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Is waiving IP protection a magic wand to make Covid-19 vaccines quicker and cheaper?

Van Anh Le[1*], Leah Samson[2]

[1]*Faculty of Law, University of Oxford, United Kingdom*
[2]*Tozers Solicitors, Exeter, United Kingdom*

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Abstract:

The Covid-19 waiver proposal put forward by India and Brazil in October 2020 has stirred public debate over the role of the intellectual property (IP) system. Many countries, including Vietnam, have expressed their support for this initiative. The waiver proponents argued that IP rights, mainly patents, have stalled global vaccination supplies. However, this paper challenges this view arguing that waiving IP rights is not a magic wand to make vaccines cheaper and quicker. Bottlenecks that slow vaccine rollout do not lie with the IP system but with manufacturing capacity, supply chain, and export restrictions. Therefore, instead of discussing the waiver proposal, world leaders should redirect their effort to address trade restrictions and improve global manufacturing partnerships. Countries with a low pharmaceutical manufacturing capacity like Vietnam should start thinking about being more well-prepared for the next pandemic.

Keywords: **Covid-19, intellectual property, patent, vaccines, waiver.**

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Introduction

At a World Trade Organization (WTO) meeting in early October 2020, India and South Africa proposed a temporary waiver of IP rights including patents, copyrights, industrial designs, and undisclosed information (trade secrets) [1]. The waiver aims at preventing, containing, or treating Covid-19 "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity". The proposal, which had a rather ambitious scope, targeted a wide range of "medical products including vaccines and medicines or to scaling-up of research, development, manufacturing and supply of medical products essential to combat Covid-19".

Although the potential adoption of the waiver will be optional and will not result in a direct application in all WTO members because each country will have to implement the waiver into their national laws, this idea has ignited fierce public debate. High-income economies such as the UK, the US, Australia, Japan, Canada, Norway, and the EU vigorously protested this ambitious proposal claiming that it will not speed up the slow vaccine rollout in developing countries [2]. However, headlines were made when the US, under the Biden administration, reversed their initial stance to support the proposal [3]. Such a change has influenced the dynamics and the whole gamut of the debate over the waiver, given the US's

*Corresponding author: Email: van-anh.le@law.ox.ac.uk

global leadership role and its well-established position as a patent fighter.

On the other hand, low and middle-income countries, including Vietnam, expressed enthusiastic support to the initiative in hopes that more vaccines would be produced due to this waiver [4]. Covid-19 proposal supporters have claimed that patent-holding companies should give up their IP protection to help other less fortunate countries [5]. Therefore, the waiver is considered a solution to unequal access to Covid-19 vaccines.

However, some developing countries, for example, Chile, Mexico, and Brazil voiced their opposition to the waiver and demanded a more data-first approach [6]. These countries required the waiver proponents to share examples where the IP system has blocked Covid-19 vaccine manufacturing and the extent to which such a waiver will give rise to widening access to Covid-19 vaccines in national laws. However, the answers to these questions remain unsubstantiated since these cited examples are sporadic and not systemic [2].

The disagreement amongst WTO members has led to a revision of the proposal published on 25 May 2021. The revised waiver would be limited only to "health products and technologies" for Covid-19 prevention, treatment, and containment. These would include vaccines, therapeutics, diagnostics, medical devices, and personal protective equipment [7]. While the original text suggested the waiver would be in place "until widespread vaccination is in place globally, and the majority of the world's population has developed immunity", the revision stated

that the waiver "shall be in force for at least three years" and subject to annual review. If the General Council of the WTO agrees that the "exceptional circumstances" leading to the waiver cease to exist, it will decide a termination date for the waiver.

This paper claims that neither patents nor other forms of IP rights, but rather the complex vaccine manufacturing and trade restrictions, have hindered vaccine distribution. This conclusion is supported by two WTO studies that have confirmed that tariffs, trade-related bottlenecks, and trade-facilitating measures have caused delays in making and distributing vaccines [8]. When the world is faced with difficulties and uncertainties, it seems easy to point the finger at the patent system and turn it into a scapegoat.

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It seems that the proposal is built on the assumption that patent (and other IP) protection is an obstacle to vaccine accessibility. Removing them will open the floodgates for better vaccine distribution. Further, once IP rights are taken down, it is assumed that Covid-19 vaccines will be made cheaper and quicker. This belief is not valid because second-generation vaccines will not be more affordable, unlike generic drugs. After all, the capital outlay for second-generation vaccines will not change [9]. The authors argue that removing the IP system might produce a countereffect to Vietnam, where vaccines produced by inexperienced manufacturers might uncontrollably infiltrate the market.

