Assessment of the proposed intellectual property waiver as a mechanism to address the COVID-19 vaccine scarcity problem

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The manufacturing and distribution of COVID-19 vaccines has faced numerous hurdles, including infrastructural shortcomings, resulting in vaccine scarcity in many areas facing the highest disease burden. Several solutions to address the scarcity problem have been proposed, with the idea of a waiver of intellectual property, in particular that covering vaccines, gaining momentum in recent months. Here, we examine the merits of the waiver in the context of the removal of proprietary barriers to the transfer or use of vaccine technology. 'Proprietary' is used here to denote certain types of rights—in the form of patents, trade secrets and other know how—in the transfer of vaccine-related technology. This commentary explains how the waiver would work if implemented, and shows that there is a mismatch between the mechanics of the waiver and the intended increase in the global production and distribution of vaccines. In sum, the proposed mechanism does not address the intertwined problems of infrastructural deficits and transfer of non-explicit knowledge.

PROPRIETARY RIGHTS AND THE TRANSFER OF VACCINE TECHNOLOGY

Most recent vaccine technology is covered by proprietary rights, consisting predominantly of patents, rights covering data associated with the development and testing of vaccine candidates, and trade secrets.[1] The law gives rightsholders the ability to prevent others from using protected technology or data without their permission, which is typically given through a licensing agreement or other form of contractually regulated cooperation between two or more parties. Additionally, certain forms of knowledge needed to produce or replicate COVID-19 vaccines may be impossible to apprehend without cooperation from the innovator. This is the case, for instance, for know how or tacit knowledge needed to produce a component of a vaccine that may not be protected under trade secrecy frameworks, but that remains extraordinarily difficult or outright impossible to acquire through reverse engineering.

The existence of multiple layers of proprietary rights—often owned by multiple entities—sometimes owned by different upstream organisations covering a given vaccine conditions the transfer of vaccine technology on a permissive or collaborative gesture on the part of the rightsholder(s).[2] Alongside this proprietary landscape, there are several other factors that affect, and may slow down, the transfer of vaccine technology. Some of these factors relate to other areas of the law and the negotiating process: for instance, before agreeing to collaborate with other parties, vaccine manufacturers typically require that liability issues be contractually addressed ahead of the transfer of technology.[3] Other factors that influence how quickly vaccine technology can be transferred relate to infrastructural and practical constraints: for instance, in face of a surge in demand for vaccine manufacturing, there may be shortages of raw materials or limited facilities available for manufacturing, as was the case early in the COVID-19 pandemic.[4] Similarly, there are shortages of human capital, as personnel in possession of critical know how continue to be in short supply and it is often difficult for companies to send key employees to the licensees' site (especially during a pandemic), particularly those who are needed in the originator facility to scale up existing production.[5] Moreover, there may also be constraints in the availability of trained personnel at the licensee's manufacturing location.[6]

THE PROPOSED INTELLECTUAL PROPERTY WAIVER

Throughout 2021, one type of potential solution to vaccine scarcity has gained momentum across the international community: a waiver of intellectual property rights covering certain products needed in the response to COVID-19. This proposal was formally initiated in October 2020 by India and South Africa, which requested that the World Trade Organization set in motion the procedure necessary to waive intellectual property rights on goods used in the 'prevention, containment or treatment of COVID-19'.[7] Current international intellectual property laws, codified in the TRIPS Agreement, do not allow for a temporary suspension of the enforcement of intellectual property rights. From a legal perspective, the practical implication of the adoption of a waiver would translate into legal certainty that countries issuing compulsory licenses covering COVID-19 products or technologies would not be deemed in violation of international intellectual property law. The TRIPS Agreement mandates the grant and enforcement of patents for qualifying technologies, which include many components of vaccines and other medical products needed to diagnose, treat and prevent COVID-19. From a legal perspective, these licenses would enable third parties to use patented technology even in situations in which the rightsholder has not given permission for those uses, and the countries issuing these licenses would not be held in violation of the TRIPS Agreement.

The proposed waiver has gained significant support across the globe. For instance, in early May 2021, the United States Trade Representative announced its support of a waiver of patent rights related to COVID-19 vaccines.[8] Major international public health organisations have also supported this proposal, including the WHO.[9] However, as indicated in the previous section, patents are not the only proprietary or quasiproprietary frameworks that may delay or otherwise erect barriers to the transfer of vaccine technology. First, the scientific and technical information necessary to replicate a complex biologic product such as a vaccine is not fully captured in patents. Absent a collaborative relationship with the innovator, it is extremely unlikely that third parties will be able to access or quickly develop the know how and other types of knowledge required to produce

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that vaccine. Second, even if the waiver mandated the transfer of trade secrets, it is hard to fathom how a forced transfer of knowledge could occur in areas characterised by trade secrecy. And third, the compelled transfer of knowledge about COVID-19 vaccines, whether in the form of knowledge captured by patents or types of knowledge that operate according to de facto proprietary frameworks, is not the only problem faced during the pandemic: a waiver would leave unaddressed issues related to lacking manufacturing infrastructure, as well as scarcity of raw materials and qualified personnel.[5]

A more viable alternative to address midterm, and to reduce longer term vaccine shortages, is to support, both financially and structurally, collaborative relationships between innovators and potential trusted regional partners.[10 11] Several African countries, for instance, entered into contractual relationships to substantially increase the amount of COVID-19 vaccine doses across the continent.[12] Trust-building partnerships, such as those that start with fill finish agreements and progress to broader manufacturing obligations, in lower-income and middle-income countries have and will not only expand both the global manufacturing networks, but also build capacity in regional suppliers. As of late 2021, 156 collaborations between rightsholders and manufacturing partners had been announced, of which 73 were with manufacturers located in lower-income and middle-income countries.[5]

We note that the formation of these partnerships also faces challenges, both in terms of coordination between players with different bargaining power[13] and in terms of attracting significant technology commitments in timely fashion during periods of heightened disruption such as a pandemic.[14] This suggests that greater efforts should be made to identify best terms and practices to increase and accelerate these partnerships ahead of future outbreaks of infectious diseases.

Although it is appealing to look to a change in laws to address the tragic insufficient supply of COVID-19 in many countries in the world, the solutions will require the harder work of building relationships, infrastructure, best contracting practices and capacity, as well as funding earlier purchases of vaccines by countries in need and procurement mechanisms such as COVAX, which purchase on their behalf.

CONCLUSION

The ongoing discussions about the waiver of intellectual property rights surrounding COVID-19 vaccines have raised awareness to the relevance of intellectual property law and policy in the transfer of technology related to vaccine development, manufacturing and distribution. However, the proposed waiver fails to address the roots of the current vaccine scarcity problem, as it does not address the intertwined problems of infrastructural deficits and transfer of implicit knowledge.

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