

CAN ANY PATENT “PREEMPT” FOLLOW-ON RESEARCH?*

Patents “preempt researchers ... and pose[] a serious threat to scientific freedom and advancement.”

American Civil Liberties Union *et al.*
at the Supreme Court in *Myriad***

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* This paper represents the personal views of the author and does not necessarily reflect the views of any colleague, organization or client thereof.

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** ACLU Supreme Court Certiorari Petition in *Myriad*, No. 11-725, December 7, 2011 (citing *Bilski v. Kappos*, 130 S. Ct. 3218, 3230-31 (2010); *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)(emphasis added).

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Executive Summary

Prometheus critically repeats a flawed premise that “[patent] preemption results in the foreclosure of innovation.” But, a central axiom of any patent system is that the public has an *immediate* right on publication of a patent to experiment *on* newly patented technology: This is *precisely* to encourage follow-on innovation. The right includes *examining* technology to see how it operates; *comparing* technology with competitive innovations; *testing* technology to demonstrate differences to the Patent Office; and, above all, *designing around* patents, to create competitive, noninfringing and sometimes better technology.

The right is a constant and essential axiom for biotechnology, pharmaceutical and organic chemistry. Yet, there is virtually no litigation against experimenters due to the often one time period of such experimentation, after which injunctive relief would in any event be pointless. In recent times with modernization of the patent laws of the world, patent applications are *published* often years before the patent grant; this creates a loophole, a patent-free zone for experimentation.

While domestic precedent has been clouded, the right to experiment on patented technology in Europe and Asia is rock solid: Any American competitor can have his experimentation conducted offshore and then import the *information* to the United States with total patent impunity.

The recent Federal Circuit *Classen* opinion in *dicta* confirms the existence of the right to experiment *on* a patented invention, following a line of case law that, come next May, dates back 200 years to legendary Supreme Court Justice Story’s seminal pronouncement in *Whittemore v. Cutter*. Since that time, the right to experiment *on* a patented invention has become a bedrock principle of the patent laws of Europe and Asia – and all around the world.

To be sure, the Federal Circuit in the past generation has not always clearly explained the right to experiment *on* a patented invention: An *en banc* pronouncement reinforcing what Joseph Story said two centuries ago would help clear the air and manifest the erroneous path taken in *Prometheus*.

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I. OVERVIEW

More than thirty years ago in *Chakrabarty* and *Diehr*, the Supreme Court established principles confirming a broad scope of patent-eligible subject matter under 35 USC § 101. *Chakrabarty* and *Diehr* signaled an open door to patenting - new frontiers of modern technology – at that time in biotechnology and software. The patent-eligibility door has remained wide open for all technologies until just the past several years; the negative trend is manifested by the *Prometheus* case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012).

There are now at least four cases in the appellate pipeline on the road to the Supreme Court which directly or indirectly may be impacted by the research “preemption” issue:

CLS Bank Int’l v. Alice Corp. Pty., Ltd., __ F.3d __ (Fed. Cir. 2012)(Linn, J.), awaiting possible petition for *en banc* review, and thereafter a petition for Supreme Court review.

GSK v. Classen, Supr. Ct. No. 11-1057, now awaiting an amicus brief calling for the views of the Solicitor General (CVSG), *opinion below on GVR remand*, 659 F.3d 1057 (Fed. Cir. 2011)(Newman, J.).

Myriad, Association for Molecular Pathology v. Myriad Genetics, Inc., Supr. Ct. 11-725, on GVR for further consideration in light of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012), *vacated opinion below*, 653 F.3d 1329 (Fed. Cir. 2011)(Lourie, J.).

Ultramercial, LLC v. WildTangent, Inc., Fed. Cir. 2010-1544, *on remand from the Supreme Court*, *WildTangent, Inc. v. Ultramercial, LLC*, __ U.S. __ (May 21, 2012), *GVR in light of Prometheus vacating panel opinion*, 657 F.3d 1323 (Fed. Cir. 2011)(Rader, C.J.).

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At the heart of the negative trend is the underlying theme that broad patents represent a research “preemption”: Patents block future innovation. One of the four cases directly confronts this issue head on: “Breadth does not negative patent eligibility.... Nor does breadth preclude investigation by others. To the contrary, *a fundamental purpose of patenting is to provide knowledge, to achieve further advance.*” *Classen*, 659 F.3d at 1073 (emphasis added). The Supreme Court’s misunderstanding is capsulized in the majority opinion in *CLS Bank v. Alice*. See § II, *Prometheus Follow-On Research “Preemption”*.

