Intellectual Property & Technology Law Journal

Edited by the Technology and Proprietary Rights Group of Weil, Gotshal & Manges LLP

VOLUME 33 • NUMBER 1 • JANUARY 2021

# Life Sciences Considerations Regarding Compulsory Licensing, March-In Rights, and the Defense Production Act During COVID-19

**Roger Kuan, Lyric Stephenson, and Joan Wang**

Under pressure to overcome the ongoing global pandemic, the United States government faces political pressure and is motivated to take any and all measures to facilitate the dissemination and use of innovation related to the diagnosis, treatment and prevention of COVID-19. There are various paths by which the federal government might seek to accomplish such goals, including via:

- Compulsory licensing;
- March-in rights under the Bayh-Dole Act of 1980; or
- The Defense Production Act.

**Roger Kuan** (*roger.kuan@haynesboone.com*) is a partner at Haynes and Boone, LLP, and chair of the firm's Precision Medicine and Digital Health Practice Group, where he counsels companies positioned in the convergence of the life/medical sciences and technology industries on how to navigate the complexities of the intellectual property, data rights, and regulatory challenges they encounter. **Lyric Stephenson** was a summer associate at the firm. **Joan Wang** (*joan.wang@haynesboone.com*), an associate in the firm's Austin office, is a registered patent attorney in the firm's Intellectual Property Practice Group.

As discussed below, the conditions under which the U.S. government can pursue one of these paths and the likelihood that it will pursue it may vary. As such, companies possessing patent rights in COVID-19 innovations should be mindful of the circumstances under which the government might interfere with patent rights to private commercial developments, the consequences of such interference, and the ways in which it might be able to avoid such government interference.

## COMPULSORY LICENSING

The United States, along with other World Trade Organization ("WTO") member countries, is permitted to issue compulsory licenses according to the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") to use, produce, or import a patented product or process, typically a generic pharmaceutical drug, without the patent owner's permission.[1]

Although the circumstances in doing so are not explicitly defined in the TRIPS Agreement, a national emergency like the COVID-19 pandemic is a recognized justification.[2] Compulsory licenses do not require that the product was federally funded, and the government can use a compulsory

license after it has made an effort to obtain a voluntary license from the patent holder on "reasonable commercial terms."[3]

If a voluntary license is unsuccessful, then the government can grant a compulsory license, though it must be non-exclusive.

In exchange for the compulsory license, the patent holder is entitled to "adequate remuneration" and can continue producing its product.[4] While it is unclear what constitutes "reasonable commercial terms" or "adequate remuneration," patent holders can generally expect low royalty rates.[5]

Compared to march-in rights, discussed below, the use of compulsory licensing in the face of a global health crisis has been more widely used by the United States and other countries alike. The U.S. government successfully used compulsory licensing in the 1950s to import an antibiotic from Italy that Pfizer was selling at what was considered an unreasonably high price.[6]

Furthermore, during the 2001 anthrax scare, the U.S. government nearly used compulsory licensing to obtain the drug ciprofloxacin until Bayer decreased its prices to a level considered "reasonable commercial terms" and increased its production.[7]

In the wake of the current pandemic, many countries are already planning on using compulsory licensing, and Israel has already issued a compulsory license to import a generic version of an antiviral drug, which could be a possible treatment of COVID-19.[8]

Currently, both Pfizer/BioNTech and Moderna are under review for emergency authorization of a COVID-19 vaccine in the coming weeks. Moderna have pledged not to enforce their vaccine-related patents during the COVID-19 pandemic; however, Pfizer/BioNTech have not done so. In order to prevent potential vaccine shortages, the U.S. government may consider using compulsory licensing in order to bypass Pfizer/BioNTech's vaccine-related patents.[9]

## MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT

Pursuant to the Bayh-Dole Act of 1980, the United States government also has "march-in" rights, which requires companies owning patents for inventions developed using federal funding to license those patents to a responsible third party – non-exclusively, partially exclusively, or exclusively under reasonable terms.[10] However, it should be noted that the Bayh-Dole Act also grants the United States government a "nonexclusive, nontransferable, irrevocable, paid-up license" for the government to practice federally funded patents under 35 U.S.C. §202(c)(4).[11]

The two most relevant conditions for the march-in rights include when: (1) "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," and (2) when it is "necessary to alleviate health or safety needs which are not reasonably satisfied."[12]

"Practical application" means to manufacture, practice, or to operate the invention, and to establish that it is being used and that its benefits are available to the public on reasonable terms.[13] Ambiguity surrounding the meaning of "reasonable terms" has led to minimal success for petitioners requesting that the government march-in during previous times of perceived public need.

