Patent Act of 1952 — Patentable Subject Matter —
Ass'n for Molecular Pathology v. Myriad Genetics, Inc.

The traditional account of patent law assumes that profits generated from patent exclusivity incentivize innovation.[1] However, many leading biotechnology innovators work for universities, government agencies, and nonprofit organizations;[2] these researchers may be driven by incentives including grant funding, academic recognition, and altruism.[3] Tensions among researchers in different sectors recently came to a head over the question of gene patentability: while for-profit companies insisted that they need patent exclusivity to attract capital investment, not-for-profit entities maintained that innovation requires a free flow of information.[4] Last Term, in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*,[5] the Supreme Court took a middle ground, holding that molecules isolated from native DNA are not patent eligible, but certain molecules synthesized in a laboratory can be patented.[6] Focusing on rules derived from statutes and precedent, the Court did not discuss underlying incentives. Avoiding this policy debate was reasonable because reconciling disparate incentives for biotechnology research requires a legislative solution.

In 1990, researchers at the University of California, Berkeley, published a paper revealing the general location of a gene linked to breast cancer.[7] Soon after, a competing group of scientists founded Myriad Genetics and obtained more than $50 million in venture capital funding to pursue related research.[8] In 1994 and 1995, Myriad announced that it had located and sequenced two breast cancer susceptibility genes, now termed BRCA1 and BRCA2.[9] Myriad then developed clinical tests to detect BRCA gene mutations that correlate with a substantially higher risk of developing breast and ovarian cancer.[10]

Myriad obtained a variety of patents related to its discoveries.[11] While some of the patents covered testing methods (the "method claims"), others involved isolated DNA molecules and synthetic cDNA

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[1] Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 116–17 (1999).

[2] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 186–88 (S.D.N.Y. 2010).

[3] Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1586 (2003).

[4] *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 190–92.

[5] 133 S. Ct. 2107 (2013).

[6] *See id.* at 2219–20.

[7] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 201.

[8] *See id.*

[9] *See id.* at 201–02.

[10] *See id.* at 203.

[11] *See id.* at 202.

molecules (the "composition claims").[12] Myriad's patents gave it the exclusive right to isolate the BRCA genes and to create BRCA cDNA.[13] And when other institutions infringed the patents, Myriad took aggressive enforcement action.[14] Since genetic testing requires gene isolation, the patents made Myriad the sole provider of BRCA1 and BRCA2 testing,[15] generating hundreds of millions in revenue.[16]

In 2009, a group of organizations and individuals filed suit under the Declaratory Judgment Act,[17] seeking to invalidate fifteen of Myriad's composition and method claims.[18] The plaintiffs included six nonprofit organizations that engage in research and advocacy, eight university-affiliated scientists whose work was impeded by Myriad's patents, and six individuals who were unable to obtain desired BRCA screenings because of Myriad's monopoly on testing.[19]

Aided by briefing from more than two dozen amici,[20] Judge Sweet of the Southern District of New York granted summary judgment for the plaintiffs.[21] In a prior proceeding, the court had found that all of the plaintiffs had standing.[22] Turning to the merits, the court noted that U.S. law allows patenting of "any new and useful process, machine, manufacture, or composition of matter."[23] To be patentable, an invention or discovery must satisfy three requirements: novelty, utility, and statutory subject matter.[24] This suit involved only the third requirement, generally termed "patent eligibility."[25] As the Supreme Court has determined, no one may patent "laws of nature, physical

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[12] *See id.* at 212. Isolated DNA molecules are segments extracted from longer strands of naturally occurring DNA. Complementary DNA (cDNA) is synthesized in a laboratory and contains only the exons, not the noncoding introns, from a genetic sequence. *See id.* at 196–99. The U.S. Patent and Trademark Office (PTO) granted patents for both types of molecules, and about twenty percent of human genes had been claimed as intellectual property in the United States by the time the *Myriad* litigation commenced. *See id.* at 185, 208.

[13] *Myriad*, 133 S. Ct. at 2113.

[14] *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 204–05. For instance, researchers at the University of Pennsylvania offered BRCA screening using a different method but the same isolated genes as Myriad. *Id.* Myriad sent cease-and-desist letters, then filed a lawsuit; the researchers ultimately ceased performing BRCA testing to settle the case. *See id.*

[15] *Myriad*, 133 S. Ct. at 2114.

[16] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 203.

[17] *See id.* at 186, 211. The Declaratory Judgment Act authorizes courts to "declare the rights and other legal relations of any interested party" in any "actual controversy" regardless of "whether or not further relief is or could be sought." 28 U.S.C. § 2201(a) (2006).

