

The Race for a COVID-19 Vaccine is On: Key Factors May Impact Patent Protection

Article By:

Chinh H. Pham

The search for a vaccine for the COVID-19 strain of coronavirus has put the spotlight once again on the innovative pharmaceuticals sector. As pharmaceutical companies and innovators across the globe work diligently on a vaccine, many of these companies may be looking to protect their innovation. While patents have many benefits, in the face of a global health emergency, there are some key factors innovators should consider.

Timeline for Patent Registration

Patents can provide broad protection for invention and innovation. They can also create a significant advantage in the marketplace. However, patent registration takes time and may require significant resources. According to the United States Patent and Trademark Office (USPTO), on average, it takes approximately 22 months to get patent approval. This period may be shortened by taking advantage of one of the USPTO's accelerated examination procedures and may be shortened by utilizing the USPTO prioritized examination option, where a final decision on patentability is made within 12 months from the filing date of the patent application.

For a potential COVID-19 vaccine being developed now, the [USPTO recently announced a new pilot program](#), where the USPTO will waive typical fees associated with prioritized examination to applicants who qualify for small or micro entity status. In addition, the USPTO will endeavor to reach a final decision on the applications in this pilot program within six months.

A shorter period to a patent decision may cut down on the costs to a company and allow the company to enjoy the benefits of exclusivity that come with a patent. However, such exclusivity may be short-lived, especially in the presence of an ongoing pandemic.

Compulsory Licenses

In time of crisis, the U.S. government may force patent owners to grant compulsory licenses when there is a threat to public safety. A compulsory license refers to the government's authority to grant permission to a party seeking use of a patent owner's invention without the consent of the patent owner and is provided broadly by 28 U.S.C. § 1498 ("Section 1498").

Under Section 1498, the U.S. government has the “right to use patented inventions without permission, while paying the patent holder ‘reasonable and entire compensation.’” The statute also “allows federal agencies and third-party government contractors to manufacture and/or use any invention without authorization from the patent holder.” The U.S. government has invoked or threatened to invoke this right in the past when faced with a national health emergency.

For example, with anthrax in the early 2000s, a pharmaceutical company holding the patent for an anthrax antidote was faced with the possibility of Section 1498 being invoked by the US Secretary of Health and Human Services. The pharmaceutical company ultimately responded by supplying the anthrax antidote to the public at a 50% discount.

March-In Rights

March-in rights, a provision of the Bayh-Dole Act of 1980 and is codified in 35 U.S.C. § 203, may also be invoked if there is a threat to public safety. March-in rights allow the federal government the right to grant patent licenses to other parties or take licenses for themselves, if the patented invention was researched and developed with the help of federally funded dollars.

No U.S. federal agency has exercised its power to march-in and grant a license to the patent rights. Nevertheless, the possibility of march-in rights being invoked needs to be considered should a company contemplates receiving government funding for research and development of a drug or vaccine that may someday provide a significant benefit to the public.

Caveat

Innovators have always been creative in employing a variety of approaches to protect their intellectual property. But when faced with a global health crisis and the immediate need for public access to patented inventions, innovators should be mindful when exploring patent protection, as their exclusive rights in the patented invention may be superseded by the greater need of the public.

Take steps to assure you understand the measures available to the U.S. government before investing significant resources or taking on government funding in developing your next drug or vaccine.

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