Unlike small-molecule drugs having bioequivalent generics, there is nothing called generic vaccines. Instead, second-generation vaccines are called biosimilars, which are highly similar in structure, function, and clinical effect to the innovator product. According to the FDA's report, bioequivalence refers to the absence of "a significant difference in the rate and extent that an active ingredient in pharmaceutical equivalents has contact with the site of the drug's action" [10]. Generic manufacturers can demonstrate the bioequivalence between patented medicines and generics through limited types of clinical tests. These companies merely imitate what others have made to offer a much lower price than the originator. They can omit the clinical trials, the most costly and laborious phase during the pharmaceutical R&D process, to save a substantial amount of money and thereby reduce the cost of the generics.

Meanwhile, bioequivalence cannot be shown in the case of vaccines because every new vaccine is considered a new creature. Regardless, companies used the same technology, which was not used to manufacture previously available vaccines [9]. Being a living product makes vaccines fragile. They are sensitive to heat and prone to microbial contamination. Therefore, even the simplest biologicals must undergo clinical trials because simple bioequivalence cannot determine efficacy and safety. All vaccines must pass human studies and bear the related costs to be circulated on the market [9]. Any subtle modifications in the production process, whether in scale, process, or presentation, may change the final product and affect its purity, safety, or efficacy. Therefore, regulatory authorities must assess and approve such changes again to ensure that the quality of

the final product does not change before its widespread implementation [11]. For complex vaccines like Covid-19, hundreds of quality control checks are required for the approval of each batch [9]. Having to conduct clinical trials is one of the reasons why the second-generation Covid-19 vaccines are unlikely to be cheaper, as is the case for generic medicines.

Quality controls are applied throughout the vaccine manufacturing process and represent up to 70% of the manufacturing time from the manufacturing standpoint [11]. To underscore the difficulties of producing Covid-19 vaccines, even by experienced third parties in the context of contractual technology transfer, companies like Emergent had issues in making the Johnson & Johnson vaccine. Indeed, they had to discard up to 15 million doses in May 2021 [12]. AstraZeneca, the company whose principal activities are not vaccine manufacturing, also had challenges at the beginning of the production, which caused a delay in supplying vaccines to certain countries. Challenges in making vaccines can also be well illustrated by Sanofi's decision to abandon the development of a Pfizer-style vaccine, even though this French pharmaceutical company is one of the very few vaccine manufacturers in the world [13].

Difficulties in vaccine manufacturing do not lie only in physical infrastructure but also in human labour. For example, the Swiss government helped recruit staff for Lonza, a Swiss company, to operate the production lines at Lonza's facility in Visp city (Switzerland) [14]. However, they could only find 25 qualified employees to fill critical positions, whereas Lonza was reported to need 75 skilled workers.

The US export restrictions have also aggravated the situation. The US Defence Production Act of 1950, which allows for the rating of specific medical items and reserves them to produce vaccines for Americans, has severely affected the availability of particular inputs to manufacture the vaccines. Such abovementioned trade restrictions have disrupted vaccine supplies where there is essential interdependency across all vaccine manufacturers. For example, manufacturing the Pfizer vaccine involves "280 components, 86 suppliers, 19 countries" [15]. Therefore, the lack of a single component could stop the entire manufacturing process and may result in the disposal of a batch that might already have been in production for several weeks.

Developing countries also need to take responsibility. The Indian government's decision to temporarily stop AstraZeneca's vaccine from being exported hit other poorer countries badly. The Indian-made AstraZeneca vaccine has been given to the Serum Institute of India, the world's largest vaccine maker and the most significant supplier to COVAX, a scheme through which many less developed countries receive their doses. India has adopted a two-faced approach. On the international front, it suggested that other countries should waive IP protection. On the national level, India has confessed that even discussions or a mention of exercising governmental power for essential drugs or vaccines that has patent protection "would have serious, severe and unintended adverse consequences" and "any exercise of statutory powers [...] can only prove to be counter-productive at this stage" [16].

