Congressional Research Service
Informing the legislative debate since 1914

Legal Sidebar

COVID-19 Medical Countermeasures: Intellectual Property and Affordability

March 18, 2020

Federal agencies and private industry have begun efforts to develop and test medical countermeasures (such as antiviral treatments and vaccines) to combat COVID-19, the disease caused by the novel coronavirus SARS-CoV-2. For example, Gilead Sciences has begun clinical trials, both in China and in the United States, to test whether its experimental antiviral drug remdesivir is safe and effective against COVID-19. In February 2020, the Biomedical Advanced Research and Development Authority (BARDA), a division of the Department of Health and Human Services (HHS), entered into agreements with two pharmaceutical companies—Johnson & Johnson and Sanofi—to develop vaccines for COVID-19. BARDA has also partnered with Regeneron Pharmaceuticals to develop a monoclonal antibody treatment for COVID-19. (See this CRS report for further detail on these and other potential countermeasures against COVID-19.)

Some Members of Congress have raised concerns about whether these medical countermeasures, if shown to be safe and effective, will be affordable and accessible to the public—especially if federal funds contribute to their development. The Coronavirus Preparedness and Response Supplemental Appropriations Act (CPRSA), enacted into law on March 6, 2020, contains two provisions relating to affordability of COVID-19 countermeasures. First, products purchased by the federal government using funds appropriated by CPRSA, including vaccines, therapeutics, and diagnostics for COVID-19, "shall be purchased in accordance with Federal Acquisition Regulation guidance on fair and reasonable pricing." Second, CPRSA states that the Secretary of HHS "may take such measures authorized under current law to ensure that vaccines, therapeutics, and diagnostics developed from funds provided in this Act will be affordable in the commercial market."

This Sidebar reviews several intellectual property (IP) rights provisions under current law that the federal government could use to try to ensure that COVID-19 countermeasures are accessible and affordable. Other actions that the federal government might hypothetically take—such as additional spending, production by federal agencies, governmental negotiation, or direct price controls—are beyond the scope of this Sidebar, in that such measures do not implicate IP rights and may require additional legislative action beyond the "current law" referenced in CPRSA.

Congressional Research Service
https://crsreports.congress.gov
LSB10422

Patent Rights in Inventions Made with Federal Assistance

Patent Basics

Under the Patent Act, any person who "invents or discovers any new and useful process, machine, manufacture, or composition of matter" may apply for a patent on the invention with the U.S. Patent and Trademark Office (PTO). PTO patent examiners evaluate the application to ensure it meets all the applicable legal requirements to merit the grant of a patent. If the patent examiner concludes that the claimed invention is new, nonobvious, useful, directed at patentable subject matter, and adequately disclosed and claimed, PTO will issue the patent. If granted, patents typically expire twenty years after the initial patent application is filed.

Patents are available for almost every field of technology, including biotechnology, chemistry, computer hardware, electrical engineering, mechanical engineering, and manufacturing processes. In the pharmaceutical context, if an inventor is the first to synthesize a particular chemical that is useful in treating disease, she may seek a patent claiming the chemical itself. That said, patents on a pharmaceutical's active ingredient are only a subset of patents relating to pharmaceuticals and other medical treatments. Particular drug formulations, methods of using the pharmaceutical to treat a particular disease, methods and technologies to administer a pharmaceutical, methods and technologies to manufacture a pharmaceutical, as well as methods and technologies for testing for and diagnosing disease, are all patentable if they meet Patent Act's requirements.

To encourage innovation, a valid patent holder has the exclusive right to make, use, sell, and import (collectively, "practice") the patented invention in the United States. Patents are thus said to confer a "temporary monopoly" on the patent holder: anyone else who wishes to practice the invention needs to obtain permission from the patent holder to do so (and, typically, pays for that permission). In some situations, patent rights can confer substantial market power on patent holders, enabling them to charge higher-than-competitive prices for the patented product, as a monopolist would. Some empirical studies have found patent rights are among the most important factors driving high prices for pharmaceuticals. At least to some extent, higher prices are part of the patent system's design, in that they enable inventors to recoup the costs of research and development necessary to produce the invention in the first place. Fundamentally, IP law seeks to balance the importance of providing incentives to innovate against the costs that IP rights impose on the public in the form of higher prices and reduced competition.

