

WEGNER RED LETTER

A Monthly Newsletter Looking to What's Next in Patent Law
SUPPLEMENT (Feb. 3, 2015)



Is There a Right to “Experiment On” a Patented Invention?

“[A] *limited preemption is inherent in every patent*: the right to exclude for a limited period of time. ... When the patent expires, the public is entitled to practice the invention of patent. That is true of all inventions; *during the term of the patent, unauthorized parties are ‘preempted’ from practicing the patent*, but only for its limited term.”

Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.)(citing 35 U.S.C. § 154(a)(1)(emphasis supplied), *subsequent proceedings sub nom Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)

The traditional view both domestically and internationally is *yes*, there *is* a right to experiment on a patented invention to see how it operates, to make improvements and to design around the invention. An affirmative answer destroys much of the policy basis for the anti-patent holdings in *Alice* and other recent Supreme Court cases.

Unfortunately, the Federal Circuit is deeply divided on this issue. The Federal Circuit owes it to the patent community to confirm, once and for all, that patents *encourage* research and that the patent right does not block such research.

Attached is a paper exploring the issue: *Is There a Right to “Experiment On” a Patented Invention?*



WEGNER RED LETTER is the sole work product of Harold C. Wegner and may be cited as “Wegner Red Letter” [Month, Year], Los Angeles Intellectual Property Law Association, available at www.laipla.net/category/wegners-writings. Correspondence address: WegnerRedLetter@gmail.com

IS THERE A RIGHT TO “EXPERIMENT ON” A PATENTED INVENTION? *

Harold C. Wegner **

<i>Preface: Statements over the Right to Experiment On a Patented Invention from the Supreme Court:</i>	2
<i>Preface: Statements over the Right to Experiment On a Patented Invention from the Federal Circuit</i>	3
I. OVERVIEW	4
II. THE BREYER PREMISE: PATENTS “PREEMPT” RESEARCH	5
III. FOLLOW-ON RESEARCH “PROMOTE[S] THE PROGRESS...”	7
IV. RESEARCH PREEMPTION IN ALL TECHNOLOGIES	21
V. A MAINSTREAM EXPERIMENTAL USE DEFINITION	23
VI. CONCLUSION	25
APPENDIX: The Post- <i>Merck</i> Paper	26

* This paper is a revision of “*The Unasked En Banc Predicate Issue in CLS Bank: If Patents Do ‘Preempt’ Follow-On Research How can Any Patent ‘Promote the Progress of * * * the Useful Arts?’*”, which was prepared for the session, *Supreme Court and Patent Law*, Second Annual Naples Midwinter Patent Experts Conference, University of Akron School of Law, February 10-11, 2014, Naples Hilton (discussing the *Myriad* case, *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.) (“[Third] parties are ‘preempted’ from practicing the patent....”). The paper represents the views of the author at the time of that conference and does not necessarily reflect the views of any colleague, organization or client thereof. This version February 9, 2015.

** WegnerIPconsultant@gmail.com. The writer is an independent academic consultant on patent matters. The views expressed are his own and do not necessarily reflect the views of any present or former colleague, organization or clients thereof.

Preface: Statements over the Right to Experiment On a Patented Invention from the Supreme Court:

“[T]he pre-emption concern [] undergirds our §101 jurisprudence.”

Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014)(Thomas, J.)

“[T]here is a danger that grant of patents that tie up [laws of nature, physical phenomena, and abstract ideas] will *inhibit future innovation* premised upon them, a danger that becomes acute when a patented process amounts to *no more than* an instruction to 'apply the natural law,' or otherwise *forecloses more future invention than the underlying discovery could reasonably justify.*”

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1301(2012)) (emphasis supplied in part), *subsequent proceeding*, 717 F.3d 1269 (Fed. Cir. 2013)(en banc), *aff'd sub nom Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), *quoted in CLS Bank Int'l v. Alice Corp. Pty.*, 685 F.3d 1341, 1350 (Fed. Cir. 2012)(Linn, J.).

“We have described *the concern that drives this exclusionary principle* [under 35 USC § 101 to bar patents to laws of nature, natural phenomena and abstract ideas] *as one of pre-emption*. See, e.g., *Bilski* [v. *Kappos*, 561 U.S. 593, 611-02 (2010)] (upholding *the patent would pre-empt use of this approach in all fields*, and would effectively grant a monopoly over an abstract idea). Laws of nature, natural phenomena, and abstract ideas are ‘the basic tools of scientific and technological work.’ *Myriad, supra*. [M]onopolization of those tools *through the grant of a patent might tend to impede innovation* more than it would tend to promote it, thereby thwarting the primary object of the patent laws. *Mayo* [*Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012)]; see U.S. Const., Art. I, § 8, cl. 8 (Congress shall have Power . . . To promote the Progress of Science and useful Arts). We have repeatedly emphasized this . . . *concern that patent law not inhibit further discovery* by improperly tying up the future use of these building blocks of human ingenuity. *Mayo, supra*] (citing *Morse, supra*, at 113).”

Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014)(Thomas, J.)(emphasis added)

Preface: Statements over the Right to Experiment *On* a Patented Invention from the Federal Circuit

“[As to] the experimental use excuse, *neither the statute nor any past Supreme Court precedent gives any reason to excuse infringement* because it was committed with a particular purpose or intent, such *as for scientific experimentation* or idle curiosity....”

Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1353 (Fed. Cir. 2000)(Rader, J., concurring)(citation omitted)

“[A] *limited preemption is inherent in every patent*: the right to exclude for a limited period of time. 35 U.S.C. § 154(a)(1) (‘Every patent shall contain . . . a grant to the patentee, his heirs or assigns, of the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States . . . ’). When the patent expires, the public is entitled to practice the invention of patent. That is true of all inventions; *during the term of the patent, unauthorized parties are ‘preempted’ from practicing the patent*, but only for its limited term.”

Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.)(emphasis supplied), *subsequent proceedings sub nom Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)

Overly broad claiming “is *an attempt to preempt the future* before it has arrived.”

Abbvie Deutschland GmbH & Co. v. Janssen Biotech, Inc., 759 F.3d 1285, 1301 (Fed. Cir. 2014)(Lourie, J.)(emphasis added) (quoting *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993))

I. OVERVIEW

Do patents “preempt” follow-on research and other experimentation *on* the patented invention?

If patents *do* preempt follow-on research, then how can patents in any way promote the *Progress* of the Useful Arts?

If the answer is yes, that patents do “preempt” research, this provides ammunition to those who wish to restrict the scope of patent-eligibility because “preemption” could be argued to stifle innovation. An affirmative a

At least one member of the Federal Circuit takes this view.

While there is *dicta* in various Federal Circuit opinions suggesting a negative viewpoint, *dicta* is *dicta*. Such *dicta* is also in conflict with various panel opinions including, for example, *In re Rosuvastatin Calcium Patent Litigation*, 703 F.3d 511 (Fed. Cir. 2012)(Newman, J.). In that case, she concludes that there *is* a right for third parties to use a patented invention for analysis and study that can result in further improvements. Thus, *Rosuvastatin Calcium Patent Litigation* says that patents *do not* “preempt” research.

The starting point for this paper is an exposition of the various statements of the Court that suggest that broad patents are bad for innovation because patents “preempt” follow-on research. *See* § II, *Supreme Court View that Patents “Preempt” Research*. In fact, it is not at all clear that this premise has *any* validity to the extent there is a right to experiment *on* a patented invention. *See* § III, *Follow-On Research “Promote[s] the Progress...”*

While the focus in recent years has been on software and computer-implemented innovations, decisions on patent-eligibility in all technologies have a boomerang effect. This is graphically seen from the proceedings in *Myriad*. See § IV, *Research Preemption in All Technologies*. A model definition of what is – and is *not* – an infringing experimental use is provided. See § V, *A Mainstream Experimental Use Definition*.

II. THE BREYER PREMISE: PATENTS “PREEMPT” RESEARCH

A Supreme Court focus on “research preemption” is a constant theme of *Bilski v. Kappos*, 130 S.Ct. 3218 (2010), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012). The premise of the opinions is that broad patents “preempt” research, and hence impede (rather than promote) the Progress of the Useful Arts. This premise is explored by the panel opinion in the *CLS Bank* case:

“Several [Supreme Court] decisions have looked to the notion of ‘preemption’ to further elucidate the ‘abstract idea’ exception [to Section 101 patent-eligibility]. In *Bilski*, the Supreme Court explained that ‘[a]llowing petitioners to patent risk hedging **would preempt use of this approach in all fields** ...’ 130 S.Ct. 3231. Previously, in *O’Reilly v. Morse*, 56 U.S. 62 (1853), the Supreme Court held that a claim to electromagnetism was not eligible for patent protection because the patentee ‘claim[ed] *the exclusive right to every improvement*....’ Id. at 112-13 . The Morse Court reasoned that the claim would effectively ‘**shut[] the door against inventions of other persons . . .** in the properties and powers of electro-magnetism’... Id. at 113 (emphasis added). Again, in *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Supreme Court emphasized the concept of ‘pre-emption,’ holding that a claim directed to a mathematical formula with ‘no substantial practical application except in connection with a digital computer’ was directed to an unpatentable abstract idea because ‘**the patent would wholly pre-empt the mathematical formula**...’ Id. at 71-72.

In *Parker v. Flook*, 437 U.S. 584 (1978), the Court again emphasized *the importance of claims not ‘preempting’ the ‘basic tools of scientific and technological work...’* Id. at 589.

“In contrast to *Morse*, *Benson*, and *Flook*—where the claims were found to ‘pre-empt’ an ‘idea’ or algorithm—in *Diehr*, the Supreme Court held that the claims at issue ... did not ‘*pre-empt the use of th[e] equation.*’ *Diehr*, 450 U.S. at 187. ...

“Our Constitution gave Congress the power to establish a patent system ‘[t]o promote the Progress of Science and useful Arts’ U.S. Const. art. I, § 8, cl. 8. *The patent system is thus intended to foster, not foreclose, innovation.* See *id.*

...[N]o one is entitled to claim an exclusive right to a fundamental truth or disembodied concept that *would foreclose every future innovation in that art.* See *Morse*, 56 U.S. at 112-13. As the Supreme Court has ‘repeatedly emphasized . . . *patent law [must] not inhibit further discovery by improperly tying up the future use of laws of nature.*’ *Prometheus*, 132 S. Ct. at 1301. ‘[T]here is a danger that grant of patents that tie up [laws of nature, physical phenomena, and abstract ideas] will *inhibit future innovation* premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to ‘apply the natural law,’ or otherwise forecloses more future invention than the underlying discovery could reasonably justify.’ Id. (emphasis added)... Thus, *the essential concern is not preemption, per se, but the extent to which preemption results in the foreclosure of innovation.*

Claims that are directed to no more than a fundamental truth and *foreclose, rather than foster, future innovation* are not directed to patent eligible subject matter under § 101. *No one can claim the exclusive right to all future inventions.* *Morse*, 56 U.S. at 112-13; *Benson*, 409 U.S. at 68.

CLS Bank v. Alice, 685 F.3d at 1349-51 (emphasis added)

III. FOLLOW-ON RESEARCH “PROMOTE[S] THE PROGRESS...”

The genesis for American patent law and for the right to conduct follow-on research *on* the patented invention is the “Promote the Progress” provision of the Constitution:

“Pursuant to its power ‘[t]o promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries,’ U.S. Const., Art. I, § 8, cl. 8, Congress has passed a series of patent laws that grant certain exclusive rights over certain inventions and discoveries as a means of encouraging innovation.”

Bilski, 130 S.Ct. at 3236.

Supreme Court precedent in both patents and copyrights has interpreted the “Promote the Progress” clause of the Constitution as encouraging certain noninfringing uses of the intellectual property right. *See* § III-A, *The Story Progeny and the Supreme Court*. The long acceptance of experimentation *on* a patented invention as not violating patent rights is underscored by a history of governmentally required comparative testing of patented inventions. *See* § III-B, *Governmentally Mandated Experimentation*.

The United States model that permits an otherwise infringing use of an invention for follow-on research *on* the patented invention is now a global standard. *See* § III-C, *Global Acceptance of the American Model*. The only major forum which has had difficulty with defining the right to experiment *on* a patented invention is the Federal Circuit where an intra-circuit split exists even today. *See* § III-D, *Myriad Says Patents “Preempt” Research*.

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

Particularly since *Madey*, a significant portion of the academic community has failed to grasp the limited holding of this and other cases which has perpetuated a false understanding of the case law. See § III-E, *Uncertainties within the Academic Community*. Given the importance of the right to experiment on a patented invention as a lynchpin of the Supreme Court precedent on patent-eligibility, *en banc* clarification is important. See § III-F, *En Banc Resolution of the Intra-Circuit Conflict*

Developments prior to 1985 are based upon what is set forth herein as the “Post-Merck paper”: Wegner, *Post-Merck Experimental Use and the “Safe Harbor,”* 15 Fed. Cir. B.J. 1 (2005), attached as an Appendix.

A. The Story Progeny and the Supreme Court

The right to conduct follow-on research within the scope of a patented invention, to thus experiment *on* a patented invention, stems from the interpretation of the Constitution by legendary Supreme Court Justice Joseph Story.

The “Promote the Progress” Clause of the Constitution governs intellectual property rights for both copyrights and patents. For both, the Clause provides the foundation for exemptions from infringement for fair use or experimental use, respectively, because such exemptions “promote the Progress”.

“[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts.’”

Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617, 626 (2008), quoting *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917).

Wegner, *Is there a Right to "Experiment On" a Patented Invention?*

In the quoted *Motion Picture Patents* case, historical perspective is provided:

“Since *Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1 (1829)[(Story, J.)], was decided . . ., this court has consistently held that the primary purpose of our patent laws is not the creation of private fortunes for the owners of patents, but is ‘to promote the progress of science and the useful arts’ (Constitution, art. 1, § 8),-an object and purpose authoritatively expressed by Mr. Justice Story, in that decision, saying:

“ ‘While one great object [of our patent laws] was, by holding out a reasonable reward to inventors and giving them an exclusive right to their inventions for a limited period, to stimulate the efforts of genius, the main object was ‘to promote the progress of science and useful arts.’”

“Thirty years later this court, returning to the subject, in *Kendall v. Winsor*, 62 U.S. (21 How.) 322 (1858), again pointedly and significantly says:

“‘It is undeniably true, that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly.’”

“This court has never modified this statement of the relative importance of the public and private interests involved in every grant of a patent, even while declaring that, in the construction of patents and the patent laws, inventors shall be fairly, even liberally, treated. *Grant v. Raymond*, 31 U.S. (6 Pet.) 218 (1832); *Winans v. Denmead*, 56 U.S. (15 How.) 330 (1854); Walker, Patents, § 185.”

Motion Picture Patents, 243 U.S. at 510-11.

Sixteen years before *Pennock v. Dialogue*, the author of that case explained the right to experiment on a patented invention:

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

“[I]t could never have been the intention of the legislature to punish a man, who constructed such a machine merely for [scientific] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”

Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.) (riding circuit) (The text of the opinion speaks of “philosophical experiments” which, in the context of contemporary usage, means “scientific experiments”).

Whittemore v. Cutter is not an isolated case. Justice Story next explained the right to experiment *on* a patented invention in *Sawin v. Guild*, 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) (Story, J.). There, Justice Story first emphasizes that commercial use of an invention is patent infringement. “[T]he making of a patented machine to be an offence within the purview of it, must be the making with an intent to use for profit....” *Sawin v. Guild*, 21 F. Cas. at 555.