The *Prometheus* understanding of a research “preemption” is dead wrong when one considers the fundamental right under the patent system to experiment *on* a patented invention, free from any patent liability. This fundamental concept dates back to May 1813, nearly 200 full years ago, and the pen of Joseph Story. The experimental use doctrine has become a vibrant cornerstone of all the major patent systems of the world, albeit with clouded dicta in the past generation in the United States. See § III, *Right to Experiment “On” a Patented Invention*

In the practical world of the laboratories of the United States (and the world) there is an absolute *necessity* to rely upon the right to experiment “on” a patented invention. The research world would come to a standstill under any other approach. See § IV, *Research Realities in the Labs and Commerce*.

Academic research that utilizes a patented invention for its commercial purpose clearly *is* an infringing use as held in *Madey*. But as to experimentation “on” a patented invention, which is central to the research purpose of an academic institution, this clearly is *not* an infringing use – notwithstanding discouraging but uninformed *dictum* in *Madey*. See § V, *Madey University Research, a Red Herring*.

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The “research tool” industries, particularly in biotechnology, have legitimate concerns that the line be clearly drawn between non-infringing experimentation “on” a patented invention versus infringing experimentation “with” a patented invention, particularly insofar as experimentation with research tools must remain an infringing event. *See* § VI, *Biotechnology “Research Tool” Patents*

Rarely is a fact pattern of an experimentation *on* a patented invention presented to a Court. Such a case arose in *Merck v Integra*: Clearly, the activity in that case was an experimentation *on* a patented invention. But, counsel for the accused infringer at the Federal Circuit expressly *waived* this argument. That there has been scant litigation concerning experimentation “on” a patented invention is seen from the realities of laboratory research coupled with the economics of patent litigation. *See* § VII, *Paucity of “Experimentation ‘On’” Litigation*

Even at this late date in 2012 – nearly 200 years since the origin of the doctrine – there remain uncertainties about the scope of the right to experiment “on” a patented invention. It is not enough to blame the litigants in *Merck v. Integra* for failing to properly address the issue. The pronouncement in *Classen* itself is at best *dicta*. Yet, there are several cases in the appellate pipeline on the road to the Supreme Court. The Federal Circuit has within its power the ability to grant *en banc* hearing in one of more of these cases to resolve the tension between the research “preemption” argument versus the right to experiment “on” a patented invention.

Prometheus is not the final chapter in what has become a negative view of the scope of patent-eligibility at the Supreme Court. If the Federal Circuit elects not to clarify the right to experiment on a patented invention, then the matter by default will need to be addressed by the Supreme Court, perhaps obliquely as in

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Merck v. Integra where a result permitting experimentation on a patented invention was shoe-horned into the framework of the “safe harbor” of the Drug Price Competition Act. Several cases now in the appellate pipeline are prime candidates for further Supreme Court review:

Currently in the appellate pipeline are several cases which conceivably will wind up at the Supreme Court where at least one may well pass *certiorari* muster and lead to yet another interpretation of the scope of patent-eligibility. Ongoing cases still in the Supreme Court pipeline include *CLS Bank v. Alice* (awaiting *en banc* and/or *certiorari* petition on software patent-eligibility), *Classen* (awaiting Solicitor General’s CVSG brief on scope of “safe harbor”) and *Myriad* (awaiting Federal Circuit decision following Supreme Court GVR in light of *Prometheus* on DNA product claim patent-eligibility). Each case directly or indirectly implicates the policy concerns of the right to experiment “on” a patented invention. Absent *en banc* Federal Circuit clarification of the right to experiment “on” a patented invention, it is inevitable that further cases will reach the Supreme Court that will further deal with the research “preemption” myth of *Prometheus*. See § VIII, *Circuit En Banc vs. Supreme Court Resolution*.

Citation of Authorities

Citations not fully identified, here, can be found in in the “Post-Merck Paper”, Wegner, *Post-Merck Experimental Use and The “Safe Harbor,”* 15 Fed. Cir. B.J. 1, 33 (2005); also helpful is the “Baylor Paper”, a more comprehensive discussion of experimental use by Professor 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 (2004); see also Janice M. Mueller, *No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001).

