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Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in the Absence of an Experimental Use Exception

Kimberly M. Thomas†

Abstract

The experimental use exception permits researchers and their institutions to make certain uses of patent inventions for purposes of experiment or research. Unfortunately, this judicially created doctrine is applied infrequently and is interpreted narrowly. Thus, in most cases, researchers do not have a patent infringement defense under which they can conduct basic research. This comment argues that a compulsory patent licensing provision based on a reformation of the Bayh-Dole Act may solve this problem. This comment analyzes several economically developed foreign nations that use patent compulsory licensing provisions as a base for the U.S. implementation. Section II discusses the history of the U.S. experimental use exception. Section III discusses the impact and implications of the Madey v. Duke University decision on U.S. research. Section IV gives the doctrinal background on the theory of compulsory licensing, international treatment of compulsory licensing, and the purpose of Bayh-Dole Act in the United States. Section IV also discusses how the U.S. can utilize the ideas of other countries to reanalyze and amend the Bayh-Dole Act to produce our own compulsory licensing legislation in light of a non-existent experimental use defense. Section V provides some final observations on compulsory licensing.

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I. INTRODUCTION

In the United States, the common law experimental use exception permits researchers and their institutions to make certain uses of patent inventions for purposes of experiment or research. The exception is a favorable defense against a claim that the accused researcher has infringed a valid patent. The exception is neither a part of the patent granting process nor is it within the jurisdiction of the United States Patent and Trademark Office. Instead, the exception is under the jurisdiction of the courts whenever a patent infringement case is before it. In short, one must look to commercial practice, legislation, and past court decisions in order to understand the nature of the exception.

While the courts recognize the exception to patent infringement, this judicially created doctrine is described as very narrow and rarely applied. In particular, the exception applies only for actions performed “for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.” Further, the exception is not applied if there is the slightest hint of a commercial application. This would also exclude non-commercial use that is consistent with legitimate business. In short, the U.S. does not possess a ‘much-needed’ patent infringement defense that researchers could utilize for conducting basic research.

Through compulsory licensing, the government can compel a patent holder to license the patent, allowing for production and distribution of patented products to the public. This comment argues for a patent compulsory licensing provision, with an emphasis on

3. See id. at 2169-70.
4. See id.
5. Id. at 2173-74.
7. Id. at 1362.
8. Id. The court, in its reasoning, provided that the institution’s research projects, including education and enlightening students and faculty that took part in research projects, furthered the institution’s legitimate business objectives. Id.
A COMPULSORY LICENSING PROVISION

II. HISTORY OF THE EXPERIMENTAL USE EXCEPTION IN THE US

The experimental use defense in U.S. patent law has its origin in an opinion written in 1813 by Justice Story. In *Whittemore v. Cutter*, a patent infringement case, Justice Story stated "that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects." Unfortunately for academic and non-

10. See 35 U.S.C. §§ 200-212 (2000). The Bayh-Dole Act allows recipients of federal funds, regardless of their for-profit or non-profit status, to patent their inventions. These patentees may then sell or grant exclusive or non-exclusive licenses, though there is a preference for licensing to small businesses, and non-profit entities may need federal permission to fully assign their patent rights.

11. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002). *Madey* significantly narrowed the experimental use exception, and is likely to significantly influence the way in which academic scientific research is conducted. *Id.* at 1362.


13. *Id. See also* Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D.Mass. 1813) (No. 12,391) ("This court has... held that the making of a patented machine to be an offence... must be the making with an intent to use for profit, and not for the mere purpose of philosophical experiment, or to ascertain the verity... of the specification." (citing Whittemore, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600)).
profit researchers, the view that there is no infringement and thus, no requirement for a license to practice the patented invention if such experiments are for the sole purpose of philosophical inquiry, does not carry forward to the present day. Instead, if the products of the experiment are sold or used by the researcher or if the experiments are conducted with a view to adapting the invention for commercial purposes, the acts of the researcher are infringing and thus the proper subject of a license from the patent owner.

In addition, subsequent cases have limited the doctrine to very narrow grounds. In Roche Products, Inc. v. Bolar Pharmaceutical Co., the United States Court of Appeals for the Federal Circuit ("Federal Circuit") recognized the existence of a common law experimental use exception but construed its scope very narrowly. The court held that the use of a patented active ingredient by the competitor to perform tests necessary to obtain approval of the Food and Drug Administration (FDA) for a generic drug did not fall within the experimental use exception to the patent right. The court reasoned that the competitor's experimental use was "solely for business reasons and not for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." In particular, the court stated that the competitor could not "construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and non-insubstantial commercial purposes.'