Inventions Made with Federal Assistance

Patent rights initially vest in the individual inventor or inventors, as a general rule. Commonly, however, employees agree by contract to assign their patent rights to inventions made in the course of their employment to their employer, who may seek a patent on an employee's behalf.

When private parties rely on federal assistance to develop an invention, any resulting patent rights will typically be owned by either the U.S. government or the federal contractor, depending on the nature of federal involvement. For inventions made by federal employees during their official duties, the federal government will typically obtain title to the patent. The federal government's general policy for federally owned inventions, under the Stevenson-Wydler Technology Innovation Act and the Federal Technology Transfer Act of 1986, is to encourage their commercialization by licensing the federally owned patent rights to private parties—a process called "technology transfer." Under technology transfer agreements, federal agencies grant private parties the exclusive or nonexclusive right to practice the invention, while the U.S. government retains: (1) a "nontransferable, irrevocable, paid-up license . . . to practice the invention or . . . by or on behalf of" the United States (the "government-use license"); and (2) the power "to terminate the license in whole or in part" based on grounds similar to the conditions for "march-in rights" (discussed below).

The Bayh-Dole Act of 1980 (Bayh-Dole), as amended, applies to inventions that a federal contractor conceives or first reduces to practice during the performance of a funding agreement with a federal agency. Under Bayh-Dole, the federal contractor may elect to retain the patent rights for a federally funded invention. In exchange, however, the contractor provides the federal agency with a government-use license, and the United States retains the authority to grant compulsory licenses to third parties in certain circumstances ("march-in rights"). Although Bayh-Dole, by its terms, only applies to federal contractors that are nonprofit organizations or small businesses, longstanding executive practice (codified by regulation) has applied Bayh-Dole to all federal contractors, regardless of size.

Finally, federal laboratories and private parties may enter into cooperative research and development agreements (CRADAs) in which both parties agree to provide services, facilities, equipment, IP, or other resources, but the federal government does not provide federal funding to the non-federal party. In this situation, ownership of IP rights may depend on the terms of the agreement. However, the federal laboratory generally has the authority to license existing federally owned IP to a private party as part of a CRADA, as well as to license or assign inventions made in whole or part by a federal employee working under a CRADA. In return, the federal government retains a government-use license and compulsory-licensing authority similar to Bayh-Dole march-in rights.

These general rules for patent ownership are subject to various exceptions and waivers, depending on the agency and circumstances. For example, some agencies (including BARDA and the National Institutes of Health) have the authority to enter into transactions that are *not* contracts, grants, or cooperative agreements, known as "other transaction" authority. "Other transactions" are exempt from many statutory provisions and procurement regulations, including Bayh-Dole's requirements. BARDA's template for other transactions includes contractual patent provisions much like those of Bayh-Dole, including march-in rights provisions. These patent provisions are "fluid and negotiable," however, and may be different for particular transactions. In addition, both Stevenson-Wydler's and Bayh-Dole's requirements contain specific exceptions. For example, Bayh-Dole's patent provisions do not apply to contractors located outside the United States, nor in "exceptional circumstances," including if necessary "to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."

Governmental Compulsory Patent Licenses

As explained above, a patent holder generally has the exclusive right to make, use, sell, and import an invention. Thus, any other person who wishes to practice that invention will ordinarily need a license (i.e., permission) from the patent holder, or else be exposed to legal liability. In certain cases, however, patents may be subject to a "compulsory license," which allows another person to practice the invention *without* the consent of the patent holder. Compulsory licenses require the sanction of a governmental entity and the payment of compensation to the patent holder. Compulsory licenses differ from ordinary licenses in two important respects. First, the person seeking to use the invention need not obtain permission from the patent holder. Second, the compensation paid to the patent holder is determined by operation of law, not by private contractual negotiations between the licensee and the patent holder.

March-in Rights under the Bayh-Dole Act (35 U.S.C. 203)

Although Bayh-Dole generally allows federal contractors to take title to patents on inventions created with federal funding, the federal government retains the authority to "march in" and grant compulsory licenses to third parties in some circumstances. Specifically, the federal agency that provided the funding may require the federal contractor to grant a patent license to a third party if the agency determines that either:

> (1) action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
>
> (2) action is *necessary to alleviate health or safety needs* which are not reasonably satisfied by the contractor, assignee, or their licensees;
>
> (3) action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
>
> (4) action is necessary because the agreement [to prefer U.S. manufacturing of the invention by any of the contractor's exclusive licensees] has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of its agreement [to prefer U.S. manufacturing].

