Madey v. *Duke University* Clarifies Patent Protection and Bolsters Patentee Rights

SCOTT M. LOWRY*

I. UNITED STATES PATENT LAW AND THE EXPERIMENTAL USE EXEMPTION[1]

Patent law in the United States is endorsed by the United States Constitution such that Congress has the power "[t]o promote the Progress of Science and useful Arts."[2] Having such authority, Congress subsequently conferred to inventors[3] the "exclusive Right" in a patented invention.[4] The exclusive right in a patent includes the ability to prevent unauthorized third parties from "mak[ing], us[ing], offer[ing] to sell, or sell[ing] any patented invention, within the United States or import[ing] into the United States any patented invention during the term of the patent."[5] A third party may practice a patented invention only when explicitly[6] or implicitly[7] authorized by the patent owner. Under current law, however, there are two specific exemptions that circumvent the patent owner authorization requirement: (1) a statutory exemption under 35 U.S.C. § 271(e)(1);[8] and (2) a judicially created experimental use exemption.[9] Justice Story first promulgated the experimental use exemption in *Whittemore* v. *Cutter* by suggesting that a third party may use a patented invention without inventor authorization for purposes of philosophical experimentation, to satisfy curiosity, or ascertain functionality of the patent.[10]

In 2001, the nearly 200 year old exemption first created in *Whittemore* was litigated in the United States District Court for the Middle District of North Carolina.[11] Madey, a patent owner and former Duke

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* J.D. Candidate, 2006, Franklin Pierce Law Center – Concord, NH; Business Editor, *Pierce Law Review*; B.S.E. Mechanical Engineering, 2003, University of Michigan – Ann Arbor, MI. Contact the author via email at: slowry@umich.edu.

[1] In this article the term "experimental use" in the university setting includes practicing a patented invention for both experimental *and* research purposes.

[2] U.S. Const. art. I, § 8, cl. 8.

[3] The term "inventor(s)" is used interchangeably with "patentee(s)" throughout this article.

[4] U.S. Const. art. I, § 8, cl. 8.

[5] 35 U.S.C. § 271(a) (2000).

[6] A license agreement is an example of an *explicit* conveyance of authority to practice the invention without being subject to infringement under 35 U.S.C. § 271(a). *Id*.

[7] The doctrine of exhaustion is an *implicit* authorization to practice an invention. A patentee that sells an item embodying the claimed invention implicitly exhausts the right to prevent the buyer from practicing the invention.

[8] *Id*. at § 271(e)(1). A third party may practice an unexpired patent under the narrow patent infringement exemption in § 271(e)(1) "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." *Id*.

[9] *Whittemore* v. *Cutter*, 29 F.Cas. 1120 (C.C. 1813).

[10] *Id*. at 1121.

[11] *Madey* v. *Duke U.*, 266 F. Supp. 2d 420 (M.D.N.C. 2001).

University professor, sued Duke University for patent infringement.[12] Duke University moved for partial summary judgment arguing that any use of Madey's patented technology was non-commercial and protected by the experimental use exemption.[13] The district court held that mere speculation of commercial benefit from the patented technology does create a genuine issue of material fact.[14] Thus, the district court granted Duke University's motion for partial summary judgment of non-infringement.[15]

Madey appealed to the Court of Appeals for the Federal Circuit ("Federal Circuit") in *Madey* v. *Duke University* ("*Madey*").[16] The question in *Madey* was whether Duke University's unauthorized use of a patented invention, in furtherance of the school's educational mission,[17] is protected by the experimental use exemption.[18] The Federal Circuit held that the district court "erred in its application of the common law experimental use defense" by relying too heavily on the University's "non-profit, educational status."[19] Thus, the district court "incorrectly found that there was no genuine issue of material fact upon which Madey could prevail."[20] The narrow question on remand is whether the University's use of Madey's patent was "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry" or whether the University's use has "definite, cognizable, and not insubstantial commercial purposes."[21]

This article analyzes the potential ramifications that *Madey* has on the experimental use exemption in university research. Critics argue *Madey* eliminated the absolute patent infringement liability protection previously enjoyed by universities conducting unauthorized experimentation with

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[12] *Id*. at 421.
[13] *Id*. at 424.
[14] *Id*. at 428.
[15] *Id*.
[16] 307 F.3d 1351, 1352 (Fed. Cir. 2002).
[17] *Id*. at 1356. Duke's patent policy preamble stated that the University is "'dedicated to teaching, research, and the expansion of knowledge . . . [and] does not undertake research or development work principally for the purpose of developing patents and commercial applications.'" *Id*.
[18] *See generally Whittemore*, 29 F.Cas. at 1121.
[19] *Madey*, 307 F.3d at 1362, 1364.
[20] *Id*. at 1364.
[21] *Id*. at 1362-63. In footnote seven, the Federal Circuit did not hesitate to point out that "Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream." *Id*. at 1352.

patented inventions.[22] Intellectual property law associations are renewing the call to Congress to pass a statutory experimental use exemption.[23] An experimental use exemption is not pending before Congress, but this article examines suggested statutory changes in view of historical United States patent law, its statutory and judicial development, and *Madey's* impact on university exempted experimental use.

Furthermore, this article explores the background of patent rights conferred to inventors under the Constitution, Section 35 of the United States Code, and the common law. The history of the judicially created experimental use exemption is examined up to the *Madey* decision. The controversy in *Madey* is discussed and the holding analyzed in light of major political and policy implications potentially affecting future university research. Opinions from the American Intellectual Property Law Association, National Research Counsel, and a Congressional Report are then explored. The arguments in these articles are dissected for points advocating Congress to enact a statutory research exemption. Furthermore, this article interprets the impact of such legislation on universities and patent holders.

Lastly, the Bayh-Dole Act is analyzed in relation to its goal of encouraging research and inventions in universities by enticing universities to file patent applications with the United States Patent and Trademark Office ("USPTO") before traditional publications. The rights of inventors, universities, the government, and potential patent infringers are discussed in relation to patent protected technologies in the university realm. Strong patentee rights are weighed against major public policy considerations when considering whether Congress should consider enacting a statutory experimental use exemption.

II. BACKGROUND INFORMATION

A. *The Patent Statutes: The United States Code Historically Protects Inventors' Rights*

Through the United States Constitution, Congress has the implied power to "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to

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[22] National Research Council, *A Patent System for the 21st Century* 167 (Stephen A. Merrill, Richard C. Levin, & Mark B. Myers, Eds., National Academies Press 2004) [hereinafter NRC, *Patent System*]; *see also* Am. Intell. Prop. L. Assn., *AIPLA Response to the National Academies Report Entitled "A Patent System for the 21st Century"* http://www.aipla.org/Content/ NavigationMenu/IP_Issues_and_Advocacy/Comments/Comments.htm (Sept. 23, 2004) [hereinafter AIPLA, *AIPLA Response*]; John R. Thomas, *Scientific Research and the Experimental Use Privilege in Patent Law* http://www.fas.org/sgp/crs/misc/index.html (Oct. 28, 2004).

