

Myriad Choices: University Patents Under the Sun

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How universities handle potentially patentable discoveries made by their faculty reflects important policy decisions that affect the greater public. While few research administrators in higher education would dispute that any university-owned patent should be used for society's benefit, the relationship between patents and the public good may be less apparent to those whose primary familiarity with patents stems from recent news reports of "patent trolls"¹ and billion-dollar battles in the smartphone industry.²

Yet no matter the staggering financial rewards often at stake with patents, furthering the public good is, at root, the motivating principle behind the government's award of any patent. The U.S. Constitution provides that, "[t]o promote the Progress of Science and useful Arts," Congress has the power to grant inventors "exclusive Right to their . . . Discoveries."³ When a patent is awarded, the public benefits from access to knowledge the inventor otherwise might not have disclosed. In exchange for that disclosure, the federal government awards a period of

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1. See, e.g., Ashby Jones, *When Lawyers Become 'Trolls,'* WALL ST. J., Jan. 23, 2012, <http://online.wsj.com/article/SB10001424052970203750404577173402442681284.html> (describing growth and functioning of patent troll industry); *This American Life: When Patents Attack!*, Chicago Public Radio (July 22, 2011), <http://www.thisamericanlife.org/radio-archives/episode/441/transcript/>.

2. See, e.g., Steve Lohr, *Apple-Samsung Patent Battle Shifts to Trial*, N.Y. TIMES, July 29, 2012 (noting that "[p]atents can be powerful tools for determining the rules of engagement for major companies in a fast-growing industry like smartphones"); Nick Wingfield, *Jury Awards \$1 Billion to Apple in Samsung Patent Case*, N.Y. TIMES, Aug. 24, 2012, <http://www.nytimes.com/2012/08/25/technology/jury-reaches-decision-in-apple-samsung-patent-trial.html> (describing the Apple-Samsung trial and the substantial damages awarded to Apple); Charles Duhigg & Steve Lohr, *The Patent, Used as a Sword*, Oct. 7, 2012, <http://www.nytimes.com/2012/10/08/technology/patent-wars-among-tech-giants-can-stifle-competition.html> (describing the use of software patents as "destructive weapons").

3. U.S. CONST. art. I, § 8, cl. 8.

exclusivity (currently twenty years)⁴ to the inventor to practice the invention—a substantial carrot believed to spur innovation that helps us all.

As early as 1813, former president Thomas Jefferson—himself an inventor and one of the nation’s founding members on the Board of Arts, which served as the nation’s first patent examination office⁵—acknowledged “the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.”⁶ Implicit in Jefferson’s remark is the understanding that not every “invention” should be awarded a patent. Yet the thrust of Congressional action and judicial interpretation in the 20th Century was to embrace an expansive view of the subject matter eligible for patent protection.⁷ Quoting from the Patent Act’s legislative history in a landmark case decided in 1980, the Supreme Court famously declared that “anything under the sun made by man” is eligible for patent protection, assuming the statutory criteria of novelty, utility, and “nonobviousness” are met.⁸ The decision effectively launched the biotechnology industry and, along with the Bayh-Dole Act of 1980, hastened the involvement of universities in patenting discoveries made by their faculty and researchers—an activity that has increased substantially in the past decade.⁹

To be sure, much good has come from these developments. Writing in 2002, *The Economist* magazine labeled the Bayh-Dole Act “innovation’s golden goose,”¹⁰ and it is easy to understand why. Recombinant DNA,

4. See 35 U.S.C. § 154, amended by Pub. L. No. 112-211 (2012) 126 Stat. 1527 (specifying patent term of twenty years from the date of application).

5. JEFFREY H. MATSUURA, *JEFFERSON VS. THE PATENT TROLLS* 79 (2008).

6. Letter from Thomas Jefferson to Isaac McPherson, Aug. 13, 1813.

7. This expansiveness has been curtailed, to a degree, by recent Court decisions that rearticulated some of the outer limits of subject matter eligible for patent protection. See *Bilski v. Kappos*, 130 S. Ct. 3218, 177 L. Ed. 2d 792 (2010) (affirming rejection of an application for a method of hedging losses in the energy industry; disputed claims constituted an abstract idea not eligible for patent protection); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 1305 (2012) (holding as invalid claims directed to a method of giving a drug to a patient, measuring metabolites of that drug, and with a known threshold for efficacy in mind, deciding whether to increase or decrease the dosage of the drug; disputed claims involved applying a law of nature, which is not eligible for patent protection).

8. See *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 100 S. Ct. 2204, 2207 (1980).

9. DAVID C. MOWERY, RICHARD R. NELSON, BHAVEN N. SAMPAT, & ARVIDS A. ZIEDONIS, *IVORY TOWER AND INDUSTRIAL INNOVATION: UNIVERSITY-INDUSTRY TECHNOLOGY TRANSFER BEFORE AND AFTER THE BAYH-DOLE ACT IN THE UNITED STATES* 93-94 (2004).

