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Reconsidering Experimental Use

Rochelle Cooper Dreyfuss

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RECONSIDERING EXPERIMENTAL USE

*Rochelle Cooper Dreyfuss**

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This section 101 issue [on patentable subject matter] appears to have its foundation in a misunderstanding of patent policy, for the debate about patent eligibility under section 101 swirls about concern for the public’s right to study the scientific and technologic knowledge contained in patents. The premise of the debate is incorrect, for patented information is not barred from further study and experimentation in order to understand and build upon the knowledge disclosed in the patent.

Judicial clarification is urgently needed to restore the understanding that patented knowledge is not barred from investigation and research. The debate involving section 101 would fade away, on clarification of the right to study and experiment with the knowledge disclosed in patents.¹

For nearly 200 years, the U.S. patent regime incorporated a defense allowing scientists to use patented inventions without authorization, so long as the purpose was for basic research. Over the last two decades, however, this defense, along with other public-regarding doctrines, has

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1. CLS Bank Int’l v. Alice Corp. Pty., 717 F.3d 1269, 1321–22 (Fed. Cir. 2013) (Newman, J., dissenting), *aff’d*, 134 S. Ct. 2347 (2014).

been eviscerated. The repercussions are significant.² In 2006, in a dissent from the denial of certiorari, Justice Breyer announced that in his view, patents could now “impede rather than ‘promote the Progress of Science and useful Arts.’”³ Unsurprisingly, in a series of subsequent cases interpreting § 101 of the Patent Act,⁴ which sets out the core requirements of patentability, the Supreme Court restricted the availability of patents for fundamental scientific advances. In the life sciences, it held that natural phenomena and laws of nature must be freely available to all innovators and are not the appropriate subject matter for patent protection.⁵ In other areas, such as software, the Court emphasized the unpatentability of abstract ideas.⁶

Anecdotal evidence suggests that the Supreme Court’s § 101 jurisprudence is creating uncertainties that have a deleterious impact on business and innovation, particularly in the life sciences.⁷ While incentives to invent must now be discounted by the risk that nonpatentability will affect the profits of firms engaged in medical research, the patents that do issue can continue to exert substantial control over subsequent generations of innovators. As the quotation above from a dissenting opinion by Judge Pauline Newman suggests, however, the concerns about impeding research could be assuaged in a very different way. Instead of denying patents because of concerns that they will chill progress, the experimental use defense could be clarified so that it is clear that patent rights cannot impede upstream research. An

2. See Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 *Ariz. L. Rev.* 457 (2004); Part I, *infra*.

3. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from the dismissal of certiorari).

4. 35 U.S.C. § 101 (2017).

5. See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012); see also *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (both in the life sciences). The Court has also raised the inventive step. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The Federal Circuit has followed through by narrowing the scope of claims. See *Ariad Pharms. v. Eli Lilly & Co.*, 598 F.3d 1336 (2010) (written description); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736-37 (2002), *vacating* 234 F.3d 558 (Fed. Cir. 2000) (doctrine of equivalents).

6. *Bilski v. Kappos*, 561 U.S. 593, 609-10 (2010) (business method); *Alice v. CLS Bank Int’l*, 134 S. Ct. 2347, 2355-56 (2014) (computerized business method). The Court has also raised the inventive step, *KSR Int’l Co.*, 550 U.S. at 418, and the Federal Circuit has followed through by narrowing the scope of claims, see *Ariad Pharms.*, 598 F.3d 1336 (written description); *Festo Corp.*, 535 U.S. at 736-37.

7. See, e.g., David Rodham & Brad Sheafe, *Who Will Protect Life Sciences Innovation?*, CORPCOUNSEL.COM (June 2016), available at <http://dominionharbor.com/wp-content/uploads/2016/06/How-to-Protect-Life-Science-Innovations.pdf>. Cf., *Where Do We Stand One Year After Alice?*, LAW 360 (June 17, 2015), available at <http://www.law360.com/articles/668773/where-do-we-stand-one-year-after-alice>.

attempt along these lines was made in 2011 as part of the America Invents Act (the AIA).⁸ That effort failed, but another legislative package of patent reforms is likely to be introduced in the near future.⁹ This Article, based on the Oldham Lecture at the University of Akron,¹⁰ makes the case for including a statutory provision to protect a researcher's ability to use patented inputs, a proposal that could be coupled with new language in § 101 that clarifies the availability of patents on fundamental scientific discoveries.

My argument focuses on the field of life sciences, although similar issues may well exist in other fields where the output of basic science is closely associated with marketable products. The Article proceeds as follows. Part I traces the demise of the experimental use defense and then discusses the many significant changes that have occurred subsequent to the AIA's failure to revive this defense legislatively. Part II argues that these changes militate in favor of a renewed effort to enact a research defense. Using European Union (EU) patent law as an example, this part compares the U.S. patent regime to the system in other developed countries and shows why the current situation could lead to research arbitrage, brain drain, and—ultimately—the loss of U.S. technological dominance. Part III discusses proposals to restore an experimental use defense.

I. THE EXPERIMENTAL USE DEFENSE

A. *The History*

Until the Federal Circuit was created in 1982, a research defense was securely enshrined in U.S. law. In two 1813 cases, Justice Joseph Story interpreted the Patent Act as distinguishing between uses of the patented invention “with an intent to . . . profit” and uses “for the mere purpose of philosophical experiment or to ascertain the verity and exactness of the specification.”¹¹ As William Robinson summarized the

8. Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 15, 28, 35, 42, and 51 U.S.C.).

9. See, e.g., H.R. 9, 114th Cong. (2015-2016); *Patent Progress's Guide to Federal Patent Reform Legislation*, PATENT PROGRESS, available at <http://www.patentprogress.org/patent-progress-legislation-guides/patent-progress-guide-patent-reform-legislation/> (last visited March 7, 2017).

10. Rochelle C. Dreyfuss, Pauline Newman Professor of Law at New York University School of Law and co-Director of its Engelberg Center on Innovation Law and Policy, The Albert & Vern Oldham 2016 Fall Lecture: Reconsidering Experimental Use (Nov. 4, 2016).

11. *Sawin v. Guild*, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (Story, J.). See also *Whittemore v. Cutter*, 29 F. Cas. 1120, 1121 (C.C.D. Mass. 1813).

conclusion to be drawn from these cases:

[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 an intellectual character in the promotion of . . . knowledge.

But if the products of the experiment are sold, or used for the convenience of the experimenter, or . . . with a view to the adaptation of the invention to the experimenter's business, the acts of making or of use are violations of the rights of the inventor and infringements of his patent.¹²

Justice Story's carefully constructed exception began to crumble soon after the establishment of the Federal Circuit in 1982.