Compared to many other traditional therapeutics, vaccine manufacturing is one of

the most challenging industries regarding its components and the technologies required to produce vaccines. The complication and difficulty of production, the rigidity of quality assurance and control, and numerous regulations require an enormous investment and production cost to set up a manufacturing facility in the industry. These requirements are considered barriers to market entry for new manufacturers [9]. As a result, the vaccine market is relatively small compared to the traditional pharmaceutical industry. The bottlenecks to vaccine manufacture are factual and significant, and for that reason, collaboration, not division, is needed to ensure global partnership and remove all roadblocks. The authors of this paper maintain that the hindrance of the inoculation program has nothing to do with IP rights but, instead, lies in manufacturing, supply chain, transportation, and other non-IP factors.

Potential dangers behind the removal of the IP eco-system

The innate complexity of vaccine production has turned IP rights into a quickly blamed target. We should accept that vaccine rollout is not a one-dimensional issue of IP rights but a multi-faceted problem where know-how, manufacturing facilities, skilled labour logistics, etc., are jointly needed to vaccinate the globe.

Following the above analysis, while it is unclear whether the waiver proposal would improve the vaccines inaccessibility, such an emotionally charged approach would potentially disincentivise vaccine development in response to new Covid-19 variants. For a country like Vietnam, waiving IP might adversely impact Foreign Direct Investment. The government is in a more vulnerable position than ever since it has just come out of a mysterious wave of Covid-19, which started in May 2020. Eroding IP rights, including the patent system, will send the wrong signal to the investors who might reconsider investing in exploring uses of future vaccine technology such as mRNA. Moreover, the comprehensive waiver of all IP rights ignores the stark reality that coronaviruses mutate swiftly and are more deadly.

It is naïve to hope that relinquishing the IP system will facilitate a vaccine blueprint. As mentioned above, vaccine manufacturers will need knowledge transfer, know-how, or trade secrets [17]. This information is, nonetheless, not disclosed in patent applications. Trade-secret and know-how are especially critical to producing complex vaccines, such as mRNA, where a "recipe" from a patent is hardly sufficient for production. In addition, new vaccine manufacturers might not even know what they need to know to make the vaccine. It is hard to imagine that the waiver proposal will force the rights holders to pass on these non-registered IP rights. Even with no IP protection, we should ask if any generic companies would embark on a precarious and research-intensive business without specific outcomes? The answer is probably no. Although Moderna assured others that they would not take legal actions regarding their Covid-19-related patents [18], no manufacturer has seized this opportunity to make the Moderna vaccine.

Existing legal tools, such as compulsory licensing, are not practical for vaccine production. Since the pandemic began, many

countries such as Canada, Chile, Ecuador, France, Israel, Indonesia, and Germany modified their current laws or passed a new law to issue a compulsory licence once Covid-19 treatment was found. Nevertheless, not one country has granted such a licence. Neither has a request for a voluntary licence ever been made. Lack of vaccine manufacturing capacity is, probably, one of the main reasons behind such inaction. As mentioned above, the vaccine manufacturing process requires highly sophisticated technology and rigorous quality control to preserve its safety and efficacy. Therefore, removing the entire ecosystem of IP rights is, indeed, attacking the wrong root cause.

The authors argue that world leaders would need months to negotiate and then agree on the language of the Covid-19 waiver. Then WTO members will have to transpose the waiver into their domestic laws. Such effort should be redirected to tackle real problems of vaccine manufacturing and not wasted discussing the proposal text while Covid-19 is quickly mutating.

Furthermore, dismantling patent protection might lead to substantial risks. Suppose patent-holding companies either decline to collaborate with local partners in obtaining marketing authorisation (by sharing required data and know-how) or cannot impose specific quality controls due to the IP waiver [19]. In those cases, ineffective vaccines manufactured by inferior processes could cause public distrust. Speeding up vaccine manufacturing must not be done at the expense of vaccine quality, efficacy, or safety. While patents and other IP rights are generally viewed as an incentive to fuel innovation, little know that they also suppress counterfeiting. Indeed, the WHO has determined that counterfeiting is facilitated where "[...] there is lack of effective intellectual property protection" [20]. Consequently, dismantling the IP system can result in a more widespread pharmaceutical crime.

