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Compulsory Licensing of Patented Inventions

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Summary

The term "compulsory license" refers to the grant of permission for an enterprise seeking to use another's intellectual property without the consent of its proprietor. The grant of a compulsory patent license typically requires the sanction of a governmental entity and provides for compensation to the patent owner. Compulsory licenses in the patent system most often relate to pharmaceuticals and other inventions pertaining to public health, but they potentially apply to any patented invention.

U.S. law allows for the issuance of compulsory licenses in a number of circumstances, and also allows for circumstances that are arguably akin to a compulsory license. The Atomic Energy Act, Clean Air Act, and Plant Variety Protection Act provide for compulsory licensing, although these provisions have been used infrequently at best. The Bayh-Dole Act offers the federal government "march-in rights," although these have not been invoked in the three decades since that legislation has been enacted. 28 U.S.C. Section 1498 provides the U.S. government with broad ability to use inventions patented by others. Compulsory licenses have also been awarded as a remedy for antitrust violations. Finally, a court may decline to award an injunction in favor of a prevailing patent owner during infringement litigation, an outcome that some observers believe is akin to the grant of a compulsory license.

A number of international agreements to which the United States and its trading partners are signatories, including the Paris Convention for the Protection of Industrial Property, World Trade Organization agreements, and certain free trade agreements, address compulsory licensing. In contrast to the United States, the patent statutes of many other nations include general provisions that allow for the award of compulsory licenses under specified conditions. A number of U.S. trading partners, including Brazil, South Africa, and Thailand, have invoked these provisions. The March 9, 2012, decision of the Indian government to grant a compulsory license on the chemotherapy drug sorafenib has attracted controversy.

Some commentators have expressed concern that compulsory licenses substantially diminish incentives for firms to conduct research and development. Others support the grant of such licenses under certain conditions, noting that many patent-granting states suffer from poverty, dire health needs, and a lack of access to patented technologies.

Congress has previously monitored the issuance of compulsory patent licenses by U.S. trading partners and may wish to continue to do so. Legislation dating from the 109th Congress would have allowed the Secretary of Health and Human Services to declare a compulsory license on a patented invention that was needed to address a public health emergency. This legislation was not enacted and has not been reintroduced.

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Introduction

Congressional interest in the patent system has been demonstrated by the recent enactment of the Leahy-Smith America Invents Act (AIA),[1] arguably the most significant amendments to the patent laws since 1952.[2] Subsequent to the enactment of the AIA, Members of Congress have expressed criticism with respect to the grant of compulsory licenses on patented inventions by the trading partners of the United States.[3] Compulsory patent licenses have in fact been a longstanding source of tension between the United States and other nations.[4] However, U.S. law also provides for compulsory licensing of patented inventions under certain circumstances.[5]

The term "compulsory license" refers to the grant of permission for an enterprise seeking to use another's intellectual property to do so without the consent of its proprietor.[6] The grant of a compulsory patent license typically requires the sanction of a governmental entity and provides for compensation to the patent owner. In the patent system, compulsory licenses most often relate to pharmaceuticals and other inventions pertaining to public health, but they potentially apply to information technologies, manufacturing methods, and any other sort of patented invention.

For some observers, compulsory patent licenses present an unwise derogation from the exclusive rights awarded to patent owners. In their view, the routine grant of compulsory licenses will diminish incentives for innovation.[7] On the other hand, other observers believe that compulsory licenses may serve important national interests such as public health and technology transfer.[8]

This report provides an overview of compulsory licenses on patented inventions. It begins with a brief introduction of the patent system and the concept of compulsory patent licenses, including limitations imposed upon World Trade Organization members by the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS" Agreement).[9] The report next reviews the availability of compulsory licenses under U.S. law. The report next considers the practice of compulsory licensing on patented inventions abroad. The report closes with a

[1] P.L. 112-29 (September 16, 2011).

[2] P.L. 82-593 (July 19, 1952).

[3] See Hearing Before the House Committee on the Judiciary, Subcommittee on Intellectual Property, Competition and the Internet, on "International IP Enforcement: Protecting Patents, Trade Secrets and Market Access" (June 27, 2012), 16 (available at http://judiciary.house.gov/hearings/printers/112th/112-119_74817.PDF).

[4] See Christopher Gibson, "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation," 25 *American University International Law Review* (2010), 357.

[5] See Johanna Jacob, "Should Our Genes Be Part of the Patent Bargain? Maximizing Access to Medical Diagnostic Advances While Ensuring Research Remains Profitable," 28 *Santa Clara Computer & High Technology Law Journal* (2012), 403.

[6] See Jarrod Tudor, "Compulsory Licensing in the European Union," 4 *George Mason Journal of Comparative Law* (2013), 222.

[7] See Jon Matthews, "Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards Are Most Dangerous to the United States Healthcare Industry," 4 *Journal of Business, Entrepreneurship, and the Law* (2010), 119.

[8] See, e.g., Chris Strobel, "Wind Power and Patent Law: How the Enforcement of Wind Technology Patents May Lead to Restricted Implementation in the US, and Necessary Solutions," 19 *Journal of Environmental and Sustainability Law* (Spring 2013).