[23] *See* AIPLA, *AIPLA Response* at 25-26; NCR, *Patent System* at 172-73; Thomas, *Scientific Research* at 18-19.

their respective Writings and Discoveries."[24] Congress first codified inventor rights with the passage of the Patent Act of 1790.[25] Section 1 first granted inventors the "sole and exclusive right and liberty of making, constructing, using and vending to others to be used, the said invention or discovery."[26] Naturally, the right to exclude included "any person . . . devis[ing], mak[ing], construct[ing], us[ing], employ[ing], or vend[ing] within the[] United States . . . any invention or improvement upon . . . without the consent of the patentee."[27] The Patent Act of 1793 enhanced the language of the Patent Act of 1790 to vest in inventors "the full and exclusive right and liberty of making, constructing, using, and vending to others to be used, the said invention"[28] such that the inventor could exclude "any person . . . mak[ing], devis[ing] and us[ing], or sell[ing] the thing so invented . . . without the consent of the patentee."[29] Additionally, the Patent Act of 1793 further bolstered patentee rights by including a provision concerning patenting improvements of original inventions, such that:

> any person, who shall have discovered an improvement in the principle of any machine, or in the process of any composition of matter, which shall have been patented, and shall have obtained a patent for such improvement, he shall not be at liberty to make, use or vend the original discovery, nor shall the first inventor be at liberty to use the improvement.[30]

This section of the Patent Act of 1793 recognizes the need to protect base proprietary technology from subsequent improvement inventors. As a result of this statute, an inventor who patents an improvement is barred from using the improvement if the original patent is required to practice the improvement.[31] Even dating back nearly 200 years before the decision in *Madey*, Congress recognized the obligation to provide strong patentee rights to those with proprietary inventions.

Congress again modified the patent statutes in 1800 to further bolster and clarify inventor rights. The key language modification of the Patent Act of 1800 was in Section 3, which read in relevant part:

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[24] U.S. Const. art. I, § 8, cl. 8.
[25] Edward C. Walterscheid, *Charting a Novel Course: The Creation of the Patent Act of 1790*, 25 AIPLA Q. J. 445, 448 (Fall 1997).
[26] 1 Stat. 109, § 1 (1790).
[27] *Id*. at § 4.
[28] 1 Stat. 318, § 1 (1793).
[29] *Id*. at § 5.
[30] *Id*. at § 2.
[31] *Id*.

> where any patent shall be, or shall have been granted pursuant to this . . . act, and any person without the consent of the patentee . . . shall make, devise, use, or sell the thing whereof the exclusive right is secured to the said patentee . . . [the calculation of damages shall be the] sum equal to three times the actual damage sustained by such patentee.[32]

Congress specifically eliminated the word "and" from the Patent Act of 1793, which read in relevant part "make, devise and use, or sell,"[33] and added a comma after "devise" in the Patent Act of 1800, which read in relevant part: "make, devise, use, or sell."[34] The statutory language in the Patent Act of 1800 effectively broadened the scope of potential infringers from those that "make, devise *and* use, *or* sell"[35] to encompass all those that "make, devise, use, or sell" the patented invention.[36] Despite these blatant Congressional statutory changes during the late 1700s and early 1800s to broaden the class of potential patent infringers, Justice Story's opinion in *Whittemore* in 1813 effectively created a judicially excepted class of potential infringers.[37] Thus, the debate between maintaining strong patentee rights versus allowing some form of free experimental use ensued.

B. *Judicially Created Experimental Use Exception*

The judicially created experimental use exemption originated in *Whittemore* v. *Cutter* in 1813. Justice Story, writing for the Circuit Court in the District of Massachusetts, considered an "objection . . . that the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right."[38] Reflecting on the statutory construction of the patent laws in the early 1800s, Justice Story noted 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."[39] But, the defendant in *Whittemore* made an infringing machine "to use . . . for profit."[40] Justice Story recognized the "strong presumption[] that the

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[32] 2 Stat. 37, § 3 (1800).
[33] 1 Stat. 318, § 5.
[34] 2 Stat. 37, § 3.
[35] 1 Stat. 318, § 5 (emphasis added).
[36] 2 Stat. 37, § 3.
[37] 29 F.Cas. at 1120.
[38] *Id*. at 1121.
[39] *Id*.
[40] *Id*.

legislature intended to make every one of the enumerated acts a substantive ground of action"[41] after analyzing the legislative changes in the patent laws from 1793 to 1800.[42] Therefore, Justice Story had "no difficulty in holding, that the using or vending of a patented composition" being "equally as applicable to machines . . . is a violation of the right of the proprietor."[43] *Whittemore* created the experimental use exemption for those who use patented technology "for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[44]

In the last sixty or so years Congress significantly changed several specific aspects of United States patent law to favor stronger patentee rights – despite *Whittemore*. The passage of the Patent Act of 1952 codified the patent statutes into the basic modern day patent law structure in Section 35 of the United States Code.[45] In the early to mid 1980s Congress enacted several statutes to strengthen patentee rights in the United States.[46] Specific changes of paramount importance to this article include: 1980 – passage of the Bayh-Dole Act[47] that incorporated special provisions to promote collaboration between commercial entities and universities to better commercialize federally funded inventions;[48] 1982 – formation of the Federal Circuit created a specific patent appellate court designed to uniformly interpret the federal patent statutes;[49] and 1984 – passage of the Waxman-Hatch Act which exempted from patent infringement clinical studies and other activities performed to obtain FDA marketing approval.[50] Thus, Congressional action during the early to mid 1980s bolstered patentee rights with incentives to accelerate technological innovation in the United States to meet world competition.[51]

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[41] *Id*.
[42] *Supra* nn. 33-36 (describing the statutory changes from the Patent Act of 1793 to the Patent Act of 1800 that enlarged the class of potential patent infringers).
[43] *Whittemore*, 29 F.Cas. at 1121.
[44] *Id*.
[45] 35 U.S.C. §§ 100-376 (2000).
[46] Herbert F. Schwartz, *Patent Law and Practice* 4 (4th ed., BNA Books 2003) (noting that "[a] relative increase in technological innovation throughout the rest of the world as compared with that in the United States became manifest by the late 1970s").
[47] 35 U.S.C. §§ 200-212 (2000).
[48] 35 U.S.C. § 200.
[49] Schwartz, *Patent Law and Practice* at 5.
[50] Thomas, *Scientific Research* at 2.
[51] *See generally* Schwartz, *Patent Law and Practice* at 5.

