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**GENE PATENTS AND THE PUBLIC INTEREST: LITIGATING
ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS
AND LESSONS MOVING FORWARD**

*Sandra S. Park**

I want to thank the *North Carolina Journal of Law & Technology*, Mike Frongello, and John Conley for the invitation and for putting together this terrific symposium. I also want to acknowledge my fellow symposium presenters, almost all of whom directly contributed in important ways to the case. Jim Evans, Bob Cook-Deegan, Andrew Chin, Chris Holman, and Lori Andrews filed amicus briefs. I extend special and deep appreciation to Lori, who worked on this issue for many years, pushed us to take on the case, and did a masterful job with the amicus briefs on behalf of the American Medical Association and other medical groups. I am grateful for all of your insights, support, and friendship.

It is a pleasure to be here. It has been eight months since the Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*,¹ and in many ways, I am still processing the journey that led up to the opinion, and what the future holds. I want to use our time together to talk about the development of the case and lessons we learned that I think have interesting implications for biotech patents, patent law and litigation, as well as patent law advocacy done in the public interest, moving forward.

* Senior Staff Attorney, ACLU Women's Rights Project. Park represented the twenty plaintiffs who challenged the BRCA1 and BRCA2 gene patents in the litigation resulting in *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013). The views expressed here are her own. The following are the prepared remarks of Keynote Speaker, Sandra Park, the *North Carolina Journal of Law & Technology* Symposium, February 21, 2014.

¹ 133 S. Ct. 2107 (2013).

I. DEVELOPMENT OF THE LITIGATION

A. *Origins of the Case*

I first started working at the ACLU seven years ago. At the time, the ACLU had a wonderful science advisor—Tania Simoncelli—who is not a lawyer but was tasked with identifying science policy issues that raise civil liberties concerns. The practice of patenting human genes was one of them.

The ACLU is 94 years old, and over that time our work has touched on most areas of American law, including other areas of intellectual property law such as copyright. But until we began looking into gene patents, the ACLU had never been involved in patent litigation. The ACLU Women's Right Project, where I work, was co-created by Ruth Bader Ginsburg in 1972 to advance gender equality and the civil liberties of women and girls.² One of the privileges of my position is that we are empowered to think expansively about how to truly advance women's rights. Justice Ginsburg pioneered that approach from the start. She crafted a strategy of representing men in some of the landmark cases challenging laws and policies that explicitly discriminated based on sex or gender.³ Once we decided that a challenge to gene patents should center on the BRCA1 and BRCA2 gene patents, the issue fit squarely within our mandate because of the direct effects of these patents on women's health and the restrictions placed on people's access to their own genetic information. On a more fundamental level, our commitment to ensuring people's rights to bodily integrity, human dignity, and scientific freedom gave rise to a deep discomfort with the notion that the government could grant rights over pieces of the human body, simply because they are isolated from the body.

² AM. CIVIL LIBERTIES UNION, FIGHTING SEX STEREOTYPES IN THE LAW: REFLECTIONS ON 40 YEARS OF THE ACLU WOMEN'S RIGHTS PROJECT (Dec. 2012), *available at* https://www.aclu.org/files/assets/2012.12.20_released_version_of_wrp_40th_report.pdf.

³ *See, e.g., Califano v. Goldfarb*, 430 U.S. 199 (1977); *Weinberger v. Weisenfeld*, 420 U.S. 636 (1975).

There was a core group within the ACLU who studied the issue and advocated internally to take on a challenge to gene patents. The team included my colleague Chris Hansen from the ACLU Speech, Privacy & Technology Project, Tania, Aden Fine, Lenora Lapidus, and me, as well as Dan Ravicher from the Public Patent Foundation. We received strong support from the ACLU's Executive Director, Anthony Romero.

We talked with many who had a stake in the issue—patent experts, geneticists, clinicians, law professors and other scholars, patient advocates, and patients. These conversations were aimed at learning about the issue and people's experiences, and to make sure we were doing the right thing. We wanted to know whether ending gene patents would serve patient interests and lift existing barriers to science, medicine, and innovation.