[18] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 211.

[19] *See id.* at 186–89. The defendants were Myriad Genetics, the PTO, and the directors of the University of Utah Research Foundation, a part owner of the patents. *Id.* at 189–90.

[20] *See id.* at 190–92.

[21] *Id.* at 184–85.

[22] *Id.* at 186.

[23] *Id.* at 218 (quoting 35 U.S.C. § 101 (2006)).

[24] *Id.* at 219 (discussing "what considerations were salient" in an analysis of 35 U.S.C. § 101).

[25] *See id.* at 220.

phenomena, and abstract ideas."[26] To be patent eligible, an invention must have "a distinctive name, character, or use."[27] Without this limitation, the law would provide "too much patent protection" and would "impede rather than 'promote'" scientific progress.[28]

Applying this standard, Judge Sweet found for the plaintiffs on all claims.[29] Starting with the composition claims, he argued that a "clear line" of Supreme Court precedent has established that "purification of a product of nature, without more, cannot transform it into patentable subject matter."[30] DNA "serves as the physical embodiment of laws of nature," so Myriad's claims were valid only if the isolated DNA and cDNA molecules were "markedly different" from natural DNA.[31] The molecules failed this test because their function and utility stem from the naturally occurring nucleotide sequences.[32] Judge Sweet also held the method claims to be invalid because they involved mental processes of analyzing and comparing, which cannot be patented.[33]

The Federal Circuit affirmed in part and reversed in part.[34] The Supreme Court granted certiorari, then vacated and remanded for reconsideration[35] in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.[36] In *Mayo*, the Court held that a process for determining the appropriate dosage of a medication was not patent eligible because the method involved little more than a description of natural laws.[37] Writing for all nine Justices, Justice Breyer emphasized that granting monopolies over laws of nature through patents would impede future research rather than promote innovation.[38]

On remand, the Federal Circuit adhered to its original positions.[39] All three judges agreed that only one plaintiff had standing.[40] The

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[26] *Id.* at 218 (quoting Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980)).

[27] *Id.* at 222 (quoting Am. Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 12 (1931)).

[28] *Id.* at 219 (quoting Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting from dismissal of certiorari)) (emphasis omitted).

[29] *Id.* at 185.

[30] *Id.* at 227.

[31] *Id.* at 228.

[32] *Id.* at 229.

[33] *Id.* at 232–37. Since he was able to resolve the issues and provide the requested relief on statutory grounds, Judge Sweet dismissed the constitutional claims against the PTO. *Id.* at 238.

[34] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1333–34 (Fed. Cir. 2011).

[35] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794 (2012) (mem.) (order granting certiorari, vacating, and remanding).

[36] 132 S. Ct. 1289 (2012).

[37] *See id.* at 1294, 1297.

[38] *See id.* at 1293, 1294, 1301–04.

[39] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1308–09 (Fed. Cir. 2012).

[40] *Id.* at 1308–09; *id.* at 1337 (Moore, J., concurring in part); *id.* at 1348 (Bryson, J., concurring in part and dissenting in part). In patent suits, standing requires "meaningful preparation to con-

panel then affirmed Judge Sweet's invalidation of some of the method claims, but a majority reversed his findings on the composition claims and held that all were valid.[41] Like the district court, the Federal Circuit began with the premise that no one can patent "[l]aws of nature, natural phenomena, and abstract ideas."[42] In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*,[43] the Supreme Court determined that a bacteria mixture for inoculating plants was not patent eligible because the product's useful qualities were the "work of nature."[44] By contrast, in *Diamond v. Chakrabarty*,[45] the Court held that a bacterium genetically engineered to break down crude oil was patent eligible because it had "markedly different characteristics" and functions from anything found in nature.[46] Extending these holdings, the panel unanimously agreed that cDNA is patent eligible because the molecules lack introns present in natural DNA, rendering the molecules "especially distinctive."[47]

The panel fractured on the disposition of claims related to isolated DNA. Writing for the majority, Judge Lourie focused on the chemical structure of molecules[48] and argued that isolated DNA is "markedly different" from native DNA because it has been separated from a larger molecule.[49] Breaking covalent bonds requires "skill, knowledge, and effort"[50] and gives isolated DNA a "distinctive chemical identity."[51] Judge Lourie also noted that the U.S. Patent and Trademark Office (PTO) had a longstanding policy of granting patents for gene sequences and argued that any changes should come from Congress.[52] Despite this professed reticence to address policy questions,[53] he did address the incentive to innovate, noting that "patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights."[54]

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duct potentially infringing activity." *Id.* at 1318 (majority opinion). The panel found that only one researcher alleged "a sufficiently real and imminent injury" because he alone claimed "an intention to actually and immediately engage in allegedly infringing *BRCA*-related activities." *Id.* at 1319.