10. *Innovation’s Golden Goose*, *THE ECONOMIST*, Dec. 12, 2002, <http://www.economist.com/node/1476653>; but see *Bayh-ing for Blood or Doling Out Cash?*, *THE ECONOMIST*, Dec. 20, 2005, <http://www.economist.com/node/532766> (three years later, however, the magazine’s enthusiasm for the Bayh-Dole Act had tempered, noting concerns with university behavior enabled by the Bayh-Dole Act).

Coumadin® (a blood thinner), the OncoMouse® (a genetically modified mouse intended for laboratory testing), TrophAmine® (a nutritional support for premature babies), Gatorade®, the Honeycrisp apple, and the Breathalyzer® are some of the many and varied inventions to have benefitted the public and derived from research activities conducted by university scientists.¹¹ While many of these inventions are or once were protected by patents—which allow universities to license the manufacture and use of inventions to companies in industry—no federal law requires universities to seek patent protection for their researchers' discoveries unless they elect to take title to federally funded inventions.¹²

Yet increasingly, with a growing emphasis on translational research over basic science research, patent rights drive university research activities under the theory that they are necessary to attract private investment to commercialize inventions with possibly wide application. According to this theory, companies are not interested in translating research findings into marketable products unless patent rights exist to provide them with some expectation of market exclusivity and/or monopoly pricing.¹³ In turn, the potential to generate revenue through licensing patents can create incentives for universities to license their patents exclusively, which can lead to what amounts to monopolistic control by companies

11. See generally Maryann P. Feldman, Alessandra Colaianni & Connie Kang Liu, *Lessons from the Commercialization of the Cohen-Boyer Patents: The Stanford University Licensing Program*, in INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1797-1808 (Anatole Krattiger et al. eds., 2007); Munir Pirmohamed, *Warfarin: Almost 60 Years Old and Still Causing Problems*, 62 BRITISH J. OF CLIN. PHARMACOLOGY 509-511 (Nov. 2006); *Bioethics and Patent Law: The Case of the Oncomouse*, WIPO MAGAZINE 16-17 (June 2006); *Columbia Research Goes to Market: Earns More Income from Intellectual Property Than Any Other University*, 7 BIOMEDICAL FRONTIERS: ADVANCES IN SCIENCE, TECH., AND MED. AT COLUMBIA UNIV. HEALTH SCIENCES 10 (Fall 1999); DARREN ROVELL, *FIRST IN THIRST: HOW GATORADE TURNED THE SCIENCE OF SWEAT INTO A CULTURAL PHENOMENON* (2005); Edward Lotterman, *New Apple Raises Land-Grant Fairness Questions Anew*, ST. PAUL PIONEER PRESS, Sept. 23, 2010, at C1; History of the Center for Studies of Law in Action and the Borkenstein Course, <http://www.borkensteincourse.org/history.html>.

12. Often misunderstood as mandating university ownership of patents, the Bayh-Dole Act merely permits universities to elect to retain title to inventions that are developed with federal funds. See 35 U.S.C. § 202 (2012) (describing the disposition of rights under Bayh-Dole). If a university elects to retain title to such an invention, it must seek patent protection on the invention and engage in efforts to commercialize it. See 35 U.S.C. § 202(c)(3); Sean O'Connor, Gregory D. Graff, & David E. Winickoff, *Legal Context of University Intellectual Property and Technology Transfer*, NATIONAL ACADEMY OF SCIENCES REPORT 29 (2010).

13. C.f. 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 U.S. Academic Institutions: An Empirical Survey*, 24 NATURE BIOTECHNOLOGY 31-39 (Jan. 2006) ("Exclusive licensing [of patents] is consistent with the need to lower the perceived risk of investing in unproven technology to attract private risk capital.").

of new drugs, diagnostic tools, or other products of great importance to the public's health and welfare.

Recently, for example, Ohio State University announced its intention to commercialize extracts from a tropical tree that grows on the island of Borneo.¹⁴ The extracted compound, covered by a patent owned by the university, is believed to be an anticancer agent that could treat mantle cell lymphoma.¹⁵ We can hope that a cure from this compound soon will be derived. But if it is, patients in need and their insurers—which, given government health entitlements, always includes the taxpaying public—could pay a premium for the privilege of purchasing the medicine, assuming the university licenses the patent exclusively, to only one company, which is likely. While private companies that develop new drug compounds primarily have profits, not public service, as their goal when they market their products, we should expect a more public-serving approach from universities that are the social and scientific catalysts for potentially life-saving discoveries of wide application. Indeed, public service is at the heart of why universities emerged in the public sphere.¹⁶

Not every faculty invention with widespread, life-saving potential disclosed to a university need be patented, even if it constitutes subject matter that is eligible for patent protection.¹⁷ Jonas Salk's heralded discovery of the polio vaccine in 1955 provides a fitting example. Edward R.