A license granted under Bayh-Dole's march-in provisions must be "upon terms that are reasonable under the circumstances," which may require that the licensee pay compensation to the patent holder (i.e., the federal contractor or its assignee).

The federal government has never exercised march-in rights under Bayh-Dole. Advocacy groups have petitioned the National Institute of Health (NIH) several times to exercise march-in rights based on the high prices of certain drugs developed with federal funding, such as treatments for HIV/AIDS. NIH has rejected these petitions, contending that pricing concerns alone are insufficient to exercise march-in rights—so long as the invention is on the market and available to patients. In the context of a pandemic like COVID-19, the "health or safety needs" language would appear to provide a possible basis for the exercise of march-in rights, should the federal agency determine that compulsory licensing is necessary to address public health needs unmet by a federal contractor.

Governmental Use Rights (28 U.S.C. § 1498)

A broader statutory authority than march-in rights, 28 U.S.C. § 1498 (section 1498), applies to any patented invention—not just inventions made with federal funding. Under section 1498, sometimes described as an "eminent domain" provision for patents, the U.S. government has the authority to use or manufacture any patented invention "without license." In practice, this means that if the U.S. government determines that it needs to practice an invention, it need not ask permission from the patent holder to do so, and—despite the existence of the patent—courts will not order the government to cease infringing activity. The patent holder, however, has the right to sue in the U.S. Court of Federal Claims for "reasonable and entire compensation" for the government's use of the patented invention. In effect, then, section 1498 allows the United States to issue itself a compulsory license to make and use any patented invention without obtaining the permission of the patent holder, in exchange for consenting to liability in a suit seeking reasonable compensation for the government's use.

In the context of COVID-19 medical countermeasures, the U.S. government could rely on section 1498 to make and use any patented invention without the consent of the patent holder. Because section 1498 extends to infringement "by a contractor, a subcontractor, or any person, firm, or corporation for the [U.S.] Government and with the authorization or consent of the [U.S.] Government," the federal government could also extend its section 1498 authority to the actions of private entities by authorizing them to practice a patented invention on behalf of the government.

Targeted Legislation and the Takings Clause

U.S. patent rights were created by an act of Congress. Thus, should patent rights inhibit access to or affordability of COVID-19 countermeasures and should Congress conclude that existing legal authorities are insufficient, targeted legislation is a possible option. Although the U.S. Constitution grants Congress the authority to create a patent system, it does not require Congress to do so. Congress therefore has wide

discretion in designing the patent system's scope and operation. So long as it operates prospectively (and consistent with its international treaty obligations), Congress may exclude certain technologies from patent protection. For example, a provision in the 2011 Leahy-Smith America Invents Act prohibits the PTO from issuing a patent on inventions "directed to or encompassing a human organism."

When legislation operates retroactively to invalidate a patent or diminish patent rights, however, it raises issues under the Takings Clause of the Fifth Amendment to the U.S. Constitution. The Takings Clause states that if "private property [is] taken for public use" by the U.S. government, it must provide "just compensation." The Supreme Court has suggested several times that patents are private property under the Takings Clause, but it has never held so explicitly. Presuming that patents are private property under the Fifth Amendment, legislation that retroactively impairs patent rights could give rise to a constitutional claim for just compensation. Recognizing this, Congress has often provided for compensation in past legislation that has retroactively invalidated patents. For example, the Atomic Energy Act of 1954 "revoked" existing patents on "any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon," while providing a process to provide just compensation to any such patent holder.

If Congress seeks to preclude the exercise of exclusive patent rights over COVID-19 medical countermeasures, it could pass legislation preventing the PTO from issuing such patents, or invalidating already-issued patents relating to countermeasures. In the latter case, some mechanism for compensation to the patent holder might be required under the Takings Clause. In either case, such legislation could raise issues under the United States' treaty obligations, including the treaty on Trade-Related Aspects of Intellectual Property Rights of the Marrakesh Agreement establishing the World Trade Organization (WTO), in which WTO members agree to make patents available in "all fields of technology," with some exceptions. In addition, preclusion of patent rights could reduce incentives to create and develop medical countermeasures against COVID-19.

Author Information

Kevin J. Hickey
Legislative Attorney

Disclaimer

as a CRS Report may include copyrighted images or material from a third party, you may need to obtain the permission of the copyright holder if you wish to copy or otherwise use copyrighted material.