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The Political Economy of the Research Exemption in American Patent Law

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Cover Page Footnote

Nicholas Short obtained a juris doctorate degree from Hastings College of the Law and subsequently spent seven years litigating patent and trade secret cases in state and federal court. He is currently a graduate student in the Technology Policy Program at the Massachusetts Institute of Technology. The views expressed in this Article are those of the author and do not necessarily reflect the views of the Massachusetts Institute of Technology, the Program on Emerging Technologies, or the Synthetic Biology Engineering Research Center. The author would like to thank Kenneth Oye, Leonard Miller, Arti Rai, and F.M. Scherer for their helpful criticism and commentary.

The Political Economy of the Research Exemption in American Patent Law

Nicholas Short*

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INTRODUCTION

[A] patent system must be related to the world of commerce rather than to the realm of philosophy.

–Justice Fortas¹

One of the most important questions in patent policy today is whether the acts of making and using a patented invention for research purposes should be exempt from infringement liability. The basic idea, as Justice Fortas hinted in 1966, is to ensure that those who obtain patents can use the monopoly power inherent in the patent grant to capture profits from competing sales and other commercial activity, but not to stifle the research and experimentation that promotes innovation and helps government officials evaluate the health and safety risks associated with new technological developments.

Appropriately, the research exemption (also known as the experimental use doctrine) has been the subject of significant legal scholarship and at least one major congressional inquiry over the

¹ Brenner v. Manson, 383 U.S. 519, 536 (1966).

last thirty years.² Yet much of the legal scholarship has focused on normative questions like whether the law should have an exemption and what form it should take. Less attention has been given to the doctrine's legal and political history, or to the arguments and economic interests of the individuals and institutions that have shaped the law in this area into its current convoluted form.³

The call for such an analysis is amplified by the appearance, over the last decade, of several pivotal studies of the political economy of intellectual property law, emphasizing changes in the law since the 1970s. These studies tend to be "horizontal" in the sense of analyzing large policy regimes and revealing broad themes. The narrowest among them focuses on the entire patent system (Scherer),⁴ while others go even broader to include legal developments in copyright (Landes and Posner)⁵ and finance (Coriat and Weinstein).⁶ Few if any "vertical" studies trace the historical development of a single issue within the patent system to illustrate or challenge arguments about broader themes in the political economy of intellectual property law.

This Article approaches the research exemption, and related legal developments, as a case study in the political economy of patent law. Part I recounts the history of the research exemption, touching briefly on historical origins but emphasizing developments since the 1970s in legislative, executive, and judicial forums. It also examines changes during the same time frame in related

² See Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1065-66 (1989); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1205 (2000). On the congressional inquiry, see *infra* Section I.F.2.

³ For a notable exception, emphasizing the relationship between the common law exemption and biotechnology policy, see Maureen Boyle, *Leaving Room For Research: The Historical Treatment of the Common Law Research Exemption in Congress and the Courts, and Its Relationship to Biotech Law and Policy*, 12 YALE J.L. & TECH. 269 (2009).

⁴ F.M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 7 J. TELECOMM. & HIGH TECH. L. 167 (2009).

⁵ WILLIAM M. LANDES & RICHARD A. POSNER, *THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW* (2004).

⁶ Benjamin Coriat & Olivier Weinstein, *Patent Regimes, Firms and the Commodification of Knowledge*, 10 SOCIO-ECON. REV. 267 (2012).

areas of patent law, like the Bayh-Dole legislation and the attempted repeal of state immunity from patent infringement liability. These legal developments indirectly affected the research exemption, or implicated similar concerns about imbalance in the patent system and the use of patents to tax, control, or inhibit research activity.

Part II analyzes this history to illustrate and expand upon two major themes in the political economy of patent law, namely the surprising persistence of faulty economic ideology in patent policymaking and the institutional bias exhibited by the Court of Appeals for the Federal Circuit in shaping modern patent law. One major conclusion is that together these forces have created an excessively complex and ill-designed policy environment that is placing a significant strain on the national research system, a strain that executive agencies and the courts have tried to alleviate through ad hoc agreements and modifications of other patent doctrines, like the doctrine of subject matter eligibility.

I. THE POLITICAL HISTORY OF THE RESEARCH EXEMPTION

The research exemption has a long and colorful history in American law. Legendary Supreme Court Justice Joseph Story first articulated the idea in a case from 1813.⁷ But since the middle of the 1970s, the idea of protecting future research and development from patent infringement liability has endured increasing criticism and attack in both judicial and legislative forums. In 1985, an administrative law court interpreted the Patent Act in a way that rendered obsolete a specific research exemption codified in a separate statutory scheme, the Plant Variety Protection Act.⁸ In 1990, Congress rejected an attempt to clarify and codify Story's common law doctrine and, at the same time, passed a bill to eliminate the immunity from patent infringement that states and their universities historically enjoyed.⁹ And in 2002, the Court of Appeals for the Federal Circuit narrowed Story's common law doctrine so significantly that

⁷ See *infra* text accompanying notes 12–17.

⁸ See *infra* text accompanying note 78.

⁹ See *infra* Section I.F.

it no longer has much impact.¹⁰ One notable exception runs contrary to this trend: in 1984, Congress created a robust research exemption for patents on pharmaceuticals that require regulatory approval, and the Supreme Court has thus far remained stalwart in protecting that statutory exemption from judicial attempts to narrow it.¹¹ Overall, these developments have created a complex and convoluted system when it comes to protecting research and development from patent infringement liability, a convoluted framework that is proof of political forces at work.

A. The Research Exemption is Born: Whittemore v. Cutter and Sawin v. Guild (1813)

A research exemption has existed in American common law since at least 1813 when Justice Story decided *Whittemore v. Cutter*. In this patent infringement case, the trial judge instructed the jury that “the making of a machine fit for use, and with a design to use it for profit” violated the Patent Act of 1800.¹² The defendant (oddly) objected to this instruction on grounds that making a patented machine can never be infringement, whether made with a design to use it for profit or not.¹³ On the defendant’s motion for a new trial, Justice Story (who was riding circuit in Massachusetts) denied that objection.¹⁴ In doing so, he noted that the instruction was favorable to the defendant, and that the trial judge had appropriately concluded “that it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects.”¹⁵

Justice Story also suggested that the exemption flowed from the definition of the statutory acts constituting infringement, and not from any perceived lack of harm to the patent holder. The defendant had also argued that the making of a machine alone, without use of the machine for profit, cannot be an act of patent infringe-

¹⁰ See *infra* text accompanying notes 146–53.

¹¹ See *infra* Section I.D.

¹² *Whittemore v. Cutter*, 29 Fed. Cas. 1120, 1121 (C.C.D. Mass. 1813).

¹³ *Id.*

¹⁴ *Id.*; see also Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC’Y 617, 619 (1985).

¹⁵ *Whittemore*, 29 Fed. Cas. at 1121.

ment since the patent holder suffers no damages from the act of making the machine.¹⁶ Justice Story denied that objection on grounds that every act of infringement is actionable, even if only for nominal damages.¹⁷ Thus, the exemption's legal basis primarily lies in the contention that research and experimentation are not actionable instances of "making" or "using" an invention, regardless of whether those acts technically cause any harm or not. In recent years, the analysis has focused more heavily on the intent prong of Story's framework or on the patent holder's expectation (i.e., harm), but this early emphasis on categories of protected *conduct* arguably remains the most appropriate and useful way for thinking about the research exemption.

Later that same year, *Sawin v. Guild* presented the question of whether a sheriff can seize and sell a patented machine to satisfy a judgment against the owner.¹⁸ The owner of the patented machine, John Sawin, sued the sheriff, John Guild, alleging that the sale of the patented machine was an act of infringement.¹⁹ The court entered a nonsuit in favor of the sheriff on grounds that such a sale does not constitute an act of infringement within the meaning of the patent laws.²⁰ Justice Story, who also decided *Sawin*, noted that the plain language of the Patent Act must be interpreted in a "reasonable fashion" so as not "to introduce public mischiefs," and that the expansive definition of an infringing "sale" must yield to the broader public policy favoring orderly execution of judgments.²¹ Justice Story emphasized that this limitation on the definition of infringing sales flowed naturally from the same concerns that motivated limitations on the definition of the infringing acts of making and using a patented invention articulated in *Whittemore*.²²

In the 169 years after *Whittemore* and *Sawin*, and before the Federal Circuit entered the scene, the federal courts attempted to further refine the scope of the common law exemption, and gener-

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Sawin v. Guild*, 21 Fed. Cas. 554, 554 (C.C.D. Mass. 1813).

¹⁹ *Id.*

²⁰ *Id.* at 555.

²¹ *Id.* at 554.

²² *Id.* at 555.

ally invoked the exemption to protect those who wished to adapt an invention to their own business purpose (i.e., to determine whether or not to purchase or negotiate a license to a patented invention), so long as they did not profit from the experimentation or adaptation itself.²³ While seldom invoked or litigated, the exemption provided a well-known safe harbor for “philosophical experiment” as well as for testing a patented invention, but fell short of protecting experimentation for the purpose of improving or designing around an invention with the intent to profit from that research in the future.

B. The Plant Variety Protection Act: A Special Statutory Exemption for Plants that Reproduce Sexually (1970)

In 1970, Congress considered whether it should expand the boundaries of patent eligible subject matter to include plants that reproduce sexually.²⁴ The prior Congress had investigated whether the “plant section” of the Patent Act,²⁵ which allowed patents for plants that reproduce asexually, should simply be amended to also allow patents on plants that reproduce sexually, but that approach raised “[a] number of objections.”²⁶ The 91st Congress therefore considered and ultimately passed the Plant Variety Protection Act of 1970 (“PVPA”), which allowed the Department of Agriculture to issue “certificates” (similar to patents) for novel varieties of sexually reproduced plants.²⁷

The purported purpose of the PVPA was “to encourage the development of novel varieties of sexually reproduced plants and to make them available to the public . . . thereby promoting progress in agriculture in the public interest.”²⁸ The Department of Agriculture and incumbent seed breeders aligned unanimously in favor of

²³ Hantman, *supra* note 14, at 638–39.

²⁴ *Plant Variety Protection Act: Hearing on S. 3070 Before Subcomm. on Agric. Research and Gen. Legis. of S. Comm. on Agric. and Forestry*, 91st Cong. (1970) [hereinafter *1970 Plant Variety Protection Act Hearing*].

²⁵ 35 U.S.C. § 161 (2012).

²⁶ S. REP. NO. 91-1246, at 3 (1970).

²⁷ Plant Variety Protection Act, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified as amended in scattered sections of 7 and 28 U.S.C.); S. REP. NO. 91-1138, at 1 (1970).

²⁸ S. REP. NO. 91-1138, at 1.

the bill, arguing that legislation “is needed to provide incentive to plant breeders to develop new and improved varieties.”²⁹

This idea—that patents encourage or incentivize innovation—is what we might call the “central dogma” of patent law, for it is the standard refrain of those seeking to expand patent rights to encompass formerly un-patentable subject matter, or eliminate doctrines like the research exemption that narrow the reach of the patent grant. The merits of this hypothesis (and it is only a hypothesis) are discussed in Part II. Here, it is important simply to acknowledge that, despite the incredible frequency with which this hypothesis is repeated in judicial and legislative settings, it is not necessarily true for the patent system as a whole, nor is it a useful way for comparing alternative policies and determining which is optimal.

Importantly, the PVPA included a statutory research exemption, most likely because Congress wanted to ensure that American farmers and seed companies could compete with agribusiness in England and the nations of Western Europe, most of whom had joined an organization—the International Union for the Protection of Plant Varieties (“UPOV”)—that promulgated a series of legal standards which included a research exemption.³⁰ In essence, Con-

²⁹ 1970 *Plant Variety Protection Act Hearing*, *supra* note 24, at 1 (statement of Sen. Jordan of N.C.); *see also* S. REP. NO. 91-1138, at 14 (1970) (stating that the Department of Agriculture supports the bill and “believe[s] that it is desirable to provide incentive for private enterprise to undertake the research and development required to produce novel varieties of sexually produced plants”).