[9] See Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994).

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discussion of the role of compulsory licenses in innovation policy and a review of possible congressional options.

Patent Fundamentals

The patent system is grounded in Article I, Section 8, Clause 8 of the U.S. Constitution, which states that "The Congress Shall Have Power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries...." U.S. patent rights do not arise automatically. Inventors must prepare and submit applications to the U.S. Patent and Trademark Office (USPTO) if they wish to obtain patent protection.[10] USPTO officials known as examiners then assess whether the application merits the award of a patent.[11]

In deciding whether to approve a patent application, a USPTO examiner will consider whether the submitted application fully discloses and distinctly claims the invention.[12] In addition, the application must disclose the "best mode," or preferred way, that the applicant knows to practice the invention.[13] The examiner will also determine whether the invention itself fulfills certain substantive standards set by the patent statute. To be patentable, an invention must consist of a process, machine, manufacture, or composition of matter that is useful, novel, and nonobvious. The requirement of usefulness, or utility, is satisfied if the invention is operable and provides a tangible benefit.[14] To be judged novel, the invention must not be fully anticipated by a prior patent, publication, or other state-of-the-art knowledge that is collectively termed the "prior art."[15] A nonobvious invention must not have been readily within the ordinary skills of a competent artisan at the time the invention was made.[16]

If the USPTO allows the patent to issue, the patent proprietor obtains the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[17] Those who engage in these acts without the permission of the patentee during the term of the patent can be held liable for infringement. Adjudicated infringers may be enjoined from further infringing acts.[18] The patent statute also provides for the award of damages "adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."[19]

[10] 35 U.S.C. §111.

[11] 35 U.S.C. §131.

[12] 35 U.S.C. §112.

[13] Ibid.

[14] 35 U.S.C. §101.

[15] 35 U.S.C. §102.

[16] 35 U.S.C. §103.

[17] 35 U.S.C. §271(a).

[18] 35 U.S.C. §283.

[19] 35 U.S.C. §284.

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The maximum term of patent protection is ordinarily set at 20 years from the date the application is filed.[20] At the end of that period, others may employ that invention without regard to the expired patent.

Patent rights are not self-enforcing. Patentees who wish to compel others to observe their rights must commence enforcement proceedings, which most commonly consist of litigation in the federal courts. Although issued patents enjoy a presumption of validity, accused infringers may assert that a patent is invalid or unenforceable on a number of grounds.[21] The U.S. Court of Appeals for the Federal Circuit (Federal Circuit) possesses national jurisdiction over most patent appeals from the district courts.[22] The U.S. Supreme Court enjoys discretionary authority to review cases decided by the Federal Circuit.[23]

Introduction to Compulsory Licenses

As noted, patents afford their owners the right to exclude others from practicing the patented invention.[24] Patent owners may decline to enforce their exclusionary rights and allow another entity to use their proprietary technology, however. This permission is typically granted in exchange for the payment of a royalty or other consideration. This private contractual arrangement is termed a "license."[25]

In addition to a voluntary license, patents may be subject to a compulsory license. Although no universally accepted definition exists, the term "compulsory license" implies that anyone who meets certain statutory criteria may use the patented invention. The permission of the patent owner is not required. Depending upon particular national laws, the grounds for government award of a compulsory license may include:

- Circumstances of national emergency or extreme urgency.
- Where the invention serves vital public health needs.
- A strong societal interest has arisen in access to the patented invention.
- The patent owner has failed to practice the patented invention in the jurisdiction that granted the patent within a reasonable period of time.
- The patent owner has abused its economic power in such a manner as to violate the antitrust laws.
- In circumstances where multiple patents held by different owners cover a particular technology. For example, combination therapies—such as triple

[20] 35 U.S.C. §154(a)(2). Although patent term is based upon the filing date, the patentee gains no enforceable legal rights until the USPTO allows the application to issue as a granted patent. A number of Patent Act provisions may modify the basic 20-year term, including examination delays at the USPTO and delays in obtaining marketing approval for the patented invention from other federal agencies.

[21] 35 U.S.C. §282.

[22] 28 U.S.C. §1295(a)(1).

[23] 28 U.S.C. §1254(1).

[24] 35 U.S.C. §271.

[25] See, e.g., Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617 (2008).