Thereafter, in Embrex, Inc. v. Service Engineering Corp., the Federal Circuit reconfirmed the restricted nature of the common law experimental use doctrine. Citing Roche, the court did not exempt experiments that were conducted in order to design around the patented subject matter. The patented subject matter related to

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15. See generally id.
16. See generally id.
18. Id.
19. Id.
20. Id.
22. Id.
"methods of inoculating birds against disease by injecting vaccines into a specified region of the egg" before hatching. The court held that the patent was infringed, as tests performed by the competitor to investigate the possibility of injecting chicken embryos outside the region covered by the patent were neither experimental use nor de minimis, since the tests were performed for commercial purposes.

Despite the court's narrow interpretation of the experimental use exception, academic researchers have long believed that the scope of the experimental use exception should extend to at least experimentation performed at universities or non-profit institutions. This belief, however, was dispelled by the Madey v. Duke University decision. In Madey, The Federal Circuit held that Duke University was not immunized from patent infringement when it used patented research equipment for experimental purposes. The decision called for a restricted status against universities that pursued aggressive patent policies and obtained substantial revenue from their patents.

The exception's restricted nature has caused researchers to fear that they will have to redirect their attention from research activities to expensive and time-consuming patent searches, infringement opinions, licensing activities, and inevitable litigation - all of which will cause substantial administrative and financial costs. Furthermore, researchers are concerned that U.S. academic research will be diverted to foreign institutions in countries with broader experimental use exceptions. More importantly, the narrow reading of the exception limits a researcher's access to state of the art technologies and thus discourages further technological development in the interest of the public.

The basic research conducted by academic and non-profit institutions leads to innovations and inventions, in such areas as

23. Id. at 1346.
24. Id. at 1349.
27. Id. at 1362.
28. Id. at 1362-63 n.7.
29. See Cai, supra note 25, at 185.
31. See id.
pharmaceuticals, health care, and biotechnology, which is an industry that has been built almost entirely on the shoulders of academic research.\textsuperscript{32} It has been determined that, in the U.S., universities are significantly responsible for more than half of the basic research.\textsuperscript{33} For example, statistics show that in 1997 universities contributed and conducted 14.5\% of all research and developmental activity.\textsuperscript{34} Therefore, it cannot be overlooked that researchers at universities and non-profit institutions have played a key role in scientific advancements that benefit the American public's safety and welfare.

As research grows increasingly complicated, it becomes imperative that researchers must collaborate not only with each other but also must seek legal and legislative changes to solve the challenges that they face.\textsuperscript{35} Therefore, many university researchers and non-profit institutions understand that to promote their scientific endeavors, they must now depend on access to proprietary enabling research and technologies held by others.\textsuperscript{36} However, the \textit{Madey} decision made such transfer of knowledge more difficult through the increase of researchers' administrative burdens.\textsuperscript{37} Despite this fact, it cannot be denied that some of the "mega-universities" of the U.S. are very much in the "business" of research and are not completely separated from commercial enterprises. As \textit{Madey} states, Duke University, like many other major educational research institutions, is "not shy in pursuing an aggressive licensing program from which it derives a not insubstantial revenue stream."\textsuperscript{38} Therefore, such savvy profit-producing institutions' use of the patented inventions of others leaves them vulnerable with no immunity from claims of patent infringement.\textsuperscript{39} However, because university researchers are less knowledgeable in the legal analysis of infringement, many rarely check patent databases to determine whether their innovations infringed any patents issued to commercial or industrial entities.\textsuperscript{40}

\begin{footnotes}
33. Id.
34. Id.
39. See Barash, \textit{supra} note 35, at 698.
40. Id.
\end{footnotes}
Therefore, should universities and non-profit institutions be penalized in their quest to conduct the basic research that is needed to continue to keep this country safe, healthy, and flourishing?

III. THE EFFECT OF A NON-EXISTENT EXCEPTION ON ACADEMIC AND NON-PROFIT RESEARCH IN THE U.S.

The Madey decision provoked outcries among universities and non-profit research institutions that feared the decision would significantly impede the nation’s scientific advancement by either limiting or totally eliminating the experimental use exception. In 1998, Dr. John Madey sued Duke University, a prestigious private university, for patent infringement of his two patents. The issue in Madey was whether research using patented technology by the major research university, whose legitimate business includes conducting research, constitutes “experimental use.” Duke asserted the experimental use defense as one of its defenses to the charge, arguing that it had set up the equipment that used Madey’s two patents only to run experiments in the University’s free electron laser laboratory.