Despite continued Congressional action to bolster the strength of patent rights, the application of the judicially created experimental use exemption was recently challenged in a pair of Federal Circuit cases[52] and a similar Supreme Court case that, in 2005, interpreted the statutory experimental use exemption under 35 U.S.C. § 271(e)(1).[53] Of particular importance is the holding in *Madey* v. *Duke University*.[54] The *Madey* opinion is analyzed in view of the historical and recent patent law changes in law and policy, especially the Bayh-Dole Act of 1980. Specifically, this article considers whether the experimental use exemption excuses universities from patent infringement liability concerning the use of commercial patents and government patents resulting from federally funded research.

C. *Analyzing Madey v. Duke University*

Madey v. *Duke University* is a modern era case that addressed the judicially created experimental use exemption[55] pertaining to a university's right to conduct research using patented inventions.[56] The case originated in the United States District Court of the Middle District of North Carolina under 35 U.S.C. § 1338(a).[57] Accordingly, the Federal Circuit had exclusive appellate jurisdiction of Madey's appeal under 35 U.S.C. § 1295(a)(1).[58] In the mid-1980s Stanford University employed Madey as a research professor.[59] During his tenure at Stanford, Madey obtained sole ownership of two patents.[60] In 1989, Madey left Stanford University for a position in the Duke University physics department.[61] To prepare for Madey's arrival, Duke University built a new laboratory to house Madey's research equipment, including equipment covered by the two Madey patents.[62] Madey directed the lab and the use

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[52] *Integra Lifesciences I, Ltd.* v. *Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003); *Madey*, 307 F.3d at 1351.
[53] *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005).
[54] 307 F.3d at 1351.
[55] *Whittemore*, 29 F.Cas. at 1121 (allowing the free use of patents for "philosophical experiments" and to "ascertain[] the sufficiency of the machine to produce its described effects").
[56] *Madey*, 307 F.3d at 1352.
[57] *Id.*; 28 U.S.C. § 1338(a) (2000) ("The district courts shall have original jurisdiction of any civil action arising under any Act of Congress relating to patents. . . . Such jurisdiction shall be exclusive.").
[58] 28 U.S.C. § 1295(a)(1) (2000) (The Federal Circuit has "exclusive jurisdiction . . . of an appeal from a final decision of a district court of the United States . . . if the jurisdiction of that court was based, in whole or in part, on section 1338 of this title.").
[59] *Madey*, 307 F.3d at 1352.
[60] *Id.*
[61] *Id.*
[62] *Id.*

of the equipment until 1998, when he resigned due to a controversy with Duke University officials.[63] Duke University continued to maintain and run the laboratory equipment after Madey ceased employment at the University.[64] The details of the two Madey patents were not at issue on appeal because Duke University seemingly conceded infringement by asserting the experimental use exemption defense.[65]

The question the Federal Circuit answered on appeal was "whether or not . . . [Duke University's] use [of Madey's patents] was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[66] The Federal Circuit cautioned that the question is not determinative on "the profit or non-profit status of the user."[67] Instead, the court focused on the restrictive interpretation of the experimental use exemption in light of Federal Circuit cases that gradually narrowed the class of exempted patent infringers originally set forward in *Whittemore* nearly 200 years earlier.[68] Two cases are of particular importance: *Roche Products* v. *Bolar Pharmaceuticals*, decided immediately after the inception of the Federal Circuit in 1982,[69] and *Embrex* v. *Service Engineering*, decided in 2000.[70] In both cases the court held the experimental use exemption inapplicable as a defense to patent infringement because the unauthorized use of the patented technology was for "commercial purposes"[71] and "business reasons"[72] instead of for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry."[73] Exemption from patent infringement liability in *Roche* and *Embrex* was therefore narrowly construed to three exceptions: (1) amusement, (2) curiosity, or (3) philosophical inquiry.[74] In fact, the narrow interpretation in *Roche* prompted immediate remedial action by Congress.[75] Thus, it seems clear from *Roche* and

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[63] *Id*. at 1352-53.
[64] *Id*. at 1353.
[65] *Id*.
[66] *Id*. at 1363.
[67] *Id*. at 1362.
[68] *Id*. at 1355, 1360, 1362; *Whittemore*, 29 F.Cas. at 1121.
[69] *Roche Prods., Inc.* v. *Bolar Pharm. Co., Inc.*, 733 F.2d 858 (Fed. Cir. 1984).
[70] *Embrex, Inc.* v. *Service Engr. Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).
[71] *Embrex*, 216 F.3d at 1349.
[72] *Roche*, 733 F.2d at 863.
[73] *Embrex*, 216 F.3d at 1349 (quoting the Federal Circuit in *Roche*, 733 F.2d at 863); *Roche*, 733 F.2d at 863.
[74] *Embrex*, 216 F.3d at 1349 (finding that the Federal Circuit "construed both the experimental use and *de minimis* exceptions very narrowly"); *Roche*, 733 F.2d at 863 (holding "experimental use exception to be truly narrow").
[75] The Hatch-Waxman Act of 1984 superseded *Roche*. The Act permitted generic drug companies to conduct clinical studies and other activities to obtain FDA marketing approval before patent expiration. Performing the necessary testing before patent expiration prevents *de facto* patent term extension. *See* 35 U.S.C. § 271(e)(1).

Embrex that the Federal Circuit intends to continually restrict the scope of the experimental use exemption notwithstanding Congressional action. Did the restrictive question posed by the Federal Circuit in *Madey* limit the circumstances where a university may shield itself from patent infringement liability under the experimental use exemption? Did the court aim to eliminate the experimental use exemption doctrine in the realm of university research? Before exploring *Madey*, it is important to first discuss the holdings in *Roche* and *Embrex*.