We investigated the effects of these patents, and it was these consequences that ultimately convinced us to take on the case.⁴ At that point, gene patents had been in existence for 25 years, and so we could examine many years of experience with them, including research that looked at gene patents and their effects.⁵ And ultimately, we concluded that this category of patents did not fulfill the constitutional mandate of Article I that patents must “promote the progress of science.”⁶ Because isolation of DNA is a prerequisite step to most serious scientific work with a gene, including testing, the Patent Office's practice of granting patents

⁴ For a more detailed description of the policy and legal analysis undertaken, see Tania Simoncelli & Sandra S. Park, *Making the Case Against Gene Patents*, PERSPECTIVES ON SCIENCE (forthcoming 2014).

⁵ See, e.g., *Stifling or Stimulating – The Role of Gene Patents in Research and Genetic Testing: Hearing Before the H. Subcomm. on Courts, the Internet and Intellectual Property* (Oct. 25, 2007) (statement of Wendy Chung); Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. MOLECULAR DIAGNOSTICS 3, 6 (2003); Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239 (2005); Kimberly Blanton, *Corporate Takeover Exploiting the US Patent System*, BOSTON GLOBE MAG., Feb. 24, 2002.

⁶ U.S. CONST. art. I, § 8, cl. 8.

on “isolated DNA” gave patent holders the right to exclude all others from engaging in any scientific work with that gene.⁷

The most immediate impact of these patents could be seen on clinical diagnostic testing. Studies established that patent holders had used their rights to shut down other labs from providing genetic testing relating to a wide range of conditions, including hemochromatosis, muscular dystrophy, Long QT syndrome and others.⁸ I spoke with lab directors who told me they regularly received cease and desist letters and that they stopped offering certain genetic tests as a result. Gene patent holders could determine the type of testing offered, which mutations were looked for, the cost, and the availability of confirmatory testing, as well as control the data about a gene.

In the case of the BRCA1 and BRCA2 patents, Myriad stopped other labs that already were doing BRCA testing once it got its patents, even when they were using different testing methods.⁹ The price of its testing went up over time, even as the cost of testing dropped with technological advancements. Eventually, they charged over \$4000 for their standard test and their testing for large rearrangements on BRCA1 and BRCA2.

For many years, Myriad did not offer testing on certain genetic large rearrangements that were known in the scientific community to be correlated to cancer risk, leading to a false negative rate of 12% in patients from high-risk families.¹⁰ Even when it began offering that testing, it chose to package its testing in such a way that patients would need to order and pay for large rearrangement

⁷ U.S. Patent & Trademark Office, Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001).

⁸ Declaration of Mildred Cho, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), *available at* https://www.aclu.org/files/pdfs/freespeech/brca_Cho_declaration_20090826.pdf.

⁹ Declaration of Arupa Ganguly, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181, *available at* https://www.aclu.org/files/pdfs/freespeech/brca_Ganguly_declaration_20090826.pdf.

¹⁰ Tom Walsh et al., *Spectrum of Mutations in BRCA1, BRCA2, CHEK2, and TP53 in Families at High Risk of Breast Cancer*, 295 J. AM. MED. ASS’N 1379 (2006).

testing separately.¹¹ I met many patients who never received that testing and thus never had a complete picture of their genetic risk.

Moreover, Myriad did not allow confirmatory testing of negative results. It stopped sharing the data it collected, interfering with the ability of the scientific community to work more collaboratively to determine the clinical significance of less common genetic variants.¹²

We were also concerned about studies that showed that these patents had a chilling effect on research, because researchers knew that patent holders could seek to assert their rights if their research on the genes proved to be valuable.¹³ And the concept of patenting individual genes was in conflict with where the science and technology have led us: inexpensive multi-gene tests to obtain a fuller understanding of the many genes that are associated with a particular condition—such as the BROCA test out of the University of Washington which tests more than 20 genes related to hereditary breast and ovarian cancer—and whole genome sequencing.