The Federal Circuit was not persuaded by Duke’s arguments and held that “regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain,” the experimental use defense is unavailable “so long as the act is in furtherance of the alleged infringer’s legitimate business...” Legitimate business was defined as “educating and enlightening students and faculty participating in... projects,... increas[ing] the status of the institution, and lur[ing] lucrative grants, students and faculty.” In essence, legitimate business refers not only to commercial endeavors in the marketplace, but also to any activity that serves an institution’s mission, even when that mission is manifestly noncommercial. Therefore, in this formulation, research conducted at a research university qualifies as legitimate business activity for which no

43. See id. at 1361-62.
44. Id. at 1353.
45. Id. at 1362.
46. Id. (stating that all research institutions “are in the business of conducting research and development.”)
infringement protection applies. The effect of the Federal Circuit refusal to delineate and craft an appropriate judicial standard for the experimental use exception in Madey is to restrict access to patented research and technology, limiting the types of creative and intellectual works that researchers can produce.48 With virtually no immunity and protection from unscrupulous patent infringement suits, the general research activities aimed at creating and improving inventions at academic and non-profit research institutions will come to a halt unless a solution is brought to the forefront of this troublesome issue.

IV. THE NEED FOR A COMPULSORY LICENSING PROVISION IN THE U.S. FOR PUBLIC INTEREST REASONS

One does not have to reach back far in time to find a situation that could have benefited from a public interest compulsory licensing provision. In the aftermath of the terrorist attacks of September 11, 2001 and the subsequent anthrax scares,49 the Bush administration


On September 18, 2001, letters containing coetaneous anthrax spores traveled through New Jersey postal facilities bound for Tom Brokaw and The New York Post . . . . Once medical personnel determined that the suspect letters contained anthrax, . . . . [p]ublic health officials fear[ed] a national shortage of the antibiotic, [ciproflaxin,] in the event of a future mass exposure. The Canadian government became so engrossed in the possibility of a mass exposure that it hastily granted a compulsory license for ciproflaxin production to a Canadian producer. U.S. Senator, Charles E. Schumer, . . . . urged the Bush Administration that allowing the generic production of ciproflaxin was imperative to procure a sufficient ciproflaxin stockpile for use by the American people in the event of a widespread bioterrorism attack. Tommy Thompson, the United States Department of Health and Human Services (HHS) Secretary, initially did not believe he had the authority to grant Senator Schumer's request. Upon ascertaining his legal authority to override the ciproflaxin patent, Secretary Thompson refrained from implementing Senator Schumer's proposal.

The Secretary intended to negotiate with Bayer for a better price for taxpayers, rather than break the ciproflaxin patent. If Bayer did not meet the price concessions desired by the U.S. government, Secretary Thompson possessed the power to authorize generic production of ciproflaxin under U.S. law and the TRIPS agreement. After negotiations, Bayer granted the United States government a significant price reduction for ciproflaxin, bringing its governmental price from $1.86 per pill, to $0.95 per pill. Faced with a public health emergency, the United States implemented a developing country's negotiation tactics and thereby broadened Article 31's interpretation.

Id. at 403-05.
considered invoking a compulsory license for an antibiotic that was approved for treatment of the infection. While the parties were able to reach an agreement before a compulsory licensing provision was enacted, it should not be overlooked that it took a threat of 'mega-proportion' to threaten the invocation of such legislation. Should Congress forever be required to move quickly to enact legislation only when a national emergency arises? It seems plausible that with an effective compulsory licensing scheme already in place and within the laws of the U.S., the citizens of this country would not have to walk such a thin rope in protecting their interests.

Consequently, the U.S. needs a proactive mechanism to quickly access enabling research and technology to grapple with public interest matters in time-sensitive situations and emergencies. The mechanism could be carried out in a "ready-to-go" public interest compulsory licensing scheme enacted by Congress. The proposed compulsory licensing scheme in the U.S. should be based on the philosophy that researchers and scientists best conduct science. As a result of compulsory licensing legislation, researchers are given the benefit of the doubt as they determine when experimentation begins and ends. Therefore, society encourages innovation and protects what is most important, America's well being.

The idea of infringing a patent and enacting compulsory licensing for the public's interest is not a far-fetched idea in the U.S. For example, in City of Milwaukee v. Activated Sludge, Inc., the Court of Appeals for the Seventh Circuit vacated an order enjoining the infringement of a patent where the result would have created a threat to public health. In Activated Sludge the inventor of an apparatus for treating raw sewage by aeration sued the City of Milwaukee for patent infringement. Although the court agreed that the patent had been infringed upon, it believed that enjoining the city from using the patent would have led to closing of the sewage plant and would have

51. See Kapczynski, supra note 32, at 1078 (arguing that universities have the "power to act to improve the lives of patients and also to collectively persuade [the] private sector . . . of the need for an open licensing approach.").
52. Aaron Miller, Repairing the Bayh-Dole Act: A Proposal for Restoring Non-Profit Access to University Science, 2005 B.C. INTELL. PROP. & TECH. F. 093001 (Sept. 30, 2005), available at http://bcipi.com/index.php?option=com_content&task=view&id=18&Itemid=30. Similarly, some have suggested a waiver system, which "would provide certainty for researchers who would have an actual government permit . . . " Id.
53. City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1934).
54. See id. at 579, 593.
forced the city to dump raw sewage into Lake Michigan, resulting in pollution and a public health risk.\textsuperscript{55} Thus Activated Sludge serves as an excellent example where a purported patent infringer was granted immunity because of the public interest.

