Duke Law Journal

VOLUME 63 OCTOBER 2013 NUMBER 1

PATENTS AND THE UNIVERSITY

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ABSTRACT

This Article examines the intersection of patent law and academic science. It advances two novel claims about the internalization of academic science within the patent system and the concomitant evolution of "academic exceptionalism." Historically, relations between patent law and the university were characterized by mutual exclusion, based in part on perceived normative conflicts between academic culture and exclusive rights. These normative distinctions helped inform academic exceptionalism—the notion that the patent system should exclude the fruits of academic science or treat academic entities differently than other actors—in patent doctrine. As universities began to embrace patents and the nature of scientific research evolved, however, academic science has become internalized within the traditional commercial narrative of patent protection. Nowadays, courts frequently invoke universities' commercial nature

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to reject exceptional treatment for academic institutions. The twin trends of internalization and exceptionalism have evolved again in recent legislative patent reform. On the one hand, the interests of academic science have become completely internalized within the patent system to the extent that they inform general rules of patentability applying to all inventions. On the other hand, academic exceptionalism (which courts have rejected as a doctrinal matter) has been resurrected in the form of special statutory carve-outs for universities. Turning from the descriptive to the normative, this Article concludes with recommendations for improving the patent system's regulation of academic science in multiple contexts.

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INTRODUCTION

In December 2012, Carnegie Mellon University won a $1.17 billion jury verdict in a patent infringement suit against Marvell Technology Group.[1] If the verdict withstands post-trial motions and appeals, it will be the largest award in the history of U.S. patent litigation.[2] The case is notable not only because of the enormous stakes involved, but also because of the identity and behavior of the patentee—a university. Carnegie Mellon has been accused of being a "patent troll," an entity that amasses patents, does not manufacture any products, and exploits exclusive rights to extract rents from

1. Rich Lord, *Carnegie Mellon Wins $1.17 Billion in Patent Case*, PITTSBURGH POST-GAZETTE, Dec. 27, 2012, at B1. The suit involved patented hard-disk technology. *Id.*

2. Joe Mullin, *University Wins Record $1.17 Billion Verdict Against Marvell Semiconductor*, ARS TECHNICA (Dec. 26, 2012, 8:00 PM), http://arstechnica.com/tech-policy/2012/12/jury-slams-marvell-with-mammoth-1-17-billion-patent-verdict.

innovative parties.[3] In a broader sense, Carnegie Mellon's suit illustrates a remarkable transformation in universities' relationship with the patent system since the humble origins of academic patenting about a century ago.

The question of how universities should fit into the patent system is an important one, for universities possess enormous innovative potential. In 2010, universities spent $61.2 billion on research and development, with federal funds accounting for 61 percent of this total.[4] Academic research has produced thousands of important inventions, from medicines to search engines.[5] In fiscal year 2011, universities received 4,700 U.S. patents, executed 4,899 licenses, and received over $2.5 billion in patent-related income.[6] Though impressive to some, such statistics also raise concerns over the commercialization of universities and the subordination of academic values to financial imperatives. Indeed, the unique norms, incentives, and missions of universities suggest that academic inventions fit uncomfortably in a patent system predicated on exclusive rights and profit maximization. Such considerations give rise to significant policy questions regarding how universities should interact with the patent system to advance academic, technological, and economic objectives.

To address this question, this Article examines the coevolution of patent law and the university. First, integrating historical analysis with recent doctrinal and statutory reforms, it advances a novel descriptive theory regarding the "internalization" of academic science within patent law. Although patents' permeation of university culture

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3. Mike Masnick, *Patent Trolling Carnegie Mellon Wins What Could Be Largest Patent Verdict Ever: $1.2 Billion*, TECHDIRT (Dec. 27, 2012, 9:55 AM), http://www.techdirt.com/articles/20121226/17582221493/patent-trolling-carnegie-mellon-wins-what-could-be-largest-patent-verdict-ever-12-billion.shtml.

4. *Almanac of Higher Education: University Research-and-Development Spending Financed by the Federal Government, FY 2010*, CHRON. HIGHER EDUC. (2012), https://chronicle.com/article/University/133233.

5. Examples include Bufferin, computer-aided design, diagnostic tests for cancer and osteoporosis, Gatorade, Lycos, music synthesizers, stannous fluoride, Taxol (an anticancer drug), and the "gene splicing" technique that produced the biotechnology industry. John Fraser, *Communicating the Full Value of Academic Technology Transfer: Some Lessons Learned*, 1 TOMORROW'S TECH. TRANSFER 9, 10 (2009); Donald S. Siegel, David A. Waldman, Leanne E. Atwater & Albert N. Link, *Toward a Model of the Effective Transfer of Scientific Knowledge from Academicians to Practitioners: Qualitative Evidence from the Commercialization of University Technologies*, 21 J. ENGINEERING & TECH. MGMT. 115, 118 (2004).

6. ASSOC. OF UNIV. TECH. MANAGERS, U.S. LICENSING ACTIVITY SURVEY HIGHLIGHTS FY2011, at 2–3 (2012), *available at* http://www.autm.net/AM/Template.cfm?Section=FY_2011_Licensing_Activity_Survey&Template=/CM/ContentDisplay.cfm&ContentID=8731.

has attracted significant attention,[7] this Article explores the underappreciated, reciprocal trend of academic science's permeation into the core of patent law. Historically, relations between patent law and the university were characterized by mutual exclusion, based in part on perceived normative conflicts between academic culture and exclusive rights. However, as universities began to embrace patents in the late twentieth century, academic science became similarly internalized within the patent system. These days, the content, norms, and practices of academic science—a formerly peripheral concern for the patent system—are frequent subjects of patent litigation and doctrine. Contemporary patent courts, responding to institutional changes, view universities as fully integrated into the commercial narrative of patents. More recently, academic science has been internalized not only in patent doctrine, but also in statute. Due to legislative reforms and the influence of the university lobby, the institutional interests of academic science are now hardwired in the patent statute. Patent law regulates a significant portion of academic activity, and universities are wielding their political influence to regulate patent law.

Second and relatedly, this Article argues that throughout this process of mutual internalization, "academic exceptionalism" has evolved considerably. Academic exceptionalism stands for the proposition that the patent system should exclude the fruits of academic science or treat academic entities differently than other innovative actors. It arises in part from perceived normative and behavioral distinctions between universities and commercial, profit-maximizing entities. Throughout most of the history of the patent system, prudential interests in keeping foundational discoveries in the public domain as well as judicial recognition of the noncommercial nature of university science helped contribute to academic exceptionalism in patent doctrine. More recently, however, courts have rejected such exceptionalism as patentable subject matter has expanded, academic science has become more aggressive, and universities have begun behaving more like typical commercial entities. Turning from doctrine to statute, academic exceptionalism has recently evolved again in the legislative context. On the one hand,

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7. *See generally, e.g.*, Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, SOC. PHIL. & POL'Y, Summer 1996, at 145; Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77 (1999).

exceptionalism has vanished to the extent that academic interests now inform general rules of patentability that apply to all inventions. On the other hand, academic exceptionalism has seen a resurgence in special legislative carve-outs that specifically benefit universities.

Third, turning from the descriptive to the normative, this Article assesses these developments and offers prescriptions for enhancing the patent system's regulation of academic science. This inquiry is a complicated one, for universities interact with the patent system in multiple ways, and the patent system is far from monolithic; it encompasses a wide range of regulatory mechanisms exerting both hard and soft power over entities falling within its domain. This Article explores the tensions that arise between the twin trends of academic internalization and exceptionalism. It observes that academic exceptionalism is neither categorically desirable nor undesirable but is warranted in certain contexts when treating universities differently than other innovative entities advances broader policy objectives related to promoting research and access to technology. Offering several prescriptions, this Article argues against academic exceptionalism in the general rules of patentability. However, it argues in favor of exercising equitable discretion to enhance access to patented university inventions in some instances and for targeted, soft regulation of university patenting and licensing decisions by federal funding agencies. Finally, it endorses a robust research exception for scientific inquiry in the infringement context.

Before proceeding, it is important to acknowledge several distinctions. First, in addressing university science, it is important to distinguish individual academic scientists from the universities that employ them. In some cases, the norms, motivations, and interests of individual scientists can differ from those of the institutions where they work, as illustrated in recent high-profile disputes over the ownership of academic inventions.[8] Second, universities display great internal and external heterogeneity. Among universities, attitudes toward patenting may differ between public versus private, secular versus religious, and land-grant versus non-land-grant institutions. Within a single university, high-level leadership, technology transfer administrators, and faculty scientists may all view patents differently. Although this Article acknowledges these distinctions, they should

8. *See, e.g.*, Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188, 2192 (2011) (holding that title to an invention initially vested in a Stanford University scientist rather than in Stanford University).

not obscure the commonalities that bind these constituencies together.[9] University-based, academic research is a discrete and powerful domain of innovation that interacts with patent law in unique and significant ways, a phenomenon that this Article explores in detail.

This Article proceeds in five Parts. Part I explores the historical separation of academic science and patent law, manifested both in noncommercial university norms and academic exceptionalism in patent doctrine. Part II explores a historical shift culminating in the late twentieth century, when the Bayh-Dole Act[10] and other statutory, legal, and scientific developments led patents to move to the core of academic science. Part III considers the contemporary period in which patents have significantly permeated the culture of university science. It explores the less appreciated ways in which patent doctrine has internalized academic science and rejected academic exceptionalism based in part on increasingly commercial norms on the part of universities. Part IV examines the culmination of academia's internalization within the patent system in legislative patent reform, most notably the America Invents Act.[11] It also describes how academic exceptionalism, which courts have rejected in doctrine, has been resurrected in statute. Part V turns from the descriptive to the normative, proposing enhancements to the patent system's regulation of various aspects of academic research and patenting.

I. THE TRADITIONAL EQUILIBRIUM: SEPARATION AND EXCEPTIONALISM

The first phase of academic science's interactions with patent law was largely characterized by mutual exclusion. Although U.S. universities have long served practical needs, academic norms often discouraged patenting. Furthermore, when universities first entered the patent system, they did so to advance uniquely noncommercial values. In reciprocal fashion, courts viewed academic science as falling outside of the scope of patentability and afforded universities a

9. *See* Rai, *supra* note 7, at 92 ("Basic scientific research norms share many similarities with the norms of academic institutions generally.").

10. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

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

rather privileged normative status within the patent system, thus reflecting academic exceptionalism.

A. Academic Science Viewing Patent Law: Noncommercial Norms and Forbearance

1. *The Applied Nature of U.S. Universities*. At first glance, universities' historical segregation from the patent system appears rather curious given the pragmatic orientation of U.S. academic institutions.[12] Early American colleges and universities assumed a highly practical nature to help meet the needs of a young country.[13] In this spirit, Thomas Jefferson established the University of Virginia in 1825 to provide "an useful American education."[14] The decentralized nature of American universities contributed to this orientation; universities depended on local funding for revenue and thus had to be responsive to local economic and educational needs.[15] A major development in orienting universities toward practical imperatives was the establishment of land-grant colleges in the mid-nineteenth century.[16] Contrary to the largely "verbalistic" curricula of prior

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12. *See* JENNIFER WASHBURN, UNIVERSITY, INC.: THE CORPORATE CORRUPTION OF AMERICAN HIGHER EDUCATION 26 (2005); Walter W. Powell & Jason Owen-Smith, *Universities and the Market for Intellectual Property in the Life Sciences*, 17 J. POL'Y ANALYSIS & MGMT. 253, 254 (1998) ("U.S. universities have long had a more practical orientation than universities in the United Kingdom or Germany."); Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC MONTHLY, Mar. 2000, at 39, 45 ("Certainly, in comparison with their European counterparts, U.S. universities have always displayed a pragmatic bent.").

13. *See* ALEXIS DE TOCQUEVILLE, DEMOCRACY IN AMERICA 530–31, 534–35 (Gerald Bevan trans., Penguin Books 2003) (noting the practical, applied nature of the American scientific mind).

14. WASHBURN, *supra* note 12, at 26.

15. Nathan Rosenberg & Richard R. Nelson, *American Universities and Technical Advance in Industry*, 23 RES. POL'Y 323, 325 (1994).

16. *See* 7 U.S.C. §§ 301–329 (2012); Jennifer L. Croissant & Laurel Smith-Doerr, *Organizational Contexts of Science: Boundaries and Relationships between University and Industry*, *in* THE HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES, 691, 692–93 (Edward J. Hacket, Olga Amsterdamska, Michael Lynch & Judy Wajcman eds., 3d ed. 2007); Yong S. Lee, *'Technology Transfer' and the Research University: A Search for the Boundaries of University-Industry Collaboration*, 25 RES. POL'Y 843, 850 (1996) ("American higher education can be said to have roots in the landgrant philosophy embodied in the Morrill Act of 1862 and the Hatch Act of 1887, which emphasize service to industry and agriculture."); Joshua E. Powers, *Commercializing Academic Research: Resource Effects on Performance of University Technology Transfer*, 74 J. HIGHER EDUC. 26, 45 (2003) ("[T]he economic development role for America's research universities had historically centered on the land-grant institutions."). Even before the Morrill Act of 1862, ch. 130, 12 Stat. 503 (codified as amended at 7 U.S.C. § 301–305, 307–309), the federal government granted land for the creation of public universities. Vernon Carstensen, *A Century of the Land-Grant Colleges*, 33 J. HIGHER EDUC. 30, 30 (1962).

universities,[17] these colleges focused on solving practical problems[18] and providing instruction in agriculture and the mechanical arts.[19] This trend was bolstered by the establishment of Agricultural Experiment Stations under the direction of land-grant colleges.[20] Although these experiment stations conducted basic research, they were "'in the business' of developing findings and techniques that were ready for use by farmers" and had a clearly pragmatic character.[21] Notably, these Agricultural Experiment Stations facilitated a public seed distribution system that disseminated the fruits of research free to the public.[22]

Consistent with their practical orientation, many early U.S. universities cultivated close connections with industry.[23] From 1890 to 1900, several universities established partnerships with commercial entities in the Northeast industrial corridor.[24] In an era of scarce public funds for research, universities relied substantially on private money for support.[25] Universities played a key role in the development of new engineering and applied sciences disciplines[26] as well as in the development of research-based pharmaceutical firms.[27] Rather than focusing exclusively on fundamental scientific principles,

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17. Carstensen, *supra* note 16, at 35–36.

18. WASHBURN, *supra* note 12, at 29; Dov Greenbaum, *Academia to Industry Technology Transfer: An Alternative to the Bayh-Dole System for Both Developed and Developing Nations*, 19 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 311, 333–34 (2008).

19. Morrill Act of 1862 § 4, 12 Stat. at 504; *see* Carstensen, *supra* note 16, at 31. Congress passed a second Morrill Act in 1890 that extended the land-grant college program to former Confederate states. Morrill Act of 1890, ch. 841, 26 Stat. 417 (codified as amended at 7 U.S.C. §§ 321–326, 326a, 328).

20. 7 U.S.C. § 361a; *see* Carstensen, *supra* note 16, at 34–35.

21. Jeannette Colyvas, Michael Crow, Annetine Gelijns, Roberto Mazzoleni, Richard R. Nelson, Nathan Rosenberg & Bhaven N. Sampat, *How Do University Inventions Get into Practice?*, 48 MGMT. SCI. 61, 65 (2002); *see* Arthur D. Little, *Industrial Research in America*, 38 SCIENCE 643, 649–50 (1913) (discussing examples of the experiment stations' work and its practical character).

22. KEITH AOKI, SEED WARS 15 (2008).

23. Croissant & Smith-Doerr, *supra* note 16, at 691; Henry Etzkowitz, *Entrepreneurial Science in the Academy: A Case of the Transformation of Norms*, 36 SOC. PROBS. 14, 15 (1989).

24. GARY W. MATKIN, TECHNOLOGY TRANSFER AND THE UNIVERSITY 18 (1990). Some commentators around this time period, however, questioned the ability of universities to work with industry. *See* C.E. Kenneth Mess, *The Organization of Industrial Scientific Research*, 42 SCIENCE 763, 766 (1916).

25. WASHBURN, *supra* note 12, at 34.

26. Rosenberg & Nelson, *supra* note 15, at 327.

27. Jeffrey L. Furman & Megan J. MacGarvie, *Academic Science and the Birth of Industrial Research Laboratories in the U.S. Pharmaceutical Industry*, 63 J. ECON. BEHAV. & ORG. 756, 774 (2007).

much university research throughout the late nineteenth and twentieth centuries addressed practical problems in agriculture, public health, and industry.[28] Particularly in the life sciences, relationships between universities and industry flourished between World War I and World War II.[29] By 1940, 50 U.S. companies were supporting 270 biomedical research projects at 70 universities.[30]

2. *Antipatenting Norms*. Given the pragmatic orientation of U.S. universities, these institutions' historical aversion to patenting might seem somewhat odd. However, scientific norms prioritizing communal sharing over individual property rights contributed to deep skepticism of patents.[31] As sociologist Robert Merton documented in the early twentieth century, academic science relies heavily on the sharing of information, theories, and research materials for collective progress.[32] Scientific knowledge thus constitutes "a common heritage in which the equity of the individual producer is severely limited."[33] Drawing on his empirical work, Merton argued that science combines

28. Little, *supra* note 21, at 652; David C. Mowery & Bhaven N. Sampat, *The Bayh-Dole Act of 1980 and University-Industry Technology Transfer: A Model for Other OECD Governments?*, 30 J. TECH. TRANSFER 115, 124 (2005). Of course, such commercial forays were not without their critics. *See* THORSTEIN VEBLEN, THE HIGHER LEARNING IN AMERICA: A MEMORANDUM ON THE CONDUCT OF UNIVERSITIES BY BUSINESS MEN 30 (1918); Dean Barus, *Quotations: Research and Teaching*, 57 SCIENCE 445, 446 (1923); Charles Baskerville, *University and Industry*, 30 SCIENCE 919, 920 (1916); H.A. Rowland, *A Plea for Pure Science*, 29 SCIENCE 242, 243 (1883). By the 1920s, however, opinion had solidified among many academic scientists that universities could legitimately serve industrial interests. DEREK BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 139 (2003).

29. David Blumenthal, *Academic-Industrial Relationships in the Life Sciences*, 349 NEW ENG. J. MED. 2452, 2452 (2003).

30. *Id.*

31. Michael J. Madison, Brett M. Frischmann & Katherine J. Strandburg, *The University as Constructed Cultural Commons*, 30 WASH. U. J.L. & POL'Y 365, 381 (2009); *see* Bhaven N. Sampat, *Patenting and US Academic Research in the 20th Century: The World Before and After Bayh-Dole*, 35 RES. POL'Y 772, 776 (2006) ("[I]t is likely that strong norms militating against academic patenting checked any ambitions universities may have had to patent in instances where publication or open dissemination would suffice for 'technology transfer.'"(citing David C. Mowery & Bhaven N. Sampat, *University Patents and Patent Policy Debates in the USA, 1925–1980*, 10 INDUS. & CORP. CHANGE 781, 781 (2001)).

32. Merton's empirical observations resonated with theoretical models of scientific progress. *See, e.g.*, THOMAS KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (1996) (highlighting the importance of communal work in establishing and displacing scientific paradigms); Michael Polanyi, *The Republic of Science: Its Political and Economic Theory*, 1 MINERVA 54 (1962) (describing an autonomous scientific community with a high degree of internal communication).

33. ROBERT K. MERTON, THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS 273 (Norman W. Storer ed., 1973).

four normative pillars: universalism, communism, disinterestedness, and organized skepticism.[34] Patents particularly conflict with the Mertonian norm of communism, the principle that "[t]he substantive findings of science are a product of social collaboration and are assigned to the community."[35] In a system in which scientists freely disclose their discoveries and build upon each other's claims, individual property rights in scientific knowledge are whittled "down to a bare minimum."[36] As Merton observed, "The communism of the scientific ethos is incompatible with the definition of technology as 'private property' in a capitalistic economy."[37]

Of course, Merton's classic account of the communal norms of academic science has been subject to critique. Commentators argue that Merton's norms are more "prescriptive" than "descriptive"[38] and note that academic science has always exhibited secrecy, rivalry, and noncommunitarian incentives.[39] Indeed, generalizations are difficult in this realm, for some institutions and scientists embraced patenting even in the early twentieth century. Some observers have disputed not the existence of academic sharing norms, but rather the perceived incompatibility of these norms with patents. Ironically, some early commentators cited the tenacity of communal norms as a safeguard that weighed in *favor* of patenting university discoveries; because scientists were so committed to disinterested inquiry, they argued, it was unlikely that patents and profit motives would adulterate research agendas.[40]

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34. *Id.* at 270–78; Etzkowitz, *supra* note 23, at 14; *see also* Rai, *supra* note 7, at 89 (noting that other sociologists of science, such as Bernard Barber and Warren Hagstrom, came to similar conclusions).

35. MERTON, *supra* note 33, at 273.

36. *Id.*; *see* Eisenberg, *supra* note 7, at 1047.

37. MERTON, *supra* note 33, at 275; *see* Margo Bagley, *Academic Discourse and Proprietary Rights: Putting Patents in Their Proper Place*, 47 B.C. L. REV. 217, 226–27 (2006) (describing traditional norms of openly disclosing research results).

38. F. Scott Kieff, *Facilitating Scientific Research: Intellectual Property Rights and the Norms of Science—A Response to Rai and Eisenberg*, 95 NW. U. L. REV. 691, 697 (2001); *see* Greenbaum, *supra* note 18, at 328–29; *see also* Eisenberg, *supra* note 7, at 1048 n.128.

39. *See* Greenbaum, *supra* note 18, at 328–29 ("[T]he modem science establishment has long had the anti-Mertonian vices of secrecy, rivalry, and inducements outside of noble curiosity and concern for social welfare." (footnote omitted)); Merges, *supra* note 7, at 147 ("The many limitations on truly public dissemination lead, in fact, to the conclusion that science is not so much given freely to the public as shared under a largely implicit code of conduct among a more or less well-identified circle of similarly situated scientists.").

40. *See* C.J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES 212 (1930).

Although subject to some debate, there is little doubt that academic norms of open disclosure and communal sharing informed universities' early resistance to patenting. In the early twentieth century, many actors in academic science looked down upon patenting.[41] Jacques Loeb of the Rockefeller Foundation, for example, warned that "if the institutions for pure science go into the handling of patents I am afraid pure science will be doomed."[42] The foundation even threatened to stop funding the research of UC Berkeley's Herbert Evans if he tried to benefit financially from his research through patents.[43] Following World War I, there was an international movement, primarily based in Europe, to protect "scientific property" with exclusive rights.[44] Tellingly, however, this movement never gained much traction in the United States, and several committees of the National Research Council rejected the feasibility and desirability of establishing rights to scientific property.[45]

Based in part on these traditional scientific norms, university scientists in the early twentieth century rarely patented their discoveries.[46] Instances of patenting occasionally arose, however, and the first wave of meaningful university patenting occurred after

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41. *See, e.g.*, Etzkowitz, *supra* note 23, at 396 (describing the debate over patent policy at the Massachusetts Institute of Technology (MIT) in the 1930s); Daniel J. Kevles, *Principles, Property Rights, and Profits: Historical Reflections on University/Industry Tensions*, 8 ACCOUNTABILITY IN RES. 293, 295 (2001) ("Many [professors] had long contended, likely with the support of their administrators, that university science should be unadulterated by commercial considerations."); Rai, *supra* note 7, at 88 (noting that communal norms largely governed the scientific community prior to 1980).

42. Charles Weiner, *Universities, Professors, and Patents: A Continuing Controversy*, TECH. REV., Feb.–Mar. 1986, at 33, 35; *see also* MATKIN, *supra* note 24, at 56.

43. BOK, *supra* note 28, at 139.

44. *See, e.g.*, HAMSON, *supra* note 40, at 6; STEPHEN P. LADAS, THE INTERNATIONAL PROTECTION OF INDUSTRIAL PROPERTY 844–72 (1930); Stephen B. Ladas, *The Efforts for International Protection of Scientific Property*, 23 AM. J. INT'L L. 552, 552–53 (1929); John H. Wigmore & Francesco Ruffini, *Scientific Property*, 22 ILL. L. REV. 355, 355 (1927).

45. Letter from Albert L. Barrows, Assistant Sec'y, Nat'l Acad. of Sci., to Dr. William Allen Pusey (Nov. 5, 1931) (on file with the *Duke Law Journal*); Letter from Vernon Kellogg, Permanent Sec'y, Nat'l Acad. of Sci., to J. David Thompson, Sec'y, Am. Comm. on Int'l Intellectual Cooperation, Nat'l Research Council (May 2, 1928) (on file with the *Duke Law Journal*).