After consulting with relevant stakeholders, we found that there was near unanimity within the medical and scientific communities that ending gene patents would benefit patients, science, and medicine. So contrary to the rhetoric that surrounded this case from the beginning, our purpose was not to hurt the biotech industry or even Myriad—exactly the opposite. Gene patents were an obstacle to the creation of new tests, tools, and drugs. Our goal was to end monopolies on genes that prevented everyone, including industry players, from working with specific genes. The Nobel Laureate economist Joseph Stiglitz filed a declaration in our case arguing that the patents impeded

¹¹ Supplemental Declaration of Ellen Matloff, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181, available at https://www.aclu.org/files/pdfs/freespeech/brca_suppdeclaration_Matloff_20100120.pdf.

¹² Declaration of Elizabeth Swisher, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181, available at https://www.aclu.org/files/pdfs/freespeech/brca_Swisher_declaration_20090826.pdf.

¹³ See, e.g., Kenneth G. Huang & Fiona E. Murray, *Does Patent Strategy Shape the Long-run Supply of Public Knowledge? Evidence from Human Genetics*, 52 ACAD. MGMT. J. 1193, 1200 (2009).

innovation,¹⁴ and other testing laboratories filed amicus briefs along the way agreeing with our position.¹⁵

On the question of whether a legal challenge would succeed, almost everyone we talked with said we would lose in court. Yet, when we evaluated the legal issues, we concluded that the patents were invalid under Section 101. We looked closely at the Supreme Court's precedent on Section 101 of the Patent Act, going back 150 years. While the Court had yet to decide *Bilski* or *Mayo*, the Court again and again affirmed that laws and products of nature and abstract ideas are not patentable, and that simply removing something from its natural environment and making trivial changes to it does not create an invention.¹⁶

We still knew that the odds were long and our only chance of ultimate success would be at the Supreme Court. Regardless of what happened at the district court, we fully expected an appeal to the Federal Circuit, which we knew would likely disagree with our arguments based on their narrow interpretation of the exception to patent eligibility under Section 101.

However, you are likely to be disappointed if a Supreme Court decision in your favor is your only goal. The Court takes very few cases, and as far too many lawyers know, even when you think you're right on the law, the Court does not always agree. But unlike some of the other issues we work on, a negative ruling would not do much harm. The status quo was firmly entrenched,

¹⁴ Declaration of Joseph E. Stiglitz, *Ass'n for Molecular Pathology*, 702 F. Supp. 2d 181, available at https://www.aclu.org/files/assets/2010_01_20_-_Declaration_of_Joseph_E_Stiglitz.pdf.

¹⁵ Brief for GeneDx and Law Professors as Amici Curiae Supporting Petitioners, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) (No. 12-398), 2013 WL 417733; Brief for Invitae Corporation as Amicus Curiae Supporting Petitioners, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 432953.

¹⁶ See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127 (1948); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931); *O'Reilly v. Morse*, 56 U.S. 62, 14 L. Ed. 601 (1853). The Supreme Court issued two important Section 101 cases while our litigation was pending. See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010).

rooted in the Patent Office's policy and the Federal Circuit's tacit approval of gene patents.¹⁷

We therefore considered what could be achieved by pursuing litigation challenging gene patents beyond a win in the courtroom. This is a part of lawyering you don't necessarily learn in law school but is an important element of a public interest lawyer's job: litigation as one strategy in making institutional, political, legal, and social change, generally a long and hard process.

So beyond a win in court, we had other overarching goals. First, we wanted to start a serious public debate about gene patenting that could ultimately help spur legislative or policy change. In that respect, we were building on work begun by many others, including many who became plaintiffs, experts, and amici. These patents had sparked much controversy early on within the scientific community. Dr. James Watson, who co-discovered of the DNA double helix, resigned from the National Institute of Health ("NIH") because he disagreed with the government seeking its own gene patents.¹⁸ But after the Patent Office came out with its utility guidelines in 2001, which permitted patents on isolated DNA but made it more difficult to simply patent expressed sequence tags ("EST"s),¹⁹ the debate largely died down. With the exception of the study of gene patents underway by the Health and Human Services' Secretary's Advisory Committee on Genetics, Health, and Society,²⁰ gene patents were accepted as the status quo by those in the know.