³⁰ *See, e.g.*, H.R. REP. NO. 91-1605, at 1-2 (1970) (describing England’s and Western Europe’s progress); *Plant Variety Protection Act Amendments of 1993: Hearing on S. 1406 Before the Subcomm. on Agric. Res., Conservation, Forestry, and Gen. Legis. of the S. Comm. on Agric. Nutrition and Forestry*, 103d Cong. 2 (1993) (arguing that the PVPA was enacted in part “to alleviate the competitive disadvantage that American agriculture and breeders face because European countries offered protection under UPOV”). For the text of the exemption in the PVPA, see *Plant Variety Protection Act* § 114, Pub. L. No. 91-577, 84 Stat. 1542 (1970) (codified at 7 U.S.C. § 2544) (“The use and reproduction of a protected variety for plant breeding or other bona fide research shall not constitute an infringement of the protection provided under this [Act].”). The Act of 1961 of the International Convention for the Protection of New Varieties of Plants contained a form of research exemption in Article 5(3), which permitted use of a protected variety without the breeder’s permission “either for the utilization of the new variety as an initial source of variation for the purpose of creating other new varieties or for the marketing of such

gress may have simply “borrowed” the research exemption for sexually reproduced plants from the UPOV legal regime, without too much inquiry into its merits, so that American businesses could compete on equal footing with foreign firms. Another possibility is that the United States wished to one day join the UPOV, which it ultimately did in 1981, and needed a research exemption to do so.³¹

During a Senate subcommittee hearing on the bill, one witness noted the connection between the research exemption and the bill’s purported purpose, in a way that anticipated the Bayh-Dole Act a decade later.³² George Babcock, a manager from the Grower Seed Association in Lubbock, Texas, argued that the research exemption would allow public research agencies—whom many cooperatives and small seed companies relied on—to continue their research agenda without the prospect of infringement liability *and*, importantly, the potential revenue generated from intellectual property protection would allow public agencies to invest more money in research and development.³³ Babcock therefore suggested that a broad safe harbor for research combined with stronger patent rights for private firms and public agencies alike might create an optimal balance in the law.³⁴

Congress amended the PVPA in 1980 to eliminate an exclusion that major soup companies had obtained for certain vegetables, and to extend the term of protection by one year; but the debate over the bill quickly went beyond these narrow proposals and into a deeper assessment of the PVPA as a whole.³⁵ Opponents of the PVPA argued that it was eliminating genetic plant diversity and encouraging the formation of monopolistic seed companies that were driving up seed prices.³⁶ Some advocates, including Representatives Tom Daschle and Tom Harkin, argued that while the narrow amendments in the bill should become law, Congress would

varieties.” International Convention for the Protection of New Varieties of Plants, art. 5(3), Dec. 2, 1961, 33 U.S.T. 2703, 815 U.N.T.S. 89.

³¹ Boyle, *supra* note 3, at 286–87.

³² *1970 Plant Variety Protection Act Hearing*, *supra* note 24, at 71–73 (statement of George B. Babcock, Manager, Grower Seed Association).

³³ *Id.* at 72.

³⁴ *Id.*

³⁵ Pub. L. No. 96-574, 94 Stat. 3350 (1980).

³⁶ H.R. REP. NO. 96-1115, at 10 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6954, 6959.

need to return to these broader issues at a later time.³⁷ In contrast, the American Patent Law Association argued in favor of the PVPA because the United States was lagging behind other nations when it comes to innovation in plant breeding, and that the patent laws “provide strong incentives for industry to invest in research and development.”³⁸

The congressional hearings and reports on the 1980 amendments show that Congress believed the PVPA was a success.³⁹ The House subcommittee that reported favorably on the bill argued that the PVPA had dramatically increased both private expenditures in research and the number of new plant varieties available to farmers in the marketplace, citing the sugar snap pea as an exemplary by-product of the Act.⁴⁰ Importantly, if one adopts that evidence as proof of a beneficial causal effect (which is highly suspect), then the PVPA is also evidence that a broad research exemption does not significantly undermine the basic incentives provided in the statutory scheme.

Just as with the original legislation, the debate over the PVPA amendments also elicited insightful testimony from those who opposed the law. Cary Fowler, of the National Sharecropper’s Fund, argued that the evidence relating increased research expenditures and varieties to the PVPA was shaky at best, since research expenditures were on the rise long before the PVPA became law, and the evidence on increased varieties was inappropriately counting varieties developed before the PVPA was enacted as evidence of post-PVPA inventions.⁴¹ Fowler also invoked a study by the National Academy of Sciences which described the purported successes relied on by the Carter administration as “fine-tuned adjustments” to existing varieties and not “major breakthrough[s].”⁴²

³⁷ *Id.* at 40.

³⁸ *Plant Variety Protection Act: Hearing on S. 23, S. 1580, and S. 2820 Before the Subcomm. on Agric. Res. and Gen. Legis. of the S. Comm on Agric., Nutrition, and Forestry, 96th Cong. 143 (1980) [hereinafter 1980 Plant Variety Protection Act Hearing]* (statement of Donald Dunner, President, American Patent Law Association).

³⁹ *See generally id.*; H.R. REP. NO. 96-1115 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6954.

⁴⁰ H.R. REP. NO. 96-1115, at 5, *reprinted in* 1980 U.S.C.C.A.N. 6954, 6957.

⁴¹ *1980 Plant Variety Protection Act Hearing, supra* note 38, at 117 (statement of Cary Fowler, National Sharecroppers Fund).

⁴² *Id.*

Fowler was also concerned about the PVPA's impact on competition and research, and raised early warnings about the United States' interest in joining the UPOV. Specifically, Fowler noted that domestic and international plant breeding organizations were finding that patent rights over plants were restricting "the exchange of scientific information and breeding materials" and creating monopolistic markets that stifled innovation, despite existing research exemptions.⁴³ And, according to Fowler, the Carter administration had not explained why the United States should join the UPOV in the first place, since "[t]here are strong suspicions that the benefits to be derived [from joining] will flow to a handful of multinational corporations who are attempting to gain entry into foreign markets."⁴⁴

C. Bayh-Dole and the Reform of Rights in Publicly Funded Research (1980)

In the same year that it debated amendments to the PVPA, Congress also passed two laws that fundamentally altered the relationship between federal agencies (including federal laboratories), universities, and private industry. In 1980, the Bayh-Dole Act created a presumption that universities or small businesses that receive federal funding for research and development would retain title to any patents stemming from that research.⁴⁵ And the Stevenson-Wydler Act "required the principal government agencies conducting [research] in-house to set up Research and Technology Applications offices" in order to "to negotiate exclusive patent licenses with industry for inventions resulting from agency research."⁴⁶ Later, in 1986, the Federal Technology Transfer Act ("FTTA") empowered government laboratories to enter into cooperative research arrangements with private industry, "with the

⁴³ *Id.* at 119.

⁴⁴ *Id.* at 122.

⁴⁵ Scherer, *supra* note 4, at 183; *see also* Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-211 (2012)).

⁴⁶ Scherer, *supra* note 4, at 183; *see also* Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 (codified as amended at 15 U.S.C. §§ 3701-3714).

industrial partners retaining principal patent rights but paying royalties to cooperating agencies and their inventor employees.”⁴⁷

The political debates surrounding these controversial pieces of legislation are described in detail in the law review literature, but a few specific points about the Bayh-Dole Act deserve further discussion here.⁴⁸ First, the Act’s proponents seem to have anticipated that the proliferation of patent rights flowing from publicly funded research might lead to certain kinds of abusive behavior, like refusing to commercialize an invention or asserting patent rights in a manner that would harm public health or safety.⁴⁹ At the same time, the safeguards enacted to protect against those potential abuses are extremely cumbersome, which suggests that those who supported the Act perceived the risk of abuse to be extremely low. These safeguards have since come under significant scrutiny.⁵⁰

Second, the Act’s adherents failed to anticipate the possibility that the proliferation of patent rights in inventions developed with federal money might be used to stifle or tax research and innovation.⁵¹ Perhaps as a result, there is no mention of the research exemption in either the House or the Senate reports, or in the transcript of the Senate hearing, on the bills that became the Bayh-Dole Act.⁵² The prospect of an institution using patents to suppress or attach onerous conditions to further experimentation simply was not considered.

Finally, the Bayh-Dole Act and the related legislative reforms of the 1980s significantly influenced the political dynamics in de-

⁴⁷ Scherer, *supra* note 4, at 183; *see also* Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, 100 Stat. 1785 (codified at 15 U.S.C. § 3710).

⁴⁸ *See* Scherer, *supra* note 4, at 180–86; *see also* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663–95 (1996).

⁴⁹ *See* Scherer, *supra* note 4, at 212.

⁵⁰ Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 293–95 (2003).

⁵¹ *Id.* at 302 (describing an example of this outcome with work on the NF-kB pathway).

⁵² *See generally* *The University and Small Business Patent Procedures Act: Hearing on S. 414 Before the Comm. on the Judiciary*, 96th Cong. (1979); H.R. REP. NO. 96-1307(II) (1980), *reprinted in* 1980 U.S.C.C.A.N. 6492; H.R. REP. NO. 96-1307(I) (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460; S. REP. NO. 96-480 (1979).

bates over the research exemption by creating a new political interest group: that of the professionals working in university technology transfer offices, individuals who do not necessarily have the same values or interests as academic scientists and whose responsibility is not to promote the public interest, but to generate revenue for their employer.⁵³ Some legal scholars have since argued that university technology transfer officials—organized under the auspices of the Association of University Technology Managers (“AUTM”)—now pose the most serious obstacle to patent reform in the United States,⁵⁴ even though there is limited evidence that, as a whole, universities do more than break even under the Bayh-Dole regime.⁵⁵ This contention appears to have some support when it comes to the research exemption. In 2004, when the National Research Council and a prominent organization of intellectual property lawyers announced their support for codification of a research exemption, the AUTM opposed that proposal.⁵⁶ And in 2010, when an advisory group to the Department of Health and Human Services recommended codification of a research exemp-

⁵³ Rai & Eisenberg, *supra* note 50, at 303, 305–06 (noting that universities have delegated their responsibilities under Bayh-Dole to technology transfer professionals “who are not themselves academics” and “who see their primary job as bringing licensing revenue into the university”).

⁵⁴ See, e.g., Elizabeth Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006). Rowe’s argument against the exemption is premised on the assumption that it would only apply to universities, which is not necessarily true, but her examination of university interests in current debates over the exemption is insightful nevertheless.

⁵⁵ Eisenberg, *supra* note 48, at 1712 n.192.

⁵⁶ See *AIPLA Response to National Academies Report Entitled “A Patent System for the 21st Century,”* AM. INTELL. PROP. L. ASS’N 2, <http://www.aipla.org/advocacy/executive/Documents/NAS092304.pdf> [<https://perma.cc/7TZ5-6TYB>] (last visited Mar. 13, 2016) (“Codifying such an exemption as recommended by the NAS Report, would remove the uncertainty that now exists over the manner in which a patented invention can be used to better understand and/or extend what is patented.”). I have been unable to obtain a formal position on this issue from the AUTM. A copy of a webpage from autm.net, cached by Google on July 12, 2015, says “AUTM Formal Positions—published: 03/19/2014 . . . Patent Law Research Exemption AUTM opposes a recommendation by the American Intellectual Property Law Association to codify a research and experimentation exception in the patent laws.” See *Cached Search Results of AUTM Website* (on file with author).

tion for certain kinds of genetic research, the AUTM opposed that proposal as well.⁵⁷

D. The Federal Circuit's First Assault on the Research Exemption: The Bolar Decision and the Hatch-Waxman Act (1984)

In 1982, Congress created the Court of Appeals for the Federal Circuit as a specialized court to hear all appeals from patent cases in the federal district courts (as well as some other cases involving the federal government).⁵⁸ In doing so, Congress discounted various warnings that a specialized appellate court, with the unique ability to create national precedent on patent law issues, would suffer from “tunnel vision” and be susceptible to being captured by special interests.⁵⁹

Within the first two years of its existence, the Federal Circuit tried to limit the common law research exemption. In *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, the court decided that “the limited use of a patented drug for testing and investigation strictly related to [Food and Drug Administration] drug approval requirements” was an infringing use under the Patent Act and was not protected by the research exemption.⁶⁰ The court ultimately held that the research exemption was “truly narrow” and that it would “not expand it under the present circumstances.”⁶¹

In reaching this conclusion, the Federal Circuit ignored cases interpreting the research exemption that arose from the federal district and appellate courts, and chose to only consider precedent from its predecessor court, the Court of Claims.⁶² The Federal Circuit then disregarded three such cases where the Court of Claims acknowledged the exemption, finding the statements in those cases to be dicta or lacking precedential value, and relied on the one case where the Court of Claims chose not to apply the ex-

⁵⁷ Katherine L. Record, *University Opposition to Unfettered Research: A New Bedfellow for Biotech?*, 22 HEALTH MATRIX 139 (2012).