Shortly after formation in 1982, the Federal Circuit first considered the experimental use exemption in *Roche*.[76] Roche was the assignee of a disputed patent that claimed a sleeping pill selling under the prescription name Dalmane.[77] A competing drug manufacturer, Bolar, endeavored to manufacture and sell a generic brand of Dalmane when the Roche patent expired.[78] Bolar needed authorization from the United States Food and Drug Administration ("FDA") before marketing a generic version of Dalmane.[79] The FDA's New Drug Application required Bolar to submit results of a series of tests and studies on the generic drug.[80] To successfully complete the FDA testing by the expiration of the Roche patent, Bolar needed to develop and test a generic version of Dalmane that otherwise infringed the Roche patent. Roche filed a patent infringement claim against Bolar immediately after Bolar submitted the New Drug Application to the FDA.[81]

The Federal Circuit considered the narrow question of whether "the limited use of a patented drug for testing and investigation strictly related to FDA drug approval requirements during the last 6 months of the term of the patent constitute a use which, unless licensed, the patent statute makes actionable."[82] When considering the experimental use exception in *Whittemore*,[83] the Federal Circuit held that "Bolar's intended 'experimental' use is solely for business reasons and not for amusement, to satisfy idle curiosity,

[76] 733 F.2d 858.
[77] *Id*. at 860.
[78] *Id*.
[79] *Id*.
[80] *Id*.
[81] *Id*.
[82] *Id*. at 861.
[83] *Whittemore*, 29 F.Cas. at 1121.

or for strictly philosophical inquiry."[84] Because the "law is diligent to protect the patentee,"[85] the Federal Circuit refused to "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 not insubstantial commercial purposes."[86] Thus, the Federal Circuit held that Bolar infringed the Roche patent.[87] The Federal Circuit reiterated the narrow construction of the experimental use exemption by noting that for "the experimental use exception to be truly narrow . . . [it should] not [be] expand[ed] . . . under the present circumstances."[88]

On comparable grounds to *Roche*, the Federal Circuit considered the construction of the experimental use exemption again in *Embrex* in 2000.[89] Embrex was the exclusive licensee of a patent developed with federal funds under the Bayh-Dole Act.[90] The patent in dispute claimed a method for immunizing chickens *in ovo* – chicken immunization while still in the egg.[91] Service Engineering Corporation ("SEC") experiments aimed to circumvent the claim scope in the Embrex patent.[92] After continued failure to provide sufficient immunity to the chicken embryos, SEC developed and offered to sell an *in ovo* immunization injection device that infringed the Embrex Patent.[93] While performing tests and developing a working prototype, SEC solicited orders from a number of potential purchasers.[94] Subsequently, Embrex sued SEC for patent infringement based on lost sales due to SEC's marketing.[95] After acknowledging that a narrow defense to infringement exists only for "amusement, to satisfy idle curiosity, or for strictly philosophical inquiry," the Federal Circuit held that "SEC performed the tests expressly for commercial purposes. . . . [by] demonstrate[ing] to its potential customers the usefulness of

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[84] *Roche*, 733 F.2d at 863.
[85] *Id*. at 862.
[86] *Id*. at 863.
[87] *Id*. at 865.
[88] *Id*. at 863.
[89] *Embrex*, 216 F.3d at 1343.
[90] *Id*. at 1346.
[91] *Id*.
[92] *Id*.
[93] *Id*.
[94] *Id*. at 1347 (SEC "offered to sell its machines to Hudson Foods in the U.S. and Courvoir Dufo in Canada.").
[95] *Id*.

the methods performed by its *in ovo* injection machines."[96] Thus, the "guise of scientific inquiry . . . [did not] immunize its acts."[97] Justice Rader wrote separately and concurred with the majority opinion.[98] In noting that "intent is irrelevant to infringement,"[99] Justice Rader opined that "the extraordinarily narrow form [of the research exception] recognized in *Roche* . . . . retains some lingering vitality, [but] the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable."[100]

In light of the narrow questions in *Roche* and *Embrex*, it is no surprise that the Federal Circuit presented the same narrow experimental use exemption question in *Madey*.[101] The court reaffirmed the notion that "the 'slightest commercial implication'" effectively disqualifies an infringer from asserting the experimental use exemption.[102] Federal Circuit precedent does not "immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications."[103] The court suggested that the use of Madey's patents for education, student enlightenment, faculty research grants, or the enhancement of school prestige, are all in the realm of the "institution's legitimate business objectives."[104] Unless the use of Madey's patents are *solely* for (1) amusement, (2) curiosity, or (3) philosophical inquiry, Duke University "does not qualify for the very narrow and strictly limited experimental use defense" regardless of the University's non-profit status in light of its patent and licensing policy.[105] The court asserted that "Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."[106] Thus the question remains: May the experimental use exemption preclude university liability in a patent infringement suit? How does the role of Bayh-Dole interact with the Federal Circuit's decision in *Madey*?

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[96] *Id*. at 1349.
[97] *Id*.
[98] *Id*. 1352-53.
[99] *Id*. at 1353.
[100] *Id*.
[101] *Madey*, 307 F.3d at 1363.
[102] *Id*. at 1362.
[103] *Id*.
[104] *Id*.
[105] *Id*. at 1362-63.
[106] *Id*.

III. STATUTORY PROTECTIONS FOR UNIVERSITY PATENTING UNDER THE BAYH-DOLE ACT

Congress set forth a set of policy objectives in the Bayh-Dole Act of 1980 consistent with the Constitution and in support of inventor rights and commercialization.[107] Congress specifically described the objectives of the Bayh-Dole Act in 35 U.S.C. § 200:

> It is the policy and objective . . . to promote the utilization of inventions arising from federally supported research or development . . . to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations . . . promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; [and] to ensure that the Government obtains sufficient rights in federally supported inventions.[108]

The underlying aim of the Bayh-Dole Act is the promotion, commercialization, and retention of patent rights in inventions procured with federally funded money for the utilization of the public and industry in the United States. Congress specifically enacted Bayh-Dole to promote collaboration among universities and industry by granting universities greater control of patents procured with federal funds. Since the enactment of Bayh-Dole, universities nationwide formed technology transfer offices with the sole purpose of developing, patenting, and licensing innovative and cutting edge technology. This concept strikes the heart of the Bayh-Dole versus traditional university publication policy conflict: the provisions of Bayh-Dole avidly promote university and commercial industry invention collaboration aimed to faster deliver technology to the marketplace – for profit; as opposed to traditional university policies that historically pursue research and development as educational, for the advancement of society – not for profit. It is the former research and development interest that might fall under the experimental use umbrella in *Whittemore*[109] and potentially excluded in view of *Roche*,[110] *Embrex*,[111] and *Madey*.[112]

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[107] 35 U.S.C. §§ 200-212.
[108] 35 U.S.C § 200. "[N]onprofit organization" is defined as "universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 . . . and exempt from taxation under section 501(a) of the Internal Revenue Code . . . or any nonprofit scientific or educational organization qualified under a State nonprofit organization statute." 35 U.S.C. § 201(i). For the purposes of this article, the term "nonprofit organization" is generally referenced as "university."
[109] *Whittemore*, 29 F.Cas. at 1121.
[110] *Roche*, 733 F.2d at 863.
[111] *Embrex*, 216 F.3d at 1349.
[112] *Madey*, 307 F.3d at 1362-63.