At the time the Federal Circuit was established, efforts were being made to foster a generic drug industry with the hope that, after patent expiration or invalidation, the generics would sell medicines at lower prices than the originators charged and lower the cost of healthcare. In 1983, one such generic firm, Bolar, decided to market the generic equivalent of Dalmane, a sleep disorder medication, as soon as the patent expired.¹³ To be ready at that time, Bolar conducted studies during the term of the patent to meet a preclearance requirement that it demonstrate to the federal Food and Drug Administration (FDA) the bioequivalence of its formulation to the originator's version.¹⁴ When Roche, the originator, sued for infringement, Bolar defended on the ground that its use was, if not exactly experimental in the Justice Story sense of the term, in the public's interest nonetheless, and therefore should be exempt from infringement liability.¹⁵ The Federal Circuit disagreed. In *Roche v. Bolar*, it held that it is "the role of Congress to maximize public welfare through legislation."¹⁶ Thus, the court declined to extend the experimental use exception to cover this rather clear commercial use.¹⁷

Significantly, Congress quickly stepped in. In the Hatch Waxman Act of 1984,¹⁸ it provided originator firms with the opportunity to extend

12. WILLIAM C. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 Vol. III (1890).

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

14. *Id.*

15. *Id.* at 865.

16. *Id.*

17. *Id.* at 863.

18. Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360cc (2000) and

the term of their patents to cover delays caused by their own premarket clearance obligations.¹⁹ In exchange, the legislature created an exception to infringement liability:

to make, use, offer to sell, or sell within the United States 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 manufacture, use, or sale of drugs or veterinary biological products.²⁰

But despite Congress's embrace of room for experimentation in Hatch Waxman, in several subsequent cases the Federal Circuit further narrowed the exception, doubling (really, tripling) down on *Bolar*.

In *Embrex, Inc. v. Service Engineering Corp.*, the court held that an academic scientist, in trying to find a cheap and effective way to design around a patent for a method for inoculating chicks in ovo against disease, infringed the patent.²¹ According to the court, the common law defense was inapplicable, even though the work was conducted at a university for research purposes, because the ultimate intent was commercial.²² Indeed, Judge Randall Rader would have gone further. In a concurring opinion, he suggested “the Patent Act leaves no room for any de minimis or experimental use excuses for infringement.”²³

Madey v. Duke University provided the court with the opportunity to bring the law closer to Judge Rader's vision.²⁴ In that case, Duke University was using patented laser technology in its teaching and research laboratories.²⁵ Duke did not have a license from the patentee because (like all nonprofit universities) it thought pure academic research and teaching to be quintessential examples of “philosophical” experimentation.²⁶ The Federal Circuit disagreed. It rejected the curiosity/profit distinction that had driven previous case law and instead looked to whether the conduct at issue was “in keeping with the alleged infringer's legitimate business, regardless of commercial implications.”²⁷ Since Duke's objectives in using the laser—education

35 U.S.C. §§ 156, 271, 282).

19. 35 U.S.C. § 156 (2017).

20. 35 U.S.C. § 271(e) (2017).

21. *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

22. *Id.*

23. *Id.* at 1352 (Rader, J., concurring).

24. *Madey v. Duke Univ.*, 307 F.3d 1351, 1352-53 (Fed. Cir. 2002).

25. *Id.*

26. *Id.* at 1362.

27. *Id.*

and enlightenment—increased the university’s status and attracted lucrative research grants, as well as great students and a distinguished faculty, the court concluded that its acts could not “qualify for the very narrow and strictly limited experimental use defense.”²⁸

Embrex and *Madey* concerned the common law defense developed by Justice Story.²⁹ The third case, *Integra Lifesciences I, Ltd. v. Merck KGaA*, interpreted the Hatch Waxman Act’s statutory defense.³⁰ In this case, the patent covered a compound that promoted the healing of wounds.³¹ Suspecting that the compound might also halt tumor growth, the defendant conducted its research without authorization, reasoning that if the work panned out, it would submit its data for regulatory approval of what would be a new treatment for cancer.³² In a suit brought by the patent holder, the Federal Circuit found the activity infringing.³³ Just as it had narrowed the common law defense, the court, per Judge Rader, stressed congressional use of the term “solely” and held that the Hatch Waxman Act defense applied only to clinical testing (that is, patient testing) of pharmaceuticals already on the market. In other words, Judge Rader confined the exemption to the situation present in *Bolar*.³⁴

Significantly, Judge Pauline Newman dissented in part.³⁵ She was not on the panels in *Embrex* or *Madey*, so she used her participation in *Integra* to challenge the Federal Circuit’s growing hostility to experimentation.³⁶ In her view,

[t]he purpose of a patent system is not only to provide a financial incentive to create new knowledge and bring it to public benefit through new products; it also serves to add to the body of published scientific/technologic knowledge. The requirement of disclosure of the details of patented inventions facilitates further knowledge and understanding of what was done by the patentee, and may lead to further technologic advance. The right to conduct research to achieve such knowledge need not, and should not, await expiration of the patent. That is not the law, and it would be a practice impossible to

28. *Id.*

29. *See Embrex, Inc. v. Serv. Eng’g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000); 307 F.3d 1351 (Fed. Cir. 2002).

30. *Integra Lifesciences I, LTD. v. Merck KGaA*, 331 F.3d 860, 864-65 (Fed. Cir. 2003), *vacated*, *Merck KGaA v. Integra Lifesciences I, LTD.*, 545 U.S. 193, 545 U.S. 193 (2005).

31. *Integra Lifesciences I, LTD.*, at 862-63.

32. *Id.* at 863.

33. *Id.* at 872.

34. *Id.* at 866-68.

35. *Id.* at 872.

36. *Id.* at 873 (Newman, J., dissenting in part).

administer. Yet today the court disapproves and essentially eliminates the common law research exemption. This change of law is ill-suited to today's research-founded, technology-based economy.³⁷

Thus, according to Judge Newman, the court should have determined that the defendant's research did not infringe on the plaintiff's patent.

Judge Newman's position found considerable support in the broader research community and among legal scholars. For example, in a report that heavily influenced the contours of patent reform, *A Patent System for the 21st Century*, the National Academies of Science Committee on Intellectual Property Rights in the Knowledge Based Economy questioned the result in *Madey*.³⁸ While the Report acknowledged that a study funded by the National Academies on academic research showed that among academics there was "widespread indifference to the existence of patents" on research inputs,³⁹ the Committee nonetheless argued that there were several worrisome trends. These trends included an increase in demand letters, an expansion in patenting research tools, and a rise in reliance on exclusive licenses.⁴⁰ The Committee reviewed several scholarly papers and proposed a research exemption, called for further consideration of the issue, and suggested that funding agencies condition financial support on agreements that researchers make their discoveries available to other researchers.⁴¹ The Committee on Intellectual Property Rights on Genomic and Protein Research and Innovation, also organized under the auspices of the National Academies, reiterated these concerns in a subsequent study.⁴² Significantly, it did so despite a second National

37. *Id.*

38. NATIONAL RESEARCH COUNCIL, ET AL., *A PATENT SYSTEM FOR THE 21ST CENTURY* 108-12 (Stephen A. Merrill et al., 2004).

39. See John P. Walsh, Ashish Arora & Wesley M. Cohen, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, in *PATENTS IN THE KNOWLEDGE-BASED ECONOMY* 285, 292-93 (Wesley M. Cohen & Stephen A. Merrill 2003). See also John P. Walsh, Ashish Arora, & Wesley M. Cohen, *Working Through the Patent Problem*, 299 *SCIENCE* 1021, 1021 (2003).