But, as a caveat, there is no infringement if the use of the invention was “for the mere purpose of [scientific] experiment, or to ascertain the verity and exactness of the specification.” *Id.*

As previously explained in the *Post-Merck* paper:

“*Evans v. Eaton*, [16 U.S. (3 Wheat.) 454 (1818),]...sheds further light on the view that there should be experimenting on a patented invention to make a yet further patented invention – but that the commercial practice of that later patented invention had to give way to the rights of the earlier patentee. Thus, *Evans* recognizes that an infringing improvement invention can be made during the term of an earlier patent, but not practiced commercially free from the senior patent. Citing as authority a contemporaneous English precedent,

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

Evans states that “[i]f a person has invented an improvement upon an existing patented machine, he is entitled to a patent for his improvement; but he cannot use the original machine, until the patent for it has expired.”

Post-Merck paper at 7 (quoting *Evans*, 16 U.S. (3 Wheat.) app. at 17, citing *Ex parte Fox*, 35 Eng. Rep. 26 (1812) (The Lord Chancellor Eldon)).

Professor Dreyfuss quotes with approval from Professor William Robinson's leading late nineteenth century patent law treatise:

“[W]here [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of intellectual character ... But if the products of the experiment are sold ... the acts of making or of use are violations of the rights of the inventor and infringements of his patent.”

Rochelle Cooper Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 *Ariz. L. Rev.* 457, 458 (2004) (quoting William C. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890)).

Professor Dreyfuss concludes that “[i]n other words, to early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce-- between using the patent to satisfy curiosity or using it to turn a profit.”

Id.

With citations again starting with Joseph Story, the Supreme Court in the *Pretty Woman* Case explains the “Promote the Progress” Clause in the copyright context:

Wegner, *Is there a Right to "Experiment On" a Patented Invention?*

“ From the infancy of copyright protection, some opportunity for fair use of copyrighted materials has been thought necessary to fulfill copyright's very purpose, ‘[t]o promote the Progress of Science and useful Arts....’ U.S. Const., Art. I, § 8, cl. 8. For as Justice Story explained, ‘[i]n truth, in literature, in science and in art, there are, and can be, few, if any, things, which in an abstract sense, are strictly new and original throughout. Every book in literature, science and art, borrows, and must necessarily borrow, and use much which was well known and used before.’ *Emerson v. Davies*, 8 F.Cas. 615, 619 (No. 4,436) (CCD Mass.1845).

Similarly, Lord Ellenborough expressed the inherent tension in the need simultaneously to protect copyrighted material and to allow others to build upon it when he wrote, ‘while I shall think myself bound to secure every man in the enjoyment of his copy-right, one must not put manacles upon science.’ *Carey v. Kearsley*, 4 Esp. 168, 170, 170 Eng.Rep. 679, 681 (K.B.1803). In copyright cases brought under the Statute of Anne of 1710, [An Act for the Encouragement of Learning, 8 Anne, ch. 19,] English courts held that in some instances ‘fair abridgements’ would not infringe an author's rights, see W. Patry, *The Fair Use Privilege in Copyright Law* 6-17 (1985) []; Leval, *Toward a Fair Use Standard*, 103 Harv.L.Rev. 1105 (1990)[], and although the First Congress enacted our initial copyright statute, Act of May 31, 1790, 1 Stat. 124, without any explicit reference to ‘fair use,’ as it later came to be known, the doctrine was recognized by the American courts nonetheless.”

Pretty Woman Case, Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 576-76 (1994)(footnotes deleted) Again in the copyright context in *Eldred*, the “Promote the Progress” clause was explained by reference to patents:

“‘[I]mplicit in the Patent Clause itself’ is the understanding ‘that free exploitation of ideas will be the rule, to which the protection of a federal patent is the exception. Moreover, the ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure.’” *Eldred v. Ashcroft*, 537 U.S. 186, 225 (2003)(Stevens, J., dissenting)(quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989)).

B. Governmentally Mandated Experimentation

If there were no right to experiment *on* a patented invention, then, surely, neither the courts with expertise in patents nor the Patent Office would *require* litigants or patent applicants to engage in infringing conduct, which would precisely be the case if there were no right to experiment *on* a patented invention. Thus, it is not uncommon for comparative tests against a patented invention to show how that invention works and compares to a later invention, testing that is classically an experiment *on* a patented invention. Testing for administrative and judicial proceedings are in cases constitute experimenting *on* a patented invention:

It has always been axiomatic that a person may use the invention of another for the purpose of presentation of evidence to the U.S. Patent and Trademark Office (USPTO) or the courts. It is necessary that those seeking to invalidate a patent have the ability to experiment on a patented invention to determine its operability in accordance with the teachings of the patent specification. Experimentation may be necessary to establish patentability of a new invention through comparative testing to establish presence of a secondary consideration under *Graham v. John Deere Co.*

In *Beidler v. Photostat Corp.*, a court confirmed the right of an accused infringer to make and test an otherwise infringing embodiment for the purpose of a presentation of comparative evidence to the court:

“Plaintiff claims that defendant's possession of the single machine used as an exhibit [for the court proceeding] is a past and continuing act of infringement It has not been used or exhibited except for the purposes of this litigation. Its presence in court was important to enable the court to visualize and compare the mechanism and principles of operation [one] machine with the [other] machines The possession [of an otherwise infringing machine] as a model does not constitute actual or threatened infringement in the absence of proof that the machine is held for purposes of profit in violation of the exclusive right of the patentee to make, use, and sell the patented invention”

Without a right to reproduce a patented invention it is impossible to prove matters such as scope of operability or to establish nonobviousness through comparative testing. For example, it is necessary that those seeking to invalidate a patent have the ability to experiment with an invention to determine its operability in accordance with the teachings of the patent specification.

Experimentation may be necessary to establish patentability of a new invention through comparative testing to establish presence of a secondary consideration. Detailed regulations have been established by the USPTO that essentially require comparative testing. Professor Adelman explained the policy supporting the right to use the patented invention in this situation:

“A [noninfringing] scenario would be to generate information for administrative agencies or courts. For example a member of the public may seek to check prophetic examples (paper examples in a patent) to see whether the patent itself has a fatal flaw. Of course even those examples that the patentee actually carried out can be checked to see if the patentee made a serious experimental error that would fatally effect one of [sic] more claims of the patent. In essence these tests would be designed for use either in court or in the PTO.”

Post-*Merck* Paper at 10-11 (footnotes deleted)

C. Global Acceptance of the American Model

In 1813 *Whittemore v. Cutter* created the right to experiment *on* a patented invention, nearly two full centuries after the 1623-1624 Statute of Monopolies but sixty-five years before *Frearson v. Loe*, 9 Ch. D. 48 (Ch. 1878)(Lord Jessel), the leading English case. Thus, long after Justice Story spoke in *Whittemore v. Cutter*, a parallel result was reached in England in *Frearson v. Loe*. There, the court said that "if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention ... or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity [from] exercising their talents in a fair way." *Frearson v. Loe*, 9 Ch. D. at 66-67.

Frearson v. Loe is the leading case among Commonwealth countries, followed in *Monsanto Co. v. Stauffer Chem. Co.*, [1985] R.P.C. 515, 529 (U.K. Court of Appeal 1985)(UK); *Smith Kline v. Douglas Pharms. Ltd.* [1991] F.S.R. 522 (N.Z. Court of Appeal).

Whether emulating or simply independently creating their laws on experimental use, Great Britain has codified the law from *Frearson v. Loe*, while, Germany and Japan also have statutory definitions of the experimental use right that corresponds to the American case law right to experiment *on* a patented invention. (*Whittemore v. Cutter* came decades before the creation of the German *Reich* and during the period of the Tokugawa Shogunate, decades before the arrival in Japan of the Black Ships of Admiral Perry. *A fortiori*, *Whittemore v. Cutter*

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

antedated the patent laws of Germany and Japan, not to mention specific patent law doctrines such as experimental use.)

Professor Mueller notes that “[m]ost [] countries around the world (including most industrialized countries and the world's leading patent systems-- Germany, Japan, and the U.K.) have long included a research use exemption in their domestic patent laws. These patent systems have not fallen apart because of the exemption, nor has innovation in these countries stopped.” Janice M. Mueller, *Facilitating Patient Access To Patent-Protected Genetic Testing*, 6 J. Bus. & Tech. L. 83 (2011)(footnotes omitted).

She quotes statutory provisions adopted in Germany that “[t]he effects of a patent shall not extend to ... acts done for experimental purposes relating to the subject matter of the patented invention”; the United Kingdom that “[a]n act which... would constitute an infringement ... shall not [be such] if... it is done for experimental purposes relating to the subject-matter of the invention”; and Japan that “[the] patent right shall not extend to the working of the patent [] for the purposes of experiment or research”. *Id.* at n. 81.

D. Myriad: Patents “Preempt” Research

The Federal Circuit case law is problematic as one member of the Court has expressly stated that, without qualification, “[third] parties are ‘preempted’ from practicing the patent....”. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 689 F.3d 1303, 1331 (Fed. Cir. 2012)(Lourie, J.).

The *Myriad* statement is in direct conflict with the pronouncement of the Chief Judge that “information in patents * * * * * is not insulated from analysis, study, and experimentation * * *.” *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348, 1376 (Fed. Cir. 2012)(Rader, C.J.,

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

dissenting), quoting *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1072 (Fed. Cir. 2011)(Newman, J.).

The message from *Momenta* and *Classen* that the public is free to experiment on a patented invention has been more recently underscored in *Rosuvastatin Calcium Patent Litigation*:

[P]atenting does not deprive the public of the right to experiment with and improve upon the patented subject matter. As discussed in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001), “[t]he disclosure required by the Patent Act is ‘the quid pro quo of the right to exclude,’ “ quoting *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 484 (1974). It is not necessary to wait for the patent to expire before the knowledge contained in the patent can be touched. The patent's right to exclude was explained by Justice Story in *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D.Mass.1813):

“[I]t 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.”

Id. at 1121; see *Chesterfield v. United States*, 159 F.Supp. 371 (Ct.Cl.1958) (experimental study is not infringement).

Rosuvastatin Calcium Patent Litigation, 703 F.3d at 527.

Prior to 1985 there were voices aligned with the Lourie viewpoint, but they have either changed (as quoted in *Momenta*) or, particularly, the author of the *dicta* in *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002), has resigned his commission from the Federal Judiciary. Other at first blush problematic cases involved readily distinguished *dicta* as discussed in the Post-*Merck* paper.

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

While Joseph Story two centuries ago and the Supreme Court in modern times have focused on the importance of the public right which includes the right to conduct experimentation or follow-on research *on* a patented invention, *Myriad* represents a continued intra-circuit split whether there is any practical experimental use right.

E. Uncertainties within the Academic Community

Comparative patent law expert (then a law student) Andrew Baluch explains the confusion generated by the *Madey dictum*:

“[T]he Federal Circuit's inquiry has now shifted away from how the experiments were performed (research-stage experimenting ‘on’ the invention vs. development-stage testing ‘with’ the invention) to asking who performed the experiments (idle tinkerer vs. research institution).”

Andrew S. Baluch, *Relating the Two Experimental Uses In Patent Law: Inventor's Negation and Infringer's Defense*, 87 B.U. L. Rev. 213, 239 (2007)(citing *Madey*).

Baluch explains the difficulties created by the unfortunate explanation of experimental use in *Madey*: “[Duke University]’s experimental use defense should have properly been denied on the ground that [it] was using the patented laser technology not to study how the laser worked or to improve upon its performance, but to study the physical properties of other materials - i.e., exactly how such research tools are intended to be used.” *Id.* (citing Mueller, 56 Baylor L. Rev. at 940-41).

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

To the contrary, “the *Madey* court based its holding on the fact that the use of the patented laser technology was ‘in furtherance of the alleged infringer’s legitimate business,’ namely ‘educating and enlightening students and faculty participating in these projects,’ and ‘pursuing an aggressive patent licensing program.’” *Id.* (citing *Madey*, 307 F.3d at 1362 & n.7.)

As Baluch correctly concludes, the *dictum* has created an important misunderstanding in the patent arena: “Unfortunately for the research community, *Madey*’s ‘sweeping dictum’ appears to eliminate ‘any real-world case of experimentation that would win immunity from infringement liability.’” *Id.* at 239-40 (citing Mueller, 56 Baylor L. Rev. at 942).

In contrast to Baluch, Professor Golden provides a mainstream academic interpretation of the case: He concludes that *Madey* “find[s] that ‘research projects with arguably no commercial application’ nonetheless ‘further [a research university’s] legitimate business objectives,’ and that, ‘so long as [an] act is in furtherance of the alleged infringer’s legitimate business ..., the act does not qualify for the very narrow and strictly limited experimental use defense’.” John M. Golden, *WARF’s Stem Cell Patents and Tensions Between Public and Private Sector Approaches to Research*, 38 J.L. Med. & Ethics 314, 317 n. 44 (2010) .

In line with Golden, Professor Sarnoff summarizes *Madey* as a case where “the Federal Circuit held that the historic experimental use exception to infringement is very narrow, and is not available to universities for research using patented inventions that furthers the economic business of education.” Joshua D. Sarnoff, *Abolishing the Doctrine of Equivalents and Claiming the Future after Festo*, 19 Berkeley Tech. L.J. 1157, 1203-04 (2004)(citing *Madey*).

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

Consistent with Professors Golden and Sarnoff, the U.S. PTO Deputy Commissioner for Patent Examination Policy in his capacity as a government official gave the following summary of the *Madey* case: “

As explained in *Madey*, the scope of the experimental use defense is ‘very narrow and strictly limited ... to actions performed for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.’” Stephen G. Kunin, *Workshop on Future Public Policy And Ethical Issues Facing the Biotechnology Industry*, 86 J. Pat. & Trademark Off. Soc'y 501, 503 (2004).

F. *En Banc* Resolution of the Intra-Circuit Conflict

Were experimental use an issue of limited importance, then whether the Federal Circuit resolves the intra-circuit conflict might be of lesser importance. Given that the experimental use issue strikes at the very heart of the research “preemption” argument in patent-eligibility, the Federal Circuit would be wise to accept responsibility for *en banc* clarification of its position on this issue.

IV. RESEARCH PREEMPTION IN ALL TECHNOLOGIES

The issue of “preemption” is at the heart of the patent-eligibility controversy in all fields. Perhaps the best example of “preemption” is found in the *Myriad* “isolated DNA” patent-eligibility case where the petition for *certiorari* now pending at the Supreme Court makes repeated references to what it characterizes as the bad policy of “preemption”:

[D]espite *Mayo*'s explicit discussion of preemption, Judge Lourie [in *Mayo*] seemingly rejected the relevance of preemption in *any* patent case by emphasizing that patents are supposed to be preemptive.

* * *

As *Mayo* makes clear, a key aspect of the Section 101 analysis turns on whether the patent preempts use of the laws and products of nature. Does the patent ‘risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries ...’ ‘relative to the contribution of the inventor?’ 132 S. Ct. at 1294, 1303;

* * *

The broad *preemptive effect* of these patents is further evidence that they claim laws and products of nature. *** The patents grant *Myriad* the authority *to prevent all research* and clinical testing of the genes, raising the same concerns about patenting a “building-block” that has troubled the Court. *See Mayo*, 132 S. Ct. at 1303. These patents tie up basic uses of the genes, “foreclose[ing] more future innovation than the underlying discovery could reasonably justify.” *Id.* at 1292

* * *

The Federal Circuit *** failed to consider the[patents’] preemptive effects while giving undue weight to patentees' interests.