As the disposition of rights set forth,[113] the Bayh-Dole Act specifically strengthens university rights in "'subject invention[s]'"[114] by enabling universities to (a) retain title to a subject invention resulting from federal funding;[115] or (b) refuse to sublicense inventions owned by the university that are not subject inventions.[116] The funding Federal agency retains the right to "a nonexclusive, nontransferable, irrevocable, paid-up license to practice . . . any subject invention throughout the world."[117] Furthermore, universities are: prohibited from assigning the rights to a subject invention without federal agency approval;[118] required to share royalties with inventors;[119] bound by subject invention disclosure;[120] bound by written election requirements;[121] required to file patent applications prior to statutory bar dates;[122] required to report on efforts concerning patent utilization;[123] and required to specify Federal agency funding support on patents.[124] While Congress offered university inventors substantially greater patent rights to retain ownership in subject inventions, the federal government did reserve several key interest rights in patents developed with federally funded money.

First, the government reserved march-in rights of any subject invention resulting from a Federal agency funding agreement.[125] The Federal agency may require the "contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license . . . to a

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[113] *See generally* 35 U.S.C. § 202.
[114] "[S]ubject invention" as defined in the Bayh-Dole Act is generally "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement." 35 U.S.C. § 201(e). This section is also subject to university compliance with: § 202(c)(1) (proper subject invention disclosure); § 202(c)(2) (election requirements); and § 202(c)(3) (requiring the filing of a patent application before applicable statutory bar dates in the United States or foreign countries). *See generally* 35 U.S.C. § 202(c).
[115] 35 U.S.C. § 202. There are a limited number of exceptions that may exclude inventor ownership, including: § 202(a)(i) (contractor residing outside the United States); § 202(a)(ii) (exceptional circumstances that better promote the policies and objectives of 35 U.S.C. § 201); § 202(a)(iii) (retaining foreign intelligence or counter-intelligence activities for national security); or § 202(a)(iv) (operating Department of Energy facilities dedicated to naval nuclear propulsion or weapons related programs). *See generally* 35 U.S.C. § 202(a).
[116] 35 U.S.C. § 202(f) (allowing exceptions such as prior justification and approval by the agency and/or in the event use of the invention by others is necessary to practice the subject invention).
[117] 35 U.S.C. § 202(c)(4).
[118] *Id*. at § 202(c)(7)(A).
[119] *Id*. at § 202(c)(7)(B).
[120] *Id*. at § 202(c)(1).
[121] *Id*. at § 202(c)(2).
[122] *Id*. at § 202(c)(3).
[123] *Id*. at § 202(c)(5).
[124] *Id*. at § 202(c)(6).
[125] *Id*. at § 203.

responsible applicant."[126] Reservation of march-in rights ensures that universities properly commercialize subject inventions. There are four general situations, though rarely exercised, where the government may assert march-in rights: (1) the university fails to bring the invention to practical application in the specific field of use of the patent;[127] (2) the university fails to take the necessary actions to alleviate public health or safety needs;[128] (3) the university fails to meet the public use requirement specified by the Federal regulation;[129] or (4) for failure to adequately waive or conform to the requirements in 35 U.S.C. § 204.[130]

Second, to increase the breadth of patent protection for inventions developed with federal funding, the government reserves the right to file foreign or domestic patent applications when the university either fails to elect title to the subject invention or chooses not to file an application in a specific country.[131] The government may "apply for, obtain, and maintain patents . . . in the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest."[132] Retaining rights in subject inventions developed with federal funds under 35 U.S.C. § 207 enables the government to "grant nonexclusive, exclusive, or partially exclusive licenses under federally owned inventions."[133] Thus, the government may "transfer custody and administration, in whole or in part, to another Federal agency, of the right, title or interest in any federally owned invention."[134] This provision is important. Any governmentally owned patent obtained with federal funds is thus transferable anywhere inside the government agency; including transfer to any university conducting research with federal grant money. The risk of patent infringement liability for universities doing research with patents

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[126] *Id*. at § 203(a).
[127] *Id*. at § 203(a)(1).
[128] *Id*. at § 203(a)(2).
[129] *Id*. at § 203(a)(3).
[130] *Id*. at § 203(a)(4). Section 204 prohibits universities from exclusively licensing a subject invention unless the products embodying the invention are substantially manufactured in the United States. 35 U.S.C. § 204. The requirement is only waived in situations where (1) "reasonable but unsuccessful efforts have been made to grant licenses" that effectuates substantial manufacture in the United States; or (2) where substantial manufacture in the United States is commercially unfeasible. 35 U.S.C. § 204.
[131] *Id*. at § 202(c)(2).
[132] *Id*. at § 207(a)(1).
[133] *Id*. at § 207(a)(2). The government may grant exclusive or partially exclusive licenses under several Bayh-Dole provisions: (1) where the license is used as an incentive to (a) obtain investment funding; or (b) promote public utilization of the invention; (2) practical commercialization and public utilization; (3) sustain commercial competition; or (4) enhance United States industry in foreign commerce. 35 U.S.C. § 209(a)(2)-(a)(5).
[134] *Id*. at § 207(a)(4).

granted to the federal government is certainly reduced, if not eliminated. The continued development of the original patented technology is certainly no longer limited to the developing university. Instead, the government may license the technology to any university under § 207 to effectively utilize diverse intellectual properties resources nationwide.

As previously noted, the Bayh-Dole Act conveys powerful rights to university inventions developed with federally funded money. Does the common law protection differ if a university used a patent developed under Bayh-Dole as opposed to a patent developed by industry? While Duke University, a non-profit institution, argued that using Madey's patents was solely for education and technological advancement, the Federal Circuit clearly stated that such unauthorized use is infringement *unless* solely for (1) amusement, (2) curiosity, or (3) philosophical inquiry. The experimental use exemption seemingly survived at the university level for over 200 years. But, the enactment of the Bayh-Dole Act, in light of recent judicial interpretations, suggests that the scope of the exemption continues to dwindle. Especially in view of *Madey*, universities are no longer capable of asserting experimental use as a defense to patent infringement when in accordance with legitimate research and educational business objectives.[135] Bayh-Dole carved a new niche for university commercialization. Universities, now more than ever, work with the federal government and industry for the sole *purpose* of brining researched technology to the marketplace.