II. THE *PROMETHEUS* RESEARCH “PREEMPTION”

A central theme of *Prometheus* is the concept that there is a “research preemption” that is the price to pay for grant of a patent right: In essence, broad patents should be avoided because of the wider swath of the “research preemption” that is an apparent necessary evil of the patent system.

The focus on a research “preemption” is underscored in the majority opinion in *CLS Bank v. Alice*:

“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. ...

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“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, ___ F.3d at ___ (emphasis added)

III. RIGHT TO EXPERIMENT “ON” A PATENTED INVENTION

The year 2013 marks the 200th anniversary of the patent-free right to “experiment on” a patented invention; on that date the doctrine of experimental use was created *sui generis* by legendary jurist and academic Joseph Story in *Whittemore v. Cutter*, 29 F.Cas. 1120, 1121 (C.C.D.Mass.1813) (No. 17,600).

As perhaps best explained by Professor Janice Mueller, the public has a right to *experiment on* a patented invention. One has a right to see how the invention works, to compare the invention as a standard to other technologies and to design around the invention. In contrast, an experimentation *with* a patented invention is a business use that is not free from infringement liability, whether it is to experiment

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with a branded pharmaceutical to gain regulatory approval of a drug as in *Roche v. Bolar*; to satisfy contractual obligations with the government as in *Deuterium*; or to use a laboratory research tool such as the *Madey* laser in experiments with the laser (as with compared to seeing how the laser works or improve the laser).

A. *Classen*, the Latest Word from the Federal Circuit

While there has been *dicta* in several cases casting doubt about the existence of the right to experiment *on* a patented invention, no Federal Circuit case has reached a *holding* that denies the right to experiment *on* a patented invention.

“[T]he subject matter of patents may be investigated and verified and elaborated; the technological/scientific contribution to knowledge is not insulated from analysis, study, and experimentation for the twenty years until patent expiration.

“... The statutory requirements of description, enablement, and best mode... facilitate understanding and elaboration of the inventor's contribution. Were such information prohibited from study until patent expiration, not only would the advance of science be slowed, but *the design-around of patented subject matter would be inhibited, if not excluded, if a new design could not be derived from study of the old.* Justice Story commented in *Whittemore v. Cutter*, 29 F.Cas. 1120, 1121 (C.C.D.Mass.1813) (No. 17,600), that ‘it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical [‘science’] experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.’ Such use of the information in the patent is not a violation of the patent, whereas ‘the making of a machine fit for use, and with a design to use it for profit, was an infringement of the patent right.’ *Id.*”

Classen, 659 F.3d at 1072-73 (emphasis added)(footnote integrated into text).

B. The *Embrex* Hiccup, Dicta in a Concurring Opinion

The *Classen* majority opinion has special significance through its *sub silentio* treatment of *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000)(per curiam).

In *Embrex* there was a clear case of commercial testing of a machine useful in a patented process; the testing clearly was not an experiment *on* the patented invention but rather a *demonstration* of the patented invention for the purpose of generating sales of the machine: “[The accused infringer] *performed the [accused infringing] tests expressly for commercial purposes. ... [Its] commercial purpose was to demonstrate to its potential customers the usefulness of the methods performed by its in ovo injection machines.*” *Embrex*, 216 F.3d at 1349 (emphasis added).

Accordingly, the holding of infringement was entirely based upon the clear absence of any valid argument of an experimentation *on* the patented invention:

The experimental use doctrine had nothing to do with the facts of the *Embrex* case. Nevertheless, one member of the panel added his opinion that there simply is no experimental use doctrine that is viable under the patent law. *Embrex*, 216 F.3d at 1352-53 (Rader, J., concurring). The concurrence states that:

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“[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 or idle curiosity. Rather, the Supreme Court and this court have recently reiterated that *intent is irrelevant to infringement*. See *Warner-Jenkinson Co., v. Hilton Davis Chem. Co.*, 520 U.S. 17, 34 (1997) (‘Application of the doctrine of equivalents, therefore, is akin to determining literal infringement, and neither requires proof of intent.’); *Hilton Davis Chem. Co. v. Warner-Jenkinson Co.* 62 F.3d 1512, 1519 (Fed. Cir. 1995) (‘Intent is not an element of infringement.’), *rev'd on other grounds*, 520 U.S. 17 (1997). These recent pronouncements should dispose of the intent-based prong of SEC's argument.” *Embrex*, 216 F.3d at 1353 (Rader, J., concurring)(emphasis added).

