Prelude to "Pigs Fly:" The Early History of the Myriad Case

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Abstract

How and why did the American Civil Liberties Union (ACLU) and the Public Patent Foundation file a lawsuit against Myriad Genetics Corporation in 2009, challenging Myriad's patents on *BRCA1* and *BRCA2* genes? In June 2013, the Supreme Court handed down its much-heralded ruling in *Association for Molecular Pathology v Myriad Genetics (AMP v. Myriad)*. The genesis of the case is far less well known. Personal interviews conducted with the instigators of the case reveal a compelling story about the process of strategically framing patent policy as public interest litigation. The ACLU's initial goal was to raise public awareness about gene patenting. They were not at all certain they would prevail, but believed that at least the case would greatly increase awareness of a perceived problem, and become the focus of public debate… and possibly policy change. In interviews and background documents, the major players describe how the ACLU was able to build a strong coalition, and as a result, beat the odds.

I. *Association for Molecular Pathology et al. vs. Myriad Genetics, Inc., et al.*

Are human genes patentable? These four words framed the landmark case brought before the Supreme Court in 2013 by the American Civil Liberties Union (ACLU) and the Public Patent Foundation against Myriad Genetics, Inc., the company that holds the patents on the *BRCA1* and *BRCA2* genes correlating with an increased risk of breast and ovarian cancer. *AMP v. Myriad* challenged the validity of the generally accepted practice of gene patenting in the United States. On June 13, 2013, the United States Supreme Court released its decision, unanimously agreeing that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring" (*Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al., No. 12-398, U.S. 2013).* In supporting the Association for Molecular Pathology's position, the Supreme Court's detailed ruling held, "In this case… Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention" (*Association for Molecular Pathology et al. v. Myriad Genetics, Inc. et al., No. 12-398, U.S. 2013).*

II. ACLU's Involvement

The case against Myriad Genetics originated in 2009 when the American Civil Liberties Union (ACLU) and the Public Patent Foundation filed suit in Federal District Court for Southern New York to overturn the patents Myriad held on the *BRCA1* and *BRCA2* genes. These patents entitled Myriad to preclude all others from using the isolated DNA in breast cancer diagnostics,

research, and treatment. In essence, by issuing these patents, the U.S. government granted Myriad a monopoly on the breast cancer genes.

Four years prior to the ACLU's filing of the lawsuit, Tania Simoncelli, Science Advisor at the ACLU, brought the issue of gene patenting to the attention of ACLU senior management. Simoncelli's long-standing interest in the social implications of biotechnology and emerging genetics led her to join the ACLU in the newly created position of Science Advisor in 2003. Specifically, it was her job to identify cutting edge science and technology issues (with a particular emphasis on genomics and life sciences) that might infringe on civil liberties, and to develop the supporting information and argument for ACLU participation. Likely areas of interest included reproductive cloning, germline debates, designer babies, behavioral genetics, genetic discrimination, DNA forensics, and stem cells. Simoncelli accepted the offer from the ACLU over the opportunity to earn a Ph.D. at MIT because of the excitement and challenge of shaping an influential organization's position on emerging life science issues, particularly with respect to civil liberties and law (Simoncelli).

The ACLU purposely crafted Simoncelli's job description as Science Advisor so that it would be undefined and unstructured. Anthony Romero, the Executive Director of the ACLU, created this position and sought a candidate who could look broadly on 21st Century challenges in emerging sciences through a civil liberties lens. Simoncelli joined the ACLU's Technology and Liberty Project initiative that seeks to ensure that civil liberties are enhanced rather than compromised by advances in science and technology. Where others on the Technology and Liberty Project were involved with well-established and documented civil liberties issues such as internet privacy and profiling transportation passengers in a post-9/11 world, Simoncelli endeavored to find the intersection between life science and social consciousness. She began

organizing interdisciplinary brainstorming sessions in 2004 with legal scholars, sociologists, scientists, and anthropologists in order to update them on emerging life science technologies. As part of this project, Simoncelli coordinated and moderated a panel on gene patenting to explore its civil liberties implications. Subsequently, she organized a panel focusing on behavioral genetics and neuroscience. Dan Kevles, a Yale University science historian with an interest in the intersection of science and society, delivered the keynote address on the history of eugenics in the United States. In his closing remarks, Kevles insightfully suggested that the ACLU could play a meaningful role in any debate on individual rights as they relate to gene patenting (Simoncelli).