⁵⁸ See Scherer, *supra* note 4, at 191.

⁵⁹ *Id.* at 187–88 (quoting *Commission on Revision of the Federal Court Appellate System Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195, 236 (1975)).

⁶⁰ *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 861 (Fed. Cir. 1984).

⁶¹ *Id.* at 863.

⁶² *Id.* at 862–63.

emption.⁶³ The legal basis for taking such a narrow view of the relevant precedent is somewhat suspect, and reflects a certain degree of reverse engineering in support of a pre-determined outcome.

Ironically, by the time the Federal Circuit decided the case, Roche's patent had expired, and because the sole remedy Roche had requested was an injunction, the basic issue in the case was moot.⁶⁴ In other words, the Federal Circuit no longer had the power to enjoin Bolar from testing the patented drug for purposes of obtaining regulatory approval because the patent had expired, and so the only remedy left available to Roche was for monetary damages in the district court, damages which were "nominal" according to Roche's own counsel.⁶⁵ The Federal Circuit rendered a decision anyway, even though its decision threatened to upset negotiations over an expansive overhaul of drug regulation and patenting that was before Congress at the time: the Hatch-Waxman Act.

Congress quickly amended the Hatch-Waxman Act to repeal the *Bolar* decision.⁶⁶ Overall, the Hatch-Waxman Act reflects a bargain between generic and non-generic pharmaceutical manufacturers, where the former obtained the right to seek approval from the Food and Drug Administration ("FDA") based on a simple showing that the generic product was "bioequivalent" to a patented drug (thus avoiding the expense of clinical trials), and the latter obtained longer patent terms to account for regulatory delays at the FDA.⁶⁷ After the Federal Circuit decided *Bolar*, Congress amended the bill to allow drug manufacturers to infringe pharmaceutical patents "solely for uses reasonably related to the development and submission of information under a Federal law."⁶⁸

⁶³ *Id.* at 863.

⁶⁴ *Id.* at 865-67.

⁶⁵ *Id.* at 866.

⁶⁶ See Scherer, *supra* note 4, at 197 (noting that section 202 was dubbed the "*Bolar* amendment").

⁶⁷ For a more thorough description of the bill's history, see Scherer, *supra* note 4, at 195-99.

⁶⁸ H.R. REP. NO. 98-857(II), at 26 (1984), reprinted in 1984 U.S.C.C.A.N. 2686, 2710 ("Proposed subsection (e)(1) provides that it shall not be an act of infringement to make, use, or sell a patented invention solely for uses reasonably related to the development and submission of information under a federal law which regulates the approval of drugs.").

Some of the issues specific to the Hatch-Waxman Act—especially the bill’s focus on the length of patent terms for pharmaceutical companies—influenced the legislative debate over the research exemption in this context. For instance, opponents to the exemption for the first time characterized the policy as a shortening of the pharmaceutical industry’s patent terms and a taking of its property. The Assistant Secretary and Commissioner of Patents and Trademarks argued that the exemption “would serve as an unfortunate precedent curtailing the exclusionary rights accorded a patentee during the patent term.”⁶⁹ A member of the Board of Directors of Johnson & Johnson made the same argument, as did the President and CEO of Hoffman-La Roche, adding that the exemption would also be an unconstitutional taking of property.⁷⁰

The pharmaceutical industry’s emphasis on takings apparently influenced the congressional analysis of the *Bolar* amendment, as the House Committee on the Judiciary dedicated a significant portion of its report to rebutting the takings argument (persuasively) under then-existing law.⁷¹ Subsequent legal developments have proved this analysis sound.⁷² But even though the Committee reported favorably on the bill (including the *Bolar* provision), it also speculated that “there would be no need” to create a similar exemption to allow, for example, engineers in the automobile industry to test a patented engine, because no regulatory regime blocked car manufacturers from competing as soon as the patent expired.⁷³ The report also contains no mention of *Whittemore*, *Sawin*, or any other federal cases articulating the common law research exemption, suggesting that the House Judiciary Committee may not have

⁶⁹ *Drug Price Competition and Patent Term Restoration Act of 1984: Hearing on S. 2748 Before S. Comm. on Labor and Human Res.*, 98th Cong. 164 (1984) (statement of Gerald J. Mossinghoff, Assistant Secretary of Commerce and Comm’r of Patents and Trademarks).

⁷⁰ *Id.* at 129, 132 (statement of Verne Willaman, a member of the Board of Directors of Johnson & Johnson) (claiming that the provision would “shrink existing patent protection” and is “clearly inequitable”).

⁷¹ See H.R. REP. NO. 98-857(II), at 61 n.18, *reprinted* in 1984 U.S.C.C.A.N. 2686, 2721.

⁷² See, e.g., *Zoltek Corp. v. United States*, 442 F.3d 1345, 1352 (Fed. Cir. 2006) (*per curiam*) (holding that patents do not constitute property under the Takings Clause), *vacated in part on other grounds*, 672 F.3d 1309 (Fed. Cir. 2012); see also *id.* at 1370 (Dyk, C.J., concurring).

⁷³ H.R. REP. NO. 98-857(II), at 27, *reprinted* in 1984 U.S.C.C.A.N. 2686, 2714.

even been aware of the doctrine's legal origins. Similarly, the House Committee on Energy and Commerce argued in favor of the provision because "experimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent."⁷⁴ These arguments do not accurately capture the basic legal principles supporting the research exemption in a broader form, a form not limited to testing of pharmaceuticals for FDA approval. The basic principle is that making and using a patented drug for experimentation is arguably a type of activity that the patent laws should promote rather than punish, irrespective of any alleged impact on a patent's term or the need to pass regulatory hurdles in order to enter the market once a patent expires.

E. The Death of the PVPA and its Special Research Exemption: Ex parte Hibberd (1985)

In 1980, in the historic case of *Diamond v. Chakrabarty*, the Supreme Court determined that a genetically modified bacterium was patentable (i.e., was eligible subject matter).⁷⁵ The result is consistent with the general trend, in this period, toward expanding patentability, and this case is often credited, perhaps falsely, with ensuring that the patent system would accommodate the coming explosion in biotechnology research.⁷⁶

But the decision also had one important unintended consequence. By proclaiming that a bacterium—a "living thing"—was patentable under the Patent Act, the Supreme Court challenged the basic assumption that had motivated Congress to pass the Plant Patent Act ("PPA") of 1930 and the PVPA of 1970. In other words, when Congress passed the PVPA, it had done so on the

⁷⁴ H.R. REP. NO. 98-857(I), at 46 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2679.

⁷⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

⁷⁶ See H.R. REP. NO. 100-888, at 38, 69 (1988). The House Committee on the Judiciary inferred a causal relationship between the *Chakrabarty* decision and the four billion dollar domestic biotechnology industry, and argued without evidence that "[t]he availability of patent protection for biologically derived inventions has been the catalyst for the current biotechnology industry." *Id.* at 69. This argument (and others like it) relies on the observation of concurrent increases in biotech investment and/or biotech patenting after *Chakrabarty*, trends that are difficult to interpret given the many changes occurring in patent law at this time (including the Bayh-Dole reforms), and which do not prove a causal impact in any event. See *id.* at 39.

premise that sexually reproduced plants could not be patented under the Patent Act.⁷⁷ Ten years later, in *Chakrabarty*, the Supreme Court suggested that this assumption was false.

Subsequently, an administrative law court housed in the Department of Commerce, known then as the Board of Patent Appeals and Interferences (“BPAI”), used the *Chakrabarty* decision to effectively repeal the PVPA. In *Ex parte Hibberd*, the BPAI held that sexually reproduced plants can be patented under the Patent Act, and so there were, in effect, two separate statutory regimes for obtaining exclusive rights in plants that reproduce sexually.⁷⁸ As a practical matter, the ruling meant that patent applicants would always choose the Patent Act over the PVPA because the Patent Act did not include statutory limitations on the patent holder’s rights, like the farmer’s saved seed exemption or a statutory research exemption.

The BPAI’s reasoning has several flaws, but the most perplexing among them is the conclusion the BPAI reached regarding Congress’ burden at the time it passed the PVPA. The BPAI approached the issue through the analytical framework of “implicit repeals,” based on the fact that Congress did not, in the PVPA, explicitly repeal section 101 of the Patent Act to the extent that section allowed for patents on plants that reproduce sexually.⁷⁹ Yet Congress did not explicitly repeal *any* part of the Patent Act because it did not believe it had to, as the legislative history makes clear.⁸⁰ Congress believed that the Patent Act did *not* allow patents on plants that reproduce sexually, so it had no motivation for indi-

⁷⁷ S. REP. NO. 91-1138, at 3 (1970); see also H.R. REP. NO. 91-1605 (1970), reprinted in 1970 U.S.C.C.A.N. 5082, 5083 (“No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds.”); S. REP. NO. 91-1246, at 3 (1970).

⁷⁸ *Ex parte Hibberd*, 1985 WL 71986, at *2-3 (B.P.A.I. Sept. 24, 1985). In 1999, when the United States acceded to the 1991 Act of the International Convention for the Protection of New Plant Varieties, it did so pursuant to a reservation in Article 35(2) that it can continue to provide protection for novel varieties of sexually reproduced plants “by an industrial property title other than a breeder’s right [(i.e., under the Patent Act)] . . . without applying this Convention to those varieties.” International Convention for the Protection of New Varieties of Plants, art. 35(2), Mar. 19, 1991. As a result, the United States’ participation in the Convention is now essentially pro forma.

⁷⁹ *Ex parte Hibberd*, 1985 WL 71986, at *4-5.

⁸⁰ See *supra* note 77 and accompanying text.

cating otherwise.⁸¹ Because of the BPAI's view of the law regarding "implicit repeals," Congress must explicitly repeal hypothetical changes in the judicial interpretation of a statute that may or may not come to pass in the coming decades. Curiously, the Supreme Court sanctioned this view sixteen years later.⁸² In the majority opinion of *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, the Court effectively ruled that in deciding what Congress intended to do when it passed the PVPA, it is important to ignore the factual predicates and assumptions that motivated congressional action if the Supreme Court presently disagrees with them.⁸³

The *J.E.M.* dissent, authored by Justice Breyer, analyzed the legislative history and concluded that "Congress intended the two more specific statutes," namely the PPA and the PVPA, "to exclude patent protection under" section 101 of the Patent Act "for the plants to which the more specific Acts directly refer."⁸⁴ Justice Breyer also acknowledged that the majority's forced reading of the statutory history effectively eliminated the PVPA's statutory exemptions, including the research exemption.⁸⁵

F. Congress Tackles the Research Exemption: The Patent Competitiveness and Technological Innovation Act of 1990

By the late 1980s, a host of patent reform measures were under congressional consideration. The 101st Congress considered five separate patent reform measures that had been raised in previous

⁸¹ See *supra* note 77 and accompanying text.

⁸² *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 134 (2001).

⁸³ *Id.* ("This does not mean, however, that prior to 1930 plants could not have fallen within the subject matter of § 101. Rather, it illustrates only that in 1930 Congress *believed* that plants were not patentable under § 101..."); see also *id.* at 135 ("Whatever Congress may have believed about the state of patent law and the science of plant breeding in 1930, plants have always had the *potential* to fall within the general subject matter of § 101..."); see also *id.* at 141 ("The relevant statements in the legislative history reveal nothing more than the limited view of plant breeding taken by some Members of Congress who believed that patent protection was unavailable for sexually reproduced plants. This view stems from a lack of awareness concerning scientific possibilities.").