46. Mowery & Sampat, *supra* note 31, at 781; Charles Weiner, *Patenting in Academic Research: Historical Case Studies*, 12 SCI. TECH. & HUMAN VALUES 50, 50 (1987); *see* Elizabeth Popp Berman, *Why Did Universities Start Patenting? Institution-Building and the Road to the Bayh-Dole Act*, 38 SOC. STUD. SCI. 835, 841 (2008) (noting that "university patenting was clearly not institutionalized by the late 1960s").

World War I.[47] In the early twentieth century, scientific norms against exclusive rights in academic discoveries merged with institutional norms of serving the public interest to define a uniquely noncommercial approach to university patenting.

3. *University Patenting Policies*. Early patent policies on the part of universities reveal a unique academic skepticism of patents. To begin, many universities had no official patent policy prior to World War II,[48] thus illustrating the peripheral status of intellectual property within academia. Even though the University of California required employees to report patentable inventions to the university starting in 1926,[49] it did not adopt a formal patent policy until 1943.[50] Even more revealing, early patent policies heavily emphasized using patents to serve the public interest. Although a 1925 policy from Columbia University noted the university's objective of financially benefitting from patents, it also stressed the importance of monitoring the quality of manufactured articles and ensuring that the public could obtain them at reasonable prices.[51] The Massachusetts Institute of Technology's (MIT) first patent-ownership policy from 1932 was typical in stating that the university "shall hold and administer these rights for the ultimate benefit of the public."[52]

Universities were particularly reluctant to use patents to restrict access to health-related technologies. Harvard University decided in the 1920s to refuse to profit from faculty research in public health and therapeutics.[53] Its 1934 patent policy stated, "No patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President

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47. Mowery & Sampat, *supra* note 31, at 783.

48. *Id.* at 789.

49. David C. Mowery, Richard R. Nelson, Bhaven N. Sampat & Arvids A. Ziedonis, *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 102 (2001).

50. MATKIN, *supra* note 24, at 62.

51. *The Administration of Patents by Columbia University*, 61 SCIENCE 382, 383 (1925); *see also* Archie M. Palmer, *Medical Patents*, 137 JAMA 497, 498 (1948) ("Patenting [medical] discoveries is not considered to be wrong in itself, but to be desirable in order to control them in the public interest.").

52. MATKIN, *supra* note 24, at 62. This policy also cautioned against unduly encouraging faculty members to engage in invention at the expense of other academic duties. Henry Etzkowitz, *Knowledge as Property: The Massachusetts Institute of Technology and the Debate over Academic Patent Policy*, 32 MINERVA 383, 399 (1994).

53. Sally Smith Hughes, *Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology*, 92 ISIS 541, 547 (2001).

and Fellows; nor will such patents be taken out by the University itself except for dedication to the public."[54] Similarly, Yale University's 1934 policy stated that "it is, in general, undesirable and contrary to the best interests of medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine."[55] An influential 1948 survey of patent policies confirmed similar policies at leading universities.[56] According to the survey, many scientists felt that "the results of their research, both patentable and otherwise, should be shared 'without fee or stipulation.'"[57]At Harvard, Johns Hopkins, Columbia, and Chicago, policies against patenting biomedical discoveries lasted until the 1970s.[58]

4. *University Patenting Practices*. Case studies of university patenting in the early twentieth century reveal deep anxiety over blending academia and commerce as well as a commitment to utilizing patents to serve the public interest. In 1907, Frederick Cottrell at UC Berkeley invented the electrostatic precipitator, a filtration device that removes harmful particles from flowing gases. In a rather novel move, he patented his discovery.[59] He did not, however, assign his patent to UC Berkeley, for Cottrell was wary of the impact of patenting and licensing on scientific culture.[60] For its part, the university was concerned that its charter did not permit involvement in commercial ventures.[61] In 1912, motivated largely by a desire to separate the university from commercial concerns, Cottrell established an independent firm called Research Corporation to

54. MATKIN, *supra* note 24, at 69. Over the next forty years, "Harvard took out perhaps a half-dozen patents, dedicating all of them to the public." Kevles, *supra* note 41, at 296.

55. Palmer, *supra* note 51, at 500. The policy, however, did allow patenting on a case-by-case basis when necessary to protect the public interest as long as profits would not accrue to the scientist or the university. *Id*.

56. *Id.* at 498.

57. *Id.*

58. Mowery & Sampat, *supra* note 31, at 791. At Harvard, this policy was only altered when the university entered into a sponsored research agreement with Monsanto, which received the right to secure exclusive licenses for all inventions arising from such research. *See* MARTIN KENNEY, BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX 58–60 (1986) (describing the agreement between Harvard Medical School and Monsanto). In 1975, Harvard adopted a new patent policy that "implicitly abandoned its commitment to dedicate patents in medical therapeutics and public health to the public." Kevles, *supra* note 41, at 299.

59. U.S. Patent No. 895,729 (filed July 9, 1907).

60. Sampat, *supra* note 31, at 774.

61. Weiner, *supra* note 46, at 51.

manage his patents.[62] Consistent with its academic origins, Research Corporation channeled whatever licensing revenues it generated back into funding scientific research.

Academic, noncommercial norms also surrounded T. Brailsford Robertson's patenting of tethelin. A decade after Cottrell, Robertson, also of UC Berkeley, discovered tethelin, a substance that promotes human tissue growth. He patented his invention[63] and assigned his rights to the university, thus producing what may have been the first patents owned by the University of California.[64] The Board of Regents of the University of California was initially reluctant to take the patents because of the perceived impropriety of a public university contracting with private firms.[65] Indeed, this arrangement was so novel that *Science* magazine declared that it "should be subjected to careful scrutiny and the fullest possible criticism."[66] Ultimately, the Regents established an independent patent-management corporation, naming themselves as trustees, rather than taking title in the university itself.[67] Throughout, Robertson and the university stressed their intention to use the patents to serve the public interest.[68] Among other objectives, patenting would ensure that the University of California could monitor the quality of tethelin-based therapies,[69] thus safeguarding patient health. Notwithstanding these lofty goals, Robertson's plan elicited significant criticism from an academic community deeply suspicious of patents.[70] Johns Hopkins University later rejected Robertson as a candidate for a chair in physiology in part because he had patented tethelin.[71]

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62. MATKIN, *supra* note 24, at 59–60; *see* F.G. Cottrell, *Patent Experience of the Research Corporation*, 28 TRANSACTIONS AM. INST. CHEM. ENGINEERS 222, 222–23 (1932).

63. U.S. Patent No. 1,218,472 (filed Oct. 8, 1915). Robertson also obtained British patent rights. U.K. Patent No. GB15683 (filed Nov. 6, 1915).

64. MATKIN, *supra* note 24, at 59.

65. Weiner, *supra* note 46, at 52.

66. T. Brailsford Robertson, *The Utilization of Patents for the Promotion of Research*, 46 SCIENCE 371, 372 (1917).

67. *See* Rima D. Apple, *Patenting University Research: Harry Steenbock and the Wisconsin Alumni Research Foundation*, 80 ISIS 375, 382 (1989).

68. *See* Robertson, *supra* note 66, at 371; Charles Weiner, *Science in the Marketplace: Historical Precedents and Problems*, *in* FROM GENETIC EXPERIMENTATION TO BIOTECHNOLOGY—THE CRITICAL TRANSITION 123, 125 (William J. Whelan & Sandra Black eds. 1982).

69. *See* Robertson, *supra* note 66, at 376.

70. Weiner, *supra* note 46, at 52.

71. BOK, *supra* note 28, at 139. Of course, not all academics opposed patenting. *See, e.g.*, B.S. Hedrick, *On Patent Laws as a Means for the Advancement of Science*, 1 SCIENCE 166

The patenting of an antitoxin for scarlet fever also aroused considerable controversy. During World War I, researchers George and Gladys Dick of the University of Chicago developed an antitoxin for the bacterial toxin that causes scarlet fever.[72] Concerned that low-quality imitations of their product could jeopardize patient health, the Dicks decided to patent their discovery.[73] After the American Medical Association declined to take the patents, the Dicks created an independent, nonprofit Scarlet Fever Committee to manage them.[74] Nonetheless, the Dicks received intense criticism from the medical community. In the 1920s, numerous editorials and articles criticized their decision to patent a substance with great therapeutic value.[75]

The patenting of insulin further reflects academic skepticism of patents and the altruistic manner in which universities tried to use them. In 1923, researchers at the University of Toronto patented a method of making insulin and assigned it to the university.[76] The decision to patent insulin was highly controversial and clashed with traditional norms discouraging the privatization of research discoveries.[77] In making this decision, the researchers were influenced by the University of Minnesota's patenting of thyroxin, which allowed the university to safeguard the commercial manufacture of related therapeutics.[78] Following this model, the University of Toronto established an "insulin committee" in 1922 to manage the patent even

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(1880). Land-grant universities, which have a particularly applied orientation, were more open to patenting. Furthermore, patents in engineering aroused less suspicion than those in health and medicine.

72. Weiner, *supra* note 46, at 52.

73. *Id.* at 53.

74. *Id.*

75. *Id.*; *see, e.g.*, George F. Dick & Gladys Henry Dick, Correspondence, *The Patents in Scarlet Fever Toxin and Antitoxin*, 88 JAMA 1341, 1341–42 (1927); *Ethics and Patents*, 16 AM. J. PUB. HEALTH 919 (1926).

76. U.S. Patent No. 1,469,994 (filed Jan. 12, 1923).

77. Maurice Cassier & Christiane Sinding, *'Patenting in the Public Interest:' Administration of Insulin Patents by the University of Toronto*, 24 HIST. & TECH. 153, 154 (2008); *see* Etzkowitz, *supra* note 52, at 383–84 (indicating that "large profits, public health and the reputation of the university were at stake" and that problems regarding the "creation of the private ownership of knowledge" needed resolution).

78. Cassier & Sinding, *supra* note 77, at 154–55. The inventors who patented thyroxin sold their rights to the University of Minnesota on the condition that the university manage the commercialization of the patent to serve the interests of the medical profession. *Id.* Accordingly, the university established a committee to manage the patent and "retained . . . strict control over the preparation, sale, and price of thyroxin" once it was licensed. *Id.* at 155. At the University of Toronto, the researchers declined to take any revenues from the insulin patent and assigned their rights to the university for one dollar each. Kevles, *supra* note 41, at 296.

before it was granted.[79] The university was wary of monopolies on manufacturing insulin, so after granting Eli Lilly a one-year exclusive license for experimental development,[80] the university nonexclusively and widely licensed the patent.[81] In so doing, the university used the patent as "a tool to discipline the industrial world, to organize the distribution and use of the new drug, and to guarantee its accessibility."[82] Indeed, the university exploited its normative leverage as a public, academic institution in negotiations with commercial licensees.[83] Ultimately, this "democratization of industrial property" facilitated the wide availability of manufactured insulin.[84]

The University of Wisconsin's patenting practices reveal both the public-minded nature of academic patenting as well as the high standard of conduct expected of academic entities. In the 1920s, university researcher Harry Steenbock invented a process for irradiating food with ultraviolet light, thus enhancing its vitamin D content.[85] Steenbock's process represented a promising treatment for rickets, a disease caused by vitamin D deficiency that particularly afflicted poor populations.[86] Quite controversially,[87] Steenbock obtained four patents related to irradiation technology.[88] Steenbock's motivations for patenting ranged from the altruistic to the parochial. On the one hand, he was influenced by the University of Toronto's experience with insulin to utilize patents to ensure the "safest, most healthful dissemination" of irradiated foods.[89] Additionally, he sought

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79. Cassier & Sinding, *supra* note 77, at 155; Kevles, *supra* note 41, at 293–94.

80. Blumenthal, *supra* note 29, at 2452.

81. MATKIN, *supra* note 24, at 60; Cassier & Sinding, *supra* note 77, at 155.

82. Cassier & Sinding, *supra* note 77, at 156.

83. *Id.* at 166.

84. *Id.* at 160.

85. Weiner, *supra* note 46, at 55–57.

86. *Id.* at 55.

87. *See* Apple, *supra* note 67, at 378–79; Mowery & Sampat, *supra* note 31, at 788; Weiner, *supra* note 46, at 56.

88. U.S. Patent No. 2,057,399 (filed May 14, 1932); U.S. Patent No. 1,871,136 (filed Dec. 27, 1926); U.S. Patent No. 1,871,135 (filed Dec. 27, 1926); U.S. Patent No. 1,680,818 (filed June 30, 1924).

89. Apple, *supra* note 67, at 377; *see* Harry Steenbock & A. Black, *Fat-Soluble Vitamins: The Induction of Growth-Promoting and Calcifying Properties in a Ration by Exposure to Ultra-Violet Light*, 61 J. BIOLOGICAL CHEMISTRY 405, 405 (1924) ("[T]o protect the interest of the public in the possible commercial use of these findings, applications for Letters Patent, both as to processes and products, have been filed with the United States Patent Office . . . ."); Harry Steenbock, *The Induction of Growth Promoting and Calcifying Properties in a Ration by Exposure to Light*, 60 SCIENCE 224, 225 (1924) (stating the same).

to preempt "patent pirates" who would patent inventions related to his discovery and then charge exorbitant fees for their application.[90] Furthermore, he aimed to generate licensing royalties to fund further research.[91] On the other hand, Steenbock also sought to use patents to protect the local dairy industry in Wisconsin by keeping irradiation technology away from manufacturers of oleomargarine, the "butter of the poor."[92] Although some of his motivations were self-interested, Steenbock felt that as a scientist, he should distance himself and the university from the commercial, profit-making aspects of patenting.[93] For this and other reasons,[94] Steenbock helped create the Wisconsin Alumni Research Foundation (WARF), an independent entity that manages the university's patents.[95] Tellingly, Steenbock initially refused to accept any share of royalties.[96] In its rather sharp business practices, WARF was the exception that proved the rule regarding the norms of academic patenting. WARF received significant criticism for its hard-nosed business arrangements and threats of patent enforcement,[97] which were all the more controversial given that they diverged from traditional academic patent practices.

5. *The Institutional Structure of University Patenting and Licensing*. Universities' unease with patenting further manifested itself in the institutional separation of academic and patenting functions. The perceived impropriety of mixing academia and commerce, as well as the difficulty of managing patents, discouraged

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90. Apple, *supra* note 67, at 377. Patent "piracy" was a commonly perceived problem in the early years of university patenting. *See* Mowery & Sampat, *supra* note 31, at 784.

91. Apple, *supra* note 67, at 377.

92. *Id.* at 377–78.

93. *Id.* at 380; *see* RIMA APPLE, VITAMANIA: VITAMINS IN AMERICAN CULTURE 42 (1996).

94. In addition, Steenbock had had some rather frustrating experiences with university administration in the past. Apple, *supra* note 67, at 381–83.

95. Weiner, *supra* note 68, at 127–28.

96. Apple, *supra* note 67, at 388. Steenbock later relented, partly at the urging of WARF, which argued that other inventors would not assign their patents to WARF without such inducement. *Id.*

97. *See* Etzkowitz, *supra* note 52, at 389; *see also* Mowery & Sampat, *supra* note 31, at 788; H.A. Toulmin, Jr., *Commercial Research by Universities Threatens Science and Education*, PRODUCT ENGINEERING, June 1947, at 81, 82–82 (criticizing WARF for exploiting publicly sponsored technology while not granting licenses for products outside of the dairy industry); Weiner, *supra* note 46, at 56–57 (describing a 1943 U.S. Senate subcommittee hearing during which WARF was accused of abusing its patent rights); *Monopoly On Vitamin D Charged, Official Denounces Research Foundation*, DESERET NEWS (Salt Lake City), Oct. 21, 1943, at 5.

universities from directly handling patenting and licensing.[98] Accordingly, early forays into the patent system were marked by functional segregation. As noted, Cottrell created Research Corporation largely to insulate the University of California from the commercial aspects of patenting.[99] In 1937, MIT signed an invention administration agreement with Research Corporation for similar reasons,[100] and dozens of other universities followed suit.[101] As described above, the University of California did not take title to Robertson's tethelin patent directly but created an independent corporation to manage it.[102] Finally, the WARF model proved very influential; by 1956 there were more than fifty similar, separately incorporated organizations handling university patents.[103] As these examples demonstrate, anxiety over integrating universities into the patent system manifested itself even in the institutional structure of academic patenting.

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In norms, policy, and practice, universities and university scientists sought to distance themselves from the commercial aspects of patents while utilizing exclusive rights to serve the public good. Throughout much of the twentieth century, universities shied away from direct involvement in patenting and licensing "because of fears that such involvement might compromise, or might be seen as compromising, their commitments to open science and their institutional missions to advance and disseminate knowledge."[104] University entities were reluctant to patent scientific discoveries, particularly in the realm of health and medicine. Jonas Salk, the University of Pittsburgh researcher who developed the polio vaccine, famously declined to patent his discovery, noting, "Who owns my

98. Berman, *supra* note 46, at 842; Mowery & Sampat, *supra* note 31, at 782, 787; Palmer, *supra* note 51, at 508. Cottrell warned that any institution dealing with licensees "cannot avoid being eventually drawn into every phase of the problem" of technological development. Cottrell, *supra* note 62, at 225.

99. *See* Mowery & Sampat, *supra* note 31, at 791.

100. Etzkowitz, *supra* note 52, at 403–04; Mowery & Sampat, *supra* note 31, at 788; Sampat, *supra* note 31, at 774–75.

101. Sampat, *supra* note 31, at 775.

102. *See supra* note 67 and accompanying text.

103. Apple, *supra* note 67, at 390.

104. Sampat, *supra* note 31, at 774.

polio vaccine? The people! Could you patent the sun?"[105] When universities did patent discoveries, they did so not simply to maximize revenues, but to ensure product safety, prevent patent piracy, and disseminate technologies widely to the public.[106] Furthermore, institutional segregation helped buffer scientists and universities from the business of patents.

B. Patent Law Viewing Academic Science: Separation and Exceptionalism

While universities distanced themselves from patent law, patent doctrine also distanced itself from academic science. In several ways, patent courts created doctrinal hedges that tended to separate the fruits of academic science from the domain of exclusive rights.[107] In some contexts, patent doctrine further engaged in academic exceptionalism by treating university entities differently than other actors in the patent system. Such separation and exceptionalism arose from multiple factors, including a prudential desire to keep "upstream" discoveries in the public domain and to not burden nonprofit research with patents. Notably, they arose in part from courts' perception of the noncommercial character of university science. The communal, public-spirited norms of academic research and technological development helped inform a rhetorical vision of universities that helped justify—or at least rationalize—a hands-off approach to academic science. A stable equilibrium thus emerged between noncommercial patenting practices by university entities and academic exceptionalism in patent doctrine.

1. *Patentable Subject Matter*. The doctrinal separation of academic science from patent law is best illustrated in the law of

105. Sara Boettiger & Brian D. Wright, *Open Source in Biotechnology: Open Questions*, INNOVATIONS, Fall 2006, at 45, 48; *see also* Josephine Johnston & Angela A. Wasunna, *Patents, Biomedical Research, and Treatments: Examining Concerns, Canvassing Solutions*, HASTINGS CTR. REP., Jan.–Feb. 2007, at S2, S2. A significant funder of Salk's research, the National Foundation for Infantile Paralysis (now the March of Dimes), did not allow patents or the receipt of royalties for funded inventions. Seth Shulman, *Cashing in on Medical Knowledge*, MIT TECH. REV. Mar.–Apr. 1998, at 38, 42.

106. *See* Mowery & Sampat, *supra* note 31, at 784–85.

107. *Cf.* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 462 (2004) (arguing that a traditional distinction between basic and applied science was "essentially hardwired into law").

patentable subject matter.[108] Drawing on English antecedents,[109] U.S. doctrine has long prohibited patenting abstract principles and natural properties, thus excluding raw scientific discoveries from patentability.[110] In 1852, the Supreme Court observed:

> It is admitted, that a principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known. . . . The same may be said of electricity, and of any other power in nature, which is alike open to all, and may be applied to useful purposes by the use of machinery.[111]

The next year, Justice Grier, dissenting in the famous case of *O'Reilly v. Morse*,[112] stated:

> The mere discovery of a new element, or law, or principle of nature, without any valuable application of it to the arts, is not the subject of a patent. But he who takes this new element or power, as yet useless, from the laboratory of the philosopher, and makes it the servant of man . . . is the benefactor to whom the patent law tenders its protection.[113]

Lower courts reiterated this distinction between the "laboratory of the philosopher" and the domain of patentable technologies. In 1862, the Circuit Court of the Southern District of New York stated that patentable subject matter arises "beyond the mere domain of discovery," when an inventor has directed some principle, force, or

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108. *See* 35 U.S.C. § 101 (2006) (defining patentable subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof"). The statutory definition of patentable subject matter has remained largely unchanged over the history of the U.S. patent system.

109. Boulton v. Bull, (1795) 126 ENG. REP. 651, 667 (Ct. Com. Pl.) (opinion of Lord Eyre, C.J.) ("Undoubtedly there can be no patent for a mere principle."); *see* Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski*: History and Theory*, 63 HASTINGS L.J. 53, 63 (2011).

110. Peter Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine To Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 92–98 (2005). The exclusion of abstract ideas and natural products from patentable subject matter tends to "force[] patents downstream, away from unfinished research and toward completed products or processes more suitable for the market." DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 124 (2009).

111. Le Roy v. Tatham, 55 U.S. (14 How.) 156, 174–75 (1853).

112. O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1854).

113. *Id.* at 132–33 (Grier, J., concurring in part and dissenting in part).

law to act on "the material world."[114] Similarly, in 1895, the Ninth Circuit held that employing a scientific discovery in the same fashion as it is applied in nature is not patentable.[115] Notably, the court invoked this distinction to invalidate three of WARF's irradiation patents in 1943, observing that the patent statute aimed to reward the "inventor," not the "pure scientist."[116]

The segregation of academic discoveries from the patent system was further corroborated by cases holding that natural phenomena are not eligible for patenting.[117] As the Supreme Court stated in 1948, "He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end."[118] Thus the passive observation of nature, a primary function of academic science, does not yield patentable subject matter.

Courts' traditional exclusion of natural laws, natural phenomena, and abstract principles from patentability arose from several rationales, at least some of which resonate with the traditional Mertonian norms discussed above.[119] For example, patentable subject matter doctrine reflected a communalistic theory of technological progress in which scientists and inventors could draw from a shared pool of upstream basic knowledge to further their research and develop downstream technologies.[120] As economist Richard Nelson observes, "For this reason scientists have long argued for free and wide communication of research results, and for this reason natural 'laws' and facts are not patentable."[121] This sentiment is reflected in

114. Morton v. N.Y. Eye Infirmary, 17 F. Cas. 879, 881 (C.C.S.D.N.Y. 1862) (No. 9865) (emphasis added).

115. Wall v. Leck, 66 F. 552, 558 (9th Cir. 1895) (citing 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS § 186 (Bos., Little, Brown & Co., 1890)).

116. Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 58 U.S.P.Q. (BNA) 293, 295 (9th Cir. 1943).

117. *See, e.g.*, Parke-Davis & Co. v. H.K. Mulford Co., 189 F. 95, 101 (S.D.N.Y. 1911); *Ex Parte* Latimer, 1889 Dec. Comm'r Pat. 123, 125 (1889); *see also* Hector M. Holmes, Book Review, 45 HARV. L. REV. 1428, 1432 (1932) (reviewing C.J. HAMSON, PATENT RIGHTS FOR SCIENTIFIC DISCOVERIES (1930)).

118. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); *see* Sarnoff, *supra* note 109, at 89.

119. *See supra* notes 32–37 and accompanying text.

120. *See* Peter Lee, *The Evolution of Intellectual Infrastructure*, 83 WASH. L. REV. 39, 63–68 (2008).

121. Richard R. Nelson, *The Simple Economics of Basic Scientific Research*, 67 J. POL. ECON. 297, 302 (1959).

patent decisions likening natural phenomena and abstract principles to "basic tools of scientific and technological work" that must remain in the public domain.[122]

Additionally, courts also justified excluding academic findings from patentability based on the noncommercial nature of academic research. As the Second Circuit observed in 1944,

> Epoch-making "discoveries" of "mere" general scientific "laws," without more, cannot be patented. So the great "discoveries" of Newton or Faraday could not have been rewarded with such a grant of monopoly. Interestingly enough, apparently many scientists like Faraday care little for monetary rewards; generally the motives of such outstanding geniuses are not pecuniary. Perhaps (although no one really knows) the same cannot be said of those lesser geniuses who put such discoveries to practical uses.[123]

In this regard, the Second Circuit invoked the Mertonian image of the financially disinterested scientist.[124] This image had some empirical support. The opinion cites scholarship by economist Paul Howard Douglas noting that prominent scientists such as Michael Faraday, James Maxwell, Charles Darwin, Louis Pasteur, and Louis Agassiz were not motivated by profits in their scientific research.[125] Rather, intellectual passion and a genuine excitement for discovery trumped other motivations.[126] The rhetorical trope of the noble, financially disinterested scientist thus provided another rationale for excluding natural laws and other academic discoveries from patentable subject matter.[127]

2. *Utility*. Moving beyond patentable subject matter, the doctrine of utility also tended to drive a wedge between academic science and

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122. Gottschalk v. Benson, 409 U.S. 63, 67 (1972); *see* Parker v. Flook, 437 U.S. 584, 591–92 (1978).