But most people were not in the know. It is fair to say that 99.9% of the public had no idea that the government was engaged in this practice before the litigation—and that was true of many

¹⁷ *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1292–96 (Fed. Cir. 2010) (Dyk, J., concurring-in-part and dissenting-in-part).

¹⁸ Brief for James D. Watson, Ph.D. as Amicus Curiae Supporting Neither Party at 14–15, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 432951.

¹⁹ ESTs are DNA fragments where the function of the genes from which they were derived was often unknown.

²⁰ See Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS), *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (April 2010), available at http://osp.od.nih.gov/sites/default/files/SACGHS_patents_report_2010.pdf.

patients most directly affected by patented genes. We thought the litigation could be a tool for public education and lay the groundwork for policy reform.²¹

We succeeded in changing one important policy on gene patents, even before the Supreme Court decision: the position of the U.S. government, which of course issued these patents in the first place. We sued the Patent Office, along with Myriad, as part of the case. But once the case reached the Federal Circuit, the government announced in an amicus brief that they now believed that patents on isolated DNA were invalid as a matter of law.²² The government stated that the litigation had caused them to reexamine their position after consulting with all of the relevant parts of the federal government, including the NIH. I believe that shift in government position would never have been expressed without the litigation, as the Patent Office remained firmly behind its policy. And perhaps directly naming the government as a defendant in the original lawsuit forced the government to confront this issue and its policy head on, leading to the welcome change in its position. Even if I do not agree with its view on the patent eligibility of cDNA, I highly commend all of the people within the federal government who came to this issue with open minds and made this shift in policy possible, including Neal Katyal, who was the Acting Solicitor General at the Department of Justice, and Francis Collins, the Director of the NIH.

A second, much related, goal was to broaden the understanding of patent law litigation and how it can be used in the public interest. U.S. patent law is structured, for the most part, to exclude any explicit consideration of the public interest when it comes to individual patents or even categories of patents. Unlike many countries in Europe, there is no conception of the public interest

²¹ We engaged in a wide range of media and other communications activities, obtaining mainstream coverage and editorials, and producing our own videos, blog posts, and infographics. Some can be found at www.aclu.org/genepatents.

²² Brief for the United States as Amicus Curiae Supporting Neither Party at 18, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 653 F.3d 1329 (2011) (No. 2010-1406); *see also* Brief for the United States as Amicus Curiae in Support of Neither Party, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 390999.

built into the Patent Act. For that reason, almost all patent litigation in the United States involves two competitors suing each other. While the resolution of those cases might sometimes serve a broader public interest, that is rarely the aim.

We believed that patent law should not be seen as an esoteric area of law in which only specialists engage. There are social justice values implicated in what patents are issued, what areas of research are stymied or encouraged, and which patients are denied access to their genetic information. We saw the revival of Section 101 as a meaningful doctrine as an important lever to help advance the public interest by recognizing where patents could impede innovation and scientific freedom. We also observed that the patent establishment—by which I mean the patent bar, the Patent Office, and the Federal Circuit—had accepted that Section 101 had little meaning. In our view, bringing this lawsuit and asserting Section 101 would help highlight the Supreme Court’s Section 101 precedents and spark greater attention to this area of the law and the public’s stake in ensuring that patents promote, rather than hinder, progress.

B. *Key Strategic Decisions*

So these goals—to achieve a possible win at the Supreme Court, to begin a public debate to set the groundwork for policy change, and to shift patent law doctrine—shaped the decisions we made in answering some key strategic questions.