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> antiretroviral drugs—may be subject to more than one patent. In such cases, if one patent owner refuses to license, then the technology may not be marketed absent a compulsory licensing.[26]

These statutes typically require an interested party formally to request the compulsory license from a foreign government. Competent authorities then decide whether to grant the license as well as the terms of any granted license. While some accounts suggest that formal compulsory licenses are awarded infrequently, the mere existence of a compulsory licensing statute may do much to encourage bargaining between a patentee and an interested manufacturer, on terms favorable to the manufacturer.[27]

Two notable multilateral international agreements address compulsory patent licenses. The first, the Convention of Paris for the Protection of Industrial Property,[28] has been joined by 175 countries including the United States.[29] The Paris Convention states that its member states "have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."[30] Paris Convention member states have agreed that a compulsory license "may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons."[31]

The other significant multilateral agreement that speaks to compulsory patent licensing, a component of the international agreements forming the World Trade Organization (WTO), is the Agreement on Trade-Related Aspects of Intellectual Property Rights.[32] The so-called "TRIPS Agreement" places further limitations upon the ability of WTO member states to award compulsory licenses for the use of another's patented invention. Among the most detailed provisions of the TRIPS Agreement, Article 31 imposes in part the following restrictions upon the issuance of compulsory licenses:

- Each application for a compulsory license must be considered on its individual merits.
- The proposed user must have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. However, this requirement may be waived in the case of national emergency or other circumstances of extreme urgency.

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[26] See, e.g., Katharine W. Sands, "Prescription Drugs: India Values Their Compulsory Licensing Provision—Should the United States Follow in India's Footsteps?," 29 *Houston International Law Journal* (2006), 191.

[27] See Robert P. Merges, "Intellectual Property Rights and the Bargaining Breakdown: The Case of Blocking Patents," 62 *Tennes*See *Law Review* (1994), 75.

[28] 13 I.S.T. 25 (1962) ("Paris Convention").

[29] The list of signatories is available at http://www.wipo.int.

[30] Paris Convention, Art. 5(A)(2). The phrase "failure to work" indicates that the patent proprietor has not practiced the patented invention in that jurisdiction.

[31] Ibid. Art. 5(A)(4).

[32] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Annex 1C, 33 I.L.M. 1197 (1994).

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- The scope and duration of the compulsory license is limited to the purpose for which it was authorized.
- The compulsory license must be nonexclusive—that is to say, the patent owner and possibly other licensed parties may also practice the patented invention.
- Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.
- The compulsory license must be revocable if and when its motivating circumstances cease to exist and are unlikely to recur.
- The patent owner must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.
- The legal validity of any decision relating to the authorization of such use shall be subject to judicial or other independent review.

Article 31(k) of the TRIPS Agreement waives some of these requirements when use of a patented invention "is permitted to remedy a practice determined after judicial or administrative practice to be anti-competitive." In addition, Article 31(l) allows for a compulsory license to issue to allow holders of improvement patents to make use of dominant patents that would otherwise bar the commercialization of an important technical advance.[33]

In November 2001, WTO signatories adopted the Doha Declaration on the TRIPS Agreement and Public Health.[34] The Doha Declaration stated that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." The Doha Declaration granted broad discretion with regard to compulsory licensing, asserting that WTO signatories have "the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] can be granted." In addition, WTO signatories proposed an amendment to the TRIPS Agreement in the form of Article 31bis. That provision allows WTO member states with limited or no manufacturing capacity to declare a compulsory license to import generic drugs from other countries.[35]

The conditions for compulsory licensing within the TRIPS Agreement involve a number of ambiguities. Such terms as "national emergency" or "circumstance of extreme urgency" are not further defined. It is arguably not clear what exactly is meant by the requirement that a compulsory license be granted primarily for the supply of the domestic market. Nor is there any precise definition of what level of "adequate remuneration" to the patent holder suffices. The application of these limitations may not be further understood until a competent tribunal is called upon to interpret them, an event that has yet to occur.[36]

In addition to the TRIPS Agreement and Paris Convention, the United States has entered into a number of free trade agreements that also address compulsory patent licenses. These agreements

[33] See Jerome H. Reichman, "Intellectual Property in the Twenty-First Century: Will the Developing Countries Lead or Follow?," 46 *Houston Law Review* (2009), 1115.

[34] See World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1,41.I.L.M. 746.

[35] See Dina Halajian, "Inadequacy of TRIPS and the Compulsory License: Why Broad Compulsory Licensing Is Not a Viable Solution to the Access to Medicine Problem," 38 *Brooklyn Journal of International Law* (2013), 1191.

[36] See Daniel R. Cahoy, "Breaking Patents," 32 *Michigan Journal of International Law* (2011), 461.

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require their signatories to grant compulsory patent licenses on more restrictive terms than permitted by the TRIPS Agreement or Paris Convention. For example, the Free Trade Agreement between the United States and Australia[37] provides:

> A Party shall not permit the use of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:
>
> (a) to remedy a practice determined after judicial or administrative process to be anticompetitive under the Party's laws relating to prevention of anti-competitive practices; or
>
> (b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:
>
> (i) the Party shall limit such use to use by the government or third persons authorised by the government;
>
> (ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and
>
> (iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.[38]

To the extent that compliance with treaties is desired, member states of the Paris Convention, TRIPS Agreement, and other pertinent international agreements may need to take these provisions into account when addressing compulsory licensing.

Compulsory Licenses Under U.S. Law

In contrast to the patent statutes of many nations, the U.S. patent code does not include a general compulsory licensing provision. However, other domestic laws include provisions that allow for the compulsory licensing of patented inventions. In addition, circumstances that are arguably akin to a compulsory license may occur through antitrust enforcement, judicial determinations in patent infringement litigation, and activities of the federal government.