* * *

Wegner, *Is there a Right to “Experiment On” a Patented Invention?*

[A] claim that includes small segments of DNA that are not limited to the patented genes, like claim 5 of patent '282, preempts researchers from working with that segment wherever it appears in the genome, foreclosing scientific inquiry far beyond what Myriad's discovery of two genes could ever justify. *See Bilski*, 130 S. Ct. at 3230-31; *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972); *Funk Bros.*, 333 U.S. at 130. *See also Lab. Corp. of Am. Holdings*, 548 U.S. at 126-27 (Breyer, J., dissenting) (“[S]ometimes too much patent protection can impede rather than ‘promote the Progress of Science and useful Arts.’”).

* * *

Testing the effectiveness of a potential therapeutic by comparing its effect on cell growth with the cell growth occurring without the compound is routine, conventional science. *Preventing any researcher from engaging in this science to find a cancer treatment is precisely the preemptive effect that led this Court to invalidate the claim in Mayo* and should invalidate this claim as well.

Myriad Petition for Certiorari, 2012 WL 4502947 (emphasis supplied in part).

V. A MAINSTREAM EXPERIMENTAL USE DEFINITION

An experimental use definition is proposed that is consistent with the historical Story line of case law, the modern statutory schemes of the United Kingdom, Germany and Japan, and which insulates the “research tool” community from those who use their inventions for their intended purpose:

Experimentation on a patented invention is not an act of infringement, whereas **experimentation with** a patented invention is an act of infringement:

A noninfringing **experiment on** a patented invention includes acts done for experimental purposes or research relating to the subject matter of the patented invention including use with the view of improving upon the invention ... or with the view of seeing whether an improvement can be made or not. The patent right does not insulate information in patents from analysis, study, and experimentation.

An infringing **experimentation with** a patented invention includes any use of the patented invention for its intended purpose where the object of the experimentation is to conduct an experiment where the patented invention is used for its normal purpose without focus on study, analysis or modification of the patented invention.

A laboratory “research tool” used in an experiment for its intended purpose as a laboratory research tool is an example of an infringing experimentation *with* a patented invention.

Sources for the wording of this provision are set forth in the following chart:

Experimental Use Defined	
Experimentation <i>on</i> a patented invention is not an act of infringement, whereas experimentation <i>with</i> a patented invention is an act of infringement:	
A noninfringing experiment <i>on</i> a patented invention includes:	
acts done for experimental purposes or research relating to the subject matter of the patented invention including	<p>“[t]he effects of a patent shall not extend to ... acts done for experimental purposes relating to the subject matter of the patented invention” (German law)</p> <p>“[a]n act which... would constitute an infringement ... shall not [be such] if... it is done for experimental purposes relating to the subject-matter of the invention” (UK Law)</p> <p>“[the] patent right shall not extend to the working of the patent [] for the purposes of experiment or research” (Japanese law).</p>
use with the view of improving upon the invention ... or with the view of seeing whether an improvement can be made or not.	<p>“[I]f a man makes things ... with the view of improving upon the invention ... or with the view of seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.” <i>Frearson v. Loe</i>, 9 Ch. D. at 66-67.</p>
The patent right does not insulate information in patents from analysis, study, and experimentation.	<p>“[I]nformation in patents * * * * * is not insulated from analysis, study, and experimentation”. <i>Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.</i>, 686 F.3d 1348, 1376 (Fed. Cir. 2012)(Rader, C.J., dissenting), quoting <i>Classen Immunotherapies, Inc. v. Biogen IDEC</i>, 659 F.3d 1057, 1072 (Fed. Cir. 2011)(Newman, J.)</p>
An infringing experimentation <i>with</i> a patented invention includes any use of the patented invention for its intended purpose where the object of the experimentation is to conduct an experiment where the patented invention is used for its normal purpose without focus on study, analysis or modification of the patented invention.	
A laboratory “research tool” used in an experiment for its intended purpose as a laboratory research tool is an example of an infringing experimentation <i>with</i> a patented invention.	

VI. CONCLUSION

The Federal Circuit should provide a clear, *en banc* statement on the scope of experimental use, of the right to *experiment on* a patented invention. It is important that a conclusion is reached no matter the outcome. If the answer is affirmative and agreed upon by the Supreme Court, then this would undercut the Breyer theory that patents “preempt” research. If the answer is negative, this would then provide a clear target or remedial legislation.

Appendix:

“The Post-Merck Paper”

[Harold C. Wegner, *Post-Merck Experimental Use and the “Safe Harbor,”* 15 Fed. Cir. B.J. 1 (2005)]



The
Federal Circuit Bar
Journal

*The National Quarterly Review
of the United States Court of Appeals for
the Federal Circuit*

Volume 15 Number 1

Published by
The Federal Circuit Bar Association

Post-*Merck* Experimental Use and the “Safe Harbor”*

Harold C. Wegner**

Introduction

The *Merck KGaA v. Integra Lifesciences I, Ltd.*¹ reversal of the United States Court of Appeals for the Federal Circuit (Federal Circuit) decision below² confirms the Supreme Court’s broad interpretation of a statutory *safe harbor* for patent infringement-free testing of drugs, building upon an earlier broad interpretation of the same statutory provision in *Eli Lilly & Co. v. Medtronic, Inc.*³ The safe harbor is a statutory infringement-free zone for experimentation on pharmaceuticals that permits the use of a patented invention of another during the testing of drugs for regulatory approval at the Food and Drug Administration (FDA): “[I]t shall not be an act of infringement to . . . use . . . or import into the United States a patented invention . . . solely for uses rea-

* Earlier drafts were presented at seminars at the Max-Planck-Institut für Geistiges Eigentum (Munich, Germany); the Japanese Group of AIPPI (Tokyo, Japan); and the GRUR-Bezirksgruppe Frankfurt-am-Main (Frankfurt, Germany). The author acknowledges with appreciation critical commentary or participation in such seminars by Pavan Agarwal, Dan Burk, Lynn Eccleston, Günter Isenbruck, Steve Maebius, Robert Merges, Kimberly Moore, Leon Radomsky and Peter Reuss. This Article in part reflects joint research conducted with Lynn E. Eccleston of The Eccleston Law Firm, some of which appears in her brief amicus curiae filed on behalf of the Bar Association of the District of Columbia PTC Section in the *Merck* case. Brief of Amicus Curiae Bar Association of the District of Columbia PTC Section, *Merck KGaA v. Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372 (2005) (No. 03-1237).

** Former Director of the Intellectual Property Law Program and Professor of Law, George Washington University Law School; Partner, Foley & Lardner LLP. Send correspondence to hwegner@foley.com. The views expressed herein are personal and do not necessarily reflect the views of any organization or client thereof.

¹ 125 S. Ct. 2372 (2005) [hereinafter *Merck*].

² *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) [hereinafter *Integra*], *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005). The panel vote in the Federal Circuit was 2-1. *Integra*, 331 F.3d at 862. For the sake of clarity, the Supreme Court decision is denoted throughout this article as *Merck* while the decisions of the Federal Circuit and the district court are denoted as *Integra*.

³ 496 U.S. 661 (1990). *Compare id.* at 665–69 (establishing the safe harbor provision), *with Merck*, 125 S. Ct. at 2380 (confirming the broad interpretation of the safe harbor provision).

sonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs.”⁴

Unlike the garden variety application of the safe harbor contemplated at the time of enactment to permit a generic drug manufacturer to conduct testing of an *existing* drug for safety and bioequivalency, *Merck* involved the testing of Merck’s own new compounds to determine which of several compounds would be suitable for clinical trials necessary for regulatory approval.⁵ The preliminary experimentation included comparative testing of analogs and efficacy tests—all *preliminary to any clinical testing*.⁶ The fact pattern fits squarely within the common law experimental use defense to patent infringement, but also arguably within the statutory safe harbor.

Before one can properly understand the role of the safe harbor in the fabric of patent law, it is necessary to consider first common law experimental use as it evolved from early nineteenth century case law.⁷ The common law infringement defense applies only to experimentation *on* a patented invention.⁸ This includes, for example, screening of suitable drug candidates and preliminary *in vitro* and *in vivo* testing of such drug candidates, and is in contrast to experimentation *using* a patented invention—such as the regulatory testing of a generic drug. A correct distinction was drawn in the holding of *Roche Products, Inc. v. Bolar Pharmaceutical Co.*,⁹ where generic regulatory testing of a known drug was held to be an infringement.¹⁰ Within months, the narrow holding of that case was statutorily overruled,¹¹ giving birth to the statutory safe harbor.¹² In the wake of dictum in *Roche*, the statutory creation of the

⁴ *Merck*, 125 S. Ct. at 2380 (quoting 35 U.S.C. § 271(e)(1)). Deletions shown here are as shown in the quotation of the statute by the Court. *Id.* In *Medtronic*, the Court judicially extended the scope of the safe harbor to cover not only drugs but also other subject matter that requires regulatory approval by the FDA. *See Medtronic*, 496 U.S. at 665–69. In *Medtronic*, the subject matter at issue was a medical device. *Id.* at 664.

⁵ *Merck*, 125 S. Ct. at 2377–79.

⁶ *Id.* at 2378.

⁷ *See* discussion *infra* Part I.

⁸ *See* Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17–18 (2001).

⁹ 733 F.2d 858 (Fed. Cir. 1984).

¹⁰ *Id.* at 860.

¹¹ *See* H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2678–79; H.R. REP. NO. 98-857, pt. 2, at 27 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2711–12.

¹² *See* discussion *infra* Part II (discussing Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202(e)(1), 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1) (2000)).

safe harbor, and dicta in several relatively recent cases, a perception emerged that the common law experimental use defense was dead.¹³

With a proper understanding of the interaction of the common law defense and the statutory safe harbor, it is then possible to properly consider *Merck*.¹⁴ This aspect of the Article commences at the trial level where Merck argued *both* the common law experimental use defense and the safe harbor defenses.¹⁵ Indeed, at trial, Merck *won* on several questions of experimental use, but the case on appeal was transformed into a test of the safe harbor.¹⁶ By the time *Integra* was appealed to the Federal Circuit, the common law defense had been *abandoned* by new lead counsel; the panel gave the safe harbor a narrow construction, focusing on the original statutory purpose to permit regulatory testing of generic drugs.¹⁷ On appeal to the Supreme Court there was virtually no defense by the parties or amici of the *Integra* narrow interpretation of § 271(e)(1); even Respondent conceded this point and instead took the desperate move of asking the Court to *dismiss* the case.¹⁸

Had this been a case about a better *aspirin*, the outcome may well have been different. With the *res* of this case involving the discovery of new cancer cures,¹⁹ the audience—nine senior citizens, including one very seriously ill with cancer and two cancer survivors—could not have been less sympathetic to a strict statutory construction that would have permitted the patentee to bar the exploration of new cancer drugs. Any doubt about the outcome of this case was surely over after the final several minutes of questioning of Respondent about cancer drug “efficacy” testing.²⁰

The chilling colloquy over cancer efficacy testing ended whatever suspense there may have been concerning the outcome of the case as to the rights of the parties. Thereafter, the main issue for the patent bar was the controversial push by the United States as amicus curiae that the upstream boundary of the safe harbor should be interpreted to include even the screening of literally *thousands* of compounds in order to select the best targets for regulatory approval.²¹ With the cancer issue at the fore, it is hardly any wonder that the

¹³ See discussion *infra* Part III.

¹⁴ See discussion *infra* Part IV.

¹⁵ *Merck*, 125 S. Ct. 2372, 2379 (2005).

¹⁶ *Id.* at 2379–80.

¹⁷ See *Integra*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

¹⁸ Respondent’s Brief at 28, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

¹⁹ See *Merck*, 125 S. Ct. at 2378.

²⁰ See discussion *infra* Part IV.E; Oral Argument Transcript at 37–44, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

²¹ See Brief for the United States as Amicus Curiae Supporting Petitioner at 18–19, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

Court took the broadest imaginable approach to extend the safe harbor far upstream, quoting the amicus curiae brief of the United States with approval.²² Significantly, the Court expressly declined to consider the implications of “research tool” patents.²³

From a comparative standpoint, the decision of the Court is hardly remarkable. Both the German and Japanese courts have taken a broad approach to infringement-free testing of new products.²⁴

Various calls for statutory reform have been put forward, seemingly based upon the premise that the Federal Circuit—or the Supreme Court—will never resolve the controversy over experimental use.²⁵ While there are a wide variety of solutions that have been proposed, none appears to have any realistic chance of enactment due to the polarization among the various interest groups.²⁶

There never should have been a *Merck* case keyed to the question of an upstream boundary of the safe harbor in the first place; it came to pass only due to the failure of the judicial system to have earlier provided clear guidance on the experimental use defense. Unless and until such guidance is provided, cases will percolate through the system and eventually reach the Supreme Court once again. The Court will clearly push whatever statutory interpretation is necessary in the patent law to reach the result that the common law defense has historically provided. Thus, if there *is* an experimental use case that does reach the Court it is clear that from the public policy colloquy in the *Merck* oral argument concerning the freedom to conduct cancer research, the experimental use defense will again be strongly endorsed.²⁷

I. Common Law Experimental Use

Experimental use continues as a vibrant patent law doctrine, most recently revisited by the Court in *Pfaff v. Wells Electronics, Inc.*²⁸ The doctrine dates back to nineteenth century cases that first established the right of the public to conduct scientific (or *philosophical*) experiments on an invention, particularly improvements on the patented invention, and later to cases that involved tolling the patent filing deadline for experiments to complete its reduction to

²² See *infra* note 161 and accompanying text.

²³ *Merck*, 125 S. Ct. at 2382 n.7. It is in any event difficult to characterize or define what a research tool comprises. See Mueller, *supra* note 8, at 10–17.

²⁴ See discussion *infra* Part V.

²⁵ See, e.g., Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 471 (2004).

²⁶ See discussion *infra* Part VI.

²⁷ See discussion *infra* Part VI.E.

²⁸ 525 U.S. 55, 64 (1998) (“The law has long recognized the distinction between inventions put to *experimental use* and products sold commercially.”) (emphasis added).

practice.²⁹ Controversy swirls today over the original experimental use right to experiment *on* a patented invention, which is too often confused with the infringing *use* of a patented invention for experimentation. As explained in a 1990 legislative report, “[t]he easiest method of limiting and describing the ‘experimental use . . . exception’ is to differentiate between *experimentation on* a patented invention and *experimentation using* a patented invention in order to accomplish another purpose, the former type of experimentation constituting the scope of the exception.”³⁰ The experimenting *on*/experimenting using distinction is widely recognized,³¹ yet it is not without difficulties in its application.³²

More than one hundred ninety years ago Joseph Story³³ confirmed the right

²⁹ See, e.g., *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600). Experimental use to experiment *on* a patented invention as an exemption from patent infringement is keyed to the infringement statute, 35 U.S.C. § 271 (2000). Experimental use to experiment *on an improved* invention as a toll to the statutory bar is keyed to a different statutory home, 35 U.S.C. § 102(b) (2000). The case law unique to the latter issue was directly implicated in *Pfaff* and is otherwise outside the scope of the remainder of this Article. See *Pfaff*, 525 U.S. at 57 & n.2, 60, 64–65, 68.

³⁰ H.R. REP. NO. 101-960, pt. 1, at 44 (1990) (emphasis added). This legislative proposal is considered *infra* in the text accompanying notes 188–193.

