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The Case Against Patent Waivers: Adopting A Practical Approach to the COVID-19 Vaccine Crisis

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Nouf Ali S Algazlan*
PhD Candidate in Law

Harsh Arya
LLM Candidate in Law

Tejal Manish Katkoria
LLM Candidate in Law

Karishma Puri
Legal and Compliance Associate

* The City Law School, City, University of London, London, EC1V 0HB

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Nouf Ali S Algazlan, Harsh Arya, Tejal Manish Katkoria and Karishma Puri
The City Law School

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The Case Against Patent Waivers: Adopting A Practical Approach to the COVID-19 Vaccine Crisis

Nouf Ali S Algazlan, Harsh Arya, Tejal Manish Katkoria and Karishma Puri*

Abstract

The paper strives to participate in the academic debate of whether the Coronavirus Disease 2019 ("COVID-19") patent waiver is the answer to solving the calamities caused by the pandemic. We recognise vaccine inequality to lie at the core of the issues caused by the pandemic. Moreover, we argue that although patent law's protectionist nature can lead to the assumption that patent law is the problem, patents play a minor role in the inaccessibility of the COVID-19 vaccines. The way the vaccine market operates means that technical assistance is necessary to boost production and accessibility that requires a cross-disciplinary approach. As a solution to this, instead of a COVID-19 waiver to rectify vaccine inequality, we push for solutions of a more compulsory nature.

Keywords: Patent – Law – COVID-19 – Waiver - Pandemic

* This paper was originally written and submitted as a group assessment during the completion of an LLM, finalised in May 2022.

Introduction

Our paper strives to participate in the academic debate of whether the Coronavirus Disease 2019 (“COVID-19”) patent waiver is the answer to solving the calamities caused by the pandemic. We recognise vaccine inequality to lie at the core of the issues caused by the pandemic. Moreover, we argue that although patent law's protectionist nature can lead to the assumption that patent law is the problem, patents play a minor role in the inaccessibility of the COVID-19 vaccines. The way the vaccine market operates means that technical assistance is necessary to boost production and accessibility that requires a cross-disciplinary approach. As a solution to this, instead of a COVID-19 waiver to rectify vaccine inequality, we push for solutions of a more compulsory nature.

Chapter 1 lays down a foundation for understanding the pandemic, the COVID-19 waiver, the public policy and public interest debates that have resulted from it, and eventually concludes that the core issue of the pandemic is vaccine inequality fuelled by global selfishness. In Chapter 2, the focus shifts to the deficiencies in the current patent law system, namely the deficiencies in the disclosure requirement and the faults of compulsory licensing. It also analyses the failure of proposed voluntary collaboration initiatives, such as COVID-19 Technology Access Pool (“C-TAP”) and COVAX and explores the shortfalls of a voluntary scheme in light of the bigger problem of global selfishness. Chapter 3 then emphasises our case against patent waivers as a solution to the problem of vaccine inequality. Finally, Chapter 4 provides our proposed solutions of a more compulsory nature. We propose amendments to the current compulsory licensing and Doha declaration regime. We also propose a possible policy-based solution, and how expanding public-private partnerships would be ideal in tackling the behemoth issue of vaccine inequality.

For the purposes of this paper, a few reasonable assumptions have been made. Firstly, the COVID-19 vaccine patent is referred to as an invention rather than a product, process, or product by process patent. Secondly, it is assumed that the Intellectual Property (“IP”) rights for COVID-19 vaccines are sufficiently justified. It is also worth mentioning that due to the contemporary nature of this argument, there is not a great deal of academic literature for us to call upon. We have, however, drawn upon older, albeit still relevant, academic opinions, as well as a range of news articles, books, and case law.

Chapter One: Background

Chapter 1 begins by providing a brief background to the COVID-19 pandemic and the popular opinion that patent rights and pharmaceutical monopolies obstruct access to vaccines. We consider the challenges of finding a balance between patent law policies and public health

interests. Finally, we focus on how vaccine inequality has essentially made the pandemic a disease of "poor people and poor nations"[1] and how vaccine nationalism is destroying the goals of the patent system and harming public health.

Factual Background - The COVID-19 Pandemic

On 1st March 2020, the World Health Organisation ("WHO") ruled that COVID-19 is the second pandemic of the 21st century.[2] It became, and still is, a global health crisis leading to more than 5.5 million deaths.[3] As governments and administrations try to find ways to impose rules to minimise and reduce the rapid growth of the disease, health authorities, scientists and private companies rush to produce and advance vaccines.

The UK set about their first vaccination application on 8th December 2020.[4] A result of 300 different vaccine trials (a combination of pre-existing technologies and new methods). Even though it takes many years to produce a vaccine, scientists globally have come together and desperately worked to make sufficient, safe, and secure vaccines in a timely manner.[5] In the UK, the most used vaccines[6] are Pfizer,[7] AstraZeneca,[8] and Moderna.[9] Such vaccines are protected by Intellectual Property Rights ("IPRs"), mainly copyright, industrial designs, and patent rights – the latter of which is the focus of this essay.

Owing to patent rights, several countries argue that access to vaccines is obstructed or restricted. Stern patent procedures impede the common and all-round access to medicines due to monopolies that allow medicines to be at a certain price that cannot be afforded by

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[1] Nicola Davis, 'Covid Now A Pandemic Of Poor Nations, WHO Envoy Tells UK Mps' (*the Guardian*, 16th November 2021) <https://www.theguardian.com/world/2021/nov/16/covid-now-a-pandemic-of-poor-nations-who-envoy-tells-uk-mps> accessed 12 March 2022.

[2] World Health Organisation, 'WHO announces COVID-19 outbreak a pandemic' (*WHO*, 12TH March 2020) <https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic> accessed Monday 7th March 2022. Also, See Saad I. Mallah & others, 'COVID-19: breaking down a global health crisis' (*BMC*, 18th May 2021) https://ann-clinmicrob.biomedcentral.com/articles/10.1186/s12941-021-00438-7#ref-CR1 accessed 7th March 2022.

[3] This data is from 1 November 2021 and is hence subject to change due to the ongoing pandemic. David Adam, 'The Effort to Count The Pandemic's Global Death Toll' (*Nature*, January 2022) https://www.nature.com/articles/d41586-022-00104-8 accessed 7th March 2022.

[4] UK Health Security Agency, 'COVID-19 Vaccination Programme Information for healthcare practitioners' (*UK Health Secuirty Agency,* Republished 9 March 2022) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1054355/COVID-19-vaccine-Information-for_healthcare-practitioners-11022022.pdf accessed Monday 10th March 2022.

[5] Ibid 12.

[6] Ibid 14; These vaccines are the ones presently operating in the UK, but this may be subject to change.

[7] Ibid 14; COVID-19 Vaccine Pfizer BioNTech (Comirnaty 30 micograms/dose) and COVID-19 Vaccine Pfizer BioNTech (Comirnaty 10 micrograms/dose).