A year after *Embrex* the author of the concurrence made the following statement at a comparative law conference concerning the *Embrex* case:

“With regards to the experimental use excuse, neither the [statute] 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*.” Post-Merck Paper at 14 (emphasis added).

Indeed, intention *is* irrelevant. Rather, it is the *objective* view of the use of the patented invention that is critical. If the research involves studying the invention, seeing how it works or designing around the invention, this can easily be seen from an objective standpoint as experimentation “on” a patented invention. In contrast, experimentation *with* an invention is readily distinguishable, whether to meet government regulatory requirements as in *Roche v. Bolar* or government specifications as in *Deuterium* or using a laboratory tool for its purpose in conducting experiments as in *Madey*.

To be sure, the *Embrex* case was decided without the benefit of full briefing by the parties that explains the distinction between noninfringing experimentation “on” an invention versus infringing experimentation “with” the invention.

IV. RESEARCH REALITIES IN THE LABS AND COMMERCE

An innovation-focused patent system best operates with the synergy of a strong, exclusive right to the commercial exploitation of an invention coupled with a vibrant right to experiment *on* a patented invention.

A. The “Constitutionally Mandated Goal”

“A limited but meaningful experimental use exemption would further the patent system's constitutionally mandated goal of ‘promoting the progress of ... the useful arts’ through the dissemination of new innovation. Most innovation necessarily builds on that which came before. Unrestricted use of the earlier innovation for experimental purposes can only enhance the process of creating new and improved inventions. The publication of information about a new invention in the form of an issued patent is of little use to society if that information is effectively kept ‘on ice’ for seventeen-eighteen years by means of a patent owner's unchecked right to exclude others from use for any purpose.” Baylor Paper at 921.

Indeed, *improvements* in existing technology is at the center of the patent system:

“As implemented by the Framers, the constitutional mandate of promoting progress in the ‘useful arts’ specifically contemplated the patenting of improvements of earlier inventions. The making of an improvement invention typically involves the study of information provided in the patent for the corresponding basic invention. *That study likely requires experimenting on the basic invention in order to make an improvement that is a sufficiently novel and nonobvious variant to warrant an independent patent.* Patent law rules that flatly prohibit unauthorized experimentation as a precursor to making improvement inventions contravene the cornerstone goal of promoting technological progress through improvement innovation.” *Id.* at 975-76 (emphasis added; footnotes omitted).

B. The Need to Experiment on the Latest Technologies

Such experimentation is necessary to *compare* new technologies against the patentee’s standard; within the confines of patent practice alone, *many hundreds* (if not *thousands*) of comparative tests are run each year to demonstrate the nonobviousness of inventions. The tens of thousands of biotechnology and pharmaceutical scientists on a daily basis explore the latest scientific advances; they reproduce experiments to see whether they work or to see how they can be modified to reach better results. It is difficult to imagine such researcher first conducting a patent search before doing this preliminary, experimentation *on* a patented invention. Even if patented, is the researcher going to go to a patent attorney for an opinion if only interested in seeing how the published scientist achieved his result or making such simple experiments *on* the invention? Is the researcher expected to have his lawyer find out the identity of the published scientist’s lawyer to negotiate a license? Whether the researcher operates out of one of the Top Ten Pharma giants within one of the cavernous research laboratories along the New Jersey Turnpike or works in a startup in Silicon Valley, it is manifest that essentially everyone experiments *on* patented inventions on a frequent and often daily basis.

C Pro-Competitive Nature Experimentation *On* a Patented Invention

Even more important as a public policy matter, such experimentation *on* the patented invention leads to further discoveries that would otherwise be impossible to achieve. Particularly when a patent is an apparent blockbuster with broad claims that supersedes the current state of the art in terms of commercial importance, here it becomes *necessary* for researchers to explore the patented invention to *design around* the patent, to create new and even better technologies.

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The “design around” incentive is one of the critical and most important aspects of the right to experiment *on* a patented invention.

It also defies logic to imagine a system where a patentee would be able to sit on his exclusive patent right until twenty years after he filed his application to bar third party experimentation to create better alternatives, blocked by this unused patent grant. If anything, the existence of the right to experiment on a patented invention is the very spur to force the patentee into earliest exploitation of his invention: If he sits on his patent rights, third parties *will* design around the patent, rendering the original patentee’s rights obsolete.