⁸⁴ *Id.* at 147 (Breyer, J., dissenting).

⁸⁵ *Id.* at 155 ("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.").

legislative sessions, with all five of the measures bundled together as different titles in the same bill, the Patent Competitiveness and Technological Innovation Act of 1990 (“PCTIA”).⁸⁶

Two of the measures in the PCTIA implicated the research exemption. The first proposed to repeal the immunity from infringement liability that the states—and their universities—enjoyed under the doctrine of sovereign immunity.⁸⁷ The second proposed to codify, once and for all, a broad research exemption with a carve out only for “research tools.”⁸⁸ The repeal of state sovereign immunity passed the House and the Senate and became law, while the codification of the research exemption did not.

1. Repeal of State Sovereign Immunity Passes

In 1985, the Supreme Court decided a sovereign immunity case in which it emphasized its prior holding that, absent a waiver of immunity by a state, a lawsuit against a state (or its agencies) may proceed only if Congress has the Constitutional authority to abrogate sovereign immunity and does so “by making its intention unmistakably clear in the language of the statute.”⁸⁹ Following this command, the Federal Circuit noted, in a separate case, that Congress had not stated its intent to repeal state sovereign immunity for patent infringement under the Patent Act.⁹⁰ Because of these rulings, Congress entertained proposals to explicitly repeal state immunity from patent infringement, and one of those proposals was ultimately incorporated into the PCTIA. In this specific setting—where the Federal Circuit had indicated that it viewed that common law research exemption as “truly narrow,” the *Bolar* exemption provided protection only for drug and medical device re-

⁸⁶ H.R. 5598, 101st Cong. (1990).

⁸⁷ *Id.* §§ 301–303. Though sovereign immunity is a separate and distinct doctrine, of constitutional and not common law origin, it accomplishes a similar purpose in the patent context since the doctrine immunizes state agencies and universities (where much experimentation takes place) from the risk of infringement liability.

⁸⁸ *Id.* at §§ 401–403; H.R. REP. NO. 101-960(I), at 32 (1990).

⁸⁹ *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985).

⁹⁰ *Chew v. California*, 893 F.2d 331, 334 (Fed. Cir. 1990) (“Assuming the Congress has the power to subject the states to patent infringement suits, a complex question we do not resolve herein, we conclude, as a matter of statutory interpretation, that Congress has evidenced no intent to exercise such power in the patent statute.”).

search, and the BPAI had effectively eliminated the statutory research exemption under the PVPA—sovereign immunity provided a significant liability shield, allowing scientists at public universities to ignore non-pharmaceutical patents in the course of their research. The proposal to repeal state sovereign immunity was intended to remove that shield.

Importantly, developments in international trade negotiations influenced the debate over the repeal of state sovereign immunity. At the time that Congress was considering the PCTIA, American industry was in the midst of its efforts to extend U.S. patent standards to the rest of the world through the Uruguay Round of trade negotiations, negotiations that resulted in the Trade-Related Aspects of Intellectual Property (“TRIPS”) agreement.⁹¹ A group composed of the chief executives of thirteen major companies worked with U.S. trade negotiators and representatives of the U.S. Patent and Trademark Office (“PTO”) to implement a strategy of “linkage,” whereby the United States consistently refused to ratify any treaty unless it included provisions bringing all member nations’ intellectual property laws up to U.S. standards.⁹² An important negotiating point was whether less developed countries would retain compulsory licensing rights, giving those governments the power to infringe a patent in certain circumstances, such as if the nation wanted to manufacture or import a drug that had critical health consequences for its people but could not reach an agreement over licensing terms with the patent holder.⁹³ For the proponents of TRIPS, these compulsory licensing rights were a form of governmental or sovereign immunity.

Against this backdrop, the House debated the proposal to repeal state sovereign immunity.⁹⁴ In a House subcommittee hearing, Jeffrey Samuels, the Acting Commissioner of the PTO, expressed the Department of Commerce’s support for the proposal, arguing

⁹¹ Scherer, *supra* note 4, at 203–05.

⁹² *Id.* at 204–05.

⁹³ *Id.* at 205–06.

⁹⁴ While not important here, parallel provisions for trademark and copyright infringement were also debated and passed. *See* Trademark Remedy Clarification Act, Pub. L. No. 102-542, 106 Stat 3567 (codified as amended in scattered sections of 15 U.S.C. (1992)); Copyright Remedy Clarification Act, Pub. L. No. 101-553, 104 Stat 2749 (codified as amended in scattered sections of 17 U.S.C. (1990)).

that sovereign immunity squelches the fundamental incentive to innovate created by the patent law.⁹⁵ He also argued that failing to repeal state sovereign immunity “makes a mockery” of U.S. trade negotiations because the United States had requested that its trading partners eliminate all “nonvoluntary licensing and governmental use provisions” in their patent laws.⁹⁶ A representative of an association of 6,000 intellectual property lawyers agreed with that position.⁹⁷ Samuels also took the position that Congress did *not* need to extend to the states any of the same limitations on liability that the federal government enjoyed.⁹⁸

The legislative debate suggests that, to some, it was not clear how the repeal of sovereign immunity would affect the common law research exemption under *Whittemore*. Samuels argued that the repeal of state sovereign immunity would have “no effect” on the exemption.⁹⁹ But Ray Farnbee, Vice Chancellor and General Counsel at the University of Texas, warned that the bill was overly broad and as a result, “it will encompass basic research at state-supported colleges and universities which historically have” benefited from a research exemption.¹⁰⁰ The perspective of state attorneys general and universities may not have been thoroughly presented because, according to the Senate report, none of them accepted invitations to appear at the hearing.¹⁰¹

⁹⁵ *Patent Remedy Clarification Act: Hearing on H.R. 3886 Before the Subcomm. on Courts, Intellectual Prop. and the Admin. of Justice of the H. Comm. on the Judiciary*, 101st Cong. 47 (1990) (statement of Jeffrey Samuels, Acting Comm’r of Patents and Trademarks, Dep’t of Com.) (arguing that sovereign immunity “extinguishes the stimulus needed to innovate”).

⁹⁶ *Id.* at 8.

⁹⁷ *Id.* at 47 (“We have introduced very strong principles in the [General Agreement on Tariffs and Trade] proposals and elsewhere to overcome this. To have 50-State carve outs in our country while we are trying to maintain that posture in these negotiations is not consistent.”).

⁹⁸ *Id.* at 20.

⁹⁹ *Id.* at 22. The Chairman specifically asked “what, if any, effect would this change in law have on the research exemption in patent law as far as State universities are concerned?” to which Mr. Samuels responded, “In my view, it would have no effect.” *Id.*

¹⁰⁰ *Id.* at 85.

¹⁰¹ S. REP. NO. 102-280, at 2 (1992), *reprinted in* 1992 U.S.C.C.A.N. 3087, 3088 (“The House subcommittee invited state attorneys general and representatives of state universities to testify, but none accepted the invitation.”).

The House Committee on the Judiciary essentially adopted the Bush administration's position, as articulated by Samuels, and reported favorably on the measure. The Committee argued that sovereign immunity diminishes incentives to innovate, especially for "the types of inventions that are of particular uses to states, including, for example, auto emission testing processes."¹⁰² The Committee did not address whether the states could rely on public agencies for those innovations, or whether it made economic sense to expose all public universities to liability for patent infringement for the sake of "incentivizing" such a narrow range of developments. The Committee also determined that it was not appropriate to extend any of the limitations on federal liability to the states.¹⁰³

The Senate report expressed the same concern about diminishing incentives for innovation, but paid more attention to the way that sovereign immunity caused disparate treatment between public and private universities, and between state and federal government agencies.¹⁰⁴ The Senate report failed to explain why, if the avowed purpose of the bill was to treat state and federal governments equally, the bill did not extend the same liability limitations the federal government enjoyed to the states. The measure passed and became law.¹⁰⁵

After the bill passed, the United States failed to procure a concession from less developed countries that would eliminate compulsory licensing in the TRIPS agreement, and compulsory licensing remains an important way for less developed countries to induce pharmaceutical manufacturers into making significant price concessions.¹⁰⁶ In the end, then, the United States' unsustainable position on compulsory licensing made a mockery of the debate over sovereign immunity, at least for a time. It remains to be seen

¹⁰² H.R. REP. NO. 101-960(I), at 38 (1990); *see also id.* at 37 (stating that "public policy supports the broad applicability of the patent laws" and arguing that States must be liable in order to protect the "Constitutionally mandated incentive to create").

¹⁰³ *Id.* at 39.

¹⁰⁴ S. REP. NO. 102-280, at 8-9, *reprinted in* 1992 U.S.C.C.A.N. 3087, 3094-95 ("Allowing a State to freely infringe upon the protection granted by the Patent Code and the Trademark Act effectively discourages future innovative.").

¹⁰⁵ Patent and Plant Variety Protection Act Remedy Clarification Act, Pub. L. No. 102-560, 106 Stat. 4230 (1992) (codified in scattered sections of 7 and 35 U.S.C.).

¹⁰⁶ Scherer, *supra* note 4, at 207.

whether foreign nations will concede to further limitations on compulsory licensing rights in the Trans-Pacific Partnership or other future trade agreements.

Several years later, the Supreme Court invalidated the bill and restored state sovereign immunity from patent infringement liability.¹⁰⁷ While Congress had expressly repealed that immunity, the question was whether Congress had the authority to do so in the first instance, pursuant to the Fourteenth Amendment of the Constitution. The Federal Circuit held that Congress had that power.¹⁰⁸ The Supreme Court reversed and struck down the law, thereby restoring sovereign immunity to the states.¹⁰⁹ But while the Supreme Court's decision ostensibly preserves a great deal of academic freedom for scientists at public universities, it has also unfortunately created a legal regime that treats public universities differently from private universities, and the private companies that collaborate extensively with both types of universities under the Bayh-Dole regime.

2. Codification of the Research Exemption Does Not Pass

At the same time that the House considered the repeal of state sovereign immunity, it also considered a proposal to codify the research exemption. As had happened previously, the debate over the research exemption arose out of a larger debate over the boundaries of patent eligible subject matter. In 1987, the PTO decided that genetically modified animals are patentable¹¹⁰ and, almost one year later, issued the first patent on a genetically engineered mouse.¹¹¹ The 100th Congress then entertained various bills to codify the PTO's decision, making genetically modified or "transgenic" animals patentable.

¹⁰⁷ Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627 (1999).

¹⁰⁸ Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 148 F.3d 1343, 1355 (Fed. Cir. 1998), *rev'd*, 527 U.S. 627 (1999).

¹⁰⁹ Fla. Prepaid, 527 U.S. at 630.

¹¹⁰ *Ex parte Allen*, No. 86-1790, 1987 WL 123816, at *2 (B.P.A.I. Apr. 3, 1987).

¹¹¹ U.S. Patent No. 4,736,866 (issued Apr. 12, 1988). For a discussion of the OncoMouse patent, and the disputes it provoked, see *infra* Section I.G.

The proposal drew tremendous support from the biotechnology industry and patent lawyers. Again, those witnesses in favor of patenting transgenic animals viewed “the patent law as an important incentive for the development of innovations.”¹¹² One intellectual property lawyer took the usual refrain one step further by making patents the answer to looming crises of global health and poverty, arguing that patents on transgenic animals were both necessary and imperative “to provide an incentive for the agricultural research and development needed to alleviate predicted world-wide food shortages.”¹¹³

As in previous debates, some remained skeptical about the extent to which the patent system actually incentivizes innovation, and whether the research exemption might be important for the patent system to achieve that goal in any event. The Environmental Policy Institute, for example, “questioned the need for an animal patent to achieve advances in livestock productivity because we already have seen advances in agriculture without the incentive of a patent.”¹¹⁴ The Wisconsin Farmer’s Union argued that publicly funded research formed the real basis for American biotechnology industry, and “questioned both the fairness in granting a monopoly market position to these corporations through a patent, and the necessity of patents to promote scientific progress.”¹¹⁵ Dennis Jelle, the President of the National Farmer’s Organization, and Tom Saunders, a dairy farmer, respectively noted that plant patent statutes had caused great amounts of consolidation among seed companies, and that allowing patents for transgenic animals would “result in a less diverse productive base.”¹¹⁶

The original bill making transgenic animals patentable contained a research exemption, but the House Committee on the Judiciary deleted that provision for two reasons: because the Committee believed that the existing common law exemption made the

¹¹² H.R. REP. NO. 100-888, at 6 (1988).