Specialized Statutes

A modest number of additional compulsory licenses exist with respect to U.S. patents, each pertaining to specialized subject matter.[39] For example, the Atomic Energy Act allows for compulsory licenses "if the invention or discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy."[40] The Clean Air Act contains a similar provision relating to devices for reducing air pollution.[41] Finally, the Plant

[37] United States-Australia Free Trade Agreement, 118 Stat. 919 (May 18, 2004).

[38] Ibid. at Chapter 17.9, Paragraph 7.

[39] *Dawson Chemical Co. v. Rohm and Haas Co.*, 448 U.S. 176 n.21 (1980).

[40] 42 U.S.C. §2183 (2006).

[41] 42 U.S.C. §7608 (2006).

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Variety Protection Act provides for the compulsory licensing of seed-bearing plants that are protected by plant variety certificates, a patent-like instrument granted by the Department of Agriculture.[42]

Research completed in connection with this report has failed to discover even a single instance where any of these compulsory licenses has actually been invoked. Plainly, none of these provisions have been frequently employed in the past.[43] Some commentators speculate that the threat of a compulsory license usually induces the grant of contractual licenses on reasonable terms. As a result, there is no need for the government to invoke a compulsory license formally.[44]

Antitrust Enforcement

Enforcement of the antitrust laws by government entities and private parties on occasion results in a patent owner either agreeing to license its patents to competitors or being compelled to do so.[45] Stated broadly, if an enterprise has been found to have acted in an anticompetitive manner in connection with its patents, then government or private enforcement authorities may call for the enterprise to license those patents to interested parties.[46] This step is arguably akin to the grant of a compulsory license.

The Bayh-Dole Act

The Bayh-Dole Act and accompanying regulations allow government contractors to obtain patents on inventions they made using federal funding.[47] However, the government retains a "march-in right" that allows the funding agency to grant additional licenses to other "reasonable applicants."[48] March-in rights are available only where the contractor

- has not taken effective steps to achieve practical application of the invention;
- has not reasonably satisfied health and safety needs;
- has not met requirements for public use specified by federal regulation; or
- has granted an exclusive right to use the patented invention to another without obtaining the promise that the invention will be manufactured substantially in the United States.[49]

[42] 7 U.S.C. §2404 (2006).

[43] See Kenneth J. Nunnenkamp, "Compulsory Licensing of Critical Patents Under CERCLA?," 9 *Journal of Natural Resources and Environmental Law* (1993-94), 397, 406 (noting that "there Seems to have been no attempts to actually use the compulsory licensing provision" of the Clean Air Act).

[44] Stephen Pericles Ladas, *Patents,Trademarks and Related Rights: National and International Protection* (Cambridge, Mass., Harvard University Press 1975), 427.

[45] See Colleen Chien, "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?," 18 *Berkeley Technology Law Journal* (2003), 853.

[46] See, e.g., Untied States v. 3D Systems Corp., 2001 WL 964343 (D.D.C. 2001).

[47] See CRS Report RL32076, *The Bayh-Dole Act: Selected Issues in Patent Policy and the Commercialization of Technology*, by Wendy H. Schacht.

[48] 35 U.S.C. §203(a).

[49] Ibid.

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The march-in right, which is arguably identical or similar to a compulsory license, has yet to be exercised.[50]

Judicial Denial of Injunction

An injunction consists of a court order preventing or commanding a particular action. Prior to 2006, courts would virtually always enjoin an adjudicated infringer from future practice of the patented invention. This rule changed following the issuance of the Supreme Court decision in *eBay Inc. v. MercExchange, L.L.C.*[51] There the Court unanimously held that an injunction should not automatically issue based on a finding of patent infringement. Under the *eBay* ruling, courts must weigh equitable factors traditionally used to determine if an injunction should issue, including whether the patent proprietor suffered an irreparable injury; the award of damages would be inadequate to compensate for that injury; that considering the balance of hardships between the patent owner and infringer, an injunction is warranted; and that the public interest would not be disserved by a permanent injunction.[52]

Following the *eBay* decision, courts most often award an injunction to the prevailing patentee.[53] They have also declined to do so, however, particularly where the patent owner does not commercialize the claimed invention, where the patented invention forms a small component of a larger product, and where the patent owner had liberally licensed its patented invention to others.[54] In such cases the adjudicated infringer may continue to practice the patented invention but usually must pay a royalty to the patent proprietor until the term of the patent expires.[55]

Judicial unwillingness to enjoin an adjudicated infringer differs as a technical matter from the usual understanding of a compulsory license. Compulsory licenses are generally available to any entity that meets the statutory requirements, in contrast to the specific adjudicated infringer involved in a single litigation. As a result, some federal jurists prefer to use the term "ongoing royalty" to describe circumstances where courts have declined to award a permanent injunction but require the payment of royalties by the infringer during the term of the patent.[56] However, for some, the distinction between a compulsory license and an "ongoing royalty" is one without a difference.[57]

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[50] See Nida Shakir, "The National Institutes of Health, Patents, and the Public Interest: An Expanded Rationale of Justice Breyer's Dissent in Stanford v. Roche," 17 *Marquette Intellectual Property Law Review* (Winter 2013), 143

[51] 547 U.S. 388 (2006).

