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What If Gov't Allows Patent Infringement For COVID-19 Drugs?

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The outbreak of the novel coronavirus and the disease caused by it, COVID-19, has turned the world upside down. Hundreds of thousands of cases have been confirmed in dozens of countries, and the death toll continues to rise.

In this period of uncertainty, governments and private entities across the globe are searching for safe and effective ways to not just treat those infected with the virus, but also to vaccinate the population against it. Many companies are working to develop treatments and vaccines, some with the support of U.S. government funding. And while a few drugs have been identified as potential treatments and many clinical trials have begun, no drug has yet been approved by the U.S. Food and Drug Administration for the treatment of COVID-19.[1]

When treatments or a vaccine are eventually identified, the demand will be vast. The closest recent comparison may be the 2009-2010 H1N1, or swine flu, outbreak: When the H1N1 vaccine was first identified in late 2009, the U.S. government quickly ordered hundreds of millions of doses to inoculate the population, helping to put an end to the pandemic.[2]

The U.S. government seems likely to take an even more aggressive approach to treating COVID-19 once treatments are identified, as it appears to be more deadly than H1N1.[3] But, as with many drugs, potential treatments and vaccines may be covered by patents — and while patent owners may be motivated by a sense of public duty to help alleviate the current crisis, they will likely also want to receive reasonable compensation to help recoup the often immense expenses of bringing such patented drugs to market.

So what might happen when the public's need for a COVID-19 vaccine and/or treatment collides with privately held patent rights? If demand for a treatment outstrips a patent owner's ability to supply the product, or if the patent owner seeks what are deemed to be excessive profits to take advantage of the fervent demand for a solution to this burgeoning health crisis, the U.S. government has the ability to step in and authorize others to manufacture the patented treatment or vaccine.

But the method by which the government could issue such authorization — as well as who would be liable for paying royalties to the patent owner — likely depends on how the patent was developed in the first place. Could the government exercise so-called march-in rights under the Bayh-Dole Act, or might it employ its eminent domain powers to take a license under an often overlooked statute, Title 28 of U.S. Code Section 1498?

Either way, the government should tread lightly, lest its actions have a chilling effect on biopharmaceutical innovation right when such innovation is so sorely needed.

Bayh-Dole March-in Rights

The Coronavirus Preparedness and Response Supplemental Appropriations Act signed in early March by President Donald Trump authorized $8.3 billion to prevent, prepare for and respond to COVID-19.[4] These funds support efforts to combat COVID-19, including more than $3 billion allocated to the development of necessary countermeasures and vaccines and the purchase of vaccines, therapeutics and diagnostics, as well as other medical supplies.

To the extent that any COVID-19 treatment or vaccine is developed and patented using these funds — or was developed in the past using federal funding — the federal government may march-in and grant a compulsory license under the Bayh-Dole Act.[5]

Congress enacted the Bayh-Dole Act in 1980 to address concerns about the commercialization of technology developed with public funds.[6] Prior to the act, the government would commonly take ownership of patents generated through government-funded research, but few of these government-owned patents were commercially licensed and brought to market.

Under the Bayh-Dole Act, the U.S. Department of Commerce created a standard patent rights clause that is included in federal funding agreements with nonprofits, such as universities, as well as small businesses.

When a nonprofit or small business creates an invention through government-funded research, it may elect to retain title to that invention subject to some limitations under the act and its implementing regulations. But in the era of increased scrutiny for a high-profile coronavirus treatment or vaccine, it is possible that the government agency funding the research — in the context of the Coronavirus Preparedness and Response Supplemental Appropriations Act, the U.S. Department of Health and Human Services — may seek to alter the standard language included in the agreement to allow it to instead possibly retain title to the patent.[7]

But even if the government-funded patent is owned by a private entity, under Bayh-Dole the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” to the patent for uses made “for or on behalf of the United States.”[8] This means that to the extent the U.S. government was to seek to source vaccines or medications (covered by a patent developed using government funds) from an entity other than the patent owner, the federal government may potentially be able to do so on a royalty-free basis, subject to showing that the use is truly for or on behalf of the government.

Furthermore, the government has the authority to march-in and grant compulsory licenses to third parties for federally funded inventions under certain specified circumstances, including when “action is necessary to alleviate health or safety needs which are not reasonably satisfied by the ... assignee.”[9] A license granted pursuant to Bayh-Dole’s march-in provisions must be “upon terms that are reasonable under the circumstances,” which may require the compulsory licensee to pay some compensation to the patent owner.[10]

Despite periodic requests to invoke Bayh-Dole march-in rights over the last few decades — especially in the pharmaceutical space — the federal government has never exercised them.[11] And under the present circumstances, given the strong public relations incentive for a patent owner to come to reasonable terms with other manufacturers if the patent owner is unable to supply the U.S. public, it seems unlikely that march-in rights would be necessary here. Yet, if the patents at

issue were derived from government-funded research, march-in rights remain a potential tool for the government to use, if necessary.

Eminent Domain for Patents Under Section 1498

Even if the development of the vaccine or treatment was not funded by the U.S. government, the government may nonetheless seek to use its eminent domain authority, grounded in the takings clause of the U.S. Constitution, to obtain a license from the patent owner and authorize a contractor to make the treatment on its behalf. While the government (and its contractor) cannot be enjoined, the government's infringement requires the payment of "entire and reasonable compensation" to the patent owner.

