel-coronavirus-(2019-ncov)>.
101. F Abbott, 'The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic' (Research Paper 116, 7–8, South Centre, August 2020).

wish to do so against US patent owners, among others. The use of the security exception in the Saudi dispute was not something that the United States supported, as it did in the *Russia – Transit* matter. It has taken the position that use of the exception is a matter of national sovereignty. Yet, it seems unlikely that the United States would support violations of US-owned patents or trade secrets in the name of the security exception, but if it objects to other countries utilizing the exception on a self-determining basis it contradicts its general position. If the security exception was used against patents originating from producers in countries who had never supported its use in this way, those countries may well object. As the above shows, there are arguments that use of the exception could withstand scrutiny, but the idea of having to defend actions in this detailed way and before an international tribunal seems to have had a chilling effect. As noted above, countries pursued the approach at the WTO to suspend patent and other obligations rather than using the flexibilities of the TRIPS Agreement to achieve the same results. This apparent caution may likely arise from the experience of attempts to use compulsory licensing, including for AIDS treatments, that were met with resistance from both the United States and Europe, and which precipitated the Doha Declaration on Public Health.[102]

2.5 The relationship between compulsory licensing and national security

The purpose of using the TRIPS Agreement national security exception would have been to manufacture (or import) COVID-19 vaccines which are not otherwise available and cannot be supplied in a timely way. There is no economic loss where a product is not or cannot be supplied. Another way of looking at such circumstances is that there is no trade that is being harmed in the same way that imposing a tariff might cause trade-related harm. Failure to supply the market is an existing ground for compulsory licences that many countries have in their domestic laws.[103]

A compulsory licence for use of patents, under the TRIPS Agreement Article 31/31bis system, requires an application to be made to the relevant government authority and other conditions, including payment of a reasonable remuneration to the patent owner. Payment must be made even in situations of an emergency, although in such situations the payment may be delayed.[104] In contrast, action taken under the security exception would not require payment. In practice any use of a security exception to not enforce intellectual property may resemble aspects of a compulsory licence as, in both instances, a government agency will have the relevant jurisdiction to authorize use of an exception. This may result in government use of the exception or the government granting the use to a third party. In the case of the security exception, any person might be permitted to use the intellectual property without it being enforced.

As noted above, Article 31 and 31bis were not drafted with pandemics in mind. On the face of it, compulsory licensing and use of the security exception appear to overlap, but the security exception both targets a different problem and is wider than the compulsory licensing of patents. In practical effect, operationalizing the security exception could lead to use of the relevant patents and potentially use or non-enforcement of

102. See generally, E George, 'The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines' (2011) 18 Ind J Global Legal Studies 167, 188.
103. See, for example, Patents Act 1997 (UK) s 48A(1) and s 48B(1).
104. TRIPS Agreement (n 25) art 31(a).

other TRIPS Agreement rights, such as confidential information given to a regulatory approval agency.[105]

To the extent that there might be some overlap between patent compulsory licensing and security interests, that raises interpretative questions about the relationship between the compulsory licensing provisions (Articles 31 and 31bis) and the security exception (Article 73) in TRIPS. The interpretative questions are relevant to when Article 73 is relied on instead of Article 31 (and vice versa) and possibly if they are used in combination. If a WTO member relies on the security exception, then Article 31 is relevant context to interpreting the meaning of Article 73.[106] At first blush, that context could arguably mean that Article 73 should not be used for compulsory licensing of patents because there is a more specific provision in Article 31. The difficulty with that approach is, first, as noted above, Article 73 applies across the whole of the TRIPS Agreement not just to patents and, second, that it would limit Article 73 in ways that are not apparent on its wording. Such an approach also places too much weight on the notion of compulsion. The sort of facts that gave rise to the Qatari dispute, which amounted to an emergency in international relations, could not be the only sort of purpose of the TRIPS-related security exception.[107] Those facts could also be described as in practical effect amounting to compulsory use of copyright works.

