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A RESEARCH EXEMPTION FOR THE 21ST CENTURY

Introduction

On March 20, 2015, Robert Kastenmeier, who represented Wisconsin's Second Congressional District from 1959 to 1991, passed away at his home in Arlington, Virginia.¹ Though Kastenmeier may not have been well known outside of legislative circles and his home state of Wisconsin, he was in fact one of the most prolific policy makers—if not *the* most prolific policy maker—in the field of intellectual property law in the 20th century. He is impressively credited with authoring more than forty-eight laws dealing with intellectual property matters during his legislative tenure, including the Copyright Act of 1976, which remains the primary legal framework for copyright law in the United States.²

One of the last bills that Kastenmeier introduced in the House of Representatives was a major piece of patent reform legislation dubbed the Patent Competitiveness and Technological Innovation Act of 1990 (PCTIA).³ Kastenmeier introduced the bill on September 20, 1990, but left office less than four months later on January 3, 1991, after losing an election to Scott Klug. The PCTIA contained five separate titles, and dealt with subjects as varied as the patentability of inventions made in outer space to the repeal of state sovereign immunity from infringement liability.⁴ One of those titles, Title IV, garnered little attention at the time, but addressed a subject of tremendous importance today: the need to codify and strengthen the long-standing common law research exemption in American patent law.

I have written elsewhere about the political economy of the research exemption in American patent law from 1970 to the present day, with an emphasis on analyzing the political coalitions that have historically argued in favor of or against such exemptions, and the economic arguments they often invoke.⁵ The purpose of this article, in contrast, is to carry forward the torch that Kastenmeier lit, and argue in favor of codifying a robust research exemption. To that end, section two briefly

1. Adam Clymer, Robert Kastenmeier, *Liberal Voice in House for 32 Years, Dies at 91*, THE NEW YORK TIMES (Mar. 20, 2015), <http://www.nytimes.com/2015/03/21/us/robert-kastenmeier-liberal-house-voice-dies-at-91.html>.

2. *Id.*

3. H.R. 5598, 101st Cong. (1990).

4. *Id.*

5. See generally Nicholas Short, *The Political Economy of the Research Exemption in American Patent Law*, 26 FORDHAM INTELL. PROP., MEDIA & ENT. L. J. 573 (2016).

explains how the law pertaining to research exemptions has developed since 1970, with an eye towards understanding what these developments mean for policy makers. Section three summarizes the findings of relevant survey evidence and statistical studies. Section four critiques several scholarly proposals for a research exemption or proposals that attempt to accomplish similar ends through different means, like the proposal for creating a “fair use” exception in patent law, or for modifying the Bayh-Dole Act to give federal funding agencies more discretion when determining whether the results of publicly-funded research should be patented. Section five concludes by summarizing the basic argument in favor of the Robert Kastenmeier Memorial Act, a new bill to codify a robust research exemption in American patent law.

The Current Legal Framework

The first thing to know about the research exemption in American patent law is that there are, in fact, three separate exemptions. One exemption is rooted in the common law, and the other two have a statutory basis. Supreme Court Justice Story first articulated the common law exemption (also known as the experimental use defense) in a case dating back to 1813.⁶ Despite this exemption’s deep historical origins, as well as broad application to all types of patentable subject matter, the Court of Appeals for the Federal Circuit has recently interpreted the doctrine in a narrow fashion.⁷ As a result, the common law exemption “does not immunize use [of a patented invention] that is in any way commercial in nature” nor “any conduct that is in keeping with the alleged infringer’s legitimate business,” even if that business is research or education with no commercial intent.⁸ To borrow the Federal Circuit’s own phrasing, the common law exemption continues to exist, albeit “in a very limited form.”⁹

The first statutory research exemption in American patent law was created in 1970 upon the passing of the Plant Variety Protection Act (PVPA), which conferred patent-like protection to novel varieties of plants that reproduce sexually.¹⁰ Like the common law exemption though, this exemption offers few benefits today. In 1985, an administrative patent law board determined that those who invent novel varieties of sexually reproduced plants can obtain a normal utility patent under the Patent Act and need not seek the special protection of the

6. *Whittemore v. Cutter*, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813).

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

8. *Id.* at 1362.

9. *Id.* at 1360.