The clear yet narrow construction of the experimental use exemption in *Madey* will not decrease demand for research and technological innovation at universities. Nor will universities experience an increase in patent infringement lawsuits. Rather, the affirmation of strong patentee rights – the hallmark of United States patent law – provides ever increasing opportunities for universities to contract with more government projects and continuously interact with industry. Such opportunities open a realm of funding and resources previously not readily available to universities nationwide. Increased patent disclosures, liberal licensing programs, and research contracts with government and industry will likely overshadow

[135] 307 F.3d at 1362-63.

any negative affect on lost research opportunities. Therefore, a statutory experimental use exemption is not needed to continue fueling technological innovation in the United States.

IV. RECTIFYING THE EXPERIMENTAL AND RESEARCH USE EXCEPTION WITH *MADEY*

A. *Introduction: The Experimental Use Exemption after Madey v. Duke University*

Having already discussed the historical background of United States patent law over the past 200 years, this article now moves into the realm of the *Madey* holding and its impact on university research. Several distinguished intellectual properly law associations call for congressional action to remedy the so-called "inapplicable" experimental use exemption that universities supposedly relied upon when conducting research.[136] These associations allege that the narrow construction of the experimental use exemption in *Madey* detrimentally affects university research and stifles technological innovation in the United States.[137] The resolution advocated by the National Academy of Sciences ("NAS"), American Intellectual Property Law Association ("AIPLA"), and a Congressional Research Service ("CRS") report is for a statutory experimental use exception.[138] The focus of the second half of this article focuses on competing policies and legal interests of strong patentee rights against the advocacy for a statutory experimental use exemption in relation to university research and experimental use.

Consider first the overall endeavor of the United States patent system – it is to promote the dissemination and public use of technological information.[139] A patent effectively confers to the patentee an exclusive property right in a specific technology, defined by the "metes and bounds" of the patent claims – for a limited duration.[140] By granting inventors an exclusive right to exclude others from practicing patented technology, the patent system prevents "free riding."[141] Patentee rights are already juxtaposed with the general proposition that universities endeavor to freely use patented technology in furtherance of research and education. A statutory experimental use exception allows a university to

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[136] Thomas, *Scientific Research* at 1.
[137] *Id*. at 10.
[138] AIPLA, *AIPLA Response* at 24; NCR, *Patent System* at 172-73; Thomas, *Scientific Research* at 18-19.
[139] Thomas, *Scientific Research* at 3.
[140] *See generally Zenith Laboratories, Inc.* v. *Bristol-Myers Squibb*, 19 F.3d 1418, 1424 (Fed. Cir. 1994) (finding that the claims set "the metes and bounds of the invention entitled to the protection of the patent system").
[141] Thomas, *Scientific Research* at 3. A "free rider" is one who obtains benefits "at another's expense or without the usual cost or effort." *Merriam-Webster's Collegiate Dictionary* (Merriam-Webster, Inc., version 2.1, 2001).

exploit patented technology without partaking in the original cost and/or effort of to develop the technology. In essence, the university "free rides" off patented technology.

In view of the technological advancement objectives of the patent laws, the NAS advocates for a patent system designed to motivate inventors to commercialize a proprietary technology.[142] But, does a patent system containing an exempted group of potential infringers stifle the development of those very inventions needing incentives? Hesitant inventors may fail to disclose inventions if *anyone*, even research based universities, are able to freely use and improve the original patent. Suppose that an inventor exerts significant time, money, and technological resources into developing a proprietary technology. Currently, inventors are enticed to quickly file patent applications to secure broad claim coverage. Assume an inventor obtains a patent with relatively broad coverage for the proprietary technology – does the inventor's mindset change if the current state of law changes to allow universities to essentially "free ride" off the proprietary patent?

Enabling universities to freely use patented technology and to file improvement patent applications, or publish research results, may significantly impede the ability of an inventor to secure a niche market in proprietary technology. As the proprietary technology develops further, the original inventor is locked out from obtaining the needed improvement patents to prevent larger corporations from using improvements published by the university. Thus, the inventor is not capable of developing a strong intellectual property portfolio to compete with larger corporations. Hence, the inventor is discouraged from disclosing the proprietary information and not "encourage[d] . . . to research with their technologies . . . so as to increase the number of applications for their inventions and hence their own profits."[143] A more probable scenario suggests an increase in inventors vying to protect technology as trade secrets – at least until the potential patent protection in the state of the art is better developed through improvements and marketing. Ironically, NAS curses the practice of trade secrets as "not enrich[ing] the collective knowledge of society."[144] What does the public gain in this situation? Are there long term concerns?

[142] *Id*. at 4.
[143] *Id*. at 11.
[144] *Id*. at 3.

Conversely, the current patent system, absent a statutory experimental use exemption, does provide a vehicle for universities to conduct research with proprietary patented technology. Consider the inventor that developed the proprietary technology in the example in the last paragraph. Certainly it is viable and desirable for an inventor to form strategic licensing agreements with local universities or research and development firms to further progress and improve original proprietary technology. In a licensing agreement, the inventor is an active participant in the strategic development of the proprietary technology. The inventor continues to retain exclusive ownership and exclusive control in the patent rights. The inventor is not subject to "free rider" tactics by universities unwilling to pay royalties. Instead, licensing agreements reflect market value and are designed to enhance the profitability of the inventor's investment in the proprietary patent (where universities may otherwise gain free access to the technology via a statutory experimental use exemption). Universities play a critical role in assisting inventors in the development of patented technology – not "free riding" off of it. Bayh-Dole encourages universities to work closely with inventors to bring the technology to the market.

Universities may utilize other avenues of obtaining rights in patent technology absent licensing. Consider technology available for purchase via the market. Universities endeavoring to research market products may obtain rights under the "'exhaustion' doctrine," which states that "once a patent owner has sold a patented product, he cannot control the use of that particular product."[145] Patent owners relinquish the exclusive right to prevent all others from practicing the claimed invention upon sale of the patented device. Universities are then free to conduct experiments, research improvements, etc. without infringing any patent rights. Plus, a dual benefit is actually conferred. The inventor receives payment for the sale of the patented device and in exchange the university obtains the right to practice the patented device. Clearly, universities and inventors are both influenced by the desire to bring the patented technology to market. Without a commercial product, the university is restricted from freely purchasing the patented

[145] *Id*. at 12.

technology and applying the exhaustion doctrine. Therefore, if not for the commercialization of the patented device, the university is unable to freely experiment or improve the patented technology.[146]