14. NEWS MEDICAL, *Sarawak Biodiversity Centre in Malaysia, OSU to develop and commercialize anticancer agent* (Sept. 25, 2012), <http://www.news-medical.net/news/20120925/Sarawak-Biodiversity-Centre-in-Malaysia-OSU-to-develop-and-commercialize-anticancer-agent.aspx>. Extracts from trees have been put to astounding uses before. The cancer-fighting drug Taxol® was originally extracted from the Pacific yew tree. Florida State University owns patents on the drug, the licensure of which has generated the university over \$200 million in revenue. Frank Stephenson, *A Tale of Taxol*, FLA. ST. UNIV. RS. REV., Fall 2002, <http://www.rinr.fsu.edu/fall2002/taxol.html>.

15. NEWS MEDICAL, *supra* note 14.

16. See Brian Pusser, *Power and Authority in the Creation of a Public Sphere Through Higher Education*, in *UNIVERSITIES AND THE PUBLIC SPHERE: KNOWLEDGE CREATION AND STATE BUILDING IN THE ERA OF GLOBALIZATION* 27, 29 (Brian Pusser, Ken Kempner, Simon Marginson, and Imanol Ordorika, eds., 2011) (describing the “basic normative and functionalist assumption that [higher education] institutions exist to generate public and private goods in the public interest”).

17. To be sure, under the Bayh-Dole Act, universities must seek patent protection for any invention made by a member of their faculty that was conceived or first actually reduced to practice in the performance of work under a federal funding agreement, provided that the university has elected to retain title to the invention, which it need not do. See 35 U.S.C. § 202(c)(3). Even if it retains title to an invention and seeks patent protection for it, the university has options as to what to do with the patent. It could, for example, choose to license the patent for a nominal fee, on a non-exclusive basis, to anyone interested in licensing it, or to commercialize it through dedication to the public.

Murrow asked Jonas Salk, a professor at the University of Pittsburgh when he invented the vaccine, who owned the patent on his invention. Salk famously replied, “Well, the people, I would say. There is no patent. Could you patent the sun?”¹⁸

More recently, some faculty dissatisfied with patent-focused approaches to research dissemination are eschewing patent protection altogether in favor of open-source methods of sharing promising research results. Jay Bradner, a cancer researcher at Harvard Medical School, is a prominent example. When he discovered a molecule that, in mice, appeared to cause certain cancer cells to become healthy, he published the structure of the compound—an act that can foreclose the possibility of obtaining patent rights, particularly internationally¹⁹—and mailed samples of it to labs around the world, calling it “the more efficient way to do science—and maybe the more honorable way.”²⁰ Prominent organizations such as the Kauffman Foundation, the American Association of University Professors (“AAUP”), and the President’s Council on Jobs and Competitiveness support such untethering of institutional commercialization decisions from faculty research discoveries.²¹ These organizations argue that faculty inventors should have more freedom to decide the nature of their university’s involvement in commercialization decisions involving faculty discoveries, regardless of the societal utility or coffer-expanding potential of the discovery.²²

18. JANE S. SMITH, *PATENTING THE SUN: POLIO AND THE SALK VACCINE* 338 (1990).

19. See Margo A. Bagley, *The Need for Speed (and Grace): Issues in a First-Inventor-to-File World*, 23 BERKELEY TECH. L. J. 1035 (2008) (describing how publications by inventors disclosing their discoveries can operate to frustrate their patent rights). Inventors in the United States have one year to file for patent protection after publishing an article disclosing their invention. Many foreign countries do not have such a grace period. *Id.*

20. Dan Morell, *Jay Bradner*, THE ATLANTIC, Nov. 2012, <http://www.theatlantic.com/magazine/archive/2012/11/jay-bradner/309122/>.

21. See also James D. Clements, *Improving Bayh-Dole: A Case for Inventor Ownership of Federally Sponsored Research Patents*, 49 IDEA 469-516 (2009) (presenting the case for inventor ownership of patentable inventions derived from federal research dollars).

22. See, e.g., ROBERT E. LITAN & ROBERT M. COOK-DEEGAN, *Universities and Economic Growth: The Importance of Academic Entrepreneurship*, in RULES FOR GROWTH: PROMOTING INNOVATION AND GROWTH THROUGH LEGAL REFORM 55, at 74 (2011) (advocating serious consideration of “free agency” model of technology transfer, and/or inventor IP ownership); PRESIDENT’S COUNCIL ON JOBS AND COMPETITIVENESS, *TAKING ACTION, BUILDING CONFIDENCE: FIVE COMMON-SENSE INITIATIVES TO BOOST JOBS AND COMPETITIVENESS* 21 (2011) (advocating “open source” approach to technology transfer); AMERICAN ASSOCIATION OF UNIVERSITY PROFESSORS, *AAUP RECOMMENDED PRINCIPLES & PRACTICES TO GUIDE ACADEMY-INDUSTRY RELATIONSHIPS* 14 (2012) (recommending that “faculty inventor ‘assignment’ of an invention to a management agent, including the university that hosted the underlying research, should be voluntary and negotiated, rather than mandatory, unless federal statutes or previous sponsored research agreements dictate otherwise”).