10. S. 3070, 91st Cong. (1970).

PVPA.¹¹ The Supreme Court sanctioned this view in 2001.¹² As a result of the Court's decision, two completely separate statutory schemes govern the patentability of sexually reproduced plants. Justice Breyer's dissent correctly noted that the majority's decision effectively destroyed the PVPA's research exemption because inventors will always choose protection under the Patent Act over the PVPA.¹³

The second statutory exemption in American patent law was created in 1984 with passage of the Hatch-Waxman Act and also applies to a limited range of inventions, specifically pharmaceuticals and medical devices.¹⁴ In contrast to the common law and PVPA exemptions, the pharmaceutical exemption still remains in effect today, and while narrow in terms of subject matter, the Supreme Court has interpreted the exemption to be quite expansive in terms of the types of activity the exemption protects.¹⁵ Overall then, when it comes to the research exemption, American patent law currently has: a "very limited" common law exemption; a statutory exemption for the few who still seek protection under the PVPA; and a strong exemption for drug patents.

For policy makers, a couple key facts about the legal landscape stand out. First, for more than twenty years, the pharmaceutical industry has been the one industry where patents arguably play a more important role than other economic incentives, such as first-mover advantages, in facilitating research investments. That same industry has also operated under an unusually strong and broad research exemption, even by international standards, since 1984. Though there is considerable debate among economists and other social scientists as to whether patents actually do more harm than good when it comes to innovation and research across the economy,¹⁶ there is somewhat more consensus for

11. *Ex Parte Hibberd*, 227 U.S.P.Q. 443, *2-3 (B.P.A.I. 1985).

12. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 134 (2001).

13. *Id.* at 155 (Breyer, J., dissenting) ("The Court has advanced no sound reason why Congress would want to destroy the exemptions in the PVPA that Congress created. And the Court's reading would destroy those exemptions."). Those who obtain plant patents under the Patent Act are, of course, still subject to the "very limited" common law exemption described above.

14. The Federal Circuit had the misfortune of attempting, for the first time, to narrow the common law exemption in a pharmaceuticals case while Congress was debating the Hatch-Waxman Act. *Roche Products, Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984). Congress quickly amended the Act to repeal that decision. *See H.R. REP. NO. 98-857*, pt. 2, at 26 (1984), *as reprinted in U.S.C.C.A.N.* 2686, 2710.

15. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005) (holding that the exemption applies to exploratory research and early-stage experimentation).

16. *See, e.g., Michele Boldrin & David K. Levine, The Case Against Patents*, 27 J. OF ECON. PERSP., Winter 2013 at 1, 5 (finding "weak or no evidence that strengthening patent regimes increases innovation," based on a review of 24 separate studies); *see also Adam B. Jaffe, The U.S. Patent System In Transition: Policy Innovation and the Innovation Process*, 29 RES. POL'Y 531, 531 (2000).

the idea that patents play an important role in drug research.¹⁷ Yet drug research in America is also a broadly protected activity.

Paradoxically, the law currently offers *less* protection for research and development in the myriad industries where patents arguably play a small to negligible role in promoting innovation and investment compared to pharmaceuticals, and where such an exemption would therefore be *less* disruptive to the underlying economic incentives. The National Science Foundation estimates that American firms increased drug research spending from \$5.5 billion to more than \$17 billion between 1980 and 2003. Additionally, PhRMA, an advocacy group for pharmaceutical firms, estimates that total drug research spending conducted in the United States by foreign and domestic firms increased from \$6 billion to \$39 billion between 1980 and 2004.¹⁸ These numbers obviously do not provide a counter-factual for comparison, or suggest what levels of spending we would have observed in the absence of an exemption. But they do suggest that drug research investments consistently and substantially increased for at least 20 years despite the broad statutory exemption for drug research. Few if any scholars have confronted this basic fact about the drug research exemption in American patent law.

Second, the current legal framework also suffers from unnecessary complexity in part because Congress has historically dealt with the statutory exemptions in a piecemeal (subject matter-specific) fashion, and in part because Congress has failed to codify the common law exemption and has left that doctrine's interpretation to the judicial branch.¹⁹ The complexity of having three separate exemptions is compounded by the fact that, under the doctrine of sovereign immunity, public universities currently enjoy immunity from all forms of patent infringement liability (including research-based activity) while private universities do not.²⁰ Similarly, state agencies conducting research and development enjoy immunity while federal agencies do not, even though the former do much less research than the latter.²¹ A major benefit of Congressional action would be to simplify the law and treat all research

17. F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 71 J. ON TELECOMM. & HIGH TECH. L. 167, 171-75 (2009). This point is by no means settled. See Boldrin and Levine, *supra* note 16, at 13-14.

18. Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Pub. No. 2589, at 7-8 (October 2006).

19. The Federal Circuit's institutional bias against equitable doctrines, like the research exemption, means that absent Supreme Court oversight, policy will continue to be made by a Court adverse to research exemptions.

20. *Florida Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 630 (1999); see also Short, *supra* note 5, at 596.