[52] See Mark P. Gergen et al., "The Supreme Court's Accidental Revolution: The Test for Permanent Injunctions," 112 *Columbia Law Review* (2012), 203.

[53] See University of Houston Law Center, *Patstats: U.S. Patent Litigation Statistics* (June 19, 2013) (available at http://www.patstats.org/Patstats3.html).

[54] Ronald J. Schultz & Patrick M. Arenz, "Non-Practicing Entities and Permanent Injunctions Post-e*Bay*," 12 *Sedona Conference Journal* (2011), 203.

[55] See ActiveVideo Networks, Inc. v. Verizon Communications, Inc., 694 F.3d 1312 (Fed. Cir. 2012).

[56] See Paice LLC v. Toyota Motor Corp., 504 F.3d 1293, 1313 n.13 (Fed. Cir. 2007).

[57] See Andrew C. Mace, "TRIPS, *eBay*, and Denials of Injunctive Relief: Is Article 31 Compliance Everything?," 10 *Columbia Science & Technology Law Review* (2009), 232.

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Uses by the U.S. Government

The U.S. government possesses the power to take private property for public use. For example, the government may condemn a parcel of land in order to build a highway. This authority is ordinarily termed "eminent domain." This government right is not unlimited, however. In particular, in some circumstances the government must compensate the property owner for use of the property.[58]

These general principles are most frequently applied to real estate, but they potentially apply to intellectual property as well.[59] As a result, the U.S. government effectively enjoys the ability to declare a compulsory license that allows it to use a patented invention without obtaining the permission of the patentee. In turn, the federal government has consented to suit by private patent owners in order to obtain compensation.[60] Section 1498(a) of Title 28 of the U.S. Code provides in part:

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

Under Section 1498(a), all patent suits against the U.S. government are litigated in the U.S. Court of Federal Claims. That statute limits available remedies to "reasonable and entire compensation" to the patent owner. As a result, the government may not be enjoined from practicing a patented invention. The courts have also generally limited the damages that the government must pay to the patentee to the level of a "reasonable royalty." A "reasonable royalty" for purposes of patent infringement damages is "the amount that a person desiring to manufacture or use a patented article, as a business proposition, would be willing to pay as a royalty and yet be able to make or use the patented article, in the market at a reasonable profit."[61]

Compulsory Licenses Abroad

The patent statutes of many U.S. trading partners include general provisions that allow for the award of compulsory licenses under specified conditions.[62] These circumstances include public health needs, inadequacy of supply of the patented invention, failure to practice the patented invention within the jurisdiction, and other public interest rationales.[63] Reportedly, a number of jurisdictions have invoked these provisions since the advent of the TRIPS Agreement, including,

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[58] See CRS Report RS20741, *The Constitutional Law of Property Rights "Takings": An Introduction*, by Robert Meltz.

[59] Thomas F. Cotter, "Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?," 50 *Florida Law Review* (1998), 529.

[60] See Lionel Marks Lavenue, "Patent Infringement Against the United States and Government Contractors Under 28 U.S.C. §1498(a) in the United States Court of Federal Claims," 2 *Journal of Intellectual Property Law* (1995), 389.

[61] Wright v. United States, 53 Fed. Cl. 466 (2002).

[62] See Cole M. Fauver, "Compulsory Patent Licensing in the United States: An Idea Whose Time Has Come," 8 *Northwestern Journal of International Law and Business* (1988), 666.

[63] See Christopher Gibson, "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation," 25 *American University International Law Review* (2010), 357.

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among others, Cameroon,[64] Ecuador,[65] Egypt,[66] Eritrea,[67] Ghana,[68] Italy,[69] Kenya,[70] Malaysia,[71] Mozambique,[72] Zambia,[73] and Zimbabwe.[74] This paper reviews a number of notable incidents with respect to compulsory licenses on patented inventions, focusing on Brazil, India, South Africa, and Thailand.

Brazil

In response to its accession to the WTO, Brazil enacted a new industrial property law that in part addressed compulsory patent licenses.[75] The 1997 statute allowed the issuance of compulsory licenses for "non-exploitation of the object of the patent within the Brazilian territory for failure to manufacture or incomplete manufacture of the product...."[76] The United States initiated proceedings before the WTO asserting that the Brazilian law violated the TRIPS Agreement. In particular, the United States alleged that the Brazilian statute violated a TRIPS Agreement requirement that patents must be "enjoyable without discrimination as to ... whether patents are imported or locally produced."[77] Brazil and the United States ultimately agreed to a "mutually satisfactory situation" under which Brazil agreed to hold talks with the U.S. government prior to granting compulsory license on patents owned by U.S. companies.[78] The WTO proceedings were then terminated.