123. Katz v. Horni Signal Mfg. Corp., 145 F.2d 961, 961 (2d Cir. 1944) (footnotes omitted).

124. *See supra* notes 32–37 and accompanying text.

125. Paul H. Douglas, *The Reality of Non-Commercial Incentives in Economic Life*, *in* THE TREND OF ECONOMICS 153, 156–62 (1924).

126. Notably, nonfinancial incentives were important not only for traditional "men of science" but also for "'practical' scientists" working in industry. *Id*. at 173–74.

127. This perception that scientists are not motivated by profit continued to hold much sway. *See* Dickey-John Corp. v. Int'l Tapetronics Corp., 710 F.2d 329, 348 n.9 (7th Cir. 1983) ("Yet patent law has never been the domain of the abstract—one cannot patent the very discoveries which make the greatest contributions to human knowledge, such as Einstein's discovery of the photoelectric effect, nor has it ever been considered that the lure of commercial award provided by a patent was needed to encourage such contributions.").

the patent system.[128] While utility is a relatively low bar to patentability,[129] it has particular traction in the context of academic science. In *Brenner v. Manson*,[130] the Supreme Court ruled in 1966 that a process for producing chemical compounds of no known utility failed the substantial utility requirement of patentability.[131] The case does not deal with an academic invention per se. Notably, however, the process failed the utility requirement even though the chemicals it produced were under academic investigation for potential anticancer properties.[132] Evoking principles consistent with academic norms against privatizing foundational discoveries, the Court cautioned,

> Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.[133]

Citing the Second Circuit's decision in *Katz v. Horni Signal Manufacturing Corp.*, the Court further observed that "'[a] patent system must be related to the world of commerce rather than to the realm of philosophy.'"[134] Lower courts followed *Brenner*'s teaching that intermediates in the production of compounds of no known utility lack utility themselves.[135] Furthermore, courts extended this rationale to the disclosure requirements of patentability, reasoning that a patent application that does not disclose a utility also does not *enable* any claimed invention.[136] In a traditional mid-twentieth-century paradigm in which university research generally focused on upstream

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128. As Professors Dan Burk and Mark Lemley have observed, limitations on patentable subject matter worked "hand in hand" with utility doctrine to exclude upstream research tools from patents. BURK & LEMLEY, *supra* note 110, at 124.

129. *See* ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 211 (5th ed. 2011) ("The vast majority of patent applications are processed without the PTO raising any question as to utility, and the utility doctrine is also rarely litigated as a defense in infringement actions.").

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

131. *Id.* at 535–36.

132. *Id.* at 532.

133. *Id.* at 534 (footnote omitted).

134. *Id.* at 536 (quoting *In re* Ruschig, 343 F.2d 965, 970 (C.C.P.A 1965)) (citing Katz v. Horni Signal Mfg. Corp., 145 F.2d 961 (2d Cir. 1944)).

135. *In re* Joly, 376 F.2d 906, 908 (C.C.P.A. 1967); *In re* Kirk, 376 F.2d 936, 939 (C.C.P.A. 1967).

136. *See supra* note 135.

discoveries, the utility doctrine tended to restrict the patentability of academic inventions.

3. *The Common Law Experimental Use Exception*. Patent law erected boundaries between itself and academic science not only in doctrines governing patentability, but also in the law of infringement. The clearest example of such exceptionalism is the common law experimental use exception, which exempts from liability the unlicensed use of patented technology for noncommercial purposes.[137] Justice Story laid the foundation for this doctrine in the 1813 case of *Whittemore v. Cutter*,[138] in which he stated, "[I]t could never have been the intention of the legislature to punish a man, who constructed such a[n infringing] machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects."[139] Elsewhere, Justice Story equated infringing use of an invention with "the making with an intent to use for profit," in contradistinction with use for mere "philosophical experiment" or to confirm details contained in the patent specification.[140] This conception of experimental use proved highly influential;[141] one well-regarded 1890 treatise states that "no act [is] an infringement unless it affects the pecuniary interests of the owner of the patented invention."[142] Thus, by the end of the nineteenth century, "the issue of whether experimentation amounted to patent infringement seemed to have been clearly resolved"[143] in favor of experimenters.

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137. The experimental use exception has attracted significant scholarly attention. *See, e.g.*, Eisenberg, *supra* note 7; Rebecca S. Eisenberg, *Patent Swords and Shields*, 299 SCIENCE 1018 (2003); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1 (2001); Elizabeth A. Rowe, *The Experimental Use Exception to Patent Infringement: Do Universities Deserve Special Treatment?*, 57 HASTINGS L.J. 921 (2006); Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81. The experimental use exception has rarely been a successful defense in patent litigation. *See, e.g.*, Rowe, *supra*, at 926 n.18 (finding only four cases in which accused infringers successfully claimed experimental use as a defense).

138. Whittemore v. Cutter, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600).

139. *Id.* at 1121; *see* Dreyfuss, *supra* note 107, at 458; Strandburg, *supra* note 137, at 84.

140. Sawin v. Guild, 21 F. Cas. 554, 555 (C.C.D. Mass. 1813) (No. 12,391); *see also* Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

141. Mueller, *supra* note 137, at 20.

142. 3 ROBINSON, *supra* note 115, § 898; *see* Mueller, *supra* note 137, at 20–21.

143. Dreyfuss, *supra* note 107, at 457–58.

The vast majority of cases involving the experimental use exception do not involve *academic* experimentation with patented inventions per se.[144] However, one early case suggested that use of a patented invention for academic research qualified for the safe harbor. In *Ruth v. Stearns-Roger Manufacturing*,[145] the Stearns-Roger Manufacturing Company was found to have infringed a patent related to mining technology.[146] In conducting an accounting, however, the district court excluded sales of materials to the Colorado School of Mines that could be used to make an infringing device. The court concluded that some of these parts "were for use in laboratory machines used for experimental purposes, and consequently did not contribute to an infringing use."[147] The court went on to note that "[t]he making or using of a patented invention merely for experimental purposes, without any intent to derive profits or practical advantage therefrom, is not infringement."[148] Although this is a singular case, it suggests a privileged status for university research based on its noncommercial nature. Whether or not this approach was correct as a doctrinal matter, for several decades, many university scientists *believed* that the experimental use exception immunized nonprofit-university research from infringement.[149] Indeed, "most academic institutions freely infringed patents" until the Federal Circuit revisited this issue again in the early twenty-first century.[150]

4. *Remedies*. Though more speculative, there is one prominent case involving a court extending rather exceptional treatment to a university patentee in the context of remedies. In *Vitamin Technologists, Inc. v. Wisconsin Alumni Research Foundation*,[151]

144. *See, e.g.*, Chesterfield v. United States, 159 F. Supp. 371, 376 (Ct. Cl. 1958); Dugan v. Lear Avia, Inc., 55 F. Supp. 223, 229 (S.D.N.Y. 1944); Akro Agate Co. v. Master Marble Co., 18 F. Supp. 305, 333 (N.D. W. Va. 1937); Standard Measuring Mach. Co. v. Teague, 15 F. 390, 392–93 (C.C.D. Mass. 1883).

145. Ruth v. Stearns-Roger Mfg. Co., 13 F. Supp. 697 (D. Colo. 1935).

146. *Id.* at 699; *see* Jeffrey R. Armstrong, *Bayh-Dole Under Siege: The Challenge to Federal Patent Policy as a Result of* Madey v. Duke University, 30 J.C. & U.L. 619, 627 (2004); *see* Eisenberg, *supra* note 137, at 1018.

147. *Ruth*, 13 F. Supp. at 703.

148. *Id.* at 713.

149. Ed Ergenzinger & Murray Spruill, *Basic Science in U.S. Universities Can Infringe Patents*, SCIENTIST, Mar. 10, 2003, at 43, 43; Ronald D. Hantman, *Experimental Use as an Exception to Patent Infringement*, 67 J. PAT. & TRADEMARK OFF. SOC'Y 617, 633 (1985).

150. Rowe, *supra* note 137, at 928.

151. Vitamin Technologists, Inc. v. Wis. Alumni Research Found., 146 F.2d 941 (9th Cir. 1944).

WARF sued Vitamin Technologists for infringing the irradiation patents of University of Wisconsin researcher (and WARF co-founder) Harry Steenbock.[152] The Ninth Circuit ruled for the defendants, invalidating all or portions of Steenbock's three patents.[153] In doing so, however, the court also made several influential statements on the inappropriateness of injunctive relief in that case. The subtext of the case was that WARF sought to enjoin Vitamin Technologists' irradiation of oleomargarine to protect Wisconsin's dairy interests. Such enforcement would have disproportionately harmed poor communities, which favored the less expensive oleomargarine over butter itself.[154] Considering all these factors, the court noted that injunctive relief would have been inappropriate:

> The evidence and appellee's briefs are replete with well verified statements of the great boon to humanity of Dr. Steenbock's scientific discoveries for the prevention and cure of rickets. The truth of such statements make the stronger the contention that it is a public offense to withhold such processes from any of the principal foods of the rachitic poor, or, indeed, from those of any such sufferers.[155]

This dictum suggested that WARF's patents should not constrain access to an important discovery with great potential to enhance social welfare. This rationale was at odds with prevailing Supreme Court doctrine at the time, which held that patentees had no obligation to use (or license) their patents.[156] Though a singular instance—and one should not infer too much—this case represents a prominent example of a court eschewing strict enforcement of a university patent to serve the public interest.

* * *

In sum, there appears to be some reciprocity between norms and doctrine in the early history of university patenting. Scientific norms discouraged patenting, and universities sought to avoid the taint of commercialism in their early patent practices. In reciprocal fashion, in a variety of doctrinal areas, patent courts historically excluded the

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152. *Id.* at 941.
153. *Id.* at 941, 949, 951–52.
154. *Id.* at 943–44.
155. *Id.* at 945.
156. *See* Cont'l Paper Bag Co. v. E. Paper Bag Co., 210 U.S. 405, 429 (1908).

fruits of academic science from patentability or treated academic entities differently from commercial actors. Notably, these doctrinal hedges significantly paralleled the traditional academic and public-interest norms that governed university science. The outputs of basic research did not comprise patentable subject matter partly because retaining these resources in the public domain would best promote technological progress. Furthermore, patents and associated profit motives were not necessary to motivate academics to generate such discoveries, thus weighing against extending patent protection to such discoveries. Additionally, courts were reluctant to extend infringement liability to academic research, which was noncommercial in nature. Ultimately, an integrated system emerged where prevailing academic norms and patent doctrine achieved a rough equilibrium. As we will see, this mutually segregating equilibrium based on noncommercial norms and academic exceptionalism would not last, and a very different one would take its place.

II. TRANSITION: PATENTS ENTER THE ACADEMY

This equilibrium began to shift as academic institutions started to vastly increase their patenting activity. Though most observers situate the rise of university patenting at the end of the twentieth century,[157] antecedents earlier in that century contributed to this development. To generate large numbers of patentable inventions, universities needed more significant sources of research funding than the private trusts and donations upon which they had historically relied. To this end, massive increases in federal science funding during World War II infused universities with money.[158] Key technological advances—from the mass production of penicillin to the Manhattan Project—helped win the war and revealed to policymakers the importance of large-scale science funding. Vannevar Bush, who served as chief science advisor to President Franklin D. Roosevelt, argued forcefully for

157. *See, e.g.*, Univ. of Colo. Found., Inc. v. Am. Cyanamid Co., 196 F.3d 1366, 1374 (1999) (noting that the Bayh-Dole Act, which was passed in 1980, "set the stage for modern university licensing").

158. *See* MATKIN, *supra* note 24, at 20; WASHBURN, *supra* note 12, at 121; Rosenberg & Nelson, *supra* note 15, at 334 ("World War II was a watershed in the history of American science and technology and, in particular, led to a dramatic change in the roles played by American universities in scientific and technical enterprises."). Actually, federal research funding had already increased sharply during World War I, which also saw the establishment of the National Research Council. MATKIN, *supra* note 24, at 18.

expansive science funding to continue after the war,[159] particularly in medicine and public health.[160] Federal science funding increased markedly in the first post-war decade and accelerated even faster in the late 1950s.[161]

Notably, increased funding of university science was not framed in an imperative of immediate commercialization. Bush fully expected federal funds to facilitate the development of medicines, labor-saving devices, and other applied technologies.[162] However, he rejected left-leaning calls for government to directly manage scientific research to satisfy immediate social and economic needs.[163] Rather, he championed undirected scientific work and "basic" research, which promised significant, though unpredictable, long-term benefits.[164] Accordingly, the orientation of university research shifted after World War II away from short-term problem solving toward addressing more fundamental issues.[165] Within this linear model of technological advance, federal funding and university research created an upstream "reservoir of knowledge" that would facilitate downstream technological development.[166] This linear model of scientific and technological progress paralleled philosopher of science Michael Polanyi's conception of an autonomous "republic of science" that would receive public support but remain insulated from political, social, and market influences.[167] It also resonated with traditional Mertonian norms of noncommercial academic research and communal progress.

As the Cold War waned, however, federal policy shifted. Policymakers began to deemphasize military superiority and focus

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159. *See* VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER 11, 31 (1945).

160. STEPHEN P. STRICKLAND, POLITICS, SCIENCE, AND DREAD DISEASE: A SHORT HISTORY OF UNITED STATES MEDICAL RESEARCH POLICY 22 (1972); Blumenthal, *supra* note 29, at 2453.

161. Mowery & Sampat, *supra* note 31, at 793.

162. BUSH, *supra* note 159, at 10–11.

163. *Id.* at 18.

164. *Id.*; Rosenberg & Nelson, *supra* note 15, at 335.

165. Lee, *supra* note 16, at 850.

166. Timothy L. Faley & Michael Sharer, *Technology Transfer and Innovation: Reexamining and Broadening the Perspective of the Transfer of Discoveries Resulting from Government-Sponsored Research*, COMP. TECH. TRANSFER & SOC'Y, Aug. 2005, at 109, 111 & fig.1. *See generally* BUSH, *supra* note 159.

167. *See* Polanyi, *supra* note 32, at 54, 56; *see also* Kevles, *supra* note 41, at 297–98 (arguing that the federal government's massive funding of academic research lessened universities' need to partner with industry and served to shore up antipatenting norms).

more on ensuring U.S. global economic competitiveness.[168] They began to question the linear theory of technological advance that largely segregated upstream academic research from downstream commercialization. A consensus emerged that knowledge flow between academic science and industry is bidirectional[169] and that innovation was best served by collaborative relationships spanning the "triple helix" of government, academia, and industry.[170] As a result, federal science policy began to focus more on downstream research, technology transfer, and commercialization.[171]

These policy shifts ultimately culminated in the Bayh-Dole Act ("the Act"). While the conventional view holds that the Act fueled a vast increase in university patenting, academic patenting was already on the rise at the time of its enactment.[172] Responding to criticisms that government-owned patents were not being commercialized,[173] the Department of Health, Education, and Welfare (HEW) had established a system of Institutional Patent Agreements (IPAs) in the late 1960s. Under IPAs, universities with approved technology transfer capabilities could retain title to patents on federally funded inventions and grant exclusive licenses to firms.[174] Indeed, policy shifts that threatened IPAs[175] helped motivate support for the Bayh-Dole Act by universities that *already* enjoyed the benefits of patenting federally funded inventions.[176]

HEW's policy changes fed into the broader debate over who should take title to patents arising from government-funded

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168. BOK, *supra* note 28, at 11.

169. Fiona Murray, *Innovation as Co-Evolution of Scientific and Technological Networks: Exploring Tissue Engineering*, 31 RES. POL'Y 1389, 1391 (2002).

170. *See* John M. Golden, *Biotechnology, Technology Policy, and Patentability: Natural Products and Invention in the American System*, 50 EMORY L.J. 101, 119–22, 132 (2001).

171. *Id.*

172. DAVID C. MOWERY, RICHARD NELSON, BHAVEN SAMPAT & ARVIDS ZIEDONIS, IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES 104 (2004). Public universities, which focused more on applied research and had incentives to provide a return on taxpayer investments, were more active in patenting than private institutions prior to the Bayh-Dole Act. *See* Mowery & Sampat, *supra* note 28, at 119.

173. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1691 (1996).

174. *Id.* at 1691–92; Mowery & Sampat, *supra* note 31, at 795.

175. *See* Berman, *supra* note 46, at 854; Eisenberg, *supra* note 173, at 1692; Mowery & Sampat, *supra* note 31, at 795.

176. *See* Colyvas et al., *supra* note 21, at 62; Sampat, *supra* note 31, at 780.

research.[177] For several decades, federal agencies pursued different approaches: some took title to patents themselves while others allowed grantees (such as universities) to take title to patents, reserving only a license for themselves.[178] In the late 1970s, concerns grew that government-owned patents were stifling innovation, as firms would not develop inventions into commercial products without possessing exclusive rights. Empirical evidence corroborated these concerns,[179] which were exacerbated by perceptions of lagging economic competitiveness relative to Europe and Japan.[180] Political momentum began to grow in favor of reforming federal policy governing the ownership of publicly funded inventions.

To spur the commercialization of these inventions, Congress passed the Bayh-Dole Act in 1980.[181] The Act allowed and encouraged small businesses and nonprofits that received government funds to take title to patents arising from federally funded research.[182] Congress enacted this legislation on the view that exclusive rights were necessary to motivate additional private investment to develop patented inventions into commercial products.[183] This made intuitive sense for small-business grantees that could themselves develop

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177. *See* Memorandum of Aug. 23, 1971, 36 Fed. Reg. 16,887 (1971); Memorandum of Oct. 10, 1963, 28 Fed. Reg. 10,943 (1963); U.S. DEP'T OF JUSTICE, 1 INVESTIGATIONS OF GOVERNMENT PATENT PRACTICES AND POLICIES: REPORT AND RECOMMENDATIONS OF THE ATTORNEY GENERAL TO THE PRESIDENT 2, 89–90 (1947).

178. *See generally* Eisenberg, *supra* note 173.

179. In the 1970s, the National Aeronautics and Space Administration (NASA) had a commercialization rate of less than 1 percent for inventions under its free-use policy but 18 to 20 percent for inventions for which contractors controlled patents. Aaron S. Kesselheim & Jerry Avorn, *University-Based Science and Biotechnology Products: Defining the Boundaries of Intellectual Property*, 293 JAMA 850, 851 (2005). The statistical case in favor of the Bayh-Dole Act is suspect, however, in light of significant selection bias. Eisenberg, *supra* note 173, at 1702–05.

180. *See* H.R. REP. NO. 96-1307, pt.1, at 1 (1980), *reprinted in* 1980 U.S.C.C.A.N. 6460, 6460–61; H.R. REP. NO. 96-1006, pt. 1, at 17 (1980); S. REP. NO. 96-480, at 1 (1979).

181. Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200–211 (2006)).

182. In 1984, President Reagan extended this policy to large business contractors, and Congress enacted this extension the same year. *See* Trademark Clarification Act of 1984, Pub. L. 98-620, § 501(13), 98 Stat. 3335, 3367–68 (codified at 35 U.S.C. § 210(c) (2006)); S. REP. NO. 98-662, at 2 (1984), *reprinted in* 1984 U.S.C.C.A.N. 5799, 5800; Memorandum to the Heads of Executive Departments and Agencies: Government Patent Policy, 1 PUB. PAPERS 248 (Feb. 18, 1983).

183. *See* Eisenberg, *supra* note 173, at 1669. This is, of course, a highly contested premise. Some university inventions—including certain research tools—do not require additional development for useful exploitation. In this context, patents may simply increase price and decrease access with little offsetting social gain.

patented inventions into commercial products. For universities, however, patents were seen as a necessary conduit for transferring federally funded technologies to the private sector for commercialization. While grantees certainly benefitted from the Act, federal funding agencies retained several rights in subject inventions. For example, under the Act, agencies can prevent grantees from taking title to patents in "exceptional circumstances."[184] Additionally, agencies receive a paid-up nonexclusive license to practice subject inventions[185] and can "march-in" to compulsorily license inventions in certain circumstances.[186] Ultimately, the Act represented a significant statutory and policy innovation.[187] Among other effects, it created enormous commercial opportunities for universities and reflected a public policy of greater engagement between academia, the patent system, and industry.[188]

In addition to legislative reforms, scientific advances and the changing nature of university research also helped accelerate academic patenting.[189] In particular, the birth of the biotechnology industry in university laboratories helped fuel this trend.[190] In the 1970s, Stanley Cohen of Stanford University and Herbert Boyer of the University of California at San Francisco (UCSF) developed and patented the pioneering techniques of recombinant DNA

184. 35 U.S.C. § 202(a) (2006).

185. *Id.* § 202(c)(4).

186. *Id.* § 203.

187. *See* Croissant & Smith-Doerr, *supra* note 16, at 693 (characterizing the 1980 passage of the Bayh-Dole Act as marking a new "pivotal phase" in university-industry research relationships); Dreyfuss, *supra* note 107, at 464.

188. The Bayh-Dole Act was not the only legislation that helped encourage university patenting. *See* Tax Reform Act of 1986, Pub. L. No. 99-514, 100 Stat. 2085 (codified as amended in scattered sections of 26 U.S.C. (2006 & Supp. V 2011)) (expanding universities' ability to conduct industry-sponsored research while maintaining tax-exempt status); Federal Technology Transfer Act of 1986, Pub. L. No. 99-502, § 12, 100 Stat. 1785, 1785 (codified as amended at 15 U.S.C. § 3710a (2006)) (enabling cooperative research and development agreements between private entities and federal laboratories); Stevenson-Wydler Technology Innovation Act, Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at scattered sections of 15 U.S.C. (2012)) (promoting the patenting and licensing of taxpayer-funded inventions at federal laboratories).

189. *See* Richard Nelson, *Observations on the Post-Bayh-Dole Rise of Patenting at American Universities*, 26 J. TECH. TRANSFER 13, 14 (2001).

190. Colyvas et al., *supra* note 21, at 61–62; Mowery & Sampat, *supra* note 31, at 793–94. *See generally* Greenbaum, *supra* note 18, at 343–46.

technology.[191] Biotechnology generated enormous enthusiasm on university campuses, as it promised significant therapies and large revenues for academic patentees.[192] It also sparked increased industrial support for university research. Between 1980 and 1983, pharmaceutical companies contributed $140 million to research conducted at thirteen universities.[193] By 1990, genetic engineering and recombinant DNA represented the technological class in which universities owned the highest proportion of patents.[194]

The emergence of biotechnology also reflected a shift in the nature of university research. Toward the end of the twentieth century, university researchers, particularly in the life sciences, developed greater facility (and interest) in moving beyond the passive observation of nature to actively manipulating the basic building blocks of life. More broadly, much contemporary academic research in the life sciences proceeds in "Pasteur's Quadrant": although it seeks to elucidate "basic" knowledge, it also has immediate practical implications.[195] Due to the changing nature of university research, even basic investigations can yield outputs that directly or with little modification satisfy legal definitions of patentability.

Developments in the patent system also spurred greater university patenting. In 1980, the Supreme Court held in *Diamond v. Chakrabarty*[196] that a genetically engineered bacterium comprised patentable subject matter.[197] In so doing, the Court articulated an expansive conception of patentable subject matter[198] that encompassed many of the fruits of the nascent biotechnology field (as

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191. *See generally* Stanley N. Cohen, Annie C.Y. Chang, Herbert W. Boyer & Robert B. Helling, *Construction of Biologically Functional Bacterial Plasmids* In Vitro, 70 PROC. NAT'L ACAD. SCI. 3240 (1973); Hughes, *supra* note 53.

192. Nicholas S. Argyres & Julia Porter Liebeskind, *Privatizing the Intellectual Commons: Universities and the Commercialization of Biotechnology*, 35 J. ECON. BEHAV. & ORG. 427, 434 (1998). Notably, this vast commercial potential was based upon federally funded research. KENNEY, *supra* note 58, at 241.