21. *Id.* The federal government has abrogated its own immunity. See 28 U.S.C. § 1498.

institutions equally when it comes to immunity from infringement liability for research activity.

Studies for Guiding Policy

To date, no studies have directly attempted to measure the causal impact of a research exemption on research or innovation. That is to say, no studies have attempted to measure how the implementation or codification of a research exemption—whether general or subject matter-specific, whether in the United States or elsewhere—influences research expenditures or proxies for innovation outcomes (like new drug applications) while controlling for temporal trends and effects not due to the exemption.²² This is an area of ongoing inquiry.

However, some survey evidence and a handful of statistical studies that deal with the overall impact of patents on research and innovation do provide some data to consider in connection with the debate over the research exemption. For example, one notable survey found that proliferating patent rights rarely prevent biomedical researchers from moving forward,²³ but only because researchers routinely adopt a series of strategies for coping with the complex patent landscape.²⁴ And most of these coping strategies—including willful infringement, sending research offshore, and litigation—are not necessarily desirable as a matter of public policy. Other surveys report similar results among scientists generally, and not just biomedical researchers.²⁵

On the subject of willful infringement, John P. Walsh and his co-authors note that university researchers “have a reputation for routinely ignoring patents in the course of their research,” and sometimes invoke a research exemption as a basis for doing so, perhaps unaware that the Federal Circuit has significantly narrowed the application of that doctrine.²⁶ Walsh and his co-authors also found that “[a] third of the industrial respondents (and all nine university or government lab respondents) acknowledged occasionally using patented research tools

22. *But see* Kevin Iles, *A Comparative Analysis of the Impact of Experimental Use Exemptions in Patent Law on Incentives to Innovate*, 4 NW. J. TECH. & INTELL. PROP. 61 (2005) (making a general argument based on patent statistics that research exemptions do not seem to drive research off-shore).

23. Scientists doing clinical research based on diagnostic tests are one major exception. *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 318 (Wesley M. Cohen & Stephen A. Merrill eds., 2003); *see also* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1049, 1071.

24. Walsh et al., *supra* note 23, at 331-32.

25. Eisenberg, *supra* note 23, at 1066-69.

26. Walsh et al., *supra* note 23, at 324-25.

without a license, and most respondents suggested that infringement by others is widespread.”²⁷ The findings make a compelling case for codifying the research exemption, as the law in its current form is clearly forcing many American researchers to operate outside of the law in order to continue pushing the boundaries of scientific and technological development.

Another troublesome finding is that many research institutions are willing to send research offshore to avoid the reach of U.S. patents on research tools or inputs.²⁸ In this regard, research institutions can exploit the fact that holders of U.S. patents may not elect to obtain foreign equivalent patents in every potential research venue, and the fact that many other countries, including most major trading partners of the U.S., have codified some form of a research exemption that provides more protection for research activity (outside of pharmaceuticals) than U.S. law does.²⁹ Thus, in its current form, American patent law may not necessarily inhibit the progress of scientific investigation within the global research community, but because American law is so far out of step with international standards, it may indirectly cause foreign researchers to gain a competitive advantage on the technological cutting edge. This result is, on a very general level, inimical to the basic tenets of American economic policy.

Walsh and his co-authors also found that researchers “worked around” problems with patents by negotiating a license or litigating over the patent’s validity, both activities that impose significant costs and delays on research institutions.³⁰ Nearly one-third of the survey respondents indicated “that the process of sifting through a large number of potentially relevant patents and subsequent negotiations was very time consuming,” and imposed significant costs and delays on many biomedical researchers.³¹ Walsh and his co-authors also noted that, setting potential damage awards aside, the costs of engaging in patent litigation can be significant, often ranging from one to ten million dollars in attorney’s fees alone for each party to the lawsuit (this study was published in 2003).³² Such estimates ignore the true opportunity cost of

27. *Id.* at 327.

28. *Id.* at 328.

29. *See, e.g.*, Janice M. Mueller, *No “Dilettante Affair”*: Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools, 76 WASH. L. REV. 1, 37-39 (describing developments in German and Japanese law); KENNETH A. OYE & RACHEL WELLHAUSEN, THE INTELLECTUAL COMMONS AND PROPERTY IN SYNTHETIC BIOLOGY, IN SYNTHETIC BIOLOGY: THE TECHNOSCIENCE AND ITS SOCIETAL CONSEQUENCES 129-130 (Marcus Schmidt ed., 2009) (indicating that “Australia, Austria, Canada, France, Germany, Iceland, Israel, Japan, the Netherlands, New Zealand, Norway, Switzerland and the UK are among countries with research exemptions on protected property”).