Furthermore, certain statutes have also allowed for compulsory licensing of a patentee's invention.\textsuperscript{56} For instance, Congress has enacted the Clear Air Act and the Atomic Energy Act, both of which provides for compulsory licensing of patented inventions.\textsuperscript{57} Both acts justify compulsory licensing on the basis that it is in the public’s best interest to require the use of another’s patented invention.\textsuperscript{58}

It is also not far-fetched to think that compulsory licensing might provide the best option to enable institutions to further research advancements for the public’s interest\textsuperscript{59} because they "further the same goal [as] general patent laws[] [by] creating an incentive for new technologies."\textsuperscript{60} A basic assumption underlying most patent systems is that society is benefited more by the advancing innovation than it is harmed by the grant of "a monopoly to the inventor."\textsuperscript{61}

Despite the fact that compulsory licensing could guarantee that the public will receive the intended benefits that are the basis for U.S.' Patent Laws, both the U.S. courts and commentators "frequently express pro-patent sentiments hostile to the very concept of compulsory licensing."\textsuperscript{62} Furthermore, the Supreme Court has long upheld the right of the patentee to prohibit others from using his invention, although the patentee might not be utilizing the invention.\textsuperscript{63} While, some U.S. courts have suggested that public interest could provide a basis for forcing the patentee to relinquish some of his rights and license the invention, such courts have still declined to take

\textsuperscript{55} Id. at 593.
\textsuperscript{57} Id. at 445-46.
\textsuperscript{58} Id. at 446.
\textsuperscript{61} Id. at 668.
\textsuperscript{63} Hartford-Empire Co. v. United States, 323 U.S. 386, 432-33 (1945).
this path. Moreover, the U.S. has never adopted a general statute to regulate compulsory licensing of patent inventions in the area of public interest and public emergencies.

Specifically, compulsory licensing has been opposed on the grounds that it would diminish the purpose of the patent system by reducing inventors' incentive to develop new technologies by encouraging inventors to keep inventions secret. However, most systems give patentees a minimum three-to-four year time period to exploit their invention before compulsory licensing may be granted. Therefore, the inventor would have sufficient time to determine if the invention is worth pursuing, giving him a head start over his competitors in bringing the product to market. In addition, if the invention is pursued, the inventor is entitled to reasonable royalties from the licensee. Compulsory licensing, in this light, would not discourage investment in innovation or encourage inventors to keep their works a secret.

Another argument against compulsory licensing is that it reduces product competition. However, this would only be a concern if compulsory licensing were granted very liberally. Under the normal compulsory licensing schemes, licenses are not granted frequently so that a prospective inventor would be better off just trying to develop a better product than trying to obtain the patent. In opposition to the arguments against compulsory licensing, the competition between companies and inventors would lead to increased competition and better development and innovation of new products.

Critics of compulsory licensing also argue that even countries with provisions for licensing rarely grant actual compulsory licenses. However, this argument "ignores [the] cases where the possibility of a compulsory license encourages the parties to come to

65. Id. at 1278.
66. Id. at 1278.
68. Fauver, supra note 60, at 676.
69. Id.
70. See id. at 677.
72. Whitaker, supra note 66, at 165.
an agreement [between] themselves as a[n]... alternative to litigation.\textsuperscript{74} In the U.S. alone, there have been several reported instances where inventors threatened with compulsory licensing have been unable to come to an agreement with the patent holders and avoid costly litigation.\textsuperscript{75}

Moreover, the lack of a compulsory licensing provision for public interest in the U.S. is not based on a lack of effort to enact such legislation. There have been many proposals to amend the U.S. patent laws so that they would require compulsory licensing under particular circumstances.\textsuperscript{76} For instance, H.R. 2927 was submitted to the 106th Congress "to provide for compulsory licensing of certain patented inventions relating to health."\textsuperscript{77} In 2001, another bill was presented to the 107th Congress that would give the Secretary of Health and Human Services broad discretion to issue compulsory licenses to address public health emergencies.\textsuperscript{78} In 2005, Congressman Sherrod Brown urged that compulsory licensing legislation be enacted to deal with the growing need for essential medicines in the event of a public emergency.\textsuperscript{79} More to the point, Congressman Brown's proposed legislation was created to deal with major obstacles in the flu pandemic and the insufficient production of anti-virals and antibiotics to combat the illness.\textsuperscript{80}