D. United States Cannot be a Patent Island

While Joseph Story may rightly be credited with his *sui generis* creation of the experimental use right that will be 200 years old next year, Germany, the United Kingdom, China and Japan – and indeed all the major countries of Europe and Asia – each has a national patent law that include a *right* to experiment *on* a patented invention. As a consequence, if there *were* any serious domestic doubt about the right to experiment *on* a patented invention, the fact is that such experimentation could be dealt with by the multinational giants by conducting the research in China, India or elsewhere outside the territorial reach of the United States. (As established nearly a decade ago in *Bayer v. Housey* a multinational can practice a patented invention offshore to study the invention and to identify new and better products and then import the *results* of that research into the United States completely free of any patent liability).

E. The Multi-Year *De Facto* Patent Free Zone

Cutting edge research on the latest technologies is highly competitive on a global basis. Particularly in the fields of biotechnology and pharmaceuticals, the reality today is that scientists quite often publish their innovations in scientific journals even *before* a patent application is published. The patent application is automatically published 18 months from first filing in each of the major countries of the world: The full text of the patent is thus simultaneously available in Mandarin, German, Japanese, Korean and English through parallel patent application publications at this date. In the competitive biotechnology and pharmaceutical areas it may be several *years* before a patent is granted. Throughout this period there is *no* patent right to enforce so the public is free to even *commercialize* the patented invention and, *a fortiori*, there is no issue whether a use is experimental or not. *There is no patent right of any kind in existence until patents are granted.* (The provisional right to compensation for use of a published invention is only available retroactively upon grant of the patent.)

V. MADEY UNIVERSITY RESEARCH, A RED HERRING

The *Madey v. Duke University* case confirms that research in *any* environment should be governed by the same patent ground rules applicable to the commercial and academic worlds alike.

University research is easily accommodated by the right to “experiment on” a patented invention. Only to the extent that a university blurs the line with commercial research and conducts business testing of should there be any concern.

There has, however, been a great misunderstanding in the academic community concerning the *Madey* case which, *as to its holding*, should not in fact be a cause for any concern as to the law of experimentation *on* an invention.

Professor Madey owned patents that covered his patented laser technology that dominated Duke’s apparatus in his laboratory. When he left Duke, he sued for patent infringement for the continued use of that apparatus.* It is clear that the “experiments” conducted with that laser constituted experimentation *with* the patented invention: There was no “experimentation on” the laser to see how it operates, to improve the operation of the laser or to design around the laser patent.

* In 1989, tenured Stanford professor Dr. Dr. John M.J. Madey moved to Duke University for a parallel tenured position. The Duke position included directorship of a laboratory focused on Dr. Madey’s patented laser technology. Duke’s investment in Dr. Madey was quite high: It was required build an addition to its physics building to accommodate Dr. Madey’s patented technology. In 1997, Duke became vulnerable to a patent infringement suit when it sought to fire the Madey, who instead resigned the following year.

Two questions are immediately posed by what happened: Why didn’t Duke as a condition of building the laboratory first obtain a contractual right to practice Dr. Madey’s invention? Why didn’t Duke obtain a royalty-free license to use the apparatus? If Duke *had* done so, why wasn’t this pleaded? Proper contractual business practices would have rendered the patent issue moot.

VI. BIOTECHNOLOGY “RESEARCH TOOL” PATENTS

A robust biotechnology “research tool” industry has evolved over the past generation. Biotechnology “tools” are created that are invaluable for pharmaceutical and other biotechnology research. Such off the shelf research tools are used in the customers’ experiments, but such experiments are *not* to make a better research tool nor other experimentation “on” the research tool invention.

There was great concern at the time of *Merck v. Integra* that “research tool” patents could be made valueless through a broad Supreme Court ruling. *Amici* briefs were filed to distinguish the research tool patents from the *res* of *Merck v. Integra*. The *amici* were rewarded in the Supreme Court opinion where the Court expressly declined to include research tool patents within the ambit of its decision:

“The [Federal Circuit majority] suggested that a limited construction of [the safe harbor of] § 271(e)(1) is necessary to avoid depriving so-called ‘research tools’ of the complete value of their patents. [The accused infringers] have never argued the [claimed] peptides were used ... as research tools, and it is apparent from the record that they were not. See 331 F.3d at 878 (Newman, J., dissenting) (‘*Use of an existing tool in one’s research is quite different from study of the tool itself*’). We therefore need not – and do not – express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of ‘research tools’ in the development of information for the regulatory process.”
Merck v. Integra, 545 U.S. at 205 n.7 (emphasis added).