The Kauffman Foundation and AAUP have both suggested, to varying degrees, that universities should not be in the business of owning patents at all, instead leaving ownership of patentable inventions, and decisions regarding whether and how to pursue commercialization of such inventions, in the hands of the faculty who make them.²³

However, these suggested practices—which champion faculty agency over institutional control—are not the norm. By virtue of intellectual property policies that obligate faculty members to assign their rights in any patentable discoveries made by them to their employer,²⁴ universities—through their technology transfer offices and research administrators—commonly face important choices concerning which patents to seek and how to license those patents their university eventually receives.²⁵ Patents may be licensed on a non-exclusive basis to any company interested in developing a product covered by the patent. Or they may be licensed exclusively to only one company, or to multiple companies on an exclusive basis in discrete geographic regions or field[s] of use.²⁶ Inherent in these options are critical decisions that impact the public good. Exclusive licenses can generate windfall profits to licensees and universities alike, but at the cost of diminished dissemination and possible reduction in follow-on R&D that comes when only one company is permitted to exploit a patent.²⁷ While non-exclusive licenses can lead to wide dissemination and enhanced follow-on R&D, lower profits

23. LITAN & COOK-DEEGAN, *supra* note 22, at 60; AMERICAN ASSOCIATION OF UNIVERSITY PROFESSORS, *supra* note 22, at 14. However, whether faculty members would be better stewards of the public trust when it comes to their use and/or ownership of patents is unknown and invites debate.

24. See generally Margaret T. Stopp & G. Harry Stopp, Jr., *The Enforcement of University Patent Policies: A Legal Perspective*, 24 SRA J. RS. ADMIN. 5-11 (1992); Jerry G. Thursby & Marie C. Thursby, *Knowledge Creation and Diffusion of Public Science with Intellectual Property Rights*, in INTELLECTUAL PROPERTY, GROWTH AND TRADE 199-231 (Keith E. Maskus ed., 2008).

25. If a university elects not to retain ownership of a faculty member's invention under the Bayh-Dole Act, the funding agency may receive title to the invention, or allow the faculty inventor to retain rights to the invention. See 35 U.S.C. §§ 202(c)(2) & (d) (2012).

26. See Timothy Denny Green, *"All Substantial Rights": Toward Sensible Patent Licensee Standing*, 22 FED. CIR. B. J. 1, 6-7 (2012) (noting that "[a] license can be exclusive along several fronts, including: time, territory, field of use, or by core rights (make, use, or sell)").

27. See, e.g., DEREK C. BOK, UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION 112 (2003) ("Zealous campus officials can slow commercial applications and drive up prices of valuable products by granting exclusive patent licenses, where nonexclusive licenses would be feasible, merely to let the university share in any monopoly profits that the exclusive licensee manages to earn.").

and increased administration costs for university patent owners typically come with them.²⁸

A recent, high-profile case involving patents owned by the University of Utah Research Foundation (the publicly-funded university's technology transfer arm) illustrates many of the tensions that can arise when non-profit altruism confronts the legal and for-profit norms of commercial bioscience.²⁹ The case centers on patents for discoveries made by researchers in the early 1990s at the universities of Utah and Pennsylvania, Myriad Genetics, Inc. ("Myriad"), and hospitals in Canada and Japan.³⁰ The patents—now all owned by Utah's research foundation and licensed exclusively to Myriad—claim two "isolated" human genes, known as BRCA1 and BRCA2, and certain mutations in these genes found to correlate with an increased risk of breast and ovarian cancer.³¹ The patents also claim methods of comparing a patient's BRCA sequence with the normal sequence to identify the presence of cancer-predisposing mutations, as well as a method for screening potential cancer therapeutics.³²

This past August, in an ongoing challenge to the patents' validity brought by plaintiffs prompted by the ACLU, the Court of Appeals for the Federal Circuit ("CAFC") upheld the patent claims to the isolated BRCA genes, but ruled most of the method claims invalid for being "abstract mental processes" ineligible for patent protection.³³ On an earlier appeal to the U.S. Supreme Court, the justices had instructed the CAFC to reconsider its initial opinion in the case in view of recent Court precedent that ostensibly clarified the boundaries of patent-eligible subject matter.³⁴ Unsurprisingly, the pro-patent CAFC again reached the same conclusion in its August opinion.³⁵ By the end of November, the

28. See MOWERY, ET AL., *supra* note 9.

29. See E. Richard Gold & Julia Carbone, *Myriad Genetics: In the Eye of the Policy Storm*, 12(4) GENETIC MED. S39-S70 (April 2010) (noting the difficulty of "liv[ing] under both the imperative to share and the requirement to patent").

30. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 689 F.3d 1303 (Fed. Cir. 2012).

31. *Id.* at 1309-1310. Women with BRCA mutations are four to six times more likely to develop breast cancer than women without such mutations.

32. *Id.*

33. *Id.* at 1333.

34. See Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S.Ct. 1794 (2012) (vacating judgment and remanding case for reconsideration in light of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S.Ct. 1289, 182 L.Ed.2d 321 (2012)).