This course of action is authorized by Title 28 of U.S. Code Section 1498. Section 1498 applies to every U.S. patent, and it is triggered when the federal government either practices a patented invention or authorizes a contractor to do so on its behalf.

And unlike Bayh-Dole's march-in rights — which require that a federal agency first determine certain statutory requirements are met before they can be exercised — the use in question under Section 1498 need only be by or for the federal government with the government's consent or authorization. This even includes situations in which the government gives its authorization after the infringement has occurred.

Finally, instead of the licensing regime contemplated by Bayh-Dole, the patent holder is not automatically paid — it must bring a claim against the U.S. government in the Court of Federal Claims to seek compensation.

This means that if it is discovered that a COVID-19 treatment covered by a U.S. patent is effective, but the patent owner is unable (or unwilling) to fully meet the demand for it, the U.S. government might seek to use Section 1498 to source the drug from others. As noted previously, the patent owner would be highly incentivized to make the COVID-19 treatment widely available at reasonable prices, but may lack the capacity to produce treatments on the necessary scale.

In such a situation, it is possible that, using Section 1498, the government could authorize another biopharmaceutical entity with the requisite manufacturing capability to manufacture the treatment, with the government either agreeing to purchase the treatment and/or certifying that such production of the treatment is for the United States — effectively indemnifying the infringing manufacturer against later patent infringement claims.

There is some precedent for the government's using Section 1498 in the pharmaceutical space — for example, in the 1960s and 1970s, the U.S. Department of Defense used Section 1498 to purchase foreign generic antibiotics that were then under patent in the U.S.[12] And in the wake of the anthrax scare of 2001, the administration of President George W. Bush raised the potential of invoking Section 1498 in a price dispute over ciprofloxacin, an antibiotic used to treat anthrax.

But the government should proceed carefully, lest its actions have a chilling effect on biopharmaceutical research and drug development. While a patent owner may be entitled to lost profits and in some instances treble damages for willful infringement in traditional patent litigation, the courts have interpreted Section 1498 as requiring only reasonable royalties.

This could reduce the cost to the government of having an alternative version of a COVID-19 treatment manufactured and distributed, but the specter of government interference and lower returns on investment may give some companies pause about whether to engage in high-risk, expensive drug development activities in the future. Indeed, it would be ironic to deprive the very

creator of such a much-needed treatment of the reward associated with the risks it undertook to develop it.

Conclusion

Given the widespread impact of the COVID-19 pandemic on public health and the economy, the U.S. government may use whatever tools necessary to bypass any hurdles — IP-related or otherwise — that stand in the way of the public's access to a treatment or vaccine. Bayh-Dole march-in rights and Section 1498 provide the federal government broad powers when dealing with this national emergency.

But while the government may in good faith view these actions as necessary in the fight to combat COVID-19, using these tools could deter future pharmaceutical innovation. As such, the government should tread lightly.

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[1] Identified potential treatments include Remdesivir (made by Gilead), Kevzara (made by Regeneron), and Plaquenil (hydroxychloroquine). See Sydney Lupkin, Might The Experimental Drug Remdesivir Work Against COVID-19?, NPR (Mar. 21, 2020), https://www.npr.org/sections/health-shots/2020/03/21/819099156/might-the-experimental-drug-remdesivir-work-against-covid-19; Jack Hough, Regeneron's CEO Says We Could Have a COVID-19 Treatment 'Quickly', Barron's (Mar. 17, 2020), https://www.barrons.com/articles/regenerons-ceo-on-the-search-for-a-coronavirus-treatment-51584468863; Jia Liu, et al., Hydroxychloroquine, a less toxic derivative of chloroquine, is effective in inhibiting SARS-CoV-2 infection in vitro, Nature (Mar. 18, 2020), https://www.nature.com/articles/s41421-020-0156-0.

[2] John G. Bartlett, 2009 H1N1 Influenza—Just the Facts: Vaccine Essentials, Medscape (Nov. 23, 2009), https://www.medscape.com/viewarticle/709468_5.

[3] John McCormack, Coronavirus vs. the Flu: The Difference Between a 1% and 0.1% Fatality Rate Is Huge, National Review (Mar. 14, 2020), https://www.nationalreview.com/corner/coronavirus-vs-the-flu-the-difference-between-a-1-and-0-1-fatality-rate-is-huge/.

[4] H.R. 6074, 116th Cong. (2020).

[5] 35 U.S.C. § 203.

[6] John R. Thomas, Cong. Res. Serv., R44597, March-In Rights Under the Bayh-Dole Act at 1 (Aug. 22, 2016).

[7] See 35 U.S.C. § 202(a); 37 C.F.R. § 401.14 (outlining standard patent rights for licensing).

[8] 35 U.S.C. § 202(c)(4).

[9] 35 U.S.C. § 203(a). Of course, a treatment may be covered by multiple patents, and if only a subset of these were developed using government funds, that may create additional obstacles to the government requiring a compulsory license. See 35 U.S.C. §202(f).

[10] Id.

[11] See William O'Brien, March-In Rights Under the Bayh-Dole Act: The NIH's Paper Tiger?, 43 Seton Hall L. R. 1403 (2013).

[12] See Brennan, et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J.L. & Tech. 280 (2016).