Despite both the need and promise of such legislation, Congress has staunchly resisted passing any of these proposals due to strident opposition by patentees and industry interests.\textsuperscript{81} While Congressman Brown's proposal and those of others before him have been based on sound principles, most of the proposals have only dealt with emergency situations or expediting access to emergency medicines.\textsuperscript{82} Therefore, to strike a balance between the rights of inventors and the

\textsuperscript{74} Yosick, supra note 64, at 1294.
\textsuperscript{75} Id.
\textsuperscript{76} Id. at 1278.
\textsuperscript{77} Affordable Prescription Drugs Act, H.R. 2927, 106th Cong. (1st Sess. 1999). This bill was introduced in the House of Representatives on September 23, 1999.
\textsuperscript{78} Public Health Emergency Medicines Act, H.R. 3235, 107th Cong. (1st Sess. 2001). This bill was introduced by Congressman Brown of Ohio on November 6, 2001 and would give the Secretary of Health and Human Services broad discretion to issue compulsory licenses to address public health emergencies.
\textsuperscript{80} See id.
\textsuperscript{81} Yosick, supra note 64, at 1278.
\textsuperscript{82} See e.g., James Love, supra note 79.
needs of academia, the mechanism of compulsory licensing and a broader view similar to Mr. Brown’s and others, which deals with not only public emergencies but with public interest issues as a whole, should be implemented.

A. History of International Treatment of Patent Compulsory Licensing

In 1873, the Vienna Congress took place, and was the first international convention on patents. Cases that required compulsory licensing for public interest issues were discussed and adopted. Although accepted, this was not a popular resolution. Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") specifically referred to various grounds for the granting of compulsory licenses to be determined by each member country. These justifications include (1) national emergency or extreme urgency; (2) anti-competitive practices; (3) public non-commercial use; (4) dependent patents; and (5) medicine. In particular, Japan and Germany allow compulsory licensing provisions for public interest reasons.

The text of TRIPs Article 31(b) indirectly vindicates public interest as a separate ground for compulsory licensing and leaves considerable leeway to impose such licensing of patented inventions for any legitimate purpose and without undue constraints. It should

83. Kripapuri, supra note 9, at 674.
84. Id.
85. Id.
88. Jackson, supra note 14, at 121.
89. See TRIPs, supra note 86, Part II, sec. 5, art. 31(b): such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or
be noted that the flexibility embedded in Article 31 is not boundless, and other provisions in TRIPs may further constrain it. For example, one must be cautious when attempting to work around the non-discrimination requirement in Article 27(1). This article of the Agreement stipulates that patent rights shall be "enjoyable without discrimination... whether the products are imported or locally produced." Though Article 27(1) has been understood as prohibiting national laws from imposing an obligation to execute locally a patented invention, this interpretation is not unanimous and its interpretation is debatable. Nevertheless, Article 27 provides exceptions for use in instances where Members wish to protect public order and morality, including the protection of human life.

In the U.S, proponents of compulsory licensing point to foreign patent policy, which grants freedom to use the patented inventions of another for research or educational needs. Further, the patent systems of foreign nations have created a number of doctrines to maintain a reasonable balance between the rights of patent holders and innovative research developments while adhering to the requirements of TRIPs. Likewise, the U.S. can establish a compulsory licensing provision in the name of public interest based

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91. Reichman, supra note 62:
1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
92. TRIPS, supra note 86, Part II, sec. 5, art. 27(1).
94. See TRIPS, supra note 86, Part II, sec. 5, art. 27(2):
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
95. See Sung, supra note 30, at 280-81.
on well-established foreign judicial precedent and statutory law and that is consistent with the TRIPs Agreement.97

B. Compulsory Licensing for Public Interest in Japan

Japanese patent law provides for a limitation on the patent holder’s rights for the purposes of experiment or research.98 Proponents of implementing a compulsory licensing scheme in the U.S. maintain that such a scheme has not significantly diminished scientific innovation.99 In 1899, Japan enacted the Patent Law, the Design Law and the Trademark Law with the version, Law No. 121, 159, currently in force in that country.100

The essence of both the U.S. and Japanese patent system can be found in the expression of their objectives. The Japanese patent law system expressly emphasizes industrial development as the ultimate objective of patent protection.101 While on the other hand, the U.S. stresses its role as a promoter of the useful arts and does not expressly emphasize industrial development.102 Nevertheless, the objectives of U.S. and Japanese patent laws of Japan and the U.S. are quite similar. The objective of Japanese patent law is “to encourage inventions by promoting their protection and utilization and thereby to contribute to the development of industry.”103 Similarly, the objective of U.S. patent law is to “[to] promote the progress of . . . the useful arts, by securing for limited times to . . . inventors the exclusive right to their . . . discoveries.”104

The Japanese Patent Act allows the granting of compulsory licenses for implementing dependent, related inventions and for the use of inventions that have not been used for an extended period of time.105 More importantly for researchers, compulsory licenses are

97. Id. at 268-69.
101. See id. at 150.
102. See id.
104. U.S. CONST. art. 1, § 8, cl. 8.
105. Kotabe, supra note 100, at 154.
granted on patented inventions in the interest of the general public.\textsuperscript{106} Article 93 of the Japanese Patent Act, entitled "Award granting non-exclusive license for public interest," states:

(1) Where the working of a patented invention is particularly necessary in the public interest, a person who intends to work the invention may request the patentee or the exclusive licensee to hold consultations on the grant of a non-exclusive license.