Petitions are generally filed when a company's production is not meeting public need and demand, or a company has set a high price for a drug. The NIH has received at least 12 such march-in petitions, none of which it has pursued after a finding that a company's production plan was satisfactory, and that controlling drug prices was outside its scope of authority.[14]

Although march-in petitions have not successfully been granted to date, the mere threat of one was successful during the AIDS epidemic in encouraging Abbott to lower the price of its HIV drug ritonavir, at least for government purchasers including federal Medicaid and state-run AIDS drug assistance programs.[15]

**The U.S. Court of Appeals for the Federal Circuit has held that a manufacturer who is not the patent holder will not be held liable for patent infringement for manufacturing products covered under the government contract.**

Moreover, the ongoing COVID-19 health crisis has raised the prospect of march-in-rights being

invoked beyond just an academic exercise as there has been robust debate around the federal government exercising march-in-rights to ensure ready and affordable access to the vaccine candidate being developed by Moderna[16] and the potential therapeutic Remdesivir manufactured by Gilead Sciences.[17]

## DEFENSE PRODUCTION ACT

The Defense Production Act ("DPA") also grants the executive branch of the United States broad authority to circumvent patent rights, which could have significant implications for patent holders and manufacturers of COVID-19-related products.

In particular, the executive branch can require that federal government contracts are prioritized by private companies, or require that a company accept and perform government contracts to ensure adequate production of materials necessary for national defense (which could include, for example, patented products related to the diagnosis, treatment, or prevention of COVID-19), regardless of whether such performance would infringe on a third party's patent rights.[18]

The executive branch can exercise this broad power upon a finding "(1) that [a] material is a scarce and critical material essential to the national defense, and (2) that the requirements of the national defense for such material cannot otherwise be met without creating a significant dislocation of the normal distribution of such material in the civilian market to such a degree as to create appreciable hardship."[19]

The U.S. Court of Appeals for the Federal Circuit has held that a manufacturer who is not the patent holder will not be held liable for patent infringement for manufacturing products covered under the government contract.[20] Rather, the patent holder can be remedied exclusively through action against the United States in the Court of Federal Claims,[21] and the patent holder is entitled to "reasonable and entire compensation" when the patented invention is used by or for the United States without a license, while the United States is permitted to continue its use.[22]

Historically, the DPA is used in response and recovery efforts during disasters such as hurricanes, and the Department of Defense has reported placing 300,000 rated orders a year under the DPA.[23]

More recently, the president invoked the DPA to require the production of ventilators and protective equipment[24] and to apply priority rated orders for diagnostic systems and assays for COVID-19 testing to be delivered to nursing homes.[25] The DPA would similarly permit the president to aid in the production of vaccines and treatments for COVID-19, and a new bill was introduced to require the president to use authorities under DPA to require emergency productions of the supplies necessary for distributing and administering the COVID-19 vaccine.[26]

## CONSIDERATIONS AND SUGGESTIONS

Under each of the paths discussed above, the requirements and risks to private life sciences enterprises and their investors vary, but there are options where the government can interfere in the private research, development, or distribution of a patented COVID-19 product, whether or not any aspect of its development was federally funded.

As such, patent holders should be mindful of when the government can interfere, and patent holders and potential government contractors alike must consider ways in which each can avoid this interference or minimize the risks of having any expected economic incentives forcibly adjusted.

If a patent holder used federal funding in the development of its product, then the Bayh-Dole Act would apply and the government can exercise its march-in rights despite past reluctance to do so. Unless a product is wholly unavailable to the public, the risk to a company that the government will pursue its march-in rights is very low, even for pharmaceutical companies accused of high drug prices.

Nevertheless, the patent holder should be aware that if the government invokes the Bayh-Dole Act or marches in, the consequences could be grave: the patent holder will not typically receive royalties for the government's use although some restitution may be recoverable, and the government could be able to grant a license to the patent holder's competitor. For this reason, it would be beneficial for companies to carefully consider when (and for which projects) it accepts federal funding for, and when federal funding is accepted, to consider proactively licensing the resulting patent(s) to secure royalties while meeting public health and safety needs.

Where the Bayh-Dole Act does not apply because the patented product was not federally funded, or because a march-in petition was unsuccessful for other reasons, then the government can instead utilize compulsory licensing or the DPA.

However, the threshold for invoking compulsory licensing is a higher burden for the government in that it first requires preliminary negotiations with the patent holder before issuing a compulsory license.

Additionally, the conditions under which the government can invoke compulsory licensing are ambiguous. In contrast, the president can exercise its power under the DPA without much hassle in a time of national emergency to secure scarce resources. The consequences of both paths also differ slightly. With a compulsory license, a competitor is introduced into the market by the government, and the patent holder is compelled to license its rights non-exclusively in exchange for a potentially low royalty rate (e.g., when it cannot agree to "reasonable commercial terms" for a voluntary license with the government/competitor).

However, such licenses are subject to judicial review. Under the DPA, either the patent holder prioritizes its contract with the government, or a direct competitor could similarly be introduced into the market to manufacture the patent holder's product. In the latter scenario, the patent holder must pursue litigation against the government (not the competitor manufacturer) in the Court of Federal Claims to recover reasonable royalties and no direct recovery from the competitor is permitted so long as it is performing under the government contract.