A week or so before the behavioral genetics and neuroscience panel discussion with Dan Kevles, Simoncelli approached Chris Hansen, an ACLU litigator with over thirty years of experience defending the rights of individuals against the vested interests of larger private interests. Simoncelli had become discouraged due to the difficulty of convincing her colleagues at the ACLU to pay attention to science, in large part because it was a new arena to them and they did not feel equipped to deal with scientific issues. Hansen asked her what issues she felt were meaningful and she mentioned genetic discrimination and biobanking. She then brought up gene patents, asking, "Do you know that there are patents on human genes?" Hansen countered, "No way! That can't be right! What you probably mean is that there are patents on the method by which genes are extracted or the methods by which genes are used in diagnostic or treatment purposes." Simoncelli insisted, "No, there are patents on genes themselves." Hansen responded, "You mean to tell me the U.S. government is granting a temporary monopoly on parts of the human body?" Simoncelli replied, "Well technically, there are patents on isolated DNA, but in effect, it's a patent on the gene itself because you've got to isolate the DNA to actually use it."

Hansen, reluctant to believe this could possibly be accurate, urged Simoncelli to prove it. Simoncelli went back to her office and sent him a few articles, one of which was a policy argument against gene patenting written by Lori Andrews, a law professor at the Illinois Institute of Technology- Chicago Kent Law School and Director of ITT's Institute for Science, Law, and Technology. An hour later, Hansen rushed back to Simoncelli's office, exclaiming, "Oh, my God! You're right! We have to do something to challenge this. Who can we sue?" (Simoncelli)

Although Chris Hansen did not specialize in patent law and had no formal education in the field of genetics, he embraced the issue of gene patenting and vowed to learn all he could. He maintained it was fundamentally wrong for the U.S. government to grant a patent over a piece of the human body, and thus believed the ACLU to be duty bound to challenge the law. Simoncelli was taken aback that Hansen was unaware genes were patentable because patents had been granted on gene sequences for many years. An example of an early gene patent is the University of California's patent on the "isolated and purified form" of a gene that encodes the insulin protein, granted in 1982 (U.S. Patent 4,082,613). Claims in U.S. patents mentioned sequences from some twenty percent of the genes in the human body. The fact that Hansen was totally unaware of gene patenting prompted Simoncelli to realize it was likely that key ACLU decision makers had little or no background in genomic policy issues. At this pivotal moment, Simoncelli recognized that what she was doing at the ACLU was critical in shaping the organization's position on crucial issues. If Chris Hansen was not aware of something as basic as this, most of the other 100 or so ACLU lawyers were probably not aware of it either. It would be her job to remedy that (Simoncelli).

The ACLU defines its mandate very narrowly as protecting individual rights. A patent claim on a part of the human body means that no one is allowed to do research on that part of the

human body without the patent holder's permission. For example, a researcher is infringing on the patent if he or she possesses the *BRCA1* or *BRCA2* gene in an isolated form, even if it is the researcher's own *BRCA* gene. Chris Hansen asserted it was a violation of the first amendment for the government to give exclusive control over a body of knowledge. Offended by the idea of treating human genes as personal property, he stressed that patenting on genes should be managed in the public interest (Hansen).

A legal doctrine arising in Supreme Court case law states, "One cannot patent a product of nature, a law of nature, or an abstract idea." Hansen and the ACLU argued that gene patenting violated at least two of these three categories. The first argument was that a gene is a product of nature; scientists do not create a gene, nature creates a gene. The second argument was that genes are commands to the body as to what it should be doing; therefore, genes direct the body and a gene embodies the laws of nature (Hansen). The ACLU contended, "Human genes, even when removed from the body, are still products of nature, and their associations with diseases are laws of nature" (ACLU Fact Sheet). Genes are not inventions; they are naturally occurring parts of our bodies.