(2) If no agreement is reached or no consultation is possible under the preceding subsection, a person who intends to work the patented invention may request the Minister for International Trade and Industry for an arbitration decision.\textsuperscript{107}

The prevalence of compulsory licensing in Japan, a major industrial country, indicates that the country finds compulsory licensing not only beneficial but as a necessary part of their patent laws. Following Japan's lead, the U.S. should enact compulsory licensing for public interest reasons as well.

C. Compulsory Licensing for Public Interest in Brazil

Brazil's new law for patents, the Industrial Property Law, was promulgated on May 15, 1997.\textsuperscript{108} Under the Industrial Property Law the Brazilian National Institute of Industrial Property can impose a compulsory license when requested by a third party if: the patent holder exercises [their] right in an abusive manner, the requestor has a legitimate interest in a license, the requestor is technically and economically able to practice the license, and the products produced under the license are earmarked mainly for the Brazilian market.\textsuperscript{109}

However, some laws refer more broadly to public health. For instance, Brazilian Decree 3201/99 established that where the Federal Executive Authorities determines a case involves a national emergency or public interest, a temporary ex officio nonexclusive compulsory license can be granted.\textsuperscript{110} In Brazil, public interest includes "public health protection satisfying nutritional requirements, protection of the environment and other areas of fundamental

\begin{itemize}
\item \textsuperscript{106} Japanese Patent Act, supra note 103, art. 93.
\item \textsuperscript{107} Id. (emphasis added).
\item \textsuperscript{109} 2-9 BAXTER, WORLD PATENT LAW & PRACTICE § 9.01 (2006).
\item \textsuperscript{110} Correa, supra note 86, at 96 (emphasis added).
\end{itemize}
importance to the technological or social and economic development of Brazil. Section III of the Brazil Patent Laws deals with compulsory licenses. The pertinent section is as follows:

71. In cases of national emergency or of public interest, declared in a decision of the Federal Executive Power, and where the patent owner or his licensee do not satisfy such need, a temporary non-exclusive compulsory license to exploit the patent may be granted ex officio, without prejudice to the rights of the owner of the patent.

Brazil provides patented drugs free of charge to its citizens for its HIV/AIDS prevention program. In efforts to deal with its struggle against AIDS, Brazil threatened to grant a compulsory licensing for various patented AIDS drugs by implementing the safeguards set forth in TRIPs and in accordance with their national legislation. After a brief negotiation period with executives of the pharmaceutical company, Roche, Brazil’s Minister of Health announced that he planned to break the patent on the AIDS drug, nelfinavir. To authorize the grant of a compulsory license to produce nelfinavir, the Minister would have invoked Article 71’s “natural emergency” provision in accordance with Article 31 of the TRIPs agreement. This situation made Brazil the first World Trade Organization country to use Article 31 for compulsory licensing on a patented drug. Although the number of persons infected with AIDS in developing countries is rising in epidemic proportions, the United States still opposes the granting of compulsory licenses by developing countries. While this comment does not propose that compulsory licensing should be enacted to deal specifically with the AIDS epidemic, the U.S. must reaffirm its commitment to utilize all efforts and resources to guarantee the quality of universal public health, safety, and welfare. Enacting a public interest compulsory licensing provision could effectively carry out such a public policy.

111. Id.
113. Id. at art. 71.
115. Id.
116. Id. at 402.
117. Id. at 403.
118. Id. at 402.
119. Id. at 400-01.
D. Compulsory Licensing for Public Interest in Germany

Section 24(1) of the German Patent Act provides for compulsory licensing for public interest:

A non-exclusive authorization to commercially exploit an invention shall be granted by the Patent Court . . . in accordance with the following provisions (compulsory license) if

1. the applicant for a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade; and

2. public interest commands the grant of a compulsory license.\(^{120}\)

This provision relates to the requirement of public interest in order to implement legislation. Therefore, a court will only grant a compulsory license if a plaintiff can prove that the working of the defendant’s patent is in the public interest.\(^{121}\)

Using Section 24(1), a German Federal Patent Court in 1991 granted a compulsory license in favor of a German firm with respect to a patent held by a U.S. firm.\(^{122}\) The purpose of the license was to allow the marketing of a therapeutic application of interferon that had been developed by the German firm.\(^{123}\) However, the Bundesgerichtshof of December 5, 1995 \([Case No. X ZR 26/92]\) revoked the license.\(^{124}\) This revocation was not based on the fact that a compulsory license was granted based on public interest but in this specific case, on a lack of sufficient “public interest” in the present context and the particular facts of the case.\(^{125}\) In other words, a German court will not grant a compulsory license in order to redress the private interest conflict between the parties, but if exploitation of

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\(^{121}\) Id.