In any event, more than one exception under the TRIPS Agreement may be relevant to a dispute; the presence of the use of one exception does not mean another may not also be relevant. In sum, both provisions are available to Members of TRIPS. Although the use of the security exception may require similar processes to compulsory licensing, it both covers more than the patent compulsory licensing provisions and addresses an 'emergency in international relations', which is different from a 'national emergency'. Put differently, if the compulsory licensing regime or other exceptions are not capable of addressing the emergency at issue, as seems to have been the case with the COVID-19 pandemic and vaccines, then the security exception has a role to play when there is an emergency because it can address the gaps that compulsory licensing alone does not.

All the patent flexibilities in the world are not much use, however, if there is no guarantee of the efficacy and safety of any vaccine. This is where the regulators come in.

3 REGULATION OF EFFICACY AND SAFETY

The TRIPS Agreement requires that WTO Members treat data that is submitted to government regulatory agencies, relating to pharmaceutical efficacy processes, as confidential.[108] Where such information is submitted as part of the marketing approval process, and 'the origination of which involves a considerable effort', there must be protection against 'unfair commercial use'.[109] Perhaps a little convolutedly, but importantly, TRIPS also provides that: 'Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use'.[110] TRIPS gives no requirement for how long this confidentiality should last.

105. ibid art 39. See part 3 below.
106. VCLT (n 56) art 56.
107. *Saudi – IP* (n 74).
108. TRIPS Agreement (n 25) art 39.
109. ibid art 39(3).
110. ibid.

COVID-19 could provide the vector that allows for data disclosure on the basis that it is 'necessary to protect the public'. Sharing information could potentially have both improved vaccine development and sped up approval processes, both of which would have (and possibly still could) ultimately improve distribution worldwide. This sort of disclosure could be done with or without simultaneous use of the security exception. The former may be more politically tenable. However, there are no signs that regulatory health and safety information will ever be shared, in spite of the obvious public health gains in doing so. In part this is because different countries have different approaches to applying the TRIPS data protection obligation. In most of the developed world the TRIPS standard of 'unfair commercial use' is the platform for a range of much stronger data exclusivity obligations.

Data exclusivity for a defined period of time is an obligation found in many post-TRIPS trade agreements. These agreements require not only confidentiality from competitors of clinical test data but also exclusivity of that data (meaning the regulator cannot use it for its own purposes) for defined periods of five years and more.[111] The disclosure of data relating to COVID-19 vaccine regulatory procedures from countries with data exclusivity regimes may violate another trade agreement, even if such disclosure is permissible under TRIPS or under a TRIPS waiver. Also, there is considerable overlap between the patent system and the data exclusivity system. In some countries the systems are explicitly linked through what is known as patent linkage requirements, where the regulator communicates directly with the patent office. Even without express patent linkage, pharmaceutical companies will use data exclusivity as a mechanism to prolong the effective patent term.[112] They may even rely on regulatory exclusivity as a substitute for patents when secrecy rather than patent rights serves their ends better. Secrecy and exclusivity of data does not only give rise to a data-sharing problem, it also can interfere with the ability of manufacturers to meet global demand for vaccines.

Medicine approval processes are important because they are about health, but they are also often lengthy and detailed. COVID-19 has resulted in a number of regulatory agencies looking at ways to fast-track approval processes. For example, the United Kingdom passed legislation to speed up its usual approval process, while purporting to retain robust procedures.[113] In the United States emergency use procedures have been used.[114] The FDA has also said that this will not be 'at the expense of sound science and decision making. We will not jeopardize the public's trust in our science-based, independent review of these or any vaccines. There's too much at stake'.[115] Some medically qualified

111. CM Correa, 'Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals' (2002) 3(1) Chic J Int'l L 69, 72–9; D Kim, 'Enabling Access to Clinical Trial Data: When is Unfair Use Fair?' (2015) 14(2) Chicago-Kent J Intel Prop 521, 523–6.
112. See generally, RS Eisenberg, 'Patents and Regulatory Exclusivity' in PM Danzon and S Nicholson (eds), *The Oxford Handbook of the Economics of the Biopharmaceutical Industry* (Oxford University Press, 2012).
113. The Human Medicines (Coronavirus) (Amendment) Regulations 2020 (UK); United Kingdom Department of Health & Social Care, 'Government Response: Consultation on Changes to the Human Medicines Regulations to Support the Rollout of COVID-19 and Flu Vaccines' <https://www.gov.uk/government/consultations/distributing-vaccines-and-treatments-for-covid-19-and-flu/outcome/government-response-consultation-on-changes-to-the-human-medicines-regulations-to-support-the-rollout-of-covid-19-vaccines>.
114. FDA, 'COVID-19 Vaccines' <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines>.
115. ibid.