³¹ See, e.g., Janice M. Mueller, *The Evanescent Experimental Use Exemption from United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917, 940–41 (2004) (“The Duke scientists [in *Madey v. Duke University*, 307 F.3d 1351 (1352) (Fed. Cir. 2002)] were experimenting *with*, rather than experimenting *on*, the claimed laser inventions. . . . On this basis alone, the case could have been decided as one not qualifying for the experimental use exemption.”) (footnotes omitted).

³² See, e.g., Mueller, *supra* note 8, at 40. Professor Mueller points out:

When research tool transaction costs are severe enough to impede or stop the development of new biomedical products, line-drawing between “experimenting on” and “experimenting with” is no longer justified. In such cases, access to the experimental use doctrine should not turn on the relatively fine distinction between experimenting on or experimenting with the patented invention.

Id.

³³ Joseph Story has undoubtedly had a greater impact on the patent system than any other single jurist in the history of this country. This is in part because of his long tenure as a Justice on the Supreme Court, in part because he was the Circuit Justice for Massachusetts, in part because of his role as a professor at Harvard University, and—above all—because of his presence and reputation in so many divergent fields of law in the overall society at large. See *In re Nelson*, 280 F.2d 172, 178 n.2 (C.C.P.A. 1960) (discussing Judge Story); Harold C. Wegner, *Equitable Equivalents: Weighing the Equities to Determine Patent Infringement in Biotechnology and Other Emerging Technologies*, 18 RUTGERS COMPUTER & TECH. L.J. 1, 12 & n.31 (1992).

of everyone to use a patented invention for natural science—then known as natural philosophy.³⁴ As explained by Judge Newman in the dissenting portion of her opinion in *Integra*, “[t]he common law research exemption is a limited exception to the patentee’s unrestricted right to exclude.”³⁵ She quotes from *Whittemore v. Cutter*³⁶ 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.”³⁷ Professor Duffy also ap-

Justice Story’s pioneer work in intellectual property law throughout his term on the Court is epitomized by his opinion in *Folsom v. Marsh*, written nearly 30 years after he became a Justice. In that opinion he is said to have “laid down the basis for the judicially created doctrine of fair use [in copyright law] with no support from the statute at all.”

Wegner, *supra*, at 12 n.31 (citation omitted).

³⁴ See *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.).

³⁵ *Integra*, 331 F.3d 860, 874 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

³⁶ 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600) (Story, J.).

³⁷ *Integra*, 331 F.3d at 874–75 (Newman, J., concurring in part, dissenting in part) (quoting *Whittemore*, 29 F. Cas. at 1121). In a footnote, Judge Newman explains that “[b]y ‘philosophical’ experiments Justice Story was referring to ‘natural philosophy,’ the term then used for what we today call ‘science.’” *Id.* at 874 n.8. The holding in *Whittemore* is explained in a subsequent case, where Circuit Justice Story stated:

[T]he making of a patented machine to be an offence within the purview of it, 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 and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.

Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (Story, J.) (citation omitted). The second opinion in *Whittemore* shed further light. There, Justice Story explained:

By the principles of a machine, (as these words are used in the statute) is not meant the original elementary principles of motion, which *philosophy and science* have discovered, but the *modus operandi*, the peculiar device or manner of producing any given effect. The expansive powers of steam, and the mechanical powers of wheels, have been understood for many ages; yet a machine may well employ either the one or the other, and yet be so entirely new, in its mode of applying these elements, as to entitle the party to a patent for his whole combination.

Whittemore v. Cutter, 29 F. Cas. 1123, 1124 (C.C.D. Mass. 1813) (No. 17,601) (Story, J.) (emphasis added). Later, in *Bedford v. Hunt*, Justice Story explained:

If [a prior invention] were the mere speculation of a philosopher or a mechanician, which had never been tried by the test of experience, and never put into actual operation by him, the law would not deprive a subsequent inventor, who had employed

precipitates the importance of this passage.³⁸

Within five years of *Whittemore*, experimental use was considered in *Evans v. Eaton*,³⁹ the very first Supreme Court case to deal with substantive patent law;⁴⁰ the Court included a recapitulation of patent law as part of a comprehensive appendix.⁴¹ *Evans* sheds further light on the view that there *should* be experimenting *on* a patented invention to make a yet further patented invention—but that the *commercial* practice of that later patented invention had to give way to the rights of the earlier patentee.⁴² Thus, *Evans* recognizes that an infringing improvement invention can be made during the term of an earlier patent, but not practiced commercially free from the senior patent.⁴³ Citing as authority a contemporaneous English precedent, *Evans* states that “[i]f a person has invented an improvement upon an existing patented machine, he is entitled to a patent for his improvement; but he cannot use the original machine, until the patent for it has expired.”⁴⁴

his labor and his talents in putting it into practice, of the reward due to his ingenuity and enterprise.

3 F. Cas. 37, 38 (C.C.D. Mass. 1817) (No. 1,217) (Story, J.). That same year, in *Lowell v. Lewis*, Justice Story stated that “[i]t has been often decided, that a patent cannot be legally obtained for a mere philosophical or abstract theory; it can only be for such a theory reduced to practice in a particular structure or combination of parts.” 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (Story, J.) (emphasis added).

³⁸ John F. Duffy, *Harmony and Diversity in Global Patent Law*, 17 BERKELEY TECH. L.J. 685, 717–18 (2002).

³⁹ 16 U.S. (3 Wheat.) 454 (1818).

⁴⁰ Prior reported patent decisions did not deal with substantive patent law. See, e.g., *Tyler v. Tuel*, 10 U.S. (6 Cranch) 324 (1810) (denying right of partial owner to enforce patent); *Evans v. Jordan*, 13 U.S. (9 Cranch) 199 (1815) (confirming validity of private patent term extension statute).

⁴¹ *Evans*, 16 U.S. (3 Wheat.) app. at 13–29.

⁴² See *id.* at 519.

⁴³ See *id.*

⁴⁴ *Evans*, 16 U.S. (3 Wheat.) app. at 17 (citing *Ex parte Fox*, 35 Eng. Rep. 26 (1812) (The Lord Chancellor Eldon)). In *Fox*, a patent was granted for an improved steam engine versus an earlier, unexpired, more basic patent. Unstated in the opinion, there was presumably no cause of action for the experimentation that led to the creation of the improvement invention. *Fox* at 67. Insofar as the commercial use of the invention was concerned, the Lord Chancellor stated:

[i]f the [patentees] have invented certain Improvements upon [a previously patented] Engine . . . , and those Improvements could not be used without the original Engine, at the End of [the patent term] the [patentees] could make Use of a Patent, taken out upon their Improvements; though, before that Period expired, they would have no Right to make Use of the other’s *Substratum*. At the End of that Time the Public has a Choice between the Patents.

Whittemore was not an isolated case. Also in 1813, Whittemore was explained in *Sawin v. Guild*.⁴⁵

[T]he making of a patented machine to be an offence within the purview of it, 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 and exactness of the specification. In other words, that the making must be with an intent to infringe the patent-right, and deprive the owner of the lawful rewards of his discovery.⁴⁶

Whittemore is further explained in *Whittemore v. Cutter*,⁴⁷ a second opinion in that same case several months later:

By the principles of a machine, (as these words are used in the statute) is not meant the original elementary principles of motion, which *philosophy and science* have discovered, but the *modus operandi*, the peculiar device or manner of producing any given effect. The expansive powers of steam, and the mechanical powers of wheels, have been understood for many ages; yet a machine may well employ either the one or the other, and yet be so entirely new, in its mode of applying these elements, as to entitle the party to a patent for his whole combination.⁴⁸

The same approach used in the first half of the nineteenth century by Joseph Story was also taken by Lord Jessel in *Frearson v. Loe*,⁴⁹ where he elaborated on experimental use:

[I]f a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but *with the view of improving upon the invention . . . or with the view of seeing whether an improvement can be made or not*, that is not an invasion of the exclusive rights granted by the patent. Patent rights were never granted to prevent persons of ingenuity [from] exercising their talents in a fair way.⁵⁰

A. Noninfringing Experiment on the Patent

Major academics who have studied this matter extensively support the right to *experiment on* a patented invention “as a basis for follow-on innovation.”⁵¹ More colorfully, one academic goes so far as to question the sanity of anyone who would deny the existence of an experimental use defense to

Id.

⁴⁵ 21 F. Cas. 554 (C.C.D. Mass. 1813) (No. 12,391) (Story, J.).

⁴⁶ *Id.* at 555 (citation omitted).

⁴⁷ 29 F. Cas. 1123 (C.C.D. Mass. 1813) (No. 17,601) (Story, J.).

⁴⁸ *Id.* at 1124 (emphasis added).

⁴⁹ 9 Ch. D. 48 (Ch. 1878).

⁵⁰ *Id.* at 66–67 (emphasis added). This is the leading case among Commonwealth countries. See, e.g., *Monsanto Co. v. Stauffer Chem. Co.*, [1985] R.P.C. 515, 529 (Eng. C.A.); *Smith Kline v. Douglas Pharms. Ltd.* [1991] F.S.R. 522 (N.Z. C.A.).

⁵¹ See, e.g., Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 148 (2004). See also *infra* notes 52–56 and accompanying text.

patent infringement, a person who “[s]urely . . . needs the help of a mental health professional.”⁵²

1. Creation of New Inventions During the Term of the Patent

The right to experimentation to create new products and particularly to design around existing patents is well established.⁵³ Professor Rochelle Dreyfuss commented:

Until a short while ago, no one would have thought there was a need to focus on the question whether the scientific community needed the help of an experimental use defense to patent infringement. By 1890, the issue of whether experimentation amounted to patent infringement seemed to have been clearly resolved by a series of cases authored by the legendary Justice Joseph Story.⁵⁴

She then quotes with approval from Professor William Robinson’s leading late nineteenth century patent law treatise:

[W]here [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of intellectual character But if

[I]t is probably impossible to produce a bright-line rule to distinguish the two types of experimentation To deal with more difficult cases, we return to the distinction between use of the *inventive idea* as a basis for follow-on innovation and use of the *invention* for its intended purposes. “Experimenting on” is aimed at using the inventive idea, whereas “experimenting with” is aimed at using the invention. One way to get at this distinction is to ask whether, in a world of perfect communication, the experimental use of the invention could be replaced by a perfect disclosure. In other words, could the infringing experimentation have been avoided in principle by more information about the patented invention? If so, we are dealing with “experimenting on.”

Strandburg, *supra*, at 148.

⁵² 3 MARTIN J. ADELMAN ET AL., PATENT LAW PERSPECTIVES § 3.6[2] at 3-78.2(3) (2d ed. 2005).

⁵³ See, e.g., *id.* at 3-78.2(2)–(3).

There are some simple scenarios that should be kept in mind when thinking about experimental use. One is simply the use of a patented product to try and find new uses for the product. . . . [C]an a member of the public build and use the patented product to try and find new uses for it or to develop patentable improvement? A [second,] related scenario is where a patent covers a genus and then a member of the public experiments with various species to find the best species. In both cases the member of the public may patent the invention made using the patented product or the patented genus. Obviously in both cases the acts can be done with the intent . . . to both add to the world’s knowledge as well as wealth to the member. If the member of the public obtains a patent, then the added wealth created by his discovery will be shared between the patentee and the member of the public, if not the added wealth flows to the patentee alone. A third scenario is where the patented product is used to discover a product or process that if sold or used by the public would not infringe the patent.

Id.

⁵⁴ Dreyfuss, *supra* note 25, at 457–58.

the products of the experiment are sold . . . the acts of making or of use are violations of the rights of the inventor and infringements of his patent.⁵⁵

Professor Dreyfuss concludes that “[i]n other words, to early jurists, a clear distinction could be made between using patented material to learn about the patented invention and using patented material for business or for commerce—between using the patent to satisfy curiosity or using it to turn a profit.”⁵⁶

2. USPTO and Court Sanctioned Testing of an Invention

It has always been axiomatic that a person may use the invention of another for the purpose of presentation of evidence to the U.S. Patent and Trademark Office (USPTO) or the courts. It is necessary that those seeking to invalidate a patent have the ability to experiment *on* a patented invention to determine its operability in accordance with the teachings of the patent specification.⁵⁷ Experimentation may be necessary to establish patentability of a new invention through comparative testing to establish presence of a secondary consideration under *Graham v. John Deere Co.*⁵⁸

⁵⁵ *Id.* at 458 (quoting WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 898 (1890)).

⁵⁶ *Id.* She then adds a personal anecdote from her own experience as a bench chemist several decades ago, prior to her entry into the legal profession, where she was employed by one of the large Swiss-based multinational pharmaceutical companies:

[W]hen I worked in pharmacology in the late 1970s, the pharmaceutical company that I worked for had a relaxed attitude towards academic researchers. Indeed, one of my responsibilities as a bench chemist was to furnish researchers with the metabolites I generated in the course of my work. This was something I really enjoyed, seeing that the metabolites that I had found were of interest not only to the firm I worked for, but also to scholars; I thought that by sending out my samples, I was helping to foster basic science.

Id.

⁵⁷ See *Crown Operations Int’l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1381 (Fed. Cir. 2002); see also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 929 n.9 (Fed. Cir. 2004) (“[Morse] claims an exclusive right to use a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent.”) (quoting *O’Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1853)); *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) (authorizing experimentation “for the purpose of ascertaining the sufficiency of the machine to produce its described effects”); *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391) (authorizing use to “ascertain the verity and exactness of the specification”).

⁵⁸ 383 U.S. 1, 17–18 (1966). The USPTO established detailed regulations for comparative tests. *E.g.*, U.S. PATENT AND TRADEMARK OFFICE, U.S. DEPT. OF COMMERCE, MANUAL OF PATENT EXAMINING PROCEDURE § 716.02(b) (8th ed., rev. May 2004) [hereinafter MANUAL] (“Evidence of unexpected properties may be in the form of a direct or indirect

In Beidler v. Photostat Corp.,⁵⁹ a court confirmed the right of an accused infringer to make and test an otherwise infringing embodiment for the purpose of a presentation of comparative evidence to the court:

Plaintiff claims that defendant's possession of the single machine used as an exhibit [for the court proceeding] is a past and continuing act of infringement. . . . It has not been used or exhibited except for the purposes of this litigation. Its presence in court was important to enable the court to visualize and compare the mechanism and principles of operation [one] machine with the [other] machines. . . . The possession [of an otherwise infringing machine] as a model does not constitute actual or threatened infringement in the absence of proof that the machine is held for purposes of profit in violation of the exclusive right of the patentee to make, use, and sell the patented invention⁶⁰

Without a right to reproduce a patented invention it is impossible to prove matters such as scope of operability or to establish nonobviousness through comparative testing. For example, it is necessary that those seeking to invalidate a patent have the ability to experiment with an invention to determine its operability in accordance with the teachings of the patent specification.⁶¹

Experimentation may be necessary to establish patentability of a new invention through comparative testing to establish presence of a secondary consideration.⁶² Detailed regulations have been established by the USPTO that essentially *require* comparative testing.⁶³ Professor Adelman explained the policy supporting the right to use the patented invention in this situation:

A [noninfringing] scenario would be to generate information for administrative agencies or courts. For example a member of the public may seek to check prophetic examples (paper examples in a patent) to see whether the patent itself has a fatal flaw. Of course even those examples that the patentee actually carried out can be checked to see if the patentee made a serious experimental error that would fatally effect one of [sic] more claims of the patent. In essence these tests would be designed for use either in court or in the PTO.⁶⁴

B. An Infringing Experiment *Using* the Patent

If the patented invention is *fit for use* and thus simply used for its intended purpose or to *experiment* to determine its commercial worth or to establish

comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims.”).