1. *Who Should Bring the Case?*

The case is often referred to as *ACLU v. Myriad*. But of course the ACLU was not a plaintiff in the case. We represented twenty plaintiffs: four national associations of pathologists and geneticists; six individual geneticists; two genetic counselors; two breast cancer and women’s health groups; and six patients.²³

In thinking about the plaintiffs, we approached this as we would a civil rights case. Who, broadly speaking, was affected? What coalition could we build? When we started doing our

²³ For statements about the plaintiffs and why they brought the suit, see https://www.aclu.org/free-speech_womens-rights/brca-plaintiff-statements.

outreach, I was surprised to find how siloed the different stakeholders were on this issue. Many of the most affected patient groups were not in touch with the clinicians or researchers concerned about this issue. We helped start some of these conversations, and ultimately many of these people and organizations became plaintiffs. They showed the courts that diverse stakeholders—from the scientists, to the clinicians, to the patients—were joined in opposing these patents.

Their voices were so important in making the issue of gene patents come to life, especially the voices of the patients. I want to name them here because they each contributed so much—Lisbeth Ceriani, Genae Girard, Runi Limary, Patrice Fortune, Vicky Thomason, and Kathleen Raker. They spoke about their struggles with cancer, or with family histories of cancer that terrified them, and the deeply personal decisions that turned on accessing their genetic information. Their voices were essential in making this abstract issue one that we could all understand.

And I also want to recognize the organizations and individual geneticists and genetics counselors who took a stand. I was so honored to represent all of them. They each took a risk in joining this litigation, but they all chose to do so because of the impact on their patients and medicine: Association for Molecular Pathology, American College of Medical Genetics, American Society of Clinical Pathology, College of American Pathologists, Haig Kazazian, Arupa Ganguly, Wendy Chung, Harry Ostrer, David Ledbetter, Steve Warren, Elsa Reich, and Ellen Matloff. Incredibly distinguished clinicians and researchers in their own right, many had a long history of opposing gene patents. Being able to partner with them and draw on their knowledge was critical.

And there were two women's health and breast cancer organizations that saw this issue as a matter of social justice for women and breast cancer patients: Breast Cancer Action, and Our Bodies Ourselves. They were key in explaining the significance of gene patents to communities working with patients and on women's health.

2. *Who Should be Sued?*

The next question we had to grapple with was who should be sued? We sued the Patent Office along with the patent holders—Myriad and the University of Utah—to place the spotlight on the government’s practice of granting these patents in the first place. We wanted this case to squarely challenge that practice and not just be a narrow attack on Myriad’s patents. In terms of which gene patents to challenge, we decided on Myriad’s BRCA1 and BRCA2 patents for several reasons. Myriad had enforced its patents aggressively and had a monopoly on the clinical testing market. There were many laboratories that wanted and were capable of performing BRCA testing. And BRCA testing was vital to many patients, who lacked access or were being harmed in other ways due to Myriad’s monopoly.

3. *What Legal Claims Should Be Brought?*

A third question we had to answer was whether we should challenge the patent claims only on Section 101 or on other patent law grounds, such as obviousness. Many experts we spoke to urged us to bring an obviousness challenge to the claims, and we recognized that these claims were indeed vulnerable on obviousness grounds.²⁴

Ultimately, we determined that Section 101’s prohibition on patenting laws and products of nature was best suited for asserting the larger public interest in opposing gene patents. A court might prefer to focus on a narrower patent law ground, rather than Section 101, and that is certainly an approach we have seen the Federal Circuit take. But if the case were resolved on obviousness, that would be a fact-specific inquiry that turned entirely on the circumstances of Myriad’s patents and might not have much impact beyond this case. And the Supreme Court had signaled its interest in reaching Section 101 questions, based on their prior Section 101 cases on laws and products of nature.²⁵

²⁴ *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009).

²⁵ See, e.g., *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 125–39, 165 L. Ed. 2d 399 (2006) (Breyer, J., dissenting).

We also brought constitutional claims against the governmental defendants. We particularly wanted to underline that gene patents do not promote the progress of science—which is the constitutional mandate for the patent system as set out in Article I. Moreover, by allowing Myriad to monopolize particular areas of scientific inquiry—namely study of the BRCA1 and BRCA2 genes—the government’s grant of the patents violated the First Amendment’s guarantees of freedom of thought and inquiry, which are considered essential to the freedom of speech.²⁶ As far as we know, this was the first First Amendment claim brought challenging patents. However, the courts never reached the constitutional issues because we succeeded at the district court in dismissing the claims under Section 101.²⁷ How courts will consider the constitutional dimension of patent law is a big issue that remains to be developed in the future.