¹¹³ *Id.* at 12 (summary of testimony of Reid Adler); *see also id.* at 20 (lawyer Geoffrey Karyn testifying that “prohibiting or delaying patents on transgenic animals could seriously delay new life-saving medicines and major agricultural breakthroughs”).

¹¹⁴ *Id.* at 10 (summary of testimony of Jack Doyle); *see also id.* at 11 (summary of testimony of Cy Carpenter).

¹¹⁵ *Id.* at 16 (summary of testimony of Stuart Huber).

¹¹⁶ *Id.* at 16–17 (summary of testimony of Dennis Jelle and Tom Saunders).

provision “unnecessary,” and because if Congress wanted to codify a research exemption, it would be “desirable” to do so in a way that “would apply across the board to all patentable inventions” and not just transgenic animals.¹¹⁷ The Committee also noted that the international landscape had changed, since Japan and the nations in western Europe had created research exemptions in their patent laws, and as a result, such a change would not “cause any serious trade distorting effect.”¹¹⁸ The Committee did not observe that failing to codify the exemption might cause domestic researchers to relocate their efforts abroad, under more hospitable legal regimes, and potentially undermine the national research effort.

Interestingly, at this point, the Committee was also aware that the idea that patents are essential for innovation—that the benefits of stronger patent rights always outweighs the detriments—was under attack. The Committee dedicated a three page section of its report to “Patents and Economic Incentives,” noting that “[m]uch of the sound and fury about the patentability of life forms has been over whether a patent system is a necessary form of incentive for innovation, or instead a source of monopoly power.”¹¹⁹ In deciding the question, the Committee invoked the traditional arguments that, without patents, there would be no innovation because firms would free-ride on the innovation of others, or firms would rely on secrecy instead of making inventions public which would prevent the dissemination of knowledge.¹²⁰ Based on these arguments, the Committee concluded “that the political justification for the patent system (i.e., an incentive to create) has support in the economic literature,” but did not really address how the call for a research exemption would impact that political justification.¹²¹

¹¹⁷ H.R. REP. NO. 100-888, at 3, 70.

¹¹⁸ *Id.* at 51.

¹¹⁹ *Id.* at 66–68.

¹²⁰ *Id.* at 67. In this general time frame, more modern ideas about cumulative innovation were only just emerging and this more traditional mode of economic analysis remained dominant. See Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 842–44 (1990); Suzanne Scotchmer, *Standing on the Shoulder of Giants: Cumulative Research and the Patent Law*, 5 J. ECON. PERSP. 30 (Winter 1991).

¹²¹ H.R. REP. NO. 100-888, at 68.

During the 101st Congress, the House separated the research exemption proposal from the transgenic animal proposal, but the Bush administration opposed the measure. The Office of Technology Assessment (“OTA”), whom Congress had asked to evaluate the research exemption, did not respond to that request.¹²² The Assistant Secretary and Commissioner of Patents and Trademarks indicated that the administration opposed legislation creating a research exemption “because it could diminish the strong incentive provided by the patent system.”¹²³

The House Judiciary Committee reported the measure favorably, despite the administration’s opposition, and included what appears to be the first thorough analysis of the exemption in the record of public debate. Overall, this part of the report represents a significant departure from the typical legislative discussion about the patent system and its relationship to research. For example, the Committee claimed 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.”¹²⁴ The Committee then suggested that the Federal Circuit may have improperly constrained the experimental use doctrine in holding that it “does not apply if the experimental use [is] coupled with commercial use.”¹²⁵ The Committee also recognized that Bayh-Dole, Stevenson-Wydler, and the FTTA had changed the relationship between the government and research institutions, 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.”¹²⁶ And finally, the Committee recognized that the exemption made economic sense. Without an exemption, “[u]nnecessary

¹²² *Transgenic Animal Patent Reform Act: Hearing on H.R. 1556 Before the Subcomm. on Courts, Intellectual Prop., and the Admin. of Justice of the H. Comm. on the Judiciary*, 101st Cong. 19 (1989) [hereinafter *1989 Transgenic Animal Patent Reform Act Hearing*] (statement of Kevin W. O’Connor, Senior Analyst, Office of Technology Assessment) (noting that the OTA “didn’t reach any conclusions on the research exemption” in its report and that “it is an area that many scholars find to be murky”).

¹²³ *Id.* at 189–90.

¹²⁴ H.R. REP. NO. 101-960(I), at 41 (1990).

¹²⁵ *Id.* at 42.

¹²⁶ *Id.* at 43.

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.”¹²⁷ Despite this rather prescient analysis, the measure did not pass.

G. Escalating Disputes Over Access to Research Materials: The NIH Agreements Regarding the OncoMouse (1998–1999)

In the years following the failed attempt to codify the research exemption in the PCTIA, several major disputes arose that suggested the patent system was severely out of balance when it comes to protecting research activity. The first involved the OncoMouse, a major technological breakthrough in which scientists at Harvard University engineered mice with a genetic predisposition to developing cancer.¹²⁸ The technology quickly became an important tool for scientists studying cancer in humans.

At the time of the discovery, in 1984, it was not yet certain whether the PTO would issue patents on discoveries like genetically modified mice, thereby extending the logic of the *Chakrabarty* decision from bacteria to animals. But, as indicated above, in 1987, the PTO provided notice that it would issue such patents,¹²⁹ and it granted the patent covering the OncoMouse on April 12, 1988.¹³⁰ Thus, as with other disputes over genetic technologies, the OncoMouse dispute arose at a time when the federal courts and the PTO were expanding the boundaries of patent eligible subject matter.

The combination of exclusive rights and an aggressive patent licensing strategy subsequently caused a tremendous backlash among scientific researchers over the OncoMouse. The private firm, DuPont, had funded the research at Harvard, and under the

¹²⁷ *Id.* at 43–44.

¹²⁸ Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1073 (2008).

¹²⁹ MPEP § 2105 (9th ed. Rev. 7, Nov. 2015) (“Shortly after the *Allen* decision, the Commissioner of Patents and Trademarks issued a notice that the Patent and Trademark Office would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101.”) (internal citations omitted).

¹³⁰ U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

terms of the funding agreement, Harvard licensed the technology to DuPont on an exclusive basis.¹³¹ But instead of selling the mice to researchers, DuPont licensed use of the mice on terms that allowed DuPont to control future scientific inquiry and retain intellectual property rights in future discoveries flowing from the licensed use, a practice that caused considerable controversy in the research community.¹³² Disputes over DuPont's licensing strategy escalated throughout the 1990s until the National Institutes of Health ("NIH") negotiated several memoranda of understanding in 1998 and 1999 that produced, at best, an uneasy peace. These memoranda generally made the OncoMouse available to academic researchers on a royalty-free basis with no reach-through rights on subsequent innovations.

During debates over codification of the research exemption in the PCTIA, John Pratt, on behalf of the Association of Independent Research Institutes, argued that the OncoMouse controversy made the research exemption an important problem deserving congressional action. According to Pratt, inventions like the OncoMouse were essential research tools, and allowing patents on such tools gave the patent holder the power to stop researchers from making such tools in their own lab.¹³³ Pratt also argued that patent holders have already started using licensing techniques to control the direction, and appropriate the results of, research using basic tools like the OncoMouse (which Pratt accurately described as "an attempt to artificially extend the patent holder's rights beyond the scope of the invention").¹³⁴

Interestingly, social scientists have used the "openness" shock created by the NIH memoranda to study the impact that DuPont's aggressive licensing practices had on innovation outcomes.¹³⁵ The authors took advantage of the fact that every genetically engineered mouse, including those patented by DuPont, is associated with a publication describing its development and characteristics (a

¹³¹ Eisenberg, *supra* note 128, at 1072–73.

¹³² *Id.* at 1074.

¹³³ 1989 *Transgenic Animal Patent Reform Act Hearing*, *supra* note 122, at 276–78.

¹³⁴ *Id.*

¹³⁵ Fiona Murray et al., *Of Mice and Academics: Examining the Effect of Openness on Innovation* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 14819, 2009).

“mouse-article”). This allowed the authors to study the level and nature of follow-on research for each kind of mouse by analyzing the number and nature of subsequent research publications citing to the original mouse-article.¹³⁶ Overall, the authors found that the NIH agreements increased annual citation rates to mouse-articles by twenty-one percent,¹³⁷ while new authors increased by twenty-two to twenty-five percent, new keywords by twenty-five percent, and new journals by twenty-four percent.¹³⁸ The authors interpreted the results as yet more proof for the view that such licensing strategies decrease research intensity and force researchers to choose different research paths, while openness increases research intensity.¹³⁹ Subsequent economic studies suggest that the effect is felt in a wide variety of industries and is not confined to biotechnology.¹⁴⁰

H. The Federal Circuit’s Final Assault on the Research Exemption: Embrex (2000), Madey (2002), and Merck (2003)

Congress’ failure to codify a research exemption in the PCTIA cleared the path for the Federal Circuit to resuscitate its interpretation of the common law research exemption as “truly narrow.” The Federal Circuit made its first move in this direction in a 2000 decision. In *Embrex v. Service Engineering Corp.*, the court was faced with the question of whether substantial evidence supported a jury verdict finding that the research exemption did not apply to certain experiments that the defendant had performed in an attempt to design around the plaintiff’s invention.¹⁴¹ In a per curiam opinion, the court affirmed the jury’s finding that the defendant had performed the experiments “expressly for commercial purposes” and that the

¹³⁶ *Id.* at 4.

¹³⁷ *Id.* at 23.

¹³⁸ *Id.* at 24–26.

¹³⁹ *Id.* at 23.

¹⁴⁰ 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) (finding that a decision invalidating a patent causes, on average, “a [fifty] 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).

¹⁴¹ *Embrex v. Serv. Eng’g Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000).

research exemption therefore did not apply.¹⁴² The court argued that the common law research exemption remained a “very narrow” doctrine as set forth in *Bolar*, and that the Hatch-Waxman Act had not wholly repealed *Bolar* but had only superseded the decision “on other grounds.”¹⁴³ Judge Rader wrote a separate concurring opinion to state his own belief that an un-related Supreme Court opinion¹⁴⁴ had precluded any further application of the research exemption, and that even if the doctrine “retains some lingering vitality, the slightest commercial implication will render the [doctrine] inapplicable.”¹⁴⁵

In *Madey v. Duke University*, the Federal Circuit made its next move towards rendering the common law research exemption inapplicable in all but the narrowest of circumstances.¹⁴⁶ In this case, physics professor John Madey sued his former employer, Duke University, alleging that Duke had infringed Madey’s patents covering three pieces of equipment in Duke’s Free Electron Laser laboratory.¹⁴⁷ Madey had moved his equipment from Stanford to Duke when Duke recruited him, but left the equipment behind nine years later when Duke removed Madey from his position as lab director.¹⁴⁸ Duke then continued to use the equipment, causing Madey to sue.¹⁴⁹

The district court granted summary judgment in Duke’s favor on grounds that Duke’s use of the patented equipment fell within the research exemption announced in *Whittemore*,¹⁵⁰ but the Federal Circuit reversed. The Federal Circuit described its ruling as a

¹⁴² *Id.*

¹⁴³ *Id.* at 1349.

¹⁴⁴ See *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17 (1997). In the opinion, the Supreme Court simply held that evidence of experimentation is not relevant to the separate inquiry of whether an accused product infringes under the doctrine of equivalents, since the established test is an objective one and does not consider subjective intent. See *id.* at 35–36. Judge Rader argued that this decision precluded consideration of intent in any patent doctrine, including the research exemption. *Embrex*, 216 F.3d at 1353 (Rader, J., concurring).

¹⁴⁵ *Embrex*, 216 F.3d at 1353.

¹⁴⁶ 307 F.3d 1351 (Fed. Cir. 2002).