commentators suggested that if the FDA fast-tracked any vaccine, it may find itself in an untenable position, particularly as fast-tracking one vaccine over another may well adversely impact existing trials of other vaccines and that is irreversible.[116] Also, even before COVID-19, there have been questions raised about the FDA's independence from pharmaceutical companies.[117]

The fast-tracking of regulatory approval has been important, but it alone is not likely to produce the most effective efficacy and safety results because it is coupled with information not being shared among regulatory agencies. The fast-tracking approaches still require regulatory agencies to keep all data confidential. In other words, data exclusivity remains the law within which fast-tracking efforts have so far been made and will continue to be made. A much better way to ensure safety and efficacy is to have as much information about vaccines shared and independently evaluated. Not only does this provide a likelihood of a more efficacious outcome it may also support more and better fast-track approvals. The oseltamivir experience, discussed above, illustrated this, and, as the pandemic has progressed, we are seeing a lack of data sharing again.

Drahos reminds us that, 'the company behind oseltamivir funded research into the drug, and much of that research failed to highlight the likelihood of serious adverse events, especially neuropsychiatric events'.[118] The Cochrane Accurate Respiratory Infections Group undertook an independent review of oseltamivir. It compiled 150 000 pages of clinical trial data on the drug, including a vast amount of material that the patent owner and regulatory systems had not made public. This systematic independent review showed evidence of potential harm from oseltamivir such as nausea, vomiting and psychiatric events. Most damningly, it concluded that governments had spent an enormous amount of money on something that would be little more effective against flu than an aspirin.[119]

Regulatory agencies cannot share clinical data in many countries unless governments mandate them to do so. Many governments will not do so because they will be in violation of existing domestic law and trade agreement commitments if they do. The TRIPS Agreement waiver does not and cannot address the problem of other trade agreement commitments unless all WTO members somehow agree that relevant bilateral and plurilateral trade agreement commitments should be waived. This seems unlikely to occur.

116. J Cohen, 'There's Only One Chance to Do This Right—FDA Panel Wrestles with COVID-19 Vaccine Issues' (*Science*, 23 October 2020) <https://www.sciencemag.org/news/2020/10/there-s-only-one-chance-do-right-fda-panel-wrestles-covid-19-vaccine-issues>.

117. See, for example, C Piller and J You, 'Hidden Conflicts? Pharma Payments to FDA Advisers after Drug Approvals Spark Ethical Concerns' (*Science*, 5 July 2018) <https://www.sciencemag.org/news/2018/07/hidden-conflicts-pharma-payments-fda-advisers-after-drug-approvals-spark-ethical>.

118. P Drahos, 'Big Pharma and the Rush to Find Vaccines, Public Health Must Come Before Patents' (*Policy Forum*, 8 September 2020) <https://www.policyforum.net/big-pharma-and-the-rush-to-find-vaccines/>.

119. P Rodgers, 'Tamiflu Is No Better Than Tylenol', quoting Cochrane Acute Respiratory Infections Group, 'We are no longer sure that oseltamivir offers a therapeutic and public health policy advantage over cheap, over the counter drugs such as aspirin. If the public is to trust in public health policies, the scientific basis informing knowledge of the harms and effects of those interventions must be public and open to independent analysis' (*Forbes*, 10 April 2014) <https://www.forbes.com/sites/paulrodgers/2014/04/10/tamiflu-is-no-better-than-tylenol-at-fighting-flu/?sh=5aa39a6ad510>.

A wrinkle in all of this is that different rules will apply to different types of vaccines. The TRIPS Agreement confidentiality requirements apply to new chemical entities,[120] but they do not apply to biologics (such as vaccines involving mRNA). Some trade agreements apply exclusivity requirements to both groups of pharmaceuticals and other trade agreements do not. For countries that have enacted data exclusivity for medicines this distinction may or may not be made in their domestic law.

Because countries and pharmaceutical companies did not agree to data share to improve the efficacy of COVID-19 vaccines, the outcomes were, in all probability, both slower and less efficacious. A variation to existing international obligations that both requires and enables such data sharing needs to be agreed by the major vaccine producer countries as it is their laws that should be varied to allow the COVID-19 and future pandemics to be better tackled.

