Professional Perspective

Attenuated IP & Patent Rights During the Global Pandemic

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As the global death toll from the coronavirus reached nearly three million, countries around the world raced to vaccinate their populations. The severity of the coronavirus crisis has led some to argue that products for the prevention and treatment of Covid-19 should be global public goods: unrestricted by intellectual property rights and free for all to use.

Citing the need for a more equitable distribution of vaccine doses, several countries have called on the World Trade Organization (WTO) to suspend or otherwise attenuate IP rights for the duration of the pandemic.

But will tolling vaccine manufacturers' IP rights adequately address issues of access? Are there other solutions that might alleviate the same concerns but balance the interests of IP holders? This article endeavors to answer these questions.

Global Calls for Action

Originally proposed by India and South Africa in October 2020, 58 sponsoring governments have now officially backed a proposal to suspend IP rights for Covid-related innovations. Their request, submitted to the WTO's Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, asks for a waiver of certain IP rights on Covid-19 medical tools and technologies until most of the world has been vaccinated against Covid-19.

The philosophy advanced by this proposal's proponents is plain: "It is important for WTO Members to work together to ensure that intellectual property rights … do not create barriers to the timely access to affordable medical products including vaccines."

However, tolling IP rights is not the only option. Given the seriousness of the current health crisis and mounting economic pressures, some governments have adopted compulsory licensing schemes under Article 31(b) of TRIPS. Section 31(b) provides that a patent may be used without the authorization of the patent holder in cases of national emergency or other extreme urgencies.

Through this mechanism, a WTO member could produce and distribute vaccines without having to undergo difficult negotiations with companies for a "reasonable" period of time. Because TRIPS does not establish uniform international law, countries are permitted to draft regulations that balance IP protection with other public policy objectives–like the need to slow the spread of a global pandemic. Vienna Convention on the Law of Treaties, May 23, 1969, art. 31.1, 1155 U.N.T.S. 331,341.

Some countries have already made this move. In March 2020, the parliament of Chile unanimously adopted a resolution declaring that the global coronavirus outbreak justifies the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis, and treatment of Chilean people infected by the coronavirus. That same month, Israel issued, and was granted, a compulsory license permit allowing the state to import a generic version of AbbVie's Kaletra for the treatment of coronavirus patients.

More sweeping measures have been taken in France, where the government passed a law, No. 2020-290, that introduced a new article to the country's public health code. Under this new law, France's prime minister has authority to order the seizure of all goods and services necessary to fight against sanitary disaster, to temporarily control the prices of products, and to take any measures necessary to make relevant medicines available to patients.

There's some precedent for this policy in the U.S. as well. Most compulsory licenses have been issued under antitrust laws to remedy anticompetitive practices. Though many would agree that the current pandemic clearly constitutes a national emergency, no concrete definition of "emergency" exists in international law. That said, governments around the world have granted 24 compulsory licenses between 2001 and 2012. Those include compulsory licenses during the Anthrax scare in the US and Canada in the early 2000s, the pandemic flu ("swine flu") in Taiwan, and the HIV epidemic in 2004.

Responses from Opponents

Unsurprisingly, pharmaceutical industry trade associations have opposed these ideas. In December 2020, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) noted that "diluting national and international IP frameworks during this pandemic is counterproductive … IP enables research and development and ensures that the next generation of inventors and investors will remain engaged." IFPMA director-general Thomas Cueni said, "At a time when the focus should be on science and innovation, undoing the very system that supports it is dangerous and counterintuitive."

The U.S. Chamber of Commerce agreed. Its Global Innovation Policy Center senior vice-president Patrick Kilbride wrote:

> Proposals to waive intellectual property rights are misguided and a distraction from the real work of reinforcing supply chains and assisting countries to procure, distribute and administer vaccines to billions of the world's citizens. Diminishing intellectual property rights would make it more difficult to quickly develop and distribute vaccines or treatments in the future pandemics the world will face.

Behind the strong rhetoric of those statements lies a strong incentive for staying the course: pharmaceutical companies invest substantial sums to develop these vaccines. Often this capital comes from outside investors, eager for a return on their investments. Any policies that threaten those returns might also make it more difficult to secure similar funding in the future.

In addition to private-sector critics, the U.S., the UK, and the European Union have also opposed proposals for an IP waiver and compulsory licenses. They reason that patents and other IP rights are not the real barrier for worldwide vaccination. Rather, because these new vaccines are complicated to manufacture, some believe that an IP waiver or compulsory license approach would not necessarily mean that manufacturers across the world could start producing the vaccines overnight.

Is There a Middle Ground?

Others advocate for a "third way," in which foreign governments support private sector partnerships. This approach was coined by the incoming WTO director-general Ngozi Okonjo-Iweala at a March 2021 meeting to discuss the IP waiver proposal. Okonjo-Iweala discussed this third way to broaden access through encouraging licensing agreements between companies, particularly generics manufacturers. One example of this policy in action is the U.S. government's move to bring Merck and Johnson & Johnson to the negotiating table regarding vaccine manufacturing.

The private sector also has its own ideas. Perhaps out of recognition of the severity of the pandemic, or perhaps in part out of a desire to avoid a policy thrust upon them by international organizations or local lawmakers, some companies have decided to take matters into their own hands. For example, in October 2020, Moderna announced that it would not enforce its patent rights related to its coronavirus vaccine during the pandemic.

Moderna also announced that it will allow open access to its patents related to messenger-RNA technology for the "pandemic period," and is willing to out-license the same IP to third-party manufacturers once the pandemic is over.

Other players, like AstraZeneca, licensed their patents at no profit with third-party manufacturers like the Coalition for Epidemic Preparedness Innovations, Gavi the Vaccine Alliance, and the Serum Institute of India so that vaccines can be manufactured at multiple sites. In addition, Novartis and Sanofi have made agreements to transfer technology, such as the finishing of vaccine vials.

Conclusion

Ending the pandemic as quickly as possible will take a global effort. So too will the widespread enacting of policies that alter the rights of IP holders while the pandemic persists. The desire to balance the rights of these stakeholders with the fair, equitable distribution of much-needed vaccines worldwide poses a unique challenge. To meet this challenge, the world may need a solution as inventive as the vaccines themselves.