41 *See id.* at 1309.

42 *Id.* at 1324 (quoting *Mayo*, 132 S. Ct. at 1293).

43 333 U.S. 127 (1948).

44 *Id.* at 130.

45 447 U.S. 303 (1980).

46 *Id.* at 310.

47 *Ass'n for Molecular Pathology*, 689 F.3d at 1329; *see also id.* at 1309; *id.* at 1337 (Moore, J., concurring in part); *id.* at 1348 (Bryson, J., concurring in part and dissenting in part).

48 *See id.* at 1330 (majority opinion).

49 *Id.* at 1328.

50 *Id.* at 1332.

51 *Id.* at 1328.

52 *Id.* at 1330, 1332–33.

53 *See id.* at 1324–25, 1330 (arguing that the judiciary should leave policy questions to the legislature).

54 *Id.* at 1324.

Judge Moore concurred in the judgment but offered distinct reasoning.[55] In her interpretation, *Funk Bros.* and *Chakrabarty* established a "flexible test" that hinges on function rather than structure.[56] Accordingly, isolated DNA is patent eligible not because of the chemical differences created by breaking covalent bonds, but instead because of its "new and distinct" uses and applications.[57] Echoing Judge Lourie's concerns, she also noted that the "dramatic step" of "destroy[ing] existing property rights" is "best left to Congress."[58]

Dissenting in part, Judge Bryson reasoned that the process of extracting DNA segments, though difficult, does not render the resulting molecules patent eligible — no one could patent a mineral merely because she extracted it from the earth or a kidney because she removed it from a body.[59] Considering both function and structure, Judge Bryson argued that the functions of isolated DNA and native DNA are identical, while the structural differences are irrelevant.[60] In this case, as in *Mayo*, the defendants' patent claims added little to the laws of nature and relied on "well-understood, routine, conventional activity" engaged in by other researchers.[61] Finally, Judge Bryson challenged the majority's reluctance to disrupt existing patent rights,[62] urging that "[t]here is no collective right of adverse possession to intellectual property, and we should not create one."[63]

The Supreme Court granted certiorari, this time to address one question: whether human genes are patentable.[64] The Court affirmed in part and reversed in part.[65] Writing for a unanimous Court, Justice Thomas noted that "extensive effort alone is insufficient" to render a product patent eligible,[66] and "[g]roundbreaking, innovative, or even

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[55] *See id.* at 1337 (Moore, J., concurring in part).

[56] *Id.* at 1338.

[57] *Id.* at 1341.

[58] *Id.* at 1345. Since longer strands of isolated DNA do not have unique functionality, Judge Moore suggested that she would find them patent ineligible if she had a "blank canvas." *Id.* at 1343. However, Congress has "authorized an expansive scope of patentable subject matter," and the PTO "has allowed patents on isolated DNA sequences for decades." *Id.* Judge Moore therefore joined Judge Lourie in upholding all of Myriad's composition claims. *See id.* at 1348.

[59] *Id.* at 1350 (Bryson, J., concurring in part and dissenting in part).

[60] *See id.* at 1354.

[61] *Id.* at 1355 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012)).

[62] *See id.* at 1356–58.

[63] *Id.* at 1358.

[64] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 694 (2012) (mem.) (order granting certiorari); Petition for a Writ of Certiorari at i, *Myriad*, 133 S. Ct. 2107 (No. 12-398). The Court therefore addressed the composition claims but not the method claims. *See Myriad*, 133 S. Ct. at 2117–19.

[65] *Myriad*, 133 S. Ct. at 2111. The Supreme Court agreed with the Federal Circuit that one plaintiff had standing under the Declaratory Judgment Act. *See id.* at 2115 n.3.