B. *Specific Provisions: The Experimental Use Exception Detailed*

The CRS argues that the judicially created experimental use exemption "'provide[s] little, if any protection in today's world'" and that universities are no longer able to rely on the exemption, after *Madey*, when conducting research.[147] Both the CRS and AIPLA urge that an experimental use exemption is fundamental to the promotion of innovation in a well refined patent system – regardless whether statutorily or judicially created.[148] The CRS points out that an "overly restrictive experimental use exception might conceivably depress technological advancement by decreasing the ability of researchers to experiment with state-of-the-art technology."[149] AIPLA concurs, commenting that an experimental use "exemption is inherent to a properly functioning patent system at least where experimentation is required to understand *what is patented, whether the patent is valid, what basic properties or characteristics the patented invention might have, and to improve upon the invention*."[150]

Academia is concerned that a restrictive experimental use exemption precludes "'tinker[ing]'" with and experimenting from patented inventions.[151] Arguably an experimental use exemption circumvents this restriction and enables researchers to freely access patented technology.[152] But, how is "tinkering" integrated into the university's educational objectives? Most universities are nonprofit and aim to advance knowledge and technology through teaching and research.[153] Can these goals be integrated after the holding in *Madey*? The CRS report cautions that "universities . . . are unlikely to be able to rely upon the common law experimental use privilege as a defense to a charge of patent infringement."[154] Should universities rely on the experimental use exemption in the first place? Since the enactment of Bayh-Dole in 1980, there are significantly more university based technology transfer offices

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[146] *Id*.
[147] *Id*. at 1, 9. The NAS argues that the exception is inapplicable on a scale broader than the university setting.
[148] *Id*. at 2; AIPLA, *AIPLA Response* at 24.
[149] Thomas, *Scientific Research* at 2.
[150] AIPLA, *AIPLA Response* at 24 (emphasis original).
[151] Thomas, *Scientific Research* at 10.
[152] *Id*. at 12.
[153] *Id*. at 8.
[154] *Id*.

nationwide. Universities derive significant income and monetarily benefiting from the licensing of patented technology – regardless whether the technology licensed is proprietary or an improvement.

Improvement patents are as important to an inventor as the original patented technology. The shield of the experimental use exemption provides a mechanism for universities to exploit the original patented technology without consent from the original inventor. This proposition is seemingly contrary to sound patent policy for several reasons. A university unauthorized to access an original patent may further develop and obtain rights to an improvement patent based on the original technology. One of two scenarios are likely to arise if a university attempts to recoup its research expenses: (1) the improvement patent is licensed back to the original inventor; or (2) the improvement patent is licensed to the inventor's competitor(s). Under either scenario, the original inventor is harmed. The original inventor must either (1) pay the university royalties to practice the improvement patent; or (2) compete with competitors that obtained rights in the improvement patent with little or no effort to advance the state of the technology (other than exercise its financial muscle to pay university royalties). Disclosure puts the inventor in a catch-22 situation. The most logical resolution is, of course, concealment of the original technology until the inventor advances the state of the art. Concealment forecloses university access to the base technology therefore eliminating any potential improvement patents. Without the improvement patent, the competitor has nothing to obtain. A larger pocketbook is then irrelevant.

AIPLA advocates for a statutory experimental use exemption based on comparative international law in order to avoid the inadvertent shift of university research from the United States to foreign countries.[155] Again, consider the balance between inventor rights and the free flow of technological knowledge at the university level. Technology may be more likely to be exported to a foreign country in the event that an otherwise infringing party could use a foreign university to experiment and improve upon the technology. That assumes, *post hoc*, that the base technology is *already developed*. Rather, it is more appropriate to first ask where an inventor is most likely to statutorily protect new technology. A country (i.e. the United States) that provides the strongest patent protection is a logical starting point.

[155] AIPLA, *AIPLA Response* at 26.

Technology that is otherwise taken overseas for *future* research is effectively patented and exploited in the United States *today*.[156] From a business perspective, investors realize that strong patentee rights accompany valuable patents. Thus, enacting a "comparable [experimental use exemption] provision" will only have a detrimental effect on disclosure and development of technology in the United States.[157]

C. *Options: Patent Licensing and Avoiding Litigation*

Patent licensing is a business entity in itself such that many universities and commercial businesses rely extensively on the practice to obtain revenues from patented inventions. AIPLA acknowledges that "licenses for any needed experimentation are generally available for nominal sums."[158] The prospect of patent infringement litigation, which is "widely regarded as costly, time-consuming and complex," is easily avoided through licensing.[159] Why, then, is there such a worrisome buzz concerning the narrow holding in *Madey*? If costly patent infringement disputes are easily avoided through cost effective licensing agreements, it seems logical that both interested parties benefit from this substantially inexpensive alternative to litigation. In reality, a patent license is a bargained for exchange – the negotiated terms of the license agreement hypothetically confer benefits upon both contracting parties. Inventors receive monetary benefits in exchange for university access to the patented technology. A university experimental use exemption eliminates the inventor's benefit and diminishes the patent value.

Even as licensing provides a low maintenance method of pursuing patented technologies, university funding outside of litigation is still a concern. The NAS contends that, before *Madey*, the experimental use exemption "may never have been robust, [but] it was widely assumed, especially by academic investigators and research administrators, to shield scientific investigation at universities from lawsuits."[160] Universities may experience increased costs as new and costly patent clearance studies may weigh heavily on increasingly tight budgets.[161] But, consider that the market may balance these costs.

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[156] Inventors failing to protect the same technology in foreign countries may fail to effectively utilize the worldwide market and ultimately risk forfeiting larger revenues.
[157] *Id*.
[158] *Id*. at 25.
[159] Thomas, *Scientific Research* at 12.
[160] NCR, *Patent System* at 167.
[161] Thomas, *Scientific Research* at 11, 14.

Higher cost structures associated with clearance opinions[162] may transpire into licensing agreements favorable to the university – to account for increased costs. Universities, e.g., may contract at lower royalty rates or contract to license technology at higher royalty rates. Market balance of these financial interests is crucial as intellectual property licensing between universities and companies increases.