⁵⁹ 10 F. Supp. 628 (W.D.N.Y. 1935), *aff'd*, 81 F.2d 1015 (2d Cir. 1936).

⁶⁰ *Id.* at 630.

⁶¹ See cases cited *supra* note 57.

⁶² See *supra* notes 57–58 and accompanying text.

⁶³ See MANUAL, *supra* note 58, § 716.02(b) (“Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims.”).

⁶⁴ See ADELMAN ET AL., *supra* note 52, § 3.6[2], at 3-78.2(3).

that the invention is safe or meets contractual requirements, this is not an experiment *on* the patented invention for a scientific study of that invention. Rather, this is simply the infringing use of the patented invention for its intended purpose. This *fit for use* distinction was recognized in the same decade as *Whittemore*.⁶⁵ In *Evans v. Eaton*, the Court held:

[T]he making of a patented machine, *fit for use, and with a design to use it for profit*, in violation of the patent right, is, of itself, a breach of [patent law], for which an action lies; but where the making only, *without a user*, is proved, *nominal* damages only are to be given for the plaintiff.⁶⁶

Thus, if the patented machine is already fit for use, then there is no longer any permitted experimentation within the contemplation of the user.

The past generation witnessed a series of cases that *correctly* held that a business-oriented testing of an invention is not exempt from patent infringement as a philosophical or scientific use of an invention.⁶⁷ For example, a pilot plant operation under a government contract to establish that a proposed system would operate in its intended manner as part of a commercialization effort clearly is outside the scope of an experimental use as envisioned by Justice Story.⁶⁸

II. Creation of a Generic Drug Safe Harbor

Roche involved a business testing of pioneer patentee Roche's drug during the term of the patent.⁶⁹ The experiments of accused infringer Bolar involved the extensive safety and bioequivalence testing of Bolar's generic version of Roche's drug for submission to the FDA.⁷⁰ The court noted that extensive testing of safety and bioequivalence of a proposed generic drug is a condition precedent to the grant of regulatory approval for marketing of a generic drug.⁷¹

⁶⁵ See *Evans v. Eaton*, 16 U.S. (3 Wheat.) 454, 475–77, app. 26 (1818).

⁶⁶ *Id.* at app. 26 (citing *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600)). The Court, again citing *Whittemore*, stated that “[i]f a *user* is proved, the measure of damages is the value of the use during the time of the user.” *Id.* (citing *Whittemore*, 29 F. Cas. at 1121).

⁶⁷ See, e.g., *id.* at 519; *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391).

⁶⁸ See *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 625, 634 (1990).

⁶⁹ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 860 (Fed. Cir. 1984).

⁷⁰ See *id.*

⁷¹ See *id.* at 863–65. Bolar did not plan to infringe the Roche patent by commercial marketing of the invention during the term of the Roche patent. See *id.* at 860. Rather, the goal was to have *approval* for marketing immediately upon the expiration of the patent. See *id.*

From the patent law standpoint, there was absolutely nothing extraordinary about *Roche*. The tests involved in *Roche* clearly had nothing to do with studying the patented invention in any of the classical senses of an experiment *on* the invention.⁷² No new properties of the invention were an object of discovery.⁷³ Rather, Bolar’s only goal was to prove that the product produced from its proposed generic manufacturing facility was both safe and bioequivalent to the patented drug sold by Roche.⁷⁴

The safe harbor of 35 U.S.C. § 271(e)(1) that was enacted into law several months after *Roche* was designed to create a very narrow statutory override of the holding of that case simply to permit the regulatory testing of generic drugs during the term of the patent for approval under an Abbreviated New Drug Application (ANDA).⁷⁵

III. Nichol’s Legacy: *Embrex*, *Madey*, and *Deuterium*

The *Embrex, Inc. v. Service Engineering Corp.*⁷⁶ and *Madey v. Duke University*⁷⁷ opinions of the Federal Circuit set the stage for *Merck* and may well have led the Petitioner in *Merck* to abandon the experimental use defense at the Federal Circuit.

A. The *Embrex* Concurrence

Much is said in *Embrex* concerning the experimental use defense, but not as part of the holding; rather, this is only the opinion of one member of the Court in a concurring opinion.⁷⁸ The concurrence completely denies the possibility that *scientific* or *philosophical* testing is an excused experimental use: “[N]either the statute nor any past Supreme Court precedent gives any reason to excuse infringement because it was committed with a particular purpose or intent, such as for scientific experimentation”⁷⁹ Equally extreme is

⁷² See *id.* at 860.

⁷³ See *id.*

⁷⁴ See *id.* at 863.

⁷⁵ See H.R. REP. NO. 98-857, pt. 1, at 45–46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2678–79; H.R. REP. NO. 98-857, pt. 2, at 27 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2649, 2711–12; Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202(e)(1), 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1) (2000)).

⁷⁶ 216 F.3d 1343 (Fed. Cir. 2000).

⁷⁷ 307 F.3d 1351 (Fed. Cir. 2002).

⁷⁸ *Embrex*, 216 F.3d at 1352–53 (Rader, J., concurring).

⁷⁹ *Id.* at 1353 (Rader, J., concurring). Judge Rader went on to say that “the Supreme Court and this court have recently reiterated that intent is irrelevant to infringement. These recent pronouncements should dispose of the intent-based prong of [the] argument.” *Id.* (Rader, J.,

the idea that a commercial enterprise cannot benefit from the experimental use exemption.⁸⁰

The author of the *Embrex* concurrence contemporaneously explained that

[t]he statute states directly that any unauthorized use of a patented invention is infringement. With regards to the experimental use excuse, neither the statute [sic] nor any precedent gives any reason to excuse infringement because it was committed with a particular intent or purpose, such as scientific experimentation or out of curiosity. Rather the Supreme Court and the Federal Circuit have reiterated that intent is irrelevant in infringement. Does the *de minimis* infringement excuse still survive? Perhaps on the books. In reality, *if there is a commercial taint at all*, and it is hard to imagine a case without such a commercial taint, it would never be called *de minimis*.⁸¹

B. The *Madey* Dictum

Perhaps most prominent and infamous of all the recent cases is *Madey*. It would not have stirred an ounce of controversy had it focused upon the *holding* that the use of a research tool for its intended purpose in research is an act of patent infringement not saved by an experimental use defense.⁸² Boiled down to essential facts, Dr. Madey's patented laser gun was used by Duke as a research tool for its intended purpose in research, but not to study the laser gun itself.⁸³ *Madey* refers to the dictum of the late Judge Nichols in *Roche*.⁸⁴ A major problem was that the late Judge Nichols in *Roche* failed to understand that Justice Story was referring to serious *scientific* research when he used the contemporary term *philosophical*; he instead equated the Story exemption to that of a curious dabbler, a "dilettante."⁸⁵

concurring) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997) and *Hilton Davis Chem. Co. v. Warner Jenkinson Co.*, 62 F.3d 1512 (Fed. Cir. 1995)).

⁸⁰ See *id.* (Rader, J., concurring) ("[E]ven if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the 'philosophical inquiry/experimental use' doctrine inapplicable.").

⁸¹ Judge Randall Rader, *Experimental Use Exception: The Federal Circuit's Interpretation of 35 U.S.C. Section 271(e)* (July 20, 2001), in 7 *CASRIP SYMPOSIUM PUBLICATION SERIES 6* (Hill et al. eds., 2002), available at <http://www.law.washington.edu/casrip/symposium/number7/> (last visited July 22, 2005) (emphasis added) (remarks at the High Technology Protection Summit at the University of Washington School of Law).

⁸² *Madey v. Duke Univ.*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

⁸³ See *id.* at 1352–53.

⁸⁴ *Id.* at 1355, 1361–62.

⁸⁵ *Roche Prods. Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (Nichols, J.).

The court in *Madey* does not even consider the facts of the case relevant to the experimental use defense in any detail.⁸⁶ But, there clearly was no *experimental* use of the patented laser technology because that technology was not the subject of experimentation.⁸⁷ The patented laser equipment was used for its intended purpose and there was nothing experimental in the way of any *scientific* curiosity concerning the patented invention. Clearly, Judge Newman correctly grasps the holding in *Madey*, which

concerned the use of a patented laser device for the purpose for which it was made, not research into understanding or improving the design or operation of the machine. The facts of *Madey* . . . do not invoke the common law research exemption, despite the broad statement in that opinion. I do not disagree with that decision on its facts; I disagree only with its sweeping dictum, and its failure to distinguish between investigation into patented things, as has always been permitted, and investigation using patented things, as has never been permitted.⁸⁸

Madey suggests that *scientific* use of an invention by a nonprofit is outside the scope of the experimental use exemption.⁸⁹ The court concludes that regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is *not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry*, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.⁹⁰

C. Special Prominence to Dictum in a Claims Court Opinion

*Deuterium Corp. v. United States*⁹¹ has attracted inordinate attention.⁹² The accused infringing use in *Deuterium* was of an *already completed* technology in a large scale pilot plant operation to determine whether the technology operated in accordance with governmental standards—a profit-oriented

⁸⁶ See *Madey*, 307 F.3d at 1360–63. The invention is only stated in general terms in the *Madey* opinion; there is no specific identification of the technology involved such as by a quotation of even a part of a claim of one of the *Madey* patents involved. See *id.*

⁸⁷ See *id.* at 1352–53, 1360–63.

⁸⁸ *Integra*, 331 F.3d 860, 878 n.10 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

⁸⁹ *Madey*, 307 F.3d at 1362.

⁹⁰ *Id.* (emphasis added).

⁹¹ 19 Cl. Ct. 624 (1990).

⁹² See *Integra*, 331 F.3d at 863 n.2. The majority in *Integra* cites *Deuterium*, a trial court opinion without precedential value which is purely dictum. *Id.*

contractual testing of *existing* technology by the government contractor.⁹³ Commentators have categorized *Deuterium* as a classic case of the commercial use of an invention that had already been completed.⁹⁴

This is once again a *business testing* of a completed invention that is an experimentation *with* the patented invention, and not experimentation *on* such an invention.

C. *Roche* Trumps Story, at Least on Madison Place

Madey cites back to dictum in *Roche v. Bolar*.⁹⁵ The dictum equated the Story context of a scientific, philosophical use with that of a dabbler, i.e., a “dilettante.”⁹⁶ But, this inaccurate restatement of the law of the Supreme Court’s leading patent scholar is no substitute for a holding, reasoning to support the dictum is entirely lacking.⁹⁷

⁹³ See *Deuterium*, 19 Cl. Ct. at 625.

D[epartment of Energy] entered a contract with PG & E to jointly fund a test of [EIC Laboratories’] steam cleansing process. The contract obligated PG & E to design, operate, test, decommission, and evaluate a facility that removes hydrogen sulfide from 100,000 pounds of steam per hour. . . . EIC planned a four-month test as the centerpiece of the demonstration. During this period, EIC planned to tap the main steam line, treat 100,000 pounds of steam per hour, and return the cleansed steam to the main line upstream of PG & E’s turbines. In fact, this test ended after 120 hours when a pipe elbow ruptured”

Id.

⁹⁴ See, e.g., Steven P. Caltrider & Paula Davis, *The Experimental Use Defense: Post-Madey v. Duke and Integra LifeSciences I Ltd. v. Merck KGaA*, 86 J. PAT. & TRADEMARK OFF. SOC’Y 1011, 1018 (2004).

Scale-up experiments in a pilot plant were found to be disqualified from the research exemption in *Deuterium* [T]he court found that the use of patented process of removing hydrogen sulfide from steam was infringing The court stated . . . that “[a]ny experimentation motivated by curiosity, amusement, or general intellectual inquiry took place long before the creation of the [pilot plant].” Significantly, the steam produced by the pilot plant was sold. . . . Experiments on a commercial process to scale up the process are not studying the patented process, but rather experiments to use the patented process on a larger commercial scale. The commercial use—selling the product—does not become an experiment when the only experiment is whether such use can be conducted on a larger scale.

Id. (quoting *Deuterium*, 19 Cl. Ct. at 634).

⁹⁵ See *Madey*, 307 F.3d at 1355, 1362.

⁹⁶ See *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984) (Nichols, J.).

⁹⁷ The *Roche* dicta concerning experimental use is essentially two sentences in length that essentially defines Story’s term—“philosophical”—as a “dilettante affair.” *Id.* This preposterous definition of “philosophical” in the context of early nineteenth century usage speaks for itself.

IV. *Merck v. Integra*

The *Merck* saga took nearly one full decade.⁹⁸ When the case finally reached the Supreme Court, what began as a classic experimental use defense to a charge of patent infringement had a new legal focus at each level; appellant twice switched horses, bringing in a new lead counsel at each appellate stage.⁹⁹ The issue finally before the Court had nothing to do with the experimental use defense nor research tools nor any issue *other than* the upstream boundary of the safe harbor of 35 U.S.C. § 271(e)(1).¹⁰⁰

The simple question before the Court was whether “the Federal Circuit err[ed] in concluding that th[e] drug-research safe harbor does not protect animal studies of the sort that are essential to the development of new drugs, where the research will be presented to the FDA.”¹⁰¹ Certainly by the time of the oral argument, it was clear that this question would be answered in favor of *Merck*. Rather, the major drama of the case was whether the aggressive position of the United States as amicus curiae would be followed, a position that urged the Court to push the upstream boundary of the safe harbor to include early screening of drug compound candidates, even “thousands” of them.¹⁰²

To take two unsupported sentences of *dicta* from an opinion to deny the existence of a two centuries old doctrine also speaks for itself.

⁹⁸ See *Merck*, 125 S. Ct. 2372, 2379 (2005) (noting that the first patent infringement suit in the case was filed on July 18, 1996).

⁹⁹ See *id.* at 2376 (E. Joshua Rosenkranz argued for Merck before the Supreme Court); *Integra*, 331 F.3d 860, 862 (Fed. Cir. 2003) (Donald R. Dunner argued for Merck before the Federal Circuit), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

¹⁰⁰ See *Merck*, 125 S. Ct. at 2376.

¹⁰¹ Petition for Writ of Certiorari at *i*, *Merck*, 125 S. Ct. 2372 (No. 03-1237). The complete question before the Court was:

To encourage development and expedite introduction of pharmaceuticals, Congress amended the patent laws in 1984 to insulate drug research from charges of infringement so long as the research is “reasonably related to the development and submission of information” to the Food and Drug Administration. Did the Federal Circuit err in concluding that this drug-research safe harbor does not protect animal studies of the sort that are essential to the development of new drugs, where the research will be presented to the FDA, and where barring the research until expiration of the patent could mean years of delay in the availability of life-saving new drugs?

Id.

¹⁰² Brief for the United States as Amicus Curiae Supporting Petitioner, at 18–19, *Merck*, 125 S. Ct. 2372 (No. 03-1237).