[8] Ibid 14; COVID-19 Vaccine AstraZeneca (Vaxzevria).

[9] Ibid 14; COVID-19 Vaccine Moderna (Spikevax).

those that need them.[10] As a result, it was requested that patent protection should be waived to improve access all around the world.

The COVID-19 Waiver Debate

The discussion surrounding the COVID-19 waiver relates to the wider issue of reviewing the healthcare inequalities that have escalated because of the COVID-19 pandemic, and also be well-equipped for later global health crises.[11] It was instigated by various developing countries (mainly India and South Africa) who proposed to the WTO to waive IP rights in light of COVID-19, including vaccines and other related products to overcome the pandemic.[12] The last time this has happened was in 2003 when the WTO decided to change its regulations around medical patented products.[13]

In the first instance, developed countries such as the United States and Germany drew back from the proposal. Berlin asserts that the waiver does not solve the issue of lack of production but will hinder future medical research.[14] Moreover, such countries also consist of the world's largest medicine manufacturers.[15] Nonetheless, in May 2021, the Biden Government was under duress to support the waiver. Since then, developing countries came together to put forward a revised proposal.[16] The proposal would be binding for at least three years and requests that IPRs for "health products and technologies"[17] related products (such as vaccines and personal protection equipment ("PPE")) be waived.

The motivation for these requests primarily comes from the need to boost the production of vaccines. TRIPS limits the administrative autonomy of member states ("MS") to some extent as it requires a positive obligation to meet the basic level standards of IP. Supporters of the waiver argue that these rules are making it difficult for other companies (other than the

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[10] Ellen 't Hoen, *Private Patents and Public Health*, (HAI, 2016), 1.

[11] Duncan Matthews, The COVID-19 Pandemic: Lessons for the European Patent System (2022) EIPR 377/2022, 1.

[12] Anshu Siripurapu, 'The Debate Over a Patent Waiver for COVID-19 Vaccines: What to Know', (*Council on Foreign Relations*, 26th May 2021) < https://www.cfr.org/in-brief/debate-over-patent-waiver-COVID-19-vaccines-what-know> accessed Monday 7th March 2022.

[13] WTO, 'Decision removes final patent obstacle to cheap drug imports' (*WTO*, 30 August 2003) <https://www.wto.org/english/news_e/pres03_e/pr350_e.htm> accessed 7 March 2022.

[14] Julian Borger and Patrick Wintour, 'US-Germany rift as Berlin opposes plan to ditch COVID vaccine patents' (*The Guardian*, 6 May 2021) <https://www.theguardian.com/world/2021/may/06/us-germany-rift-covid-vaccine-patent-waivers> accessed 7 March 2022.

[15] NationMaster, 'Pharmaceutical Industry Exports', https://www.nationmaster.com/nmx/ranking/pharmaceutical-industry-exports accessed 7 March 2022.

[16] WTO, 'Waiver from certain provisions of TRIPS agreement for the prevention, containment and treatment of COVID-19' https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669R1.pdf&Open=True accessed 7th March 2022.

[17] Ibid page 1.

producers) to produce the vaccines.[18] Supporters also explain that vaccine manufacturers receive massive amounts of funding by public authorities to aid the development of the vaccine.[19] Hence, it is only right to waive as it allows more access despite the lower profits.[20] Moreover, in the absence of the waiver and on the occasion of a public health emergency, the government can still allow other manufacturers to produce the patented invention (with the lack of the right-holder permission) through compulsory licensing. Supporters argue that this process is nevertheless too complex.[21]

On the other hand, those who do not favour the COVID-19 waiver argue that waiving the vaccines will have a limited effect on the distribution of the invention.[22] It will also harm encouragement and incentives for future creations. Government authorities along with private companies argue that low manufacturing capacity is the bigger obstacle when it comes to vaccination on a global scale, not patent rights.[23]

The Public Policy/Public Interest Debate

COVID-19 has rekindled the challenges of finding the balance between patent law and the public interest. Such challenges have questioned patent law policies, stemming from numerous countries arguing that the WTO regulations on patent rights make it harder for low-income economies to access needed medicine.[24] In contrast, it has been stated that patent laws are required to inspire the creation of new medicine.[25] However, how can we assess two contradicting notions? Are patents only one minor part of the problem or the major issue in access to medicine? These will be addressed further in turn.

Before diving into this discussion, we put forward what we believe forms a public benefit. It is often "the approach to medicine that is concerned with the health of the community as a whole".[26] The Medical Dictionary also displays three main roles of public health including (1)

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[18] Siripurapu (n 12).
[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Ibid.
[23] Ibid.
[24] See MSF Access Campaign, 'The Impact of Patents on Access to Medicines' https://msfaccess.org/search?keys=impact%20patents%20access%20medicines&sort_by=field_published_at> accessed Friday 18th March 2022. Also Yahong Li, 'Intellectual Property and Public Health: Two Sides of the Same Coin' 6 Asian J. WTO & int'l Health L. & Pol'y 389, 398.
[25] Dharshini David, 'Covid: The Vaccine patent row explained' (*BBC News*, 6 May 2021) <https://www.bbc.co.uk/news/business-57016260> accessed 20th March 2022.
[26] Melissa Conrad, 'Medical Definition of Public Health' (*MedicineNet*, 29th March 2021) <https://www.medicinenet.com/public_health/definition.htm> accessed Friday 18th March 2022.

to “identify health problems and priorities”, (2) to determine “public policies to solve health issues” and (3) to ensure all have access to care.[27] Additionally, agreeing with Jefferson’s perspective and the US Constitution, patent rights are instruments with the aim of accomplishing a common good – “Progress of Science and useful Arts”[28] – and inventions are less likely to exist until inventors have limited protection from reproduction. Moreover, there will be advancement and development when such inventions are in the public domain allowing the inventions to be utilised. Therefore, allowing patent rights is sensibly reasonable insofar as it is likely to balance the public interest. Such balance is what makes patent rights a right and not a monopoly. This balancing move is also initiated in the patentability process where strict requirements such as novelty and nonobviousness are required.

A recent case that deals with the notion of public interest is *Evalve* v *Edwards Lifesciences*.[29] Birss J explains that an element to examine is the competition aspects of a product. In detail, Birss J doubts that a generic drug would “usually”[30] draw the public interest. The use of “usually”[31] is because sometimes, in relation to specific cases, similar to COVID-19, the Government could request crown use.[32] In particular, s55-59 of The Patent Act allows the government to determine what is the public interest and allows an invention to be made available without the consent of the right holder, illustrating that UK courts are strongly mindful of the balance between the connection of the public interest during COVID-19 and patent rights.[33]

Nevertheless, it is often viewed that the COVID-19 pandemic has been a “policy disrupter,”[34] because the patent system allows private companies protection for their invention (the vaccine). As a result, the vaccine is deliberately taking a lot of time to be in the hands of several countries due to “blockages, vaccine hoarding, inequality.”[35] The incapability of protection within WTO and TRIPS leads to the inability of faster vaccine rollout.

