Compulsory Licensing and March-in Rights in COVID-19 Vaccine Production

March-in rights are a measure intended to protect against nonuse or unreasonable use of federally funded inventions. The federal agency under whose funding agreement the subject invention was made has the right to require the granting of a license to a responsible applicant.

September 29, 2021

By Keith McWha

Discussions of a waiver by the World Trade Organization (WTO) regarding certain intellectual property protections for prevention, containment and treatment of COVID-19 have once again put a spotlight on compulsory licensing and march-in rights. Undeniably the COVID-19 pandemic has changed our lives and the way we do things. However, discussions of compulsory licensing and march-in rights are not new. In the U.S., laws historically have been enacted that affect intellectual property rights during times when the need for technology was of utmost importance.

Congress, reacting to a holding of patent infringement liability on government contractors during World War I, enacted a statute that was later codified as 35 U.S.C. §68 (1926) and re-codified as 28 U.S.C. §1498 to protect wartime contractors from patent infringement. See, *Zoltek Corp. v. U.S.*, 815 F.3d 1302 (Fed Cir. 2012) (describing the history of 28 U.S.C. §1498). The later re-codified and so called "Government Use Patent Law" (28 U.S.C. §1498) provided a shield from patent infringement and provided for compensation to patent owners when the U.S. government utilized their patented technology.

Much later the Bayh–Dole Act or Patent and Trademark Law Amendments Act enacted in 1980 further implemented the Government Use Patent Law. Codified in 35 U.S.C. §200-212, Congress passed the

Bayh-Dole Act as a means to commercialize government owned patented technology and grow the economy. The Bayh-Dole Act provided, among other things, standardized federal funding agreements with contractors (37 C.F.R. §401) and uniform licensing of inventions owned by the federal government (37 C.F.R §404). Two important related provisions in the Bayh-Dole Act deal with the grant of exclusive licenses to the invention owned by the U.S. government and "march-in" rights.

March-in Rights

"March-in rights," codified at 35 U.S.C. §203, allow the U.S. government, in certain circumstances listed below, to require contractors or successors in patent title to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If refused by the patent owner, the U.S. government may grant the license by itself. U.S. federal agencies are hesitant to exercise march-in and license patent rights to others due in part to possible trade interference.

March-in rights under 35 U.S.C. §203 are a measure intended to protect against nonuse or unreasonable use of federally funded inventions. The federal agency under whose funding agreement the subject invention was made has the right to require a contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants. Specific circumstances listed under 35 U.S.C. §203 when this may occur include:

1. 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. To alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
3. 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. An agreement required 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.

March-in rights were intended to ensure patent owners commercialized federally funded inventions. However, the threat of using march-in rights has been used by the U.S. government for other reasons such as an attempt to lower certain U.S. pharmaceutical prices. Congressional Research Service Report for Congress, "The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology," by W. Schacht (Dec. 3, 2012).

Proponents of march-in rights assert that they provide an unused mechanism for combatting high drug prices and ensure that U.S. citizens benefit from federal R&D funding. Opponents state march-in rights do not provide such authority, and are limited to the above four specific circumstances. Opponents also contend that use of march-in rights will discourage private enterprise and R&D investment in the often-costly effort required to bring new technologies to commercialization.

Compulsory Licensing

The term "compulsory licensing" described herein refers to various mechanisms implemented for patent use without the patent owner's voluntary authorization. The U.S. government cannot exercise march-in rights when patents are not publicly funded like a COVID-19 vaccine developed without government funding. The U.S. government may use compulsory licensing under 28 U.S.C. §1498 to allow the U.S. government to manufacture, import, or use patented inventions without patent holder permission, but in exchange for "reasonable and entire compensation." (28 U.S.C. §1498). In 2005, the U.S. threatened to

use 28 U.S.C. §1498 to require patent owners of Tamiflu to increase manufacturing if the U.S. was confronted with an avian flu pandemic. The so-called "Physician Immunity Statute" under 35 U.S.C. § 287(c), although not a compulsory license per se, does provide immunity or a license to a medical practitioner or related health-care entity against patent infringement for practicing a medical activity.