A. Experimental Use Transformed into the Safe Harbor

A decade ago when the legal action commenced, *Merck* started out as a classic case of experimental use of compounds in early pre-clinical trials with a second defense of the safe harbor of 35 U.S.C. § 271(e)(1).¹⁰³ When the case finally reached the Supreme Court and had undergone the introduction of successive teams of counsel at the two appellate levels, the common law experimental use defense had been expressly abandoned. All that remained was whether the safe harbor should be stretched from the clinical trials at the core of the experimental use defense that is far upstream from any submissions to the FDA.¹⁰⁴ Instead of relying upon the experimental use defense, the question posed was whether the safe harbor includes experimentation to lead to the *identification and comparison* of a lead candidate.¹⁰⁵

Thus, the basic question addressed in *Merck* was whether the statutory safe harbor of 35 U.S.C. § 271(e)(1) exempts from patent infringement experimentation to create or test new compounds that may be the subject of FDA approval.¹⁰⁶ As phrased by the Court in its opinion, “35 U.S.C. § 271(e)(1) provides that ‘[i]t shall not be an act of infringement to . . . use . . . or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs.’”¹⁰⁷

The answer necessarily involves delving into public policy and the intention of Congress. While the Court largely looks to the wording of a statute and shuns legislative history, it was forced to look to public policy arguments due to the fatal ambiguities of the statutory wording to provide clear guidance.¹⁰⁸ Fifteen years ago, the Court in *Eli Lilly & Co. v. Medtronic, Inc.*¹⁰⁹ said that

[n]o interpretation we have been able to imagine can transform § 271(e)(1) into an elegant piece of statutory draftsmanship. To construe it as the Court of Appeals decided [that medical devices are included], one must posit a good deal of legislative imprecision; but to construe it as petitioner would [to exclude medical devices], one must posit that and an implausible substantive intent as well.¹¹⁰

Echoing these comments in *Merck*, the Court said that “[t]hough the contours of this provision are not exact in every respect, the statutory text makes clear

¹⁰³ *Merck*, 125 S. Ct. at 2379.

¹⁰⁴ *See id.* at 2380.

¹⁰⁵ *Id.* at 2376.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 2380 (quoting 35 U.S.C. § 271(e)(1) (2000)).

¹⁰⁸ *See id.* at 2382–83.

¹⁰⁹ *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990).

¹¹⁰ *Id.* at 679.

that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.”¹¹¹

B. A Once-Perfect Experimental Use Test Case

In a classic example of evolutionary research, the first patentee, Integra, owned patent rights to a genus—or family—of “RGD peptide.”¹¹² The second patentee, Merck, created *specific* RGD peptides that were novel and unobvious as compared to any of the specifically disclosed Integra RGD peptides,¹¹³ but nevertheless within the scope of the Integra genus or family patent.¹¹⁴ *Merck* also provides a classic example of an experimentation *on* an earlier patented invention to find a new use for products of that earlier patented invention. Here, Integra’s patents disclosed a first utility—to “promote wound healing”¹¹⁵—whereas Merck’s new RGD peptides provide a cancer treatment.¹¹⁶

Merck had no intention of commercial sale of any drug with its RGD peptides until after expiration of the Integra patents.¹¹⁷ However, it contracted with Scripps Clinic and its researcher Dr. Cheresh to use the Merck RGD

¹¹¹ *Merck*, 125 S. Ct. at 2380.

¹¹² *Id.* at 2377. The “RGD peptide” has the tripeptide sequence Arg-Gly-Asp which promotes cell adhesion by attaching to particular integrins, receptors commonly located on the outer surface of certain endothelial cells. They promote cell adhesion by attaching to particular integrins, receptors commonly located on the outer surface of certain endothelial cells; the RGD peptides find utility in treating solid tumors; none of the specific RGD peptides within Integra’s research were ultimately pursued as a drug candidate for clinical trials. *Id.* at 2377–78.

¹¹³ *See id.* at 2378. It is well settled that a first patent to a generic invention does not bar a claim to a later species if that species is novel and unobvious versus the *disclosed* specific structure supporting the genus of the first patent. *See, e.g., In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992) (“The lack of close similarity of [disclosed] structure is not negated by the fact that the claimed salt is a member of [the earlier patentee’s] broadly disclosed genus of . . . salts . . .”).

¹¹⁴ *See Merck*, 125 S. Ct. at 2378.

¹¹⁵ *Integra*, 331 F.3d 860, 862–63 (Fed. Cir. 2003), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

¹¹⁶ *See id.* at 863.

Dr. David Cheresh, a scientist at Scripps [who became a part of the Merck team], discovered that [the mechanism of its RGD peptides] inhibits angiogenesis, the process for generating new blood vessels. Inhibiting angiogenesis showed promise as a means to halt tumor growth by starving rapidly dividing tumor cells. Similarly, anti-angiogenic therapies might also treat diabetic retinopathy, rheumatoid arthritis, psoriasis, and inflammatory bowel disease.

Id.

¹¹⁷ *See id.*

peptides within the scope of Integra's patent protection for experiments on the RGD peptides, including comparative tests among several possible clinical candidates.¹¹⁸

Integra sued Merck, Scripps and Dr. Cheresch for patent infringement in July 1996 for the use of Merck's RGD peptide in experiments related to angiogenesis.¹¹⁹ Merck pursued a dual defense of common law experimental use *and* the safe harbor of § 271(e)(1).¹²⁰ At the end of trial, the court *accepted* the common law experimental use defense for all but one of the acts of alleged infringement prior to 1995, while holding that a fact question remained as to whether the post-1995 tests fell under the safe harbor of § 271(e)(1).¹²¹ A

¹¹⁸ *Id.* at 2377–79. In 1988, Merck provided Scripps Research Institute funding for angiogenesis research—a process by which new blood vessels sprout from existing vessels which plays a critical role in solid tumor cancers. *Id.* As part of Merck's research agreement, Scripps' Dr. Cheresch discovered that it was possible to inhibit angiogenesis by blocking the integrins on proliferating endothelial cells; indeed, Dr. Cheresch succeeded in reversing tumor growth in chicken embryos, first using Dr. Cheresch's own monoclonal antibody and subsequently using Merck's cyclic RGD peptide (EMD 66203)—which as an unobvious species within the Integra genus was separately patented by Merck; the results were trumpeted in leading journals and to the general media. *Id.* at 2378. In 1995, Dr. Cheresch negotiated a \$6 million, three year development contract with Merck to develop “integrin antagonists as angiogenesis inhibitors,” commencing with test tube (*in vitro*) and animal (*in vivo*) testing of RGD peptides at Scripps and culminating with the submission of an Investigational New Drug Application (IND) to the FDA. *Id.* Scripps was responsible for testing RGD peptides produced by Merck as potential drug candidates, while Merck would conduct clinical toxicology studies for the ultimate candidate selected for regulatory approval. *See id.* at 2378–79, 2378 n.4. Under the Merck-Scripps agreement, Dr. Cheresch directed *in vitro* and *in vivo* experiments on RGD peptides provided by Merck to measure the efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors, and evaluate the mechanism of action and pharmacokinetics in animals; the tests focused on the three specific RGD peptides EMD 66203 (the original target) and EMD 85189 and EMD 121974 (the closely related structures). *See id.* at 2378–79. As a result of Dr. Cheresch's tests, Merck switched horses and chose EMD 121974 as the new target to undergo human testing. *Id.* at 2379. Merck provided its information to the National Cancer Institute (NCI); in 1998, the NCI filed an IND to commence clinical trials. *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.* The jury was instructed that

[t]o prevail on th[e] defense [under § 271(e)(1), Merck] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [Merck's] and Scripps' situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that

jury found infringement and awarded damages of \$15 million.¹²²

Merck had a seemingly perfect case under the experimental use defense as its tests of the RGD peptides were to *study* and develop new RGD peptides and test their efficacy and otherwise determine which candidate RGD should be selected for clinical trials.¹²³ The tests fall squarely within the scope of classic experimental use envisioned under the common law. What happened? When the case reached the Federal Circuit on appeal, new counsel took over and *expressly abandoned* the experimental use defense and put all its noninfringement eggs into the statutory safe harbor basket of § 271(e)(1).¹²⁴

C. The Federal Circuit’s Strict Construction of the Safe Harbor

The Federal Circuit majority held that the safe harbor is focused upon freedom from infringement for testing in clinical trials or at least information that is required by the FDA for its regulatory approval process.¹²⁵ The minority opinion is not relevant to this issue.¹²⁶

The panel majority concluded that “the express objective of the [safe harbor enactment] was to facilitate the immediate entry of safe, effective generic drugs into the marketplace upon expiration of a pioneer drug patent.”¹²⁷ “The 1984 Act thus permits filing of an ANDA . . . to expedite FDA approval of

are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question.

Id.

¹²² *Id.* at 2380. Dr. Cheresch and Scripps were dismissed from the suit in post-trial motions, while the jury award was sustained as supported by substantial evidence. *Id.* On remand and prior to the Supreme Court review of the case, the damages were reduced to \$6.375 million. *Id.* at 2380 n.5.

¹²³ *See id.* at 2378.

¹²⁴ *See Integra*, 331 F.3d 860, 878 (Fed. Cir. 2003) (Newman, J., concurring in part, dissenting in part), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

[T]he district court . . . held that the common law exemption applied to one Scripps experiment in 1994, but to nothing else. The issue was before the district court, and counsel explained at oral argument that they were not pressing this argument [before the Federal Circuit] “in part because of a very recent case.”

Id. The *recent case* is obviously *Madey*.

¹²⁵ *See id.* at 867–68.

¹²⁶ *See id.* at 872–78 (Newman, J., concurring in part, dissenting in part). The dissent by Judge Newman goes into great detail as to why the *experimental use* doctrine applies to this case. *See id.* (Newman, J., concurring in part, dissenting in part). But, the dissent is without merit *for this case* because appellant expressly waived the experimental use defense on appeal. *Id.* at 863 n.2.

¹²⁷ *Id.* at 866–67.

a generic version of a drug already on the market.”¹²⁸ However, “[t]his expedited approval process [only] requires the generic drug company to perform safety and effectiveness tests on its product before expiration of the patent on the pioneer drug if the generic is to be available immediately upon patent expiration.”¹²⁹ The upstream pre-clinical testing of a new drug such as Merck’s RGD peptides was upstream of the testing necessary for generic approval and hence, per the majority, outside the scope of the safe harbor.¹³⁰

The panel majority said that the upstream testing necessary to set the stage for clinical trials of a new drug is beyond the confines of the safe harbor:

[T]he legislative record shows . . . that the [safe harbor was] narrowly tailored . . . to have only a *de minimis* impact on the patentee’s right to exclude. Therefore, the § 271(e)(1) safe harbor covers those pre-expiration activities “reasonably related” to acquiring FDA approval of a drug already on the market. . . . The exemption viewed in this context does not endorse an interpretation of § 271(e)(1) that would encompass drug development activities far beyond those necessary to acquire information for FDA approval of a patented pioneer drug already on the market. It does not, for instance, expand the phrase “reasonably related” to embrace the development of new drugs because those new products will also need FDA approval. Thus, § 271(e)(1) simply does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process. The safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests.¹³¹

Under its premise that the safe harbor was thus limited, the majority was correct in finding infringement by Scripps’ early, pre-clinical experimentation on the invention to determine which of the several Merck peptides was preferred in terms of efficacy.¹³²

D. Respondent’s Odd Quest for Vacatur to Avoid a Reversal

Petitioner’s bizarre abandonment of experimental use at the intermediate appellate stage was trumped at the Supreme Court by the even stranger tactic of Respondent who *agreed* with Petitioner as to the broad scope of the safe harbor.¹³³ Respondent stated that “[t]he [Federal Circuit] opinion should not be read as holding that *all* preclinical activities are *per se* outside the scope of the exemption,” but then boldly conceded that “[n]evertheless, if the Federal

¹²⁸ *Id.* at 867.

¹²⁹ *Id.*

¹³⁰ *See id.* at 867–68.

¹³¹ *Id.* at 867.

¹³² *See id.* at 862.

¹³³ *See* Respondents’ Brief on the Merits at 27, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

Circuit opinion actually means what Merck and the government say it means, *Integra does not defend it.*¹³⁴

Instead, Respondent sought to have the case *dismissed* based upon perceived procedural mistakes of Petitioner.¹³⁵ This point obviously amazed the Chief Justice who admonished counsel that after the Court grants an order of *certiorari*, it focuses upon the question raised and does not parse the views of the lower courts.¹³⁶ There clearly was nothing to Respondent’s argument that had anything to do with the question presented to the Court.¹³⁷ Perhaps there was no choice for Respondent, given the uniform disagreement with the *Integra* opinion by all sides to the case.¹³⁸

E. Public Policy Favoring New Cancer Drugs

Had the *res* involved been a better *aspirin* or novel skin cream, it is quite possible that the Court would have taken a more technical view of the statute and possibly arrived at a different conclusion. Instead, the subject matter in controversy was the development of new cancer drugs played out before a

¹³⁴ *Id.* at 27 (second emphasis added).

¹³⁵ *See id.* at 27–28 Respondent stated in its brief that “[a]ny legal error in the Federal Circuit’s opinion with regard to the preclinical/clinical distinction . . . is of no moment This Court reviews ‘judgments, not statements in opinions.’” *Id.* at 27 (citation omitted). Respondent seemingly asked the Court to dismiss the appeal based upon the improvident grant of *certiorari*. *See id.* at 28; *cf.* *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 31–32 (1993) (stating that the Court will consider issues not raised in the petition for *certiorari* only in the most exceptional cases).

¹³⁶ *See* Oral Argument Transcript at 34–35, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237). The Chief Justice interrupted Respondent’s oral argument to state that “[w]e’re not reviewing the District Court’s opinion? We granted *certiorari* as to the particular question which will deal with what was the Court of Appeals opinion. *We don’t ordinarily simply compare the Court of Appeals’ opinion with the District Court’s opinion to see if they parse.*” *Id.* (emphasis added).

¹³⁷ *See* Respondents’ Brief on the Merits at 20, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237). Clearly, Respondent’s procedurally-based argument had absolutely nothing to do with the question presented: “Did the Federal Circuit err in concluding that this drug-research safe harbor does not protect animal studies of the sort *that are essential to the development of new drugs . . . ?*” *Id.*

¹³⁸ Justice Breyer stated that Respondents’ brief and oral argument

suggests that the opinion below is pretty foggy. We have Merck, the Food and Drug Administration, the Government, the entire biotechnology industry, the drug industry of the United States, and everybody else telling us that the [Federal Circuit is] wrong in the way [it] state[s] the standard [for the safe harbor]. And you, yourself, urge us to look beyond the way they stated it.

Oral Argument Transcript at 34, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

forum of a Chief Justice and two colleagues who have or had cancer and their six longtime Brethren, all of an age where cancer is a word of daily usage amongst peers.¹³⁹ Respondent took the untenable position that utility and efficacy testing of a new cancer drug was of no interest to the FDA prior to clinical trials.¹⁴⁰

The Court then queried whether a patentee could block cancer testing.¹⁴¹ The questions posed by several justices were seemingly more statements of disbelief as opposed to questions raised to obtain answers.¹⁴² If not earlier from the briefing or the oral argument up until that point, it was perfectly obvious to any observer in the courtroom that by now a 9-0 reversal of the Federal Circuit was a certainty. Justice O'Connor, herself a cancer survivor, asked: “[D]o you think that the efficacy of the drug being suggested plays a role in the IND application?”¹⁴³ Respondent answered, simply, “No, Your Honor, it does not.”¹⁴⁴ She continued: “See, I think there may be a difference there, because I think the other side thinks that[']s how the drug is expected to work, in practice, and whether it, in fact, will attack a certain disease, is part of what the FDA looks at.”¹⁴⁵

¹³⁹ See *Integra*, 331 F.3d 860, 876 (Fed. Cir. 2003), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005).