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[27] Ibid.

[28] United States Constitution Article I, Section 8, Clause 8. Also see Mario Biagioli, ‘Weighing intellectual property: Can we balance the social costs and benefits of patenting?’ 2019, Vol. 57(i) 140-163, 142.

[29] *Evalve Inc, Abbot Cardiovascular Systems Inc., Abbott Medical U.K. Limited* v *Edwards Lifesciences Limited* (*Evalve* v *Edwards Lifesciences*) (2020) EWHC 513 (Pat) at 1. Also, Matthews (n 11), 6.

[30] *Evalve* v *Edwards Lifesciences* (n 29) 77.

[31] Ibid para 77.

[32] Matthews (n 29), 6.

[33] Ibid.

[34] Matthews (n 29), 2.

[35] Ibid, 1.

Whilst the main argument in supporting the COVID-19 vaccine waiver is essential to boost the production of vaccines and other needed products. In fact, many have and still argue the opposite - the patent system should not obstruct access to medicine, particularly in a health crisis.[36] Is it right to provide reasons for patent laws that are utilised in a manner that restricts the accessibility of vaccines and tries to maximise profits in a global pandemic? It's been asserted that a completely practical patent system would be the opposite relationship between the prices of the inventions and affordability in obtainment.[37]

Vaccine Inequality and Nationalism

Putting the patent bargain in context with the COVID-19 vaccine, Thambisetty and others argue that the public good has not been served well.[38] It becomes blatantly obvious when the market of the vaccine is analysed. With the current IPRs and other regulatory approvals, vaccine production is dominated by a handful of dominant players (such as Pfizer/BioNTech, Moderna, AstraZeneca/Oxford, amongst others). With this section, we argue that the patent rights awarded to current COVID-19 vaccine manufacturers have been operating against the patent bargain's intention of treating the vaccine as a public good. It suggests that although monopolistic or oligopolistic market structures are not uncommon – rather they are expected – in patent systems, the oligopolistic nature of COVID-19 vaccine producers has led to two critical overarching problems of the pandemic: vaccine inequality and vaccine nationalism.

Vaccine Inequality

To achieve the global common goal of high vaccination rates against COVID-19 as possible has proved to be a difficult task. Big Pharma is seemingly no match for the over 23 billion doses needed to fully vaccinate every person in the world.[39] As of May 2021, data highlighted that "only o.3 percent of the vaccines administered globally have been given in the 29 poorest countries where 9 percent of the world's population lives."[40] WHO envoy told UK MPs that COVID-19 "is a disease now fundamentally of poor people and poor nations."[41] The most obvious fix to this problem would be to produce more doses of the vaccine. However, it has

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[36] Enrico Bonadio and Andrea Baldini, 'COVID-19, Patents and the Never-Ending Tension between Proprietary Rights and the Protection of Public Health' European Journal of Risk Regulation, 11 (2020) 390-395, 393.

[37] Lall and Albaladejo, "Indicators of the Relative Importance of IPRs in Developing Countries" (Queen Elizabeth House Working Paper Series QEHWPPS85, 2002) at pp 2-3.

[38] Siva Thambisetty and others, 'The TRIPS Intellectual Property Waiver Proposal: Creating The Right Incentives In Patent Law And Politics To End The COVID-19 Pandemic' [2021] LSE Legal Studies Working Papers (06/2021), p 35 <https://papers.ssrn.com/abstract=3851737> accessed 5 March 2022.

[39] Fully vaccinated here means three doses per person.

[40] Ellen Hoen, 'COVID Shows The World It Needs New Rules To Deal With Pandemics - Medicines Law & Policy' (*Medicines Law & Policy*, 2021) <https://medicineslawandpolicy.org/2021/05/COVID-shows-the-world-it-needs-new-rules-to-deal-with-pandemics/> accessed 12 March 2022.

[41] Davis (n 1).

been seen that big vaccine makers have rejected offers from smaller pharmaceutical companies to help produce more doses.[42] Director of the Global Health Policy and Governance Initiative at Georgetown's O'Neill Institute, Matthew Kavanagh, shared that "the sole reason these vaccines aren't being produced widely by other makers is because these companies don't want to give up their monopoly."[43]

On the other hand, it is argued "an authorisation to manufacture is not the same as the ability to manufacture", as the latter requires extreme competence and the relevant technological infrastructure.[44] The manufacturing process for mRNA vaccine technology (such as the technology that BioNTech/Pfizer, Moderna, and CureVac vaccines are based on) is "significantly more expensive and complex than that for the established vector vaccines".[45] However, it seems unreasonable (and offensive to modern-day science) to assume that no other pharmaceutical companies are capable of producing the vaccine, no matter how complicated the process may be. The problem is rooted in how IP law incentivises health technologies and the case for making system changes to it is not new. The 2016 United Nations Secretary-General's report on access to medicines recognises how "the misalignment between the right to health on the one hand and intellectual property and trade on the other,"[46] fuels the failure of modern-day science of addressing disease burdens and emerging diseases.[47] Therefore, the severe vaccine inequality seems to be a byproduct of the inefficiencies posed by the patent protections afforded to vaccine manufacturers, who are operating against the principle of the patent bargain and inhibiting new competitors from entering the vaccine production market.

Vaccine Nationalism

The rollout of the first COVID-19 vaccine doses in December 2020 was quickly followed by competitive procurement of the vaccine –by the United States, Britain, Japan, and the

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[42] Ashleigh Furlong, 'Big Vaccine Makers Reject Offers To Help Produce More Jabs' (*POLITICO*, 2021) <https://www.politico.eu/article/vaccine-producers-reject-offers-to-make-more-jabs/> accessed 12 March 2022.
[43] Emily Baumgaertner, 'Vaccine Companies And The U.S. Government Snubbed WHO Initiative To Scale Up Global Manufacturing' (*Los Angeles Times*, 2021) <https://www.latimes.com/world-nation/story/2021-04-30/vaccine-companies-and-the-u-s-government-snubbed-who-initiative-to-scale-up-global-manufacturing> accessed 12 March 2022.
[44] Christoph J. Crützen and Maximilian Kücking, 'The Waiver Of Patent Protection For COVID-19 Vaccines — On Practicability And Purpose Of Such Measure' (*Mayer Brown*, 2021) <https://www.mayerbrown.com/en/perspectives-events/publications/2021/07/ger-the-waiver-of-patent-protection> accessed 12 March 2022.
[45] Ibid.
[46] The United Nations, 'THE UNITED NATIONS SECRETARY-GENERAL's HIGH-LEVEL PANEL ON ACCESS TO MEDICINES REPORT PROMOTING INNOVATION AND ACCESS TO HEALTH TECHNOLOGIES' (2016) <http://www.unsgaccessmeds.org/final-report/> accessed 12 March 2022.
[47] Ibid.