Conclusions

The Covid-19 waiver proposal is ambiguous, impractical, and time-consuming. While it is understandable that world leaders who are bound by moral obligations to their citizens are rushing to push for radical changes, the proposal, nevertheless, shifts the attention away from the real barriers to vaccine accessibility. The proposal is overly simplistic and unfairly blames patent protection. Abolishing patents and other IP rights on the false faith that it will accelerate the current slow vaccine rollout is illusory. While it is true that "no one is safe until everyone is safe", instead of trying to bring the whole IP system down, we can achieve this without compromising high levels of quality assurance. A classic but essential recommendation for a country like Vietnam is to build up their local manufacturing capacity and attract partnerships with research-based pharmaceutical companies. Given the complexity of the vaccine industry and manufacturing process, it usually takes between 5 to 10 years to build physical infrastructure and standardise the local industry to comply with international standards; hence, Vietnam should invest more into R&D, starting now, to be more self-sufficient in the future.

COMPETING INTERESTS

The authors declare that there is no conflict of interest regarding the publication of this article.

REFERENCES

[1] WTO, Council for TRIPS (2020), *Communication from India and South Africa, Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, IP/C/W/669.

[2] J. Bacchus (2020), "An unnecessary proposal: a WTO waiver of intellectual property rights for Covid-19 vaccines", *Free Trade Bulletin*, **78**, cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#conclusion.

[3] Office of the United States Trade Representative (2021), *Statement from Ambassador Katherine Tai on the Covid-19 Trips Waiver*, ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver.

[4] dantri.com.vn/xa-hoi/viet-nam-ung-ho-de-xuat-mien-tru-ban-quyen-vac-xin-cua-tong-thong-my-20210513173123034.htm (in Vietnamese).

[5] msf.org/countries-obstructing-Covid-19-patent-waiver-must-allow-negotiations.

[6] WTO, Council for TRIPS (2020), *Communication from Australia, Canada, Chile and Mexico, Questions on Intellectual - Property Challenges Experienced by Members in Relation to Covid-19*, IP/C/W/671.

[7] WTO, Council for TRIPS (2021), *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of Covid-19*, IP/C/W/669/Rev.1.

[8] wto.org/english/news_e/news21_e/Covid_08oct21_ e.htm.

[9] Aurelia Nguyen, Nina Schwalbe (2019), "Apples and oranges? Can vaccines become as low cost as generic medicines?", *Vaccine*, **37(22)**, pp.2910-2914.

[10] U.S. Food and Drug Administration (accessed 6 August 2021), "A primer on generic drugs and bioequivalence: an overview of the generic drug approval process", fda.gov/media/89135/download.

[11] Vaccines Europe (2020), "How are vaccines produced", vaccineseurope.eu/about-vaccines/how-are-vaccines-produced.

[12] Sharon LaFraniere and Noah Weiland (2021), "Factory mix-up ruins up to 15 million vaccine doses from Johnson&Johnson", *The New York Times*, nytimes.com/2021/03/31/us/politics/johnson-johnson-coronavirus-vaccine.html.

[13] Leila Abboud (2021), "Sanofi stops development of Covid vaccine based on mRNA technology", *Financial Times*, ft.com/content/22ec6b9f-d007-41a9-8ab9-a76d17c73a3f.

[14] Millie Nelson (2021), "Swiss gov helps Lonza recruit staff to manufacture Moderna vaccine", *Bio Process International*, bioprocessintl.com/bioprocess-insider/swiss-gov-helps-lonza-recruit-staff-to-manufacture-moderna-vaccine/.

[15] Marie O'Halloran (2021), "Taoiseach warns against global interruption of vaccine delivery", *The Irish Times*, irishtimes.com/news/politics/taoiseach-warns-against-global-interruption-of-vaccine-delivery-1.4518904.

[16] livelaw.in/pdf_upload/centres-affidavit-in-suo-moto-covid-case-supreme-court-393164.pdf.

[17] D.S. Levine (2020), "Trade secrets and the battle against Covid", *Journal of Intellectual Property Law & Practice*, **15(11)**, pp.849-850.

[18] Moderna (2020), "Statement by Moderna on intellectual property matters during the Covid-19 pandemic", investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx.

[19] R. Hilty, et al. (2021), "Covid-19 and the role of intellectual property position statement of the Max Planck Institute for innovation and competition of 7 May 2021", *Max Planck Institute for Innovation and Competition*, DOI: 10.2139/ssrn.3841549.

[20] WHO (1992), *Counterfeit Drugs: Report of a WHO/IFPMA Workshop,* WHO/DMP/CFD/92, 24pp.