¹⁴⁷ *Id.* at 1353.

¹⁴⁸ *Id.* at 1352.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.* at 1355.

natural outgrowth of binding precedent: “Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form.”¹⁵¹ The court was referring to its decision in *Bolar*.¹⁵² According to the Federal Circuit, the fundamental inquiry was not whether the use of a patented invention for research constituted a socially beneficial use that Congress never intended to punish. Instead, the Federal Circuit reframed the question as being whether the use was in furtherance of “the institution’s legitimate business objectives,” and since universities are in the business of research and education, any use in furtherance of that purpose is patent infringement, regardless of whether the university is a non-profit institution or not.¹⁵³ With that somewhat circular reasoning, the Federal Circuit effectively rendered the research exemption an almost meaningless doctrine.

The Supreme Court denied certiorari in *Madey*,¹⁵⁴ but agreed to hear a case shortly thereafter (*Merck KGaA v. Integra Lifesciences I, Ltd.*) in which the Federal Circuit attempted to further undermine the *Bolar* amendment.¹⁵⁵ As indicated above, the *Bolar* amendment protects experimental uses of a drug patent “solely for purposes reasonably related to the development and submission of information under a Federal law.”¹⁵⁶ In *Merck*, the issue on appeal was whether that safe harbor protected early-stage experiments that did not immediately result in an FDA submission, but instead allowed the experimenter to identify “the best drug candidate to subject to future clinical testing under FDA processes.”¹⁵⁷ The Federal Circuit held that the safe harbor did not protect such uses, arguing that the safe harbor “does not reach any exploratory research that rationally form only a predicate for future FDA clinical tests.”¹⁵⁸ In

¹⁵¹ *Id.* at 1360.

¹⁵² *Id.* at 1361 (concluding that “the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex* . . . and in [*Bolar*]”).

¹⁵³ *Id.* at 1362.

¹⁵⁴ *Duke Univ. v. Madey*, 539 U.S. 958 (2003).

¹⁵⁵ *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

¹⁵⁶ 35 U.S.C. § 271(e) (2012).

¹⁵⁷ *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005).

¹⁵⁸ *Id.* at 867.

a unanimous opinion authored by Justice Scalia, the Supreme Court reversed, finding that the scope of the safe harbor was much broader.¹⁵⁹ The Court held that “[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.”¹⁶⁰

This decision indicates that a broad research exemption—much broader than the historical form of the common law exemption—is legally defensible, and if Congress extended the protection currently afforded to drug researchers to other technological fields, that legislation would more likely than not survive judicial scrutiny. Recent economic studies might support such a policy shift. For example, in a major recent study evaluating how a Federal Circuit decision of invalidity impacts the number of citations to the focal patent, the authors found that in many technological fields, such a decision increases citations (suggesting that openness increases innovation), but found no impact in the case of pharmaceuticals.¹⁶¹ Coincidentally, pharmaceutical research benefited from a strong statutory research exemption, pursuant to the *Bolar* amendment and the *Merck* decision, during almost the entire time frame that the authors investigated.¹⁶²

I. Impeding Research for a Public Purpose: The Dispute Over Genetically Modified Plants (2009)

After the OncoMouse dispute, the second major controversy related to the research exemption arose over access to genetically modified plants, and it suggests a different dimension to the problem that society faces when patent holders control the course of future research. As Cornell entomologist Elson J. Shields revealed in a 2009 letter to the Environmental Protection Agency, agricultural technology companies in the United States were, at the time, using licensing restrictions (similar to those used by DuPont) not to

¹⁵⁹ *Merck*, 545 U.S. at 202.

¹⁶⁰ *Id.*

¹⁶¹ Galasso & Schankerman, *supra* note 140, at 26.

¹⁶² 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. 35 U.S.C. § 271(e)(1) (2012).

capture rights in future research, but to prevent research into the health and environmental consequences of genetically modified plants.¹⁶³ Not only did the companies prohibit use of seeds for research in their standard license agreements, they also stopped research they had previously allowed from being published if the results were contrary to the companies' business interests, and selectively chose researchers based on their perception of who was "friendly" to agribusiness.¹⁶⁴ The dispute was more or less resolved on an *ad hoc* basis when the American Seed Trade Association conceded some ground in the wake of public outrage over the Shields' letter, though an online report from 2010 noted that "questions remain over whether—and how soon—[the agreement] will alter what has been a research environment rife with obstructions and suspicion."¹⁶⁵

In this specific setting, the researchers seeking access to the patented invention were not attempting to advance the science of genetically modified crops (in competition with the patent holder) or use the invention to develop new plants with potential market value. Instead, the researchers were seeking access to the patented plant material in order to evaluate the health and environmental consequences of genetically modified crops, an issue of interest to public health and food safety officials and society at large. The controversy therefore provides a stark reminder that not all science seeks to advance the technological frontier; much scientific research seeks to ensure that existing technologies are safe for public use or consumption. Without equitable doctrines like a research exemption, patent holders have a great deal of power to control the

¹⁶³ *Do Seed Companies Control GM Crop Research?*, SCI. AM. (Aug. 1, 2009), <http://www.scientificamerican.com/article/do-seed-companies-control-gm-crop-research/> [https://perma.cc/9XZH-HKLC].

¹⁶⁴ *Id.*; see also Kevin Rodkey, *Exhaustion and Validity of Single-Use Licenses for Transgenic Seeds in the Wake of Quanta v. LG Electronics*, 19 FED. CIR. B.J. 579, 585 (2010) (noting that one firm's standard license allowed use of the seed "for planting a single crop only in single season," and prohibiting the licensee from "provid[ing] it to anyone for crop breeding, research, generation of herbicide registration data or seed production").

¹⁶⁵ Bruce Stutz, *Companies Put Restrictions On Research Into GM Crops*, YALE ENV'T 360 (May 13, 2010), http://e360.yale.edu/feature/companies_put_restrictions_on_research_into_gm_crops/2273/ [https://perma.cc/XBG2-DW3V].

nature and quality of information that public officials rely on to make public policy and guard the public's safety.

J. Disputes Over Gene Patents in Medical Research and the Myriad Genetics Decision (2013)

The third major patenting controversy that implicated the research exemption involved the patenting of genes or isolated DNA sequences. In the 1990s, many biomedical researchers became increasingly concerned about the PTOs practice of issuing patents on human genes. As a result, in 2001, the PTO proposed guidelines clarifying that it would issue patents on human DNA sequences so long as the applicant proved that the discovered sequence was sufficiently useful, which eliminated the practice of applying for a patent based on the DNA sequence alone.¹⁶⁶ Yet the question remained: could biomedical researchers use patented DNA sequences in the laboratory to conduct research without infringing gene patents?

To address the problem, Representative Lynn Rivers introduced a bill during the 107th Congress, the Genomic Research and Diagnostic Accessibility Act of 2002 ("GRDA"),¹⁶⁷ to create a form of exemption for genetic research. The GRDA proposed to allow all persons or entities, except those involved in the sale of pharmaceuticals, to freely use "genetic sequence information for purposes of research."¹⁶⁸ It also proposed to add genetic testing (diagnostic, prognostic, and predictive) to the types of "medical activities" that have immunity under the patent laws.¹⁶⁹ Finally, it proposed to amend the Bayh-Dole Act so that a government contractor must notify the public if it seeks a patent on genetic sequence information.¹⁷⁰

In her speech in support of the bill, Representative Rivers described a quandary that would later become a central aspect of a 2013 Supreme Court decision regarding the patentability of

¹⁶⁶ Utility Examination Guidelines, 66 Fed. Reg. 1092-02 (Jan. 5, 2001).

¹⁶⁷ H.R. 3967, 107th Cong. (2001).

¹⁶⁸ *Id.*

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

DNA.¹⁷¹ Specifically, she emphasized that the power to prevent scientists from doing research on genes seemed strange given that those genes exist within the human body. Rivers recounted a dispute that had arisen with Miami Children's Hospital where the hospital had used tissue samples from children dying of Canavan disease to identify the gene responsible for their condition, and then patented the gene and used the patent to prevent others from researching a cure or diagnosing children without paying a royalty.¹⁷² Instead of proposing that genes not be patentable, Representative Rivers simply proposed that the patent law be balanced with exemptions for research and medical testing.¹⁷³ The bill was referred to the House Judiciary Committee on the day it was introduced, but no further action was taken.

In 2013, the Supreme Court decided that isolated DNA sequences are not patentable¹⁷⁴ in a judicial dispute that highlights the problem with allowing patent owners to dictate the course of medical research. The defendant in the case, Myriad Genetics, had successfully patented the isolated DNA sequences for genes in which mutations are strongly correlated with a risk of developing breast and ovarian cancer (the BRCA genes).¹⁷⁵ Subsequently, the company took action to prevent all other clinical researchers from testing to determine if an individual or patient carried such a mutation.¹⁷⁶ In addition to stopping those who carry out diagnostic tests, the patents also created obstacles to those engaged in breast and ovarian cancer research (as opposed to treating physicians), as researchers must rule out BRCA causation in order to provide a valid

¹⁷¹ 148 CONG. REC. E353-03 (daily ed. Mar. 14, 2002) (“What does it mean to own a human gene patent? It means that the gene patent holder controls any use of ‘its’ gene, a gene that is found in virtually every human being on the planet. The patent holder can prevent my doctor from looking in my body to see if I have that gene. The patent holder can prevent anyone else from doing research to improve a genetic test or to develop a gene therapy based on that gene.”). Rivers also noted complaints against Myriad’s high licensing fees for breast and ovarian cancer diagnostics. *See id.* at E354.

¹⁷² *Id.* at E353.

¹⁷³ *Id.* at E354.

¹⁷⁴ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).

¹⁷⁵ *Id.* at 2114 (noting that through litigation and cease and desist letters, Myriad “solidified its position as the only entity providing BRCA testing”).

¹⁷⁶ *Id.*

scientific opinion as to alternative causes.¹⁷⁷ Myriad took the position that such experiments constituted infringing uses of its patents, and required researchers to pay royalties to conduct such research.¹⁷⁸

By holding that isolated DNA sequences are not patentable, the Supreme Court provided much needed relief to genetic researchers, and it is clear from the Court's reasoning that it intended to do so. For example, the Court noted that the categories of ineligible subject matter are "the basic tools of scientific and technological work," and without these limitations on eligible subject matter, "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.'"¹⁷⁹ In short, the Court was trying to protect the types of research activity that historically found protection under the common law research exemption. But the Court attempted to achieve that result through a legal doctrine that is much more complex and difficult to administer—that of subject matter eligibility—because it revolves around defining abstract categories of exempted subject matter rather than on protected types of activity. One way of interpreting the decision, then, is that the Federal Circuit's attack on the common law research exemption has forced the judicial system to seek refuge in other legal doctrines in order to provide more balance in the patent law.

II. ECONOMIC IDEOLOGY, INSTITUTIONAL BIAS, AND THE RESEARCH EXEMPTION

As the historical discussion above reveals, there is no single "research exemption" in American patent law. Rather, the law in this area is incredibly complex. All researchers, regardless of institutional setting, have fairly broad protection from infringement liability when the experimentation is for the development of a drug or medical device that will require FDA approval. Also, researchers at

¹⁷⁷ Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 459 (2004).

¹⁷⁸ *Id.* at 459–60.

¹⁷⁹ *Myriad*, 133 S. Ct. at 2116; *see also id.* at 2117 ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.").

state agencies and universities remain protected from any infringement liability under the doctrine of sovereign immunity. But the Federal Circuit has significantly narrowed the reach of the common law research exemption, which is not limited to any specific subject matter or institutional setting. A series of legal developments have rendered the statutory exemption in the PVPA for sexually reproduced plants a dead-letter law. It still exists on the books, but those who innovate in that setting will rarely choose the PVPA over the Patent Act. And the Supreme Court has more aggressively narrowed (or policed) the boundaries of subject matter eligibility in order to provide some of the same relief that a broad research exemption would provide.