In 2005, Simoncelli and Hansen began working in earnest on this gene patenting project, spending the next three years collecting and reading literature and meeting with experts in the field to identify the most appropriate legal theory to pursue. One of the first people Simoncelli contacted was Lori Andrews, an expert on biotechnology issues. Andrews challenged the ACLU to consider the civil liberties implications of gene patenting. Dan Kevles, a Yale science historian, met with the ACLU and generated further interest. The NIH's SACGHS (Secretary's Advisory Committee on Genetics, Health, and Society) released its draft report on this issue around this time, and Simoncelli was able to utilize this report to build additional support

(Simoncelli). For the most part, the patent lawyers they met with through this exploratory process advised them not to pursue the case because the ACLU was "flat out wrong and they would lose because isolated human genes are obviously patentable" (Hansen). On the other hand, scientists and geneticists encouraged the ACLU's interest because they believed patents should not be granted on human genes. However, since gene patenting had been going on for over twenty years at that point, many of these same scientists maintained the issue was not worth revisiting. They had waged this battle years ago and lost (Hansen). Yet, a core group of scientists and legal experts not only agreed that challenging gene patents was a good idea, they were more than willing to help by providing background knowledge and information. Among the experts with whom the ACLU consulted early in its process were Dr. Bob Cook-Deegan, Duke University's Director of Genome, Ethics, Law, and Policy; Dr. Arti Rai, an IP expert and Co-Director of Duke Law Center for Innovation and Policy; Dr. Mary-Claire King, discoverer of the genetic linkage between BRCA1 and risk of breast cancer, as well as other science and legal experts. These are the people Simoncelli and Hansen turned to for encouragement, confirmation of the end goal, and perspective (Simoncelli).

Concurrent with their research and investigation, Simoncelli and Hansen began shaping the talking points that would eventually win over the ACLU Board of Directors to the idea of challenging gene patenting. Simoncelli and Hansen knew that what they were proposing might initially be considered outside the ACLU's traditional civil liberties realm and that the eighty member board might resist the idea. After all, Simoncelli had been hired to identify cutting edge science issues, and the issue of gene patenting had been around for over twenty years; there was nothing cutting edge about it. More importantly, the ACLU had never engaged in issues

surrounding patent law. To their surprise, the board completely supported the idea, encouraging them to frame the issue as an infringement on civil liberties (Simoncelli).

The goal of Simoncelli and Hansen, and by extension, the ACLU, was to change the law and end gene patenting in the United States. When first discussing this, they realized there were several paths they could pursue. One option was to have the patent office re-examine certain patents, but any remedy would only apply to specific patents and was not going to end gene patenting overall. A second option was to seek a legislative solution, but other organizations had tried this before without success (Simoncelli). Congressional Representatives Xavier Becerra (D-CA) and Dave Weldon (R-FL) even crafted a bipartisan bill in 2007 to prohibit future human gene patenting, but the bill died in committee (Reynolds and Darnovsky).

The ACLU was interested in pushing the boundaries and changing the law. They settled on the judicial route because they realized they were not going to be successful through legislation. Hansen was a litigator and he immediately thought, "Who can we sue" (Simoncelli)? Since sequences from over 4,000 genes were already patented (Cook-Deegan), including those associated with Alzheimer's disease, muscular dystrophy, colon cancer, and asthma, the ACLU had a fairly deep pool of potential targets.