European bloc – which fed into the widespread assumption that each country will be entirely responsible for its own population.[48] Powerful countries securing vaccines at the expense of poorer countries is repeated history; Katz and others say that vaccine nationalism in this manner is "short-sighted, ineffective, and deadly."[49] COVID-19 vaccine nationalism further supplements our argument of how there is an evident conflict between the goals of patent law and the realities of the pharmaceutical industry, where vaccines and essential medications are treated as market commodities instead of a public good.[50]

It is therefore the global selfishness that operates in the COVID-19 vaccine market that has led to the failure of the patent system in regard to the effective innovation, production, and distribution of vaccines.

Conclusion

The main takeaway from this chapter is that vaccine inequality lies at the heart of the calamities caused by the pandemic. It is important to note that the patent law system does strive to strike a balance between the law and the public interest, but global selfishness has led to a destruction of that balance. The following chapter will further elaborate on how the patent law system is inadequate in dealing with vaccine inequality.

Chapter Two: Deficiencies In and Outside the Patent System

Chapter 2 will analyse the deficiencies within and outside the patent law system as it currently stands, and concludes that other solutions need to be thought of to fix the overarching issue of vaccine inequality. It will first deal with deficiencies that patenting the vaccine would create, mainly in the disclosure requirement, focusing on insufficiency of disclosure, lag in publications of patent applications, and the strategic possibilities created by overlapping patent rights. It also considers the two most popular alternatives to a patent waiver – compulsory licensing and voluntary licensing – and demonstrates their unworkability.

Deficiencies in disclosure that curtail the public benefit

As we have established how crucial the concept of the public benefit is to the patent law system, this next section elaborates on the futility of patent protection with regards to COVID-19 vaccines as patenting the vaccine only leads to destruction of the patent bargain. The patent bargain is the exchange of the disclosure of the invention for the exclusive right to the

[48] Ingrid T. Katz and others, 'From Vaccine Nationalism To Vaccine Equity — Finding A Path Forward' (2021) 384 New England Journal of Medicine, 1281.
[49] Ibid.
[50] Ibid.

invention. Securing a patent therefore involves serving a public good by virtue of the disclosure of the invention to the public, incentivising further innovation, competition, and production. However, as pointed out by Thambisetty and others, COVID-19 exposed deficiencies of the operation of the disclosure requirement.[51] There are three specific deficiencies worth mentioning in the context of the TRIPS waiver: the insufficiency of disclosure that has developed, the "lag in publications of patent applications", and "strategic possibilities created by overlapping patent rights".[52] These deficiencies are argued to thwart the patent bargain, therefore weakening the argument for the COVID-19 vaccines to be patent protected.

Insufficiency of Disclosure:

The doctrine of disclosure is enshrined in the Patents Act: s72(1)(c) states that a patent may be revoked if "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art." The way the patent system works means that there is a 'patent race', with the first person to file a patent for a particular invention being awarded the patent. As a result, disclosure often occurs during the preliminary stages of filing, leading to the filing of merely "plausible" or "credible" information.[53] Further, patent law generally does not mandate post-grant disclosures – this can be a hurdle for inventions with underlying technologies that are not fully understood at the time of disclosure. This is extremely relevant in the context of the COVID-19 vaccine with, for example, new studies periodically coming to light about the number of doses required in protecting yourself against the virus and its different variants.[54] Therefore, when patenting an invention that is so contemporary and one that requires simultaneous rigorous research to verify and fortify the invention, it can be argued that the disclosure requirement becomes redundant and the benefit to the public is curtailed.

Lag in Publications of Patent Applications:

The other deficiency in the disclosure requirement in relation to the COVID-19 vaccine is the time obligation for intellectual property offices to publish patent applications. Generally, publication of the patent application takes place up to 18 months from its filing date or priority date.[55] During this time, the information that is set to be disclosed is not yet available to the public. On top of the aforementioned argument that disclosure of a COVID-19 vaccine is

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[51] Thambisetty (n 38), 18.

[52] Ibid.

[53] JC Fromer, 'Patent Disclosure' 94 Iowa Law Review (2009) 539.

[54] Jef Akst, 'To Booster Or Not: Scientists And Regulators Debate' (*The Scientist Magazine*, 2021) <https://www.the-scientist.com/news-opinion/to-booster-or-not-scientists-and-regulators-debate-69191> accessed 6 March 2022.

[55] UK Intellectual Property Office, 'Discussion Document: Publication Of Patent Applications' (2016).

insufficient, this 18-month gap in knowledge can be a serious hindrance to other inventors in a field that requires and has shown rapid developments in the last year.

Strategic Possibilities Created by Overlapping Patent Rights

Finally, overlapping rights can be generated where there are several patent applications, all with slight modifications.[56] Patent families are created as a result, where there are a multitude of patents for essentially the same invention. These overlapping rights, in effect, mean that the patent can be protected for more than the patent lifetime of 20 years,[57] and it therefore becomes difficult to gauge the IP landscape over certain inventions. Relentless monopolies of this manner are an ongoing problem in the pharmaceutical industry, making it hard for competitors to discern if the technology is still protected or not.[58] This is problematic in this pandemic, as it undeniably obstructs the sharing of relevant scientific information within the scientific community as needed to speed up the production and distribution of the vaccine.

Conclusively, the deficiencies to the disclosure requirement that patent protection on the COVID-19 vaccines creates seemingly destroys the crux of patent protection, which is the patent bargain.

Compulsory Licensing

The COVID-19 crisis demonstrates that the flexibilities under TRIPS[59] are insufficient namely compulsory licences/ing ("CL").[60] Article 31 TRIPS enables WTO countries (granted they meet the minimum criteria) the ability to grant CL. A CL allows a third party to "manufacture a generic version of a patented pharmaceutical product without patent holder permission"[61]. The ability of countries to compel a licence has, therefore, been the foremost defence against COVID-19 waiver; the position of "why waive if you 'can' licence"[62], has also been supported by the WTO[63] and the Max Planck Institute[64].

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[56] Thambisetty (n 38) 19.

[57] Patents Act 1977 s25.

[58] Olga Gurgula, 'Strategic accumulation of patents in the pharmaceutical industry and patent thickets in complex technologies – two different concepts sharing similar features' 48 International Review of Intellectual Property and Competition Law (2017) 385.

[59] Agreement on Trade-Related Aspects of Intellectual Property Rights (Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

[60] Thambisetty (n 38), 3.

[61] TRIPS, art 31.

[62] Katarina Foss-Solbrekk, 'The IP waiver and COVID-19: reasons for unwavering support' (2021) 16 Journal of Intellectual Property Law & Practice 1347, 1349.

[63] Thambisetty (n 38) [33].

[64] Reto M. Hilty et al. 'COVID-19 and the Role of Intellectual Property Position Statement of the Max Planck Institute for Innovation and Competition of 7 May 2021' at 4–5.

