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In 'Global Arms Race' for COVID Vaccine, Patents are Key Incentive

Patent may not be an option for vaccine, U.S. government could overtake patent

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Despite the partial reopening of cities across the country, the novel coronavirus is still spreading. As of April 29, the national death toll surpassed 60,000. And as virus-related deaths continue to rise, governments around the world are calling for a cure. The search to find a vaccine to fight the virus has created a “new global arms race,” according to the National Law Review — and this race isn’t just for the cure but for the patents.

Obtaining a patent for a COVID-19 vaccine poses some challenges before even reaching the patent office, according to Justin Krieger, Denver office managing partner of Kilpatrick Townsend. Patent law in the U.S. will determine whether such a vaccine could be patented, and, if so, whether the government would take ownership of the patent.

To begin with, 35 USC 101 informs what can and can’t be patented, and biotech inventions have some special hurdles to clear in patentability. Some vaccines involve removing something like a protein from a virus, such as COVID-19, and using that as a vaccine itself. “You’re not going to be able to patent any of those naturally occurring bits and pieces, but if you’re modifying or delivering it in a novel way ... you might be able to patent that,” Krieger said. “You basically can’t patent a law of nature or natural phenomenon. You have to do something more.”

But for a vaccine, there isn’t just one invention and one potential patent. “I don’t envision this to be one person invents something and patents it and that one person has the patent to the vaccine,” Krieger said. “These vaccines are highly complicated and often involve multiple people working

together.” Often, the groups working together on such vaccines have someone working on DNA sequencing, another on delivery mechanism — so it’s very complicated and multiple patents can come out, Krieger said.

In addition to the question of whether a vaccine would be patent-eligible, there is also the possibility that the government could invoke a compulsory license and overtake the patent from the owner in the public health interest such as for fighting COVID-19.

Patent rights are protections created by the government, which are enforced by the government. Under a normal patent, a patent holder is awarded a right to exclude others from making, selling or using their invention. However, under 28 USC 1498, the government is allowed to “do whatever it wants to do with someone else’s patent right” as long as the government gives fair compensation for that use, Krieger added.

“What’s interesting here is that what the U.S. government giveth, the U.S. government can take away,” Krieger said. When a situation such as a national crisis or national security concern arises, that becomes especially true. In the coronavirus situation, a cure is of huge national importance, Krieger added, both for the economy, public health and minimizing loss of life.

Use of 1498 could very well come to play in the COVID-19 vaccine situation, Krieger said. “A company is going to use countless money, time and effort researching and developing a vaccine. Whoever is successful at developing that is entitled to compensation for that.”

Rather than taking the patent from the holder, the government forces the owner to license the product to manu-

facturers under terms that are deemed reasonable under the circumstances, Krieger said. He said the “last thing” the government wants to do is step in and interfere with a patent because it interferes with the entire patent system and motivation to develop a drug.

This compulsory license is activated when and where there is a public need, William Cochran of Cochran Freund and Young, said. When a compulsory license is invoked, the government is required to provide reasonable and entire compensation. Usually this amounts to less than 10% of the sales price of the product.

There have been several instances in which 1498 has been invoked, Cochran said. During the 1980s, a company patented night vision goggles, and the U.S. military invoked 1498 to use the technology in Operation Desert Storm, Cochran said. More recently, Bayer created the antibiotic drug Cipro and lowered the price after the government threatened a 1498 action.

Krieger said there were often stories in the news about pharmaceutical companies charging exorbitantly high prices — which they are entitled to do if there is a patent. “But, here, I think the government may very well use this section as leverage for the companies who develop this and get the patent rights for the vaccine on this.” Likely, this would be used to negotiate favorable prices for those who want to exploit the drug and use it in a way that can save many lives, he added.

However, Krieger said he cannot imagine any company charging huge prices on a COVID-19 vaccine. “Apart from the ethical implications of it, from a PR perspective would be quite a disaster if they tried to do something like that.”

And whether a private company or public institution creates the

vaccine, the procedures and rules would be the exact same. Universities are working very hard on these types of projects, James Young, also of Cochran Freund and Young, said. They’re anxious to license the inventions to pay them reasonable royalties. This in turn creates a revenue stream that allows further research.

If a vaccine was patented in another country, such as China, a Patent Cooperation Treaty application would typically come up about a year later, allowing international applicants to file a patent in other nations, Krieger said. Something as important as a COVID-19 vaccine could find its way to the U.S. patent system through that flow. “So, you’re looking at two-and-a-half years from the original filing to the U.S. filing, as a matter of course. For cases like these, two-and-a-half years with coronavirus is a tremendous amount of time,” Krieger said. Another option for patents were for filings to be made in different countries within several days of the first filings. That would probably lead to multiple filings within several days of the first filings, he said.

Krieger predicted that for something as important as a COVID-19 vaccine, the filing would happen quickly and the prosecution would be expedited to try to get it completed within a year or so.

For the future, the government could hold on to the patent in perpetuity. “In a situation that is as devastating as the coronavirus, I can’t envision a circumstance more ripe for the picking where they would have an extended ability to use the patented technology” with reasonable compensation, he added. •

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