III. Determining Whom to Sue

After reviewing target candidates, the ACLU elected to challenge the patents held by Myriad Genetics, a molecular diagnostics company based in Salt Lake City, Utah. Myriad Genetics owned the patents on the *BRCA1* and *BRCA2* genes that correlate with an increased risk

for breast and ovarian cancer. The ACLU emphasized that the general public needed to understand the significance of this issue. According to Chris Hansen, "It could not be seen as a case about genetics. It could not be seen as a case about patent law. It had to be seen as a case about public policy and health" (Hansen). The ACLU acknowledged that most would not understand genetics, yet nearly everyone would be familiar with breast cancer and would know someone personally who has been affected. Hansen and Simoncelli briefly contemplated challenging the patents on long Q-T syndrome, a rare condition that causes the heart to suddenly stop beating (leading to sudden death), but agreed it would be too difficult to explain and people would not fully understand it (Simoncelli). Long Q-T syndrome did, however, provide a compelling example of previous gene patents that harmed the patient population due to restricted access to testing (Angrist Amicus Brief to the Counsel for Amicus Curiae AARP). However, breast cancer resonates much more strongly with the public because the disease has touched nearly everyone in some way; hence, the ACLU settled rather quickly on suing Myriad Genetics (Hansen).

Another reason for choosing Myriad Genetics was that Myriad had been a "bad corporate citizen" (Hansen). In 1996, Myriad Genetics launched its BRACAnalysis® test for detecting mutations in the *BRACA1* and *BRACA2* genes that put women at substantially increased risk of developing breast and ovarian cancer. As sole owners of the *BRACA1/2* patents, Myriad kept other companies from offering a similar diagnostic test, effectively preventing women from validating test results with a second opinion. Additional genetic mutations for susceptibility were discovered after Myriad obtained its patents. However, facing no market competition, Myriad had little incentive to adopt new methods of testing, including methods that would not miss large-scale chromosome rearrangements that BRACAnalyis® missed. This led to twelve

percent of women receiving false negative results (Walsh, King). In addition, Myriad had little incentive to improve the quality of its data interpretation, often releasing results of "variants of unknown significance." By threatening lawsuits and strictly enforcing its monopoly, Myriad prohibited other laboratories from developing more accurate testing. For a period of several years, the company knowingly sent incomplete results to women who were entirely dependent on this test to determine whether or not they should take preventive measures to safeguard their health (Hansen). Myriad eventually added rearrangement testing, yet did not incorporate this sequencing into its basis BRACAnalysis® test. Instead, the company charged women $700 separately for its newer BRCA Analysis Rearrangement Test (BART®). Essentially, women were expected to undergo testing with the original BRACAnalysis® for $3400, and then if the results came back negative, they had the option of undergoing the second BART® test for $700 (FORCE – Facing Our Risk of Cancer Empowered). The high cost made *BRCA* testing unaffordable to many women. Furthermore, Myriad began controversial direct-to-consumer television and magazine advertisements promoting breast cancer susceptibility testing to women, scaring women with no family history of breast or ovarian cancer into thinking they needed to be tested.

IV. Framing the Case

Genetics and patent law are difficult subjects for those not trained in these specialties. Patents contain volumes of arcane legal and technical language that the ACLU team had to wade through to figure out which patents to pursue. Simoncelli and geneticists walked Chris Hansen through the science of genetics. They spent a significant amount of time trying to simplify.

They talked to numerous genetics experts who explained what a gene is, what the significance of a gene is, how to isolate it, and why a gene is a product of nature, and not the result of a human invention. The ACLU focused in particular on the Section 101 patent requirement of a "new and useful composition of matter." This means that both the structure as well as the function of the isolated DNA must be "markedly different from that which occurs inside the body" (*AMP v. Myriad).*

A critical decision that Hansen and Simoncelli made was to frame the case as a civil rights case rather than a patent case. Patent cases typically involve two large competing corporations suing over conflicting patents or infringing patents. They are framed narrowly. Such a patent case was of no interest to the ACLU, and the ACLU assumed it would be of little interest to the courts (Hansen). Civil rights cases tend to be framed in broad social and ethical terms. Simoncelli knew the science and could articulate all the policy arguments about what was wrong with gene patenting and what it meant for access to care and the future innovation of biomedicine. A lot of those arguments were not legal arguments. Hansen was an experienced litigator and knew how to introduce civil rights litigation. Neither Simoncelli nor Hansen could have accomplished what they did without each other (Simoncelli).