35. Nick DeSantis, *ACLU Asks Supreme Court to Invalidate U. of Utah Patents on Cancer Genes*, CHRON. HIGHER EDUC., Sept. 25, 2012, <http://chronicle.com/blogs/ticker/aclu-asks-supreme-court-to-invalidate-u-of-utah-patents-on-breast-cancer-genes/49506>.

U.S. Supreme Court granted certiorari in the case to answer one question: “Are human genes patentable?”³⁶

In the balance hangs more than just legal nuance of concern to patent lawyers and legal academics. Whether human genes should be eligible for patent protection, and whether universities should continue to seek such rights if genes are patent eligible, will propel policy decisions for all universities active in biotech research. It is now often stated in the popular press and scientific community that more than 20% of the human genome has been patented since the first such patent issued in the early 1980s.³⁷ While this figure may be overstated, at the very least, or even empirically flawed,³⁸ thousands of U.S. patents have been issued claiming human genes,³⁹ and universities own many of these patents.⁴⁰

These facts inform policy arguments in salient ways. As policy support for its legal conclusion of patent eligibility, the CAFC noted “the adverse effects on innovation that a holding of ineligibility might cause”⁴¹—namely, unsettling expectations of the inventing and investing communities. To be sure, those expectations are real and substantial. The disputed patents have provided Myriad a lucrative monopoly on diagnostic testing for the BRCA genes in the United States, leading to more than \$1 billion in revenues for it and the university since Myriad first offered the test in

36. Dennis Crouch, *Supreme Court Has Granted Cert in the Myriad Case, Question: Are Human Genes Patentable*, PATENTLY-O (Nov. 30, 2012, 2:47 PM), <http://www.patentlyo.com/patent/2012/11/supreme-court-has-granted-cert-in-the-myriad-case-question-are-human-genes-patentable.html>.

37. See Kyle Jensen & Fiona Murray, *Intellectual Property Landscape in the Human Genome*, 310 SCIENCE 239, 239-240 (Oct. 14, 2005).

38. See Christopher M. Holman, *Will Gene Patents Derail the Next Generation of Genetic Technologies?: A Reassessment of the Evidence Suggests Not*, 80 UMKC L. REV. 563, 575 (2012) (“[Jensen & Murray’s] article provides no quantitative assessment of the extent to which human genes are patented. Any assertion that their article provides evidence that 20% of human genes are patented is pure nonsense.”).

39. See Susan Decker, *Myriad Wins U.S. Appeal Over Ability to Patent Isolated DNA*, BLOOMBERG (Aug. 16, 2012), <http://www.bloomberg.com/news/2012-08-16/myriad-wins-u-s-appeal-over-ability-to-patent-isolated-dna-2-.html> (noting that “[t]he U.S. Patent and Trademark Office has issued more than 2,600 patents on genes”). Other sources put the number of gene patents at 4,000. See Jonathan Stempel, *Supreme Court to Decide If Human Genes Patentable*, REUTERS (Nov. 30, 2012), <http://www.reuters.com/article/2012/11/30/us-usa-court-genes-idUSBRE8AT19620121130> (citing lawyer for the ACLU Women’s Rights Project).

40. See Pressman, et al., *supra* note 13, at 33 (noting that of the 30 entities holding the largest number of DNA patents in the United States as of 2005, 13 were non-profit universities).

41. Ass’n. for Molecular Pathology, 689 F.3d at 1333.

1999.⁴² On the day the U.S. Supreme Court announced it had granted certiorari in the case, Myriad's stock price declined by 9%.⁴³

Although individual patients no doubt have benefited from Myriad's testing,⁴⁴ the public should question whether more women could avoid cancer if other companies could perform commercial and noncommercial testing on the genes without liability or fear of legal action.⁴⁵ Yet the CAFC shied away from entertaining concern for the impact of the university's patenting and licensing decisions on the public good, limiting its analysis to whether patent protection was available, not whether the decision to seek patents on the claimed inventions or license them exclusively to Myriad was advisable. As the court stated:

[The case] is not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion. Nor is it about whether the University of Utah, the owner of the instant patents, or Myriad, the exclusive licensee, has acted improperly in its licensing or enforcement policies with respect to the patents. The question is also not whether is it desirable for one company to hold a patent or license covering a test that may save people's lives, or for other companies to be excluded from the market encompassed by such a patent.⁴⁶

While the CAFC—like most appellate courts—might be expected to eschew normative arguments in favor of legal ones, the policy questions it dismissed as irrelevant in the Myriad case are precisely the questions that those concerned with advancing the public good through university research and commercialization should be asking.

Does seeking patents on isolated human genes further the public good, or put it at risk? Many prominent scientists and organizations argue the

42. Dennis Crouch, *Federal Circuit Hears Myriad Gene Patent Case*, PATENTLY-O (April 4, 2011, 5:45 AM), <http://www.patentlyo.com/patent/2011/04/federal-circuit-hears-myriad-gene-patent-case.html>.