193. Blumenthal, *supra* note 29, at 2453.

194. Rosenberg & Nelson, *supra* note 15, at 339.

195. *See generally* DONALD E. STOKES, PASTEUR'S QUADRANT: BASIC SCIENCE AND TECHNOLOGICAL INNOVATION (1997); Francis Narin, Kimberly S. Hamilton & Dominic Olivastro, *The Increasing Linkage Between U.S. Technology and Public Science*, 26 RES. POL'Y 317, 317 (1997); Rosenberg & Nelson, *supra* note 15, at 324.

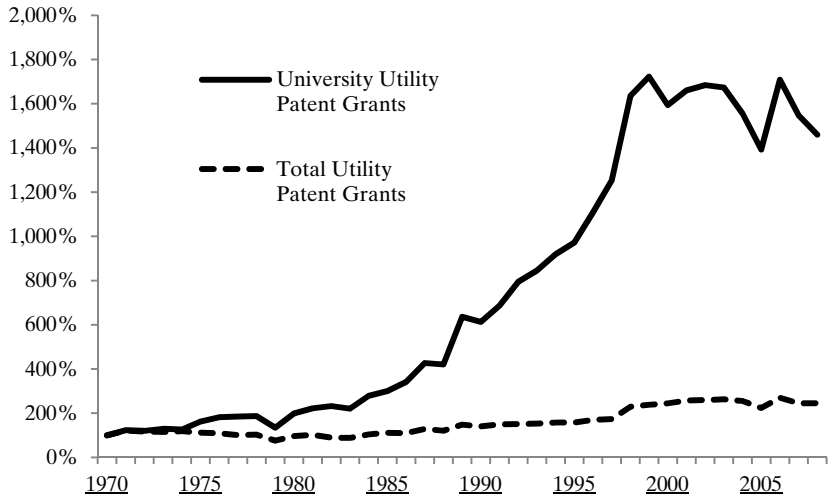
196. Diamond v. Chakrabarty, 447 U.S. 303 (1980).

197. *Id.* at 303.

198. *See id.* at 309 (suggesting that "'anything under the sun that is made by man'" is eligible for patenting (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399)).

well other fields, such as computer science).[199] As discussed further below, this and other decisions widened the door for university patents.[200] Furthermore, just two years after *Chakrabarty*, Congress established the Court of Appeals for the Federal Circuit,[201] which soon emerged as "a strong champion of patentholder rights."[202] The Federal Circuit helped create a climate even more conducive to filing patent applications, including those from university scientists.

Figure 1. Annual Utility Patent Grants As a Percentage of Utility Patent Grants in 1970 (1970–2008)[203]



	1970	1975	1980	1985	1990	1995	2000	2005
University Utility Patent Grants	198	321	394	594	1,214	1,925	3,155	2,757
Total Utility Patent Grants	64,429	72,000	61,819	71,661	90,365	101,419	157,494	143,806

199. *See* MOWERY ET AL., *supra* note 172, at 103; Bagley, *supra* note 37, at 235.

200. *See infra* notes 312–18 and accompanying text.

201. *See* Bagley, *supra* note 37, at 231; Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64 N.Y.U. L. REV. 1, 3 (1989).

202. MOWERY ET AL., *supra* note 172, at 103.

203. U.S. PATENT & TRADEMARK OFFICE, UNIVERSITY-EXTENDED: NUMBER OF PATENTS GRANTED BY YEAR OF PATENT GRANT, BREAKOUT BY COUNTRY OF ORIGIN (TABLE A1-1A) AND BY OWNERSHIP CATEGORY (TABLE A1-1B) (2013) (on file with the *Duke Law Journal*); Patent Tech. Monitoring Team, U.S. Patent and Trademark Office, *U.S. Patent Statistics Chart: Calendar Years 1963–2012*, USPTO.GOV, http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm (last visited Sept. 14, 2013).

This constellation of legal, economic, and scientific developments created a perfect storm that helped fuel a rapid rise in university patenting after 1980. In 1965, the U.S. Patent and Trademark Office (USPTO) granted 96 patents to 28 U.S. universities or related institutions.[204] In 1992, a little over a decade after the Act, the USPTO granted almost 1,500 patents to over 150 U.S. universities or related institutions.[205] By 2002, academic institutions were receiving more than 3,000 patents per year.[206] From 1980 to 2005, the average number of patents granted to U.S. research institutions increased by more than 480 percent.[207] The next Part considers the impact of this development on the norms of university science and concomitant doctrinal responses by courts in patent cases.

III. THE CONTEMPORARY LANDSCAPE: ACADEMIC INTERNALIZATION AND THE DEMISE OF EXCEPTIONALISM

Whereas traditional relationships between universities and the patent system were marked by segregation, they are now characterized by a high degree of mutual internalization. This Part briefly surveys the internalization of patents within academic culture, a phenomenon that has attracted significant attention. It then focuses on the less appreciated ways that university science has been internalized within patent doctrine. Increasingly, academic inventions, norms, and practices are the subject of patent litigation and doctrine. And patent courts increasingly view universities as fully integrated into the central, profit-oriented narrative of the patent system. Ultimately, these normative and institutional shifts have helped lead courts to reject academic exceptionalism in patent doctrine.

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204. Rebecca Henderson, Adam B. Jaffe & Manuel Trajtenberg, *Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988*, 80 REV. ECON. & STAT. 119, 119 (1998).

205. *Id.*

206. Kesselheim & Avorn, *supra* note 179, at 851.

207. Gregory K. Sobolski, John H. Barton & Ezekiel J. Emanuel, *Technology Licensing: Lessons from the US Experience*, 294 JAMA 3137, 3137 (2005).

A. Academic Science Viewing Patent Law: Increased Patenting and Attendant Cultural Shifts

As legal, economic, and scientific developments pushed universities deeper into the patent system, many academic institutions and individuals underwent a notable cultural shift.

1. *Evolving Norms and Universities' Embrace of Patenting*. Through a long (and still ongoing) process of norm contestation, academic culture has become much more receptive to exclusive rights and the commercial exploitation of scientific knowledge.[208] The rise in patenting following the Bayh-Dole Act has challenged traditional norms of openness and communal sharing and led to "the emergence of new norms about how science should be done."[209] Although universities used to be wary of patents, many now zealously embrace them,[210] and faculty members actively seek to exploit the "pecuniary content of knowledge."[211] Professors Henry Etzkowitz and Andrew Webster observe that "science and property, formerly independent and even opposed concepts referring to distinctively different kinds of activities and social spheres, have been made contingent upon each other through the concept of 'intellectual property rights.'"[212] These shifts mark a significant evolution away from the communalistic norms Merton described in the early twentieth century.

Of course, although it is easy to characterize universities' embrace of patenting as a stark break from prior practices, one should not paint with too broad a brush. First, as noted above, the notion that academia has always been a bastion of Mertonian sharing norms may be unduly romantic.[213] Second, strong antipatent norms continue to persist (and will likely always persist) in some areas of academia.[214] Third, institutions and individuals are not monolithic, and

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208. Such issues even appeared in debates leading up to the Bayh-Dole Act, when critics warned that increasing commercialization at universities would erode scientific norms. Argyres & Liebeskind, *supra* note 192, at 435–36.

209. Etzkowitz, *supra* note 23, at 26; *see* Merges, *supra* note 7, at 146; Rai, *supra* note 7, at 109.

210. *See* Sampat, *supra* note 31, at 780–81.

211. Etzkowitz, *supra* note 23, at 27; *see* BOK, *supra* note 28, at 3.

212. Henry Etzkowitz & Andrew Webster, *Science as Intellectual Property*, *in* HANDBOOK OF SCIENCE AND TECHNOLOGY STUDIES 480, 480–81 (Sheila Jasanoff, Gerald E. Markle, James C. Petersen & Trevor Pinch eds., 1995); *see* Rowe, *supra* note 137, at 923.

213. *See supra* notes 38–39.

214. *See* BOK, *supra* note 28, at 140; NORBERT WIENER, INVENTION: THE CARE AND FEEDING OF IDEAS 151 (1993); Lee, *supra* note 16, at 861; Jason Owen-Smith & Walter W.

particular universities and scientists differ in their attitudes toward patenting and commercialization.[215] Fourth, in some contexts, traditional sharing and public interest norms have not been displaced, but have been subtly adapted to a new default environment that favors exclusive rights.[216]

Notwithstanding these caveats, as a general matter, academic institutions and individuals have become much more commercially oriented.[217] Prior to 1980, few universities systematically reviewed laboratory work to find discoveries ripe for practical application.[218] The Bayh-Dole Act helped change this state of affairs and encouraged universities to act more like commercial entities.[219] According to one commentator, "Universities have evolved from public trusts into something closer to venture capital firms."[220] In the formerly financially disinterested realm of academia, some scientists have become jealous of colleagues who have translated academic discoveries into personal wealth, a phenomenon known as the "Porsche principle."[221] At the personal level, embracing commercialization has posed challenges for scientists steeped in Mertonian "role identities."[222] Some scientists delegate

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Powell, *Networks and Institutions*, *in* SAGE HANDBOOK OF ORGANIZATIONAL INSTITUTIONALISM 596, 613–14 (Royston Greenwood, Christine Oliver, Kerstin Sahlin & Roy Suddaby eds., 2008); Siegel et al., *supra* note 5, at 121; Liza Vertinsky, *An Organizational Approach to the Design of Patent Law*, 13 MINN. J.L. SCI. & TECH. 211, 244 (2012).

215. Sobolski et al., *supra* note 207, at 3138; *see* Maryann P. Feldman & Pierre Desrochers, *Truth for Its Own Sake: Academic Culture and Technology Transfer at Johns Hopkins University*, 42 MINERVA 105, 107 (2004) (describing how Johns Hopkins University, a major recipient of research funds, has traditionally been skeptical of patenting and licensing).

216. *See generally* Peter Lee, *Interface: The Push and Pull of Patents*, 77 FORDHAM L. REV. 2225 (2009); Merges, *supra* note 7.

217. *See, e.g.*, Karen Seashore Louis, David Blumenthal, Michael E. Gluck & Michael A. Stoto, *Entrepreneurs in Academe: An Exploration of Behaviors Among Life Scientists*, 34 ADMIN. SCI. Q. 110, 110 (1989).

218. BOK, *supra* note 28, at 28.

219. *Cf.* Colyvas et al., *supra* note 21, at 62 (noting that the Bayh-Dole Act encouraged universities to advertise inventions to industry).

220. Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005, at 252.

221. Bob Tedeschi, *The Idea Incubator Goes to Campus*, N.Y. TIMES, June 27, 2010, at BU1.

222. *See generally* Sanjay Jain, Gerald George & Mark Maltarich, *Academics or Entrepreneurs? Investigating Role Identity Modification of University Scientists Involved in Commercialization Activity*, 38 RES. POL'Y 922 (2009). Interestingly, researchers have found a gender gap in scientists' tendency to engage in patenting and commercial activities. *See, e.g.*, Waverly W. Ding, Fiona Murray & Toby E. Stuart, *From Bench to Board: Gender Differences in University Scientists' Participation in Corporate Scientific Advisory Boards*, ACAD. MGMT. J. (forthcoming), *available at* http://amj.aom.org/content/early/2012/10/09/amj.2011.0020; Waverly W. Ding, Fiona Murray & Toby E. Stuart, *Gender Differences in Patenting in the Academic Life*

commercialization functions to other entities (such as graduate students) and create "buffers" by establishing clear work priorities and reaffirming their commitment to nonprofit science in order to distance themselves from business activities.[223] Interestingly, these strategies parallel earlier institutional segregation within universities that allowed them to retain their academic identities while delegating patent management to independent entities.

Again, the emergence of biotechnology illustrates the evolution of academic norms. Cohen and Boyer initially resisted patenting their discovery of recombinant DNA technology, with Cohen being the primary holdout.[224] He relented, however, upon the persuasion of Niels Reimers, head of Stanford's Office of Technology Licensing.[225] Notably, Cohen told Reimers that he would renounce any future royalties arising from a patent.[226] The scientists assigned the patent to Stanford and UCSF, and it has gone on to become the most profitable patent in both schools' histories.[227] By 1996, it had generated over $150 million in royalties. Also emblematic of the times, Cohen and Boyer's involvement in commercialization extended well beyond filing patent applications. Boyer and venture capitalist Robert Swanson founded Genentech,[228] a pioneer in the biotech industry, and Cohen joined the scientific advisory board of Cetus, another important early biotech company. In general, university scientists have played formative roles in many leading biotech firms.[229] With patents as an important catalyst, academic scientists and universities have become increasingly integrated in the commercial exploitation of science.

2. *Changes in Patent Policy*. Universities' growing openness to commercial imperatives is reflected in changes to patent policy. As in earlier times, official patent policies emphasize universities' use of

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Sciences, 313 SCIENCE 665, 665 (2006) (finding that female faculty scientists patent at about 40 percent the rate of male faculty scientists).

223. Jain et al., *supra* note 222, at 923.

224. Hughes, *supra* note 53, at 549–52.

225. *See* Powell & Owen-Smith, *supra* note 12, at 264.

226. Hughes, *supra* note 53, at 550.

227. BOK, *supra* note 28, at 140; KENNEY, *supra* note 58, at 23.

228. Jeannette Colyvas, Annetine Gelijns & Nathan Rosenberg, *Intellectual Property Rights and Academic Health Centers*, *in* ECONOMICS, LAW AND INTELLECTUAL PROPERTY: SEEKING STRATEGIES FOR RESEARCH AND TEACHING IN A DEVELOPING FIELD 155, 160 (Ove Granstand ed., 2003).

229. BOK, *supra* note 28, at 13.

intellectual property to advance the public interest. Asserting exclusivity and obtaining revenues, however, are also regarded as legitimate functions of technology transfer.[230] Furthermore, as noted above, Harvard and several other leading research universities dropped longstanding policies against patenting biomedical discoveries in the 1970s. More broadly, universities have adopted policies encouraging commercial activities by faculty members.[231] Further illustrating a notable cultural shift,[232] some universities even credit patents and commercialization activities in tenure and promotion decisions.[233] Commercialization and revenue generation have become core parts of universities' institutional missions: former Duke University President Terry Sanford once noted that '"universities should do all that is reasonably possible to earn returns on inventions, and should not be timid in making prudent business arrangements to assure the largest fair return.'"[234]

3. *Contemporary Patenting Practices*. Contemporary patent practice by universities reflects new norms of exclusivity and commercialization that would have been unfamiliar in the early twentieth century. Case studies reflect a markedly aggressive attitude toward obtaining patents, particularly on fundamental discoveries. An examination of university patenting, however, reveals a complicated normative environment in which universities simultaneously seek profits while still serving traditional public objectives.

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230. *See, e.g.*, HARVARD UNIV., STATEMENT OF POLICY IN REGARD TO INTELLECTUAL PROPERTY (2010), *available at* http://otd.harvard.edu/resources/policies/IP/IPPolicy.pdf; Stanford Univ., *Research Policy Handbook: 5.1*, DORESEARCH, http://doresearch.stanford.edu/policies/research-policy-handbook/human-subjects-stem-cells-and-skeletal-remains-research/human-0 (last visited Aug. 26, 2013).

231. *See, e.g.*, UNIV. OF CAL., GUIDELINES ON UNIVERSITY-INDUSTRY RELATIONS 1 (1989), *available at* http://www.ucop.edu/ott/genresources/policy_pdf/IndRelGuidelines.PDF ("In general, faculty members are encouraged to engage in appropriate outside professional relationships with private industry.").

232. *See* Lee, *supra* note 16, at 848; *see also* BOK, *supra* note 28, at 63.

233. *See* Jeannie Baumann, *House Innovation Panel Hears Benefits of Bayh-Dole, Advances in Tech Transfer*, 84 PAT. TRADEMARK & COPYRIGHT J. 344 (2012) (noting that the Board of Regents of the University System of Maryland has modified tenure criteria to consider commercialization activities).

234. Terry Sanford, *The University and Technology: New Paths and New Perspectives*, *in* 1 THE LAW OF BUSINESS AND LICENSING: LICENSING IN THE 1980S 1-63, 1-67 (Robert Goldscheider and Tom Arnold eds., 1989).

Returning to a familiar player, WARF has attracted significant criticism for its patents on isolated human embryonic stem cells (hESCs). In the late 1990s, James Thomson of the University of Wisconsin obtained three patents on isolated hESCs and assigned them to WARF.[235] These cells have the capacity to develop into almost all kinds of human tissue and thereby represent both fundamental research tools as well as promising platforms for future therapies. The patents "cede a remarkable amount of territory to WARF,"[236] and commentators have warned that they may inhibit basic research and product development.[237] WARF has actively promoted commercialization of these cells: in exchange for $1 million of sponsored research, it exclusively licensed six important cell types that can be derived from these cell lines to Geron, a private firm.[238] WARF has, however, made efforts to enhance access to these patented cells for nonprofit research. Due in part to public pressure, WARF and the National Institutes of Health (NIH) negotiated a deal by which federally funded scientists can utilize WARF cells for research purposes, though the deal strictly restricts commercial applications.[239] WARF's stem cell patents have attracted significant criticism within the academic community and were the target of a successful reexamination challenge, which ultimately invalidated one of the patents and cast doubt on the others.[240]

Perhaps even more controversial has been Columbia University's attempt to extend patent exclusivity on cotransformation.[241] In the late

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235. U.S. Patent No. 6,280,718 (filed Nov. 8, 1999); U.S. Patent No. 6,200,806 (filed June 26, 1998); U.S. Patent No. 5,843,780 (filed Jan. 18, 1996).

236. Christopher D. Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 174 (2002).

237. *See* Lee, *supra* note 110, at 85–86 (noting such warnings).

238. *See* Mueller, *supra* note 137, at 14; Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 LAW & CONTEMP. PROBS. 289, 301 (2003).

239. Lee, *supra* note 110, at 927.

240. *See* John Conley, Allison Williams Dobson & Dan Vorhaus, *WARF Reexamination Takes Another Bite out of Biotech Patents*, GENOMICS L. REP. (May 19, 2010), http://www.genomicslawreport.com/index.php/2010/05/19/warf-biotech-patents; Alla Katsnelson, *Stem Cell Patent Battle Continues*, NEWSBLOG (May 3, 2012, 8:26 PM BST), http://blogs.nature.com/news/2010/05/stem_cell_patent_battle_contin_1.html.

241. *See* Editorial, *Ownership at Too High a Price?*, 21 NATURE BIOTECH. 953, 953 (2003); Ken Howard, *Biotechs Sue Columbia over Fourth Axel Patent*, 21 NATURE BIOTECH. 955, 955 (2003); Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1417–18 (2007); Bernard Wysocki Jr., *Columbia's Pursuit of Patent Riches Angers Companies*, WALL ST. J., Dec. 21, 2004, at A1.

1970s, neuroscientist Richard Axel and his colleagues at Columbia patented cotransformation, a process for inserting exogenous DNA into a host cell to produce particular proteins. They filed for a patent in 1980, prior to the effective date of the Bayh-Dole Act.[242] According to pre-Act rules, NIH (which helped fund the research) allowed Columbia to take title to the patent, but it cautioned the university against engaging in repressive licensing practices.[243] Columbia's cotransformation patent has been highly lucrative, with several firms paying over $300 million in combined licensing fees.[244] When the patent expired, Columbia announced that it had secured another patent in 2002—which expires in 2019—that also covers cotransformation technology.[245] Several former licensees sued to declare Columbia's patent invalid and unenforceable,[246] and Columbia received significant criticism for its attempts to extend exclusivity over this foundational research process.

Harvard, MIT, and the Whitehead Institute for Biomedical Research have also received criticism for patenting a fundamental biological process. In 2002, these academic institutions obtained a broad patent on a basic biochemical pathway known as the NF-kB cell-signaling pathway,[247] which has been linked to a wide range of diseases including cancer, osteoporosis, atherosclerosis, and rheumatoid arthritis. The institutions exclusively licensed the patent to Ariad Pharmaceuticals and joined with Ariad in suing several pharmaceutical firms for infringement.[248] Observers have criticized the breadth of the NF-kB patent as well as the universities' licensing practices and decision to sue firms that are successfully commercializing technologies related to it.[249]

Finally, the story of Myriad Genetics has become emblematic to many of the excesses of contemporary patenting. In the 1990s, University of Utah researcher Mark Skolnick led a team that sequenced BRCA1 and BRCA2, two genes related to breast and

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242. Leaf, *supra* note 220, at 261.

243. *Id.*

244. Editorial, *supra* note 241, at 953.

245. Leaf, *supra* note 220, at 261.

246. *See In re* Columbia Univ. Patent Litig., 343 F. Supp. 2d 35 (D. Mass. 2004); Biogen Idec MA Inc. v. Trs. of Columbia Univ., 332 F. Supp. 2d 286 (D. Mass. 2004).

247. Rai & Eisenberg, *supra* note 238, at 302.

248. *See infra* notes 357–61.

249. *See* Rai & Eisenberg, *supra* note 238, at 302.

ovarian cancer.[250] Shortly thereafter, the University of Utah and Myriad Genetics, a biotechnology firm cofounded by Skolnick, obtained several patents on these genes.[251] Myriad Genetics has received significant criticism for asserting its patents against medical providers seeking to perform diagnostic tests involving BRCA1 and BRCA2.[252] In particular, public health and women's advocates have alleged that Myriad's patents have raised the price and decreased the availability of diagnostic testing. In 2009, various plaintiffs represented by the American Civil Liberties Union filed a lawsuit challenging the validity of Myriad's patents on patentable subject matter grounds. The case has attracted enormous attention as it has worked its way up the federal courts, and the Supreme Court recently invalidated Myriad's patent claims covering isolated DNA.[253]

Further reflecting their aggressive patent practices, contemporary universities have become active participants in litigation.[254] Empirical work by Professor Christopher Holman found that from 2000 to 2009, there were 139 cases in which a university joined a licensee in suing another party for patent infringement and 51 cases in which universities brought patent infringement suits on their own.[255] Follow-up work by Professor Jacob Rooksby found that between January 1, 2009, and December 31, 2010, 33 universities had filed 57 separate patent infringement suits, often in conjunction with a licensee.[256] The University of California,[257] the University of

250. Robert Dalpé, Louise Bouchard, Anne-Julie Houle & Louis Bédard, *Watching the Race To Find the Breast Cancer Genes*, 28 SCI. TECH. & HUMAN VALUES 187, 195–99 (2003); Leaf, *supra* note 220, at 266.

251. Dalpé et al., *supra* note 250, at 195, 199; *see* Leaf, *supra* note 220, at 266. Interestingly, an inventorship dispute with NIH was resolved when the University of Utah and Myriad agreed to add certain NIH researchers to a patent application and share royalties with NIH. Dalpé et al., *supra* note 250, at 196.

252. *See, e.g.*, Subhashini Chandrasekharan & Robert Cook-Deegan, Commentary, *Gene Patents and Personalized Medicine—What Lies Ahead?*, 1 GENOME MED. 92.1, 92.1 (2009).

253. *See* Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2116–18 (2013).

254. *See* Bagley, *supra* note 37, at 219 n.8; Rebecca S. Eisenberg, *Patents and Data-Sharing in Public Science*, 15 INDUS. & CORP. CHANGE 1013, 1016–18 (2006); Arti K. Rai, John R. Allison & Bhaven N. Sampat, *University Software Ownership and Litigation: A First Examination*, 87 N.C. L. REV. 1519, 1552–55 (2009); Jacob H. Rooksby, *Innovation and Litigation: Tensions Between Universities and Patents and How To Fix Them*, 15 YALE J.L. & TECH. 312, 338–40 (2013); Rowe, *supra* note 137, at 936–37.

255. Christopher M. Holman, Professor, UMKC School of Law, Presentation at Santa Clara School of Law Symposium: University Patent Litigation (Jan. 30, 2009) (presentation slides on file with the *Duke Law Journal*).

256. Rooksby, *supra* note 254, at 330.

Colorado,[258] Cornell,[259] Columbia,[260] Harvard,[261] MIT,[262] the University of Minnesota,[263] and the University of Rochester[264] have all been involved in high-profile cases. Such litigation reveals a much more aggressive, commercially oriented academic culture than in past eras. Among other effects, such litigation has complicated universities' relationships with various stakeholders.[265] The political influence of a prospective defendant may influence a university's decision whether to pursue litigation, particularly for public institutions.[266] And in one notable case, Micron responded to a patent infringement lawsuit by the University of Illinois at Urbana-Champaign by announcing that it would no longer recruit any students from that university.[267]

Not surprisingly, universities have attracted criticism for exploiting patent litigation for financial gain. For example, in *Eolas Technologies, Inc. v. Microsoft Corp.*,[268] the University of California licensed a patent to a firm that is essentially a nonpracticing entity (NPE),[269] then sought to share a jury award of $520.6 million against Microsoft before ultimately obtaining $30.4 million when the case

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257. *See, e.g.*, Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

258. *See* Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1359 (Fed. Cir. 2004) (involving Competitive Technologies, Inc., which represents the University of Colorado and Cornell University).