4 A WAIVER OF TRIPS AGREEMENT RIGHTS AND OBLIGATIONS

One might ask why the existing flexibilities (compulsory licensing and national security) have not been and are not enough? In spite of the available flexibilities, discussed above, there was considerable support for WTO Members to create a pandemic-related waiver of many intellectual property obligations. The concerns that the requirements of compulsory licences are too complex to make that licensing work for COVID-19 vaccines underscored why they were not fully utilized in the pandemic. In addition, countries fear that using the TRIPS flexibilities will be challenged and will attract the possibility of more general trade sanctions.[121] As discussed above, the security exception could be used also, but countries may be reluctant to do so because of the very great likelihood of political challenge and litigation.

The phenomenon of flexibilities being available in the TRIPS Agreement but not being fully used, until such use is condoned, has occurred before. Even though compulsory licensing flexibilities were available before the Doha Declaration on Public Health, confirmation of the scope of those flexibilities became necessary.[122] There was both litigation and threats to litigate or use trade sanctions following attempts to use the flexibilities.[123] Even if interpretation of the TRIPS Agreement supports the use of these flexibilities, the very existence of the Doha Declaration on Public Health illustrates the problem. Many parts of the Declaration repeat parts of the TRIPS Agreement which should have been respected, in any event.[124] Without the Doha Declaration countries that tried to use the Article 31 compulsory licensing system found themselves subject to coercive legal action. The Article 31bis system expanded the scope of compulsory licensing so one

120. TRIPS Agreement (n 25) art 39(3).
121. See WTO Council for Trade-Related Aspects of Intellectual Property Rights, 'Examples of Issues and Barriers in COVID-19 Pandemic', Communication from South Africa IP/C/W/670 (23 November 2020); WTO Council for Trade-Related Aspects of Intellectual Property Rights, 'Response to Questions on Intellectual-Property Challenges Experienced by Members in Relation to COVID-19', Communication from the Plurinational State of Bolivia, Eswatini, India, Kenya, Mozambique, Mongolia, Pakistan, South Africa, The Bolivarian Republic of Venezuela and Zimbabwe IP/C/W/671 (15 January 2021).
122. Doha Declaration (n 52).
123. SM Ford, 'Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents' (2000) 4 Amer Uni Inter'l L R 941.
124. Frankel (n 88) at 399.

country could manufacture for another, but it has not been widely used, probably because it is cumbersome to operate. It is perhaps unsurprising then that a different approach (that of asking for a waiver) was taken by developing countries in their struggle for equitable access to COVID-19 vaccines.

A negotiated waiver could address some of those issues. While there was support for a waiver there was also considerable opposition.[125] The final waiver relates to vaccine patents only.

The limited nature of the agreed waiver leaves many difficulties. Primarily, its coverage allows compulsory licensing of some vaccine-related patents. In any event, a waiver of TRIPS obligations can only relate to what the TRIPS Agreement covers. This means it only affects some of the rights that are relevant to the protection of COVID-19 vaccines. It does not address all relevant aspects of protecting trade secrets. In any event, waiving protection of trade secrets does not mean they will be disclosed, as compulsory disclosure is a step further. Access to trade secrets may be challenging even with a waiver of enforcement of protection. Patents are publicly available documents; trade secrets are not. And the TRIPS Agreement trade secret protection is minimal and there is little global harmonization.[126]

A more fulsome waiver could also impact the secrecy of clinical trial and efficacy data submitted for government regulatory approval processes. As noted above, the TRIPS obligations extend to 'chemical entities'[127] and so do not cover both regulatory confidentiality requirements relating to vaccines which are biologics and data exclusivity arrangements that require more than confidentiality. These higher levels of protection are potentially beyond the reach of the WTO's TRIPS coverage. This is a problem as it limits the effectiveness of a WTO waiver. It also highlights a problem with the incentive rationales as this extra protection has entrenched a kind of economic nationalism that is contrary to the intellectual property incentive story.