The ACLU committed itself to putting this issue in a broader context and discussing the public policy harms that occurred as a result of *BRCA* patents (Hansen). They wanted to make the larger point that this was more than just about patent law and more than just about genetics. For example, the ACLU included a declaration from the person in charge of assembling worldwide information on breast cancer genes, stating that Myriad had stopped sharing information with the scientific community. Specifically, the company refused to participate in

the international collaborative mutaDATABASE and had not contributed to the NIH funded Breast Cancer Information Core since 2004 (Brody).

According to the lawsuit, gene patenting violates civil liberties, and in particular, the First Amendment because patents on DNA "grant control over a body of knowledge and pure information" (*AMP v. Myriad Genetics)*. Gene patents, therefore, hinder scientific progress. As sole owners of the *BRCA* genes, Myriad had the right to perform further research on individual samples of women's DNA without permission from the women. Myriad's control over the large set of data collected from its BRACAnalysis® testing was legally withheld from other researchers with significant implications for public health and breast cancer research (Hansen). The lawsuit contends that gene patents violate the Constitution's patent clause, hindering the authority of Congress to "promote the progress of science." Gene patenting stifles scientific advancement as "there is no way to invent around a gene" (ACLU Fact Sheet). To illustrate this point, Reynolds and Darnovsky argue in *The American Interest*, "Patents are meant to provide a better mousetrap, but human gene patents, in effect, claim the entire concept of catching mice" (Reynolds and Darnovsky).

The ACLU followed the same strategy in approaching the gene patenting case as it did for all its other cases – internet censorship cases, children's rights cases, women's rights cases, and social justice cases. They set out to identify a group of plaintiffs to illustrate why this case was so meaningful. They saw it as an issue that was vital for the future of biomedical innovation and for public health. If they had framed the case more narrowly, the case probably would never have been chosen to be reviewed by the Supreme Court (Hansen).

V. Gathering Plaintiffs

As the ACLU itself would have no legal standing in the case, Simoncelli and Hanson needed to establish early on who would sue Myriad Genetics. Simoncelli was in charge of plaintiff recruitment. At first it was an uphill battle. Even if a particular organization or individual seemed interested, the candidate needed to be willing to commit significant resources to this endeavor. While plaintiffs did not have to commit financial resources, they did nonetheless have to be willing to commit a substantial amount of time to review legal briefs. It was a lot to consider and it was a daunting proposition to challenge Myriad Genetics and the USPTO. Furthermore, since these potential plaintiffs had not worked with the ACLU before, the ACLU needed to gain their trust (Simoncelli). Another consideration was that most professional organizations are large membership organizations and litigation-averse. There is oftentimes someone in the organization who steadfastly takes the opposing side of an issue, and many organizations are reluctant to alienate even a minority of its members (Hansen).

The Association for Molecular Pathology (AMP) was the first to sign onto the case and became the lead plaintiff. AMP is an international non-profit professional consortium representing over 1,500 physicians, doctoral scientists, and medical technologists who perform molecular diagnostic testing. AMP joined the lawsuit because its members believed gene patents can "serve as a disincentive to innovation in molecular testing." These patents "deny access to a vital baseline of genomic information that cannot be 'invented around.' Moreover, the threat of enforcement from a patent holder and ensuing litigation costs lead to a chilling effect as clinical laboratories and manufacturers are reluctant to develop new tests that could directly benefit patients" (Association for Molecular Pathology plaintiff statement). Once AMP signed on, the ACLU built its coalition from there, finding a group of twenty plaintiffs to illustrate why this