In light of the evolution of the case law in *Bilski* and *Prometheus* will the research tool industry come out on top if there is a further review of patent-eligibility for research tools?

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It is indeed important that the line between “experimentation on” and “experimentation with” be maintained: Without a bright line distinction, any case that reaches the Supreme Court on an experimental use could conceivably sweep aside the value of research tool patents.

VII. PAUCITY OF “EXPERIMENTATION ‘ON’” LITIGATION

Over the course of the almost two full centuries since Joseph Story’s creation of the experimental use right, the entire world has adopted the right to experiment *on* a patented invention. There has been a paucity of litigation on the right to experiment *on* a patented invention due to the combination of several factors. First, there is an absence of an incentive for patentees to sue for the often very brief experimentation *on* a patented invention: Once such experimentation has taken place and the information about the patented invention has been obtained, the researcher has is no further need to use the invention. There is no issue of injunctive relief because once the researcher has completed this experimentation *on* the patented invention, there is no further need to use that invention. Damages for a one time use of the patented invention for experimentation *on* the invention should be at best minimal, considering the fact that experimentation *on* the invention can be conducted offshore patent-free with no liability whatsoever for importation of the information gained by such offshore research: Indeed, in *Bayer v. Housey* the court expressly held that the information (identifying drugs discovered offshore) using Dr. Housey’s invention is completely without patent liability.

VIII. CIRCUIT *EN BANC* VS. SUPREME COURT RESOLUTION

It is apparent that the negative trend in the patent-eligibility decisions manifested in *Bilski* and *Prometheus* is to a significant extent fueled by the research “preemption” argument. Absent *en banc* clarification of the right to conduct downstream, follow-on experimentation *on* a patented invention, it is difficult to predict a favorable patent-eligibility outcome should the Court have a merits review of *CLS Bank v. Alice*, *GSK v. Classen* (which does not directly raise patent-eligibility in the *Question Presented*), *Myriad* or *Ultramercial v. WildTangent*.

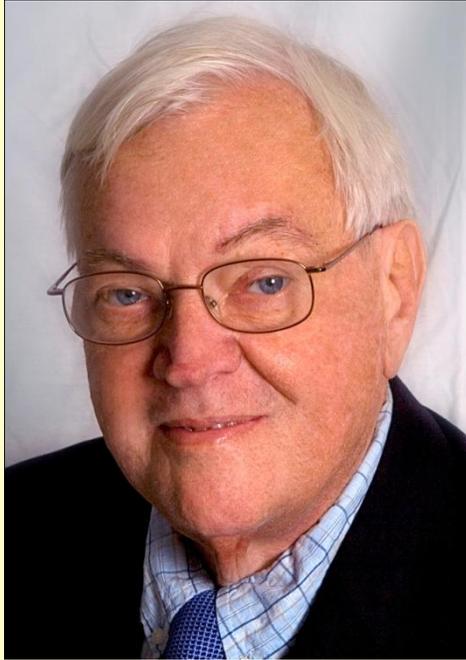
When the Federal Circuit was created thirty years ago a primary goal was to have a single appellate court to provide the several District Courts with uniform guidance on substantive patent law. To fulfill that goal, *en banc* reconsideration of the issue of the experimental use doctrine is necessary: The absence of clarity on the issue of experimentation *on* a patented invention coupled with the ongoing diverse views expressed in panel opinions on patent-eligibility in the wake of *Bilski* can only guarantee continued business uncertainty in several industries.

Even greater unpredictability may be at hand if the Federal Circuit permits one or more of the panel opinions to reach the Supreme Court without a definitive *en banc* clarification of the right to experiment *on* a patented invention. a case some consider the worst patent opinion of all since the Douglas-Black era and the *A & P Supermarket* case.

The damage to the biotechnology and pharmaceutical communities from a continuation of proceedings to the highest judicial level is simply unpredictable, a firecracker waiting to explode in directions yet unforeseen.

Wegner, *Can Any Patent “Preempt” Follow-On Research?*

ABOUT THE AUTHOR



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This paper is a pro bono effort of the writer, who has no current client representation in any of the cases in this paper; he acknowledges prior work for an amicus in the Myriad case prior to the vacated panel opinion.

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