30. Walsh et al., *supra* note 23, at 322-31.

31. *Id.* at 315.

32. *Id.*

litigation, which makes significant demands on the time of an institution's executives and scientists.³³ Another study found that in 1999 the total spent on patent litigation in the United States, across all technological settings, exceeded \$16 billion.³⁴

The high costs associated with patent licensing negotiations and litigation is a problem with many roots and potential solutions (and, in some settings, it is not necessarily a problem in the first instance). But for purposes of assessing the merits of the research exemption, the more important question is: why are private and public institutions increasingly bearing these costs at the research and development phase?

The answer, according to a handful of recent statistical studies, is that in a setting of cumulative innovation—where each invention is an input to further work—patent owners have the ability to significantly stifle follow-on research and innovation, and they are using that power to slow the pace of technological progress. One such study focuses on the agreements that the National Institutes of Health negotiated with DuPont in the late 1990s over the oncomouse, a patented mouse genetically-modified to be predisposed to developing cancer.³⁵ Under those agreements, DuPont had to make oncomice available to academic cancer researchers on a royalty-free basis with no reach-through rights on subsequent innovations,³⁶ thus putting an end to DuPont's restrictive licensing practices.³⁷ The authors found that the “openness shock” created by the agreements significantly increased levels of follow-on research according to a variety of proxies, with annual citations increasing by twenty-one percent.³⁸

Another study used similar methods to determine whether patent-like contractual provisions inhibited genetic research during the race to sequence the human genome.³⁹ The author concluded that the patent-like protection at issue “generated economically and statistically significant reductions in subsequent scientific research and product development, on the order of 20–30 percent” for multiple measures of innovation outcomes and found some evidence that the damage was

33. *Id.*

34. JAMES BESSEN AND MICHAEL J. MEURER, *PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATION AT RISK* 15-16 (Princeton Univ. Press ed. 2008).

35. Fiona Murray et al., *Of Mice and Academics: Examining the Effect of Openness on Innovation* 3-4 (Nat'l Bureau of Econ. Research, Working Paper No. 14819, 2009)

36. Reach-through rights are claims on subsequent inventions developed through use of the licensed invention. DuPont, for example, did not just demand royalties for use of the oncomice (the licensed invention), but claimed ownership or a right to royalties in all cancer therapeutics developed from research using the oncomice. *Id.* at 12-13.

37. *Id.* at 3.

38. *Id.* at 23.

39. Heidi L. Williams, *Intellectual Property Rights and Innovation: Evidence from the Human Genome*, 121 J. OF POL. ECON. no. 1, 2013 at 2.

permanent.⁴⁰ A subsequent study importantly found no reduction in innovation outcomes in a setting where the underlying technology was freely available in the human body and researchers could readily ignore patents, namely with patents on human genes.⁴¹

One additional study extended this type of analysis beyond the world of biotechnology and found that when the Federal Circuit invalidates a patent, the ruling causes on average, “a 50 percent increase in subsequent citations to the focal patent,” but that the effect is concentrated in fields characterized as technologically complex and having highly fragmented patent ownership.⁴² The authors also observed that the baseline average estimate is twenty-eight percent higher if the patent is invalidated during its first fifteen years of life.⁴³ Interestingly, the authors did not observe an increase in citations upon invalidation of pharmaceutical patents.⁴⁴ Since drug research has benefited from a statutory research exemption that spans almost the entire time frame that the authors investigated,⁴⁵ one possible explanation is that the “openness” created by an invalidity decision does not impact pharmaceutical firms because the research exemption has kept the entire industry relatively open at the exploration and product development phase. The results of such studies must be interpreted carefully, but in connection with the data on drug research spending, these types of findings suggest that we should be skeptical of claims that research exemptions will upset the fundamental economic dynamics of the patent system.

The studies mentioned above have more to do with the broader debate occurring in the social science community over whether patents play a net positive or negative role in promoting research investment and technological innovation across the economy. They also focus almost exclusively on the destructive potential of patents and not on the investments they incentivize. These studies were not designed to measure the potential benefits or detriments of implementing a research exemption in the patent law. Yet they are still relevant. These studies persuasively suggest that the problem the research exemption is intended to address—the use of the patent power to interfere with experimentation

40. *Id.* at 4, 20-22.

41. Bhaven Sampat & Heidi Williams, *How do Patents Affect Follow-on Innovation? Evidence from the Human Genome*, 3-4, 22-24 (Nat’l Bureau of Econ. Research, Working Paper No. 21666, 2014).