Economic nationalism has, in several ways, been rife in the operation of the TRIPS Agreement. As it allows for more extensive protection,[128] the TRIPS Agreement has been used as a platform for that extra protection, which clearly favours some businesses of the intellectual property provider economies, with very few exceptions to mitigate that protection in the public interest, including for health-related concerns or even to improve innovation.[129] Although these problems pre-date the COVID-19 pandemic, they are highlighted by the inequality of vaccine distribution.

The TRIPS waiver does not cover higher standards which are integral to how the pharmaceutical industry works. Pushes to increase further these higher standards of protection have been progressively made through successive bilateral and plurilateral trade agreements, made by both the EU and the United States with others. Initially, for example, the Trans Pacific Partnership[130] (TPP) had several patent law increases in

125. 'TRIPS Council Agrees to Continue Discussions on IP Response to COVID-19' (*WTO*, 20 July 2021) <https://www.wto.org/english/news_e/news21_e/trip_20jul21_e.htm>.
126. TRIPS Agreement (n 25) art 39(1) sets out an obligation of protecting undisclosed information. See generally, RC Dreyfuss and KJ Strandburg (eds), *The Law and Theory of Trade Secrecy: A Handbook of Contemporary Research* (Edward Elgar Publishing, 2012).
127. TRIPS Agreement (n 25) art 39.3.
128. ibid art 1.1.
129. For a discussion of how this matter could be addressed see S Frankel, 'Challenging TRIPS-Plus Agreements: The Potential Utility of Non-Violation Disputes' (2009) 12(4) JIEL 1023.
130. Trans-Pacific Partnership Agreement (entered into 4 February 2016, not in force) (TPP).

protection beyond the TRIPS Agreement minimum standards.[131] Those provisions are now suspended in the Comprehensive and Progressive Trans Pacific Partnership[132] (CPTTP). At the time of agreeing to the TPP the developing country parties and some of the developed countries saw little advantage in increasing patent standards. As New Zealand noted, for example, there was no gain in the patent context for it.[133] Rather the gains were to be found in the parts of the agreement other than the intellectual property chapter. The increased standards of patent protection were mostly for the benefit of the US pharmaceutical industry and so, once the US left the TPP, the other parties suspended those provisions. This push for higher standards is indicative of the behaviour of large intellectual property owners, and the governments that act on their behalf, who have always treated the TRIPS Agreement platform as something to support excessive demands,[134] and so it is entirely in keeping that the TRIPS Agreement standards could be used as the foundation of vaccine nationalism.

The only way that a TRIPS Agreement waiver, other than by explicit reference, could address more extensive protection arising from other trade agreements is for the waiver to apply on something akin to a national treatment basis. More extensive protection, relating directly to the expressed minimum standards found in TRIPS, applies on a national treatment basis.[135] Although sometimes even that is disputed, especially in the area of pharmaceuticals. The EU for example treats its patent term extension system as outside of the TRIPS Agreement and, therefore, not available on a national treatment basis.[136] As that system provides for a more extensive term than the 20-year term of patent protection required by TRIPS,[137] others would say the primary rule of national treatment applies to that extended term. For any waiver to be effective these issues would need to be negotiated rather than legally resolved as that would be a long and difficult process. The waiver would have to specify that where countries provide more extensive protection that protection would also be waived. That seems to be tricky, if not impossible, to negotiate.

The waiver that eventually emerged from the WTO may be regarded as politically important, but its scope and utility are very limited and, at best, it is a short-term fix for the existing pandemic, not a fix for a faulty system that has delivered private entities too much control over public health outcomes. To effectively address COVID-19 there needed to be far more than a TRIPS Agreement waiver. For future pandemics negotiating another waiver will be problematic. The system ought to have appropriate flexibilities to be able to address the urgent needs of the COVID-19 and it should be reformed to address the ongoing urgent needs related to the COVID-19 pandemic and future pandemics. This requires that the intellectual property hold-ups to the

131. These included standards that resulted in more incremental inventiveness being patented, patent term extension for pharmaceuticals and data exclusivity for pharmaceutical and agricultural-chemical products.
132. Comprehensive and Progressive Trans Pacific Partnership (open for signature 8 March 2018, entered into force 30 December 2018) (CPTPP).
133. See S Frankel and J Lai, *Patent Law and Policy* (Lexis Nexis, 2016) 317–18.
134. See S Sell, 'TRIPS was Never Enough: Vertical Forum Shifting, FTAs, ACTA and TPP' (2011) 18 J Intell Prop L 447.
135. TRIPS Agreement (n 25) art 4.
136. For an explanation of the EU system see Z Pacud, 'Patents, SPC and Data Exclusivity at the Service of Legal Protection for Pharmaceuticals', in S Frankel (ed), *The Object and Purpose of Intellectual Property* (Edward Elgar Publishing 2019).
137. TRIPS Agreement (n 25) art 33.

world's manufacturing capacity and distribution networks need to be removed if they are not voluntarily overcome.