259. *Id.* In a separate suit against Hewlett-Packard, Cornell obtained a jury verdict of $184 million in damages, which was later reduced to $71.3 million before the parties settled. Susan Kelley, *Hewlett-Packard, Cornell Reach Settlement in Patent Case*, CORNELL CHRON. ONLINE (June 9, 2012), http://www.news.cornell.edu/stories/June10/HPCaseClosed.html.

260. *In re* Columbia Univ. Patent Litig., 343 F. Supp. 2d 35 (D. Mass. 2004).

261. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

262. *Id.* at 1336; Mass. Inst. of Tech. v. Lockheed Martin Global Telecomms., Inc., 251 F. Supp. 2d 1006 (D. Mass. 2003); Akamai Techs., Inc. v. Speedera Networks, Inc., No. CIV.A.02-10188-RWZ, 2002 WL 1969657 (D. Mass. Aug. 26, 2002).

263. Regents of the Univ. of Minn. v. Glaxo Wellcome, Inc., 58 F. Supp. 2d 1036 (D. Minn. 1999); *see* Rowe, *supra* note 137, at 937 (noting that the litigation led to a $300 million settlement for the University of Minnesota).

264. Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303 (Fed. Cir. 2004).

265. *See* Nelson, *supra* note 189, at 17 (noting tensions between companies supporting academic research and universities claiming and asserting patent rights).

266. *See* Rooksby, *supra* note 254, at 347.

267. Dennis Crouch, *Although "Without Tact," Micron's Retaliatory Decision To Stop Hiring University of Illinois Graduates is Not Illegal*, PATENTLY-O (Apr. 11, 2013), http://www.patentlyo.com/patent/2013/04/although-without-tact-microns-retaliatory-decision-to-stop-hiring-university-of-illinois-graduates-is-not-illegal.html.

268. Eolas Techs. Inc. v. Microsoft Corp., 399 F.3d 1325 (Fed. Cir. 2005).

269. NPEs, also referred to as patent trolls, are entities that hold patents but do not produce any goods or services, relying on licensing fees and the threat of litigation for revenue.

settled.[270] Commenting on the case, a representative of the University of California simply stated, "The University expects to be fairly compensated for use of its patented technology."[271] These and other activities have led patent scholars to question whether universities are patent trolls.[272] Indeed, nearly fifty universities have contractual arrangements with Intellectual Ventures, one of the earliest and most prominent NPEs.[273]

Turning to licensing practices, an NIH study "concluded that universities have sought just about every kind of clause in research tool licenses to which they themselves have objected, including publication restrictions, rights in or the option to license future discoveries, and prohibition on transfer to other institutions or scientists."[274] As a general matter, Professor Mark Lemley identifies "a felt sense among a lot of people that universities are not good actors in the patent system."[275]

The normative landscape of university patenting, however, is quite complicated. Though universities have certainly become more aggressive in obtaining and asserting patents, particularly on "foundational" resources, vestiges of academic norms persist. Some technology transfer offices (TTOs) decline to patent fundamental research tools precisely to facilitate their wide availability to the

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270. Mark A. Lemley, *Are Universities Patent Trolls?*, 18 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 611, 618 (2008). The University of California stood to receive 25 percent of the proceeds from the verdict. Michael Kanellos & Jim Hu, *Microsoft Ordered To Pay $521 million*, CNET (Aug. 11, 2003 5:29 PM), http://news.cnet.com/2100-1012-5062409.html; *see* Todd Bishop, *Microsoft's Eolas Settlement: UC Gets $30.4m*, MICROSOFT BLOG (Oct. 10, 2007 5:02 PM), http://blog.seattlepi.com/microsoft/2007/10/10/microsofts-eolas-settlement-uc-gets-30-4m.

271. *See Questions and Answers About UC/Eolas Patent Infringement Suit Against Microsoft*, U. CAL., http://www.universityofcalifornia.edu/news/article/9812 (last visited Aug. 26, 2013).

272. Lemley, *supra* note 270, at 618; *see* Rai et al., *supra* note 254, at 1522–23 ("Additionally, because universities, and sometimes even their exclusive licensees, are nonmanufacturing patentees, the intense debate over whether such patentees employ 'holdup' strategies deleterious to innovation when they assert patents against successful commercializers directly implicates universities.").

273. Tom Ewing & Robin Feldman, *The Giants Among Us*, 2012 STAN. TECH. L. REV. 1, 8, http://stlr.stanford.edu/pdf/feldman-giants-among-us.pdf.

274. Amy Kapczynski, Samantha Chaifetz, Zachary Katz & Yochai Benkler, *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1081 (2005) (citing NAT'L INSTS. OF HEALTH, REPORT OF THE NATIONAL INSTITUTES OF HEALTH (NIH) WORKING GROUP ON RESEARCH TOOLS (June 4, 1998), *available at* http://biotech.law.lsu.edu/research/fed/NIH/researchtools/Report98.htm).

275. Lemley, *supra* note 270, at 619.

scientific community.[276] At the enforcement level, universities holding patents often assert far less than their full exclusionary force.[277] And although universities have been involved in high-profile litigation against companies, they have generally not sued other universities.[278]

Furthermore, in the licensing realm, universities are utilizing their patents in somewhat publicly spirited ways to advance noncommercial research and distributive objectives.[279] As I have described elsewhere, many TTOs retain research exemptions when licensing their technology to others.[280] That is, even when a university exclusively licenses a technology to a private firm, it will retain the right to utilize this invention for nonprofit research and to grant licenses to other nonprofit research institutions to do the same.[281] In this manner, universities are creating a contractual experimental use exception by embedding research safe harbors in patent licenses.[282] Additionally, some universities have expanded access to patented technologies—particularly health-related technologies—for low-income populations.[283] One example involves Yale University's renegotiation of its exclusive license for a patented anti-AIDS medication to allow for lower prices in South Africa.[284] Furthermore, universities are increasingly including humanitarian provisions in licenses to enhance access to patented health technologies for vulnerable populations.[285] Several years ago, Stanford University convened an influential working group of leading TTOs to identify

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276. *See* Rai, *supra* note 7, at 112 (noting that Harvard and Stanford do not file patent applications on expressed sequence tags (ESTs)).

277. Merges, *supra* note 7, at 150.

278. They have, however, been involved in interferences. *See, e.g.*, Regents of the Univ. of Calif. v. Univ. of Iowa Res. Found., 455 F.3d 1371, 1372 (Fed. Cir. 2006).

279. Peter Lee, *Contracting To Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 889, 944–46 (2009).

280. *Id.* at 945; *see* Lori Pressman, Richard Burgess, Robert M. Cook-Deegan, Stephen J. McCormack, Io Nami-Wolk, Melissa Soucy & LeRoy Walters, *The Licensing of DNA Patents by Large US Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECH. 31, 35 (2009) ("The 19 respondent academic institutions retain research-use rights themselves and insist on the right to transfer these research-use rights to other nonprofit institutions.").

281. *See, e.g.*, *Licensing Harvard Patent Rights: A Guideline to the Essentials of Harvard's License Agreements*, HARVARD U. OFF. TECH. DEV., http://www.techtransfer.harvard.edu/resources/guidelines/license (last visited Aug. 26, 2013); Exclusive Agreement, ¶ 3.4, *available at* http://otl.stanford.edu/documents/revstdagmt.pdf (last visited July 30, 2013).

282. Lee, *supra* note 279, at 946.

283. Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 978.

284. *Id.* at 980; *see* Kapczynski et al., *supra* note 274, at 1034–37.

285. Lee, *supra* note 283, at 981–82.

various licensing best practices, such as research and humanitarian exceptions.[286] While university patenting is much more explicitly commercial than in past generations, universities are conscientiously using patents to "push" certain noncommercial, academic norms into the marketplace.[287]

Ironically, these progressive licensing practices, which advance noncommercial values, are helping to drag universities deeper into patent litigation. Under U.S. patent law, ordinarily only a party holding legal title to a patent may sue for infringement.[288] In some cases, exclusive licensees may hold sufficient rights in a patent to allow them to bring suit without joining the original patentee. However, when a licensor, such as a university, retains substantial rights in an invention, it may be required to join litigation before a licensee can bring an enforcement action.[289] This was the case in *AsymmetRx v. Biocare Medical, LLC*,[290] in which the Federal Circuit held that AsymmetRx, which had licensed patents from Harvard University, did not have standing to bring an infringement suit without Harvard's participation.[291] In its licenses, Harvard had retained the right to use the subject inventions for noncommercial research as well as the right to grant additional licenses if AsymmetRx failed to meet various commercialization milestones.[292] The court held that because of these retained rights, AsymmetRx could only bring an infringement suit if Harvard joined as a plaintiff. Tellingly, the court acknowledged the public-interest objectives of Harvard's retained rights, noting that these license provisions "may also reflect the perceived needs of a university attempting to balance the public interest with commercializing the results of its professors' research."[293] Nonetheless, these retained rights have the effect of further pushing universities to participate in patent litigation.

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286. CAL INST. OF TECH. ET AL., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY 8–9 (2007), *available at* http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf.

287. *See* Lee, *supra* note 216, at 2229. *See generally* Lee, *supra* note 283.

288. *See* Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1130 (Fed. Cir. 1995).

289. *Id.* at 1131. *See generally* Rooksby, *supra* note 254.

290. AsymmetRx, Inc. v. Biocare Med., LLC, 582 F.3d 1314 (Fed. Cir. 2009).

291. *See id.* at 1322 ("We thus conclude that Harvard did not convey all substantial rights under the '256 and '227 patents to AsymmetRx in the AsymmetRx License, and, as a result, AsymmetRx lacks statutory standing, on its own, to bring an infringement suit against Biocare.").

292. *Id.* at 1316.

293. *Id*. at 1321.

4. *Shifts in Institutional Structure*. Whereas early forays into patenting were marked by institutional segregation of academic and patenting functions, the guiding theme in recent times is integration.[294] To begin, universities' embrace of patenting has resulted in significant infrastructure building, most notably the establishment of hundreds of TTOs on university campuses.[295] Unlike earlier eras when universities sought to distance themselves from actively managing patents and licenses, these days, university officials are directly involved in such activities.[296]

Furthermore, patents and commercialization have fostered a wealth of connections between university and industry. The Bayh-Dole Act "revolutionized" university-industry relations;[297] one 1996 survey found that "over 90 percent of life-science companies in the United States had some relationship with academia."[298] Oftentimes, commercial firms sponsor research at universities in exchange for exclusive licenses or options on any resulting patented inventions. Reflecting more aggressive institution building, entities such as the Whitehead Institute for Biomedical Research at MIT reflect "an attempt to create an inter-penetrating system of public and private research within a university setting."[299] Furthermore, universities have created "proof of concept centers" to help bridge the gap between research outputs and commercial products.[300] Indeed, convergence in the organization of academic and industrial research has led to "exchange of personnel, common research projects and, in some cases, large-scale joint ventures."[301] The trend of universities taking equity stakes in companies that license their patents further reflects

294. *Cf.* Etzkowitz, *supra* note 41, at 416.

295. *See* Nelson, *supra* note 189, at 13.

296. *See* Etzkowitz, *supra* note 41, at 420; Mowery & Sampat, *supra* note 31, at 811.

297. Press & Washburn, *supra* note 12, at 41; *see* Etzkowitz, *supra* note 41, at 416. Ironically, companies have at times *opposed* university patenting and the sharp business practices of university licensors. *See id*. at 395–96.

298. David Blumenthal, Nancyanne Causino, Eric Campbell & Karen Seashore Louis, *Relationships Between Academic Institutions and Industry in the Life Sciences—An Industry Survey*, 334 NEW ENG. J. MED. 368, 369 (1996).

299. Argyres & Liebeskind, *supra* note 192, at 448; *see* Stephen Heuser, *Harvard Woos Firms To Fund Research*, BOS. GLOBE, Nov. 9, 2005, at 1 (describing Harvard University's aggressive campaign to increase sponsored research).

300. *See* EWING MARION KAUFFMAN FOUND., PROOF OF CONCEPT CENTERS: ACCELERATING THE COMMERCIALIZATION OF UNIVERSITY INNOVATION 2 (2008), *available at* http://sites.kauffman.org/pdf/POC_Centers_01242008.pdf.

301. Louis et al., *supra* note 217, at 114.

the theme of academic-commercial integration.[302] In some instances, these ties linking faculty inventors, universities, and licensee firms approach vertical integration of universities and commercial partners.[303]

Indeed, patent-mediated technology transfer necessarily involves a high degree of personal contact between faculty inventors and licensees.[304] The need to transfer patent-related "tacit knowledge," for example, helps explain the important role of star academic scientists in founding and leading new biotechnology firms (many of which license university patents).[305] Moving beyond personal connections, the very cultures of academia and industry are beginning to converge. Research scientists move frequently between universities and industry, faculty members take sabbaticals at companies, and biotechnology firms mimic academic culture by creating postdoctoral fellowships.[306] Although not all of these trends are attributable to patenting per se, the profusion of patents has been part and parcel of a general cultural convergence of academia and industry.

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As reflected in norms, policy, and practice, universities and their scientists have become much more receptive to patenting and commercialization relative to the pre-Bayh-Dole Act era. Norms of open science have eroded,[307] universities have routinely patented foundational research tools and engaged in litigation, and institutional connections between universities and industry have

302. Maryann Feldman, Irwin Feller, Janet Bercovitz & Richard Burton, *Equity and the Technology Transfer Strategies of American Research Universities*, 48 MGMT. SCI. 105, 105 (2002).

303. Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CALIF. L. REV. 1503, 1556–57 (2012); *cf.* Edwin Mansfield, *Academic Research Underlying Industrial Innovations: Sources, Characteristics, and Financing*, 77 REV. ECON. & STAT. 55, 64 (1995) ("[P]ractically all of the cited academic researchers were involved in consulting relationships with firms, which helped to stimulate many of the ideas and topics taken up . . . .").

304. Lee, *supra* note 303, at 1527–28.

305. Lynne G. Zucker, Michael R. Darby & Marilynn B. Brewer, *Intellectual Human Capital and the Birth of U.S. Biotechnology Enterprises*, 88 AM. ECON. REV. 290, 302 (1998); Lynne G. Zucker & Michael R. Darby, *Star Scientists and Institutional Transformation: Patterns of Invention and Innovation in the Formation of the Biotechnology Industry*, 93 PROC. NAT'L ACAD. SCI. 12,709, 12,710 (1996).

306. Powell & Owen-Smith, *supra* note 12, at 263.

307. Rai & Eisenberg, *supra* note 238, at 310.

deepened. Although vestiges of academic and public-interest norms remain,[308] the baseline has changed as universities have become "active participants in the business of science."[309] In addition to important substantive changes, universities have also undergone an important evolution in how they are *perceived* by the outside public. Universities have long played a rhetorically important role in society as vanguards of disinterested academic inquiry. However, "[a]s universities become more identified with commercial wealth, they also lose their uniqueness in society."[310] Indeed, universities' embrace of patenting and commercial ventures has been reflected in patent doctrine, helping to define a new equilibrium between patents and the university.[311]

B. Patent Law Viewing Academic Science: Doctrinal Internalization and the Demise of Exceptionalism

Just as academic science has internalized patents, patent doctrine has internalized academic science. Academic inventions, inventors, and practices are now frequent subjects of patent doctrine. Furthermore, courts increasingly view universities as integrated into the mainstream commercial narrative of the patent system. Since 1980—the year of the Bayh-Dole Act—courts in patent cases have consistently rejected distinctions between universities and other, typically commercial, actors. Importantly, the evolving normative status of universities has played a significant role in the erosion of academic exceptionalism. Whereas uniquely academic norms, practices, and policies helped justify exceptional treatment of universities in earlier generations, modern courts view universities as much more akin to commercial entities and treat them accordingly.

1. *Eroding Doctrinal Hedges*. As mentioned above, patent doctrine itself has played a key role in erasing distinctions between

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308. *See supra* notes 276–87 and accompanying text.

309. Gary P. Pisano, *Can Science Be a Business? Lessons from Biotech*, HARV. BUS. REV., Oct. 2006, at 114, 116; *see* KENNEY, *supra* note 58, at 246; Janet Rae-Dupree, *When Academia Puts Profit Ahead of Wonder*, N.Y. TIMES, Sept. 7, 2008, at BU4.

310. Phillip A. Sharp, *The Biomedical Sciences in Context*, *in* THE FRAGILE CONTRACT: UNIVERSITY SCIENCE AND THE FEDERAL GOVERNMENT 146, 148 (David H. Guston & Kenneth Keniston eds., 1994).

311. *See* Dreyfuss, *supra* note 107, at 464–65 ("[U]niversities have begun to reach further upstream for patents and to take a harder line on licensing, which makes them look even more commercial—and even less sympathetic to the Federal Circuit.").

academic science and other types of technological work and bringing universities into the patent fold. In particular, the Supreme Court's 1980 decision in *Diamond v. Chakrabarty* marks a turning point in relations between patents and the university. Although *Chakrabarty* did not deal with an academic invention, its holding that genetically modified living organisms comprise patentable subject matter,[312] and its generally expansive approach to patent eligibility, significantly impacted universities. Notably, the University of California as well as a consortium of academic scientists and institutions had submitted amicus briefs arguing in favor of patentability and stressing the importance of patents in commercializing academic inventions.[313] Among other effects, *Chakrabarty* helped "galvaniz[e] the rush into biotechnology."[314] Its famous (though, perhaps flawed[315]) articulation of patentable subject matter as covering "'anything under the sun that is made by man'" encompassed many university discoveries in fields as diverse as biotechnology and computer science.[316] Other patentable subject matter decisions establishing the patent eligibility of software-related inventions[317] and plants[318] further widened the door for university patents.

In addition, case law of the Federal Circuit also helped usher universities into the patent system. In earlier eras, the doctrine of utility had operated as a significant bulwark separating upstream, embryonic academic discoveries from patentable technologies.[319] In *In re Brana*,[320] however, the Federal Circuit held that compounds showing therapeutic effects in artificial, nonhuman "tumor models" satisfied the utility requirement,[321] thus widening the door for patenting upstream biomedical inventions quite removed from human application. Furthermore, the Federal Circuit adopted a rather lax approach to the nonobviousness requirement for DNA inventions, holding that a claimed DNA may be nonobvious even

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

313. Kevles, *supra* note 41, at 302–03.

314. KENNEY, *supra* note 58, at 190.

315. *See* Bilski v. Kappos, 130 S. Ct. 3218, 3248–49 (2010) (Stevens, J., concurring).

316. *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. NO. 82-1979, at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2394, 2399; H.R. REP. NO. 82-1923, at 6 (1952)).

317. Diamond v. Diehr, 450 U.S. 175, 192 (1980).

318. *Ex parte* Hibberd, No. 645-91, 227 U.S.P.Q. (BNA) 443, 443 (B.P.A.I. Sept. 18, 1985).

319. *See supra* notes 128–35 and accompanying text.

320. *In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995).

321. *Id.* at 1565.

when the protein that it codes for as well as methods of gene cloning are in the prior art.[322] Such doctrine further facilitated patenting the fruits of biotechnology, a particularly active area of university research. These doctrinal developments have played a key role in further integrating university discoveries within the patent system.[323]

As universities entered the patent system en masse, the question arose as to whether patent doctrine should treat them differently than other actors, as it did in certain contexts in earlier times. Not surprisingly, universities have often argued for preferential treatment within the patent system, sometimes based on the perceived policy goals of the Act. Contemporary courts, however, have routinely rejected academic exceptionalism. Part of this development merely reflects courts' rejection of overreaching arguments from a new class of university litigants. But it also reflects courts' recognition (and reinforcement) of changing academic norms and the integration of universities into the traditional commercial narrative of patents.[324]

2. *Rejecting Academic Exceptionalism*.

a. *Priority*. For example, the Federal Circuit has refused to extend special treatment to university researchers in the context of determining priority of invention. In the 1987 case of *Griffith v. Kanamaru*,[325] the court considered a priority dispute between Griffith, an associate professor at Cornell University Medical College, and Kanamaru, an employee of Takeda Chemical Industries.[326] Both

322. *See In re* Deuel, 51 F.3d 1552, 1559–60 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781, 785 (Fed. Cir. 1993); Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 833 (1999).

323. In many respects, the treatment of university science in the patent system follows broader structural trends, such as the Federal Circuit's early enthusiasm for patents. This remains true of more recent trends, such as the recent narrowing of patentability in Federal Circuit and Supreme Court jurisprudence.

324. This commercial characterization has also arisen in determining whether public universities can enjoy sovereign immunity from patent suits. *See* Genentech, Inc. v. Regents of the Univ. of Cal., 143 F.3d 1446, 1453 (Fed. Cir. 1998) ("It is also a factor to be considered that the university's [technology transfer] actions are not at the core of the educational/research purposes for which the university was chartered as an arm of the state . . . ."). In other contexts as well, contemporary courts have been reluctant to extend any exceptional treatment to universities, which are increasingly seen as typical commercial actors. *Cf.* United States v. Brown Univ., 5 F.3d 658, 668 (3d Cir. 1993) (rejecting any exemption of universities from substantive antitrust scrutiny in the context of collusively determining financial aid); Madison et al., *supra* note 31, at 395–96 (discussing the antitrust litigation against universities).

325. Griffith v. Kanamaru, 816 F.2d 624 (Fed. Cir. 1987).

326. *Id.* at 625.

parties claimed to have been the first inventor of the technology at issue. The key question was whether Griffith, who had conceived of the invention first, had been "diligent" over an appropriate period of time before reducing the invention to practice.[327] Griffith justified his delay by claiming that he needed to obtain additional research funds as well as wait to employ a particular graduate student.[328] In doing so, he implicitly argued that the particularities of university research warranted relaxed application of the diligence requirement. As interpreted by the court, Griffith's arguments "suggest[ed] that, as a policy matter, universities should not be treated as businesses, which ultimately would detract from scholarly inquiry."[329] The Federal Circuit, however, rejected this argument and refused to draw distinctions between academic and commercial enterprises. It held that Griffith had not been diligent in reducing the invention to practice and that he could not claim priority.[330]

The opinion took the unusual step of commenting on an article by Derek Bok, former president of Harvard University, upon which Griffith had relied in his arguments. Contrary to Griffith's interpretation, the Federal Circuit observed that "Bok does not ask that the patent laws or other intellectual property law be skewed or slanted to enable the university to have its cake and eat it too, *i.e.*, to act in a noncommercial manner and yet preserve the pecuniary rewards of commercial exploitation for itself."[331] The court's implicit message was that if universities avail themselves of the benefits of the patent system, then they will be held to the same standards as any other entity. Indeed, in applying strict standards of diligence to universities, the court acknowledged that it might encourage

327. *Id.* at 626. Conception refers to the mental aspects of invention. *See* Technitrol, Inc. v. United States, 440 F.2d 1362, 1369 (Ct. Cl. 1971). Reduction to practice refers to the physical aspects of invention; for instance, building a physical embodiment of an invention. *See* DSL Dynamic Scis. Ltd. v. Union Switch & Signal, Inc., 928 F.2d 1122, 1125 (Fed. Cir. 1991). These concepts governed the determination of priority in cases, such as this one, in which the relevant patent applications were filed before the effective date of the revised novelty provisions of the America Invents Act (AIA). Within this traditional regime, in the case in which one party was the first to conceive but the second to reduce an invention to practice, that party would prevail if she was diligent from a time prior to the other party's conception through to her own reduction to practice. *See* 35 U.S.C. § 102(g) (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3(b)(1), 125 Stat. 284, 285 (2011).

328. *Griffith*, 816 F.2d at 626.

329. *Id.* at 627.

330. *Id.* at 629.

331. *Id.* at 628.

university scientists to act more like commercial actors in prioritizing certain lines of research at the expense of others.[332]

b. Statutory Bars. The Federal Circuit's reluctance to make exceptions for university research even extends to an activity that rests at the heart of academia: scientific presentations.[333] In *In re Klopfenstein*,[334] the Federal Circuit considered whether a scientist's presentations at two academic meetings constituted "printed publications" that would statutorily bar a later filed patent application.[335] These presentations were comprised of oral commentary as well as slides pasted onto poster board that were displayed for at most two-and-a-half days.[336] Considering multiple factors,[337] the court held that the slides constituted printed publications that statutorily barred Klopfenstein's patent.[338] The court did, however, exhibit some sensitivity to the unique norms of academic presentations. It noted, for example, that an entirely oral presentation would not constitute a printed publication and that a transient display of slides on a screen would not *necessarily* constitute a printed publication.[339] Furthermore, the opinion stated, "Where professional and behavioral norms entitle a party to a reasonable expectation that the information displayed will not be copied, we are more reluctant to find something a 'printed publication.' This

332. *See id.* ("Cornell has consciously chosen to assume the risk that priority in the invention might be lost to an outside inventor, yet, having chosen a noncommercial policy, it asks us to save it the property that would have inured to it if it had acted in single-minded pursuit of gain.").