Yet, CL is not without flaws. In theory, countries are able to utilise a CL in a crisis. However, in practice, it has not been feasible. For Thambisetty and others, the TRIPS regime, in particular CLs, are "bureaucratic, uncertain and/or time-consuming."[65] CLs are issued on a "country-per-country, vaccine-for-vaccine basis."[66] Issuing a wider CL for all COVID-19 vaccines is therefore not possible, which is why a wider COVID-19 patent waiver has been advocated for. There is at least a minimum of four different 'brands' of vaccines: Pfizer, Astra-Zeneca, Johnson & Johnson, and Moderna,[67] which would mean that each country would have to issue a CL for each brand. Now consider that there are different types of products in development; for example, Pfizer has developed antiviral COVID-19 pills.[68] The process is time-consuming and is only aggravated by national law.

Obtaining a CL is difficult because, as Foss-Solbrekk notes, it relies on the effectiveness of its implementation into national law.[69] Each country will therefore have its own procedure for issuing CLs. For example, a 2-year time limit and a criterion for qualification of use under Article 31bis[70] are imposed by the Canadian Patent Act.[71] Conversely, in Austria, "the period that must have expired when applying for a compulsory licence is three years after the publication of the granted patent or four years after a patent was applied for, whichever period expired first."[72] Therefore, it comes as no surprise that governments do not immediately turn to TRIPS flexibilities in a public health crisis. For example, Article 31bis was executed successfully only once with the Canada–Rwanda licence.[73] Matthews discusses the issue in detail, noting only Israel has issued a CL for a potential COVID-19 vaccine[74]. The UK government has been criticised for not using national 'flexibilities' such as the 'Crown Use Scheme' which Birss J hinted at during *Evalve,*[75] which allows the UK government to "produce

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[65] Thambisetty (n 38) [34].

[66] Ibid.

[67]WHO/N.K. Acquah, 'COVID-19 vaccines' (World Health Organization) <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/COVID-19-vaccines> accessed Thursday 10th March 2022.

[68] United States Food and Drug Administration, 'Coronavirus (COVID- 19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID - 19' (FDA, 22 December 2021) <https://www.fda.gov/news-events/press-announcements/coronavirus-COVID-19-update-fda-authorizes-first-oral-antiviral-treatment-COVID-19> accessed Friday 11th March 2022.

[69] Foss-Solbrekk (n 62), 1348.

[70] TRIPS 1994.

[71] Marumo Nkomo, 'Rwanda's New Intellectual Property Law and Compulsory Licensing for Export Under the WTO: Not Quite a Panacea' (2013) 21 Africa Journal of International and Comparative Law 279, 29.

[72] Colin McCall and Manja Epping, 'Compulsory Licensing of Patents' (*TaylorWessing*, June 2013) <https://www.taylorwessing.com/synapse/ti_compulsorylicensingpatents.html> accessed 10 March 2022.

[73] 'Bolivia and Biolyse Sign Landmark Agreement for Export of COVID-19 Vaccines' Press Release via Cision (12 May 2021). <www.newswire.ca/news-releases/bolivia-and-biolyse-sign-landmarkagreement-for-export-of-COVID-19-vaccines-832670191.html> accessed 17 March 2022.

[74] Matthews, (n 11) 5

[75] *Evalve* v *Edwards Lifesciences* (n 29) 77.

products for the public without the patentees' permission"[76]. However, the scheme was never enabled. Instead, the government 'pre-ordered' vaccines through Advance Purchase Agreements[77] – a decision that has been criticised by Torjesen.[78]

The issue of higher-income economies "pre-ordering vaccines has been a major contributor of vaccine inequality"[79] (discussed below). Collins and Holder found that "most higher-income countries were able to pre-order enough vaccines to cover their populations several times over, while lower-income economies had trouble securing any doses at all".[80] As a result, higher-income economies have had no need to issue CLs.

This does not mean CLs are not beneficial. Ooms and Hanefeld say the "threat of compulsory licences could increase access to essential medicines" and is often enough to force patent holders to decrease a medicine's price.[81] Ooms and Hanefeld illustrated this with how the US and Canada's threat of a CL following 9/11 led Bayer to reduce the price of ciprofloxacin.[82]

Overall, the COVID-19 pandemic has demonstrated that there are 'flexibilities' in place but higher-income countries ("HICs") are not motivated to use those flexibilities. Due to HICs having the ability to buy their way out of the pandemic, HICs are not interested in issuing or facilitating the use of CLs. Adjustments, therefore, need to be made to make TRIPS 'flexibilities' the first point of call in a public health crisis.

COVAX and CTAP

As previously mentioned, at the heart of vaccine inequality and vaccine nationalism lies global selfishness. Big Pharma is reluctant to give up their monopoly on vaccine production while wealthier governments rushed to procure a more-than-necessary bulk of Covid-19 vaccine doses. However, global selfishness has proven destructive in not only creating the problems of vaccine inequality and nationalism but also in efforts to solve the problems the two have created. Two specific efforts will be mentioned in this section, namely C-TAP and COVAX -

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[76] Matthews (n 11), 6-7.

[77] Foss-Solbrekk (n 62), 1347.

[78] Ingrid Torjesen, 'COVID-19: Pre-purchasing vaccine—sensible or selfish?' (2020) 370 BMJ 1-4.

[79] Keith Collins and Josh Holder, 'See How Rich Countries Got to the Front of the Vaccine Line' NY Times (New York, 31 March 2021). <https://www.nytimes.com/interactive/2021/03/31/world/globalvaccine-supply-inequity.html> accessed 1 March 2022

[80] Ibid.

[81] Gorik Ooms and Johanna Hanefeld, 'Threat of compulsory licences could increase access to essential medicines' (2019) 365 BMJ 3.

[82] Thomas F. Mullin, 'Aids, Anthrax, and Compulsory Licensing: has The United States Learned Anything? A Comment on Recent Decisions On The International Intellectual Property Rights Of Pharmaceutical Patents' (2002) 9 ILSA J Int Comp Law 185.

both global collaboration platforms that strive to boost vaccine supply to eradicate the issues caused by vaccine inequality and nationalism. This section will explore their purposes, and why they have failed, and will provide that voluntary collaboration platforms are futile as a solution when global selfishness is at the heart of the issue.

Weaknesses of voluntary licensing and platforms

Voluntary licensing is the voluntary granting of licenses to IP-holder's patents. This is commonly adopted for the production of generic medication in low and middle-income countries. This has proven to be successful – a 2016 report from the WHO shows that voluntary licenses led sofosbuvir (a medication used to treat hepatitis C) prices to fall significantly.[83] The same report also elaborated on how in order for voluntary licensing to allow a competitive market, the agreement needs to ensure transparency and include pro-competitive, public health-friendly terms and conditions.[84] It is no wonder that the voluntary licensing nature of COVAX and C-TAP are failing – the two platforms are operating in a market that is dominated by a handful of companies who are unwilling to give up their monopoly.