42. Alberto Galasso & Mark Schankerman, *Patents and Cumulative Innovation: Causal Evidence from the Courts*, 3-4, 34-35 (Nat’l Bureau of Econ. Research, Working Paper No. 20269, 2014).

43. *Id.* at 21.

44. *Id.* at 3-5, 25-26.

45. The data set includes all decisions involving issues of patent validity from 1982 until December 2008. *Id.* at 10-11. The *Bolar* Amendment was passed in 1984. Pub. L. 98-417.

as opposed to commercial sales—is very real. They also suggest that the use of the patent power to interfere with experimentation causes many researchers to ignore patents, or pursue alternative paths that are not necessarily desirable as a matter of public policy.

The risks associated with not having a research exemption are exacerbated when the underlying research is conducted for the public benefit, an issue often overlooked in analyses concerned only with investment. The studies discussed above might unintentionally suggest that most scientific research ultimately has some sort of commercial intent. In fact, a great deal of scientific research has no commercial motive at all but instead is intended to assess the health and environmental consequences of various products and activities for the benefit of lawmakers. A patent law system without a robust research exemption therefore permits patent holders to limit or distort public knowledge about consumer products. This problem became concrete when Cornell University entomologist, Elson J. Shields, wrote a public letter to the Environmental Protection Agency in 2009, decrying the widespread practice among agricultural technology companies of using patent licensing restrictions to prevent research into the health and environmental consequences of genetically modified seeds and plants.⁴⁶ These types of behavior are contrary to public policy, interfere with the legislative process, and find no sanction in any of the ideas that form the basis of American patent law.

Critique of Existing Proposals

Prominent legal scholars have articulated a variety of specific proposals for codifying a research exemption over the years, though the subject has not received much treatment within the last decade. Some have also proposed addressing access problems in the scientific research community through some other legal mechanism, like creating a patent law equivalent to the “fair use” exception in copyright law, or modifying the Bayh-Dole Act in ways that would give federal funding agencies more discretion to stop the proliferation of patents flowing from publicly-funded research. Each of these proposals offers concrete benefits and would be a significant improvement over existing law. But these proposals also suffer from a variety of pitfalls, pitfalls that have not been explicitly addressed in the literature. These pitfalls suggest that an alternative policy—one that simply extends the broad drug research

46. The Editors, *Do Seed Companies Control GM Crop Research?*, SCIENTIFIC AMERICAN, August 1, 2009.

exemption to all patentable subject matter—may make more sense as a first step towards reform.

Renowned patent scholar Rebecca Eisenberg is widely credited with articulating the first major modern proposal for codifying a research exemption, and her 1989 article has had tremendous scholarly impact.⁴⁷ Eisenberg's somewhat conservative proposal has three major planks: (1) the exemption would reach those who used a patented invention to test the patent's validity and the adequacy of the patent's written description; (2) the exemption would *not* apply to research tools—inventions for which researchers are the primary consumers—unless the use comported with (1); and (3) all other experimental uses would be subject to a liability scheme where the patent holder would be deprived of the right to enjoin or stop the use but would be entitled to recover a reasonable royalty for the use through litigation.⁴⁸ In a related proposal, Janice Mueller argues that research tools do not deserve the carve-out articulated in point (2) but should be subjected to the liability scheme of (3) with one additional caveat: the royalty should expressly include “reach-through” rights in the value of new inventions developed through the experimental use.⁴⁹

The first plank in Eisenberg's proposal is well founded both in law and in public policy. The common law research exemption arguably embraced experimentation for purposes of testing the invention and its disclosure before the Federal Circuit's *Madey* decision, and so this aspect of Eisenberg's proposal simply restores the law to its prior state. And as a matter of public policy, this aspect of Eisenberg's proposal works to ensure that only valid patents are issued and that the public receives an adequate disclosure in exchange for the patent grant, both of which are important core principles in the patent system.

The second and third planks, however, are more troublesome. The proposed carve-out for research tools is based on the unproven premise that allowing researchers to make or use an invention for experimentation, without penalty, would significantly undermine the incentives to develop research tools in the first instance. However, this cannot be true for all types of research tools. While it may be true for those inventions that are easily isolated or produced in a laboratory setting, like a human gene or biological receptor, the premise is not likely true for other tools like a sophisticated microscope.

For the former class of inventions, the studies described above suggest that researchers frequently ignore these patents anyway, and

47. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1074-1078 (1989). At present, Eisenberg's article has received more than 450 citations in the law review literature alone.

48. *Id.* at 1078.

