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Expanding Access to Patents for COVID-19

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SUMMARY. Two competing and linked sets of goals must be addressed when considering patent policy in response to a public health emergency. First is the allocation of existing resources among potential users (hospitals, patients, etc.); second is the creation of new technologies over time (innovation). Patents provide financial incentives to develop new technologies. Yet shortages of patented products often plague crisis response. In the case of COVID-19, allocative goals, particularly satisfying demand for patented medical products (e.g., vaccines, ventilators, PPE, and test kits), may be achieved through governmental interventions such as march-in and governmental use rights (compulsory licensing). But in cases involving the development of new technologies such as vaccines and therapies, incentive structures must be preserved to ensure that the private sector is appropriately motivated to act. In addition to patents, which reward inventors for financially successful innovations, a range of other incentives such as prizes, grants, and subsidies also exist to motivate technological innovation. Incentives like these, coupled with a requirement that resulting discoveries be made available on a broad and open basis, can achieve a balance between allocation and innovation goals. Governments can encourage such measures using both the incipient threat of compulsory licensing and the reward of procurement preferences and other up-front rewards.

Introduction

As COVID-19 spread around the world in early 2020, reports emerged of patent-based threats against manufacturers of products – such as ventilator valves and diagnostic test kits – needed to address the emerging public health crisis. Countries including Germany, France, Israel, and Canada rushed to enact policies to suspend patent rights on vaccines and drugs that could be used to combat the pandemic. Echoing concerns over the inaccessibility of patented vaccine technologies during the SARS and Ebola outbreaks, the World Health Organization (WHO) issued a global call to action, urging governments and the private sector to make patents broadly available in the fight against COVID-19. This Chapter offers a framework for U.S. policymakers as they consider different responses to COVID-19 that may implicate patented technologies.

Patents and the “Access versus Incentives” Tradeoff

Two competing sets of goals must be addressed when considering patent policy. Allocative considerations relate to the distribution of existing resources among potential users. In terms of many patented technologies – e.g., smart phones, aircraft engines, food additives – market forces do a pretty good job of allocating products to those who value them most highly (Landes & Posner, 2003). However, in some cases, simple market action may not achieve desired policy goals. Thus, in the case of patented drugs and health care equipment, considerations such as distributive justice, public health, health equity, and humanitarianism may

lead policymakers to consider interventions designed to promote greater public access to these technologies than the market alone would provide (Outterson, 2005; Lee, 2017). Such interventions may seek to influence product demand (e.g., by subsidizing users through public assistance programs like Medicare and Medicaid) or supply (e.g., by relaxing patent restrictions in order to enable a wider range of suppliers to produce the desired product and offer it at a reduced price (often referred to as compulsory licensing – see below)).

Unlike allocative considerations, dynamic considerations relate to the creation of new technologies over time. Patents are designed to promote innovation, as they provide financial incentives to producers of successful new technologies (at least those that are valued by the market). In addition to patents, other incentive mechanisms exist to encourage innovation, including grants, prizes, and tax incentives (Hemel & Ouellette, 2019). In many cases, several of these incentives can work in tandem (e.g., a grant-funded project that leads to a patentable invention and gives its owner the benefit of a research and development (R&D) tax credit).

These factors do not exist independently of one another, and interventions with respect to one will often affect the other. In some cases, allocative interventions may promote innovation, as when the government subsidizes individual purchases of a patented drug, thereby ensuring patient access to the drug while at the same time rewarding its developer and funding future

research. Yet, in other cases, allocative interventions such as compulsory licensing of patents (described below), may depress an innovator's financial returns and thus reduce its incentive to innovate further. This "access versus incentives" tradeoff is one of the fundamental tensions in intellectual property law (Landes & Posner, 2003; Outterson, 2005; Hemel & Ouellette, 2019). And while such tradeoffs can be justified in the pursuit of legitimate policy goals, it is important for policymakers to understand their nature and extent when considering different policy interventions. This Chapter briefly outlines policy considerations surrounding access and incentive policy interventions pertinent to COVID-19.

Access to Existing Technologies

Once a particular technology exists, there is no further need to incentivize its creation. While it may be desirable to incentivize the creation of improvements and follow-on innovations, policy decisions largely shift to allocative issues (access). Compulsory licensing is a legal mechanism designed to increase access to patented technologies that are being undersupplied by the market (i.e., by the patent holder and its delegates). When imposing a compulsory license, the government effectively requires a patent holder to license its patents to one or more third party manufacturers (usually at a reasonable rate) in order to ensure the continuity of, or an increase in, production and supply of the patented technology.

Unlike many countries, the United States lacks a general statutory framework for the compulsory licensing of patented technologies. However, U.S. law does possess two statutory mechanisms that achieve similar results: federal march-in rights under the Bayh-Dole Act of 1980 (35 U.S.C. § 301 et seq.) and governmental use under 28 U.S.C. § 1498. These two mechanisms are explained below.

