Covid conundrum

Competing proposals to waive IP rights related to Covid-19 vaccines are being considered at the WTO, but will they impact global health needs? Freeborn & Peters' **Delphine Knight Brown** examines

In October 2020, as the race for a Covid-19 vaccine forged ahead, and the global pandemic raged across the globe, World Trade Organization (WTO) members India and South Africa proposed that intellectual property protections for Covid-19 vaccines be temporarily waived and IP enforcement suspended.[1]

The waiver proposal, which was recently updated on 25 May 2021, would apply to copyrights, industrial designs, patents and trade secrets. The proposal is intended to allow WTO member countries to export vaccines manufactured by generic pharmaceuticals without risking challenges under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, which requires WTO member countries to recognise protections for IP rights.

It is worth noting that, prior to the TRIPS agreement, more than 50 countries did not recognise patent protection for pharmaceutical products.

A few months ago saw a significant realignment of positions regarding the TRIPS waiver proposal. The US now supports (having initially opposed) waiving IP protections for Covid-19 vaccines.[2] The TRIPS waiver proposal is still opposed by the European Union, UK, Switzerland and Japan. Not surprisingly, these countries are home to major pharmaceutical companies. The European Union has offered a counterproposal to waive IP protections by easing export restrictions for vaccines and providing for the issue of compulsory licences.[3] WTO members agreed to focus on language in both TRIPS waiver proposals with the lofty goal of reaching consensus in late July. Thus far, no agreement has been reached. All 164 WTO member countries must agree on the text and any approved waiver.

The TRIPS waiver proposals pit upholding patent protections against Covid-19 public health needs. To date, the G-20 countries have only agreed to voluntary sharing of IP,[4] highlighting one of the main obstacles to achieving more support for the TRIPS waiver proposals: whether pharmaceutical companies can and should be required to disclose trade secrets.

Trade secrets are considered highly confidential proprietary information by pharmaceutical companies and often relate to research and development processes and pipelines, not merely single products.

For example, the mRNA vaccines produced by Pfizer and Moderna employed technology that has been previously utilised in biomedical research but the specific manufacturing process likely can't be easily replicated. Therefore, in order for other companies to reproduce the vaccines, pharmaceutical companies might need to disclose know-how, including training, technical assistance, materials and company documents, all of which are typically considered protected trade secrets.

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Experts agree that the sharing of know-how is critical to scaling up Covid-19 vaccine production and developing second generation vaccines to address variants. However, there is no precedent for forcing pharmaceutical companies to involuntarily disclose trade secrets. Compulsory patent licences were issued in the past to boost production of AIDS and HIV drugs, but even those licences did not require disclosure of trade secrets.

Compulsory licensing could result in more litigation than compliance when trade secrets are at issue, especially when such information has application beyond current Covid-19 vaccines. To date, no vaccine company has voluntarily shared its know-how through the World Health Organization's Covid-19 Technology Access Pool (C-TAP).

The 25 May 2021 revisions to the initial TRIPS waiver proposal sought to limit its effective time period to "at least three years," but broadened its application from "preventing, treating and containing Covid-19" to "health products and technologies" related to the "prevention, treatment or containment of Covid-19."[5] The revisions seem unlikely to result in additional support for other than the voluntary sharing of IP

rights. The US would likely only support a more limited waiver covering vaccine IP rights. The EU has indicated a willingness to negotiate a waiver of limited duration consistent with its counterproposal.

Despite the current US administration's apparent support for waiving IP protection for Covid-19 vaccines, the response in the US to the proposed broader waiver would most certainly involve intense lobbying by pharmaceutical companies to reverse or severely narrow its effect. The US Congress has already introduced legislation to require Congressional approval of any waiver, and prohibit the use of federal funds to support a waiver.[6]

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If the US government seeks to enforce a TRIPS waiver, the takings clause of the Fifth Amendment to the US Constitution could be used by US companies as a sword to prevent the loss of intellectual property rights without compensation. In addition, compulsory licences issued by foreign governments to US-based pharmaceutical companies would be the subject of jurisdictional challenges and lack effective enforcement mechanisms.