The law in this area has evolved in such a complex fashion because of politics. For the last forty years, powerful economic *interests* have exerted significant influence on federal patent policy, and powerful economic *ideas* have significantly influenced the way in which policymakers across the federal government frame debates over patent policy. The research exemption provides a robust case study for analyzing these trends, and bolsters two of the major critiques in the literature on the political economy of patent policy: first, that much of patent policymaking since the middle of the 1970s is rooted in faulty economic ideology; second, that the Federal Circuit, a specialized court created in part to be the standard-bearer of that ideology, exhibits an institutional bias in favor of strengthening patent rights and weakening doctrines (like the research exemption) that provide equitable counter-balances to strong patent rights.

A. The Role of Economic Ideology in Contemporary Patent Policy

One of the most striking features in legislative debates over the research exemption is that those who have historically opposed the exemption have relied almost exclusively on one idea—the “central dogma” of patent law—to support their position. The basic hypothesis, repeated throughout the debates, is that the prospect of patent protection is the primary if not the sole reason that institutions invest in research and innovation, and as a result, any attempt to diminish the “incentives” that patents create (such as by exempting research activity) will necessarily lead to less innovation

and hurt the economy. Though individual firms and industry representatives often invoke a version of the central dogma to create an air of legitimacy when seeking government patronage, the dogma is really a systemic claim about the extent to which a given patent policy will, on balance, increase overall levels of investment and innovation across all technological settings and industries, irrespective of the impact on one or a few actors.

The main problem with the central dogma is that, despite sixty years of inquiry, there is no quantitative evidence that the existing patent system has encouraged or incentivized more innovation in the United States than would otherwise exist under a different system, such as one including a robust research exemption.¹⁸⁰ As Rebecca Eisenberg observed early on, the central dogma fails to answer “the empirical question of how much incentive is necessary for an optimal level of invention and disclosure,” and is therefore of little use in determining whether or not a policy like the research exemption is sound.¹⁸¹

On this point, the political history of the research exemption illustrates in detail a major trend in the political economy of patent law since the 1970s. As economist William Landes and Judge Richard Posner have argued, since about 1976, patent rights have greatly expanded because government actors and private firms unflinchingly believed that whatever the reigning free-market ideology said about private property must also be true about intellectual property.¹⁸² This analytical mistake is found repeatedly in the history of the research exemption. The idea that patents incentivize innovation is just a repackaged version of the fundamental principle that private property rights provide incentives for socially benefi-

¹⁸⁰ See Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 1, 5 (Winter 2013) (finding “weak or no evidence that strengthening patent regimes increases innovation,” based on a review of twenty-four separate studies); Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RES. POL’Y 531, 555 (2000) (concluding that the theoretical and empirical evidence increasingly shows that the costs of stronger patent protection may exceed the benefits, especially if resources that could be dedicated to innovation are tied up in litigation over patents); Scherer, *supra* note 4, at 171–75.

¹⁸¹ Eisenberg, *supra* note 2, at 1030.

¹⁸² LANDES & POSNER, *supra* note 5, at 22–23.

cial economic activity.¹⁸³ And the unquestioning belief that this principle applies to intellectual property, without any proof that it is true or any serious discussion of the destructive potential inherent in patents, has created a system that gives patent holders a great deal of power to squelch, control, and delay the very research and innovation that the patent system is meant to promote.

Economists and social scientists are changing the ways they model the patent system to correct for inadequacies in the models that led to the development of the central dogma. The hypothesis that patents incentivize innovation acquired a great deal of legitimacy from economic models developed in the 1950s, models that described a limited field of investment behavior, namely private investments in technological fields where copying is easy and cheap and where other economic advantages, like first mover advantages, are not significant. Those models also assumed that invention takes place in “isolated” settings rather than in “cumulative” contexts where patented inventions are not just outputs but are *inputs* to further research. As a result, when addressing the economic pitfalls of stronger patent protection in debates over the research exemption, economists and policymakers who relied on these models in prior decades tended to focus on the traditional problems associated with monopoly power, like restricted output and high prices on commercial goods that necessarily follow from reduced competition, rather than on the power to control and prevent further experimentation and product development.¹⁸⁴ In the early 1990s, a handful of lawyers and economists realized that the motivating assumptions in the early models did not accurately describe the modern research setting.¹⁸⁵ As a result, more modern theories account for the fact that levels of follow-on innovation will be lower than socially desirable when any of the traditional microeconomic assumptions breakdown (asymmetric information, high transaction costs, or

¹⁸³ See *id.* at 22 (“Markets and property rights go hand in hand. Property rights provide the basic incentives for private economic activity and the starting point for transactions whereby resources are shifted to their most valuable use.”).

¹⁸⁴ Bhaven Sampat & Heidi Williams, *How Do Patents Affect Follow-on Innovation? Evidence from the Human Genome 1* (Nat’l Bureau of Econ. Research, Working Paper No. 21666, 2015).

¹⁸⁵ Merges & Nelson, *supra* note 120, at 842–44; Scotchmer, *supra* note 120, at 30.

coordination problems) and lead to bargaining failures over access to existing innovations.¹⁸⁶

As the history of the research exemption shows, the way in which economists analyze the costs and benefits of the patent system has not only influenced patent legislation, but has also impacted the way in which jurists conceive of the patent system. When the Supreme Court indicated, in 1989, that the patent system “reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the ‘Progress of Science and useful Arts’” it was simply importing the then-standard economic justification for the patent system into the meaning of the constitutional mandate.¹⁸⁷ More recently, the Supreme Court has suggested that “[p]atent protection strikes a delicate balance between creating ‘incentives that lead to creation, invention, and discovery’ and ‘imped[ing] the flow of information that might permit, indeed spur, invention.’”¹⁸⁸ This subtle shift in the Court’s exposition of the patent system’s purposes—from a concern about the danger of monopoly power to the danger of impeding the flow of information—shows an awareness of the ways in which economic models of innovation are changing.¹⁸⁹ At the same time, no legal principle requires that the constitutional mandate take on such a purely economic meaning, and history suggests that judges should be wary of make those kinds of intellectual leaps.¹⁹⁰ Any analysis based on

¹⁸⁶ Sampat & Williams, *supra* note 184, at 1–2; *see also* Galasso & Schankerman, *supra* note 140, at 2–4.

¹⁸⁷ *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

¹⁸⁸ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2109 (2013) (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1305 (2012)).

¹⁸⁹ At least three justices—Breyer, Stevens, and Souter—are well aware of the problem. *See Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc.*, 548 U.S. 124, 126–27 (2006) (Stevens, J., dissenting) (“Rather, the reason for the exclusion is 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. The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information.”).

¹⁹⁰ *Lochner v. New York*, 198 U.S. 45, 75 (1905) (Holmes, J., dissenting) (arguing that it perverts the Constitution to import the principles of free-market capitalism and Social Darwinism into the meaning of the Due Process Clause).

standard microeconomic assumptions will necessarily exclude considerations of equity that are important in a legal setting; any static equilibrium model will say little about how to facilitate the kind of dynamic change that is called for in the constitutional command to “promote the progress of science and the useful arts.”

The power of the central dogma, however, flows not only from its influence on judicial attitudes towards the patent system, but also from the pervasive hold it has had in legislative debates. Virtually every Congressional debate from the PVPA to Bayh-Dole, Hatch-Waxman, and the PCTIA has taken place under the presumption that strong patent rights provide an almost unmitigated social benefit with virtually no costs or risks. Executive officials in the Carter, Reagan, and Bush administrations more or less espoused that same view, as their testimony makes clear.¹⁹¹ Even when Congress anticipated that patents could be used in a way that risked causing harm to public health and safety during the Bayh-Dole debates, it constructed an onerous set of safeguards to protect against those risks.¹⁹² But as the controversies surrounding the OncoMouse, genetically modified plants and seeds, and the BRCA genes suggest, these risks are increasingly becoming routine and their resolution is demanding more and more government resources.¹⁹³ Except for the House Judiciary Committee report on the proposal to codify a research exemption as part of the PCTIA, no government agency has thoroughly considered the larger set of risks (beyond monopoly power and health and safety concerns) that flow from the proliferation of patent rights and licensing practices aimed at suppressing innovation.

Those who advocated in favor of research exemptions did not adhere so rigidly to economic dogma, and proposed a variety of reasons why a robust exemption is needed as a matter of public policy. Experimentation is arguably a type of conduct that no Congress has ever intended to punish. In a post-Bayh-Dole world, the research exemption would also allow public and private researchers to buttress their research budgets with additional revenue from commercial sales, while immunizing the underlying activity that

¹⁹¹ See, e.g., text accompanying *supra* notes 21, 69, 95, 119–21, 123.

¹⁹² See *supra* Section I.C.

¹⁹³ See *supra* Sections I.G, I.I, I.J.

promotes technological progress for the benefit of all. It might minimize and in some cases eliminate transaction costs associated with research activity, thus removing a significant tax on research. It would normalize, to a degree, the impact that the patent law has on private and public universities, the latter being protected under the doctrine of sovereign immunity while the former is not. It should provide an important check on the ability of patent holders to extend the temporal and substantive scope of their patent beyond the boundaries of the initial grant. It would protect the ability of researchers to study the health and environmental consequences of new technologies in the marketplace without undue interference. And it may prevent the outsourcing of research, given that most advanced economies have adopted an exemption in one form or another. All of these arguments have been raised in favor of a research exemption.

The debates over the research exemption also demonstrate just how much of modern patent policy is born of a perceived need to use patents to promote the ability of domestic firms to compete in an increasingly global economy. The PVPA of 1970 (and its research exemption) was born of a desire to help domestic agricultural firms compete with European business, the Bayh-Dole Act was avowedly meant to increase the productivity of American businesses so that they can compete with firms in Japan and elsewhere, and the TRIPS agreement and the attempt to repeal state sovereign immunity at home were related efforts to get foreign firms to conform to U.S. patent standards. In a sense, then, the political history of the exemption also illustrates the impact that globalization had, in this time frame, on economic thinking about patents and monopoly power. As David Hart puts it, “[p]olicies that had previously been seen in the national market to be concentrationist, fostering collusion to suppress innovation, came to be seen as deconcentrationist in the global market, overcoming collective action problems that inhibited innovation.”¹⁹⁴ From this perspective, the central dogma was never intended to be an empirically defensible claim about innovation; it was just a veneer used to legitimate policies that allowed incumbent firms to acquire more economic power and

¹⁹⁴ David M. Hart, *Antitrust and Technological Innovation in the U.S.: Ideas, Institutions, Decisions, and Impacts, 1890–2000*, 30 RES. POL’Y 923, 930 (2001).

which insulated domestic firms, to a degree, from foreign competition.

As indicated above, the central dogma—the basis for so much patent policy in the 1970s and 1980s—did not go unchallenged forever. Unfortunately, by the time these challenges began to appear, the last major political opportunity for codifying a broad exemption (as part of the PCTIA¹⁹⁵) had passed. With no congressional debate or action on the subject for the next twenty-five years, the locus of debate shifted back to the Federal Circuit.

B. Institutional Bias at the Federal Circuit

Another prominent critique in the study of the political economy of patent policy is that the Federal Circuit, as a specialized court, exhibits an institutional bias in its decision-making and is prone to a subtle form of regulatory capture.¹⁹⁶ Landes and Posner, for example, argue that “a specialized court is more likely to have a ‘mission’ orientation than a generalist court,” that the Federal Circuit “has defined its mission as promoting technological progress by enlarging patent rights,” and that the Federal Circuit exhibits a strong bias in favor of enlarging patent rights and increasing the demand for services from its primary constituency: patent lawyers.¹⁹⁷ Scherer emphasizes that this concern was very much present at the time of the court’s creation and that, in the enabling legislation, Congress ignored warnings that such a specialist court “may be ‘captured’ by special interest groups” and that uniformity in federal patent law “is quite plainly not a desirable objective.”¹⁹⁸

The Federal Circuit has unquestionably exhibited an institutional bias against doctrines like the research exemption. The court

¹⁹⁵ H.R. REP. NO. 101-960(I), at 41 (1990).

¹⁹⁶ The mechanism might best be characterized as one of “cultural capture,” a channel for obtaining regulatory actions that serve private industry but which “operates through a set of shared but not explicitly stated understandings about the world.” James Kwak, *Cultural Capture and the Financial Crisis*, in PREVENTING REGULATORY CAPTURE: SPECIAL INTEREST INFLUENCE AND HOW TO LIMIT IT 79 (Daniel Carpenter & David Moss eds., 2013).