\(^{123}\) See id.


\(^{125}\) See id.
the invention is in the public interest, then a German court may consider granting a compulsory license. A broad interpretation of the experimental use exception to allow researchers in the U.S. to continue their vital work is unlikely to come to realization. If the U.S. were faced with a problem such as the German court, a more preferable solution should encompass following international trends by enacting compulsory licensing provisions for the public’s interest.

E. The Bayh-Dole Act

Since attempts to create a patent compulsory licensing scheme in the past have failed, a better approach might be to use examples of public interest compulsory licensing provisions in foreign countries. Taking ideas from the foreign provisions, Congress could expound on existing U.S. legislation, preferably the Bayh-Dole Act, to create a compulsory licensing scheme to aid universities and non-profit institutions in their quest to benefit the public’s interest and well-being. In 1980, Congress passed the Bayh-Dole Act to increase the cooperation amongst academia, federal laboratories, and commercial industry. The Act establishes a uniform governmental patent policy and allows small businesses recipients, nonprofit organizations, and universities to retain title to federally funded inventions and to work with companies in bringing them to market. On the academia side, the Act promotes technology transfer by creating incentives for university researchers to consider the practical applications of their discoveries, and for universities to search out potential companies to develop them. Conversely, the Act enables corporations to negotiate exclusive licensing agreements of promising technologies, which encourages them to invest in the additional research, development, and manufacturing capabilities needed to bring new products to market. In addition, the Bayh-Dole Act ensures that the Government can obtain sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions. This is a right the

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128. See id.
129. Id.
Government has in exchange of the rights bestowed upon universities and small business entities. This enables the Government to exercise 35 U.S.C. § 203 (2000) march-in rights against the recipients of the federal grants and contracts and compel the licensing of inventions developed with such federal assistance.\textsuperscript{131} This restriction of the Bayh-Dole Act is a type of compulsory licensing.\textsuperscript{132}

While it is clear that the federal government has the use of the inventions of a research applicant, it is possible for commercial innovators to also try and influence the government to march-in and require the universities or non-profit institutions to grant a reasonable license to their private firms.\textsuperscript{133} Thus, what is a researcher to do when they have spent a substantial amount of time, effort, and energy in conducting basic research and creating innovative inventions, only to have an outside commercial entity use those inventions so freely? It is no secret that a significant portion of scientific innovation occurs in university and non-profit environments where patents issued to such entities might not be used as often when compared to a private industry.\textsuperscript{134} Further, many academic researchers have products with commercial purposes.\textsuperscript{135} If no patent protection is available, “free riders” may easily copy inventions without investing the time and money needed to perform the basic research and development necessary for the invention, thus undercutting the academic researcher who made such an investment.\textsuperscript{136}

\footnotesize
\begin{itemize}
\item 131. Tullis, supra note 127, at 305. The government’s march-in rights to grant a license to one in the private section are deemed necessary under the following circumstances:
\begin{enumerate}
\item action is necessary because the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;
\item action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees;
\item action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees; or
\item action is necessary because the agreement required by section 204 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 obtained pursuant to section 204.
\end{enumerate}
\end{itemize}


\begin{itemize}
\item 132. Valoir, supra note 126, at 213.
\item 133. See id. n.11.
\item 134. See Barash, supra note 35, at 667-69.
\item 135. Id. at 695.
\item 136. Thomas, supra note 48.
\end{itemize}
While the need of a compulsory licensing provision is inherent for public interest reasons, it is also desired to deal with those who have utilized the research of universities and non-profit institutions but are reluctant to return the favor. In short, when in need of basic patented research, these same institutions are often frustrated to find that they are cut off from accessing the inventions of others, who may have a right under § 203 to freely access their work. As an example of the limited access that researchers have to others' inventions, academic scientists conducting agricultural research have reported access problems to important biotechnology patented inventions. It appears that the industrial owners of the patents refuse to grant licenses to the scientists "because they mistrust licensees or wish to retain a field of research for themselves." This should be a quid pro quo situation in favor of allowing a university researcher to also request the use of another's patented invention if, on the behalf of public interest, the patentee refuses to make the invention available on a reasonable basis. Nevertheless, fairness calls for public access to the patented basic research and inventions, funded with mostly government funds, of universities and other non-profit institutions. Therefore, it is imperative for the government to quickly develop a balanced compulsory licensing scheme for the researcher who may utilization and benefit from another's research and invention in their quest to make a scientific breakthrough.

