Compulsory Licensing To Cut Drug Costs Could Harm Public

By **Gabrielle Markeson, Akkad Moussa and April Isaacson** (December 18, 2020)

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Prescription drug prices, and means by which the executive branch might lower them absent legislative action, were a hot topic during the 2020 election, particularly during the Democratic primary. Multiple candidates laid out plans for presidential oversight of drug pricing.[1]

After Joe Biden won the election, Sen. Elizabeth Warren, D-Mass., called for the president-elect to "[l]ower drug prices ... using existing compulsory licensing authority."[2]

Where does the government's power to impose compulsory licenses come from? And should Biden utilize compulsory licensing to rein in perceived staggering price tags attached to certain critically important drug products in the U.S.?

In this article, we examine the history of the compulsory license and consider its possible application to the research-and-development-heavy biopharmaceutical industry. In our view, imposing compulsory licenses on innovator biopharmaceutical companies could serve to damage the system that incentivizes these companies to invest in new treatments and cures in a manner that actually harms the public.

Critically, there is no means for the drug company to stop the government's action. Rather, the drug company's remedy for this taking is to sort out a "reasonable and complete compensation" through years of litigation.

But the drop in revenue that could result from the government's nullifying a biopharma company's patent rights without contemporaneously addressing the issue of compensation may force ongoing research and development projects to be cut. Measuring the impact on the patient populations that might have benefited from such R&D programs, and thus weighing overall benefit to the public of bypassing patent rights, does not submit to a simple formula.

For these reasons, and additional uncertainties associated with this process discussed within, we urge caution in any proposed application of a compulsory license in the biopharma context and propose at a minimum that the question of compensation be resolved prior to any severe disruption in revenue from a drug to ensure the interests of all patients are protected.

The Legal Framework for Compulsory Licensing

The government's compulsory licensing authority arises from its eminent domain powers.[3] In 1910, Congress enacted Title 28 of the U.S. Code, Section 1498(a), to waive sovereign immunity and allow a patent owner to obtain compensation when the government takes a patent license.[4]

Section 1498(a) provides:

> Whenever an invention ... covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof ... the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.[5]

In 1918, Congress expanded Section 1498(a) to protect third parties acting on behalf of the government from patent infringement suits:

> For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.[6]

Notably, unlike in cases of patent infringement by a private party, injunctive relief — i.e., to stop the infringing activity — is not an available remedy against the government or a third party that manufactures or uses a patented invention "for the Government and with the authorization or consent of the Government."[7]

The government has imposed compulsory licensing in various cases, though most relate to technology for military use. In the 1980s and 1990s, for example, the government invoked its authority to protect the army's use of patented night-vision goggles.[8] The authority has also been used outside the military context.

For example, the government has imposed compulsory licensing on check fraud detection software used by the Federal Reserve.[9] In the 1960s and 1970s, the U.S. Department of Defense and the U.S. Department of Veterans Affairs used Section 1498 to procure generic versions of patented drugs.[10]

More recently, in the early 2000s, the government responded to growing concerns related to post-911 anthrax-based chemical attacks by stockpiling the antibiotic ciprofloxacin, or Cipro. When Bayer AG, Cipro's manufacturer, resisted producing enough of the drug to meet the government's demands, the U.S. Department of Health and Human Services secretary threatened to impose a compulsory license.

Ultimately, Bayer agreed to sell Cipro to the government at a steep discount thus avoiding the need for a license and ensuring no interruption of cash flow associated with the manufacture of that product.[11]

More recently, politicians and academics have called on the government to impose a compulsory license for certain antiviral medicines.[12] The government has yet to take any action.

Compensation Concerns With Biopharma Products

Should the government change course and attempt to reform drug pricing through compulsory licenses, the scope of the remedy available to biopharma patent owners would lead to great uncertainty for biopharma companies that invest in research and development of new drug candidates.

As noted above, the patent owners can recover reasonable and entire compensation from the government. However, because the courts have never addressed compulsory licensing

in the biopharma space, it is unclear what reasonable and entire compensation would actually cover.

Generally, reasonable and entire compensation captures two components: the value of the license and a delay compensation.[13] The value of a license can be determined through three methods: (1) reasonable royalty; (2) "a percentage of the governmental cost savings arising from the governmental use of the patented inventing"; or (3) lost profits.[14] In the compulsory license setting — involving nonbiopharma inventions — a reasonable royalty has been the preferred method to value a license.[15]

The reasonable royalty is the rate that would have resulted from a hypothetical negotiation at the time of the infringement.[16] This analysis would involve consideration of a nonexclusive list of factors derived from the U.S. Court of Appeals for the Second Circuit case Georgia-Pacific Corp. v. U.S. Plywood Corp.[17]

However, because no court has analyzed reasonable and entire compensation for the government taking a biopharma license, a court might ultimately apply another method for valuing the license. The delay compensation includes interest in addition to the royalty for any taking before the final judgment is paid.[18]

The preferred reasonable royalty method used in previous compulsory licensing cases is not well-suited to provide reasonable and entire compensation for a compulsory license to biopharma patents. For example, biopharma companies that research and develop innovative drug products have significant capital expenditures that might not be reflected in the statutory compensation available under Section 1498.

When setting drug prices, innovator biopharma companies seek not only to recover the costs of manufacturing the drug itself but also the associated research and development costs. In addition, the revenue from one drug product is often used to recover lost investments from failed research efforts and to finance ongoing and future research and development efforts, facilities and equipment.