March-In Rights under the Bayh-Dole Act

The Bayh-Dole Act of 1980 allows researchers to patent inventions arising from federally-funded research. In return, the Act authorizes the government to exercise so-called 'march in' rights, which compel the owner of any such patent to license it to one or more third parties to the extent necessary, among other things, to address health or safety needs. Numerous petitions have been filed over the years urging federal agencies to exercise their march-in rights under the Act, primarily in cases involving undersupplied or costly pharmaceutical products (Thomas, 2016). To date, however, neither the National Institutes of Health nor any other federal agency has exercised march-in rights under the Act.

While the federal government has been urged to exercise its Bayh-Dole march-in rights in the context of the COVID-19 response (e.g., with respect to vaccine technologies partially funded through federal programs), march-in rights have limitations. Most importantly, they apply only to inventions that were made using federal funding. While many vaccine and drug candidates have arisen from grant-funded university laboratories, a significant amount of biomedical research is conducted in the private sector without federal support. Nevertheless, march-in rights under the Bayh-Dole Act are valuable tools that have the potential to lift patent barriers that might impede the supply of at least some needed goods and services.

Governmental Use

Section 1498 of chapter 28 of the United States Code is not a compulsory licensing law, but a limited waiver by the U.S. government of its sovereign immunity. Under this statute, if the federal government (itself or through its contractors) uses or manufactures a patented invention without the permission of the owner, the owner cannot prevent this use, but may sue the government to recover "reasonable and entire compensation" in the U.S. Court of Federal Claims.

Since its enactment in the early 20th century, the federal government has periodically invoked § 1498 in cases relating to the procurement of military and other equipment. Less frequently, § 1498 has been used to bolster the U.S. supply of drugs and biomedical technologies at prices lower than those charged by patent holders. During a three-year period in the 1960s, the Department of Defense's Military Medical Supply Agency (MMSA) utilized § 1498 to obtain supplies of approximately 50 drugs including the antibiotic tetracycline (Brennan et al., 2016). Though the federal government's use of § 1498 in the pharmaceutical sector declined by the 1970s, the Department of Health and Human Services threatened to invoke the statute in 2001 during the post-9/11 anthrax scare (Brennan et al., 2016). Since then, commentators have proposed using the government's powers under § 1498 to drive down drug prices, but no meaningful utilization of this power has occurred for pharmaceutical products in nearly two decades.

But today, with highly publicized shortages of coronavirus testing kits, facial masks, ventilators, and other critical supplies, the prospect of U.S. government intervention through § 1498 has again gained traction. Section 1498 is a viable mechanism for addressing pandemic-related shortages of any product or service required by the federal government or its contractors.

Commentators who have analyzed the use of § 1498 in connection with the supply of drugs have expressed concern over its limited scope: it only applies to products that are "used or manufactured by or for the United States" (Brennan et al., 2016). In the context of ordinary prescription drugs, this scope might not be broad enough to address the needs of patients whose drug costs are covered by private insurers or health plans. However, the case for government use (and the applicability of § 1498) is stronger in the context of the new coronavirus, which the federal government has declared a national emergency. To the extent the federal government supports, procures, distributes, or administers coronavirus tests, vaccines, treatments, or equipment, such activity could be classified as government use under the terms of § 1498.

Incentivizing the Development of New (and Open) Technologies

While existing technologies are largely (though not entirely) the subject of allocative/access policy interventions, a different calculus exists with respect to as-yet-undiscovered technologies. In these cases, the focus is largely on incentivizing the discovery/creation of the new technology, whether it be a vaccine, a therapeutic, or a medical device. Under ordinary circumstances, patents are effective mechanisms for incentivizing innovation: if granted, they allow the inventor to extract rent from the market

over a multi-year period without close competition. In the case of new prescription drugs, patents enable manufacturers to recoup far more than even their substantial R&D costs. As an intervention, patents do not impose a direct cost on the government (though when government programs purchase patented drugs, they effectively subsidize the inventor), and they generally reward innovations that are successful in the market, eliminating any need to evaluate their quality independently.

However, patents are not always well-calibrated to address social needs. Because their payoff is entirely market-driven, patents incentivize innovations that are likely to be the most lucrative, rather than the most beneficial (hence the tendency of some firms to focus R&D dollars on hair loss treatments and diet pills rather than the eradication of rare diseases). In normal times, governments can seek to guide innovation in socially beneficial directions through a variety of incentive mechanisms: extended periods of market exclusivity for ‘orphan drugs’ directed to rare diseases, research grants targeted at diseases affecting underserved populations, and the like. But in times of emergency, more urgent measures may be required.