F. Proposed Patent Compulsory Licensing Provision in the U.S.

Congress can make amends for a lack of an experimental use defense and relieve the restrictions on researchers. An amended Bayh-Dole Act that implements a compulsory licensing provision would apply to university patentees as defined by the Act: researchers who, through concurrent funding by the government, are conducting research "on behalf of the United States." Further, the amended Act would also apply to commercial entities that have taken advantage of the university patentees' work in the past and who possess patented inventions that could potentially benefit public interest. After the correct parties have been identified, the government must determine whether the university or small business request for the patented

137. Tullis, supra note 127, at 289.
138. Id.
invention is to alleviate a public health/safety need or action is requested to meet the requirement of public use. As an alternative, the government can also determine whether the request meets the requirements for public use mandated by federal regulation. If any of these factors are established, the federal government could require the commercial patentee to license the invention to the institution.

The amendment would allow researchers, whose works were or are currently licensed to industrial and commercial entities, to receive in return the opportunity to use the patented inventions of those exact same commercial entities that have likewise benefited from the university's research and developments. In short, the new compulsory scheme would allow recipients of federally funds to use and implement the patented inventions of others when their work is used for basic research for public interest reasons and not to commercialize an end product. The prerequisite of public interest that must be shown should be as follows:

When it is required or necessary for public interest, a recipient of federal funds under the Bayh-Dole Act, who intends to use, work, or exploit the patent of an entity who has benefited from recipient's work, may obtain a compulsory license to do so and may without prejudice to the rights of the patent owner.

It will be in the best interest to allow the courts and other proper administrative agencies to evaluate whether the needed requisite of public interest is present if litigation arises. Nevertheless, the term must be carefully guarded and capable of changing as the economic and social climate of the time requires. Based on the TRIPs Agreement and the legislations of other countries in compliance with TRIPs, public interest should encompass the following: (1) to protect public health and nutrition; (2) to promote the public interest in sectors of vital importance (such as emergency, anti-competitive practices, and governmental use; (3) to prevent abuse of intellectual property rights; (4) to promote technological innovation; (5) to promote the improvement in the balance of trade or in industrial employment; and (6) to promote the safety and rationalization of industrial production.

Once the term "public interest" has been defined, the government can then balance the patentee's exclusive right against the public interest in an effort to rid refusal to license and promote the use of essential resources. Further, academic and non-profit scientists must give adequate notice of such use of another's inventions as to curb the worries of a commercial entity who believes the new
A COMPULSORY LICENSING PROVISION

compulsory licensing provision would give their competitors an advantage. Lastly, a patent holder will still have the opportunity and right to object when unfair and unjust circumstances necessitate the need not to grant the compulsory license. This comment does not overlook the fact that some researchers may profit from the hard work of another patentee. In that instance, a university researcher who develops a patent and issues it into commerce should pay a reasonable royalty or some form of compensation to the owners of the patent in taking their inventions. However, if the use of the researcher's inventions was used in the course of research designed as noncommercial in nature and for public interest, then the compulsory license shall be granted.

V. CONCLUSION

The Bayh-Dole Act explains that Congress' purpose of the enacted the statute was to "promote free competition and enterprise without unduly encumbering future research and discovery." By enacting a compulsory licensing provision built on the common provisions of other countries in compliance with TRIPs and the Bayh-Dole principles, the burden on future research is reduced, the private sector is adequately protected, and the gap left open by the non-existent experimental use exception is filled. While the courts and Congress have generally refuse to recognized compulsory licensing for scientific and academia interests, the usefulness and convenience of a compulsory licensing calls for enactment of a public interest provision.

Universities and other non-profit organizations disseminate knowledge in different forums and generally for a variety of public interest reasons. Therefore, U.S. patent law should reflect those concerns in order to ensure that these institutions will continue to serve the public good through their research efforts. Many academics are indeed willing to trade patenting opportunities for access to technology due to the fact that they are usually more interested in publishing rather than patenting their research and developments. Further, the desired patented technology is filled with useful scientific information and discoveries, which makes its availability essential to

141. Joseph Mohr, Unshackle Academia and Allow it to Exemplify the Purpose of Patent Law: "To Promote the Progress of Science and the Useful Art", 88 MARQ. L. REV. 671, 678-79 (2004) (stating that many universities pressure their researchers to work on industry sponsored projects rather than pursuing their own academic or intellectual projects).
expanding scientific thresholds. In essence, to continue to maintain high scientific standards and contribute to the progress of science, the laws of the U.S. should reflect the important scientific contributions made by academic and non-profit researchers. By ensuring returns on public investments in science that university and non-profit institutions have contributed, such institutions are free from patent infringement and the constitutional mandate to promote the progress of science will be fulfilled.