Outside of the compulsory licensing context, however, the U.S. Court of Appeals for the Federal Circuit has affirmed a reasonable royalty analysis that excludes costs for ongoing research for new products.[19] Therefore, a reasonable royalty would likely not provide sufficient revenue to support the heavy research and development investment by innovator biopharma companies. Fundamentally, fairly valuing the license will likely be hotly disputed and not amenable to quick resolution.

Further, any compensation resulting from a compulsory license would not be recovered until the end of a lawsuit brought under Section 1498(a). When the government takes a license, a patent owner's only recourse is to sue the government for compensation.[20] Any such litigation may take years before an ultimate payout to the patent owner.

In one recent compulsory licensing case, eight years passed between the time the patent owner filed the complaint and the Federal Circuit issued its opinion on appeal.[21] Although a biopharma company would eventually be compensated for infringing sales occurring before and during the pendency of the litigation, the company must continue to operate, potentially for several years, without that revenue until a final judgment is entered.

The consequences resulting from the delay in compensation are not readily quantifiable but may nevertheless be severe. A large unplanned interruption in revenue is likely to cause biopharma companies to pare down or even discontinue ongoing or future research and

development projects.

Given the largely empirical nature of drug discovery, there is no way for the drug company or the government to know if this product pipeline contraction might deny the world access to, or at a minimum, delay access to a new life-saving or otherwise important drug. Thus, there is no means for the government to weigh the societal benefit resulting from the compulsory licensed drug against the societal cost from the interruption of discovery research.

Because no court has analyzed a compulsory license in the biopharma context, additional uncertainties abound. For example, no court has considered whether the cloak of sovereign immunity granted to government contractors under Section 1498 extends to generic manufacturers, private insurers or pharmacies for commercial sales. It is unclear whether a commercial sale by a pharmacy and paid for by a private insurer would be considered for the government in the compulsory licensing context.

Even scholars who support compulsory licensing acknowledge that Congress might need to create a new program for patients covered by private insurance to access drug products procured through a compulsory license.[22]

Given the risk of a patent infringement suit against private insurers and pharmacies, it is uncertain whether private insurers and pharmacies would even be willing to get involved in commercial sales of drug products procured through compulsory licensing. Therefore, patients covered by private insurance might not be able to obtain access to patented drug products through compulsory licensing absent Congressional action.

Conclusion

The government's imposition of compulsory licenses to bypass the patent rights of biopharma companies in an effort to reduce drug pricing could have significant unintended and unforeseeable consequences for discovery of important innovative drug products.

Affordability and access to health care is unquestionably an important issue, and one we expect will be in the political spotlight for the foreseeable future.

Based on the existing framework for compulsory licensing, however, the health and welfare of patients would be better served by addressing perceived high drug prices using other measures.

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[1] Shefali Luthra & Victoria Knight, Warren is Right. Presidents Have the Power to Bypass Congress on Drug Pricing., KHN & Politifact Healthcheck (Jan. 31, 2020), available at https://khn.org/news/march-in-rights-elizabeth-warren-presidential-power-to-bypass-congress-on-drug-pricing/.

[2] Elizabeth Warren, What a Biden-Harris administration should prioritize on its first day, Wash. Post (Nov. 11, 2020).

[3] See Pitcairn v. United States, 547 F.2d 1106, 1114 (Ct. Cl. 1976).

[4] Adv. Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1375 (Fed. Cir. 2009).

[5] 28 U.S.C. §1498(a).

[6] Id.

[7] Compare id., with 35 U.S.C. § 283; Decca Ltd. v. United States, 640 F.2d 1156, 1166 (Ct. Cl. 1980).

[8] Gargoyles, Inc. v. United States, 113 F.3d 1572, 1574 (Fed. Cir. 1997).

[9] Adv. Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371 (Fed. Cir. 2009).

[10] See, e.g., Pfizer Co., 39 Decs. Comp. Gen. 760, 125 U.S.P.Q. 477 (1960); see also Hannah Brennan, et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J.L. & Tech. 275, 304-7 (2016).

[11] Amy Kapczynski & Aarson S. Kesselheim, "Government Patent Use": A Legal Approach to Reducing Drug Spending, 35(5) Health Affairs 791, 794-95 (May 2016), available at https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1120.

[12] Donald Zuhn, Senator Asks Department of Veteran Affairs to Break Patents on Hepatitis C Drugs, Patent Docs (May 18, 2015), available at http://www.patentdocs.org/2015/05/senator-asks-department-of-veteran-affairs-to-break-patents-on-hepatitis-c-drugs.html.

[13] Decca Ltd. v. United States, 640 F.2d 1156, 1167-68 (Ct. Cl. 1980).

[14] Id. at 1167.

[15] See Hitkansut LLC v. United States, 130 Fed. Cl. 353, 370 (Ct. Cl. 2017).

[16] See id. at 391.

[17] Georgia-Pacific Corp. v. United States Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), modified and aff'd, 446 F.2d 295 (2d Cir. 1971).

[18] See Hitkansut, 130 Fed. Cl. at 394.

[19] See Finjan, Inc. v. Secure Computing Corp., 626 F.3d 1197, 1209-11 (Fed. Cir. 2010).

[20] Decca, Ltd. v. United States, 225 Ct. Cl. 326, 334 (1980).

[21] See Hitkansut LLC v. United States, 958 F.3d 1162 (Fed. Cir. 2020); Hitkansut LLC

v. United States, 130 Fed. Cl. 353, 366 (Ct. Cl. 2017).

[22] See Hannah Brennan, et al., A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health, 18 Yale J.L. & Tech. 275, 352 (2016).