40. NATIONAL RESEARCH COUNCIL, ET AL., *supra* note 38, at 109-10. See also, *PATENTS IN THE KNOWLEDGE-BASED ECONOMY*, *supra* note 39.

41. NATIONAL RESEARCH COUNCIL, ET AL., *supra* note 38 at 110-17, citing Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 *U. CHI. L. REV.* 1017 (1989); see Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 *COLUM. L. REV.* 1177, 1205 (2000); see Rochelle C. Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course*, in *PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT* (F. Scott Kieff 2003); see Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 *WIS. L. REV.* 81 (2004). See also Dreyfuss, *supra* note 2.

42. NATIONAL RESEARCH COUNCIL, ET AL., *REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH* (Stephen A. Merrill & Anne-Marie Mazza, 2006) [hereinafter *REAPING THE*

Academies-sponsored study (by a team that included the same researchers as the earlier study) showing that scientists ignore patents.⁴³

Other voices expressed similar views. The American Intellectual Property Law Association (AIPLA), a group heavily composed of patent holders, endorsed an experimental use defense, arguing that the failure to include “a definitive provision in the patent law exempting experimentation can create many potential adverse consequences, including threatened patent litigation, complicated licensing negotiations, efforts to secure compensation based upon the fruits of any experimentation (including ‘reach-through’ royalties), royalty stacking, and delays in starting experiments until patent issues can be resolved.”⁴⁴ At around the same time, several scholars came out in favor of an experimental use defense and made specific suggestions for crafting such a measure.⁴⁵

Despite this support, a legislative fix to the research problem was not included in the bills that culminated in the AIA. There were several reasons. First, as with the National Academies studies, other follow-ups were interpreted as failing to show a significant problem developing in the research arena.⁴⁶ Scientists were ignoring patents, and patentees were ignoring scientists—perhaps because the patentees thought that any advance the scientists discovered would lead to new downstream products that would be covered by their patents. Second, various self-help measures were developed to supplement the proclivities of scientists. These included guidelines issued by the National Institutes of Health (NIH) and the Association of University Technology Managers

BENEFITS].

43. See John P. Walsh, Charlene Cho & Wesley M. Cohen, *Patents, Material Transfers and Access to Research Inputs in Biomedical Research*, in FINAL REPORT TO THE NATIONAL ACADEMY OF SCIENCES’ COMMITTEE ON INTELLECTUAL PROPERTY RIGHTS IN GENOMIC AND PROTEIN-RELATED INVENTIONS (2005), available at <http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.531.1401&rep=rep1&type=pdf>; John P. Walsh, Charlene Cho, & Wesley M. Cohen, *View from the Bench: Patents and Material Transfers*, 309 SCIENCE 2002 (2005).

44. AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, REPORT OF AIPLA SPECIAL COMMITTEE TO STUDY THE NATIONAL RESEARCH COUNCIL’S REPORT ON REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH 29 (2006), available at <http://www.aipla.org/advocacy/executive/Documents/NAS092304.pdf>.

45. See NATIONAL RESEARCH COUNCIL, ET AL., A PATENT SYSTEM FOR THE 21ST CENTURY, *supra* note 40; see Janice M. Mueller, No “Dilettante Affair”: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1 (2001); 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, 1650-51 (2001).

46. Claude Barfield & John E. Calfee, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 40-43 (AEI Press, 2007).

(AUTM), which encouraged research institutions to adopt nonexclusive licensing practices and to reserve the rights of academic researchers to use patented inputs without authorization.⁴⁷

Third, and perhaps most important, the biotechnology community saw an experimental use defense as a threat to its business model. At the time, most biomedical research was intensely upstream—the discoveries concerned basic information on living organisms, including genetic sequences, metabolic pathways, regulatory mechanisms, and methods for manipulating these discoveries. While consumer benefits were in the offing, at the time of the debate over patent reform, the commercial significance of these advances was largely as research inputs. Thus, unlike the firms represented by AIPLA, which principally held patents on consumer end-use products such as small-molecule medicines (and wanted the freedom to experiment in order to bring these products to market), the Biotechnology Innovation Organization (BIO) was concerned that a research exemption, if too broadly drafted or too generously interpreted, would interfere with the ability of its members to license their innovations and thereby jeopardize their ability to fund future research. After all, if the core use of a technology is in research, then a research exemption would obviate the need for anyone to pay tribute to the inventor.⁴⁸ With so many other controversial issues on the reform agenda, proponents of the AIA chose to delete a proposal on experimental use rather than to fight BIO.

B. *The Backlash*

Even before the AIA was enacted, it became increasingly clear that the decision to shrink the ambit of the experimental use defense would create difficulties for the innovation environment. To start, there is a profound normative question as to whether a legal regime can be said to be running smoothly if it functions satisfactorily only because important participants ignore the rule of law. The legal system requires many things of the scientific community: adherence to environmental

47. *Id.* at 54; *In the Public Interest: Nine Points to Consider in Licensing University Technology*, ASSOCIATION OF UNIVERSITY TECHNOLOGY MANAGERS (March 6, 2007), available at <http://www.autm.net/advocacy-topics/government-issues/principles-and-guidelines/nine-points-to-consider-when-licensing-university/>.

48. See Barfield & Calfee, *supra* note 46, at 61-63; *The Patent Reform Act of 2007 - Coalition Letter*, BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) (Oct. 23, 2007), available at <https://www.bio.org/advocacy/letters/patent-reform-act-2007-coalition-letter> (warning about weakening the enforceability of validly issued patents); John Raidt, PATENTS AND BIOTECHNOLOGY 32 (U.S. Chamber of Commerce Foundation 2014), available at <https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf>.

standards, fidelity to civil rights laws, and observance of pedagogical responsibilities to students. Relying on scientists to ignore patents arguably encourages the flouting of these other important legal standards and social norms. Moreover, such a regime can have an adverse impact on the careers of risk averse (which is to say, law-abiding) scientists.

Equally as important, a closer look at the studies the National Academies commissioned showed that they did not fully support the notion that the availability of a research exemption was irrelevant. While the official take-away was that scientists ignore patents, the studies had also noted that material transfer agreements (MTAs) were delaying research.⁴⁹ While MTAs can be viewed as an alternative mechanism for retaining exclusive rights over research (meaning that the problems researchers faced were not about patenting), the difficulty in concluding MTAs was arguably caused by difficulties in allocating patent rights over the fruits of the work that would be accomplished with the patented inputs. Besides, the National Academies studies both consisted of surveys of scientists who, in many cases, were the heads of research labs. Their subjective beliefs as to whether patents were inhibiting their research may have suffered from cognitive deficiencies. Research directors are not always aware of delays at the lab bench. In some cases, they may know there was delay but may attribute it to the wrong cause, such as lazy postdocs. In addition, they may have subconsciously altered their research agendas in order to stay away from areas where patents were prevalent or known to be enforced vigorously.

