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What COVID Vaccines May Reveal About SEPs Amid Crisis

By **Ryan Babcock and Jessica Lehrman** (May 11, 2023, 1:51 PM EDT)


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Intellectual property rights offer innovators the exclusive right to exploit their innovations while recovering their expenditures, by providing IP owners with the ability to stop others from commercializing infringing products.

When time is of the essence, such as during a public health crisis, these competing interests rise to the forefront.

As we saw during the COVID-19 pandemic, the patent community grappled with the question: How do we effectively balance respecting an IP owner's rights with expediting the research and commercialization of life-saving vaccines?

More than three years into the COVID-19 pandemic, we have a clearer picture of how the patent community responded to the rush to develop COVID-19 vaccines: patent pledges.

Patent pledges, public commitments that a patent holder makes to refrain from exercising some or all of its patent rights, are voluntary, including suing for patent infringement.

Prior examples of patent pledges can be found in:

- The automotive industry — e.g., electric vehicle makers Tesla Inc. and Toyota Motor Corp.;
- The software industry — e.g., IBM Corp. and Google LLC relating to open-source code; and
- The biotechnology industry — e.g., Monsanto Co. relating to genetically modified seeds and Myriad Genetics Inc.'s pledge not to assert its DNA patents against academic researchers.

In the midst of the COVID-19 pandemic, many patent holders pledged not to enforce patents needed for vaccine development, the frontline immunotherapy for combating COVID-19.

By April 2020, the Open COVID Pledge platform had been formed, allowing for the large-scale pledging not to enforce COVID-19 vaccine-related patents until Jan. 1, 2023, or one year after the end of the pandemic, as declared by the World Health Organization.[1]

However, these pledges are not permanent. For instance — on March 7, 2022, Moderna Inc. updated its previous pledge not to enforce COVID-19 related patents during the pandemic to instead state:

In non-AMC 92 countries, vaccine supply is no longer a barrier to access. In these countries, the Company expects those using Moderna-patented technologies will respect the Company's intellectual property. Moderna remains willing to license its technology for COVID-19 vaccines to manufacturers in these countries on commercially reasonable terms.[2]

Moderna put this revised pledge in action when it filed a patent infringement lawsuit against mRNA vaccine competitors Pfizer Inc. and BioNTech SE, asserting patents it considers foundational to mRNA vaccine development and which predate the COVID-19 pandemic.

In its complaint, Moderna again emphasized that it "would consider a commercially-reasonable license should [Pfizer and BioNTech] request one."[3] This dispute will likely be resolved through battling out the merits of the infringement claim in district court or by the parties agreeing to a commercially reasonable license.

However, perhaps there is an alternative to these patent pledges to facilitate the sharing of foundational patented technology that is needed to develop vaccines in response to a pressing public health emergency. In the face of other public health challenges even well before the COVID-19 pandemic, several alternative approaches were also proposed by others, including the pooling of standard- essential patents, or SEPs.[4]

This article will examine what an SEP regime may look like in the public health emergency vaccine space and the potential effects of using an SEP model on all parties involved, in view of the existing patent pledge regime that helped facilitate the development of a COVID-19 vaccine in record time.[5]

SEPs are patents claiming technology so essential to an industry's operation that the technology is considered to be industry standard.

For example, when technologies such as LTE and Wi-Fi became standardized, patents covering these technologies became SEPs. Industry-specific standard setting organizations, or SSOs, which are comprised of companies in the industry as well as other industry players, jointly determine which patents are to be categorized as SEPs.

Once the SEPs have been identified, the SSO sets a licensing arrangement so that the SEP holders make their patented technology accessible to other users under fair, reasonable and non-discriminatory, or FRAND, terms.

FRAND terms ensure that users of SEPs are able to license the patents covering the standardized technology on fair grounds from the SEP holders.

Thus, an SEP system creates a predictable licensing model for entities granting them access to patents necessary to utilize an industry's standard technology. SEPs and SSOs thus enable others to develop products that are compatible with the industry-standard technology, such as cell phones that work on LTE networks.

What would an SEP regime look like for vaccine development during a public health emergency? The

first question to consider is: In a fast moving public health emergency, could a standard technology for vaccine development emerge?

Looking to the COVID-19 pandemic, two vaccines developed by Pfizer/BioNTech and Moderna utilizing mRNA technology proved to be exceptionally effective and mRNA vaccines came to be viewed as the gold standards among COVID-19 vaccines.

Thus, this mRNA vaccine technology could be considered the standard for vaccine development against COVID-19. It is likely in future public health emergencies that another technology could emerge as the standard for vaccine development much as mRNA vaccine technology has in the COVID-19 pandemic.

With a standard technology identified, the next question to address is the composition of an SSO. An SSO often includes different types of industry participants such as distributors, producers, suppliers and inventors.

In the vaccine development space, key players such as vaccine developers, clinicians and the FDA could comprise the makeup of a SSO. Once an SSO is created, it would identify patents covering the standard.