49. See Mueller, *supra* note 29, at 9-10.

there is no evidence that codifying a research exemption would do more than normalize existing practice without modifying, in any tangible sense, the underlying economics. Nor is there any evidence that, to whatever extent such a change in the patent law would diminish the desire among institutions to commoditize research inputs, society would not benefit in the long run from that outcome. Arguably, the federal government could also compensate for any diminished private interest in research tool development (if that outcome is actually observed) by dedicating more public funding to such proposals.

For the latter class of inventions—those that are not readily available in the laboratory—a research exemption would most likely put a limit on the patent holder’s ability to set price.⁵⁰ Essentially, if the patent holder sets the price at a level that exceeds the researcher’s opportunity cost of making the technology in a laboratory setting (or makes licensing negotiations equally onerous), that would likely cause the patent holder to lose most if not all of its market. But this price-ceiling aspect of the research exemption is arguably a beneficial outcome when it comes to research tools, as it ensures that markets for research tools will perform more like traditional commodity markets where the next-best technological alternative restricts the patent holder’s ability to leverage its monopoly position. In this setting, the research exemption would also limit the ability of such inventors to control the direction of research altogether.

The third plank of Eisenberg’s proposal is also problematic because it mandates resort to an expensive mechanism, litigation, in order to compensate for certain activities that Congress arguably never intended to punish when it passed any of the Patent Acts. The risk of promoting costly litigation is aggravated by the fact that Eisenberg’s proposal incorporates so many difficult distinctions between protected and unprotected behavior. For example, even if an alleged infringer contends that it used a patented invention for purposes of testing the invention or ascertaining the adequacy of the patent’s written description, most patent holders might still choose to litigate the question of whether the experimentation was in fact undertaken for that purpose and not for some other unprotected purpose. The same holds true in situations where the patent holder contends that the invention is a research tool, but the alleged infringer disagrees. In a worst case scenario, such a scheme would not protect any activity at all so much as it would force litigation over all types of experimentation, with some researchers obtaining protection only after spending large amounts on

50. Eisenberg acknowledges as much in her discussion of oncomice. Eisenberg, *supra* note 47, at 1085 (“But if researchers were free to make the mice on their own, duPont would be limited to charging no more than the cost to researchers of making the mice in their own laboratories.”).

attorney fees. Even in those cases that clearly fall within a category of unprotected activity, determining a “reasonable royalty” for the use, as Eisenberg admits, is not easy and would require a great deal of input from both scientific and economic experts.⁵¹ Thus, Eisenberg’s proposal does not address, and would likely exacerbate, rising litigation costs that effectively tax public and private sector research. Efforts to protect research activity through similar reforms, such as Maureen O’Rourke’s novel proposal to create a “fair use” doctrine in patent law, suffer from the same fallback, as they force litigation (using multi-factor balancing tests) to obtain protection.⁵²

In many respects, Mueller’s modification of Eisenberg’s proposal only heightens these risks. First, Mueller’s proposal does not simplify the framework in any material sense. Research tools are not carved out as unprotected subject matter, in Mueller’s proposal, but are instead made part of the liability scheme for which injunctive remedies are unavailable. But because the calculation of the “reasonable royalty” for research tools would include reach-through rights, a judge would still have to determine whether or not an invention is in fact a research tool in order to determine whether reach-through rights are available. Setting aside the fact that the question of what constitutes a research tool may be difficult to decide as an evidentiary matter, by incorporating this distinction into the legal framework, both proposals also undermine the research exemption at the point it is needed most. Instead of ensuring that researchers have access to specialized tools that they use on an everyday basis, Eisenberg and Mueller’s liability schemes assist researchers only in instances where they are secondary consumers in large product markets (i.e. if the “research tool” is more like an iPhone than a microscope). Even then, Eisenberg and Mueller’s proposals only limit the availability of equitable remedies.

Mueller’s proposal is even more punitive towards researchers, in some respects, because it codifies and normalizes the controversial licensing practice of awarding the inventors of research tools a remedy that includes reach-through rights, meaning rights in the profit stream from subsequent inventions discovered with the tool. Such rights are often controversial in licensing negotiations and arguably constitute patent misuse in many circumstances. Also, in settings where there are no technological alternatives, such rights exacerbate the patent holder’s ability to control and stifle subsequent research and greatly amplify

51. *Id.* at 1078 (“Determination of reasonable royalties is never an easy task.”). The recent tightening of legal standards for proving damages in patent cases might provide some glimmer of hope in that patent holders would have to weight their ability to meet those standards when determining whether to sue.

52. See Maureen A. O’Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000).

infringement liability for those researchers who try to advance the field despite the patent holder's restrictive practices. In this regard, Mueller's proposal is not a research exemption at all, as it is designed to significantly amplify the litigation costs and liability exposure for those engaged in scientific research.

