IP Waiver For Covid 19 - An Unfitting Solution

Thought Leadership • July 4, 2022

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The article was first published by Legal Era

Unlike with patent rights, there is no clear, easy fix contained within the proposed waiver to overcome these hurdles, and pharmaceutical companies will likely strenuously resist such technology transfer if their patent rights are waived

Discussion around waiver on intellectual property rights (IP rights), particularly, patent rights, has gained immense relevance in light of the COVID-19 pandemic and the shortage of vaccines across nations. In this regard, India and South Africa had submitted the proposal for a temporary waiver on IP rights to the World Trade Organization (WTO) in October 2020 with further revisions in May 2021.

WTO Proposal for TRIPS waiver for COVID-19: Communication from India and South Africa

The proposal for waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19 inter alia states as follows:

"The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19... This waiver shall be in force for at least 3 years from the date of this decision..."

Further rounds of discussion, more recently in March 2022, have led to a tentative agreement among the four World Trade Organization (WTO) member countries, namely United States, European Union, India and South Africa on key elem which inter alia limit the scope to only patents for COVID-19. If adopted, the waiver would authorize use of "patented subject matter required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic." Further, it is also proposed that "IP rights would also be waived for ingredients and processes necessary for COVID-19 vaccine manufacture, a move aimed at granting critical know-how to many countries lacking expertise, especially for advanced mRNA-type vaccines."

Notably, the waiver is aimed to be availed by only those member countries which have exported less than 10% global exports of COVID-19 doses in 2021 and does not cover within its ambit COVID-19 treatments or tests.

The consensus is only tentative and as any agreement, for it to be adopted, it requires acceptance of 164 member countries of the WTO, which may still be a long shot.

Global discussion around waiver on IP rights for COVID-19 vaccines

Meanwhile, this discussion on IP rights' waiver has sparked rounds of debates across the globe and attracted the attention of countries and stakeholders revealing two completely opposite interpretations of the role IPRs play in this pandemic. On the one hand, WTO members supporting the proposal stress that IPRs stand in the way of scaling up vaccine production and that the flexibilities offered under TRIPs, such as import–export, compulsory licenses, are too cumbersome to be relied upon as means of enabling access. Opposing WTO members, on the other hand, claim that IPRs are a small and insignificant element impacting vaccine production and allocation and the unprecedented speed in the development of COVID-19 vaccines show that the waiver would constrain their current production ability and discourage future advances.

As per the pharmaceutical industry, adequate supply of vaccines globally can be sufficiently ensured through ongoing voluntary licensing agreements and technology transfer of COVID-19 treatments. Moreover, the ability of third-party manufacturers to produce the vaccines also remains doubtful as also ensuring their quality and efficacy. Further, if the waiver will be applicable only to patents, a patent holder would not necessarily be under any obligation to transfer technology or know-ho which is especially critical for the mRNA vaccines.

Why waiver of IP rights for COVID-19 may not fix the global shortage of COVID-19 vaccines

Vaccines involve complex biological products, raw materials with lengthy manufacturing and control processes which are far more complicated than small molecule pharmaceutical preparations. There are a number of challenges involved with vaccine manufacturing, from sourcing active pharmaceutical ingredients and machinery, to testing, packaging and storage. Substantial investment and know-how, deep expertise in the subject matter and years of experience are required at different stages of vaccine manufacturing process.

However, unlike with patent rights, there is no clear, easy fix contained within the proposed waiver to overcome these hurdles, and pharmaceutical companies will likely strenuously resist such technology

transfer if their patent rights are waived. Without knowledge transfer, it will be extremely difficult for low and middle- income countries to start COVID-19 vaccine manufacturing, regardless of the removal of patent barriers from the TRIPS waiver.

The leading vaccines using mRNA are difficult to reproduce and having the "blueprints" does not guarantee safe and effective production. The key ingredients and process of vaccine manufacturing involve know-how and trade secrets. Thus, forcing transfer of such information under a waiver is difficult to imagine.

There are various challenges to the supply and timing of delivery which depend on factors such as local regulatory approval, country readiness, logistics, capacity for in-country distribution. As per Moderna CEO, Stéphane Bancel, "It's not a matter of patents, but infrastructure capabilities' that are the greatest impediment to increasing access to affordable vaccines."

Conclusion

Efforts should be made to enable prompt and effective use of existing flexibilities in the TRIPS Agreement. Concerted and coordinated efforts involving governments and the private sector should take center stage to ensure that generic manufacturers which have the capacity and ability to manufacture vaccines, ramp up their production so as to ensure ample supply and to bring more facilities to scale.

Patents are not the bottleneck. There is no evidence that the IPRs are impeding the manufacturing and distribution of vaccines and treatments for COVID-19.

Instead, IP rights incentivize rights' holders to innovate and contribute to the R&D accessible to the public at large. Without protection of IP, there would be less new knowledge and thus less innovation. Thus, WTO members must deliberate and rationalize ways to combine efforts to reach solutions via multilateral action in international institutions and international endeavors outside the WTO. The WTO members while deciding their vote will have to bear in mind to not eliminate the incentives that are essential to inspire the innovations that make new medicines possible.

Instead, there is need for concerted and coordinated efforts on a global level involving governments to re-enforce supply chains, upgrade infrastructure and ensure distribution to provide the level of access needed to combat the global pandemic. Encouraging voluntary licenses and technology transfer of COVID-19 treatments will also increase the production capacity.

After all, killing the goose that lays the golden egg is never a wise idea.

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