Tackling the Pandemic Without Compulsory Licensing or IP Waivers: Alternatives for the Developing World

Compulsory licensing and IP waivers represent controversial topics in intellectual property. These mechanisms essentially suspend patent rights and permit countries to use a company's intellectual property without the patentholders permission.

Talk about compulsory licenses and IP waivers has increased over the course of the COVID pandemic. Last week the Biden Administration even announced an IP waiver to help increase access to the Covid-19 vaccines. While it remains unclear how countries will proceed with respect to compulsory licensing or the IP waivers, it is time to start thinking about alternative mechanisms to increasing accessibility to the vaccines.

This article will first briefly explain the practical and technical hurdles to compulsory licensing and IP waivers and then provide three possible alternative mechanisms to increasing vaccine availability and accessibility.

Hurdles to Compulsory Licensing and IP Waivers

Before we can even consider waiving IP rights and allowing others to manufacture a product – in this case a vaccine – we have to consider the likelihood of success in such a scenario. While there have been success stories with compulsory licensing, namely Brazil issuing compulsory licenses for the HIV drug, efavirenz, those stories involve small molecule products that can be chemically synthesized. The Covid-19 vaccines that are manufactured by Pfizer and Moderna are very different from efavirenz and present a whole host of new issues. As a result, the efficacy of these proposals depends

on a country's internal technical capabilities to recreate the vaccine. Below are some issues presented by the Covid-19 vaccines that render compulsory licensing and IP waivers practically futile.

Covid-19 vaccines are new forms of vaccines

Pfizer and Moderna's vaccines are not typical vaccines. Whereas traditional vaccines function by introducing parts of a virus – or a weakened form of a virus – Pfizer and Moderna's vaccines use messenger RNA to cause host cells to produce the protein themselves. These are the first vaccines to utilize this type of technology and, given their novelty, information about how to make these vaccines is limited. While the technology underlying mRNA vaccines has been in development for decades, there are likely specific technological hurdles associated with, for instance, the coronavirus, mass production and scale up, and delivery mechanisms, that needed to be developed for this specific application. This additional information is not found in scientific journals or magazine articles, and it cannot be found in any patent application, yet.

The lack of available information is even more compounded by the fact that much of the vaccine manufacturing process relies heavily on trade secrets. These trade secrets hold critical scientific know-how that could be necessary for accurately replicating these vaccines. Without information and know-how of how to make these mRNA vaccines, countries will encounter difficulties in recreating them.

Covid-19 vaccines are complex to manufacture

The complexity of these vaccines further exacerbates the difficulties in recreating them. The NY Times recently published Pfizer's 19-step process for manufacturing its vaccine. This 19-step process starts with pulling DNA from cold storage and ends with administering the vaccine. In

between are all the steps required to grow cells, harvest DNA, transcribe the DNA into mRNA, and assemble the mRNA vaccine. At each point there are strict quality control measures designed to ensure that the end product will be what it is intended to be. Deviation at any point in this 19-step process can jeopardize the safety of the vaccine and put lives at risk.

In addition to the multi-step process of manufacturing these vaccines, obtaining the raw materials and having the proper manufacturing facilities to store them presents problems. There is currently a global shortage of raw materials to the point where even Pfizer is having difficulty obtaining the necessary materials for vaccine production. Moreover, the vaccines require storage at low temperatures and improper storage can result in lost vaccines. The spoiled vaccines in Emergent BioSolutions' plant in Baltimore illustrate the difficulties of properly establishing manufacturing facilities. So even if countries possessed the necessary information about the vaccines, the complexity of manufacturing these vaccines on a large scale could be a particularly high barrier to overcome.

Alternatives to Increasing Access

Given the novelty and complexity of the Covid-19 vaccines, issues of safety, efficacy, and timing necessarily arise. Safety and efficacy because the lack of information surrounding these vaccines compounded by the complex manufacturing process increase the likelihood that any copycat vaccines will not be as safe or effective, and timing because figuring out, understanding, and scaling up the manufacturing process to the point where it can produce the desired amount of vaccine product will take time.

Instead of issuing compulsory licenses or IP waivers then, we should explore alternatives that will not only provide access to the vaccines, but do so in a safe, effective, and quick

manner.

Collective Bargaining

Collective bargaining is one such alterative and this is not a new concept. Given the high cost of drugs, developing countries have often partnered with other developing countries or non-profit organizations to collectively bargain for lower drug prices. Dr. Anthony Fauci even helped negotiate a collective agreement in 2008 to help administer treatment for AIDS. Groups like the WHO, Gavi, and the Coalition for Epidemic Preparedness (CEPI) are ones that can lead this approach. This is certainly a different approach than obtaining a right to use the underlying intellectual property for a treatment, and it requires countries or non-profits to have some financial strength to achieve an agreement as these entities will still have to pay for the treatment. Since there is strength with numbers, the cost per dose may be less if more groups are able to band together to facilitate a deal.

Provide Incentives

Another solution to this problem could be gleaned from the old adage of the “carrot and the stick.” While the compulsory licensing and IP waivers approach is akin to the “stick”, what is missing is the carrot approach. Under-developed countries could offer vaccine manufacturers other enticements that provide value other than monetary payment to secure deals for the vaccines. Such enticements could include public-private sector cooperation, the offer of real property such as facilities and equipment, name recognition, establishment of in-country programs for the development of trained labor, lowered tax rates for operation within their country, eliminated import-export tariffs/fees, and exclusive country-wide distribution as well as data collection on the offered vaccine or other products.

Corporate and Government Donations

Finally, it is important to recognize that Covid-19's unique global impact is not lost on those involved, including vaccine manufactures and governments. Moderna has already recognized this and they have provided resources for not only using their intellectual property, but also have demonstrated a willingness to help countries that lack the ability to meet the needs of the country's citizens. Moderna's recognition of the problem that is facing the world provides a glimmer of hope for struggling countries. While it is unclear if their willingness to provide transparent access to provisional patents will ultimately lead to reduced prices, it does provide some hope that the developing world will not face an uphill battle when—and if—these countries seek to negotiate the cost of these vaccines.

Similarly, western governments have indicated that they would supply their access vaccine reserves to countries in need. The Biden Administration has, in fact, promised to make "excess" vaccines available, amounting to approximately 60 million doses. Together with industry, western governments can help ensure that struggling countries receive the necessary doses needed to combat this pandemic.

Conclusion

Countries face roadblocks for producing a viable vaccine candidate based on Pfizer and Moderna's vaccines due to the hurdles in manufacturing the vaccines. Compulsory licensing and IP waivers do little to mitigate those issues. Alternatives that will allow the vaccine manufactures to continue producing their vaccines should be the primary focus.

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