Under the 1997 statute, Brazil issued a compulsory license in 2007 for the AIDS drug efavirenz, which is sold by Merck & Co. under the trademark STOCRIN®.[79] Reportedly Merck lowered the price under which it sold efavirnz to the satisfaction of the Brazilian authorities following the issuance of the compulsory license, thereby rendering this action moot.[80] In addition, the

[64] See Vera Zolotaryova, "Are We There Yet? Taking 'TRIPS' to Brazil and Expanding Access to HIV/AIDS Medication," 33 *Brooklyn Journal of International Law* (2008), 1099.

[65] See Donald Harris, "TRIPS After Fifteen Years: Success or Failure, As Measured by Compulsory Licensing," 18 Journal of Intellectual Property Law (2011), 367.

[66] See Sean Baird, "Magic and Hope: Relaxing TRIPS-Plus Provisions to Promote Access to Affordable Pharmaceuticals," 33 *Boston College Journal of Law & Social Justice* (2013), 107.

[67] See Harris, *supra*.

[68] Ibid.

[69] See Jarrod Tudor, "Compulsory Licensing in the European Union," 4 *George Mason Journal of International Commercial Law* (2013), 222.

[70] See Harris, *supra*.

[71] See Umar R. Bakhsh, "The Plumpy'Nut Predicament: Is Compulsory Licensing a Solution?", 11 *Chicago-Kent Journal of Intellectual Property* (2012), 238.

[72] See Zolotaryova, *supra*.

[73] Ibid.

[74] See Harris, *supra*.

[75] See Naomi A. Bass, "Implication of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century," 34 *George Washington International Law Review* (2002), 191.

[76] Ibid. at Art. 68 (1)(I).

[77] TRIPS Agreement, Art. 27(1).

[78] Brazil—Measures Affecting Patent Protection, WT/DS199/4 (July 19, 2001).

[79] See Mariana Moto Prado, "The Debatable Role of Courts in Brazil's Health Care System: Does Litigation Harm or Help?," 41 *Journal of Law, Medicine & Ethics* (Spring 2013), 124.

[80] See Riadh Quadir, "Patent Stalemate? The WTO's Essential Medicines Impasse Between Pharmas and Least Developed Countries," 61 *Rutgers Law Review* (2009), 437.

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Brazilian government has reportedly used the threat of issuing compulsory licensing to receive discounts on AIDS therapies.[81]

India

On March 9, 2012, the Controller of Patents issued what is reportedly India's first compulsory license.[82] The compulsory license relates to the chemotherapy drug sorafenib, sold by Bayer & Co. under the trademark NEXAVAR®. According to the Controller, Bayer failed to provide sufficient NEXAVAR® to meet public demand, did not sell NEXAVAR® at a reasonably affordable price, and did not manufacture NEXAVAR® in India. As a result, the Controller awarded a license to Natco Pharma Ltd., an Indian generic firm, to manufacture a generic version of NEXAVAR®. Under the Controller's decision, Natco was required to pay a royalty at the rate of 6% of net sales of the drug to Bayer.[83] The Intellectual Property Appellate Board of India upheld the Controller's decision on March 4, 2013, although it increased the royalty owed to Bayer from 6% to 7%.[84]

Following the grant of the NEXAVAR® compulsory license, Indian authorities are reportedly considering the grant of compulsory licenses for Genetech's breast cancer drug HERCPETIN®, BMS's breast cancer drug IXEMPRA®, and BMS's leukemia drug SPRYCEL®.[85]

South Africa

In 1997, the South African legislature passed a law to allow, among other measures, the compulsory licensing of patented pharmaceuticals. The South African Pharmaceutical Manufacturers' Association and numerous pharmaceutical companies subsequently commenced litigation, asserting that the law violated both the TRIPS Agreement and South Africa's own patent statute. South Africa agreed to redraft in keeping with the TRIPS Agreement and to consult with the pharmaceutical industry on the proposed amendment, while the pharmaceutical industry agreed to withdraw the lawsuit.[86] Domestically, the incident reportedly prompted the issuance of Executive Order 13,155 by President Clinton on May 10, 2000. That Order prohibits the United States "from taking action pursuant to section 301(b) of the Trade Act of 1974 with respect to any law or policy in beneficiary sub-Saharan African countries that promotes access to HIV/AIDS

[81] See Zita Lazzarini, "Making Access to Pharmaceuticals A Reality: Legal Options Under TRIPS and the Case of Brazil," 6 *Yale Human Rights and Development Law Journal* (2003), 103.

[82] See Naval Satarawala Chopra & Dinoo Muthappa, "The Curious Case of Compulsory Licensing in India," 8 *Competition Law International* (August 2012), no. 2 at 34.

[83] Natco Pharma Limited v Bayer Corporation, Compulsory Licence Application No 1/2011 (March 9, 2012) (available at http://patentdocs.typepad.com/files/compulsory-license-application.pdf).

[84] O.R.A. no. 35/PT/2012.

[85] See Tracy Staton, "India to Hit Roche, BMS with Compulsory License on 3 Cancer Drugs," FiercePharma (January 13, 2013) (available at http://www.fiercepharma.com/story/india-hit-roche-bms-compulsory-licenses-3-cancer-drugs/2013-01-13).