Studies relating the quantity of research to more objective factors soon appeared, including two papers by Fiona Murray that pointed in the opposite direction from the National Academies studies. In the first, Murray exploited the fact that prior to 1999, patent applications were confidential until the patent issued (leaving a period of two or more years before the existence of the patent was knowable). She compared papers in *Nature Biotechnology* that had a patent pair (that is, a patent issued on the research results) to see how often these papers were cited in the time period before the patent issued compared to the citation rate after issuance. She then compared that result with the ratio of citation rates for papers that were published at the same time, but which were not associated with patents. She found that citation rates fell faster for papers with a corresponding patent than for the others, suggesting that research decreases once a patent is issued.⁵⁰ In the second study, she compared

49. See Barfield & Calfee, *supra* note 46, at 40 n.4 (which appears on p. 96).

50. Fiona Murray & Scott Stern, *Do Formal Intellectual Property Rights Hinder the Free*

the citation rates of patented oncomice (mice bred to contract cancer) during the time when the patent holder charged a monopoly price for the mice with citation rates after the patent holder dropped the price to competitive levels. Much more research—and more varied research—was published once the mice were easily accessible.⁵¹

Anecdotal evidence of patent problems also accumulated, especially around genetic inventions. Most prominently, Myriad Genetics, the holder of patents on BRCA 1 and BRCA 2 gene sequences, which mutate in ways that are associated with early onset breast cancer, developed a diagnostic test that it refused to license to other laboratories. As a result, only Myriad could test patients: second-opinion testing became unavailable, patients whose insurance companies did not deal with Myriad could not obtain reimbursement for the tests, and there was no non-infringing way to test Myriad's work for accuracy or to see whether Myriad was staying abreast of new scientific developments.⁵² Most alarmingly, researchers looking for other causes of early onset breast cancer could not use the test to exclude patients whose condition was attributable to BRCA 1 or BRCA 2 mutations.⁵³ Frustrations regarding discrepancies between patient histories and Myriad reports led to a storm of protest within the genetics community, a comprehensive study of the genetics sector which demonstrated other social problems caused or exacerbated by exclusive patents rights over genetic tests,⁵⁴ and ultimately, a 2010 report by a committee organized by the Department of Health and Human Services recommending a research

Flow of Scientific Knowledge? An Empirical Test of the Anti-Commons Hypothesis, 63 J. ECON. BEHAVIOR & ORG. 648, 664-69 (2007).

51. See Kenneth G. Huang & Fiona Murray, *Does Patent Strategy Shape the Long-Run Supply of Public Knowledge: Evidence from Human Genetics*, 52 ACADEMY OF MANAGEMENT J. 1193 (2009). See also Heidi Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. POL. ECON. 1, 24 (2013) (showing that more work was done on genes in a public data base than on genes kept as trade secrets).

52. See generally, E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12 (4 SUPP.) GENET. MED. S39 (2010).

53. See Declaration of David H. Ledbetter, Appendix at 1505, *Ass'n for Molecular Pathology v. UPTO*, 09 Civ. 4515 (RWS) (S.D.N.Y. 2009) (describing the situation at Emory), available at <http://www.pubpat.org/assets/files/brca/CAFC/Appendix/A968%20to%20A3073%20Part%203%20of%207.pdf> & Declaration of Ellen T. Matloff, *id.* at 3020 (describing situation at Yale).

54. Robert Cook-Deegan & Christopher Heaney, *Gene Patents and Licensing: Case Studies Prepared for the Secretary's Advisory Committee on Genetics, Health, and Society*, 12 (4 SUPPL.) GENET. MED. S-1 (2011). See also Robert Cook-Deegan, John M. Conley, James P. Evans & Daniel Vorhaus, *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUROPEAN J. HUMAN GENETICS 585 (2013) (revealing Myriad's unwillingness to deposit the mutations it discovered into publicly-accessible data bases).

exemption for those who use patented genes for research purposes.⁵⁵

By 2005, the Supreme Court had also entered the fray. In a unanimous opinion citing Judge Newman's dissent in *Integra*, the Court held that the Federal Circuit's interpretation of the Hatch Waxman Act's statutory exemption was too stingy.⁵⁶ Reversing the Federal Circuit's decision in *Integra*, Justice Scalia focused on the language of the statute and emphasized that research had to be only "reasonably" related to the submission of information for premarket clearance to merit use of the exemption.⁵⁷ Thus, he reasoned, preclinical studies for the purpose of finding other medical uses for a patented composition were permissible.⁵⁸ But even though much of the Court's opinion showed an appreciation for scientific research, the decision did not go very far in creating space for experimentation. Thus, the Court cautioned that

[b]asic 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.⁵⁹

Even more obviously, research in areas unrelated to pharmaceuticals could not rely on the Hatch Waxman defense because there was no need to submit such data "under a Federal law which regulates the manufacture, use, or sale of drugs"⁶⁰

Still, the problem of fundamental research clearly bothered the Court. In a 2006 dissent from the dismissal of certiorari in a case about medical diagnostics, Justice Breyer declared that "sometimes too much patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection."⁶¹ In four subsequent cases, the Court sharply reduced the ambit of protection for fundamental life sciences research

55. DEPARTMENT OF HEALTH AND HUMAN SERVICES, GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS: REPORT OF THE SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY 97 (2010), available at http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf.

56. Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005).

57. *Id.*

58. *Id.* (the "exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of any [regulatory] information").

59. *Id.* at 205-06.

60. *Id.* at 195.

61. Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126-27 (2006) (Breyer, J., dissenting).

and for abstract inventions.⁶² Specifically, in *Mayo Collaborative Services v. Prometheus Labs.*, the Supreme Court held that the correlation between the dosage level of a drug and the blood level of a metabolite of the drug is an unpatentable law of nature.⁶³ In *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, it invalidated Myriad's claims to the BRCA 1 and 2 sequences on the ground that genomic DNA (gDNA) is a phenomenon of nature. In so holding, the Court noted that "without this exception, there would be considerable danger that the grant of patents would 'tie up' the use of such tools and thereby 'inhibit future innovation premised upon them.'"⁶⁴ Along the way, in *KSR Int'l Co. v. Teleflex Inc.*, the Supreme Court also raised the inventive step, thus making it more difficult to show that an invention is nonobvious enough to merit patent protection.⁶⁵ Moreover, the Court made it difficult to escape *Mayo's* bar on patenting laws of nature by adding a treatment step. In *Limelight Networks, Inc. v. Akamai Techs., Inc.*, the Court stressed that infringement requires one entity to perform every step of the patent claim.⁶⁶ For diagnostic inventions this is a problem because an advanced diagnostic such as gene testing is rarely performed by the person who treats the patient.

The consequences for the life sciences are acute. DNA sequences are no longer patentable and, presumably, neither are other naturally occurring materials such as proteins, RNA, hormones, enzymes, or vitamins, all of which may have therapeutic significance and which may be expensive to test for regulatory approval and to commercialize. Basic diagnostics are also unprotectable. The poster child for the change is *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,⁶⁷ which involved a way to detect genetic defects in a fetus by examining paternally-inherited fetal DNA isolated from the mother's blood.⁶⁸ The developers were the first to realize that paternal DNA was available for testing, but their patent was held invalid for several reasons: the DNA is not patentable under *Myriad*; while the inventors had to isolate the DNA and make enough of it to analyze, these are standard techniques and not inventive enough per

62. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1297 (2012); *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111 (2013) (both in the life sciences) and *Bilski v. Kappos*, 561 U.S. 593, 609-10 (2010); *Alice v. CLS Bank Int'l*, 134 S. Ct. 2347, 2361 (2014) (computerized business methods).