The failure of CTAP

In May of 2020, the WHO and its partners launched C-TAP, a program for pharmaceutical companies to voluntarily share COVID-19 information "to facilitate timely, equitable and affordable access of COVID-19 health products" by boosting supply.[85] WHO describes the platform as a "one-stop-shop" for COVID-19 health product developers to share their intellectual property, knowledge, and data through voluntary, non-exclusive, and transparent licenses.[86] The goal of having pharmaceutical companies engaging with the platform is to lower production costs, ease the issue of vaccine inequality, and, ultimately, end the pandemic sooner.[87] However, the platform has been severely underused. Charles Gore, the executive director of the Medicines Patent Pool ("MPP"), said the lack of engagement was illustrative of the globally selfish behaviour that has led to the prolongment of the pandemic – "Unfortunately what we've seen is too little of, 'Let's do this all together as a world', and a little too much of me-first."[88] This echoes what we highlighted earlier in the essay, when we explored why Big

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[83] World Health Organisation, 'Global Report On Access To Hepatitis C Treatment: Focus On Overcoming Barriers.' (2016) <http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1.> accessed 24 March 2022.

[84] Ibid.

[85] 'COVID-19 Technology Access Pool' (*Who.int*, 2021) <https://www.who.int/initiatives/covid-19-technology-access-pool> accessed 16 March 2022.

[86] Ibid.

[87] Michael Safi, 'WHO Platform For Pharmaceutical Firms Unused Since Pandemic Began' (*the Guardian*, 2021) <https://www.theguardian.com/world/2021/jan/22/who-platform-for-pharmaceutical-firms-unused-since-pandemic-began> accessed 16 March 2022.

[88] Ibid.

Pharma refuses to work with smaller companies to produce and distribute more doses of the vaccine, leading to the devastation that is vaccine inequality.

About a year and a half after the launch of WHO's C-TAP, MPP signed its first license with them for COVID-19 serological antibody technology, becoming the first, global, non-exclusive and transparent voluntary license for a COVID-19 diagnostic test.[89] More importantly, it is the first license for a health technology through C-TAP. MPP also started to reach out to key COVID-19 vaccine producers about joining the platform, but "they were very reluctant because they want to keep control of the market."[90] The head of the IP unit at WHO's division for access to medicines and health products, Erika Dueñas Loayza, says "transparency is a big problem in the case of these bilateral licensing agreements."[91] Through this, it is seemingly evident that calls for voluntary action by the information bearers themselves has been unsuccessful. Something of a compulsory nature should be considered an option to facilitate the transfer of information or the increase of distribution of supply to the countries facing the brunt of vaccine inequality – low-income economies.

The failure of COVAX

COVAX is the vaccines pillar of the Access to COVID-19 Tools Accelerator and is co-led by Gavi, the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO. It acts as a global collaboration platform and aims to to boost the development and production of COVID-19 vaccines while guaranteeing fair and equitable access for every country.[92] Similar to C-TAP, COVAX was launched as a reaction to the inequalities of vaccine production and distribution globally. Gavi's website claims COVAX as the "only truly global solution to this pandemic because it is the only effort to ensure that people in all corners of the world will get access to COVID-19 vaccines once they are available, regardless of their wealth."[93] The initial aim was to develop 2 billion doses by the end of 2021 – this prediction entailed protecting high risk people as well as frontline workers. It was to act as a lifeline for lower-income economies.

The very reasons why COVAX's success was important – to defeat global selfishness and vaccine inequality – were the same reasons why the initiative failed. COVAX struggled to

[89] Sara Jerving, 'COVID-19 Technology Access Pool Secures First Licensing Agreement' (*devex.com*, 2021) <https://www.devex.com/news/covid-19-technology-access-pool-secures-first-licensing-agreement-102168> accessed 16 March 2022.
[90] Ibid.
[91] Ibid.
[92] 'COVAX' (*Who.int*, 2021) <https://www.who.int/initiatives/act-accelerator/covax> accessed 24 March 2022.
[93] Seth Berkley, 'COVAX Explained' (*Gavi.org*, 2020) <https://www.gavi.org/vaccineswork/covax-explained> accessed 24 March 2022.

secure funding while richer countries signed unilateral deals with vaccine producers and bought limited supply, positioning rich countries in an even better position than before but the poorer countries in an even worse position. As of September 8 2021, COVAX had distributed just upwards of 240 million doses in 139 countries.[94] A formidable effort, but nowhere near the 2 billion doses they were aiming for. COVAX places blame on the world's richest countries who have bulk-bought more than enough vaccines for their populations.[95] Even with the Biden Administration pledging $4 billion to COVAX over two years in early 2021, the damage has been done.

Conclusion

While patenting the vaccine is problematic in terms of creating deficiencies in the disclosure requirement, this is not to say that the patent law is the problem, and a patent waiver is a solution. The most popular alternatives to a patent waiver – compulsory and voluntary licensing – are also unworkable. Obtaining a compulsory licensing has proven tedious and cumbersome, while voluntary licensing/platforms have proven impossible in light of global selfishness. The next chapter will further unfold our case against the patent waiver as a solution to the problems caused by COVID-19.

Chapter Three: The case against patent waivers

This chapter builds our case against a COVID-19 patent waiver as a solution to the problems caused by the pandemic. It runs through how waiving patent protection can hurt smaller pharmaceutical companies, harm existing streams of investments, and, most importantly, it would not solve the issue of vaccine inequality. We, therefore, do not consider the COVID-19 patent waiver as a valid solution.

Representatives from the European Commission ("REC") maintain the use of alternative methods to boost vaccine production.[96] Existing avenues such as CL are preferred to meet public health needs[97] and are supported by the Max Planck Institute[98].

Boldrin and Levin argue that the case for a patent waiver is "futile";[99] There are several reasons why. First, small entrepreneurial companies ("SECs") appear to be one of the innovators with

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[94] Jamie Ducharme, 'What Went Wrong With COVAX, The Global Vaccine Hub' (*Time*, 2021) <https://time.com/6096172/covax-vaccines-what-went-wrong/> accessed 24 March 2022.

[95] Ibid.

[96] Michael Rosen, 'Omicron Variant Sows Chaos but Doesn't Move Needle on Patent Waiver Debate' (*AEIdeas [Blog]*, 2 December 2021) <https://www.proquest.com/blogs-podcasts-websites/omicron-variant-sows-chaos-doesn-t-move-needle-on/docview/2605554049/se-2?accountid=14511> accessed 24 March 2022.

[97] Ibid.

[98] Hilty and others (n 64), 4–5.