The TRIPS waiver proposals have been under discussion for over 10 months with no end in sight, and will likely fall prey to months, if not years, of legal challenges if approved. Additionally, despite India and China developing mRNA vaccine candidates, when one considers the intellectual property landscape for mRNA vaccines, a handful of pharmaceutical companies still hold half of the patent applications.

Though a TRIPS waiver might free up untapped capacity for increased vaccine production to meet the huge unmet need, it seems that government and private sector partnerships could be forged much more expeditiously and result in the desired rapid ramp up of Covid-19 vaccine production. For example, Moderna and Samsung Biologics recently announced an agreement for fill-and-finish manufacturing of Moderna's Covid-19 vaccine.[7]

When the IP waiver concept was first proposed last October, Moderna agreed not to enforce its Covid-19-related patents during the pandemic. But despite Moderna's voluntary waiver of its IP rights, no other company has stepped up to manufacture the Moderna vaccine. The most significant obstacle to Covid-19 vaccine supply is not just the IP rights that companies have obtained, or are pursuing, but rather the lack of raw materials and manufacturing facilities to produce the vaccines. Currently, there are shortages of raw materials and equipment used to make vaccines and biological products.

Unlike drug manufacturing, vaccine production processes are extremely complex and difficult to develop without support from current manufacturers. Additional manufacturers would need to have or acquire skilled expertise in mRNA technology and create or reconfigure manufacturing sites. Manufacturing vaccines requires additional processing steps and testing to assure quality and consistency. Manufacturing vaccines will also likely use the patented technology of other companies, who have not waived their IP rights. Investment in manufacturing is also an important piece of the solution. Whether existing companies can retool facilities and jump start manufacturing or new facilities need to be created through investment will be outcome determinative.

There is little doubt that the waiver proposals would at the very least up-end the existing incentives, including the prospect of future pharmaceutical innovation and development of products, that resulted in the rapid development and approval of Covid-19 vaccines. Moreover, the TRIPS waiver proposals may not have the desired effect of boosting Covid vaccine production and availability of mRNA vaccines. On the other hand, recent attempts at voluntary licensing and technology transfer agreements related to adenovirus vector technology have resulted in increased vaccine production and availability. A TRIPS waiver may not be as effective for more complex vaccine production.

Scaling up Covid-19 vaccine production is not a one-size-fits-all proposition. Ensuring equitable availability and delivery complicates the matter further. Coordination and collaboration will be required within a complex network of investing in technology transfer, contracting existing and new manufacturing facilities, sourcing materials, and pooling procurement facilities. The negotiators and drafters of any TRIPS waiver have a difficult task to craft it into the cornerstone of an effective solution to the known problems of unmet need, and supply and availability, while also anticipating issues yet to arise concerning sustainability of supply, intellectual property rights for Covid-19 tests and treatments, and sharing of research. The next several months will determine whether a TRIPS waiver can be successfully negotiated, practically implemented, and make a timely and effective difference in Covid-19 vaccine availability.

Footnotes

1. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19, TRIPS communication IP/C/W/669 (2 October 2020).
2. See statement from Ambassador Katherine Tai on the Covid-19 TRIPS waiver (5 May 2021), available at https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver
3. See *Bloomberg,* EU's trade response to pandemic stops short of vaccine IP waiver, available at https://www.bloomberg.com/news/articles/2021-06-03/eu-s-trade-response-to-pandemic-stops-short-of-vaccine-ip-waiver
4. *Health Policy Watch*, G20 leaders promise to share more vaccines while EU digs in against TRIPS waiver (21 May 2021), available at https://healthpolicy-watch.news/g20-leaders-promise-to-share-more-vaccines-while-eu-digs-in-against-trips-waiver
5. Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of Covid-19, TRIPS communication IP/C/W/669/Rev. 1 (21 May 2021).
6. See, eg, HR 3236 and 3035, 117th Cong.
7. See https://www.prnewswire.com/news-releases/moderna-and-samsung-biologics-announce-agreement-for-fill-finish-manufacturing-of-modernas-covid-19-vaccine-301297280.html

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