II. THE SUPREME COURT OPINION, LESSONS LEARNED, AND MOVING FORWARD

I am going to fast forward from the filing of the lawsuit in May 2009 to June 2013, when we received the Supreme Court decision.²⁸ We were thrilled with the outcome, and especially, that it was a unanimous decision. The decision adopted our core argument that under the Court’s doctrine, articulated in cases such as *Diamond v. Chakrabarty*²⁹ and *Funk Brothers Seed Co. v. Kalo Co.*,³⁰ isolated DNA is a law and product of nature.

The Court affirmed a core principle, which had been ignored for many years—simply separating the gene from its surrounding

²⁶ We have continued to raise the First Amendment implications of patents. See Brief for Am. Civil Liberties Union as Amicus Curiae Supporting Respondents, *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, __U.S.__ (2014) (No. 13-298), available at <https://www.aclu.org/free-speech-technology-and-liberty/alice-corporation-pty-ltd-v-cls-bank-international-amicus-brief>.

²⁷ *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 237–38 (S.D.N.Y. 2010).

²⁸ *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013).

²⁹ 447 U.S. 303 (1980).

³⁰ 333 U.S. 127 (1948).

genetic material is not an act of invention. Notably, the Court recognized that Myriad's claims were "concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule."³¹ And the Court rejected giving any deference to the Patent Office's practice of awarding gene patents. The Court did not agree with us on the patent-ineligibility of cDNA, but left open the question of whether cDNA might be unpatentable on other grounds such as obviousness.

In conclusion, I want to talk about some lessons and questions raised by the litigation that I think we will continue to need to grapple with as we move forward.

One major lesson of the *Myriad* litigation is that patent law, like other areas of law, benefits from understanding all of the stakeholders' experiences with the patents at issue. I believe it is because the voices of patients, geneticists, and others were absent from the patent process that we faced a situation where gene patents had been issued for 25 years without any legal challenge as to whether they were patentable subject matter in the first place. The patent system has few mechanisms to hear from stakeholders beyond the patent applicants before patents are issued or take into account the broader public interest. Yet, the Justices, as the U.S. government did, took a more expansive view of the impact of these patents. They did not accept the automatic assumption that all patents promote progress. The Court rejected deference to the Patent Office or industry, and instead described how the patents stopped clinicians like Dr. Ostrer from offering testing services to women patients.

The *Myriad* case can also be seen as a case study in bridging the two distinct cultures of law and science.³² From the start, we seriously considered how we, as primarily non-patent attorneys, could most effectively frame a patent lawsuit that we hoped would eventually reach the Supreme Court. Myriad's overall strategy was to try to make this issue seem as complicated as possible and beyond the understanding of non-scientist mortals. They focused

³¹ *Myriad*, 133 S. Ct. at 2118.

³² See Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2 (2010).

on the difficulty of the process of isolation—even though difficulty in and of itself is not a sufficient reason under the law to get a patent. At oral argument, one of Myriad’s attorneys claimed ignorance about some of the nuances of science, saying that he was only an English major.³³

Our approach to bridging the law and science was twofold: first, effective use of experts. We worked with some of the most renowned scientists in the country and even the world to translate the science and break it down so that it could be more easily synthesized with the law. Myriad’s primary expert on the science, similar to Myriad’s overall strategy, conflated and confused some of the scientific concepts. We were able to rebut these effectively by focusing on the characteristics of isolated DNA.³⁴

We also used analogies as a way of bridging the two cultures. I would say about half of the conversations and debates that Chris Hansen and I had during the course of litigation were over which analogies to use in our briefs and hearings. We knew they would be important for non-scientists to understand the science of the case.