[99] Michele Boldrin and David Levine, 'Reforming Patent Law: The Case of COVID-19' (2021) 41 Cato J 773, 775.

regard to novel pharmaceuticals.[100] SECs rely on patent protection to advertise the quality of their limited portfolio in absence of an existing roster of products that generate revenue. A patent waiver may harm SECs by reducing their ability to attract investment. Second, pre-existing medical innovation is funded by a combination of public and private investments. Public investments lead to basic research, which is then applied in a more focused manner through private investments for clinical trials. General waivers for patents could lead to uncertainty that negatively affects existing streams of investments.[101] Finally, the underlying objective of the waiver is to expand the global production of vaccines, nonetheless, this is a "myth".[102] Pursuant to this "myth" is that regardless of how complicated the invention is, the general ideas can be outlined in a mere "blueprint".[103] The "blueprint" is then given patent protection for exclusivity (as it may be costly to create and hence should be retrieved).
The above perspective presents two wrong policy interpretations. Firstly, patent rights are essential for others to invent products. If not, then no one will suffer the cost of making the "blueprints". Secondly, when the patent is released, then others will be able to produce such an invention. Such interpretation surrounds the meaningless attempt to waive patents for COVID-19 vaccines through international rules.[104]

However, in reality, this is not what happens. The best way to explain this is via the cooking analogy.[105] Manufacturing a complex vaccine is similar to making a complex dish. The "blueprint" is only the recipe and the beginning of making this dish. You need to find a good chef that can make this dish, the relevant and natural ingredients, the advanced appliances, and most importantly, the skills that are required to provide the dish. In the vaccine sector, this recipe is the medical discovery that results in a new vaccine. The good chef is the expert that has the relevant abilities and knows how to make this vaccine (manufacturers). To achieve this, one needs the relevant appliances (essential machinery) that are required to produce the vaccines as well as the relevant elements (ingredients) which have faced their own restrictions.[106] So, why are patent regulations important?

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[100] Robert Kneller, 'The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs' (2010) 9 Nature Reviews Drug Discovery 867, 870. Also see astian Rake, 'Waiving Intellectual Property Rights: Boom or Bust for Medical Innovation?' (2022) 27 Drug Discovery Today 384, 386.
[101] Rake (n 100) 386.
[102] Boldrin and Levine (n 99) 775.
[103] Ibid.
[104] See chapter 2 on TRIPS, WTO Law.
[105] Boldrin and Levine (n 99) 775-6.
[106] Thomas J. Bollyky and Chad P. Bown, 'The Tragedy of Vaccine Nationalism', 97 <https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/bown_pres2.pdf> accessed Friday 11th March 2022

Aside from identifying the recipe or the "blueprint", patent regulations have a minor role in the vaccine invention procedure.[107] Therefore, having a patented blueprint does not generally reward creation as the inventor has the intrinsic understanding of how to make the most of it. Additionally, adding the blueprint to the public domain will only be of benefit if the understanding and knowledge are evenly issued – this is not usually the case. Moderna, one of the main COVID-19 vaccine manufacturers,[108] has not enforced patents against other manufacturers, and this still did not lead to an increase in production (even after 16 months).[109] The process needs the relevant materials, tools, and human assets.[110] Hence, as argued in this section, waiving patent rights on vaccines may not be sustainable in increasing the production of vaccines or building knowledge and manufacturing capabilities.

The focus on patents rights distracts from more important matters that result in the inequality of vaccine distribution and access to medicine. Therefore, this paper will not consider a patent waiver as a solution to the COVID-19 health crisis. The paper will instead propose amendments that can be made to the current patent regime which could improve both the production and the distribution of supplies to aid in a global pandemic.[111] These changes will be discussed in the following chapter.

Chapter Four: Solutions

The purpose of this Chapter is to answer the question of whether patent rights have played any – if at all – part in aiding the inequalities relating to access to COVID-19 vaccines.[112] In this final Chapter, we will provide recommendations to the patent regime. The recommendations will affect existing flexibilities such as CL but will also propose implementing policy-based solutions and explore the possibility of PPPs. The recommendations are not designed to be an end all solution to the COVID-19 health crisis, but we believe they will aid in alleviating vaccine inequality.

[107] Boldrin and Levine (n 99) 776.

[108] Eric Sagonowsky, 'Moderna won't enforce COVID-19 vaccine patents during pandemic' (Fierce Pharma, 8 Oct 2020) <https://www.fiercepharma.com/pharma/leading-vaccine-player-moderna-won-t-enforce-patents-against-other-companies-during-pandemic> accessed 11th March 2022.

[109] Boldrin and Levine (n 99) 776.

[110] Stanley Plotkin and others, 'The complexity and cost of vaccine manufacturing – an overview' (NIOM, June 21 2017), <https://pubmed.ncbi.nlm.nih.gov/28647170/> accessed 11 March 2022.

[111] Boldrin and Levine (n 99) 773.

[112] Ibid 775.

Compulsory Licensing

Following from chapter two, there are adjustments that can be made to both compulsory licences. Adjustments that specifically seek to make compulsory licences easier and more effective to use to increase their use as TRIPS flexibility in public health crises.

Proposed by Lee,[113] a CL can be granted with multi-country benefits. Lee points out that article 2 of the Doha Declaration provides the option of a "single compulsory licence to deliver generics drugs to multiple countries". Lee proposes that economic difficulties could be alleviated, for example, "transaction and distribution costs for generic manufacturers".[114] The pooling of these drugs may also benefit low-income countries in negotiations with patent holders.[115]

Lee also highlights the risks of a CL with multi-country benefits.[116] For Lee, a risk associated with the manufacture of generic goods is time and money. Manufacturers prepare goods ready to export under a CL, however, there is no guarantee that they will obtain the CL.[117] Kommerskollegium provides the example, that a "country may default on the order" perhaps if there is a "change in government" or changes in import/export tariffs.[118] Lee also notes other risks, for example, TRIPS provisions which "expose the generic manufacture to risk due to transparency"[119] such as the "obligation of exporting countries to notify the TRIPS Council when they grant a CL" under article 2b (ii) of the Doha Declaration.

Yet, for Lee, these risks can be mitigated through what they call a "single licence" solution. Lee provides a detailed account of this solution in their paper.[120] In summary, a "streamlined process"[121] will "promote maximum flexibility and utility for generic manufacturers"[122].[123]

In a similar vein, an adjustment could be made to allow the granting of a compulsory licence for a group of vaccines, for example, all COVID-19 vaccines. However, issuing a CL for 'all' vaccines has its problems, especially if vaccine patents are reliant on other patents, for

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[113] Stacey B. Lee, 'Can Incentives to Generic Manufacturers Save the Doha Declarations Paragraph 6?' (2013) 44 Georgetown Journal of International Law 1378, 1401.
[114] Ibid 1414.
[115] Kommerskollegium, 'The WTO Decision on Compulsory Licensing: Does it Enable Import of Medicines for Developing Countries with Grave Public Health Problems?' Report of the Swedish National Board of Trade (2008), 60.
[116] Lee (n 113) 1416.
[117] Kommerskollegium (n 115) 49.
[118] Ibid 49.
[119] Lee (n 113) 1416.
[120] Ibid 1417.
[121] Cynthia Ho, *Access To Medicine In The Global Economy: International Agreements On Patents And Related Rights* (OUP 2011) 219-20.
[122] Ibid 219-20.
[123] Ibid 219-20.

example, a patent pool. More issues arise when considering that some vaccines or related processes are not patented and are kept under trade secrets. In which case, a better solution is an adjustment could be made to the Doha Declaration to enable low-income countries to co-operate.[124] For example, countries with manufacturing capabilities can aid countries with 'know-how' so both can access vaccines.[125]

Policy-Based Recommendation

The policy-based recommendation aims to improve access to vaccines to increase public benefit. The global COVID-19 crisis ("GCC") cannot be tackled by one entity.[126] The crisis demands responsibility from various international members. The members then can raise and allocate funding to boost and support developing countries in access to vaccines.[127] The difficulty of tackling the GCC should not fall on governments, pharmaceuticals, or the WTO alone. Citizens, researchers, and the press should play a significant role as discussed in this section. Due to varying levels of COVID-19 severity across countries, it is not feasible to provide one solution to accommodate the crisis. Hence, we provide broad recommendations which need to be reviewed as the GCC develops.