[66] *Id.* at 2118.

brilliant discovery does not by itself satisfy the § 101 inquiry."[67] Instead, under *Funk Bros.* and *Chakrabarty*, a product must be "markedly different" from anything found in nature to be patentable.[68] This judicially created exception to patent exclusivity "strikes a delicate balance" between creating incentives to innovate and protecting the free flow of information.[69]

Applying this standard, the Court held that isolated DNA molecules are not patent eligible.[70] The Court rejected the Federal Circuit's contention that the chemical changes created during the isolation process made the molecules distinctive, as Myriad's patents were not articulated in terms of and did not depend on those chemical changes.[71] Additionally, the PTO's longstanding policy of granting patents for isolated DNA molecules merited no deference; Congress had not endorsed the PTO's view, and the Justice Department argued against it.[72] By contrast, the Court held that cDNA is patent eligible because it is not naturally occurring and is distinct from DNA.[73] Since "the lab technician unquestionably creates something new when cDNA is made," the Court upheld Myriad's cDNA claims.[74]

The Constitution specifies that the purpose of granting patents is to promote scientific progress.[75] However, the *Myriad* plaintiffs and defendants have fundamentally different and potentially irreconcilable conceptions of what conditions foster innovation. As a profit-driven entity, Myriad argued that the promise of patent exclusivity is essential to incentivizing investment in research and development.[76] By contrast, the academic researchers and nonprofit organizations that brought the lawsuit argued that scientific progress cannot occur without a free flow of information.[77] Though dozens of amici brought this controversy to the Court's attention, the opinion devoted minimal space to policy analysis. That focus on rules rather than policy was appropriate considering the judiciary's institutional constraints. Rec-

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[67] *Id.* at 2117.

[68] *Id.* (quoting Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980)).

[69] *Id.* at 2116 (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1305 (2012)).

[70] *Id.* at 2120.

[71] *Id.* at 2118.

[72] *Id.* at 2118–19.

[73] *Id.* at 2111, 2119.

[74] *Id.* at 2119. Justice Scalia joined most of the majority opinion but also wrote a one-paragraph concurrence to note that some of the scientific background in Part I of the majority opinion was not necessary to the holding and that he could not confirm the validity of that information. *See id.* at 2120 (Scalia, J., concurring in part and concurring in the judgment).

[75] *See* U.S. CONST. art. I, § 8, cl. 8.

[76] *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 211 (S.D.N.Y. 2010).

[77] *See id.* at 208.

onciling disparate incentives to innovate and facilitating research in all sectors — private, academic, government, and nonprofit — may require creative legislative solutions.

According to the traditional narrative, patents reward individuals for devoting time and resources to research and development by allowing those innovators to exclude others from the use of their inventions.[78] Without the promise of this reward, individuals will have less incentive to innovate.[79] Myriad and its amici — primarily biotechnology corporations, trade associations, and patent lawyers who represent for-profit corporations[80] — adhered to this account: The company and its investors relied on stable patent rights when they "risked billions of dollars to research and develop advances,"[81] and Myriad needed patent exclusivity to "recoup its vast investment in creating these new molecules."[82] Amici warned that a decision for the plaintiffs could have "grave consequences for America's global economic and scientific leadership in biotechnology" because innovation requires robust patent rights.[83] As one amicus asserted, "[b]iotechnology would not exist without patents."[84]

Plaintiffs and their amici — predominantly nonprofit research organizations, advocacy groups, and academics[85] — conveyed a different vision of scientific progress. First, they argued that patent rights are not necessary to incentivize innovation.[86] For example, competing research groups had been in a "tight race" to determine the structure of DNA even though neither team intended to seek patents related to that discovery.[87] More recently, scientists have developed genetic tests

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[78] *See, e.g.*, JOHN GLADSTONE MILLS III ET AL., PATENT LAW BASICS § 1:2 (2012), *available at* Westlaw PATBASICS.

[79] *See, e.g.*, JOHN W. SCHLICHER, PATENT LAW, LEGAL AND ECONOMIC PRINCIPLES § 1:1 (2012), *available at* Westlaw PATLEGECON.

[80] At the district court level, the defendants were supported by fifteen amici, eleven of whom represented corporate interests. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 190–92.

[81] Brief for Respondents at 5, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[82] *Id.* at 8; *see also, e.g.*, Brief of the American Bar Ass'n as *Amicus Curiae* in Support of Respondents at 9, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[83] Brief for Amicus Curiae the Biotechnology Industry Organization in Support of Respondents at 3, *Myriad*, 133 S. Ct. 2107 (No. 12-398) [hereinafter BIO Brief]; *see also, e.g.*, Brief for Amici Curiae Genentech, Inc. et al. in Support of Respondents at 11, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[84] Brief of *Amicus Curiae* National Venture Capital Ass'n in Support of Respondents at 9, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[85] At the district court level, the plaintiffs were supported by twenty-one amici, all of which were nonprofit organizations. *See Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 190.