[86] See Erika George, "The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines," 18 *Indiana Journal of Global Legal Studies* (2011), 167.

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pharmaceuticals or medical technologies and that provides adequate and effective intellectual property protection consistent with the TRIPS Agreement."[87]

Although the South African government apparently did not invoke the contested provisions, it subsequently determined that providers of two patented HIV/AIDS medicines had committed antitrust violations. In particular, in 2003 the South African Competition Commission concluded that the providers had engaged in excessive pricing and denied competitors access to an essential facility. The Commission subsequently settled with the providers on terms that required these providers to license several competitors to sell the patented medications.[88]

Thailand

Thailand issued seven compulsory patent licenses from 2006 through 2008. The compulsory licenses concerned patents claiming:

- the AIDS drug efavirenz (sold by Merck & Co. under the trademark STOCRIN®);[89]
- the combination AIDS drug of lopinavir and ritonavir (sold by Abbott under the trademark KALETRA®);[90]
- the antiplatelet drug clopidegrel (sold by Bristol Myers under the trademark PLAVIX®);[91]
- the breast cancer medicine letrozole (sold by Novartis AG under the trademark FEMARA®);[92]
- the breast and lung cancer drug docetaxel (sold by Sanofi-Aventis under the trademark TAXOTERE®);[93]
- the lung, pancreatic, and ovarian cancer drug erlotinib (sold by Roche under the trademark Tarceva TARCEVA®);[94] and
- the cancer drug Imitinab (sold by Novartis AG as GLEEVEC®).[95]

[87] 65 Fed. Reg. 30521, 30522.

[88] See Sarah Bosley, "Ruling Open the Door for Cut-Price HIV Drugs," *The Guardian* (October 17, 2003)

[89] Thawach Suntrajarn, Director General, Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public Use of Patent for Pharmaceutical Products (available at http://www.cptech.org/ip/health/c/thailand/thaicl4efavirenz.html).

[90] Thawach Suntrajarn, Director General, Decree of Department of Disease Control, Ministry of Public Heath, "Regarding Exploitation of Patent on Drugs and Medical Supplies by the Government on Combination Drug Between Lopinavir and Ritonavir" (January 29, 2007) (available at http://www.cptech.org/ip/health/c/thailand/thai-cl-kaletra_en.pdf).

[91] Prat Boonyawongvirot, Permanent Secretary, Ministry of Public Health, "Announcement Regarding Exploitation of Patents on Drugs and Medical Supplies for Clopidogrel" (January 25, 2007) (available at http://www.cptech.org/ip/health/c/thailand/thai-cl-clopidogrel_en.pdf).

[92] Ministry of Public Health and the National Health Security Office, "The 10 Burning Questions on the Government Use of Patents on the Four Anti-Cancer Drugs in Thailand" (February 2008) (available at http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf).

[93] Ibid.

[94] Ibid.

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The Thai compulsory licenses attracted controversy due to their relatively large number, Thailand's status as a middle-income country, and concerns that the Thai government had not complied with the TRIPS Agreement.[96] In addition, five of the compulsory licenses concerned drugs for treating cancer and heart diseases—chronic, noninfectious diseases that are common in developed countries.[97] However, public health advocates applauded the Thai government's willingness to address the needs of its citizens.[98]

Issues and Observations

Observers who have supported the ability of patent-granting states to issue compulsory licenses have pointed out that the rules established under the TRIPS Agreement are quite liberal. Compulsory licenses are not limited to patents relating to contagious diseases; indeed, they are not limited to health emergencies at all. Under the TRIPS Agreement, any patent may potentially be subject to a compulsory license.[99] They also assert that the United States allows compulsory licenses to issue with respect to patents through a number of mechanisms.[100]

Still others observe that many least-developed and developing nations suffer from severe public health problems. These jurisdictions also may have limited ability to pay for patented medications.[101] Further, in the view of some commentators, because many of these nations offer small markets, their use of compulsory licenses is likely to have a negligible impact on innovation.[102]

On the other hand, some commentators believe that the grant of compulsory licenses diminishes incentives for enterprises to undertake research and development.[103] In their view, the pharmaceutical industry is less likely to endeavor to develop new drugs if they can expect that their patents will be subject to compulsory licenses, thereby causing the industry to lose its

(...continued)

[95] Ibid.

[96] Mingchanok Tejavanija, "A New Kind of Drug War: Thailand's Taking on the Pharmaceutical Industry to Improve Access to HIV/AIDS Drugs Through the Use of Compulsory Licensing," 28 *Arizona Journal of International and Comparative Law* (2011), 659.

[97] Nattapong Suwan-In, "Compulsory License, a Long Debate on TRIPS Agreement Interpretation: Discovering the Truth of Thailand's Imposition on Pharmaceutical Patents," 7 *Asian Journal of WTO & International Health Law & Policy* (2012), 225.

[98] Ibid.

[99] See Cynthia M. Ho, "Patent Breaking or Balancing?: Separating Strands of Fact from Fiction Under TRIPS," 34 North Carolina Journal of International Law and Commercial Regulation," 34 *North Carolina Journal of International Law and Commercial Regulation* (2009), 371.

