Client Alert

April 2020

IP Rights vs. the Common Good: Can the Government Bring Them Together to Fight COVID-19?

As the novel coronavirus (COVID-19) pandemic spreads across the United States and the world, some companies and individuals are taking action to provide medicines and medical supplies to care for patients who have been infected and to protect others from becoming infected. At the same time, governments, universities, and the private sector are researching treatments and vaccines to halt the outbreak.

Examples of patent holders moving against these activities have made news in legal outlets.[1] After all, a benefit of patenting your invention is the right to exclude others from manufacturing or selling it without your permission. However, these stories raise concerns that patent rights could be used to hinder the pursuit of potential solutions vital to ending the world crisis.

While many patent holders would be proud if their technology alleviated suffering caused by a pandemic, they have often invested millions of dollars (or more) in research and development—e.g., for drug treatments or ventilator systems. Even if they could justify waiving patent licenses to address a worldwide health crisis, many are concerned that doing so would not only result in a loss of reasonable profit, but also diminish the value of their intellectual property (IP) going forward.

Competing humanitarian, civic, and commercial duties can place well-intentioned companies in a bind. How can they allow their technology to be made, used, and sold by others to address a crisis and yet still recoup investments, protect IP, and generally behave as a responsible and profitable business?

The federal government's authority over patent rights may be able to untie this knot.

IP Incentives and the Potential for Hold-Up

IP rights, including patents, trademarks, copyrights, and trade secrets, promote innovation. The ability to profitably exclude others from practicing an invention provides an incentive to invest in research and development of new products and take risks with uncertain technologies. It is in society's interest to support innovation, research, and development to advance technology and the greater good; IP rights are a mechanism to provide that support.[2]

While there is general agreement that IP is valuable and provides beneficial incentives, incentives can become misaligned with the greater good during urgent times, such as a pandemic.

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[1] *See*, e.g., *Labrador Diagnostics LLC v. BioFire Diagnostics LLC, et al.*, District of Delaware Case No. 1:20-cv-00348 (seeking monetary damages and an injunction against diagnostic tests).

[2] This is especially true of the development of lifesaving drug treatments and medical technologies. An ability to use such technology without compensation every time there is a public health crisis would undermine the motivation to develop it.

Examples of this with respect to COVID-19 have begun appearing. For example, in the US, Labrador Diagnostics, a nonpracticing entity, recently filed a patent infringement lawsuit against BioFire Diagnostics and its parent company, bioMérieux S.A., after they submitted a COVID-19 test to the FDA for emergency approval. In northern Italy, news reports claimed two engineers that developed an inexpensive method for 3D printing a scarce and costly valve used in breathing machines received a patent infringement threat letter from the valve's manufacturer.[3]

One presumes that companies do not wish to withhold lifesaving treatments from those who need it. However, it is also not unwarranted for them to believe in the value of their IP and that they are entitled to compensation for their inventions. From a public health perspective, the potential for patent hold-up during periods of high demand and urgency is clear.

As the current crisis continues, the likelihood of attempts to assert patent rights that interfere with treatments (in a manner of speaking) can be expected to rise.

International Law Allows Use of Your Patent Without Your Permission (But Not Without Compensation)

The United States is a member of the World Trade Organization and a party to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. Article 31 of the TRIPS Agreement provides a mechanism for a government to respond to an emergency without delay, i.e., without waiting to negotiate a license for use of a crucial invention during a crisis. For governments of member states—and entities authorized by governments—Article 31 allows use of a patent without permission from a patent holder, with or without prior notice, to address a crisis.[4] Importantly, the patent holder will eventually be adequately compensated for such use, including the economic value of the use.

Use of patented technology under Article 31 must be preceded by attempts to obtain permission under reasonable commercial terms and conditions over a reasonable period of time. So a patent holder is likely to be on notice. However, this requirement can be waived "in the case of a national emergency or other circumstances of extreme urgency."

The COVID-19 pandemic seems to fit that definition exactly. It is possible, therefore, that the US government (or authorized entity) could use a patented technology to attempt to alleviate the pandemic without first notifying the patent holder.

But even if the government uses your patented technology without notice, it must still notify you as soon as reasonably practicable. Moreover, the patented technology cannot be used without permission beyond the need to address the crisis. For example, use of a patent covering ventilators for COVID-19 patients without a patent holder's permission could occur throughout the outbreak but cannot continue into future flu seasons.

US Statutes Support the Federal Government's Use of Patented Technology to Address Crises

At least two US statutes also permit the use contemplated by Article 31: the Bayh-Dole Act[5], which covers inventions developed with federal support, and the more broadly applicable 28 U.S.C. § 1498.

[3] Neither the US nor Italy matters appear to be moving forward. Labrador offered royalty-free licenses to its diagnostic technology patents following public backlash against its complaint, and subsequent reporting in Italy indicated that the communication between the valve manufacturer and engineers did not include a litigation threat.

[4] *See* Uruguay Round Agreements Act, Pub. L. No. 103-465, §§ 531-533, 108 Stat. 4809 (1994).

[5] The Patent and Trademark Law Amendments Act, Pub. L. No. 96-517, 94 Stat. 3019 (1980); *see* 35 U.S.C. §§ 200-212.

The Bayh-Dole Act grants the federal government "march-in rights" for inventions developed by federal contractors or with federally funded research, where the government may request that a patent holder issue additional licenses under terms that are reasonable under the circumstances. If the patent holder refuses, the Act sets out circumstances under which the government may grant additional licenses without the patent holder's consent. These circumstances include the need to alleviate health or safety issues that are not reasonably satisfied by the patent holder or the existing licensees. If, for example, a drug effective in treating COVID-19 were developed with federal support by a pharmaceutical company unable to manufacture sufficiently high quantities to meet the projected demand, the government could exercise march-in rights to increase manufacturing capacity. In view of the considerable federal support for research into COVID-19, it is likely the federal government would have march-in rights for any new treatment.

For inventions not developed with federal support, the government may take action under 28 U.S.C. § 1498, which gives it the right to use or manufacture a patented invention without a license from the patent holder. Section 1498 applies to use or manufacture "by or for the United States," and accordingly covers actions taken by entities acting on behalf of the government. In such cases, while there is a means for a patent holder to be compensated, it requires bringing an action against the federal government in the Court of Federal Claims for "reasonable and entire compensation for such use and manufacture."[6]

Conclusion

Patent holders' legitimate business concerns may conflict with their humanitarian, altruistic instincts and feelings of civic responsibility. The federal government's legal authority to allow—and even compel—the use of patented technology without permission, while providing means and methods for future compensation for that use, could help alleviate certain struggles in the fight against COVID-19.

Contacts

Andrew D. Kasnevich
akasnevich@HuntonAK.com

Lawrence K. DeMeo
ldemeo@HuntonAK.com

Aimee N. Soucie
asoucie@HuntonAK.com

[6] Independent inventors, nonprofits, and entities having fewer than 500 employees may recover reasonable costs and fees for attorneys and expert witnesses, reducing the burden of litigation in some circumstances.