[86] *See, e.g.*, Transcript of Oral Argument at 11–15, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (arguing that researchers are motivated by nonpecuniary factors including recognition and curiosity); Brief of *Amici Curiae* American Medical Ass'n et al. in Support of Petitioners at 16, *Myriad*, 133 S. Ct. 2107 (No. 12-398) [hereinafter AMA Brief] ("[T]he majority of geneticists are willing to undertake the research to discover genes and develop genetic tests without the possibility of a patent.").

[87] Brief of James D. Watson, Ph.D. as *Amicus Curiae* in Support of Neither Party at 6, *Myriad*, 133 S. Ct. 2107 (No. 12-398) [hereinafter Watson Brief].

for a variety of diseases without pursuing patent protection.[88] Likewise, the plaintiffs argued that scientists with no intention of filing patents "were looking equally vigorously for the genes" at issue in *Myriad*.[89] In fact, many members of the scientific community believe that another group sequenced the BRCA2 gene before Myriad did but did not attempt to patent the discovery.[90]

Second, plaintiffs and their amici argued that broad patent exclusivity hinders scientific and medical progress by preventing further discovery and invention.[91] If Myriad's claims had been upheld, the company could have enjoined a vast range of research.[92] Though Myriad's amici assured the Court that the biotechnology industry frowns upon enforcing patents against researchers,[93] this nonbinding promise did not satisfy plaintiffs and their supporters. They contended that attorney's fees and court costs resulting from lawsuits are "devastating," especially to nonprofit organizations, even if the suit is ultimately settled or dismissed.[94] Accordingly, the threat of litigation has a powerful chilling effect.[95] Here, some of the plaintiffs had ceased BRCA testing to settle pending lawsuits, while others had voluntarily terminated research and testing to avoid any possibility of litigation — demonstrating the direct and indirect effects of Myriad's patents.[96] Even setting aside potential litigation expenses, amici argued that patent exclusivity dramatically increases the cost of research and testing.[97] For example, nonprofit organizations have estimated that they could test all 20,000 genes in the human genome for about $1000,

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[88] *See* AMA Brief, *supra* note 86, at 16 (providing examples of hearing loss, spinocerebellar atrophy, breast cancer, long-QT syndrome, Canavan disease, and hereditary hemochromatosis).

[89] Reply Brief for Petitioners at 21, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[90] AMA Brief, *supra* note 86, at 19.

[91] *See, e.g.*, Brief for Petitioners at 42, *Myriad*, 133 S. Ct. 2107 (No. 12-398) ("Patenting a gene or genetic sequence impedes scientific progress much the same way that patenting a naturally occurring element such as oxygen or gold would impede science." (quoting 1 Joint Appendix at 136 (statement of Nobel Prize–winning biologist John Sulston))); Brief *Amici Curiae* of the National Women's Health Network et al. in Support of Petitioners at 12–14, 19–24, *Myriad*, 133 S. Ct. 2107 (No. 12-398) [hereinafter Women's Health Brief].

[92] *See* Brief for Petitioners, *supra* note 91, at 3 ("Myriad can prevent researchers from determining if mutations on the genes correlate with increased risk of other diseases. . . . If it were determined that the genes could be used for purposes not now known, such as a substitute for silicon chips in computers (a use currently being explored by companies), Myriad can prevent that use. Myriad can even prevent scientists from looking at their own genes.").

[93] *See, e.g.*, BIO Brief, *supra* note 83, at 33 ("[R]ational forbearance against researchers is the norm.").

[94] Brief of Amicus Curiae AARP in Support of Petitioners at 4, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

[95] *Id.* at 3–6.

[96] Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 187–88, 204–05 (S.D.N.Y. 2010).

[97] *See, e.g.*, AMA Brief, *supra* note 86, at 11–13; Women's Health Brief, *supra* note 91, at 18–19.

but that paying royalties for each gene at Myriad's BRCA rate would inflate the total cost to $37 million.[98]

Finally, plaintiffs and their amici argued that scientific discovery thrives on communication and collaboration, not exclusivity. To maintain a "vibrant intellectual climate" conducive to innovation,[99] the scientific community must keep certain "basic knowledge tools" in the public domain.[100] For example, James Watson and Francis Crick discovered DNA's double-helix structure by building on the work of other scientists.[101] Myriad's discovery relied on the foundational research of the Human Genome Project and, more proximately, the work of the Berkeley research team that discovered the chromosomal region where the BRCA genes were located.[102] Further, Myriad used processes and techniques developed by others and collaborated with researchers from nonprofit organizations.[103]

Despite this profound and deep-seated tension between for-profit and not-for-profit entities, the Supreme Court relegated its discussion of policy issues to a few sentences.[104] The Court acknowledged the interests and goals underlying the patent system, but its brief analysis emphasized the rules rather than their constitutionally grounded rationales. However, the Court's avoidance of policy considerations is not necessarily a flaw in the opinion. Instead, the Court sidestepped an issue that the judiciary lacks the capacity to resolve.