Myriad never identified an analogy that could illustrate the stopping point for their argument. Before the Federal Circuit, they conceded that elemental lithium would be patentable.³⁵ Before the Supreme Court, their attorney seemed to suggest that the only reason parts of the kidney or liver would not be patentable is

³³ Oral Argument, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

³⁴ See, e.g., Declaration of Robert L. Nussbaum, *Ass’n for Molecular Pathology v. U.S. Patent and Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), available at <https://www.aclu.org/free-speech-womens-rights/brca-declaration-robert-l-nussbaum-md>; Declaration of Roger D. Klein, *Ass’n for Molecular Pathology*, 702 F. Supp. 2d 181, available at <https://www.aclu.org/free-speech-womens-rights/brca-declaration-roger-d-klein>.

³⁵ Oral Argument, *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011).

because we were already aware of them, not because they are parts of the human body.³⁶

How did these strategies play out in court? At the district court, we drew a judge who was excited to delve into the scientific principles, though he acknowledged the difficulty of doing so. We also were very lucky that Judge Sweet had a law clerk with a Ph.D. in molecular biology to assist him in writing a 150-page, legally and scientifically sound, opinion.

At the Federal Circuit, Judge Lourie focused on a new scientific distinction, one that Myriad had not argued—the breaking of covalent bonds—which he developed as an argument based on his background in chemistry.³⁷ In contrast, Judge Bryson emphasized that genetics, not chemistry, should be the relevant lens through which to examine the claims.³⁸ So the Federal Circuit debated even the field of science that should apply in understanding the claims and applying the law.

Judge Moore took a different approach to melding the science and the law—in her view, it was not a simple question of applying the law to the science as she understood it. She openly acknowledged that if she were working from a blank slate, she would have likely found the patents on the full-length genes invalid.³⁹ But ultimately she deferred to industry reliance on patents that the Patent Office had issued for many years. The prevailing legal understanding trumped what might be the current application of law to science.

At the Supreme Court, our strategies largely succeeded. We had built up a record that explained the science and were helped by some key amicus briefs, including a brief by geneticist Eric Lander.⁴⁰ And during oral argument at the Supreme Court, the

³⁶ Transcript of Oral Argument at 54–61, *Myriad*, 133 S. Ct. 2107 (No. 12-398), available at http://www.supremecourt.gov/oral_arguments/argument_transcripts/12-398-amc7.pdf.

³⁷ *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1308-37 (Fed Cir. 2012).

³⁸ *Id.* at 1348–54.

³⁹ *Id.* at 1343, 1358.

⁴⁰ Brief for Eric Lander as Amicus Curie Supporting Neither Party, *Myriad*, 133 S. Ct. 2107 (No. 12-398), 2013 WL 432959.

justices clearly sought to figure out the application of law to science by use of analogies—from thinking about the ingredients for chocolate chip cookies to making a bat from the branch of a tree.⁴¹ Many commented on these analogies, including faulting the justices for relying on them. I agree that it certainly matters how good your analogies are. But all of common law is premised on drawing analogies. We take principles and examples from other cases to build the law.

Lastly, the lawsuit sought to address and overcome significant institutional and procedural barriers that severely limit public access and understanding of the patent system. We made considerable progress, but there are still major obstacles. The filing of the lawsuit by an amazing coalition, and the support they received from diverse experts and amici, showed how public interest patent litigation can be brought. Daunting barriers to public interest litigation in patent law include the expense of lawsuits and the aversion of most attorneys to science. We were able to overcome both by rallying the institutional resources of the ACLU, and being open to learning the science with the aid of experts.

If we had not taken on this issue, it is very possible that no case would ever have been brought challenging these or similar patents. Patent law insiders believed that Section 101 was dead letter law, and even if they disagreed with the Patent Office's policy on gene patents, they assumed that the Federal Circuit would be the last word and that the Court of Appeals would never uphold these patents. Additionally, members of the patent bar generally were focused on those who controlled these patents, not on those negatively impacted by them. Our public interest orientation meant that we could frame the legal issue as one with major societal impact that the courts should—and ultimately did—care about.