43. Dennis Crouch, *Myriad at SCOTUS: Early Reaction*, PATENTLY-O (Dec. 3, 2012, 5:02 AM), <http://www.patentlyo.com/patent/2012/12/myriad-at-scotus-early-reaction.html>.

44. To date, Myriad has provided diagnostic testing to over 1 million people. See Stempel, *supra* note 39.

45. *C.f.* Jennifer Vogel, Comment, *Patenting DNA: Balancing the Need to Incentivize Innovation in Biotechnology with the Need to Make High-Quality Genetic Testing Accessible to Patients*, 61 U. KAN. L. REV. 257, 292 (2012) (proposing statutory research exemption "that immunizes researchers from infringement liability for performing noncommercial activities involving" patented genes).

46. Ass'n. for Molecular Pathology, 689 F.3d at 1324.

latter, viewing the human genome as part of society's collective cultural heritage that should be available for the study and benefit of everyone, without restriction caused by the potential for profit. Dr. James Watson, co-discoverer, along with Francis Crick, of the double-helix structure of DNA, calls gene patenting "lunacy."⁴⁷ In an amicus brief submitted in the Myriad litigation, Dr. Watson stated that patenting isolated forms of the double-helix he discovered was "out of the question," even though some suggested he seek such protection when he made the research breakthrough.⁴⁸ In a similar vein, a dissenting judge in the Myriad case compared extracting a gene to "snapping a leaf from a tree"⁴⁹—if anything, an act of discovery and isolation, not of invention.⁵⁰ The United Nations takes a similar view of the human genome. The Universal Declaration on the Human Genome and Human Rights cautions against genome-related activity that threatens human rights or human dignity, while also declaring that "[t]he human genome in its natural state shall not give rise to financial gains."⁵¹ All of these arguments against gene patenting fall against a broader biomedical research space that many believe to be overly privatized, resulting in an "anticommons" of underused resources caused by the "proliferation of fragmented and overlapping intellectual property rights."⁵²

47. Sandra S. Park, *James Watson, Discoverer of DNA: Patenting Human Genes Is "Lunacy,"* ACLU (June 26, 2012, 12:11 PM), <http://www.aclu.org/blog/womens-rights-free-speech-capital-punishment-criminal-law-reform/james-watson-discoverer-dna>.

48. *Id.*

49. Ass'n. for Molecular Pathology, 689 F.3d at 1352 (Bryson, J., dissenting).

50. *C.f.* Sigrid Sterckx & Hans Radder, *Knowledge Transfer from Academia to Industry through Patenting and Licensing: Rhetoric and Reality*, in *THE COMMODIFICATION OF ACADEMIC RESEARCH: SCIENCE AND THE MODERN UNIVERSITY* 44, 58 (2010) ("Patents should require invention rather than serendipitous discovery and skilled wordplay.").

51. UNITED NATIONS EDUC. SCIENTIFIC AND CULTURAL ORG., UNIVERSAL DECL. ON THE HUMAN GENOME AND HUMAN RIGHTS (Nov. 11, 1997), art. 4., available at http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html. Myriad and its supporters argue that the act of isolating the BRCA1 and BRCA2 genes, like isolation of any human genes, is an act of human intervention that removes the genes from their natural state.

52. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280(5364) *SCIENCE* 698-701 (May 1, 1998) ("Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intellectual property claims to the sorts of research results that, in an earlier era, would have been made freely available in the public domain."); *but see* Holman, *supra* note 38, at 598-599 (arguing that fears of patent thickets impeding biomedical research "have been greatly exaggerated," and that basic research and public sector research have been unaffected by the growth in patents).

Even if an organization like the University of Utah Research Foundation makes a decision to seek or obtain patents on isolated DNA, is an exclusive license like what Myriad received a necessary or even appropriate vehicle for bringing diagnostic breakthroughs into useful application, particularly when exclusive licenses, as a practical matter, may foreclose patients' ability to obtain from other sources information about their own genetic makeup?⁵³ It seems specious to assume that all groundbreaking diagnostic health tools bear no chance of making it to market and impacting patients' lives absent the award of an exclusive license. Indeed, specific to the Myriad controversy, at least two non-profit research hospitals are prepared to offer diagnostic testing for the BRCA genes, if only they could do so without potentially incurring liability.⁵⁴ The argument that only exclusive licenses justify the enormous financial expenditures that go into developing and commercializing helpful innovations is not without exceptions. To this point, it is a fitting fact that the famous Cohen-Boyer patents on recombinant DNA, which effectively precipitated the growth of the biotechnology industry, were licensed non-exclusively to more than 400 licensees by the University of California and Stanford—notably without effect on the universities' ability to achieve generous returns on research investment.⁵⁵

Other critical questions flow from the University of Utah's involvement with Myriad. For example, had the university declined ownership of the inventions that led to patents on the BRCA genes, or instead licensed the patents to anyone interested in using them, would additional scientific advances have been facilitated by those decisions? Patents can serve as fences that impede knowledge flow,⁵⁶ and exclusive licenses—while sometimes appropriate—can exacerbate this tendency,

53. Myriad has been less successful at using patents to corner the market for BRCA1 and BRCA2 testing outside the United States, leading some Americans to travel abroad in order to undergo testing to verify genetic testing results reported by Myriad. *See generally* Gold & Carbone, *supra* note 29.