Another group of proposals centers the analysis on either the nature of the research (whether basic or applied) or the funding source. Thus, Rochelle Dreyfuss has proposed an exemption for the benefit of "basic researchers," a group that could either self-identify by signing a waiver forgoing future patents rights and/or be legally defined as those who work in non-profit or educational institutions.⁵³ Additionally, Arti Rai, in collaboration with Eisenberg, has proposed amending the Bayh-Dole Act to give federal funding agencies greater discretion to determine whether the fruits of publicly-funded research should be patented or dedicated to the public domain.⁵⁴

Each of these proposals offers interesting benefits but could be improved by broadening the scope of the protection. For starters, Dreyfuss acknowledges that, since the legislative reforms surrounding the Bayh-Dole Act in the 1980s, universities and government agencies collaborate extensively with firms in the private sector and also actively patent their discoveries.⁵⁵ She therefore argues that it would be better to have "basic researchers" self-identify as undertaking the research for "noncommercial purposes" rather than provide a legal definition based on institutional affiliation.⁵⁶ In focusing on the researcher's intent, this proposal is consistent with the original motivation for the common law exemption, which was premised on the idea that patent law should not punish those who use or make an invention for certain experimental purposes. And if the self-identifying waivers were stored in a central database available to the public, the system could be administered in a way that reduces gamesmanship.⁵⁷

But more fundamentally, Dreyfuss has not explained why those who undertake basic research for noncommercial purposes are more deserving of protection than those who undertake more applied research, or those who seek to design around an invention with broad commercial appeal in order to create a technological alternative and more

53. Rochelle Cooper Dreyfuss, *Varying the Course in Patenting Genetic Material: A Counter-Proposal to Richard Epstein's Steady Course* 204-08 (NYU Law Sch. Publ. Law Research Paper No. 59), <http://ssrn.com/abstract=394000>.

54. See Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBS. 289, 310-313 (Winter 2003).

55. Dreyfuss, *supra* note 53, at 205.

56. *Id.*

57. Without publicly available waivers, most researchers would forego self-identification until confronted with a dispute, and then use the waivers as an escape from liability. Such a system does not give researchers the incentive to be clear about their intentions up front.

competition in the marketplace. In fact, the patent system should seek to promote and protect these types of activities inasmuch as it also seeks to promote and protect more basic, noncommercial scientific investigation. Just as the arbitrary distinctions between research tools and other inventions do not necessarily make sense in this context, so too do the traditional dichotomies that the academic community has used to analyze scientific institutions—public versus private, basic versus applied, research versus development—fail to provide a solid basis for delimiting the reach of the research exemption.

Rai and Eisenberg's proposal approaches the problem from a somewhat different angle, displaying more attention to the problem of patent thickets or anti-commons behavior in biomedical research. Instead of proposing a research exemption, Rai and Eisenberg seek to limit the proliferation of patent rights in inventions funded with taxpayer dollars. The proposal is premised on the insight that the traditional arguments about patent incentives break down when the taxpayer is footing the bill.⁵⁸ To limit patent proliferation, Rai and Eisenberg propose relaxing the requirements under which a federal funding agency may depart from the presumption of allowing patent rights to flow to the fund recipient and altering the way in which courts exercise judicial review over march-in rights.⁵⁹

This proposal has many benefits and would certainly provide a much needed relaxation in the excessively rigid standards of the Bayh-Dole legislation. But the main drawback to this approach is that, like Dreyfuss's proposal, it is unnecessarily limited in scope and is too incremental. Because it calls into question the patent rights only of inventions flowing from federal funds, it will have the most potential impact in those fields where public research largely drives technological advance but less impact where private research plays a prominent role. In this sense, the proposal also may be overly focused on biomedical innovation without considering alternative technological environments. It also requires faith in the ability of funding agency officials to continually monitor technological developments in a given area and make decisions about the role that patents are playing in either promoting or interfering with scientific progress, questions that may be outside the agency's expertise.

Rai and Eisenberg reject the idea of accomplishing the same ends through a research exemption, largely out of a sense of caution.⁶⁰ They warn that such exemptions involve legal changes that are "difficult to

58. Rai & Eisenberg, *supra* note 54, at 295-300 ("When research is publicly sponsored, however, the argument for strong patent rights loses much of its force.").

59. *Id.* at 310-311.

60. *Id.* at 299.

calibrate” in a setting where “the consequences of overdoing it could be grave.”⁶¹ But they advocate caution based on the importance of private investment to biopharmaceutical firms, even though all drug research currently takes place underneath the umbrella of a broad exemption. A central argument in this paper is that if pharmaceutical research elicits enormous and increasing amounts of private investment with a robust research exemption in place, then there is little reason to advocate caution in extending that protection to other technological fields, most of which are less dependent on patents for spurring innovation.