case was so far-reaching. When building the coalition, the ACLU sought to represent a wide array of organizations, physicians, researchers, and women affected by gene patenting (Simoncelli). They ended up with four national organizations of geneticists representing more than 150,000 researchers and laboratory professionals (the Association for Molecular Pathology, the American College of Medical Genetics, the American Society for Clinical Pathology, and the College of American Pathologists); six prominent geneticists (Haig Kazazian, MD, Arupa Ganguly, Ph.D., Wendy Chung, MD, Ph.D., Harry Ostrer, MD., David Ledbetter, Ph.D., Stephen Warren, Ph.D.); two breast cancer advocacy groups (Breast Cancer Action and Boston Women's Healthbook Collective); two genetic counselors (Ellen Matloff, M.S., Elsa Reich, M.S.); and six individual women with breast/ovarian cancer or at high risk for it (Lisbeth Ceriani, Runi Limary, Genae Girard, Patrice Fortune, Vicky Thomason, and Kathleen Raker) (ACLU). The individual women were included, in large part because Anthony Romero, the ACLU Director, had given his blessing to go forward with the case, but had stipulated that they involve actual women (Hansen). It was very important to him to bring this case as part of an individual right's case with stories from individual women, breast cancer survivors and those intimately affected by the *BRCA* gene. The overall group of plaintiffs asserted that its central complaint was that Myriad Genetics' patents on the *BRCA1* and *BRCA2* gene allowed it to enjoy a monopoly over human DNA that is fundamental to research, medicine, and the health and well-being of patients at high risk for breast and ovarian cancer.

It turned out that adding actual patients as plaintiffs was one of the most controversial aspects of the case. According to Chris Hansen, the Patent Bar and some of the courts were "astonishingly offended at the idea that women had a legal interest in whether these patents existed or not" (Hansen). What these entities failed to understand is that access to the gene was

more than a legal argument; it was a matter of life and death to those who carried mutations in *BRCA* genes. With Myriad's monopoly, the only place women could get tested was through Myriad's laboratory. Patients had to trust Myriad's test results, they had to assume Myriad was testing properly, they could not get a second opinion, and the cost (that may or may not be covered by insurance) put the test out of financial reach to many women. Given the limited information and options with this life-threatening disease, the ACLU found the notion that women would *not* have an interest in whether this was proper public policy or not "bizarre" (Hansen).

In order to recruit individual patient plaintiffs, the ACLU tapped into the resources of its Women's Rights Project. The focus on the *BRCA1* and *2* patents tied into the Women's Rights Project through its "shared interests in rights to women's health, rights to bodily integrity, the notion of human dignity, and promoting the progress of science" (Park). Sandra Park, its Director, took the lead in recruiting and identifying individual women plaintiffs. Patients' voices were vital in explaining how deeply personal patents could be in their lives. Park appreciated that this case was decided in the Supreme Court rather than by patent law experts because it allowed for these voices to be heard (Park, JOLT Symposium). In order to get in touch with women with an interest in *BRCA* testing, the Park and the Women's Rights Project worked through FORCE (Facing Our Risk of Cancer Empowered), a national nonprofit organization devoted to improving the lives of patients and families affected by hereditary breast and ovarian cancer. At first, FORCE was concerned that a successful outcome for the ACLU in its case against Myriad could result in a proliferation of *BRCA* gene tests on the market, and women would be confused as to which tests were accurate. However, FORCE agreed to post a request on its list serve

asking women who had experience undergoing *BRCA* gene testing to contact the ACLU (Simoncelli).

The ACLU aimed for a variety of personal history stories, including women concerned they did not receive an accurate test result due to "variants of uncertain significance," women who wanted a second opinion to determine if anyone had more information about their particular variant, and women who wanted to get tested and could not afford the high price for the test (Park). The ACLU knew that the women plaintiffs' legal standing was tenuous, but felt that it was imperative to get these stories out because it is principally women whose lives are affected by this disease. These are the women who, with a family history of breast or ovarian cancer, live in fear of a positive test for a BRCA gene mutation, knowing that a positive test means they will have up to an 87% chance of developing breast cancer in their lifetime and up to a 44% chance of developing ovarian cancer (Ford). These are the "previvors" and survivors who need access to accurate and affordable testing to empower them to take control over their destinies should they receive a positive test. Rather than wait to be cancer victims, these women have options of increased surveillance with mammograms, MRIs, and ultrasounds; chemotherapy drugs; or prophylactic bilateral mastectomies and oophorectomies (FORCE). The case had far reaching consequences for these women.