The U.S. Supreme Court has not officially opined on the use of compulsory licenses. Some opponents contend that such licenses are unconstitutional in view of the Patent Clause in Article 1, section 8, which empowers Congress to "promote the Progress of Science and useful Arts." The U.S. Supreme Court has recognized the importance of competition to the patent system emphasizing that "free competition" is "the patent system's incentive to creative effort." Limiting the duration of a patent, the Patent Clause reflects a careful "balance" between the need to encourage innovation and the avoidance of monopolies that may stifle competition without any associated advance in the "Progress of Science and useful Arts." (*See, Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 146, 156 (1989) (federal patent laws embody "a careful balance between the need to promote innovation and recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.").

WTO Waiver

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is a multilateral trade agreement on intellectual property (IP) and a WTO founding agreement. The Marrakesh Agreement established the WTO in 1995. The TRIPS Agreement provides minimum protection standards that WTO members must grant to intellectual property held by nationals of fellow WTO members, and certain exceptions to these standards. Under TRIPS, a company does not have standing to sue a WTO member country for violation of the company's intellectual property rights. Instead, the company's country needs to bring a case or threaten the use of sanctions. (*See* TRIPS Agreement, Art. 1(3)-Art. 39). Faced with the COVID-19 pandemic, some WTO members saw an IP waiver as a way to world manufacturing, distributing, and importing already developed vaccines. Absent an IP waiver, a country may suffer trade penalties if production or importation was permitted in violation of rights.

Initially, South Africa and India formally requested the TRIPS Council to recommend an IP waiver to the WTO General Council in October 2020. The request was co-sponsored by several other countries. The initial proposal covered all technologies for the detection, prevention, treatment, and response to COVID-19 including copyright, trade secrets, patents, and designs. The initial waiver proposal would include technology for diagnostic reagents for COVID test kits, manufacturing technology, and therapeutics like Redemsivir (Veklury) and Barticitnib (Olumiant). Countries that opposed this initial proposal included the U.S., E.U., U.K., and Japan. The U.S. later gave support for an IP waiver for IP rights in only vaccines.

In another proposed TRIPS IP waiver, the waiver would be for a limited time until widespread vaccination is in place globally, and would cover Section 1 on copyright and related rights, Section 4 on industrial designs, Section 5 on patents, and Section 7 on the protection of undisclosed information such as trade secrets and know-how. Proponents contend existing vaccine manufacturing capacities in the developing world remained unutilized because of IP barriers. Thus, insufficient amounts of vaccines are produced to end the pandemic. A third way was proposed by WTO Director-General Ngozi Okonjo-Iweala neither using a TRIPS Agreement waiver nor relying on Article 31 *bis* compulsory licenses. This "third way" proposal facilitates (1) technology transfer and (2) the licensing of manufacturing to other manufacturers to produce vaccines and other products. (*See*, Boomer, "International: WTO Considers Waiving Certain IP Protections for the Prevention, Containment, and Treatment of COVID-19," Library of Congress Law: Global Legal Monitor (Mar. 24, 2021).)

Opponents to an IP waiver contend that the TRIPS Agreement is already sufficiently flexible to address public health emergencies, including the use of exceptions and limitations for research, security exceptions, and the grant of compulsory licenses or government use authorizations. In the past, compulsory licenses by the WTO were granted in the event of health emergencies under Article 31 *bis* of the TRIPS Agreement. Article 31 *bis* allows compulsory licenses for the export of patented pharmaceuticals when unavailable in a country that has no or insufficient manufacturing capacity. An intergovernmental organization of developing nations argues that in the case of the COVID-19 pandemic compulsory licensing schemes are problematic because the negotiations are complex, costly, and often inefficient. Opponents also contend manufacturing of complex biologics involves multiple patents owned by different entities. By sharing trade secrets and know-how, the knowledge can be used for producing pharmaceuticals unrelated to COVID-19, threatening several businesses. Others contend the issue isn't IP rights but the challenge of scaling up manufacturing capacity. A COVID-19 vaccine batch takes 60 to 110 days to produce. As stockpiles increase, opponents point to reduction in the supply crisis before an IP waiver agreement is in place. (*See*, Bosse et. al., "US backs TRIPS waiver: More to the story than just vaccine patents," *Business Standard* (May 10, 2021)).

Conclusion

The threatened use of march-in rights and compulsory licensing in the U.S. is not new and will continue to test the balance of a competitive economy. As the world continues to face challenges due to the COVID-19 pandemic, further discussions regarding march-in rights and compulsory licensing are certain to continue.

Keith McWha *is a Partner with Lerner David Littenberg Krumholz & Mentlik, an IP boutique law firm in Cranford.*