63. *Mayo*, 132 S. Ct. at 1294, 1297.

64. *Myriad*, 133 S. Ct. at 2116 (internal citation omitted).

65. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

66. *Alice*, 134 S. Ct. at 2117.

67. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2014).

68. *Id.* at 1373.

KSR; and, as the Federal Circuit held, the relationship between paternal DNA and the characteristics of the fetus is a law of nature, and therefore runs afoul of *Mayo*.⁶⁹ Despite this ruling, the method is revolutionary: for a range of potential defects, it substitutes a simple blood test for amniocentesis, thereby obviating the risk of miscarriage that is inherent in sampling amniotic fluid.⁷⁰ Although the scientific community as a whole questioned the outcome—twenty-two amicus curiae briefs supported a petition for review—the Supreme Court denied certiorari.⁷¹

II. REPERCUSSIONS

There is irony here. The biotechnology community was opposed to a research defense because it was concerned that the defense would jeopardize the revenue stream from its research tools. What it has now is a patent system that jeopardizes the revenue stream from many of its key innovations: therapeutics based on naturally occurring compounds, diagnostics to determine a patient's condition or to decide on therapeutic sufficiency, as well as so-called companion diagnostics ("personalized medicine")—methods for testing whether a patient will respond to a particular therapy.⁷² In the run up to the AIA, BIO wanted to leave well enough alone. Instead, it must now deal with the worst of all possible worlds. It must cope with a system that sharply reduces incentives to innovate in an arena where the cost of getting to market can be extremely high,⁷³ yet the law does nothing to fix the research problem created by the patents that do issue. There is also irony in terms of what the Court sought to accomplish. Justice Breyer's call was to promote the progress of science; he apparently assumed that without patents, fundamental advances will become freely available for the use of all researchers. In fact, however, firms in the life sciences industries may

69. *Id.* at 1373-74.

70. *Id.* at 1379.

71. *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016); for a list of amici, see *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, SCOTUSBLOG, <http://www.scotusblog.com/case-files/cases/sequenom-inc-v-ariosa-diagnostics-inc/> (last visited Mar. 5, 2017).

72. See Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 J. SCI. & TECH. 246 (2015).

73. See, e.g., Arti K. Rai & Jacob S. Sherkow, *The Changing Life Sciences Patent Landscape*, 34 NATURE BIOTECHNOLOGY 292 (2016); Damian Garde, *The Supreme Court's Decision That's Shaking Up Biotech*, STAT (June 27, 2016), available at <https://www.statnews.com/2016/06/27/supreme-court-biotech-patents/>. See also Joseph A. DiMasia, Henry G. Grabowskibi & Ronald W. Hans, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20 (2016), available at <http://www.sciencedirect.com/science/article/pii/S0167629616000291> (finding that the lifecycle cost per approved drug is close to \$3 billion).

change their focus to inventions that can be kept as trade secrets,⁷⁴ yet secrecy may be more inhibiting of scientific growth than patents. Alternatively, the industry may demand other sorts of incentives, such as tax preferences and prizes, which may not be forthcoming and may create inefficiencies or impose new forms of control over research agendas.⁷⁵

To make matters even worse, firms in other countries operate in a diametrically opposite legal environment: patents are generally available on biotechnological inventions, but there is a set of doctrines that protects research and the broader public interest.⁷⁶ The situation in the EU furnishes an example. The law on patentability in all EU countries is established by the European Patent Convention (EPC),⁷⁷ which has no equivalent to the exclusions for natural products and laws of nature that the Supreme Court found in § 101. Instead, the EPC declares that inventions in all fields of technology are patentable, provided they are susceptible to industrial application.⁷⁸ To be sure, the Convention then goes on to exclude discoveries, scientific theories, and mathematical methods,⁷⁹ as well as inventions the commercial exploitation of which would be contrary to “ordre public” or morality, methods for treating the human body, and diagnostic methods practiced on the human body.⁸⁰ While these exemptions could be read to exclude patents in the life sciences arena, the EU enacted a Biotechnology Directive⁸¹ to clarify their availability. The Directive states that advances are patentable “even if they concern a product consisting of or containing biological material

74. There are some indications that Myriad is doing just that. See Robert Cook-Deegan, John M. Conley, James P. Evans & Daniel Vorhaus, *The Next Controversy in Genetic Testing: Clinical Data as Trade Secrets?*, 21 EUROPEAN J. HUMAN GENETICS 585 (2013).

75. See generally, Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 UC IRVINE L. REV. 1115 (2015).

76. Brief of Amicus Curiae The Institute of Professional Representatives before the European Patent Office in Support of Neither Party at 3; *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 136 S. Ct. 2511 (2016), available at <http://www.scotusblog.com/wp-content/uploads/2016/04/15-1182-ac-Institute-of-Professional-Representatives-Before-the-EuropeFalsepdf> (noting that the Ariosa decision has “world-wide implications, repeatedly conflict[s] with internationally accepted standards of patent-eligibility . . . and jeopardize[s] research investment in medicine and other life sciences”).

77. Convention on the Grant of European Patents (European Patent Convention), Oct. 5, 1973, 1065 U.N.T.S. 199 (entered into force Oct. 7, 1977), as amended by the Act revising the Convention on the Grant of European Patents of Nov. 29, 2000 (entered into force Dec. 13, 2007), its Implementing Regulations, Protocols, and Rules Relating to Fees [hereinafter EPC].

78. *Id.* at art. 52(1).

79. *Id.* at art. 52(2)(a).

80. *Id.* at art. 53(a) & (c).

81. Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions.

or a process by means of which biological material is produced, processed or used.”⁸² In particular, “[b]iological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.”⁸³ Similarly, diagnostic methods that are *not* practiced on the body—including genetic diagnostics of the type at issue in *Mayo*, *Myriad*, and *Ariosa*—are patentable.⁸⁴

Although EU patents can cover advances the U.S. Supreme Court would regard as patent-ineligible natural laws or phenomena of nature, these patents do not inhibit innovation within the EU. On the whole, national laws determine the scope of infringement liability, and every EU country recognizes a robust exemption for research. For example, the German Patent Act states that the effects of a patent do not extend to “acts done for experimental purposes related to the subject matter of the patented invention.”⁸⁵ Commonly considered to distinguish between research *on* the patented invention, which is permissible, and research *with* the patented invention, which is not, this provision would protect researchers such as those involved in the *Integra* and *Embrex* cases, as well as those who study how genetic sequences affect health or use the patented invention to verify the accuracy of existing testing procedures.⁸⁶ Germany also has another provision to exempt research necessary to meet premarket clearance requirements.⁸⁷ Thus, research of the sort conducted in *Bolar* would also be entitled to protection. Significantly, however, neither of these provisions would cover the situations that BIO was concerned with during the run up to the AIA. Experiments *with* a patented input—use of an invention that is a research tool for the purpose of conducting research—do not fall within the scope

82. *Id.* at art 3(1).