The women's personal stories were compelling. One of the plaintiffs, Lisbeth Ceriani, was a single mother diagnosed with bilateral stage IIA breast cancer at age 42. Ceriani's health insurance, Mass Health, would cover the cost of *BRCA* genetic testing provided a contracted provider performed the test. Myriad Genetics, the only lab in the country authorized to conduct *BRCA* testing, refused to agree to a contract with Mass Health because the proposed reimbursement was too low. Ceriani was forced to save for eighteen months and pay out of her

own pocket to undergo *BRCA* testing, all the while coping with the uncertainty of her future health. She learned that she did, in fact, carry a mutation (ACLU plaintiff statements).

Another plaintiff, an Asian-American woman named Runi Limary, was diagnosed with an aggressive form of breast cancer at age 28. Her doctor recommended *BRCA* testing to determine if she was at risk for ovarian cancer and/or a second occurrence of breast cancer. Her results from Myriad came back indicating her *BRCA* gene had a "variant of unknown significance." This ambiguous result is reported disproportionately in minority women. Limary, at 28 and with no children yet, struggled with reaching a decision as to whether or not to have her ovaries removed prophylactically. She wanted a second opinion in hopes of improving her understanding of the ambiguous result before undergoing such a life-changing surgery. Limary was unable to obtain a second opinion because Myriad had a monopoly on the testing (ACLU plaintiff statements).

Another woman, Genae Girard, had a double mastectomy after being diagnosed with breast cancer at age 36. She tested positive for a mutation, but she wanted to have these results validated with a second opinion before having her ovaries removed. She, like Runi Limary, was unable to confirm the results with a second opinion since Myriad exclusively conducted the testing (ACLU plaintiff statements).

Two other women plaintiffs, Kathleen Raker and Vicky Thomason, both tested negative with BRACAnaylsis®, but were informed they needed to pay Myriad $700 upfront for additional BART® testing. Kathleen Raker's mother died from breast cancer at the age of 28 and her maternal grandmother died from breast cancer at 52. She worried about having a genetic predisposition for cancer, but could not afford further testing. Vicky Thomason was diagnosed

with ovarian cancer and wanted to make a decision about prophylactic treatment if she was predisposed to cancer, yet the cost of the additional testing was beyond her means (ACLU plaintiff statements). The ACLU's inclusion of these individual women as plaintiffs was purposefully designed to illustrate the fact that these patents were a life and death matter to real people.

Our Bodies Ourselves (OBOS) was one of two advocacy groups, along with Breast Cancer Action, that became a plaintiff in the suit. Our Bodies Ourselves is also known as the Boston Women's Health Book Collective and is listed as such on the record of official plaintiffs. Lori Andrews, a strong and vocal opponent of gene patenting from Chicago Kent Law School, recruited OBOS, and OBOS, in turn, recommended Breast Cancer Action (Norsigian). OBOS, while not specifically a breast cancer advocacy group, deals with women's health in general. OBOS provides information to its constituents on many issues, including breast cancer, and is committed to providing women with the tools for informed decision making. One of its missions is "to advocate for women's health by challenging institutions and systems that block women from full control over their bodies" (Our Bodies Ourselves). The organization debated in the beginning if it would legally have standing in the case, but ultimately believed it would (Norsigian, Harvard STS).

Judy Norsigian, the Executive Director and one of the founders of OBOS, outlined at the Harvard Science, Technology, and Society symposium in November 2013 the reasons why her organization became involved in the case against Myriad. OBOS leaders believed that Myriad's patents on the *BRCA* genes impeded women's control over their own healthcare by restricting access to information necessary to make healthcare decisions. The high cost of the Myriad BRACAnalysis® test troubled OBOS and the organization was aware of geneticists who could