Alternatively, the NAS contends that university researchers should at least have the ability to freely use patents to determine whether (a) the patent functions as claimed; (b) the patent works in conditions not disclosed in the specification; (c) research could discover something unknown about the patent; and (d) research will produce improvements.[163] To achieve these ends, a narrow alternative to a research exemption may strike an adequate balance between strong patentee rights and enabling universities to advance technology through research and commercialization. The CRS report notes that a "broad experimental use privilege [may be] inappropriate" because it would "greatly ease the ability of competitors to 'design around' the invention or develop competing technologies."[164] Thus, patentees would "be less able to appropriate the returns of their investments in research and development."[165]

D. *Proposals: Historical Legislation and the Future of the Experimental Use Exemption*

Congress considered an experimental use exemption in 1990.[166] The Judiciary Committee recommended a bill to address the experimental use exemption that pertained specifically to research tools – similar to an exemption passed by European legislation.[167] The sample legislation, titled the *Patent Competitiveness and Technological Innovation Act of 1990*, provided in § 402 that:

> It shall not be an act of infringement to make or use a patented invention solely for research or experimentation purposes unless the patented invention has a primary purpose of research or experimentation. If the patented invention has a primary purpose of research or experimentation, it shall not be an act of infringement to manufacture or use such invention to study, evaluate, or characterize such invention or to create a product outside the scope of the patent covering such invention.[168]

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[162] Universities may use clearance opinions to avoid willful infringement liability for research conducted with potentially patented technology.
[163] NCR, *Patent System* at 172.
[164] Thomas, *Scientific Research* at 9.
[165] *Id*.
[166] Thomas, *Scientific Research* at 18-19.
[167] NCR, *Patent System* at 173.
[168] Thomas, *Scientific Research* at 18-19. Proposed legislation suggested adding § 271(j). AIPLA, *AIPLA Response* at 26.

The proposed statute contains competing interests: competitiveness and free technological innovation. By its very nature, an exemption is *not* competitive. An exemption enables a university to develop a technology without the consent, cooperation, or knowledge of the actual inventor.

Consider whether the above legislation promulgates innovation. The initial reaction is that increased access to patented technology enhances technology and innovation. Major universities, having a wealth of information, money, and resources, may quickly develop emerging technologies that would otherwise take years. This scenario is positive assuming proprietary inventors continue disclosing proprietary inventions at relatively embryonic states. But, common sense and a solid business perspective leads any prudent investor down a different path. What good is an investment in new technology if a university, a potential infringer under the current state of patent law, could pluck any technology out of the air and create improvements that hypothetically block the original proprietor from practicing the original invention? As already premised, one of two scenarios are likely to arise: (1) the inventor does not disclose the invention until a more commercially feasible business plan and marketing strategy is developed;[169] or (2) the embryonic technology is never explored because the corresponding patent protection does not outweigh the financial risk.

Should the United States enact an experimental use exemption based on the patent laws in foreign countries? Other countries already enacted legislation similar to the Patent Competitiveness and Technological Act of 1990. Similar laws include: Article 69(1) of the Japanese Patent Act; and Article 27(b) of the Community Patent Convention.[170] AIPLA supports the NAS's contention that Congress should enact an experimental use exemption.[171] Specifically AIPLA argues to exempt the following actions from patent infringement liability:

> (1) evaluating the validity of the patent and the scope of protection afforded under the patent; (2) understanding features, properties, inherent characteristics or advantages of the patented subject matter; (3) finding other methods of making or using the patented

[169] Under this scenario, inventions that are otherwise submitted to the USPTO at and early developmental stage never make it out of the lab for risk that universities will develop the technology for competitors.
[170] AIPLA, *AIPLA Response* at 26.
[171] *Id*. at 25.

> subject matter; and (4) finding alternatives to the patented subject matter, improvements thereto or substitutes therefore.[172]

Admittedly, AIPLA's suggestions are modestly on point, but the need for enacting a statutory exemption to foster these recommendations is unnecessary.

The current patent law system provides mechanisms for universities to achieve AIPLA's recommendations. First, all patents issued by the USPTO are presumed valid. The patent claims and specification provide a mechanism to understand the scope of the protected technology without practicing the invention. Second, the features, properties, and inherent characteristics or advantages of the patented subject matter are disclosed in the specification. The very purpose of the patent specification is to notify the public of these features. To obtain a Notice of Allowance from the USPTO requires that the specification enable one of ordinary skill in the art to make and use the invention.[173] Thirdly, the current patent system allows for "designing around" inventions; and actually encourages the practice. In fact, "designing around" the scope of a claimed invention is, and should be, the only way to manufacture a similar product. This practice diversifies original patented technology and furthers creative innovation in the development of alternative products. In the end, consumers benefit from a larger product pool.

Lastly, obtaining an improvement patent to an existing patented technology confers little benefit to the university. While advancing technology through improvements is important, the practice is not as effective without the authorization of the original inventor. The use of the improvement patent is hypothetically blocked by the original patent. What is the commercial value of an improvement patent that can not be practiced without the authority of the original inventor? Universities will find few willing commercial entities eager to enter into licensing agreements because of the threat of a patent infringement lawsuit from the original inventor. How does the public benefit from such an improvement patent if commercial entities are unwilling to license the technology for fear of being sued? Unless the original inventor licenses the technology from the university, will the improvement patent ever make it to the market? Should the university market the improvement patent without the consent of the original

[172] *Id.*
[173] 35 U.S.C. § 112 ¶ 1.

inventor? Can the university license the improvement patent so as to enable another commercial entity to bring the improvement patent to market? Surely the experimental use exemption proposed by AIPLA does not enable a university to license an otherwise infringing improvement to a commercial competitor through Bayh-Dole.

V. CONCLUSION

The United States is at the forefront of technological innovation and disclosure. Despite some of the intricacies of the patent system, it would be unwise for Congress to consider enacting an experimental use exemption, regardless of breadth. University research has an important role in the advancement of technology in the United States. Congress clarified that role with the enactment of Bayh-Dole. University research has since become increasingly intertwined with industry and the commercialization of products. This close knit interaction with commerce and revenue, coupled with the increase in technology licensing, threatens the legitimacy of the university's stance as a non-competitor to patentees. Furthermore, exempting universities from patent infringement liability only threatens the strength of inventor rights that has developed in the United State patent system over the last 200 years.

Additionally, the free market will welcome university technology transfer with open arms. The increasing importance of universities in research and development will continue to attract entrepreneurs searching for inventive assistance – so long as strong patentee rights are retained. The market currently facilitates a number of mechanisms that enable universities to obtain access to patented inventions. These mechanisms confer benefits to each participant in the agreement. Therefore, the increasing value of intellectual property rights in patents will continue to promulgate through, not only industry, but also university communities. The provisions of Bayh-Dole provide enhanced patent retention and protection for universities and the federal government and Bayh-Dole encourages the disclosure of patents conferred with federal funds. Thus, while the holding in *Madey* potentially narrowed the experimental use exemption, it will not adversely affect university funding or research opportunities. Universities are prepared to step out of the traditional nonprofit role and embrace a new direction under Bayh-Dole – as the Act provides sufficient protection for continued technological advancement in the United States.