333. Under the prevailing novelty and statutory bar provisions prior to the AIA—which is still the relevant law for patent applications filed before March 16, 2013—printed publications describing an invention that arise more than one year before an inventor files a patent application will "statutorily bar" a patent. 35 U.S.C. § 102(b) (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 286 (2011). Under the first-inventor-to-file regime of the AIA, statutory bars are essentially subsumed into novelty analysis. *See* Leahy-Smith America Invents Act § 3, 125 Stat. at 285–87 (to be codified at 35 U.S.C. § 102).

334. *In re* Klopfenstein, 380 F.3d 1345 (Fed. Cir. 2004).

335. *See* Bagley, *supra* note 37, at 243–44; Sean B. Seymore, *The Printed Publication Bar After* Klopfenstein*: Has the Federal Circuit Changed the Way Professors Should Talk About Science?*, 40 AKRON L. REV. 493, 509 (2007).

336. *In re Klopfenstein*, 380 F.3d at 1347.

337. These factors included "the length of time the display was exhibited, the expertise of the target audience, the existence (or lack thereof) of reasonable expectations that the material displayed would not be copied, and the simplicity or ease with which the material displayed could have been copied." *Id.* at 1350.

338. *Id.* at 1352.

339. *Id.* at 1349 n.4.

reluctance helps preserve the incentive for inventors to participate in academic presentations or discussions."[340] Nonetheless, Klopfenstein's temporary poster displays statutorily barred the patent.

Notwithstanding the Federal Circuit's nod to academic norms, commentators have warned that the court's broad conception of printed publications may chill academic presentations and force scientists to delay sharing research results.[341] Noting that "patent rules too often are dictating the pace, form, and scope of discourse and sometimes even the direction of the research itself," Professor Margo Bagley advocates altering the novelty rules of both U.S. and foreign patent systems to better accommodate academic practices.[342] Existing patent doctrine, however, has been less solicitous of such academic exceptionalism, and it continues to exert a constraining effect on rapid publication of scientific findings.

c. The Written Description Requirement. In a series of cases, the Federal Circuit has rejected preferential treatment for university inventions in establishing a stringent written description requirement for biomedical technologies. Under prevailing law, patent claims must correspond to the "written description" of an invention appearing in the patent specification.[343] In 1997, the Federal Circuit established a high bar for the written description requirement for DNA-based inventions. In *Regents of the University of California v. Eli Lilly & Co.*,[344] the court invalidated several University of California patent claims related to genetically engineered plasmids and microorganisms that produce insulin.[345] Noting that the University of California's patent described complementary DNA (cDNA) that produced *rat* insulin,[346] the Federal Circuit invalidated the University of California's broader claims covering cDNA that produced *vertebrate* and *mammal*

340. *Id.* at 1351; *see also* Cordis Corp. v. Bos. Scientific Corp., 561 F.3d 1319, 1333–34 (Fed. Cir. 2009) (citing *In re Klopfenstein*, 380 F.3d at 1351) (noting that academic norms created an expectation of confidentiality regarding the review of a scientific manuscript).

341. Bagley, *supra* note 37, at 221.

342. *Id.* at 223–24, 269.

343. *See* 35 U.S.C. § 112 (2006).

344. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997).

345. *Id.* at 1562.

346. Complementary DNA is comprised of only the DNA sequences of a gene that actually code for a particular protein, with noncoding DNA (introns) removed. *See* Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207–08 n.4 (Fed. Cir. 1991).

insulin. In addition to spurring significant doctrinal controversy,[347] *Regents of the University of California* is notable for imposing constraints on DNA-related inventions, an area of significant university patenting.

In another case involving the written description requirement, the Federal Circuit expressly rejected special treatment for university inventions. In *University of Rochester v. G.D. Searle & Co.*,[348] the Federal Circuit invalidated Rochester's patent on COX-2 inhibitors, an important class of anti-inflammatory medications, on written description grounds.[349] Although the patent claimed a process for inhibiting COX-2 (an enzyme related to inflammation), it did not disclose an actual COX-2 inhibitor that could perform this function.[350] Notably, the court rejected Rochester's calls to interpret the written description requirement leniently for university inventions. According to Rochester, an unduly strict written description requirement would "vitiate[] universities' ability to bring pioneering innovations to the public,"[351] thus undermining the Bayh-Dole Act's objective of commercializing academic inventions.[352] The University of California and the University of Texas joined this argument as amici, asserting that a high written description requirement would jeopardize university technology transfer.[353] The court, however, refused to bend the rules for university inventions. It flatly noted that the Act "was not intended to relax the statutory requirements for patentability" to benefit university patentees.[354] Notwithstanding the

347. In particular, it sparked a robust debate regarding whether the written description requirement should apply to *original* as well as amended claims (as the Federal Circuit so construed) or whether it should only apply to amended claims. *See* Peter Lee, *Antiformalism at the Federal Circuit: The Jurisprudence of Chief Judge Rader*, 7 WASH. J.L. TECH. & ARTS 405, 420 (2012).

348. Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004).

349. *Id.* at 917.

350. *Id.* at 930.

351. *Id.* at 929.

352. *Id.*

353. *Id.*

354. *Id.*

burdens on university patentees,[355] the Federal Circuit has insisted on a high written description standard for biomedical inventions.[356]

The Federal Circuit continued to reject academic exceptionalism in a 2010 en banc case, *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*[357] As noted, Harvard, MIT, and the Whitehead Institute for Biomedical Research obtained a broad patent on a basic biochemical pathway known as the NF-kB cell-signaling pathway, then exclusively licensed it to Ariad.[358] Ariad and the universities sued Eli Lilly and others for infringement, but a three-judge panel of the Federal Circuit held that certain claims in Ariad's patent were invalid for failing the written description requirement.[359] Upon en banc review, the Federal Circuit affirmed, clarifying (against the universities' arguments) that the written description requirement exists as an independent criterion of patentability alongside enablement.[360] Furthermore, the Federal Circuit rejected the patentees' policy argument that a stringent written description requirement would disfavor universities, whose scientists often discover upstream, basic inventions for which providing an adequate written description is particularly difficult:

> Much university research relates to basic research, including research into scientific principles and mechanisms of action, and universities may not have the resources or inclination to work out the practical implications of all such research, i.e., finding and identifying compounds able to affect the mechanism discovered. That is no failure of the law's interpretation, but its intention.[361]

Notwithstanding the somewhat unique nature of academic research, the Federal Circuit has frequently maintained that it will treat university patentees no differently than other players in the patent

355. *See* Univ. of Rochester v. G.D. Searle & Co., Inc., 375 F.3d 1303, 1313–14 (Fed. Cir. 2004) (denial of rehearing en banc) (Rader, J., dissenting) ("Must a university or small biotech company expend scarce resources to produce every potential nucleotide sequence that exhibits their inventive functions?").

356. *See* Carnegie Mellon Univ. v. Hoffman-La Roche Inc., 541 F.3d 1115, 1122–28 (Fed. Cir. 2008) (invalidating Carnegie Mellon's patents on novel recombinant plasmids and related inventions on written description grounds).

357. Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

358. *See supra* notes 247–49 and accompanying text.

359. Ariad Pharms., Inc. v. Eli Lilly & Co., 560 F.3d 1366, 1380 (Fed. Cir. 2009), *aff'd on reh'g en banc*, 598 F.3d 1336 (2010).

360. *Ariad Pharms., Inc.*, 598 F.3d at 1343.

361. *Id.* at 1353 (citation omitted).

system regarding the strictures of the written description requirement.

d. The Common Law Experimental Use Exception. Turning from patentability to infringement, a particularly visible example of contemporary patent doctrine's rejection of academic exceptionalism is the Federal Circuit's narrow conception of the experimental use exception. As discussed above, courts have traditionally exempted noncommercial, experimental uses of patented inventions from infringement.[362] In at least one case, this exemption appeared to apply to university research involving patented inventions.[363] Whether or not true as a doctrinal matter, many academic scientists *believed* that their noncommercial research qualified as noninfringing experimental use. In more recent times, however, courts have articulated a rather narrow conception of the exception.[364] In 1984, in a case not involving academic research, the Federal Circuit characterized the experimental use exception as "truly narrow" and cautioned against construing it "so broadly as to allow a violation of the patent laws in the guise of 'scientific inquiry,' when that inquiry has definite, cognizable, and not insubstantial commercial purposes."[365] In a 2000 concurrence, Judge Rader of the Federal Circuit even declared that "the Patent Act leaves no room for any *de minimis* or experimental use excuses for infringement."[366]

This trend came to a head in 2002, when the Federal Circuit directly addressed the experimental use exception's application to university research. In *Madey v. Duke University*,[367] the court rejected Duke University's invocation of the experimental use defense in a patent infringement suit brought by a former faculty member.[368] The Federal Circuit noted that Duke's ongoing research projects involving Madey's patented laser "unmistakably further [Duke's] legitimate business objectives, including educating and enlightening students

362. *See supra* notes 137–50 and accompanying text.

363. *See supra* notes 144–50 and accompanying text.

364. *See, e.g.*, Pitcairn v. United States, 547 F.2d 1106, 1125 (Ct. Cl. 1976) (holding defendant liable for patent infringement even when it used the invention for "testing, evaluational, demonstrational or experimental purposes").

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

366. Embrex, Inc. v. Serv. Eng'g Corp., 216 F.2d 1343, 1349 (Fed. Cir. 2000) (Rader, J., concurring); *see* Mueller, *supra* note 137, at 28–30.

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

368. *Id.* at 1362.

and faculty participating in these projects."[369] The court's language is striking in highlighting the "business objectives" of a nonprofit research university. The opinion further notes that "Duke . . . like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream."[370] Indeed, Duke's status as a nonprofit institution was immaterial to resolving this case.[371]

Among other implications, *Madey* is notable for reflecting a new normative vision of universities as commercial entities. As Professors Michael Madison, Brett Frischmann, and Katherine Strandburg note, "Perhaps because of their increasing commercial entanglements, universities were no longer seen by the court as inhabiting a distinctive, noncommercial realm."[372] The Federal Circuit's conception of the modern research university diverges sharply from "Justice Story's early-19th-century picture of a gentleman scientist driven by idle curiosity."[373] In contemporary times, universities have "shed their noncommercial innocence to reach deeper into the pockets of commercial firms."[374] After *Madey*, universities and their scientists largely lost whatever privileged normative status they may have enjoyed,[375] particularly their claim to "disinterested stewardship of knowledge in the public interest."[376] In the context of infringement, universities' embrace of patenting and commercialization has helped courts reject academic exceptionalism.

e. Remedies. In addition to the Federal Circuit, other courts—notably the Supreme Court—have also rejected academic exceptionalism. In determining remedies for patent infringement, the Supreme Court has recently suggested that universities should be treated just like any other actor in the patent system. The Court articulated these views in the 2006 case of *eBay v. MercExchange*,[377] which established a four-factor equitable test to determine the

369. *Id.* at 1363.

370. *Id.* at 1362 n.7.

371. Rowe, *supra* note 137, at 931.

372. Madison et al., *supra* note 31, at 395.

373. Eisenberg, *supra* note 137, at 1018.

374. *Id.*

375. *See* Greenbaum, *supra* note 18, at 377 (noting that after the decision in *Madey*, "no one, not even academics, are [sic] above the intellectual property laws").

376. Eisenberg, *supra* note 137, at 1019.

377. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388 (2006).

appropriateness of injunctive relief following a finding of patent infringement.[378] Notably, the Court stated,

> [S]ome patent holders, such as university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves. Such patent holders may be able to satisfy the traditional four-factor test, and we see no basis for categorically denying them the opportunity to do so.[379]

Thus, even though universities do not produce any products, they may still be eligible to receive injunctions against parties infringing their patents.[380] Although a per se rule prohibiting injunctions for university patentees would have been rather surprising, the Court's lumping together of universities and other inventive entities tends to elide any historical distinctiveness of universities in the patent system. Indeed, the Court's statement that university patentees may obtain injunctive relief actually facilitates their status as NPEs that has attracted so much criticism.

In applying *eBay* to academic patentees, lower courts have also highlighted the commercial nature of academic institutions. In *Commonwealth Scientific and Industrial Research Organisation v. Buffalo Technology Inc.*,[381] the Eastern District of Texas granted a permanent injunction to the Commonwealth Scientific and Industrial Research Organisation (CSIRO), a nonprofit scientific research foundation established by the Australian government, after finding that Buffalo Technologies had infringed one of CSIRO's patents.[382] Though not a university, CSIRO is a nonprofit academic institution,[383] and this decision provides an indication of how courts are likely to treat universities under the *eBay* framework. Applying *eBay*, the

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378. *Id.* at 391.

379. *Id.* at 393.

380. Not surprisingly, academic representatives argued in congressional testimony that universities should be eligible to receive injunctive relief even though universities do not manufacture any products. *See Patent Law Reform: Injunctions and Damages: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 109th Cong. 41–42 (2005) [hereinafter *Patent Law Reform: Injunctions and Damages: Hearing*] (statement of Carl Gulbrandsen, Exec. Dir., Wis. Alumni Research Found.).

381. Commonwealth Scientific & Indus. Research Org. v. Buffalo Tech. Inc. (*CSIRO*), 492 F. Supp. 2d 600 (E.D. Tex. 2007).

382. *Id.* at 608.

383. CSIRO is not a university but is analogous to the United States National Science Foundation or NIH. *Id.*; *see* Rai et al., *supra* note 254, at 1559–60.

court ruled that CSIRO would be irreparably harmed by Buffalo's continued infringement in the form of delayed funding and lost opportunities to advance technological projects.[384] The court noted that CSIRO faces competitive pressures to obtain resources, ideas, and personnel and that infringement of its patent may place CSIRO at a competitive disadvantage.[385] In ruling that monetary damages were inadequate, the court explicitly compared CSIRO to a commercial enterprise, noting that CSIRO's "reputation as a research institution has been impugned just as another company's brand recognition or good will may be damaged."[386] The case is notable both for demonstrating that nonpracticing academic patentees may obtain injunctive relief[387] and for the markedly commercial characterization of such institutions.

f. Ownership of Federally Funded Inventions. More recently, the Supreme Court also rejected special treatment for universities in a case involving the ownership of federally funded patents. In *Board of Trustees of the Leland Stanford Junior University v. Roche Molecular Systems, Inc.*,[388] the Court considered whether the Bayh-Dole Act vests title to university inventions directly in universities themselves or whether title initially vests in faculty inventors.[389] Stanford argued that the Act reflects a federal policy in favor of university-based technology transfer and that it vests title to inventions directly in universities themselves.[390] The Association of American Universities, the Association of American Medical Colleges, the Association of Public and Land-grant Universities, the Association of University

384. *CSIRO*, 492 F. Supp. 2d at 604.

385. *Id.*

386. *Id.* at 605.

387. Andrew Beckerman-Rodau, *The Aftermath of* eBay v. MercExchange*, 126 S. Ct. 1837 (2006): A Review of Subsequent Judicial Decisions*, 89 J. PAT. & TRADEMARK OFF. SOC'Y 631, 655 (2007). From one perspective, this may represent an instance of academic exceptionalism, as universities have achieved higher-than-average rates of obtaining injunctions relative to other NPEs. Colleen V. Chien & Mark A. Lemley, *Patent Holdup, the ITC, and the Public Interest*, 98 CORNELL L. REV. 1, 10 (2012); *see* BURK & LEMLEY, *supra* note 110, at 139 ("[A]n aberrational Texas district court . . . held that special rules should apply to nonprofit entities."). Although this may be interpreted as exceptionalism, it may also reflect courts' lumping together of universities with traditional commercial patentees (that is, productive, innovative entities) as opposed to grouping them with less favorable NPEs.

388. Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188 (2011).

389. *Id.* at 2192.

390. Brief of Petitioner at 30, 38, *Roche*, 131 S. Ct. 2188 (No. 09-1159).

Technology Managers, and the Council on Government Relations all supported Stanford's argument.[391] The Court, however, disagreed. It held that the Act did not modify longstanding patent doctrine regarding the ownership of inventions, which vests title to inventions in inventors themselves.[392] Applying the general law of patent ownership to university inventions, the Court again rejected academic exceptionalism.

3. *The Integration of Universities Within Patent Doctrine*. In several ways, patent decisions from the past three decades reflect the internalization of academic science within patent doctrine. Expansive approaches to patentability and the changing nature of university research have created an environment in which many outputs of academic research now fall within the patent system's regulatory grasp. Academic science—previously peripheral to the patent system—is now a frequent subject of litigation and doctrine. Indeed, academic science has played a key role in shaping cutting-edge patent doctrine. To be sure, courts have used doctrines governing priority, statutory bars, and the written description requirement to invalidate university patents. However, courts have applied these doctrines not based on a principled stance that academic discoveries are categorically inappropriate for patenting, but to rebuff overreaching behavior by zealous university patentees.

During this period, courts have largely rejected academic exceptionalism. In some cases, this rejection has been based on a more commercially oriented conception of universities. Earlier doctrinal hedges separating the patent system from academic science were often predicated on conceptions of academic entities as nonpecuniary stewards of the public interest. In recent decades, however, court opinions have reflected a new reality, lumping universities and scientists together with commercial, revenue-seeking entities. In a variety of doctrinal contexts—perhaps most notably the common law experimental use exception—courts have treated universities as just another set of commercial actors in the patent system. Here again, patent law exhibits some degree of reciprocity between norms and doctrine: to the extent that universities have shed

391. Brief of Ass'n of Am. Univs. et al. as Amici Curiae Supporting Petitioner at 1–5, *Roche*, 131 S. Ct. 2188 (No. 09-1159).

392. *Roche*, 131 S. Ct. at 2199.

traditional academic norms and embraced commercialism, patent courts will not treat them any differently from other parties.

Of course, one must place these developments within the context of broader trends in patent law. In many ways, universities' integration into the patent system was part and parcel of the patent-friendly doctrine of the Supreme Court and especially the Federal Circuit in the 1980s and 1990s.[393] Expansive interpretations of patentable subject matter, utility, and nonobviousness helped extend patent protection to more university discoveries, thus fueling the institutional changes to which courts later responded. Interestingly, universities have also been caught up in the more recent trend of both the Supreme Court and the Federal Circuit *narrowing* patentability since the late 1990s. Decisions constraining patentable subject matter,[394] utility,[395] nonobviousness,[396] and (as discussed above) the written description requirement[397] have made it more difficult to obtain patents. In some respects, these changes have disproportionately impacted university inventions, which tend to be rather upstream and embryonic.

Viewed from one angle, courts' flattening of the academic/commercial distinction and the rejection of preferential treatment for universities is not surprising. Historically, opportunities for universities to argue for (and for courts to reject) academic exceptionalism were limited simply because universities were not significant litigants in the patent system. It is somewhat predictable that as universities have become more active in litigation, they have argued for doctrinal interpretations favorable to their interests and that courts have been skeptical of such claims. After all, the United States is committed to a unitary patent system that at least nominally treats all inventors and inventions equally.[398] As discussed further

393. *See supra* notes 312–23 and accompanying text.

394. Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012); Bilski v. Kappos, 130 S. Ct. 3218, 3221 (2010).

395. *See In re* Fisher, 421 F.3d 1365, 1367 (Fed. Cir. 2005) (rejecting an application claiming ESTs because of a lack of specific and substantial utility).

396. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 422 (2007); *In re* Kubin, 561 F.3d 1351, 1352 (Fed. Cir. 2009).

397. *See supra* Part III.B.2.c.

398. As Professors Dan Burk and Mark Lemley have demonstrated, however, the patent system subtly distinguishes between different inventive fields. *See* Dan L. Burk & Mark A. Lemley, *Is Patent Law Technology-Specific?*, 17 BERKELEY TECH. L.J. 1155, 1156 (2002) ("[W]e

below, courts have been largely prudent in rejecting universities' arguments for preferential interpretations of patentability doctrines, particularly given the embryonic, upstream nature of many academic inventions.[399] Given this state of affairs, however, it is quite curious that even though academic exceptionalism has largely died in the courts, it has adopted new life in the legislative sphere, a development to which this Article now turns.

IV. STATUTORY INTERNALIZATION AND THE REVIVAL OF ACADEMIC EXCEPTIONALISM

Turning from doctrine to statute, the twin themes of academic internalization and exceptionalism take interesting turns in the context of legislative patent reform. In significant part, the internalization of academic science within patent law, which started in doctrine, has reached its apex in the legislative arena. The interests of academic science, formerly peripheral to the patent system, are now hardwired in the patent statute. Within this project of "statutory internalization," academic exceptionalism has evolved in interesting ways. On the one hand, academic exceptionalism has been completely erased to the extent that the interests of academic science help shape general rules of patentability that apply to all inventions. Such internalization suggests that there is nothing "exceptional" about academic science at all. On the other hand, academic exceptionalism has intensified in the guise of specific statutory carve-outs for universities, thus illustrating classic legislative rent-seeking.[400] The curious result is that even though courts have rejected academic exceptionalism, it has achieved new life in Congress.

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have noticed an increasing divergence between the rules themselves and the application of the rules to different industries.").

399. *See infra* Part V.B.1.

400. *See* Robert P. Merges, *Intellectual Property Rights and the New Institutional Economics*, 53 VAND. L. REV. 1857, 1867 (2000); Robert P. Merges, *One Hundred Years of Solicitude: Intellectual Property Law, 1900–2000*, 88 CALIF. L. REV. 2187, 2236 (2000). *See generally* TOWARD A THEORY OF THE RENT-SEEKING SOCIETY (James M. Buchanan, Robert D. Tollison & Gordon Tullock eds., 1980). Of course, interest-group lobbying is endemic to other patent legislation as well, including the American Inventors Protection Act of 1999. *See* Edward R. Ergenzinger Jr., *The American Inventor's Protection Act: A Legislative History*, 7 WAKE FOREST INTELL. PROP. L.J. 145, 146 (2006).

A. The Bayh-Dole Act

Of course, the primary legislation that intensified universities' participation in the patent system is the Bayh-Dole Act. As noted above, myriad political and economic factors motivated the Act,[401] which accelerated the rise in university patenting already underway in 1980.[402] This Section extends the earlier discussion by highlighting the significant involvement of university representatives in securing the Act's passage.

University officials were involved throughout the Act's genesis and passage. Early in the bill's drafting, Ralph Davis (patent administrator from Purdue University), Howard Bremer (a WARF administrator), and Norman Latker (NIH's first patent counsel) met with Senator Birch Bayh and an aid to convince them of the worthiness of the proposed legislation that would become the Bayh-Dole Act.[403] In significant part, university officials were motivated to support the bill because of their positive experiences with patenting federally funded inventions under IPAs.[404] According to Professor Elizabeth Popp Berman, the "proto-institution" of IPAs helped establish university patenting as a legitimate activity and galvanized a professional community of technology transfer administrators around protecting and expanding university patent rights.[405] This professional community ultimately organized under the rubric of the Association of University Technology Managers (AUTM), which argued forcefully in favor of the Bayh-Dole Act and has continued to lobby in favor of university patenting.[406] Among other actions, advocates for the Act employed an effective political strategy of framing the Act in terms of enhancing U.S. economic competitiveness,[407] thus connecting the legislation to important national imperatives.

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401. *See supra* notes 168–80 and accompanying text.

402. *See supra* note 172 and accompanying text.

403. Berman, *supra* note 46, at 856.

404. *See* Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 95 (2004) (describing the testimony of WARF's Howard Bremer in favor of the proposed legislation).

405. Berman, *supra* note 46, at 836; *see* Mowery & Sampat, *supra* note 28, at 119.

406. AUTM began as the Society of University Patent Administrators (SUPA) in 1974, which changed its name in the late 1980s. SUPA members participated in the hearings leading to the Bayh-Dole Act. *See* Jon Sandelin, *SUPA/AUTM Role in Bayh/Dole Legislation* 1, 7–8, 30 BAYH-DOLE, http://b-d30.org/app/webroot/doc/AUTMrole_in_BayhDole.pdf.