Prizes for Open Innovation

In addition to patents, mechanisms such as grants, subsidies, tax incentives, and prizes are used to incentivize innovation. The field of vaccine development offers a useful illustration. In general, vaccine development does not begin until a particular disease strain is identified and recognized as a significant threat (Rutschman, 2018). Patents are often held by diverse entities, making consolidation and effective R&D difficult (Rutschman, 2018; Rutschman 2019). Moreover, vaccines are generally viewed as less profitable than therapeutic drugs, further contributing to their lack of development (Rutschman, 2019; Xue & Ouellette, 2020). And while the number of patents covering vaccine technologies continues to rise, vaccine development is still severely lacking (Rutschman, 2019).

The problem of optimizing vaccine development is dynamic – it relates not to the allocation of existing resources, but to the creation of new ones. To incentivize vaccine development during a major disease outbreak, some commentators have proposed increasing monetary incentives for successfully producing a vaccine in the form of substantial grants, subsidies, or prizes (Lichtman, 2018; Xue & Ouellette, 2020). An important condition of such financial incentives could be a requirement that the awardee make any resulting patents openly available to the public, at least for purposes of COVID-19 response. This requirement would “open” patents for all to use in connection with the present emergency, thus addressing allocative issues, while at the same time permitting the innovator to monetize the invention in other fields and settings (i.e., therapies for diseases other than COVID-19), thereby reducing impediments to dynamic innovation (see, e.g., the Open COVID Pledge (opencovidpledge.org), which allows a patent holder to pledge its technology for free usage in addressing the COVID-19 pandemic, while retaining the right to charge for it elsewhere).

Encouraging Patent Pools

According to some accounts, the largest barrier to effective vaccine development is not insufficient funding during an outbreak (when funding often increases dramatically), but the inability of diverse patent holders to cooperate to productively combine their technologies (Rutschman, 2018; Rutschman, 2019). Accordingly, the twin issues of rights fragmentation and lack of coordination must be addressed (Heller & Eisenberg, 1998).

One well-known method for addressing these related issues is the pooling of patents held by multiple parties – making those patents available as a group to others in the industry. In cases of national emergency, government can encourage (or pressure) private parties to participate in such arrangements. This approach was famously employed in the months prior to U.S. entry into World War I. At that time, “the development of the aircraft industry in the United States was seriously retarded by the existence of a chaotic situation concerning the validity and ownership of important aeronautical patents” (“*MAA v. United States*,” 1933). Fearing that the military would be unable to procure sufficient aircraft, government officials pressured the two leading holders of aviation patents, Wright–Martin and Curtiss–Burgess, to pool their patents with the rest of the industry, thereby alleviating fears throughout the industry that the manufacture of aircraft would lead to litigation.

Patent pools have been proposed in connection with viral outbreaks before, including the 2002–03 SARS outbreak, the 2005 H5N1 influenza outbreak, and the 2009 H1N1 influenza pandemic. Yet, despite the perceived need for aggregation of distributed patent rights in order to combat these diseases, patent pools were never formed for a variety of practical and competitive reasons. In March 2020, the government of Costa Rica called on the WHO to form a patent pool relating to COVID-19. Such a pool, which could address a range of technologies beyond vaccines, would clearly be beneficial to public health.

In the United States, the government could encourage the formation of one or more COVID-19 pools using a carrot and stick approach. On one hand (the stick), government can threaten to enact compulsory licensing mechanisms to compel patent holders to make their patents available to competitors if they do not voluntarily accede to such a pool. On the other hand (the carrot), government can commit to procure relevant medical products only from participants in such pools.

Conclusion

Formulating patent policy to address public health crises involves both allocative considerations as well as incentives for innovation. Neither can be ignored, so solutions that achieve some balance between broad access to patented technologies and incentives for future technology development are needed. Fortunately, several such approaches are available in the area of COVID-19 response and remediation. 🌟

Recommendations for Action

Federal government:

- The federal government, acting through the Centers for Disease Control or another appropriate agency, should assess the patent landscape for technologies critical to COVID-19 response, including the licensing practices of key patent holders, and identify any areas in which the combination of patent protection and a demonstrated unwillingness of patent holders to make their rights available to others could plausibly hinder the rapid development and deployment of technologies necessary to combat the pandemic.
- With respect to such patents, the government should develop and publish a plan for asserting governmental use and march-in rights under 28 U.S.C. § 1498 and the Bayh-Dole Act, with the proviso that any patent holder that voluntarily pledges its patents for COVID-19 response on a broad, royalty-free basis (e.g., the Open COVID Pledge) would not be subject to such measures.
- In areas key to COVID-19 response, the government should select technology targets requiring further research and development and develop incentive programs (e.g., prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (e.g., the Open COVID Pledge) for purposes of COVID-19 response.
- The government should encourage users of complementary patents to form patent pools, and commit to procuring products and supplies only from entities participating in such pools.

State governments:

- In areas key to COVID-19 response, state governments should select technology targets requiring further research and development and develop incentive programs (e.g., prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (e.g., the Open COVID Pledge) for purposes of COVID-19 response.
- The government should encourage users of complementary patents to form patent pools, and commit to procuring products and supplies only from entities participating in such pools.



About the Author

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