At each stage of the litigation, courts were limited to upholding or invalidating Myriad's patent claims. The opinions reflect the full range of options: invalidate all claims like the district court did, uphold all claims like the Federal Circuit did, or invalidate some claims and uphold others like the Supreme Court did. Though the Federal Circuit devoted considerable attention to the type of environment that best fosters innovation, the panel did not resolve the conflicting demands; each judge merely took a side in an ongoing policy debate.[105] This impasse reflects an institutional constraint that persisted even at the Supreme Court — none of the available dispositions could have

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98 *See* AMA Brief, *supra* note 86, at 13.

99 Brief of Professor Eileen M. Kane as *Amicus Curiae* in Support of Petitioners at 6, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

100 *Id.* at 5; *see also, e.g.*, Brief for Canavan Foundation et al. as *Amici Curiae* in Support of Petitioners at 7–9, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

101 *See* Watson Brief, *supra* note 87, at 6.

102 *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181, 201 (S.D.N.Y. 2010).

103 *See id.* at 201–03.

104 *See Myriad*, 133 S. Ct. at 2116.

105 *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1333 (Fed. Cir. 2012); *id.* at 1347 (Moore, J., concurring in part); *id.* at 1356 (Bryson, J., concurring in part and dissenting in part).

meaningfully reconciled the disparate incentives prevalent in different sectors of the biotechnology industry. Indeed, during the previous Term, a similar group of amici presented a nearly identical conflict in *Mayo*.[106] The Supreme Court acknowledged the policy arguments for each side but concluded that Congress is better suited to crafting new, industry-specific rules.[107]

Like the Supreme Court, numerous scholars and scientists have argued that accounting for the different actors engaged in contemporary biotechnology research requires a novel legislative solution. As alternatives to patent exclusivity, amici suggested monetary prizes for particular discoveries[108] or the creation of other forms of intellectual property such as a transferrable right to accelerated FDA review.[109] Other commentators have proposed compulsory licensing to ensure universal access at a reasonable cost,[110] tax incentives to donate intellectual property to charitable organizations,[111] federal contracts conditioned on the development of open-source products,[112] and legislative codification of a common law "safe harbor from infringement" for nonprofit research and testing,[113] among many other possibilities. These solutions could accommodate the needs of the *Myriad* plaintiffs and defendants alike. While for-profit companies would retain access to funding, not-for-profit entities would be free from the threat of infringement suits.

Unable to order or implement solutions like these, the Supreme Court was sensible to focus on the current state of patent law and leave further action to Congress. Framing the issue as whether the Court should defer to PTO policy or avoid altering existing property rights, as the Federal Circuit judges did, misses the point.[114] Instead, as the Federal Circuit and *Mayo* opinions demonstrated, the range of available options would not have allowed the Justices to do more than take sides. Optimizing patent law for the mix of incentives at play in the biotechnology industry is a path open only to Congress.

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106 *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1304–05 (2012).

107 *Id.*

108 Brief of *Amicus Curiae* Knowledge Ecology International in Support of Petitioners at 13–15, *Myriad*, 133 S. Ct. 2107 (No. 12-398) (discussing, among other things, two bills introduced in Congress that would have created cash prizes to promote innovation).

109 *Id.* at 11–12.

110 Watson Brief, *supra* note 87, at 19–20.

111 Xuan-Thao Nguyen & Jeffrey A. Maine, *Giving Intellectual Property*, 39 U.C. DAVIS L. REV. 1721, 1725 (2006).

112 Peter Lee, *Contracting to Preserve Open Science: Consideration-Based Regulation in Patent Law*, 58 EMORY L.J. 889, 893–94 (2009).

113 Kenneth Offit et al., Special Article, *Gene Patents and Personalized Cancer Care: Impact of the* Myriad *Case on Clinical Oncology*, 31 J. CLINICAL ONCOLOGY 2743, 2747 (2013).

114 *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1330, 1332–33 (Fed. Cir. 2012); *id.* at 1345 (Moore, J., concurring in part).