¹⁹⁷ LANDES & POSNER, *supra* note 5, at 26–27.

¹⁹⁸ Scherer, *supra* note 4, at 187–88 (quoting *Commission on Revision of the Federal Court Appellate System Structure and Internal Procedures: Recommendations for Change*, 67 F.R.D. 195, 236 (1975)).

first attempted to eliminate the reach of the common law research exemption in the context of pharmaceutical patents in *Bolar* (1984). Though Congress swiftly rejected that action by creating a statutory exemption for research connected to FDA submissions, the Federal Circuit remained committed to its original view and essentially eliminated what was left of the common law exemption (as applied to other technological domains) in *Embrex* (2000) and *Madey* (2002). The court has also been receptive to arguments that Congress has the power to abrogate state sovereign immunity from infringement liability in a patent context (*Florida Prepaid*, 1998), and even attempted to narrow the scope of the *Bolar* exemption in *Merck* (2003). All of these actions are consistent with a strong ideological commitment to eliminating or narrowing immunities and exemptions from infringement liability, even those that have a firm statutory basis.

Part of the explanation may lie in the fact that Congress has effectively delegated policymaking power to a judicial venue where judges are bound to follow precedent and do not readily embrace a policymaking role. Congress explicitly created the Federal Circuit “to strengthen the United States patent system in such a way as to foster technological growth and industrial innovation” and to “provide nationwide uniformity in patent law.”¹⁹⁹ And yet, some of the judges have indicated that they have difficulty achieving those objectives within the confines of their institutional setting. Judge Michel has publicly lamented the court’s insularity and described its process as an echo chamber, while Judge Rader has decried the fact that the court’s institutional arrangement seems to stunt the pace of common law development.²⁰⁰ When faced with criticism that the court does not incorporate social science scholarship in their decision-making, some of the judges (including Michel) defaulted to the traditional view that federal courts do not set policy but simply apply existing law to the facts.²⁰¹

At the same time, none of the Court’s decisions concerning the research exemption appear to rest on such firm precedent that the

¹⁹⁹ H.R. REP. NO. 97-312, at 4 (1981).

²⁰⁰ Craig Allen Nard & John F. Duffy, *Rethinking Patent Law’s Uniformity Principle*, 101 NW. U.L. REV. 1619, 1622 (2007).

²⁰¹ *Id.* at 1648 n.102.

Federal Circuit can reasonably claim to have had its hand forced. In two of the six decisions (*Florida Prepaid* and *Merck*), the Supreme Court actually reversed the Federal Circuit. In a third decision (*Bolar*), the Federal Circuit showed some selection bias in choosing what precedent to rely on, and ultimately precipitated a congressional repeal—an uncommon event in patent law. Though the two most recent opinions narrowing the common law research exemption (*Embrex* and *Madey*) have evaded Supreme Court review, neither seems to have indisputably firm roots in legal precedent, especially since both effectively rely on *Bolar*.

Factors like the timing of the judicial appointment (before or after the creation of the Federal Circuit) or the political affiliation of the appointing president do not persuasively explain the court's institutional bias in the small set of decisions considered in this paper. As the table below shows, though five of the six panels were composed of judges appointed independently to the Federal Circuit after 1982, the one exception—*Bolar*—is the opening salvo in the court's attempts to narrow or eliminate the common law research exemption. The political affiliation of the appointing president also seems to have played an ambiguous role, despite the strong presence of Republican appointees on the court. Five of the six panels were composed of at least two judges appointed by Republican presidents, but the one exception—*Madey*—arguably represents the most significant attack, since *Bolar*, on the common law exemption.

<i>Federal Circuit Case</i>	<i>Judges (opinion author in bold)</i>	<i>Appointing President and Year (party)</i>	<i>Patent Background</i>
<i>Bolar</i> ²⁰²	Howard Markey	Nixon 1972 to CCPA (R)	Yes
	Philip Nichols, Jr.	Johnson 1966 to COC (D)	No
	Shiro Kashiwa	Nixon 1972 to COC (R)	No

²⁰² Roche Pods., Inc. v. Bolar Pharm. Co., 733 F.2d 858 (Fed. Cir. 1984).

<i>Federal Circuit Case</i>	<i>Judges (opinion author in bold)</i>	<i>Appointing President and Year (party)</i>	<i>Patent Background</i>
<i>Florida Prepaid</i> ²⁰³	Raymond C. Clevenger, III	H.W. Bush 1990 (R)	No
	Randall R. Rader	Reagan 1988 (R)	Yes
	William Bryson	Clinton 1994 (D)	No
<i>Embrex</i> ²⁰⁴	Alan D. Lourie	W. Bush 1990 (R)	Yes
	Raymond C. Clevenger, III	H.W. Bush 1990 (R)	No
	Randall R. Rader (concurring)	Reagan 1988 (R)	Yes
<i>J.E.M.</i> ²⁰⁵	Haldane Robert Mayer	Reagan 1982 to COC, 1987 to Fed. Cir. (R)	No
	Pauline Newman	Reagan 1984 (R)	Yes
	Alan D. Lourie	W. Bush 1990 (R)	Yes
<i>Madey</i> ²⁰⁶	William Bryson	Clinton 1994 (D)	No
	Arthur Gajarsa	Clinton 1997 (D)	Yes
	Richard Linn	Clinton 1999 (D)	Yes
<i>Merck</i> ²⁰⁷	Pauline Newman (concurring in part and dissenting in part)	Reagan 1984 (R)	Yes
	Randall R. Rader	Reagan 1988 (R)	Yes
	Sharon Prost	W. Bush 2001 (R)	No

A stronger case could be made for the idea that judges with a patent background—and all the ideological baggage that comes with it—are biased against doctrines like the research exemption, at least from the year 2000 forward. Even more notable is the

²⁰³ Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd., 148 F.3d 1343 (Fed. Cir. 1998).

²⁰⁴ Embrex v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000) (per curiam).

²⁰⁵ Pioneer Hi-Bred Int'l, Inc. v. J.E.M. Ag Supply, Inc., 200 F.3d 1374 (Fed. Cir. 2000).

²⁰⁶ Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002).

²⁰⁷ Integra Lifesciences I, Ltd. v. Merck KGaA, 331 F.3d 860 (Fed. Cir. 2003), *vacated*, 545 U.S. 193 (2005).

prominent presence in the decisions of those who were affiliated with the court's founding; though even here, specific individuals amongst the subset of those affiliated with the court's founding have exhibited strong ideological bias against the research exemption, while others have offered strong support. Judge Markey, then a judge on the Court of Customs and Patent Appeals, ultimately testified in favor of creating the Federal Circuit. Before doing so, he argued that the main problem with obtaining consistency in the patent law was the federal courts' frequent reliance upon judicial tests that were not rooted in statutory language.²⁰⁸ That critique suggests that Judge Markey believed the common law should develop in a very restricted manner in the context of patent cases. Judge Rader served on the U.S. Senate Judiciary Committee in the 1980s, during the time that the bill to establish the Federal Circuit was being debated, and since his appointment to the court, he has taken a very strident view towards the research exemption. In both *Embrex* and *Merck*, Judge Rader articulated perhaps the strongest ideological bias against the research exemption (in both common law and statutory forms).²⁰⁹ Judge Newman played a role in organizing corporate patent counsel to lobby Congress when the bill to create the Federal Circuit was stalled.²¹⁰ At the same time, she has also provided one of the strongest defenses of the research exemption on the judicial record.²¹¹

Consistent with other studies that look for institutional bias at the Federal Circuit in the development of doctrine,²¹² the history of debates over the research exemption illustrate a significant institu-

²⁰⁸ Paul M. Janicke, *To Be or Not to Be: The Long Gestation of the U.S. Court of Appeals for the Federal Circuit*, 69 ANTITRUST L.J. 645, 657-59 (2002).

²⁰⁹ See, e.g., *Embrex*, 216 F.3d at 1353 (Rader, J., concurring) ("Even if the experimental use excuse retains some lingering vitality, the slightest commercial implication will render the . . . doctrine inapplicable, as occurs in the court's resolution today.").

²¹⁰ Pauline Newman, *Origins of the Federal Circuit: The Role of Industry*, 11 FED. CIRC. B.J. 541, 543 (2002) ("We didn't know why this reluctance existed, but out marched the corporate patent counsel . . . We brought the industrial might of the nation. We brought our chief executives and our research directors and our union leaders. The industries that were now working to create this court represented three-quarters of the nation's industrial product.").

²¹¹ *Merck*, 331 F.3d at 872-78 (Newman, J., concurring in part and dissenting in part).

²¹² See generally Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1 (1989); Nard & Duffy, *supra* note 200.

tional bias against common law exemptions and immunities, a bias that seems to originate from shared understandings and ideologies about the way the patent system works and the Federal Circuit's role in shaping patent law. But the history of the research exemption also suggests some deeper problems associated with the delegation of policymaking authority to a judicial forum where the ideological biases of certain individuals can be significantly amplified, and where policy is made without the benefit of public hearing, fact gathering, and debate that goes beyond the interests of the private litigants.

CONCLUSION

The temporal evolution in federal policy concerning the idea of exempting research activity from infringement liability provides an interesting case study in the political economy of patent policy, one that illustrates two of the main themes in the field. The un-nuanced economic ideology that pervades legislative debates over the research exemption, embodied in the central dogma, appears to have influenced a great deal of judicial and legislative analysis of patent policy over the course of the last forty years. The implantation of this ideology into the Patent Clause of the Constitution is cause for special concern because it means that almost all legal analysis of the patent system takes place under an analytical framework that is wholly unconcerned with questions of equity, protecting public health and safety, or promoting progress (divorced from profit), and which leaves very little room for integrating patent law with the objectives of other economic policy domains.

The Federal Circuit has a fairly strong institutional bias against liability exemptions and immunities. One plausible explanation for that bias is that Congress created the Federal Circuit with a specific mission, one rooted in certain ideological precepts about the role of the patent system in the American economy and the role of the judges in strengthening that system, and that this ideological framework favors expanding and strengthening rights of individual patent holders rather than strengthening the innovative capacity of the system as a whole. This ideological bias may be exacerbated by the fact that much policy, in this area, is made in an institutional

setting that hears *individual* disputes and does not (always) embrace the idea of itself as an institution responsible for setting systemic policy.

A temporal or chronological approach to studying the political economy of patent policy provides certain benefits over more expansive, systemic studies. Among those benefits is the ability to embed attitudes towards a specific policy within historical context, and examine the relationship between the policy and other related developments in the broader domain of patent law. The perspectives of those who opposed or supported the research exemption did not develop in isolation. At the very least, those opinions were shaped by the economic recession of the late 1970s, concerns about the competitiveness of American industry in a global economy, international debates over patent standards, judicial developments regarding sovereign immunity, and a whole host of developments regarding patent eligible subject matter. Such an approach also reveals how the constituencies of advocates for and opponents to the research exemption change with time. For example, the shift from opposition to support amongst some groups of patent lawyers, and the surprising emergence of strident opposition from university officials, is much more visible in this type of vertical, issue-specific analysis.

Though the political history of the research exemption provides much fuel for skeptics about the real benefits of patent law, the news is not all bad. Granted, the complexity of policymaking in this area and the contingencies of history have led to an unnecessarily complicated legal framework when it comes to the research exemption. And much of the political history told herein proves that those with economic power and an interest in perpetuating the status quo are, predictably, very good at getting at what they want. But Congress has on two separate occasions enacted some form of a statutory research exemption, and on one of those occasions—the *Bolar* amendment—Congress created one of the strongest exemptions in the world in terms of the amount of protected activity. Congress did so, amazingly, in the one industry where most economists and policymakers agree that patents are actually important for eliciting private investments. Perhaps more importantly, the House has al-

ready considered one such proposal and its report²¹³ on the matter provides a solid foundation for further debate—debate that should at least account for changes in economic analysis of the patent system over the last twenty years. The time is therefore ripe for Congress to revisit the research exemption.

²¹³ H.R. REP. NO. 101-960(I) (1990).