407. Berman, *supra* note 46, at 854.

Throughout legislative hearings, university representatives extolled the benefits of vesting title to federally funded patents in universities.[408] For instance, representatives argued that universities were better conduits for technology transfer than government agencies because they were more familiar with the inventions at issue and had direct access to faculty inventors.[409] In particular, universities could facilitate the direct interaction between inventors and licensees that is often critical to technology transfer.[410] Summarizing the involvement of universities in the bill's passage, Bremer notes, "[F]inally universities were speaking with a loud single voice in this arena. I think that is ultimately what carried the day."[411]

The Bayh-Dole Act represents an important instance of the statutory internalization of academic science within the patent system. The Act significantly deepened universities' participation in patenting and licensing. On a meta-level, it also represented a political awakening for universities, thus integrating them within a *legislative* system of lobbying Congress for favorable patent legislation, a practice that universities have continued with fervor.

B. The CREATE Act

Even though the Bayh-Dole Act changed federal policy governing the ownership of publicly funded patents, it did not change the general rules of patentability. More recent legislation, however, has done just that to favor the interests of academic research, further illustrating the statutory internalization of academic science within the patent system.

For example, university interests helped change the law of nonobviousness in the Cooperative Research and Technology Enhancement Act of 2004 (the CREATE Act).[412] Because this

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408. *Id.* at 856.

409. *See Government Patent Policies: Institutional Patent Agreements: Hearings Before the Subcomm. on Monopoly & Anticompetitive Activities of the S. Select Comm. on Small Bus.*, 95th Cong. 383 (1978) (statement of Howard W. Bremer, Patent Counsel, Wis. Alumni Research Found.).

410. *Id.* at 255 (statement of Charles H. Herz, Gen. Counsel, Nat'l Sci. Found.); *id.* at 309, 311 (statement of Thomas F. Jones, Vice Pres., Research, Mass. Inst. of Tech.).

411. Berman, *supra* note 46, at 856 (quoting Interview by Barry Teicher with Howard W. Bremer, Patent Counsel, Wis. Alumni Research Found. (2001) (on file with Univ. of Wis.-Madison Oral History Program)).

412. Cooperative Research and Technology Enhancement (CREATE) Act of 2004, Pub. L. No. 108-453, § 2, 118 Stat. 3596, 3596 (current version at 35 U.S.C. § 103(c) (2006 & Supp. V 2011)).

legislation is rather technical, some context is in order. Before the CREATE Act, Congress had enacted a specific provision in 1984, which was recodified in 1995 at 35 U.S.C. § 103(c),[413] to foster research, development, and patenting within large corporate enterprises. In particular, § 103(c) prevented certain types of nonpublic subject matter from serving as "prior art" that could render a later claimed invention obvious when the subject matter and the invention were "owned by the same person or subject to an obligation of assignment to the same person."[414] In the absence of such a safe harbor, certain nonpublic information generated by one research team within an organization (such as Merck) might constitute prior art that would render obvious the claimed inventions of other research teams within the same organization. In 1995, however, the Federal Circuit held that the § 103(c) safe harbor did *not* apply to researchers from *different* organizations working pursuant to a joint research agreement.[415] Among other implications, this holding denied the benefit of the § 103(c) safe harbor to university scientists and corporate scientists who worked together under a joint research agreement with no obligation to assign their inventions to a common entity. Without this safe harbor, the work of one party to a joint research agreement could render obvious the inventions of another party to that same agreement.

To ameliorate this situation, Congress enacted the CREATE Act, which extended the prior art safe harbor to joint research agreements.[416] The CREATE Act thus changed the law of nonobviousness by establishing that certain forms of nonpublic information would not count as prior art for nonobviousness in the context of a joint research agreement. Significantly, Congress enacted the CREATE Act in large part to promote university-industry research collaborations.[417] In introducing the CREATE Act, Senator Orrin Hatch stated:

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413. Patent Law Amendments Act of 1984, Pub. L. No. 98-622, § 1, 98 Stat. 3383, 3384, *amended by* Act of Nov. 1, 1995, Pub. L. No. 104-41, § 1, 109 Stat 351, 351 (codified at 35 U.S.C. § 103(c) (Supp. I 1996)).

414. 35 U.S.C. § 103(c) (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 285 (2011).

415. OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1403 (Fed. Cir. 1997).

416. *See* CREATE Act § 2, 35 U.S.C. § 103(c), *amended by* Leahy-Smith America Invents Act § 3, 125 Stat. at 285.

417. *See Patent Act of 2005: Hearing on H.R. 2795 Before the Subcomm. on Courts, the Internet, and Intellectual Prop. of the H. Comm. on the Judiciary*, 109th Cong. 20 (2005) [hereinafter *Hearing on H.R. 2795*] (statement of Carl E. Gulbrandsen, Managing Dir., Wis.

> This bill makes a narrow, but important change in our patent laws to ensure that the American public will benefit from the results of collaborative research efforts that combine the erudition of great public universities with the entrepreneurial savvy of private enterprises. . . . [W]e must encourage—not discourage—public institutions and private entrepreneurs to combine their respective talents in joint research efforts.[418]

Similarly, Senator Patrick Leahy specifically linked the CREATE Act to the objectives of the Bayh-Dole Act: "When Congress passed the Bayh-Dole Act in 1980, the law encouraged private entities and not-for-profits such as universities to form collaborative partnerships in order to spur innovation."[419] Members of Congress intended the CREATE Act to facilitate even more of these partnerships (thus further integrating universities and commercial interests) by altering the rules of nonobviousness. Indeed, the CREATE Act has enhanced the importance of joint research agreements between universities and industry.[420] Far from being on the periphery of the patent system, interests related to academic science are now helping to determine general rules of patentability. As we will see, this trend finds even greater expression in the America Invents Act.

C. The America Invents Act

The statutory internalization of academic science within patent law has reached its zenith with the America Invents Act (AIA). In 2011, after six years of debate, Congress enacted the AIA, the most sweeping patent reform since the modern patent act of 1952[421] and arguably the most significant reform since the establishment of an examination system in 1836.[422] The AIA covers an enormous amount of subject matter, and the interests of academic science are reflected in several provisions. In some sense, the formative influence of

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Alumni Research Foundation) ("Science today depends on collaborative research, and the CREATE Act will stimulate numerous inventive activities in the future."); James G. McEwen, *Is the Cure Worse than the Disease? An Overview of the Patent Reform Act of 2005*, 5 J. MARSHALL REV. INTELL. PROP. L. 55, 62 (2005) (discussing the CREATE Act).

418. 150 CONG. REC. 3999 (2004) (statement of Sen. Orrin Hatch).

419. *Id.* (statement of Sen. Patrick Leahy).

420. Greenbaum, *supra* note 18, at 364; *see* Bagley, *supra* note 37, at 228 (noting that "many researchers receive study funding from industry sources").

421. Act of July 19, 1952, ch. 950, 66 Stat. 792.

422. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 435 (2012).

academic interests within the AIA represents a complete inversion of academic exceptionalism. Such internalization suggests that the interests of the university community are no longer "exceptional" and that they may legitimately inform general rules of patentability that apply to all inventions.

1. *First-Inventor-To-File-or-Disclose*. The influence of academic science is greatest in the most prominent reform of the AIA, the shift from first-to-invent to first-inventor-to-file.[423] Nominally, the AIA shifts the United States from a "first-to-invent" jurisdiction, in which priority is based on the date of invention, to a "first-to-file" jurisdiction, in which priority is based on the date of filing a patent application.[424] Congress made this move to simplify priority determinations, reduce administrative costs, and harmonize U.S. law with international norms (virtually all other countries have first-to-file regimes). As this Article will demonstrate, however, universities played an instrumental role in ensuring that the AIA does not create a pure first-to-file system.

Initially, university representatives vehemently opposed the shift to first-to-file.[425] Universities favored the traditional first-to-invent system in which they could rely on early inventive activities by academic scientists (who generally keep good records of such activities) to establish priority vis-à-vis parties who invented later but filed patent applications earlier. Academic representatives argued that a "pure" first-to-file system would impose significant costs on universities, which would have to rush to file expensive patent applications on all promising technologies to maintain patent rights. Furthermore, first-to-file conflicted with academic norms of rapid publication. University scientists often seek to publish their findings—which may include descriptions of patentable technologies—as soon as possible. Under a pure first-to-file system, however, any publication prior to filing a patent application destroys novelty. Such concerns are mitigated in the traditional first-to-invent system in which novelty is based on the date of invention and in which the statutory bar regime contains a one-year grace period during which an inventor can disclose his invention before filing a

423. *See id.* at 449.

424. *Compare* 35 U.S.C. § 102 (2006), *with* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 285–87 (2011) (to be codified at 35 U.S.C. § 102).

425. *See* BURK & LEMLEY, *supra* note 110, at 101.

patent application and still maintain patent rights. For all of these reasons, in 2005 testimony regarding a previous patent reform bill, managing director of WARF Carl Gulbrandsen argued that "[t]he first-inventor-to-file proposal would be a hardship for a vast majority of universities."[426]

Based in significant part on university pressure, the AIA does not create a pure first-to-file system. Rather, it creates what has been characterized as a "first inventor-to-file-or-disclose" regime. It retains vestiges of the older statutory bar system by integrating a one-year grace period within a first-to-file system.[427] Because of this grace period, certain public disclosures of an invention within one year before filing a patent application will not destroy that invention's novelty.[428] The retention of a one-year grace period is rather unique to the United States; many other jurisdictions have an "absolute novelty" regime in which any public disclosure of an invention prior to filing a patent application destroys novelty.[429]

The retention of a one-year grace period within a nominal first-to-file system represents a significant concession to university interests. Not surprisingly, universities played an important role in crafting this regime.[430] Although other stakeholders also advocated for retaining the grace period,[431] universities represented a particularly vocal and influential group. In hearings from 2005, Charles Phelps, provost of the University of Rochester, shared his thoughts on behalf

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426. *Hearing on H.R. 2795*, *supra* note 417, at 29–30 (statement of Carl E. Gulbrandsen, Managing Dir., Wis. Alumni Research Found.).

427. *See* Leahy-Smith America Invents Act § 3, 125 Stat. at 286 (to be codified at 35 U.S.C. § 102(b)).

428. This is one reason why the U.S. system is often called a "first-inventor-to-file system." A first inventor who publicly discloses an invention and then files a patent application within one year will prevail against an *earlier* filer (but later inventor) who, for example, simply copied the invention from the prior inventor.

429. *See* Robert P. Merges, *Priority and Novelty Under the AIA*, 27 BERKELEY TECH. L.J. 1023, 1032 (2012).

430. *See, e.g.*, *Hearing on H.R. 2795*, *supra* note 417, at 59 (statement of Carl E. Gulbrandsen, Managing Dir., Wis. Alumni Research Found.). In general, universities have developed a very significant presence on Capitol Hill; between 1998 and 2007, lobby expenditures by universities increased from $30.8 million to $90.2 million. Jay P. Kesan & Andres A. Gallo, *The Political Economy of the Patent System*, 87 N.C. L. REV. 1341, 1359 tbl.3 (2009). The percentage of lobbying expenditures devoted to intellectual property laws, however, is unknown and likely relatively low. *See id.* at 1359.

431. *See* 157 CONG. REC. S1098 (daily ed. Mar. 2, 2011) (statement of Sen. Amy Klobuchar) ("[W]e have heard from stakeholders from across the spectrum—from high tech and life sciences to universities and small inventors—in support of the transition to the first-to-file system.").

of the Association of American Universities, American Council on Education, Association of American Medical Colleges, and Council on Governmental Relations. Phelps explained the importance of maintaining a grace period for academic inventors, who often publish their findings immediately and need time to assess whether to patent them.[432] According to Phelps, university groups would support the transition to first-inventor-to-file only upon retaining a one-year grace period.[433] Maintaining a grace period had long been on the academic legislative agenda. As far back as 2004, the National Research Council recommended that the United States retain a grace period and persuade other countries to adopt one, particularly to accommodate academic patentees.[434]

The resulting one-year grace period is especially beneficial to academic inventors. As noted, this one-year grace period accommodates the academic norm of speedy publication. For example, if a faculty inventor publishes an article describing some new technology, then files a patent application within one year of publication, she would not defeat her own novelty.[435] Publication offers a particularly important benefit, for it even protects a patent applicant against disclosures by *independent inventors*. Unlike a pure first-to-file system, the AIA creates a first-inventor-to-file-or-disclose regime that heavily benefits academic inventors.

The legislative history of the AIA reveals the importance of university interests in retaining the grace period. Senator Patrick Leahy, one of the sponsors of the bill, stated that "the first-inventor-to-file provisions that are included in the America Invents Act were drafted with careful attention to the needs of universities and small inventors."[436] A House committee report similarly notes that "[t]he Committee heard from universities and small inventors, in particular, about the importance of maintaining that grace period in our

432. *Perspectives on Patents: Harmonization and Other Matters: Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 109th Cong. 75 (2005) [hereinafter *Perspectives on Patents: Harmonization and Other Matters: Hearing*] (statement of Charles E. Phelps, Provost, Univ. of Rochester).

433. *See id.* ("[T]he broad grace period of current law operating in a first inventor to file system would encourage open communication of research discoveries and preserve a broad opportunity for the filing of patent applications.").

434. NAT'L RESEARCH COUNCIL, A PATENT SYSTEM FOR THE 21ST CENTURY 127 (2004).

435. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 3, 125 Stat. 284, 286 (2011) (to be codified at 35 U.S.C. § 102(b)(1)(A)).

436. 157 CONG. REC. S1090 (daily ed. Mar. 2, 2011) (statement of Sen. Patrick Leahy).

system,"[437] and goes on to cite testimony from Phelps and Gulbrandsen, among others.[438]

One must not paint with too broad of a brush, however, and it is important to acknowledge internal dissent within the university community regarding the shift to first-inventor-to-file. Notably, WARF led a consortium of universities in breaking ranks with most higher-education associations to oppose the AIA, primarily because it perceived the "safeguards" of the first-inventor-to-file-or-disclose regime to be inadequate.[439] Such concerns were based both on the lengthy amount of time it takes for academic papers to be published as well as the uncertainty surrounding the sufficiency of a prior disclosure that would be necessary to maintain novelty in the first-inventor-to-file-or-disclose system.[440] Notwithstanding the criticisms of WARF and its cohorts, the grace period provisions of the AIA were adopted in significant part to accommodate university interests.

The adoption of a grace period in the new first-inventor-to-file regime reflects a significant stage in the statutory internalization of academic science within patent law. As the AIA's grace period provisions reveal, the interests of academic science have journeyed to the center of patent law; a once-marginal activity is now helping to define general rules of novelty that apply to all inventions. Other legislative reforms further illustrate the internalization of academic interests within patent law, though they offer a new twist on the theme of academic exceptionalism.

2. *The Prior User Rights Defense*. In other areas of the AIA, academic interests are manifested not in altering the general rules of patent law, but in establishing specific carve-outs for academic entities. In this sense, academic exceptionalism, which courts have rejected in doctrine, has been resurrected in statute.

For example, universities preferentially benefit from the newly expanded "prior user rights" defense to patent infringement. In the American Inventors Protection Act of 1999,[441] Congress established a

437. *See* H.R. REP. NO. 112-98, pt. 1, at 41 (2011), *reprinted in* 2011 U.S.C.C.A.N. 67, 71.

438. *Id.*

439. *See* Goldie Blumenstyk, *Several Universities Oppose Pending 'Patent Reform' Legislation*, CHRON. HIGHER EDUC. (June 21, 2011), http://chronicle.com/blogs/ticker/several-universities-oppose-pending-patent-reform-legislation/34091.

440. I thank Jacob Rooksby for these helpful observations.

441. American Inventors Protection Act of 1999, Pub. L. No. 106-113, tit. IV, 113 Stat. 1501, 1501A-552 (1999) (codified as amended at 35 U.S.C. §§ 5, 6, 273, 297, 311–318).

relatively narrow defense to infringement based on one's prior commercial use of an invention before another party patented it. For example, if A reduced to practice a process and (secretly) used it for over a year before B filed a patent application on it, A could invoke its prior use as a defense if B sued A for patent infringement. Although this prior use defense covered parties who engaged in prior "commercial" use of a patented invention,[442] the statute clarified that the defense extended to "activities performed by a nonprofit research laboratory or nonprofit entity such as a university, research center, or hospital" as long as these activities aimed to benefit the public.[443] The prior user rights defense thus applied to a university that used an invention for a year before it was patented by another party. Notably, this provision reflects an instance of statutory academic exceptionalism, as Congress stretched the definition of "commercial use" to encompass use by universities. This defense was rather narrow, however, as it only applied to alleged infringement of certain patented business methods.[444]

With the AIA, Congress expanded the prior user rights defense beyond patented business methods to patented processes more generally. Universities accused of infringement fully benefit from this expanded defense, for the AIA preserves the notion that prior "[n]onprofit laboratory use" constitutes a prior *commercial* use that relieves a defendant of infringement liability.[445] Thus, even though laboratory use by an academic institution seems to be the opposite of commercial use, it still qualifies for the "prior commercial use" defense to patent infringement.

More importantly, under the AIA, university *patentees* receive special treatment when infringers attempt to assert the prior user rights defense against them. In a provision entitled "University Exception," the AIA states that a defendant may not invoke the prior user rights defense if the patent in suit "was, at the time the invention was made, owned or subject to an obligation of assignment to either an *institution of higher education* . . . or a *technology transfer organization* . . . ."[446] In other words, a defendant may not invoke the

442. 35 U.S.C. § 273(b)(1) (2006), *amended by* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 5, 125 Stat. 284, 297 (2011).

443. *Id.* § 273(a)(2).

444. *See id.* § 273(a)(3).

445. Leahy-Smith America Invents Act § 5, 125 Stat. at 297 (to be codified at 35 U.S.C. § 273(c)(2)).

446. *Id.*, 125 Stat. at 298 (to be codified at 35 U.S.C. § 273(e)(5)(A)) (emphasis added).

prior user rights defense when sued by a university for patent infringement.[447] This, of course, greatly and asymmetrically benefits university patentees.[448]

Not surprisingly, university representatives were quite influential in securing this preferential treatment.[449] Originally, university representatives argued against expanding the prior user rights exception because of the belief that such a defense would encourage protecting patentable inventions as trade secrets, which would negatively impact academic institutions.[450] WARF in particular opposed any categorical expansion of prior user rights.[451] Academic representatives would only support expanding the prior use rights defense if it contained special accommodations for university patentees.[452] Exercising their political muscle, universities helped secure preferential treatment in the AIA.[453]

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447. *See* H.R. REP. NO. 112-98, pt. 1, at 71 (2011) *reprinted in* 2011 U.S.C.C.A.N. 67, 96 ("H.R. 1249 would prohibit public and private entities from using the prior-use defense to patent infringement claims for business processes brought by a university or technology-transfer organization.").

448. *See* Arti K. Rai & Bhaven N. Sampat, *Accountability in Patenting of Federally Funded Research*, 30 NATURE BIOTECH. 953, 953–54 (2012) ("The privileged position universities and their assignees and/or licensees now hold in patent litigation, even against prior, independent commercializers, makes proper information as to whether those patents involved federal funding even more important.").

449. *See* H.R. REP. NO. 112-98, pt. 1, at 44, *reprinted in* 2011 U.S.C.C.A.N. at 75 ("This narrow expansion of prior-user rights balances the interests of patent holders, *including universities*, against the legitimate concerns of businesses that want to avoid infringement suits relating to processes that they developed and used prior to another party acquiring related patents." (emphasis added)).

450. *See Hearing on H.R. 2795*, *supra* note 417, at 29 (statement of Carl E. Gulbrandsen, Managing Dir., Wis. Alumni Research Found.); *Patent Law Reform: Injunctions and Damages: Hearing*, *supra* note 380, at 101 (statement of Carl E. Gulbrandsen, Managing Dir., Wis. Alumni Research Found.); *Perspectives on Patents: Harmonization and Other Matters: Hearing*, *supra* note 432, at 73 (statement of Charles E. Phelps, Provost, Univ. of Rochester).

451. *See* Briefing Paper, Wis. Alumni Research Found., U.S. Patent Reform and the Case Against Expansion of Prior User Rights (Apr. 13, 2011), *available at* http://democrats.judiciary.house.gov/sites/democrats.judiciary.house.gov/files/documents/WARF110413.pdf ("Now, as patent reform legislation nears completion, an attempt by proponents of prior user rights has been made to turn back the clock and enact language that would benefit a few at the expense of society.").

452. *See Patent Law Reform: Injunctions and Damages: Hearing*, *supra* note 380, at 101 (statement of Carl E. Gulbrandsen, Managing Dir., Wis. Alumni Research Found.) ("Prior user rights establish a general defense against infringement. WARF opposed the proposed expansion.").

453. *See* Memorandum from Hunter R. Rawlings III, President, Ass'n of Am. Univs., Molly Corbett Broad, President, Am. Council on Educ., Darrell G. Kirch, President & CEO, Ass'n of Am. Med. Colls. & M. Peter McPherson, President, Ass'n of Pub. & Land-grant Univs., to Ass'n

3. *Micro Entity Status*. Finally, the AIA exhibits a rather blatant example of academic exceptionalism by lowering fees for patent applicants under an obligation to assign or license their applications to universities.[454] Again, this represents a new (and rather explicit) model of academic exceptionalism based in statute rather than doctrine. Under the AIA, such applicants qualify for "micro entity" status and are thus eligible for a 75 percent reduction in fees. Although the name suggests that micro entities are individuals or small firms, this is a misnomer, as the micro entity categorization also encompasses inventors at institutions of higher education.

The political horse-trading at the heart of this provision is rather apparent in its legislative history. In March 2011, Senator Harry Reid offered an amendment to the micro entity provision that would have extended such status to public universities participating in a program aimed at benefitting institutions deemed to be receiving an inadequate share of federal research and development funds.[455] Senators from states with universities *not* participating in this program objected, and eventually the Senate voted to extend micro entity status to all public universities.[456] In the House of Representatives, objections from *private* universities led members of Congress to expand micro entity status to all institutions of higher education, both public and private.[457] In this manner, university interests won a significant reduction of patent fees in the AIA.[458] Not surprisingly, universities,[459] research institutions,[460] TTOs,[461] and

Constituencies, Support H.R. 1249, the America Invents Act 2 (June 14, 2011), http://judiciary.house.gov/issues/Patent%20Reform%20PDFS/AAU%20ACE%20AAMC%20APLU.pdf.

454. Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 10, 125 Stat. 284, 319 (2011) (to be codified at 35 U.S.C. § 123(d)).

455. *See* Matal, *supra* note 422, at 495.

456. *See id.*

457. *See id.* at 496.

458. Universities won preferential treatment in other areas of the AIA as well. *See* Leahy-Smith America Invents Act § 4, 125 Stat. at 294 (to be codified at 35 U.S.C. § 115(d)) (allowing patent applicants (such as universities) to file a substitute statement when an inventor does not execute the ordinarily required oath); *id.* § 13(a), 125 Stat. at 327 (to be codified at 35 U.S.C. § 202(c)(7)(E)(i)) (increasing royalties that universities can retain from licensing inventions at government-owned, contractor-operated research facilities); H.R. REP. No. 112-98, pt. 1, at 43 (2011), *reprinted in* 2011 U.S.C.C.A.N. 67, 73 (noting that the AIA preserves the intent of the CREATE Act to promote joint research activities and subtly expanding its reach).

459. Comment from Rockefeller Univ., to U.S. Patent & Trademark Office, Comment on Notice of Proposed Rulemaking, Federal Register, Volume 77, Number 104, May 30, 2012 Changes to Implement Micro Entity Status for Paying Patent Fees (July 3, 2012), http://www.uspto.gov/patents/law/comments/me_rockefeller_03jul2012.pdf.

organizations such as the Association of American Universities, the Association of Public and Land-grant Universities, the Association of American Medical Colleges, and the Council on Governmental Relations[462] all actively contributed to rulemaking governing this special treatment for universities. Ultimately, preferential treatment for universities—previously peripheral players in the patent system—is now hardwired in patent statutes and regulations.

V. ANALYSIS, ASSESSMENTS, AND PRESCRIPTIONS

A. *The Mutual Internalization of Academic Science and Patent Law and the Evolution of Academic Exceptionalism*

Historically segregated, academic science and patent law have over the past several decades engaged in a process of mutual internalization. Along the way, academic exceptionalism has evolved considerably. In the early to mid-twentieth century, academic researchers largely adhered to scientific norms that eschewed patents, and universities' early forays into the patent system were marked by uniquely academic, noncommercial values. For its part, patent law exhibited academic exceptionalism by excluding the fruits of academic science and sometimes treating academic entities differently than ordinary commercial actors. Due to a host of developments culminating in the late twentieth century, however, patents began to permeate academic culture.[463] Contemporary universities have

460. Comment from Priti Phukan & Thomas Fitting, Office of Patent Counsel, Scripps Inst., to U.S. Patent & Trademark Office, Comments on Proposed Rule Making—Micro Entity Status (June 21, 2012, 1:26 PM), http://www.uspto.gov/patents/law/comments/me_fitting_21jun2012.pdf.