83. *Id.* at art. 3(2). That said, there are exclusions for, among other things, the human body, art. 5(1), processes for cloning human beings, and uses of human embryos for industrial or commercial purposes, art. 6(2)(a) & (c).

84. See, e.g., Geertrui Van Overwalle, *Policy Levers Tailoring Patent Law to Biotechnology: Comparing U.S. and European Approaches*, 1 UC IRVINE L. REV. 435, 455 (2011).

85. See, e.g., § 11 No. 2, German Patent Act. See also § 60 U.K. Patent Act; Japanese Patent Law of 1959, as amended through May 6, 1998, effective June 1, 1998, § 69(1). See generally, Hans-Rainer Jaenichen & Johann Pitz, *Research Exemption/Experimental Use in the European Union: Patents Do Not Block the Progress of Science*, COLD SPRING HARBOR PERSPECTIVES IN MEDICINE (Cold Spring Harbor Laboratory Press, Nov. 6, 2014), available at <http://perspectivesinmedicine.cshlp.org/content/5/2/a020941.full?sid=8eeea22f-8ab0-4a44-84a9-ff20baa08523>; Van Overwalle, *supra* note 84, at 490-91 (describing Belgian law).

86. See *Embrex, Inc. v. Serv. Eng'g Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

87. § 11 No. 2b German Patent Act. See also § 60(5)(i) UK Patent Act. See generally Hans-Rainer Jaenichen & Johann Pitz, *supra* note 85, at 6-7.

of either provision.⁸⁸ The same situation will apply if, as planned, participating countries in the EU adopt a unitary patent. Under the Agreement on a Unified Patent Court, patent rights do not extend to acts done privately and for non-commercial purposes, to acts done for experimental purposes relating to the subject matter of the patented invention, or to research necessary to generate data to clear pharmaceuticals for marketing.⁸⁹

There are also other safeguards in Europe to protect the public interest. Some European countries have taken the position that gene product patents cover only the function disclosed in the patent.⁹⁰ Thus, researchers are free to investigate patented genes for other functions and uses. The Court of Justice of the European Union has further limited the ambit of gene patents by holding that the patent on a gene is infringed only when the gene is performing its biological function.⁹¹ In addition, unlike U.S. antitrust law, which permits a party with an exclusive position to refuse to deal with potential licensees,⁹² European competition law requires licensing when the refusal to deal would block the appearance of a new product for which there is potential consumer demand, when the refusal to license would eliminate all competition, and when the refusal lacks business justification.⁹³ Thus, Myriad's unwillingness to license laboratories to offer second opinions would raise a question under European competition law (or it would create enough of a concern to induce the right holder to license). Finally, several EU countries' patent laws include the possibility of awarding compulsory licenses when patent holders interpose unreasonable obstacles to access.⁹⁴

The bottom line is that in the EU, patents are available to motivate

88. Hans-Rainer Jaenichen & Johann Pitz, *supra* note 85, at 4.

89. AGREEMENT ON A UNIFIED PATENT COURT, art. 27 (a), (b) & (d), *available at* <https://www.unified-patent-court.org/sites/default/files/upc-agreement.pdf> [hereinafter UPC Agreement].

90. Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen [Statute Implementing the European Council's Biotechnology Directive], Jan. 21, 2005, BGBL I at 146, § 1a (4) (Ger.); CODE DE LA PROPRIÉTÉ INTELLECTUELLE art. L613-2-1 (Fr.).

91. Case C-428/08, *Monsanto Tech. LLC v. Cefetra BV*, 2010 E.C.R. 7.

92. *Verizon Comm'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407-08 (2004).

93. *Telefis Eireann and Independent Television Publications Ltd v. Commission of the European Communities* (Magill), 1995 ECR I-743 (Court of Justice Apr 6, 1995) (joining Cases C-241/91P and C-242/91P).

94. *See, e.g.*, Patents Act, 1977 c 37, § 48A(1)(b)(i) (Eng); 2 J.W. BAXTER, *WORLD PATENT LAW AND PRACTICE* § 8.02, 2001). *See also* Rochelle C. Dreyfuss, *Implications of the DNA Patenting Dispute: A U.S. Response to Dianne Nicol*, 22 J. L. INFO. & SCI. 1 (2013).

research at the cutting edge of life sciences research, including work required to isolate naturally occurring substances and find their therapeutic value or to work that correlates genomic and phenomic characteristics and contributes to the development of personalized medicine. At the same time, the public's interest is protected through exemptions. To put this another way, many countries have created an atmosphere that, as compared to the United States, is much more conducive to research. Americans can certainly benefit from the work accomplished in these other countries. For example, because research data can be imported back into the United States even when produced using methods patented in the United States, the drug approval process would not change if life sciences research mainly took place abroad.⁹⁵ However, the advantageous legal climate in other countries could easily lead to research arbitrage, a decrease in research institutions and research jobs in the United States, a brain drain, and eventually the loss of U.S. technological dominance.⁹⁶

At one time, the notion that innovation would move abroad may have seemed a rather remote possibility. After all, the U.S. government provides outstanding support for research and U.S. lab facilities and research personnel have long been viewed as the best in the world. It is not, however, a sure thing that these advantages will continue. As other countries have become aware of the importance of technological innovation to the economy, other governments have begun to nurture and support the research enterprise. A 2015 study of the Organization for Economic Co-operation and Development (OECD) is illuminating.⁹⁷ It demonstrates that Asia and the EU are devoting increasing attention to technological research and that the research and development (R&D)

95. See *Bayer AG v. Housey Pharm., Inc.*, 340 F.3d 1367 (Fed. Cir. 2003) (interpreting 35 U.S.C. § 271(g)).

96. See, e.g., Pamela Samuelson, *Intellectual Property Arbitrage: How Foreign Rules Can Affect Domestic Protections*, 71 U. CHI. L. REV. 223 (2004). Cf. Ryan Davis, *Kappos Calls for Abolition of Section 101 of the Patent Act*, LAW 360 (April 12, 2016), available at <http://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act> (noting that Kappos, a former Director of the Patent and Trademark Office, "has begun telling clients that patent protection for biotechnology and software inventions is more robust in other countries like China and Europe and they are better off seeking patents in those places, because of the way U.S. courts have interpreted Section 101").

97. ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *OECD SCIENCE TECHNOLOGY AND INDUSTRY SCOREBOARD 2015: INNOVATION FOR GROWTH AND SOCIETY* (2015), available at http://www.keepeek.com/Digital-Asset-Management/oecd/science-and-technology/oecd-science-technology-and-industry-scoreboard-2015_sti_scoreboard-2015-en#page1 [hereinafter *OECD Scoreboard*].

expenditures of foreign companies are also on the rise.⁹⁸ This has translated into an increase in scientific publications, particularly in China,⁹⁹ which, in 2014, was also the leader in patent activity. Indeed, its intellectual property office is receiving more applications than those in the United States and Japan *combined*.¹⁰⁰ Significantly, the OECD study also shows that international collaborations, as well as citations across economies, are growing,¹⁰¹ which suggests that scientists themselves recognize that excellence in science is no longer concentrated in one country. Researchers have also become more mobile. Where the United States once experienced a net influx of scientists, the flow has changed direction, as scientists now migrate to the places they view as offering the best opportunities.¹⁰² In a few technologies, the U.S. has already lost its dominant position.¹⁰³

III. PROPOSALS

I am not alone in seeing the connections among the uncertainties generated by § 101 jurisprudence, the concerns about investment in innovation, and the ability to conduct research. The U.S. Patent and Trademark Office has convened two roundtables on subject-matter eligibility and heard from a variety of individuals and institutions about the need to change the law on which inventions are considered patentable.¹⁰⁴ Tellingly, a statement filed by a group of twenty-two legal practitioners and scholars linked the need to revise § 101 with the experimental use defense, noting that clarification of the right to experiment would “assure that no vestige remains of the Supreme Court’s justification for imposing a judicial eligibility exception.”¹⁰⁵ The so-called Banbury Statement suggested legislatively overruling the

98. *Id.* at 15-16, 38, 57-60. *See also id.* at 97-100 (showing levels of support for higher education and educational institutions, where research is performed, in the United States and elsewhere).

99. *Id.* at 61.

100. WORLD INTELLECTUAL PROPERTY ORGANIZATION, WORLD INTELLECTUAL PROPERTY INDICATORS 23 (2015), *available at* http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2015.pdf.

101. OECD Scoreboard, *supra* note 97, at 66-67.

102. *Id.* at 68, 128-29.

103. *Id.* at 76, 78-79.

104. *See Patent Subject Matter Eligibility*, UNITED STATES PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patent/laws-and-regulations/comments-public/patent-subject-matter-eligibility-roundtable-2> (last updated Feb. 16, 2017).

105. BANBURY CENTER, COLD SPRING HARBOR LABORATORY, A PROPOSED PATH FORWARD FOR LEGISLATIVELY ADDRESSING PATENT ELIGIBILITY LAW (2016), *available at* <https://www.uspto.gov/sites/default/files/documents/Updated%20Banbury%20Statement.pdf>.

recent § 101 decisions, a revision to § 101 that would limit patents to “inventions contributing to the technological arts,” and an exemption “targeted in a manner that is consistent with the 2006 recommendation of the National Academies.”¹⁰⁶

As always, the devil is in the details. I leave it to others to consider the revision of § 101 (and to expound on what technological arts might mean¹⁰⁷); here, I concentrate on the experimental use exemption. As noted earlier, in the lead up to the AIA, several scholars proposed research defenses. For example, Rebecca Eisenberg would have allowed researchers to use patented materials without authorization, but in certain types of cases, would have charged a “reasonable royalty” after the invention was developed in order to compensate for the patent holder’s initial investment.¹⁰⁸ Janice Mueller’s idea was to create a reach-through royalty based on the contribution the patented input made to the products the researcher developed.¹⁰⁹ Maureen O’Rourke suggested the adoption of a patent analogue to copyright’s four-factor fair use defense,¹¹⁰ but would have suggested five factors and, unlike in copyright, would have allowed the court to levy a royalty in some cases.¹¹¹ Because the actual payments under all these proposals would have been difficult to calculate and, in most cases, the calculation would occur long after the infringement, it was not certain that any of them would be effective in enticing researchers to make full use of patented inputs.

In my earlier work, I took a somewhat different tack and suggested that bona fide researchers (as determined by their institutional affiliation) be required to seek authorization from the patentee. However, if the patent holder refused to license, the researcher could then use the technology without permission. There was, however a catch: researchers who used patented material without authorization would be required to commit to publishing the resulting research and either put the advances made into the public domain or patent them under the understanding that they would be licensed out on a nonexclusive basis and on reasonable terms.¹¹² My thinking was that the

106. *Id. at 1.*

107. *See, e.g.,* David J. Kappos, John R. Thomas & Randall J. Bluestone, *A Technological Contribution Requirement for Patentable Subject Matter: Supreme Court Precedent and Policy*, 6 NW. J. TECH. & INTELL. PROP. 152 (2008).

108. Eisenberg, *supra* note 41, at 1078.

109. Mueller, *supra* note 45, at 58.

110. O’Rourke, *supra* note 41, at 1208-09; 17 U.S.C. § 107.

111. *Id.*

112. Dreyfuss, *supra* note 2, at 471. *See also* Richard R. Nelson, *The Market Economy and the Scientific Commons*, 33 RES. POL’Y 467 (2004) (endorsing this proposal).

identification requirement would eliminate the need to determine what constituted a research use. Further, this scheme would encourage scientists engaged in fundamental research to make their work freely available or available on reasonable terms, and it would obviate the need to engage in complex royalty calculations on downstream commercial products.

However, since I made this recommendation, two things have happened—one that weakens it and one that somewhat strengthens it. On the negative side, the rise in collaborative research and institutional interest in patenting have made it much more difficult to identify bona fide basic researchers by their affiliation. The Bayh-Dole Act has turned academics into entrepreneurs and many of their spin-off companies (and the firms that acquire these spin offs) also engage in the sort of research that should be regarded as basic, fundamental science.¹¹³ Thus, the limit placed on who can benefit from the exemption no longer makes sense; should this proposal move forward, it would have to be expanded to all researchers and include a definition of “experimental.” On the positive side, the idea of requiring patent holders to promise to freely license on reasonable terms now has considerable currency, for this type of licensing is regularly used by standard-setting organizations to ensure that the patents essential to a standard are freely available to all the participants in an industry.¹¹⁴ While there are sometimes problems in determining what constitutes a reasonable royalty,¹¹⁵ reasonable and nondiscriminatory licensing (RAND) has been shown to be a feasible way of ensuring the accessibility of materials that are needed to facilitate interoperability (e.g. among cellphones), backward and forward compatibility (for things like word processing programs), and the prevention of products (like the betamax video system) from becoming stranded. There are strong commonalities between scientists researching the same technical problem who need the same inputs and firms manufacturing equipment that need technological components drawn to the same specifications. Accordingly, it is not surprising that the same solutions might be applicable to both problems. Interestingly, Ryan Vacca and his coauthors have suggested the use of a RAND licensing

113. Cf. Rochelle Cooper Dreyfuss, *Tailoring Incentives: A Comment on Hemel and Ouellette’s Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 131, 136 (2014); See also Peter Lee, *Patents and the University*, 63 DUKE L.J. 1, 37-38 (2013).

114. See generally, Jay P. Kesan & Carol M. Hayes, *FRAND’s Forever: Standards, Patent Transfers, and Licensing Commitments*, 89 IND. L.J. 231 (2014).