To avoid inadequate compensation or the introduction of competition on unfavorable terms, a patent holder should consider proactively licensing its product under reasonable royalty terms or, in the case of pharmaceutical companies, decreasing drug prices to be more affordable. These options avoid or reduce the risk of government interference and the legal fees that would be required of the patent holder to sue for adequate compensation.

Furthermore, third party manufacturers that are not the patent holders should be mindful that they are only immune from infringement liability so long as they are performing under such a government contract, and a manufacturer that wishes to manufacture a patented product (e.g., by voluntarily producing more COVID-19 treatment products beyond the government contract) should seek out a license directly from the patent holder.

## Notes

1. Compulsory licensing in the United States is codified in 28 U.S.C. § 1498. *See* World Trade Organization, *Compulsory licensing of pharmaceuticals and TRIPS*, WTO.ORG, *available at https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm* (last visited Aug. 27, 2020).
2. ERIC BOND & KAMAL SAGGI, COMPULSORY LICENSING, PRICE CONTROLS, AND ACCESS TO PATENTED FOREIGN PRODUCTS 3 (Dept. of Economics, Vanderbilt Univ. 2012), *https://www.wipo.int/edocs/mdocs/mdocs/en/wipo_ip_econ_ge_4_12/wipo_ip_econ_ge_4_12_ref_saggi.pdf*.
3. *See* Article 31 of the TRIPS Agreement *available at https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm*.
4. *Id*.
5. Patent holders can expect a royalty rate below five percent. *See* BOND & SAGGI, *supra* note 2.
6. Michael Liu, et al., *March-In Rights and Compulsory Licensing-Safety Nets For Access to a COVID-19 Vaccine*, HEALTH AFFAIRS, *https://www.healthaffairs.org/do/10.1377/hblog20200501.798711/full/* (last visited Aug. 27, 2020).
7. *Id*.
8. *See* HILARY WONG, THE CASE FOR COMPULSORY LICENSING DURING COVID-19 (Univ. of Edinburgh 2020), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7242884/*.
9. Adam Houldsworth, Pfizer's covid vaccine found 90% effective, but raises IP questions, *https://www.lexology.com/library/detail.aspx?g=600d8fb8-03f3-4a68-87e5-cf339e8fc77b*.
10. 35 U.S.C. § 203.
11. 35 U.S.C. § 202(c)(4).
12. 35 U.S.C. § 203.
13. 35 U.S.C. § 201(f).
14. *See* U.S. DEPT. OF COMMERCE, RETURN ON INVESTMENT INITIATIVE FOR UNLEASHING AMERICAN INNOVATION (2019), *available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1234.pdf*.
15. *See* Carolyn L. Treasure, et al., *Do March-In Rights Ensure Access to Medical Products Arising From Federally Funded Research? A Qualitative Study*, THE MILBANK QUARTERLY (Dec. 2, 2015), *available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4678939/*.
16. *See* Bob Herman, *The NIH claims joint ownership of Moderna's coronavirus vaccine,* Axios (Jun. 25, 2020), *available at https://www.axios.com/moderna-nih-coronavirus-vaccine-ownership-agreements-22051c42-2dee-4b19-938d-099afd71f6a0.html*.
17. *See* Joseph Allen, No, You Can't March in On Remdesivir, IPWatchdog (Aug. 6, 2020), *available at https://www.*

*ipwatchdog.com/2020/08/06/no-cant-march-remdesivir/id=123868/*.

18. 50 U.S.C. § 4511(a).
19. Section 4511(b).
20. *See Astornet Techs. Inc. v. BAE Sys., Inc.*, 802 F.3d 1271, 1277 (Fed. Cir. 2015).
21. *See* 28 U.S.C. § 1498(a).
22. *Id*.
23. Contrast this with the DHS which placed no more than 2,000 rated orders in 2018. U.S. Dept. of Homeland Sec., The Defense Production Act Committee Report to Congress (2019), *https://www.fema.gov/media-library-data/1582898704576-dc44bbe61cce3cf763c-c8a6b92617188/2018_DPAC_Report_to_Congress.pdf*.
24. *See Executive Order on Prioritizing and Allocating Health and Medical Resources to Respond to the Spread of COVID-19*, whitehouse.gov (Mar. 18, 2020), *available at https://www.whitehouse.gov/presidential-actions/executive-order-prioritizing-allocating-health-medical-resources-respond-spread-covid-19/*.
25. *See Trump Administration Uses Defense Production Act to Aid Our Most Vulnerable,* HHS.gov (Aug. 20, 2020), *https://www.hhs.gov/about/news/2020/08/20/trump-administration-uses-defense-production-act-to-aid-our-most-vulnerable.html*.
26. *H.R. 8508: COVID-19 Vaccine Distribution and Production* Act, (Oct. 2, 2020), *https://www.congress.gov/bill/116th-congress/house-bill/8508/text*.