461. Comment from Dale Zetocha, Exec. Dir., N.D. State Univ. Research Found., to U.S. Patent & Trademark Office, Comments Provided in Response to "Changes to Implement Micro Entity Status for Paying Patent Fees" from Vol. 77, N. 104 of the Federal Register, in Reference to the Leahy-Smith America Invents Act (June 21, 2012), http://www.uspto.gov/patents/law/comments/me_ndsurf_27jul2012.pdf.

462. *See* Comment from Hunter R. Rawlings III, President, Ass'n of Am. Univs., Peter McPherson, President, Ass'n of Pub. & Land-grant Univs., Darrell G. Kirch, President & CEO, Ass'n of Am. Med. Colls. & Anthony P. DeCrappeo, President, Council on Governmental Relations, to James Engel, Senior Legal Advisor, Office of Patent Legal Admin., Office of the Deputy Comm'r for Patent Examination Policy, Changes to Implement Micro Entity Status for Paying Patent Fees (RIN 0651-AC78) (July 27, 2012), http://www.uspto.gov/patents/law/comments/me_aau_27jul2012.pdf.

463. This transformation has been particularly stark in the life sciences. Whereas universities were historically wary of profiting from health technologies, biomedical research has been a site of intensive patenting in contemporary times. Mowery & Sampat, *supra* note 28, at 786.

internalized patents, and the patent system has internalized university science. Nowadays, university inventors and inventions are frequent subjects of patent doctrine, and courts perceive little difference between universities and profit-oriented actors in the patent system. Based in part on the increasingly commercial tenor of university patenting, courts have systematically rejected academic exceptionalism in patent doctrine. The internalization of academic science has reached its zenith with legislative patent reform, in which the interests of academic science held much sway. On the one hand, academic exceptionalism has vanished to the extent that the interests of academic science now inform general rules of patentability. On the other hand, academic exceptionalism has been reborn in statute, the product of legislative rent-seeking by universities.

Although the shifting normative status of universities has helped drive these developments, it is important to recognize other contributing factors as well. Focusing on patent doctrine, contemporary courts' rejection of academic exceptionalism is part and parcel of broader structural trends in patent law. As a historical matter, the sharp rise in university patenting—and courts' rejection of academic exceptionalism—has coincided with the tenure of the Federal Circuit. Given this court's mission to unify patent law and make it more consistent,[464] a project of eliminating preferential treatment for a particular set of institutions is not surprising. Even though this unifying tendency may contribute to the Federal Circuit's rejection of academic exceptionalism, however, the changing normative status of universities remains quite relevant. The Federal Circuit has frequently referenced the commercial nature of modern university patenting in rejecting any preferential treatment for such institutions. Furthermore, the rejection of academic exceptionalism is not unique to the Federal Circuit: the Supreme Court and district courts have also rejected preferential treatment for universities as well.

In many ways, the developments described here reflect increased aggressiveness on the part of universities in multiple contexts. First, university research has become more *scientifically* aggressive, shifting from passively observing nature to actively manipulating the building blocks of life. The development of monoclonal antibodies and recombinant DNA technology, and the concomitant rise of

464. *See* Dreyfuss, *supra* note 201, at 7 ("[C]hannelling patent cases into a single appellate forum would create a stable, uniform law . . . .").

biotechnology, ushered in an era in which the fruits of academic research increasingly cross the threshold to qualify as patentable inventions. Second, universities became more *commercially* aggressive as they sought to realize (and enlarge) profits from intellectual property. Third, universities became more *politically* aggressive as they turned to the legislative process to consolidate their gains from technology transfer. Now that universities have become entrenched within the patent system, they have wielded their political might to help regulate the legal framework that regulates them. In other areas of intellectual property law, parties have invoked the trope of the "romantic author" to justify stronger protection.[465] Somewhat analogously, representatives of academia have invoked the rhetorical trope of the "romantic university" to justify preferential treatment under the patent laws. Although universities may indeed possess some unique characteristics, in many ways, this behavior simply reveals that universities act like typical rent-seeking institutions in both the economic and political spheres.

Ultimately, these developments help define a narrative of reciprocity between norms and law.[466] Historically, relations between universities and the patent system were marked by a stable equilibrium in which university scientists rarely patented their discoveries and the patent system regarded universities—in their limited interactions—through the lens of academic exceptionalism. Later, legal changes such as the Bayh-Dole Act and *Chakrabarty* helped usher universities more deeply into the patent system. Once there, universities began to behave more like commercial entities, thus losing their special normative status. In an iterative fashion, the patent system responded to its own creation by highlighting the increasingly commercial nature of universities and rejecting academic exceptionalism. And in strictly construing rules regarding priority and prior art, courts interpreting patent doctrine actually pushed universities to act more like commercial entities. Universities, eager to consolidate their newfound gains, turned to the legislative sphere

465. *See* JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEENS: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY x–xiii (1996) (noting that invocations of the "romantic author" have contributed to a proliferation of intellectual property rights); Keith Aoki, *(Intellectual) Property and Sovereignty: Notes Toward a Cultural Geography of Authorship*, 48 STAN. L. REV. 1293, 1333–38 (1996); Peter Jaszi, *Toward a Theory of Copyright: The Metamorphoses of "Authorship,"* 1991 DUKE L.J. 455, 456.

466. *See* Rai, *supra* note 7, at 84 (describing the dynamic relationship between norms and law).

to shape patent reform, thus fully integrating academic science into the fabric of patent law.

B. Assessments and Prescriptions

Turning from the descriptive to the normative, this Article returns to the question of whether and how the patent system should treat universities differently than other actors. Given the patent system's historical commitment to a unitary system that treats all parties equally, the burden of persuasion rests on those who would extend special treatment to academic entities. In theory, however, social welfare concerns may justify such exceptionalism; as Professor Margo Bagley notes, "Some may question whether university inventors should receive special treatment in the patent system. The answer is they should not, unless special treatment will inure to the public good."[467] This Article argues that universities are sufficiently unique actors in the patent system that they warrant differential treatment in some, but not all, contexts.

In important ways, the question of how universities should interact with the patent system depends on one's normative vision of universities in society. As mentioned earlier, there is great diversity among academic institutions.[468] The norms, histories, and missions of public versus private, secular versus religious, and land-grant versus non-land-grant institutions may lead to different visions about a university's role in society and how patenting and technology transfer advance (or do not advance) that role.[469] Such institutional missions should arise through processes of self-governance based on consultation with relevant stakeholders. In general, however, universities as a whole occupy a distinct and discrete role in society as nonprofit institutions committed to advancing knowledge, teaching students, and serving their respective communities. As a descriptive and normative matter, universities *are* different in important ways from the typical commercial entities that fall within the regulatory grasp of the patent system. It is within this very broad normative framework that this Article offers the assessments and prescriptions that follow.

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467. Bagley, *supra* note 37, at 265.

468. *See supra* note 9 and accompanying text.

469. *See* Lee, *supra* note 216, at 2234–35 (noting a high degree of diversity among universities and approaches to technology transfer).

The question of how the patent system should regulate university science is further complicated in several ways. First, the patent system is not a monolithic entity but is instead comprised of a constellation of regulatory forces including courts, Congress, the USPTO, funding agencies, and civil society. Second and relatedly, regulation can take the form of hard law as well as more informal soft regulation (such as through the lever of federal research funding) or even public pressure. Third, universities intersect with the patent system in different ways, for example as patentees (and enforcers), licensors, and infringers. As an overarching principle, this Article argues that the right regulatory approach will vary based on context.

As suggested above, this analysis proceeds on the principle that academic exceptionalism in the abstract is neither categorically good nor bad. The key inquiry—which is an admittedly difficult one—is recognizing when exceptional treatment is warranted because differential rules for university research serve broader social interests.[470] In most contexts, general rules of patent law should apply without exception to academic entities. Thus, for example, this Article argues against any preferential treatment for universities in the basic requirements of patentability; in this manner, among other implications, existing doctrine can usefully constrain universities' ability to patent upstream, embryonic inventions. In the remedies context, courts should carefully exercise their equitable discretion to deny injunctions to university patentees in certain circumstances, thus enhancing access to academic technologies. Turning to soft regulation, federal funding agencies should leverage the power of the purse to encourage more progressive patenting and licensing decisions by patentees. In some instances, public policy objectives counsel in favor of extending preferential treatment to universities, for example, by providing a more robust experimental use exemption so that noncommercial academic research may proceed relatively unimpeded.

1. *Patentability*. As discussed above, academic patentees have occasionally argued to relax various requirements of patentability, such as the definition of diligence and the written description

470. And, of course, when policy objectives counsel in favor of academic exceptionalism, such exceptionalism may take the form of disparate treatment that either advances or contravenes universities' own articulated preferences.

requirement,[471] for university inventions. They have sometimes supported their arguments by citing the Bayh-Dole Act, which (they contend) demonstrates Congress's endorsement of university patenting and technology transfer. For a variety of reasons, however, courts and Congress should not relax the requirements of patentability for academic inventions.

First, although selectively relaxing patentability requirements would increase academic patenting, there is no evidence that the number of patents owned by universities is suboptimal. If anything, commentators suggest that universities are obtaining too many patents, thus creating potentially deleterious anticommons regimes and patent thickets.[472] Many university inventions, such as some research tools, can achieve widespread dissemination and commercialization without patents. Approached from a different angle, if universities were particularly good stewards of inventions, there might be a plausible policy argument for selectively relaxing patentability requirements to increase the number of university patents. However, there is little indication that universities are particularly effective or enlightened stewards of technology. As seen in cases involving human embryonic stem cells, cotransformation, and genes related to breast cancer, universities have exhibited many of the same rent-seeking, self-interested tendencies as commercial entities.[473] And in the cases of COX-2 inhibitors and NF-kB, patents did not facilitate technology transfer so much as allow universities and their licensees to sue manufacturers who were already developing useful products.[474]

Second, relaxing patentability requirements for universities would have deleterious effects on the *kind* of inventions patented by academic institutions. In particular, relaxing patentable subject

471. *See supra* notes 325–32, 343–61 and accompanying text.

472. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) ("[P]rivatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research.").

473. As noted above, however, universities have sometimes made patented inventions widely available to the research community. *See supra* notes 276–82 and accompanying text. Some commercial firms do this as well, however.

474. *Cf.* Nelson, *supra* note 295, at 16. As these examples demonstrate, the "problem" of overreaching in academic patenting may be addressed through restricting general doctrines of patentability. However, doctrinal modification represents a rather blunt instrument, and a more targeted intervention would involve influencing the particular patenting and licensing decisions of individual university patentees. *See infra* Part V.B.2.

matter, utility, enablement, or written description requirements would permit more embryonic, upstream technologies to qualify for patenting. This would not be a welcome development. To be sure, Professor Edmund Kitch's "prospect theory" famously defends broad patents on early stage technological prospects.[475] According to this view, allowing a single patentee to coordinate technological development prevents wasteful races for patents and duplicative effort.[476] There are indeed conceptual parallels between prospect theory and the Bayh-Dole Act, both of which contemplate a single entity (for example, a university) managing the development of an early stage technology. Commentators, however, have challenged the propriety of early, broad patents on technological prospects, particularly when rivalry and competition in innovation markets has been extremely effective in driving invention and commercialization.[477] Ultimately, allowing patents on overly embryonic inventions would be counterproductive both because of the significant effort that would still be required to create commercial products and because of the potential for broad patents to stymie multiple avenues of technological development.[478]

Third, strategic considerations also weigh against relaxing the standards of patentability for academic inventions. If universities qualified for special treatment, commercial entities could easily game this distinction by sponsoring research at universities and then exclusively licensing any resulting patented inventions. Such gamesmanship would erode whatever social value preferential treatment for academic inventions was intended to generate.

Turning from the rules of patentability to patent fees, the AIA's extension of micro entity status to universities, which qualifies academic patentees for lower fees, is also unwarranted. First, as noted, there is little empirical evidence suggesting that universities are not patenting enough. Second, although university scientists are the named inventors on patent applications, they typically do not pay

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475. Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977).

476. *Id.*

477. *See* Mark A. Lemley, *Ex Ante Versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 135–41 (2004); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 872–77 (1990).

478. *See* Brenner v. Manson, 383 U.S. 519, 534–35 (1966) (articulating a concern that a patent on a process of producing compounds of no known utility could "block off whole areas of scientific development").

patent fees; that responsibility falls to universities (more specifically, TTOs), many of which are rather macro, well-heeled institutions. Third, many sophisticated TTOs identify a prospective licensee to cover patent fees *before* initiating prosecution. In such cases, subsidizing university patent applications might actually chill this favorable screening practice. There appears to be little principled reason for extending lower fees to academic patentees, which reflects blatant legislative rent-seeking on the part of universities.[479]

Even though courts and Congress should resist favoring universities in the requirements of patentability, general reforms to patent law informed by the unique needs of academic research are not necessarily problematic. First, the CREATE Act's extension of the § 103(c) safe harbor to joint research agreements[480] fosters partnerships between university and industrial scientists while helping to preserve the patentability of resulting inventions. Although such collaborations give rise to concerns over the commercialization of academia, they also serve as valuable conduits for transferring academic technical knowledge to the private sector (and vice versa).[481] Second, the AIA's establishment of a first-inventor-to-file-or-disclose system rather than a true first-inventor-to-file system represents good policy. Maintaining a one-year grace period is particularly congruent with academic norms of rapid publication and may decrease the chilling effects that patenting would otherwise exert on academic discourse. The rub here, however, arises not from academic exceptionalism, but from American exceptionalism. The value of the United States's one-year grace period is severely limited to the extent that most other jurisdictions maintain systems closer to pure first-inventor-to-file regimes. Thus, if a university seeks patent rights on a technology in multiple jurisdictions (which will be the case for the vast majority of technologies of commercial importance), then it must abide by the more stringent first-to-file rules of those countries.[482]

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479. *See, e.g.*, *Micro-Entity Status: Can We All Qualify?*, PATENTLY-O (Aug. 26, 2012, 3:31 PM), http://www.patentlyo.com/patent/2012/08/micro-entity-status-can-we-all-qualify.html (quoting independent inventor Raoul Drapeau).

480. *See supra* notes 412–20 and accompanying text.

481. Lee, *supra* note 303, at 1549–51.

482. An academic inventor who discloses an invention and then files for a patent within one year will be able to obtain a patent in the United States because of the one-year grace period. However, she will not be able to obtain patent rights in other jurisdictions that follow an absolute novelty regime with no grace period. Thus, for all commercially valuable inventions with a potential global market, a prudent patentee should not engage in any public disclosure prior to filing a patent application.

2. *Remedies*. With respect to enforcement, an important issue is the appropriate remedy that university patentees should obtain upon successfully asserting their patents. In *eBay*, the Supreme Court clarified that university patentees should not be categorically excluded from obtaining injunctive relief, even though they do not manufacture any products.[483] In exercising their equitable discretion, however, courts should be mindful of the unique role of universities as nonprofit, public-interest institutions as well as the individual circumstances of technology transfer. In some cases, the absence of irreparable harm, adequacy of legal remedies, balance of hardships, and public interest may counsel *against* granting an injunction, and ongoing royalties may be sufficient to compensate the university for infringement. In particular, for the subset of university inventions that arise from federal funding, it would be helpful for courts to consider the policy aims of the Bayh-Dole Act in their injunction analyses. Given that federal funds have satisfied the incentive to invent such technologies, injunctive relief is best justified based on providing incentives to develop an invention into a commercial product. Courts should consider whether exclusive rights are necessary to serve this function when a plaintiff asserts a university patent. In some cases, patented university technologies achieve wide commercialization *despite* the patent,[484] thus calling into question whether an injunction would truly serve the public interest.

3. *Decisions to Obtain and License Patents*. As illustrated in various case studies above, problematic instances of academic patenting arise not simply from liberal doctrines of patentability, but from universities' specific decisions to patent particular technologies (as opposed to leaving them in the public domain) and license them restrictively. Notably, although the Bayh-Dole Act allows universities to patent federally funded inventions, it does not require them to do so; universities maintain significant discretion regarding whether to seek exclusive rights and how to assert them. Accordingly, although courts and Congress should resist modifying general rules of patentability either in favor of or against university inventions, soft regulation can bear valuable fruit in shaping individual university

483. *See supra* Part III.B.2.e.

484. *See, e.g.*, Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188 (2011); Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336 (Fed. Cir. 2010) (en banc).

patenting and licensing practices. As demonstrated above, some universities have exploited their discretion in publicly spirited ways, declining to patent technologies that do not require additional private investment for exploitation or licensing patents at lower rates for noncommercial versus commercial uses. Government intervention can help encourage and expand these practices. Whereas legal doctrine and statutory reforms are rather blunt instruments for guiding patenting and licensing decisions, funding agencies can utilize the power of the purse to influence academic grantees in a more targeted, contextually sensitive manner.

Indeed, agencies like NIH have put strings on government money to influence universities' patenting and licensing practices.[485] For instance, NIH has discouraged grant recipients from patenting DNA sequences within the Human Genome Project and has encouraged (if not required) grantees to widely license patented research tools for academic investigation.[486] Furthermore, it has issued guidance for licensing research tools and genomic inventions[487] and offered recommendations regarding corporate sponsors' control over academic scientists.[488] Funding agencies, which possess technical expertise and do not directly profit from government-financed patents, should continue to help shape university patenting and licensing practices to serve the public interest.

Agencies, however, can do more. In particular, NIH has been notoriously reluctant to exercise rights under the Bayh-Dole Act to enhance access to federally funded inventions.[489] These mechanisms—particularly march-in rights—have great potential to enhance access to federally funded inventions for research and healthcare purposes,

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485. Indeed, the Supreme Court has tacitly recognized that funding agencies may influence the behavior of grantees. *Cf. Roche*, 131 S. Ct. at 2199 ("Agencies that grant funds to federal contractors typically expect those contractors to obtain assignments [of patents from inventors].").

486. *See, e.g.*, Lee, *supra* note 279, at 928–29; *NHGRI Policy Regarding Intellectual Property of Human Genome Sequence*, NAT'L HUMAN GENOME RES. INST. (Apr. 9, 1996), http://www.genome.gov/10000926.

487. *See* Best Practices for the Licensing of Genomic Inventions: Final Notice, 70 Fed. Reg. 18,413, 18,413–15 (Apr. 11, 2005); Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, 64 Fed. Reg. 72,090, 72,092 n.1 (Dec. 23, 1999); *NIH Policy on Sharing of Model Organisms for Biomedical Research*, NAT'L INST. HEALTH (May 7, 2004), http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html.

488. *See* Cristina Weschler, *The Informal Experimental Use Exception: University Research After* Madey v. Duke University, 79 N.Y.U. L. REV. 1536, 1567 (2004).

489. *See* Lee, *supra* note 283, at 951–55.

but NIH has rarely exploited them. Part of the difficulty lies in the Act's relatively high standards for instituting these mechanisms. In this regard, the findings of this Article support the proposal of Professors Arti Rai and Rebecca Eisenberg to modify the Bayh-Dole Act to allow funding agencies more flexibility to determine whether and how universities patent and license federally funded inventions.[490]

4. *Universities as Infringers*. Turning from universities as patentees to potential infringers, this Article identifies one context in which social welfare concerns favor academic exceptionalism. In this regard, this Article joins others in arguing for an experimental use exception to patent infringement for nonprofit university researchers.[491] Although universities increasingly behave like commercial entities, there is still much social value to academic research unfettered by patent constraints.[492] Even though early fears of a tragedy of the anticommons in biomedical research[493] have not materialized (particularly toward the upstream end of scientific research), the potential for exclusive rights to inhibit productive activity persists.[494] In some ways, an experimental use exception would simply safeguard the current state of affairs in which patentees almost never sue university researchers for infringement, and university

490. Rai & Eisenberg, *supra* note 238, at 310–13. The case for discouraging university patents on software is particularly strong given the relatively low development costs of such inventions. *See* Rai et al., *supra* note 254, at 1550.

491. *See, e.g.*, Dreyfuss, *supra* note 107, at 471–72 (advancing a waiver proposal); Mueller, *supra* note 137, at 54–57 (arguing for a liability-rule model to allow nonconsensual "development use" of patented research tools that are not readily available); Katherine J. Strandburg, *Users as Innovators: Implications for Patent Doctrine*, 79 U. COLO. L. REV. 467, 535 (2008) [hereinafter Strandburg, *Users as Innovators*] (advocating a "double-edged sword" research exception); Strandburg, *supra* note 137, at 138–44 (proposing a delayed compulsory license regime for research tools).

492. *See* Strandburg, *Users as Innovators*, *supra* note 491, at 503 ("It is in society's interest to have research performed by the quickest and most effective researchers."). It should be acknowledged that an experimental use exception may also benefit commercial firms, particularly if those firms sponsor research at universities with the aim of exploiting the exception and then licensing any resulting inventions arising from that research. Although policymakers can monitor such situations, they need not be particularly troubling if the "quasi-commercial" research still has significant academic value and does not significantly erode the incentives of patentees.

493. *See* Heller & Eisenberg, *supra* note 472, at 698.

494. *See* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059, 1080–84 (2008) (identifying several negative effects on university research).

researchers rarely attempt to clear patents.[495] Not surprisingly, university representatives[496] as well as organizations supporting academic research, such as the National Research Council,[497] have called for an experimental use exception.

A thorny question, however, is the precise mechanism by which such an experimental use exception would arise, an issue upon which scholars have offered detailed proposals.[498] The most promising approach would take the form of a statutory amendment to the Patent Act. In this regard, it bears mentioning that many other countries have formally codified an experimental use exception.[499] As Professor Katherine Strandburg argues, such a statute should distinguish between "experimenting on" and "experimenting with" patented technologies;[500] the former certainly appears to be well-qualified for a research exception. Given the Federal Circuit's decision in *Madey*, an ex ante experimental use exception is unlikely to arise in doctrine. However, an intermediate, ex post approach may emerge from remedies analysis. As I have argued elsewhere, courts should utilize *eBay*'s equitable flexibility to consider denying injunctive relief when a university scientist infringes an "infrastructural" patent, the exploitation of which promises significant social benefits relative to costs.[501] Although this approach would provide less ex ante certainty to would-be infringers, it may be a more palatable intervention for patentees, as it provides compensation and thus maintains incentives to invent and commercialize.

CONCLUSION

Patents and the university, once operating at each other's peripheries, have moved into each other's cores. This Article has traced the twin trends of academic internalization and exceptionalism within patent law. Before the late twentieth century, academic science

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495. *Cf.* Katherine J. Strandburg, *User Innovator Community Norms: At the Boundary Between Academic and Industry Research*, 77 FORDHAM L. REV. 2237, 2266 (2009).

496. *See, e.g.*, *Perspectives on Patents: Harmonization and Other Matters: Hearing*, *supra* note 432, at 11 (statement of Charles E. Phelps, Provost, Univ. of Rochester).

497. NAT'L RESEARCH COUNCIL, *supra* note 434, at 82.

498. *See supra* note 491.

499. *See* Strandburg, *supra* note 137, at 89 (including Germany, the United Kingdom, and Japan).

500. *Id.* at 88–89.

501. Lee, *supra* note 120, at 102–09.

was largely peripheral to the patent system. However, as academic science has grown more aggressive and as universities have vastly increased their patenting activities, academic research and practices have frequently become the subject of patent doctrine. Courts, responding to normative and behavioral changes on the part of universities, now view academic science as fully integrated into the commercial narrative of the patent system. The internalization of academic science within patent law has reached its zenith in legislative patent reform, as the interests of university research are now hardwired in statute.

Along the way, academic exceptionalism has evolved considerably. Up until the late twentieth century, patent courts, citing traditional academic norms, erected barriers between universities and the patent system and occasionally extended differential treatment to academic institutions. As universities began to embrace commercial norms, practices, and policies, however, contemporary patent courts have rejected academic exceptionalism. Whereas academic exceptionalism died in the courts, it has been resurrected in statute, as universities have wielded their political power to secure preferential treatment in recent patent reform legislation.

Turning from the descriptive to the normative, this Article has argued that in certain contexts, university research does indeed warrant special treatment in the patent system. Courts have been correct to reject universities' attempts to relax standards of patentability, but they should consider the unique circumstances of university patenting and technology transfer in determining the appropriateness of injunctive relief. Federal funding agencies should utilize soft regulation to guide universities' patenting and licensing decisions to serve the public interest. One area in which academic exceptionalism is warranted is infringement, where an experimental use exception can ensure that valuable scientific research proceeds uninhibited by patents. Through combining various hard and soft regulatory mechanisms, the patent system can better regulate and unleash the enormous innovative potential of the modern research university.