54. Plaintiffs in the Myriad case include physicians at the University of Pennsylvania School of Medicine and New York University School of Medicine, all of whom offered BRCA testing until they faced litigation and litigation threats from Myriad. *See* Ass'n. for Molecular Pathology, 689 F.3d at 1314-16.

55. The universities received more than \$254 million in licensing fees. *See* Feldman, et al., *supra* note 11, at 1803.

56. Jason Owen-Smith, *Trends and Transitions in the Institutional Environment for Public and Private Science*, 49 HIGHER EDUC. 91, 94 (2005) (as opposed to academic publications that act as funnels for knowledge flow, describing patents as "fences in the sense that they offer limited monopoly rights to the 'plot' of knowledge their claims demarcate").

although Myriad contends otherwise.⁵⁷ More importantly, what if people had options for BRCA gene testing? Presumably cancer patients would be able to ascertain more quickly if they have the genetic mutations in question—perhaps more quickly than the up to three weeks it takes Myriad to conduct the testing and return results. If market substitutes existed, cancer patients and their insurers also would likely pay less than the over \$3,000 Myriad charges to administer the test.⁵⁸ It seems hard to argue that quicker and cheaper access to this information about one's own genetic disposition would not plant itself firmly in the public interest.

As budget woes and harrying by entrepreneurial state lawmakers and revenue-conscious administrators and business leaders prompt universities to reimagine their research programs and treatment of intellectual property,⁵⁹ many may feel more pressure than ever to pounce on any

57. Ass'n. for Molecular Pathology, 689 F.3d at 1322 (noting that Myriad argues that “over 18,000 scientists have conducted research on the BRCA genes and over 8,600 research papers have been published” since when Myriad first published the discoveries claimed in its patents).

58. See Robert Langreth, *Do-It-Yourself Gene Testing Threatens Myriad's Monopoly*, FORBES (Oct. 10, 2011, 11:05 AM), <http://www.forbes.com/sites/robertlangreth/2010/10/11/do-it-yourself-gene-testing-threatens-myriards-monopoly/> (reporting that Myriad Genetics charges \$3,000 to test for breast cancer risk).

59. See, e.g., E. Gordon Gee, *Colleges Must Find Innovative Ways to Finance Their Missions*, CHRON. HIGHER EDUC., Oct. 30, 2011, <http://chronicle.com/article/Colleges-Must-Find-Innovative/129568/> (Ohio State University president, arguing that universities must reconceptualize how they finance their core missions by “finding innovative ways to leverage the market” and “commercializing technological innovations”); Michael M. Crow, *Beyond the “New Normal” in American Higher Education: Toward Perpetual Innovation*, in SMART LEADERSHIP FOR HIGHER EDUCATION IN DIFFICULT TIMES 50, 58 (David W. Breneman & Paul J. Yakoboski eds., 2011) (Arizona State University president, arguing that “[i]n order to maximize the potential for innovation, institutions must organize to exploit complementarities and establish new degrees of connectivity, both internally and externally, with stakeholders in the public and private sectors”); Goldie Blumenstyk, *U. of Maryland to Count Patents and Commercialization in Tenure Reviews*, CHRON. HIGHER EDUC., June 13, 2012, <http://chronicle.com/article/U-of-Maryland-to-Count/132261/> (reporting that the University System of Maryland will give formal credit in tenure and promotion decisions for faculty work that leads to patents, as part of the system’s “broader push to promote the commercialization of academic research”); Monica Mendoza, *Research Partners: UCCS Creating Legal Terms to Court Private Industry*, COLO. SPRINGS BUS. J., Nov. 9, 2012, <http://csbj.com/2012/11/09/research-partners-uccs-creating-legal-terms-to-court-private-industry/> (reporting that the University of Colorado at Colorado Springs “is drawing up new legal agreements that list the university and private industry as co-developers. It’s like a pre-nup of sorts: Each partner—the university and the company—that comes to the union with its own intellectual property walks away with it. It’s a shrewd move for [the university], but one that could woo more industry partnerships.”); John C. Lechleiter, *Let's Build on Our Strengths in the Life Sciences*, INDIANAPOLIS STAR, Nov. 25, 2012, at B7 (CEO of Indiana-based Eli Lilly & Co., arguing that “Indiana’s great research universities—public and private—must embrace the notion that one of their prime functions is to actively assist in the process of translating new knowledge into useful products that serve the larger society. We need an infusion of entrepreneurial spirit into our