There are still substantial institutional and procedural impediments to vindicating the public interest in patent law. We are seeing it play out with the post-Supreme Court litigation, where *Myriad* sued some companies who began offering BRCA genetic testing. Given the monopoly *Myriad* has enjoyed, it appears that it

⁴¹ Transcript of Oral Argument at 35–37, 48, *Myriad*, 133 S. Ct. 2107 (No. 12-398).

will litigate to protect it for as long as possible.⁴² Notably, other companies decided to affirmatively sue Myriad.⁴³ We believe that the Supreme Court's reasoning should apply to invalidate any patents that would authorize Myriad to maintain its monopoly on any examination of the BRCA1 and BRCA2 genes.⁴⁴ But it is a difficult situation for labs that may want to offer testing and cannot afford the threat of litigation. One commentator has called Myriad's actions another form of patent trolling.⁴⁵

Another procedural hurdle is the doctrine of standing—who can bring a case. It is a barrier that we deal with in civil rights litigation all of the time. The Federal Circuit held that only Dr. Harry Ostrer had standing because he had received direct communication from Myriad. Yet, the court recognized that Myriad's patent enforcement actions had not just affected Dr. Ostrer, but also forced every other similarly situated researcher and institution to refrain from BRCA genetic testing.⁴⁶ That certainly included other geneticists and pathologists that we represented. Unfortunately, the Supreme Court did not review this issue, and ultimately it did not affect the outcome because Dr. Ostrer had standing. It was troubling, however, that the Federal Circuit did not recognize the standing of other plaintiffs, who under traditional standing law should have the right to bring a case. That limited view of standing could affect attempts in the future to bring patent law litigation like this one.

⁴² See, e.g., *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*, No. 2:13-cv-00640-RJS, 2014 WL 931057, at *1 (D. Utah filed March 10, 2014).

⁴³ *Id.*

⁴⁴ See generally Brief for Am. Civil Liberties Union et al. as Amici Curiae Supporting Appellee, *Univ. of Utah Research Found. v. Ambry Genetics Corp.* (Fed. Cir. June 9, 2014) (Nos. 14-1361, -1366), available at https://www.aclu.org/sites/default/files/assets/brief_of_aclu_et_al._as_amici_curiae_in_support_of_appellee.pdf (arguing that Myriad's motion for a preliminary injunction should be denied because its asserted patent claims are invalid under Section 101 and the public interest would be undermined).

⁴⁵ See Timothy B. Lee, *Patent Trolls Have A Surprising Ally: Universities*, WASH. POST (Nov. 30, 2013), <http://www.washingtonpost.com/blogs/the-switch/wp/2013/11/30/patent-trolls-have-a-surprising-ally-universities>.

⁴⁶ *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1308–09, 1320–21, 1323 (Fed. Cir. 2012).

While the case broke down some of the barriers to broader public engagement in patent law issues, the patent world is still fairly insular. The Patent Office issued guidance immediately after the Supreme Court decision, stating it would no longer approve patents on isolated nucleic acids,⁴⁷ yet we have seen problematic patents issued post-*Mayo*. As new issues arise with how the Patent Office responds to the *Myriad* and *Mayo* decisions, there will certainly need to be ongoing collaboration among all the different stakeholders—clinicians, scientists, lawyers, patients, and others. We now have a strong foundation for those partnerships. For me personally, those discussions and collaborations were the best and most fulfilling parts of working on the case. And that's why I appreciate this opportunity to begin a conversation with all of you about these issues. I look forward to your questions.

⁴⁷ Andrew H. Hirshfeld, Deputy Comm'r for Patent Examination Policy, *Supreme Court Decision in Association for Molecular Pathology v. Myriad Genetics, Inc.*, U.S. PATENT & TRADEMARK OFFICE (June 13, 2013), http://www.uspto.gov/patents/law/exam/myriad_20130613.pdf; see also Andrew H. Hirshfeld, Deputy Comm'r for Patent Examination Policy, *2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products*, U.S. PATENT & TRADEMARK OFFICE (Mar. 4, 2014), http://www.uspto.gov/patents/law/exam/myriad-mayo_guidance.pdf (providing additional guidance regarding the *Myriad*, *Mayo*, and other Section 101 decisions).