¹⁴⁰ See Oral Argument Transcript at 37–38, 41–42, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237). Arguing as amicus curiae on behalf of the United States, the Assistant to the Solicitor General took the opposite view:

[A]t the IND stage the question for FDA is whether a drug should be given to human beings. And because there's no such thing as an absolutely safe drug, because all drugs entail at least some safety risks, FDA will not let human clinical trials proceed unless there's some reason to believe that the study could be useful. *It's a . . . benefit-risk analysis. The Court looks to whether the potential benefits of the test would outweigh the risks of the test; and if not, the Court will not let a test proceed.*

Id. at 22–23 (emphasis added).

¹⁴¹ See *id.* at 30–33.

¹⁴² See *id.*

¹⁴³ *Id.* at 35.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* Thereafter, Respondent appeared to lose the Court completely when he switched from law to pharmacology for the unsupported statement that “the simple fact is that until there[are] clinical trials in humans, there's no way [to] tell whether this drug [is] going to be effective.” *Id.* at 38. Immediately, Justice Souter disagreed:

[t]here's got to be some way to tell whether [the drug] even addresses the disease. That is essentially a threshold . . . question. . . . Congress described the need that there be some relationship between the consequences of taking the given drug and the disease which is supposed to be addressed by taking the drug. If they didn't use the word “efficacy,” what word did they use?

F. Defining the Upstream Boundary of the Safe Harbor

Respondent in essence abandoned efforts to win reversal on the merits of the question presented to the Court. Rather, Respondent focused its efforts upon an attempt at vacatur. Respondent *conceded* that it did not disagree with the Petitioner or the United States as amicus curiae on the broad scope of the safe harbor.¹⁴⁶

Rather, the focus of attention switched to just how far upstream to basic research the safe harbor would be stretched. Would the boundary be simply for tests that are for submission to the FDA?¹⁴⁷ Or, would the boundary be pushed far upstream, even to the point of screening of thousands of compounds to determine the best drug candidate, as was argued by the United States as amicus curiae?¹⁴⁸ If the latter approach were taken, this would clearly render much of the need for the common law experimental use defense moot for pharmaceuticals.¹⁴⁹

1. Amicus United States: Screening “Thousands” of Compounds

The United States as amicus curiae argued that even the screening of literally thousands of compounds to find the best drug should be immune from infringement under the statute.¹⁵⁰ It noted that the Federal Circuit majority suggested that the [safe harbor] should not apply to work intended to “identify] the best drug candidate to subject to future clinical testing,” but instead should apply only after a researcher settles on a single “compound featured in an Investigational New Drug Application.” A researcher could not, however, settle on a particular compound unless it had already run tests on that compound that revealed it to be the best candidate for use in the drug. Thus, “screening” of compounds for use in a particular drug, including testing designed to compare the effects of the different compounds, is reasonably related to the development and submission of information to FDA because it allows the researcher to identify the appropriate compound or compounds to submit. The court of appeals’ contrary view would eviscerate the exemption with respect to non-generic

Id. at 38–39. Respondent stuck to his central theme that although “FDA is [only] very concerned about efficacy . . . after it gets data from human clinical trials.” *Id.* at 41. Justice O’Connor sharply disagreed: “No, I’m not sure. If there’s data earlier [in the pre-clinical stage] as a result of the lab tests and the animal tests, I would think that would be part of the [safe harbor] exemption.” *Id.*

¹⁴⁶ See *id.* at 48.

¹⁴⁷ See *id.* at 32.

¹⁴⁸ See *id.* at 18–19; Brief for the United States as Amicus Curiae Supporting Petitioner at 18–19, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

¹⁴⁹ Obviously, the safe harbor would have no applicability in agricultural or other areas of chemistry which are outside the jurisdiction of the FDA. In those cases the issue of experimental use remains a key point.

¹⁵⁰ Brief for the United States as Amicus Curiae Supporting Petitioner at 18–19, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237).

drugs, because a researcher would always have to conduct infringing tests before its work could qualify for the exemption.¹⁵¹

In response to the argument that its broad construction of the upstream boundary could include tests on literally *thousands* of compounds, the United States, in its brief, boldly agreed, stating that

the number of compounds screened is often a matter of happenstance. As FDA has explained, “[s]ometimes, scientists are lucky and find the right compound quickly.” Other times, “hundreds or even thousands [of compounds] must be tested.” As long as a scientist is working on developing a particular drug, however, the number of compounds screened has nothing to do with whether the screening was reasonably related to the development and submission of information to FDA. Instead, it reflects the luck (or intuition) of the scientist, or the difficulty of the task.¹⁵²

2. Supreme Court Agreement with the Government

The Court first agreed with the Federal Circuit that the safe harbor “does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process.”¹⁵³ The Court wrote:

We do not quibble with [this] statement. Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not “reasonably related to the development and submission of information” to the FDA.¹⁵⁴

Research is never conducted by a pharmaceutical company without “a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce.”¹⁵⁵ Otherwise, it would be totally pointless to conduct any experimentation.

Emphasizing that it sees a far upstream boundary to the safe harbor, the Court explains that

[I]t does not follow . . . that § 271(e)(1)’s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.¹⁵⁶

As to the qualification for the safe harbor of tests that are ultimately not a part of the FDA submission, the Court stated that the Federal Circuit’s premise

¹⁵¹ *Id.* at 18 (citation omitted).

¹⁵² *Id.* at 18–19 (citations omitted).

¹⁵³ *Merck*, 125 S. Ct. 2372, 2382 (2005) (quoting *Integra*, 331 F.3d 860, 867 (Fed. Cir. 2003)).

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

disregards the reality that, even at late stages in the development of a new drug, scientific testing is a process of trial and error. In the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments. That is the reason they conduct the experiments. Thus, to construe § 271(e)(1), as the Court of Appeals did, not to protect research conducted on patented compounds for which an IND is not ultimately filed is effectively to limit assurance of exemption to the activities necessary to seek approval of a generic drug. One can know at the outset that a particular compound will be the subject of an eventual application to the FDA only if the active ingredient in the drug being tested is identical to that in a drug that has already been approved.¹⁵⁷

Linking its conclusion to the statute, the Court noted that

[t]he statutory text does not require such a result. Congress did not limit § 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds “reasonably related” to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs.¹⁵⁸

Trial and error experimentation was held to be squarely within the scope of the safe harbor:

We decline to read the “reasonable relation” requirement so narrowly as to render § 271(e)(1)'s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: *At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is “reasonably related” to the “development and submission of information under . . . Federal law.”*¹⁵⁹

Under a parallel rationale, experimentation that does not find its way into a submission to the FDA is within the safe harbor.¹⁶⁰

¹⁵⁷ *Id.* at 2382–83.

¹⁵⁸ *Id.* at 2383.

¹⁵⁹ *Id.* (quoting 35 U.S.C. § 271(e)(1) (2000)) (emphasis added).

¹⁶⁰ *See id.* As the Court explained:

For similar reasons, the use of a patented compound in experiments that are not themselves included in a “submission of information” to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the “development and submission of information” to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA. Moreover, many of the uncertainties that exist with respect to the selection of a specific drug exist as well with respect to the decision of what research to include in an IND or NDA. As a District Court has observed, “[I]t will not always be clear to

The Court then underscored its agreement with the United States as amicus curiae by quoting from its brief: “We thus agree with the Government that the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is *a reasonable basis for believing that the experiments will produce the types of information that are relevant to an IND or NDA.*”¹⁶¹

V. Moving Closer to Europe and Japan

A. The German Supreme Court is *Broadening Experimental Use*

German patent law states that “[t]he rights conferred by the Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention.”¹⁶² The German Supreme Court has the most progressive view of any of the highest courts in Europe in paving the way for widespread use of any patented invention for the purpose of using such an invention to create new technologies or for regulatory testing to gain approval of such new technologies. In its 1995 leading case, *Klinische Versuche I*,¹⁶³ the German Supreme Court confirmed the right to use a patented invention to create new uses for patented technology,¹⁶⁴ without distinction to whether

parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency’s approval.”

Id. (quoting *Intermedics, Inc. v. Ventritex, Inc.* 775 F. Supp. 1269, 1280 (N.D. Cal. 1991), *aff’d*, 991 F.2d 808 (Fed. Cir. 1993)). Furthermore, the Court stated:

This is especially true at the preclinical stage of drug approval. FDA regulations provide only that “[t]he amount of information on a particular drug that must be submitted in an IND . . . depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the developmental phase of the drug.”

Id. (quoting 21 C.F.R. § 312.22(b) (2005)).

¹⁶¹ *Id.* at 2383–84 (quoting Brief for the United States as Amicus Curiae Supporting Petitioner at 23, *Merck*, 125 S. Ct. 2372 (2005) (No. 03-1237)) (emphasis added).

¹⁶² Heinz Goddar, *The Experimental Use Exception: A European Perspective*, 7 CASRIP SYMPOSIUM PUBLICATION SERIES 10 (Hill et al., eds. 2002), available at <http://www.law.washington.edu/casrip/symposium/number7/> (last visited July 22, 2005) (translating German Patent Act, Art. 11.2).

¹⁶³ [1997] R.P.C. 623 (German Supreme Court).

¹⁶⁴ See *Klinische Versuche II*, [1998] R.P.C. 423 (431) (German Supreme Court).

This [Court] recognised in [*Klinische Versuche I*] that an act with research aims based on the object of an invention, and thus lawful, can [be permitted] in the sense of [the experimental use exception under] section 11 No. 2 of the [German] Patent Act, if a patented active pharmaceutical agent is introduced in [a] clinical experiment with the aim of finding out whether, and, if necessary, in which form the active agent is suitable to cure or alleviate diseases in humans. This permission is granted fundamentally

commercial purposes are behind the testing.¹⁶⁵

The strong policy push for permitting testing of inventions even for business purposes is manifested best by the German patent law *judicial* creation of a right for business testing of pharmaceuticals for regulatory approvals.¹⁶⁶ Thus, while the United States modified its *statutory* patent law to permit clinical trials of patented inventions for pharmaceutical regulatory approval, no such change was made by the Bundestag in Germany; yet, the *courts* judicially overruled prior case law to permit the same result.¹⁶⁷ Thus, even late stage clinical trials of a new drug are exempt under German law, even though the purpose of such testing is virtually entirely business oriented toward gaining market approval.¹⁶⁸ The German Supreme Court recognized that particularly

regardless of whether or not business interests exist in the background beyond the pure research character of the experiment.

Id.

¹⁶⁵ *Id.* at 432–33.

[A]ll experimental activities which relate to the object of the invention should be exempted. This exemption should be granted regardless of any additional motivations that might be taken up and to which purposes the obtained results will ultimately be determined to serve. As section 11 No. 2 of the [German] Patent Act neither qualitatively nor quantitatively limits the experimental activities, we are given to understand that the examinations and tests can range from purely scientific experiments to commercially-oriented tests. According to the wording of the law it does not make any difference whether the experiments supply scientifically or commercially usable results, or whether the test of a protected active agent achieves the aim of obtaining data for legal pharmaceutical permission, thus preparing the access to the market for after the expiration of the term of protection of the patent. It is presupposed merely that, through the test, results should be obtained concerning the object of the invention—including its application—which ought to eliminate an existing insecurity. This is also the situation if . . . a pharmaceutical compound which contains the protected active agent should be tested in a clinical experiment with regards to its effectiveness and digestibility. That a commercial orientation of the experimental activity or the setting of an industrial goal should exclude the possibility of an exemption is not apparent from the wording of the law.

Id.

¹⁶⁶ *See, e.g., id.* at 433 (noting that the German Patent Act makes no distinction between experiments for scientific results and experiments to obtain data for legal pharmaceutical permission).

¹⁶⁷ *Id.* at 432–33 (reviewing prior case law but concluding that experimental activities that relate to the object of the invention are within the wording of the German Patent Act).

¹⁶⁸ *See id.* at 437.

[T]he commercial purpose of achieving the market authorisation for the active agent, which is connected with the clinical test, is not a suitable criterion for dividing exempted research activities in which the research purposes stand in the forefront from the impermissible activities of exploitation. In the hearing of this case, the court de-

in genetic engineering, the realities of the industry and costs make research in the commercial sector often a necessity—and one that should be protected in appropriate circumstances.¹⁶⁹

B. Japanese Parallel Evolution to German Practice

1. A Broad Statutory Exemption

Japan has a black and white and crystal clear *statutory* definition of the experimental use under its law: “The effects of the patent right shall not extend to the working of the patent right for the purposes of experimentation or research.”¹⁷⁰ While there may be a dispute as to the scope of the United

bated the question as to whether it is possible to establish an objectively unequivocal demarcation in the use of pharmaceuticals developed by genetic engineering between Phases II and III of the clinical tests, which was precisely the matter in question in the case they had at hand. The parties submitted that the results obtained in Phases I and II are secured in Phase III through further experiments, in which one strives to exclude any hitherto unknown side effects. The defendant further indicated that in the case of genetically engineered materials there are no generic products and therefore even in Phase III there can be no talk of any commercial purpose. Seen in this way it would be hardly possible, in practice, to have any handy demarcation as to the degree of commercial intention, that is, to undertake after the fact to establish the extent to which the research was commercially or scientifically oriented. In a series of experiments, the extent to which the research interests are still in the forefront, or still sufficiently present, and when the interest in later commercial exploitation supplants the scientific interest, will be examined in the individual case, not only according to the nature of the tested active agent and the conditions in the clinical surroundings, but above all according to the intentions of the people and companies involved.

Id.

¹⁶⁹ *Id.* at 437–38.

As research in genetic engineering mostly takes place in commercial corporations due to the high costs associated with such research, and given, as well, that in the case of research carried out in universities or institutes commercial interests are also decisive, clinical experiments with a genetically engineered pharmaceutical will always be based on commercial considerations. The intention that is thus associated with an activity begun and carried out for research purposes cannot categorise said activity as an unlawful activity of infringement merely on the basis of the fact that the results of the research will not solely serve research purposes but above all will serve commercial purposes as well. An activity is much rather exempted and therefore permissible in accordance with section 11 No. 2 of the [German] Patent Act if it is oriented towards clearing up uncertainties with regard to the object of the patented invention or bringing out new discoveries about said object, provided these activities with research purposes relate to the object of the patented invention.

Id.

¹⁷⁰ TANABE & WEGNER, JAPANESE PATENT LAW 289 (1979) (translating Japanese law, Art. 69(1)). This provision can be traced back to 1909. See Katsuya Tamai, *The Experimental Use*

States experimental use right, there is no doubt that the Japanese law applies to any "experimentation or research."¹⁷¹

Business testing of an invention in Japan is also an act of infringement under the leading case on regulatory testing of the 1980's, *Monsanto Co. v. Stauffer Chemical Co.*¹⁷² case from the Tokyo District Court.¹⁷³ *Stauffer* defended *Monsanto's* infringement charge on the basis that *Stauffer* was using its herbicide only for testing for regulatory approval and hence was using the invention for experimental purposes.¹⁷⁴ Following the same line of reasoning as in the American *Roche* case, the Tokyo District Court held that the experimental testing exemption did not apply.¹⁷⁵

Japan for some time did not permit the regulatory testing of pharmaceuticals as an experimental use.¹⁷⁶ Indeed, it followed a line of reasoning in *Monsanto* parallel to *Roche*.¹⁷⁷ While the American law was changed in 1984, that change was made by *statute* so this statutory change provided no legal reasoning to

Exception: A Japanese Perspective, 7 CASRIP SYMPOSIUM PUBLICATION SERIES 15 (Hill et al., eds. 2002), available at <http://www.law.washington.edu/casrip/symposium/number7/> (last visited July 22, 2005).