115. See Daryl Lim, *Standard Essential Patents, Trolls, and the Smartphone Wars: Triangulating the End Game*, 119 PENN ST. L. REV. 1, 35-47 (2014).

scheme in the seed sector, which presents another situation in which an input is patented, yet fundamental to an entire industry.¹¹⁶

Still, a reasonable royalty is not the same as free, and as we have seen in other developed countries, experimental uses are free of any payment obligation. Katherine Strandburg has come the closest to proposing an equivalent resolution for the United States.¹¹⁷ Her idea is to adopt the “use on/use with” distinction and thus permit essentially the same unauthorized uses permitted in Europe.¹¹⁸ While she would tack on a compulsory license scheme to ensure the availability of research tools to conduct research,¹¹⁹ it is likely that such an addition would continue to be a deal breaker for tool manufacturers such as the members of BIO. But because, as Strandburg notes in another article, the tools of interest to fundamental researchers are often invented by other fundamental researchers,¹²⁰ the self-help measures developed by AUTM and the NIH may be sufficient to ensure their availability.¹²¹

The remaining question is whether a statute of this type would provide enough certainty to patent holders, researchers, or courts. Because the measure appears to work exceedingly well elsewhere,¹²² U.S. courts could rely on foreign case law to flesh out the rudimentary distinction between “on” and “with.” In any event, the provision likely operates less as a rule of decision in infringement litigation and more as a norm generally agreed upon by the scientific community, or as an in terrorem clause that prevents right holders from denying researchers the right to experiment. Nonetheless, more detail may be required for an exemption to be politically palatable in countries like the United States, which is highly litigious and relies on a common law method that can obfuscate rather than clarify poorly specified standards. A study by the UK Royal Society, referring to the EU situation, found that between the extremes of infringement and exemption “there is doubtful ground, and prudent people avoid doubtful ground.”¹²³ Thus, it concluded that it

116. Benjamin M. Cole, Brent J. Horton & Ryan Vacca, *Food for Thought: Genetically Modified Seeds As De Facto Standard-Essential Patents*, 85 U. COLO. L. REV. 313, 347-53 (2014) (suggesting the use of RAND licenses in cases in which a farmer can show that a genetically modified seed has become a de facto standard).

117. Strandburg, *supra* note 41, at 119-22. *See also* Katherine J. Strandburg, *Bend or Break? The Patent System in Crisis: Patent Fair Use 2.0*, 1 UC IRVINE L. REV. 265 (2011).

118. *Id.*

119. *Id.* at 142-46.

120. *See* Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467 (2008).

121. *See supra* text accompanying note 46.

122. *See e.g.*, Jaenichen & Pitz, *supra* note 85.

123. THE ROYAL SOCIETY, KEEPING SCIENCE OPEN: THE EFFECTS OF INTELLECTUAL

would be “conducive to the development of science if the position of scientific work under these exemptions was clearer.”¹²⁴

AIPLA’s 2006 proposal included substantially more detail. Notably, this formulation was substantially accepted as a recommendation by the National Academies’ Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation, and it was endorsed in the Banbury Statement issued in 2016. Built in part on a bill considered by the House of Representatives in 1990,¹²⁵ the proposal, as reformulated by the National Academies, would expand upon the research on/research [with] distinction as follows:

Making or using a patented invention should not be considered infringing if done to discern or discover:

- a. the validity of the patent and scope of afforded protection;
- b. the features, properties or inherent characteristics or advantages of the invention;
- c. novel methods of making or using the patented invention; or
- d. novel alternatives, improvements, or substitutes.

Further, making or using the invention in activities incidental to preparations for commercialization of a non-infringing alternative should also be noninfringing.¹²⁶

This exemption would permit the research in *Integra*, where the idea was to find other uses for the wound-healing medicine (subsection (c)); it would also cover the researcher in *Embrex* who was looking for alternative ways to inoculate chick eggs (subsection (d)). It would similarly immunize from liability work carried out to discover other

PROPERTY POLICY ON THE CONDUCT OF SCIENCE, § 3.23 (2003), available at https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2003/9845.pdf.

124. *Id.*

125. The House proposal would have added 35 U.S.C. § 271(j):

(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 subsection (e)(1) applies.

H.R. 5598, 101st Cong. § 402 (1990). See AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION, RESPONSE TO THE NATIONAL ACADEMIES REPORT ENTITLED “A PATENT SYSTEM FOR THE 21ST CENTURY” at 26, available at <http://www.aipla.org/advocacy/executive/Documents/NAS092304.pdf> [hereinafter AIPLA RESPONSE].

126. REAPING THE BENEFITS, *supra* note 42, at 14; AIPLA RESPONSE, *supra* note 125, at 25.

causes of early-onset breast cancer (subsections (c) and (d)), and incidental uses of the patented inventions to verify the accuracy of Myriad's tests for BRCA 1 and 2-related breast cancers. However, it would not permit the unauthorized use Duke was making of the laser at issue in *Madey*, for that is best analyzed as research use *with* the laser.¹²⁷ But that is a feature, not a bug: as we have seen, an exemption for research use of research tools is problematic because it could arguably undermine incentives to invent research tools.

In short, the National Academies/AIPLA provision targets exactly the activities that should be beyond the scope of infringement liability while identifying the uses that should be subject to the patent holder's authority, and it ensures that those that are within that authority will not be found exempt from liability. Presumably, it is this careful wording that allowed Hans Sauer, Deputy General Counsel of BIO, to join the Banbury Statement and come around to the notion that a legal regime that includes a robust safeguard for research offers a better environment for biomedical science.

IV. CONCLUSION

The United States patent system is no longer well suited to the needs of the life sciences sector. Patents cannot be obtained in many key areas, including for the development of medicines that involve naturally occurring materials such as proteins, hormones, enzymes, or vitamins. More important, there is likely insufficient protection for the important new field of personalized medicine. While that arena does not currently require the extensive testing demanded of pharmaceuticals and medical devices, the FDA is interested in ensuring the quality of these tests, and thus the situation could easily change.¹²⁸ The Supreme Court denied protection in these areas out of concern that patents would chill research and impair the advancement of science. In fact, however, the current legal climate risks the ability of the United States to fully participate in the Knowledge Economy and threatens its competitive position as an innovator. It is therefore time to consider reinstating a research exemption to patent liability. With such an exemption, the patent system

127. Indeed, the Federal Circuit has hinted that a better view of *Madey* may be as a research tool case, see *Integra Lifesciences I, LTD. v. Merck KGaA*, 331 F.3d 860, 867 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005). See also *id.* at 878 (Newman, J., dissenting).

128. See U.S. FOOD AND DRUG ADMINISTRATION, PAVING THE WAY FOR PERSONALIZED MEDICINE: THE FDA'S ROLE IN A NEW ERA OF MEDICAL PRODUCT DEVELOPMENT (2013), available at <http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf>.

would be available to incentivize fundamental research and patents would no longer endanger the onward march of science.

This paper focused on the research exemption. However, it also behooves Congress to consider the environment for research more generally. Refusals to deal are also exacting a toll on scientific inquiry. Thus, a harder look at anticompetitive conduct on the part of patent holders would likewise be worthwhile. Lawmakers should consider invigorating the patent misuse defense, restoring antitrust liability, and introducing law that would permit compulsory licenses in cases where right holders block the ability of researchers to develop new products or otherwise prevent such products from entering the marketplace.