potential revenue-generating discovery made in their laboratories.⁶⁰ But just because prevailing law allows certain forms of patent activity does not mean universities must engage in it. Indeed, we should expect more from our public-serving universities, always questioning whether a licensing deal that is lucrative for a university is concomitantly rewarding for the public. As part of this scrutiny, decisions to retain ownership over, and subsequently patent, any faculty member's discovery related to the human genome—whether isolated DNA or diagnostic methods based on such products—must be carefully considered. In this time of increased emphasis on university commercialization, as well as heightened judicial attention on what is and is not eligible for patent protection, university leaders should be forthcoming about how patenting and licensing decisions in the health sciences further, and do not frustrate, the public good.⁶¹ More than anything, university leaders must resist the

research universities—more people open to pursuing the applications of their research, working collaboratively with others outside their own walls, including industry, and, yes, even starting companies.”); Scott Jaschik, *Ties Grow Between Drug Industry, Biomedical Research*, INSIDE HIGHER ED (Nov. 26, 2012, 3:00 AM), <http://www.insidehighered.com/quicktakes/2012/11/26/ties-grow-between-drug-industry-biomedical-research> (reporting that “the pharmaceutical industry has come to support more [biomedical] research [at universities] than does the federal government”); Peter Lee, *Transcending the Tacit Dimension: Patents, Relationships, and Organizational Integration in Technology Transfer*, 100 CAL. L. REV. 1503, 1572 (arguing that organizational innovations are starting to “blur the institutional boundaries between universities and firms”).

60. See, e.g., Jens Krogstad, *Universities Struggle With Falling Invention Royalties*, USA TODAY, Nov. 25, 2012, <http://www.usatoday.com/story/money/business/2012/11/25/universities-struggle-with-falling-invention-royalties/1725591/> (noting that “[a]dministrators are pushing faculty to patent and commercialize products” in view of budgetary woes and tightened research budgets, according to the Vice President for Research and Economic Development at Iowa State University); BOK, *supra* note 27, at 9 (former president of Harvard University, stating that “[u]niversities share one characteristic with compulsive gamblers and exiled royalty: there is never enough money to satisfy their desires. [. . .] The need for money, therefore, does not merely occur now and then in the wake of some ill-considered decision on the part of state officials to cut university budgets. It is a chronic condition of American universities.”); Ken Auletta, *Get Rich U.: There Are No Walls Between Stanford and Silicon Valley. Should There Be?*, THE NEW YORKER, Apr. 30, 2012, http://www.newyorker.com/reporting/2012/04/30/120430fa_fact_auletta?currentPage=all (“But Stanford’s entrepreneurial culture has also turned it into a place where many faculty and students have a gold-rush mentality and where the distinction between faculty and student may blur as, together, they seek both invention and fortune.”); Graelyn Brashear, *Biotech U: Marrying Academia and Industry in Charlottesville*, C-VILLE WEEKLY, May 8, 2012, http://www.cville.com/Biotech_U_Marrying_academia_and_industry_in_Charlottesville/ (reporting that the executive director of innovation at the University of Virginia “acknowledges that he measures his success as chief innovator in part by his ability to create conflicts of interest”).

61. *C.f.* BOK, *supra* note 27, at 118-119 (“Looking back over the history of commercialization, one quickly perceives a persistent tendency to exaggerate the benefits and overlook or underestimate the dangers. Such a tendency is hardly surprising given the nature of the costs and benefits involved. The principal advantage to the institution—money—will usually seem immediate,

temptation to narrow the space for knowledge production and dissemination in any of their forms.⁶²

tangible, and extremely useful to help meet pressing needs. In contrast, the dangers—to the conscientiousness of faculty, or to the moral education of students, or to the trust of the public—are all intangible and remote. They may never materialize, at least not for a long time, so that it is all too easy to overlook them.”); Daniel Lee Kleinman, *The Commercialization of Academic Culture and the Future of the University*, in *THE COMMODIFICATION OF ACADEMIC RESEARCH: SCIENCE AND THE MODERN UNIVERSITY* 24, 40 (Hans Radder ed., 2010) (“Those of us who want to see the university as a unique institution, relatively independent of the market, should draw on the prominence of traditional academic norms in the popular imagination to push policy makers and university officials to build institutions broadly in keeping with that image.”); SHEILA SLAUGHTER & GARY RHOADES, *ACADEMIC CAPITALISM AND THE NEW ECONOMY: MARKETS, STATE, AND HIGHER EDUCATION* 107 (2004) (“The academic capitalist system is setting up an alternative system of rewards in which discovery is valued because of its commercial properties and economic rewards, broad scientific questions are couched so that they are relevant to commercial possibilities (biotechnology, telecommunications, computer science), knowledge is regarded as a commodity rather than a free good, and universities have the organization capacity (and are permitted by law) to license, invest, and profit from these commodities.”).

62. *C.f.* Pusser, *supra* note 16, at 42 (raising concerns about the influence of neoliberalism on higher education, arguing that “[i]t is time to turn greater attention to market reality and to rein in its excessive influence on elite universities, not as a judgment but to create an opportunity for a measured discussion, critique, and analysis of the role of the market in higher education”).