[100] See James Love and Tim Hubbard, "Prizes for Innovation in New Medicines and Vaccines," 18 *Annals of Health Law* (Summer 2009), 155.

[101] See Rudolf V. Van Puymbroeck, "Basic Survival Needs and Access to Medicines—Coming to Grips with TRIPS: Conversion+Calculation," 38 *Journal of Law, Medicine & Ethics* (2010), 520.

[102] See Kristina M. Lybecker and Elisabeth Fowler, "Compulsory Licensing in Canada and Thailand: Comparing Regimes to Ensure Legitimate Use of the WTO Rules," 37 *Journal of Law, Medicine & Ethics* (2009), 222.

[103] See Richard A. Epstein and F. Scott Kieff, "Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents," 78 *University of Chicago Law Review* (2011), 71.

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expected earnings.[104] To the extent that the U.S. firms are subject to these measures, the issuance of compulsory licenses may also negatively impact the U.S. economy.[105]

Commentators have also observed that although most compulsory licenses have been issued by developing and least-developed nations, these jurisdictions might have the most to lose by doing so. Pharmaceutical firms might devote fewer resources towards developing cures for diseases, such as malaria and tuberculosis, which primarily plague the developing world. Instead, a rational actor would allocate resources towards medicines that are likely to have a successful commercial market in developed countries.[106] In addition, the issuance of compulsory licenses may discourage foreign direct investment in that jurisdiction.[107]

Should Congress consider current circumstances with respect to compulsory licenses to be appropriate, then no action need be taken. Alternatively, Congress may wish to review whether domestic legislation providing for compulsory patent licenses is appropriate. The most recent bill relating to compulsory licensing, the Public Health Emergency Medicines Act in the 109th Congress, would have created an additional compulsory license in the patent law. This bill, H.R. 4131, would have allowed the government to use the patented invention without the patent owner's permission if the Secretary of Health and Human Services determined that the invention is needed to address a public health emergency. Under the bill, the Secretary of Health and Human Services would have determined compensation for government use of the patented invention. In determining the reasonableness of remuneration for use of a patent, the Secretary of Health and Human Services may consider—

> (1) evidence of the risks and costs associated with the invention claimed in the patent and the commercial development of products that use the invention;
>
> (2) evidence of the efficacy and innovative nature and importance to the public health of the invention or products using that invention;
>
> (3) the degree to which the invention benefitted from publicly funded research;
>
> (4) the need for adequate incentives for the creation and commercialization of new inventions;
>
> (5) the interests of the public as patients and payers for health care services;
>
> (6) the public health benefits of expanded access to the invention;
>
> (7) the benefits of making the invention available to working families and retired persons;

[104] See Samuel Mark Borowski, "Saving Tomorrow from Today: Preserving Innovation in the Face of Compulsory Licensing," 36 *Florida State University Law Review* (2009), 275.

[105] See Jamie Feldman, "Compulsory Licenses: The Dangers Behind Current Practice," 8 *Journal of International Business* Law (2009), 137.

[106] Stephanie Skees, "Thai-Ing Up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand's AIDS Epidemic?," 19 *Pace International Law Review* (2007), 233.

[107] See Lawrence A. Kogan, "Commercial High Technology Innovations Face Uncertain Future Amid Emerging 'BRICS' Compulsory Licensing and Its Interoperability Frameworks," 13 *San Diego International Law Journal* (2011), 201.

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(8) the need to correct anti-competitive practices; and

(9) other public interest considerations.[108]

This legislation was not enacted.

Congress may also wish to continue to monitor the activity of U.S. trade partners with respect to compulsory patent licenses. For example, on June 18, 2013, 171 Members of Congress wrote to President Obama expressing concern over India's "intellectual property (IP) climate." The letter in part observed:

> [T]he Indian Government issued its first compulsory license (CL) on a stage three liver and kidney cancer drug. It has been reported that additional drugs may be subject to CLs imminently and that the decisions related to these CLs are being improperly driven by an interest in growing the pharmaceutical market in India. These actions by the Indian Government greatly concern us because innovation and the protection of intellectual property are significant driving engines of the U.S. economy.[109]

The letter urged the President "to make sure these issues are raised at the highest levels of the Indian government."

Compulsory licenses for patented inventions highlight the tension between two competing aspirations of the patent system: Encouraging the labors that lead to innovation, on one hand, and placing the fruits of those labors before the public, on the other. As different patent-granting states possess distinct perceived interests and values with respect to innovation, proprietary rights, and public health and other social needs, conflicts among these jurisdictions have occurred in the post-WTO era. Assessing the role of compulsory licenses within the patent system of the United States and our trading partners remains a matter for congressional judgment.

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[108] H.R. 4131, Section 2 (proposing to add a new §158 to the Patent Act). The bill had been previously introduced in the 109th Congress as H.R. 4102.

[109] The letter is available at http://paulsen.house.gov/uploads/India%20IP%20Letter%20Signed.pdf.

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