¹⁷¹ TANABE & WEGNER, *supra* note 170, at 289.

¹⁷² Tokyo Dist. Ct., July 10, 1987, Case Nos. (WA) 7463/1985, (WA) 6428/1985, (WA) 671/1986 (Tokyo Dist. Ct. July 10, 1987).

¹⁷³ See generally Mark F. Wachter, *Patent Enforcement in Japan: An American Perspective for Success*, 19 AIPLA Q.J. 59, 66–67 (1991) (discussing *Monsanto*).

¹⁷⁴ Jennifer A. Johnson, Comment, *The Experimental Use Exception in Japan: A Model for U.S. Patent Law?*, 12 PAC. RIM. L. & POL'Y J. 499, 512–13 (2003).

[I]n *Monsanto v. [Stouffer] Japan* K.K. *Monsanto*, the owner of a patented herbicide[] filed an infringement action against [Stouffer] Japan. [Stouffer] Japan admitted to using *Monsanto's* patented herbicide in experiments required for obtaining government approval for their generic version of the herbicide, but argued that their use was permitted under the Japanese experimental use exception in § 69(1). The Tokyo District Court held that [Stouffer] Japan's use did not fall under the Japanese experimental use exception, and therefore, [Stouffer] Japan infringed *Monsanto's* patent. The court stated that "[a]grochemical experiments carried out for the purpose of securing government registration of the herbicide are not intended to advance technology and therefore do not fall within the scope of the 'experiment or research' exception to an otherwise infringing use." The court focused its interpretation on the legislative intent behind § 69(1), reasoning that the Japanese experimental use exception protects only research or experiments that advance technology. The court reasoned that experiments for obtaining regulatory approval are solely commercial in character, do not advance science, and thus do not fall within the § 69(1) experimental use exception.

Id. (footnotes omitted).

¹⁷⁵ See Wachter, *supra* note 173, at 67.

¹⁷⁶ See, e.g., Johnson, *supra* note 174, at 510–18 (reviewing the development of the Japanese experimental use exception for pharmaceuticals).

¹⁷⁷ See *id.* at 510.

persuade the Japanese courts to make a change.¹⁷⁸ Furthermore, German law was consistent with both the American and Japanese precedents.¹⁷⁹

Erosion for the support of the old position for pharmaceuticals gained great strength within Japan when European case law was modified to judicially overrule precedent parallel to *Roche* and *Monsanto*.¹⁸⁰ The ultimate ruling in Japan was the judicial legislation of its Supreme Court in *Ono Pharmaceuticals Co. v. Kyoto Pharmaceutical Industries, Ltd.*¹⁸¹

2. Japanese Public Policy Favors Experimentation

Experimental use of a patented invention is a fundamental necessity of any modern patent system, given that the fundamental principle of *any* patent system is that it promote societal technological innovation. In Japan, “[t]he purpose of th[e] [Patent] Law shall be to *encourage inventions* by promoting their protection and utilization so as to contribute to the development of industry.”¹⁸² In terms of the primary objectives of the patent system, whatever rewards may be given to the owners of a patent or the inventors are clearly secondary and only ancillary to the overall goal of promoting the level of technology, to help society reach a higher level of development.

A critical integer of the patent system is the early disclosure of patented innovation to the world, so that the latest techniques may be learned and improvements made as soon as possible upon state of the art technology. Critical is the ability to *understand* the newly patented technology, which necessarily involves the right to experiment with a patented invention to see that it operates in the manner stated in the patent and to use that technology as a basis for *further* innovation; comparative testing of further innovations with this patented technology necessarily is critical and must be permitted. The so-called experimental use right to use patented inventions is therefore at the very heart of every major patent system in the world.

Rare agreement is reached by Tokyo University Professors Nakayama and Tamai. The former notes that “it would not make a great contribution to [raise the technological level of society in general] if third parties could only read

¹⁷⁸ See Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202(e)(1), 98 Stat. 1585, 1603 (1984) (codified as amended at 35 U.S.C. § 271(e)(1) (2000)).

¹⁷⁹ See discussion *supra* Part V.A.

¹⁸⁰ In particular, note the German influence from *Klinische Versuche II*, discussed *supra* Part V.A.

¹⁸¹ Japanese Supreme Court, April 16, 1999, Case No. 153; see Johnson, *supra* note 174, at 514 (discussing *Ono Pharmaceuticals*).

¹⁸² Japanese Patent Law, Law No. 121 of 1959, art. 1, available at http://www.wipo.int/clea/docs_new/en/jp/jp006en.html (last visited July 22, 2005).

through the specification[,]”¹⁸³ while the latter states that “[i]t is clear why Japan employed the statutory exception [now found in Art. 69(1)] relatively early Reverse engineering was needed in all fields of technology. The experimental use exception was recognized explicitly [in the Japanese patent law] so that people could develop new technology.”¹⁸⁴

C. A Unique American Patent Isolationist View

While the Supreme Court in *Merck* has moved in the same direction as the tribunals of Germany and Japan, the Federal Circuit stands in isolation through its narrow construction of experimental use. Professor Duffy notes that

[t]he United Kingdom, Germany, Japan, Korea and many [other countries] expressly recognize an experimental use exception in their statutory law. Perhaps because of the express statutory recognition, those jurisdictions have interpreted the experimental use doctrine broadly in recent cases. Yet even Canada, which does not have any express experimental use provision in its statutory law, takes a broad view of the exception in its case law. Interestingly, this diversity of law on the experimental use exception provides incentives for certain industries—specifically, those conducting commercial research on patented technologies hoping to obtain patentable improvements—to locate their research operations outside of the United States.¹⁸⁵

Because foreign jurisdictions generally recognize the experimental use doctrine, the recent U.S. restriction on the doctrine may have only a modest effect on companies. Firms seeking to research improvements in a patented technology can always locate their research overseas and still maintain the right to obtain U.S. patents on the results of that research. The effect on skilled professional scientists in the United States, however, will be more serious as more and more companies take their research offshore.¹⁸⁶ Professor Mueller explains that

[w]ithout such an exemption, scientific research functions that require the use of patented inventions are more likely to be shifted offshore to legally hospitable forums. With an ever-growing number of professional and service sector jobs already being outsourced to foreign countries, a patent law rule whose effect is to add scientific research to the job exodus is one the United States can ill afford.¹⁸⁷

¹⁸³ NOBUHIRO NAKAYAMA, 1 INDUSTRIAL PROPERTY LAW § 7(3)(Item 1)(1) (English trans., 2d ed. 2002), available at <http://www.iip.or.jp/translation/nakayama> (last visited July 22, 2005).

¹⁸⁴ Tamai, *supra* note 170, at 15.

¹⁸⁵ Duffy, *supra* note 38, at 718–19 (footnotes omitted).

¹⁸⁶ See *id.* at 717–19 (discussing the effect of the divergence between the U.S. law on experimental use and the laws of other nations).

¹⁸⁷ Mueller, *supra* note 31, at 920 (footnotes omitted); see also Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. MICH. J.L. REFORM 141, 184 (2004) (noting as a result of the

VI. A Statutory Solution

Spurred on in major part by the writings of Professor Rebecca S. Eisenberg,¹⁸⁸ legislation was introduced in 1990 that would have codified a statutory research exemption.¹⁸⁹ Accompanying this legislation was a committee report that provided a great deal of insight that differentiates between a noninfringing *experimentation* on a patented invention as opposed to the infringing use of a research tool by *experimenting using* a patented invention: “The easiest method of limiting and describing the ‘experimental use . . . exception’ is to differentiate

infringement-free foreign environment “some firms may use patented technology offshore to avoid infringement”).

¹⁸⁸ See generally Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987). This is the seminal scholarly work of the past fifty years on the experimental use right. Well over one hundred papers cite to Professor Eisenberg’s paper, including papers by Professors Mark S. Lemley and Lawrence Lessig of Stanford University, Professor Rochelle Dreyfuss of New York University, Professors Arti K. Rai and Jerome H. Reichman of Duke, Professors Robert P. Merges and Peter S. Menell of Boalt Hall, Professor Richard R. Nelson of Columbia University, Professor Dan L. Burk of Minnesota, Professor Janice M. Mueller of Pittsburgh, Professor John R. Thomas of Georgetown, Professor Martin J. Adelman of George Washington University, Professor F. Scott Kieff of Washington University in St. Louis, Professor R. Carl Moy of William Mitchell, Professor Cynthia M. Ho of Loyola, Professor Joseph P. Liu of Boston College, Professor Lawrence M. Sung of Maryland, Professor Wendy J. Gordon of Boston University, Professor Clarisa Long of Virginia, Raymond T. Nimmer of Houston, and Professor Jessica Litman of Wayne State. A search conducted on July 22, 2005, on Westlaw TP-ALL for [eisenberg /s “proprietary rights”] shows 155 citations, including the writings of leading intellectual property academics.

Her article makes it absolutely clear that the United States has always enjoyed an experimental use exemption from patent infringement for limited research and testing purposes. See generally *id.* What makes her major work more notable than its citation by essentially every serious scholar in the field is the *total absence of any citation by the Federal Circuit in even one opinion*. A search conducted on July 22, 2005, on Westlaw CTAF for [eisenberg /s “proprietary rights”] shows no citation of this work.

¹⁸⁹ Patent Competitiveness and Technological Innovation Act, H.R. 5598, 101st Cong. § 402 (1990).

Section 271 of title 35, United States Code . . . is amended by adding . . . the following: “(j) 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. This subsection does not apply to a patented invention to which [35 U.S.C. § 271](e)(1) applies.

Id. See also 136 CONG. REC. H7498-01 (1990) (statement of Rep. Kastenmeier).

between *experimentation on* a patented invention and *experimentation using* a patented invention in order to accomplish another purpose, the former type of experimentation constituting the scope of the exception.¹⁹⁰ Thus,

[u]nder this approach [the *experimenting on* activities constituting] the following acts would not constitute patent infringement: (1) testing an invention to determine its sufficiency or to compare it to prior art; (2) tests to determine how the patented invention works; (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention; (4) experimentation for the purpose of "designing around" a patented invention; (5) testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and (6) academic instructional experimentation with the invention.¹⁹¹

While the *experimenting on/experimenting using* distinction is widely recognized¹⁹² it may be an imperfect test as one difficult to apply in practice.¹⁹³

A wide variety of legislative proposals have been proposed by academics. Professor Dreyfuss proposes a patent "waiver" solution to permit research by an academic willing to forfeit patent rights.¹⁹⁴ Professor Dreyfuss also notes that

Maureen O'Rourke, Janice Mueller, Donna Gitter, and others have made proposals along the lines of what [Professor] Eisenberg was suggesting in 1989. They would add defenses similar in effect to the fair use defense of copyright law, utilizing multifaceted analyses to identify spheres where work could be accomplished freely, as well as areas where payment (but not authorization) would be required. These proposals are quite interesting from a theoretical point of view. However, they demand difficult pricing decisions. More important, they require hard line drawing—in some cases, exactly the type of scrutiny that Judge Rader was so concerned about in his separate opinion in *Embrex*.¹⁹⁵

¹⁹⁰ H.R. REP. NO. 101-960, pt. I, at 44 (1990).

¹⁹¹ *Id.* at 44–45.

¹⁹² *See, e.g.,* Mueller, *supra* note 31, at 940–41.

¹⁹³ *See, e.g.,* Mueller, *supra* note 8, at 40.

¹⁹⁴ Dreyfuss, *supra* note 25, at 471. Under her proposal:

[A] university or other nonprofit research institution that wants to use patented material and cannot obtain a license from the patentee on reasonable terms could use the technology without permission if it is willing to sign a waiver. The waiver would require the institution to promptly publish the results of work conducted with the patented technology and to refrain from patenting discoveries made in the course of that work.

Id.

¹⁹⁵ *Id.* at 470 (citing Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument For Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1637 (2001); Mueller, *supra* note 8, at 17; Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000)) (footnotes omitted).

Professor Strandburg proposes an approach that would in essence codify the existing common law exemption, much like the Kastenmeier legislation from 1990.¹⁹⁶

It is possibly too late for any solution of any kind to be made through Congress due to the deep division of interest amongst the several interests groups. Whether it is the research-based larger pharmaceutical companies, the smaller research tool companies, or the academic community, each has in common the power on Congress to stalemate any legislative proposal that would deeply cut into their own interests. It is difficult to imagine any compromise at this time that would satisfy both the the large pharmaceutical companies and the research tool interests.

Conclusion

The jagged and amorphous upstream boundary of the safe harbor represents a business person's worst dream, an invitation to test such boundaries as opposed to the opportunity to operate under a clear set of defined rights. Unlike the abandonment of the experimental use defense that occurred in *Merck* at the intermediate appellate level, perhaps the next accused infringer facing a *Merck*-like situation will present the dual defenses of both the safe harbor and the classic experimental use defense under the Story line of cases. While such a dual attack may be expected in the pharmaceutical field, the pressure for the right to *experiment on* a patented invention will continue in other technologies which are outside the scope of drugs and the statutory safe harbor. Legislation is not the answer. There are far too many diverse interests in the mix to create a consensus to support any one position.

¹⁹⁶ Strandburg, *supra* note 51, at 119–21, 130–47. Professor Dreyfuss characterizes the Strandburg proposal as follows:

Katherine Strandburg suggested implementing a different approach, one close to that used in Europe, which is to distinguish between experimenting on a patented invention and experimenting with the patented invention. The free right to experiment on the invention would permit peer review, and would also fulfill one of the key purposes of the patent system, one that Judge Newman pointed out in her separate opinion in *Integra*: it “facilitates further knowledge and understanding of what was done by the patentee and may lead to further technologic advance.” Of course, experimenting with the patented invention could also advance understanding, but in Strandburg’s view, an “experimenting with” defense would cut too deeply into the market of those whose business it is to develop research tools. Thus, it would erode incentives to innovate in what has become an important area of biotechnology.

Dreyfuss, *supra* note 25, at 470–71 (quoting *Integra*, 331 F.3d 860, 873 (Fed. Cir. 2003) (Newman, J., concurring), *vacated, remanded by Merck*, 125 S. Ct. 2372 (2005) and Strandburg, *supra* note 51, at 121).

Particularly where Europe and Japan clearly *do* permit an *experiment on* a patented invention, the absence of a clear experimental use defense in the United States will further push research offshore.

QUESTIONS

accompanying the paper:

IS THERE A RIGHT TO “EXPERIMENT ON” A PATENTED INVENTION?

What is the Law Around the World?

QUESTION 1: Roberts patented a Microwave Electron Gun for laboratory experiments to test the strength of various objects. Smith defended a patent infringement lawsuit on the basis that his testing objects *with* the patented Microwave Electron Gun is exempt from patent infringement.

Is the Smith experimentation *with* the patented Microwave Electron Gun (for its intended purpose of experiments *with* objects) free from infringement under an “experimental use” exception?

QUESTION 2: Assume the identical facts for Question 1, except that the accused infringer is Nonprofit University:

Is NonProfit University (having non-profit status) excused from infringement because of its nonprofit status?

QUESTION 3: CalWeeds, Inc. is a herbicide manufacturer interested in creating an unpatented ethyl-substituted pesticide. CalWeeds compares its new pesticide with Nebco’s patented methyl-substituted pesticide. Thus, CalWeeds made and used Nebco’s methyl-substituted pesticide solely for comparative tests versus its own ethyl-substituted pesticide.

Is CalWeeds’ comparative experimentation with the patented methyl-substituted pesticide free from infringement?