5 CONCLUSION

The ideal way to have overcome the challenges of the manufacture and supply of COVID-19 vaccines, to meet all of the world's needs, was for those inventing the technology to have voluntarily licensed it and to assist in capacity building to improve manufacturing and distribution, in a timely way. This should have occurred early in the pandemic. Early in the pandemic some pharmaceutical companies were involved in COVID-19-related vaccine development agreements that could have also led to third party licences but, for the most part, there have been no such licences.

The claims around incentives to innovate that are used to justify proprietary patent exclusivity and confidentiality of the regulatory approvals process have proved to be somewhat ill-suited to respond to all the urgent needs of the pandemic. In the circumstances of the pandemic, blanket claims to innovation incentives (and the associated recouping of R&D expenses) as requiring worldwide exclusivity are not supported. The entire world has purchased COVID-19 vaccines (sometimes at great expense) and so the first mover advantage in the marketplace has been real everywhere in the world. Vaccine sales in the early stages of the pandemic undoubtedly more than recouped investment and expenditure. The patent and regulatory systems, as presently framed, gave rise to the possibility of a few first movers trying to control worldwide manufacture and distribution. This sort of worldwide demand meant there was opportunity for there to be many innovators in different places, but the first movers have used their advantage to limit licensing. One way this is illustrated is that pharmaceutical companies, for the most part, did not sign up to support the COVAX initiative in ways that would make the vaccine more affordable for COVAX to buy and distribute sooner. They later 'donated' vaccines to COVAX, many of which were near the end of their useful life.

Even if all patent, trade secret and regulatory hurdles are resolved for the COVID-19 pandemic, the fissures exposed in the systems should not be allowed to linger. What we have seen is that the pharmaceutical companies are prepared to change direction and to focus huge amounts of effort on COVID-19 vaccines because of the profits they foresaw they would make and will continue to make from ongoing global demand. At the same time, governments have invested in this research and there are liability waivers in place to fast-track vaccine availability. In combination, these factors mean that the usual risk to pharmaceutical companies, that at least is said to underpin the patent incentive, has been and is absent. Further, there was a lack of preparedness for massive manufacturing and effective distribution of COVID-19 vaccines and the distribution problem lingers. And a big part of this is because pharmaceutical companies do not have a tradition of licensing rights, capacity building and manufacturing as widely as possible.

The wealthy nations negotiated the best access to any vaccine for themselves, potentially leaving some parts of the developed world and much of the developing world behind. In 2021 pharmaceutical companies were having trouble keeping up with even the existing contractual arrangements with developed countries. Why did they not license more manufacturers to make the vaccine? Some delays occurred because of lack of materials and resources, including possible manufacturing capacity

and expertise, but a lack of effective licensing almost certainly has been a problem. Further, a shortage of manufacturing capacity and expertise should be addressed so that the world is not trapped this way again. All the world needs the vaccines and as has happened in early 2022 the developed world has enough people vaccinated (for the time being), but the need to distribute vaccines in the developing world still exists. Some of this is infrastructure problems but the pharmaceutical industry's exploitation of the patent, trade secret and regulatory systems is not separate from distribution problems, it contributes to their existence. Governments must revisit the patent, trade secrets and regulatory systems so that the hold-ups in terms of distribution and efficacy traced back to those systems, including failures to license patents and trade secrets (and provide related capacity building) and lack of regulatory clinical data sharing, are mitigated in relation to COVID-19 and do not happen for future pandemics.[138]

138. Drahos notes that there have been 15 pandemics this century, P Drahos, 'Public Lies and Public Goods: Ten Lessons from When Patents and Pandemics Meet' (EUI Working Paper, LAW 2021/5).