Conclusion

The House Judiciary Committee report on Section IV of the PCTIA, which attempted to codify a research exemption in the patent law, represents a remarkable departure in thinking about the patent system compared to previous times. Under Kastenmeier’s leadership, the Committee abandoned most of the usual platitudes about “incentives” that characterized then-contemporary debates about the patent system. Instead, the Committee argued that “[i]t is a central tenet of American patent law that there is a right to use scientific information to create new and better inventions in competition with the patented invention.”⁶² The Committee also criticized the Federal Circuit’s interpretation of the experimental use doctrine⁶³ and concluded that in an era of increasing public-private partnerships, “government and university scientists should not be confused about the permissible parameters of their research and experimentation.”⁶⁴ And when it came to discussing the economic justification for codifying an exemption, the Committee argued that without such an exemption, “[u]nnecessary litigation occurs, excessive threats are leveled, transaction costs are raised, . . . experimentation and research are chilled,” and “[m]ore importantly, legitimate scientific activities are driven outside the United States.”⁶⁵

The specific reform the Committee proposed had its own downfalls. The most significant concession was the adoption of the “research tool” carve-out from Eisenberg’s 1989 proposal, which is critiqued above. The Committee’s report also suggested some confusion over the proposed law’s reach, as it indicated that “[b]usiness testing is clearly not an experimental use,” but it did not define “business testing” and so the thrust of this statement is unclear. In the prior paragraph, the report

61. *Id.*

62. H.R. REP. 101-960 at 41 (1990).

63. *Id.* at 42.

64. *Id.* at 43.

65. *Id.* at 43-44.

explicitly indicates that experimentation for purposes of designing around an invention or developing an improvement (both of which are, broadly speaking, business testing) would not constitute infringement. Nevertheless, by its plain language, the proposal was rooted in a desire to create a broad sphere of legally protected activity—not a liability scheme—and the economic arguments levied in favor of such an approach remain as true today as in 1991.

Since Kastenmeier's time in office, social scientists have made significant progress in identifying the industries where patents play a constructive role in generating private investment and in analyzing the potential risks associated with the proliferation of patent rights on research inputs. Most significantly, we now know that in a setting of cumulative innovation, patent holders can and do use the patent power to suppress further research and innovation. We also know that these effects are not generally observed in environments where researchers can freely ignore patents or where a robust research exemption is in place. Survey evidence and some quantitative studies also give meaning to Kastenmeier's warning about unnecessary litigation and escalating transaction costs. This suggests that the legislative remedy should offer a bright-line safe harbor for research activity, one that does not invoke tenuous distinctions that will only produce more litigation. American law in this area is also unnecessarily complex, with three different research exemptions in place, and sovereign immunity for state, but not federal, and public, but not private, researchers. American law is also out of step with international standards, and although many of those standards also suffer under the weight of litigation-inspiring legal distinctions,⁶⁶ they still offer more protection outside of drug research than American law does which invites the relocation of research to offshore locations. All of these factors make the issue of the research exemption ripe for Congressional review.

For these reasons, Congress should debate and consider legislation along the following lines:

SEC. 101. SHORT TITLE.

This title may be cited as the "Robert Kastenmeier Memorial Act".

66. In some European countries, with Belgium being a notable exception, many laws try to distinguish between experimenting "on" as differing from experimenting "with" a patented invention.

SEC. 102. RESEARCH EXEMPTION FROM PATENT INFRINGEMENT.

Section 271 of title 35, United States Code is amended by adding at the end the following:

“(j) It shall not be an act of infringement to make or use a patented invention for research, experimentation, or education. Protected acts of making or using a patented invention include: studying, evaluating, or characterizing such invention or the invention’s written description; improving upon or creating a product outside the scope of the patent covering such invention; testing or evaluating the consequences of such invention or its commercial embodiments for human health or safety or for the environment; demonstrating or manipulating an invention to educate students or researchers; and any act undertaken solely to advance the progress of science or the technological arts. This subsection does not apply to a patented invention to which subsection (e)(1) applies.”

SEC. 103. EFFECTIVE DATE.

(a) IN GENERAL.-Subject to subsection (b), the amendment made by section 102 shall apply only to research or experimentation conducted on or after the date of the enactment of this Act.

(b) APPLICABILITY OF PRIOR SUBSTANTIVE LAW.-The substantive law in effect before the date of the enactment of this Act shall apply to cases arising from research or experimentation conducted before the date of enactment.