Once the standard is agreed upon and SEPs are identified, the SSO will set a licensing arrangement in which SEP holders commit to making their patented technology accessible to other entities under FRAND terms. FRAND terms help to ensure that SEP implementers are able to license and use standardized technology on fair grounds.

Like the existing patent pledge system, adopting an SEP regime may promote efficiency in the development of vaccines, but perhaps in a different way. Such a regime would pool complementary IP into a single, centralized source, creating a one-stop-shop for licensing packages of essential platform technologies.

This would streamline the development and commercialization of inventions where there are multiple patent rights on the underlying technology, as is frequently the case in the life sciences, and reduce the need to individually negotiate and license different aspects of inventions.

The use of FRAND terms would create predictable licensing arrangements, saving money and time, reducing transaction costs, and offering stability and certainty at a time when both are lacking and needed.

By reducing the logistical and transaction costs, an SEP regime may expedite research and development, which in the vaccine context frequently takes years.

An SEP model may also offer the benefit of standardizing certain platform technologies and promoting further focused development that builds upon the standard. By its very nature, an SEP regime would standardize technology deemed essential.

In the life sciences, the establishment and adoption of such a technical standard may lead to superior and more consistent treatments, reducing the risks of side effects associated with technologies that do not conform to the standard. For example, in May 2022, the U.S. Food and Drug Administration limited the use of Janssen Pharmaceuticals' COVID-19 vaccine, which utilizes an adenovirus platform, to certain patient subpopulations due to the risk of side effects.[6]

If a given technology emerges as a clear front-runner — as Moderna's and Pfizer's mRNA vaccine did — an SEP model would incentivize future research and development focusing and building upon the standardized technology, rather than technologies that do not conform to the standard. This focused and directed research would promote the development and integration of complementary innovations and expedite the development of vaccines for other disease targets in the future.

However, even though an SEP model may offer critical benefits, its potential implementation needs to be weighed against the existing voluntary patent pledge system, which offers many benefits as well, some of which would be absent in an SEP model.

One benefit of the voluntary patent pledge system is that it incentivizes further innovation while still maintaining the flexibility to develop different and improved technologies. This flexibility is found in two primary ways.

First, the patent pledge system creates a framework that encourages the research and development of diverse technologies. By removing the threat of IP litigation or lowering the licensing costs associated with a technology, patent pledges can encourage a multitude of players to become involved in vaccine research and development.

Unlike an SEP model, the patent pledge system does not cause a given technology (the essential technical standard) to become established and engrained.[7] This model thus permits and incentivizes the development of new and different technologies — including ones that may even outshine the current state of the art.

Second, patent pledges can be tailored in the degree that they limit IP owner's rights, such as in their duration and scope. As we have already seen, Moderna terminated their pledge in March 2022.

Additionally, IP owners can decide, on an individual basis, the scope of their IP that they wish to include or exclude from the pledge, or limit their pledge to specific fields of use (e.g., addressing COVID-19), so as to not relinquish their IP rights in the technology entirely.

Voluntary patent pledges are also beneficial because they promote efficiency, which cannot be understated during a public health emergency. Using the patent pledge model,COVID-19 vaccines were developed in record time[8] — a mere 11 months — a feat that many thought was impossible.

Previously, the mumps vaccine held the record, with its development taking four years. With individual IP owners voluntarily pledging their IP rights, researchers and various market players can collaborate and streamline vaccine research and development, without first having to wait for a particular technology to be deemed the "standard" for addressing the public health emergency. Market players can also avoid delays associated with patent enforcement, as well as the administrative, financial, and political delays that have handicapped prior efforts to pool patents in the face of public health emergencies.

Finally, patent pledges offer strategic business advantages as well, including setting a collaborative tone for other market players, promoting corporate social responsibility, and positioning oneself as a de facto standard that is widely adopted early in the development process. Some have speculated that Moderna's patent pledge early in the development process may cultivate a new mRNA market founded on their technology and position them to capitalize on licensing deals.[9]

Both the patent pledge and SEP regimes offer distinct advantages to all parties involved. As we are sure to face unknown pandemics in the future, it may be worthwhile to explore these ideas now so as to prepare the most efficient and effective way to develop vaccines that will combat the public health emergency while also properly incentivizing and protecting the efforts of innovators who develop the technology.

With the right preparation and regime to manage IP rights, we may be poised to set new records in the development of future vaccines.

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[1] https://opencovidpledge.org/.

[2] https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2022/Modernas-Updated-Patent-Pledge/default.aspx.

[3] https://htv-prod-media.s3.amazonaws.com/files/01-main-1661517480.pdf.

[4] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3358839.

[5] https://www.uclahealth.org/news/the-fastest-vaccine-in-history.

[6] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-janssen-covid-19-vaccine-certain-individuals.

[7] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2370113.

[8] https://www.uclahealth.org/news/the-fastest-vaccine-in-history.

[9] https://ipwatchdog.com/2020/11/11/breaking-modernas-covid-19-patent-pledge/id=127224/.