To develop the arguments under "The Public Policy/Public Interest Debate" – public benefit includes identifying the health problems (i.e., lack of access to vaccines in a global pandemic), producing public policies, and ensuring access to care. Goals which can be achieved through various means.

Firstly, to improve access to vaccines in developing countries, there needs to be a worldwide responsibility to fund health developments.[128] Developing countries such as India and South Africa do not have the relevant technologies[129] or funds for this measure. Hence, developed countries should guide and take action to finance the changes of the present insufficient medical framework that exists within these LICs. The goal can be achieved by increasing tax or allocating funds to finance the worldwide measure. Nonetheless, these methods are criticised as they are not attractive to governments due to potential backlash from citizens.[130] The solution should also involve the press and international bodies (for example, WHO).

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[124] Ooms and Hanefeld (n 81) 3.
[125] Ibid, 3.
[126] Bryan Mercurio, 'Resolving the public health crisis in the developing world problems and barriers of access to medicine' 5 Nw. J. Int'l Hum. Rts, 12.
[127] Ibid.
[128] Ibid.
[129] Ann Danaiya Usher, 'South Africa and India push for COVID-19 patents ban' (The Lancet, December 2020) <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext> accessed 26th March 2022.
[130] Mercurio (n 126) 17.

These actors have an important part in circulating, informing, and influencing people to encourage global sympathy.

In the past, Attaran and Gillespie-White stated that "the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa."[131] Therefore, the lack of effort and commitment from developing countries in prioritising healthcare should be changed. The change could be having a policy that is "comprehensive and well-planned"[132] aimed to bring essential vaccines.

Public-Private Partnerships and Joint Ventures

The ability of existing collaborative platforms such as COVAX and C-TAP to achieve their goals is uncertain. There is a lack of technical 'know-how', manufacturing, and infrastructure[133] in place. In addition, global organisations have been reluctant to pursue a COVID-19 patent waiver.[134]

PPPs can, therefore, be a way to incentivise collaboration during the GCC as successful PPPs can provide funding, information on health emergencies, and resources. The proposed solution suggests the creation of joint ventures and PPPs to achieve cooperation between HIEs, LIEs, international organisations, and host countries,[135] incentivising the voluntary sharing of patents, vaccine production knowledge, and sharing the risk of setting up new facilities.[136] Taking a sustainable approach will increase the production of COVID-19 vaccines and improve the capabilities of pharmaceutical companies in LIEs to facilitate a global manufacturing framework capable of meeting public health needs.[137]

In a PPP, pharmaceutical companies from HIEs with strong patent production may benefit from the expansion of production capacity and entry into new markets. As pharmaceutical companies hold both knowledge, technology, and technical know-how, local pharmaceutical companies in LIEs will benefit. Investment by a PPP may help ease barriers-to-entry and political risk while improving the public image in nations where production is located.[138]

The benefits include efficiently utilising the existing capabilities of Multinational Enterprises ("MNE"). MNEs have a focus on innovation and the deliverability of goals. Additionally, the

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[131] Ibid.

[132] Mercurio (n 126), 22.

[133] Xiaolan Fu and others, 'The World Has a Unique Opportunity: Accelerating Technology Transfer and Vaccine Production through Partnerships' [2021] Journal of International Business Policy, 2.

[134] Hilty and others (n 64), 4–5.

[135] Fu and others (n 133), 5.

[136] Ibid, 1.

[137] Ibid, 6.

[138] Ibid, 6.

transfer and sharing of global resources may improve production capacity and contribute to a global supply chain. MNEs allow for the recoupment of research and development costs by expanding production and increasing their presence in LIEs. The joint venture approach provides regional hubs, and pharmaceutical companies in LIEs the unique opportunity to benefit from knowledge and technology transfer and increase production capabilities whilst also increasing job opportunities. However, there are also risks. For instance, any joint venture or PPP requires shared goals and a well-defined vision as a prerequisite. A difference in the goals of such a project or the sharing of profits may endanger the entire venture. Risk can, therefore, be mitigated through parties having similar expectations and goals.

Conclusion

This final chapter proposed alternate solutions to the COVID-19 crisis, since, as evinced in previous chapters, the COVID-19 patent waiver would be insufficient in effectively tackling it. We propose amending existing flexibilities such as CL, implementing policy-based solutions that make the whole world jointly responsible in tackling vaccine inequality (rather than each government being responsible for only their own population), and implementing PPPs, so some of the pain caused by the pandemic may be alleviated.

Conclusion

The paper concludes that the inaccessibility of COVID-19 vaccines is not a failing of the patent system. The failure of COVID-19 vaccines to be manufactured and distributed effectively was caused by global selfishness. Simply, well-developed countries knew that they did not have to rely on the safeguards of the intellectual property regime to vaccinate their citizens, so they did not (as demonstrated by the failure of C-TAP and COVAX). Consequently, leaving low-income countries unable to vaccinate their citizens.

Therefore, a COVID-19 waiver would prove ineffective in increasing access. Our paper demonstrates the case against a COVID-19 waiver and highlights the potential adverse effect on SECs and future investment in medical research. Empirical evidence also shows that Moderna not enforcing their COVID-19 vaccine patents has not had a positive effect on vaccine production. The concerns are further supported by the reluctance of global intellectual property bodies to support a patent waiver.

The COVID-19 pandemic has demonstrated that amendments need to be made, not just to TRIPS ‘flexibilités’ but to joint global endeavours, to better facilitate global access and prevent vaccine inequality. Due to the disinterest in a COVID-19 waiver, the paper proposes solutions that directly amend CL and the Doha declaration. We also proposed a policy-based solution

focused on wider collaboration ranging from governments to citizens and a proposal to expand the use of joint ventures and PPPs.

Through the implementation of the above amendments, the paper hopes to achieve not only an increase in the accessibility of COVID-19 vaccines globally, but also a reduction in vaccine inequality and of vaccine nationalism.

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