perform testing for substantially less; however, these geneticists did not have the legal resources to engage in a lawsuit after receiving cease-and-desist letters. Women's inability to obtain second opinions also concerned the leaders of OBOS, and with that, the possibility of poor personal medical decisions based on lack of knowledge. OBOS also contended that gene patenting undermined research. In particular, the lack of data sharing and analysis was a cause for concern. To OBOS, it did not make sense for Myriad to have the sole right to use or not use the information to better understand breast and ovarian cancer genetics. In addition, OBOS was bothered by the limited information on breast cancer susceptibility for underserved populations. African Americans, Latinos, and Asian American women were disproportionately likely to receive ambiguous results with Myriad testing, yet these women had nowhere to go for a second opinion to clarify ambiguous results. It was clear to OBOS that the protection afforded by these gene patents was negatively affecting women's health (Norsigian, Harvard STS).

Norsigian knew of women who lived in Boston and flew to Europe to be tested with a more accurate analysis for less than it cost them to be tested at home. Others did the same, not for cost savings, but for a second opinion. The economics had become skewed because European health care systems, operating within the fixed budgets of universal health care coverage, found themselves similarly in a bind with respect to the cost of Myriad testing. These countries could not afford to offer testing for all women at risk. In May of 2004, the European Patent Office revoked Myriad's patents after ruling that, while Myriad had figured out the key genes involved with a higher risk of breast and ovarian cancer, it had done nothing to meet the "inventiveness" standard required of a patent. The company had simply discovered something that already exists in nature. Faced with a similar health care dilemma, the Canadian government announced that the province of Ontario would simply ignore the Myriad patents and

conduct its own *BRCA* testing at publicly funded labs. With this alternative testing, Canadians received BRCA test results much sooner than they did with Myriad, and at one third the cost. Acting on Myriad's behalf, the U.S. Ambassador to Canada responded by threatening trade sanctions. All of these reasons convinced Our Bodies Ourselves of the validity of the case and the organization's leaders wrote opinion pieces to generate interest among the public in this lawsuit (Norsigian, Harvard STS).

Dr. Wendy Chung, M.D., Ph.D., a clinical and molecular geneticist and director of Clinical Genetics at Columbia University, enthusiastically joined the case as a plaintiff (Simoncelli). Chung believes that gene patenting compromises both access to and quality of care that patients receive. Since Myriad Genetics had exclusive rights for *BRCA* genetic testing, the lack of competition stifled opportunities for improvements in both the test and in its data interpretation. Chung also expressed dissatisfaction with Myriad's unnecessarily slow turnaround time for testing. In addition, exclusivity allowed Myriad to charge excessively high prices that often put testing out of reach of many women. From the time Myriad developed the test in 1996 through 2003, many insurers did not cover *BRCA* testing, or the lengthy preauthorization processes discouraged patients from pursuing coverage. Some of Dr. Chung's patients died during the preauthorization process, leaving family members with no genetic information to guide the future care of other relatives. Medicare did not cover the cost of testing until 2003. Medicaid did not begin to cover the cost until 2005, and at the time the case went to the Supreme Court, Medicaid still did not cover the cost in many states (ACLU plaintiff statements).

Dr. Harry Ostrer, a Professor of Pediatrics, Pathology and Genetics at the Albert Einstein College of Medicine of Yeshiva University and Montefiore is another medical researcher who

joined the case as a plaintiff. He formerly served as Professor of Pediatrics, Pathology, and Medicine and Director of the Human Genetics Program at New York University School of Medicine. Dr. Ostrer oversaw the genetic risk assessment program at NYU Langone Medical Center (NYULMC) as well as New York's Bellevue Hospital. When Tania Simoncelli first approached Dr. Ostrer about becoming involved in the case, he indicated he was not interested. However, something Simoncelli said persuaded him, and he mulled the decision over in his mind for several weeks before contacting her again. He was convinced "gene patents were stifling innovation" (Simoncelli). There had been no innovation, for example, in breast cancer genetic testing in the previous five years since Myriad Genetics had introduced its most recent test. Gene patents presented significant hurdles to Ostrer's work and many of his high-risk patients at Bellevue Hospital could not afford BRACAnalysis®. He also noted that frequent test results of "variants of unknown significance" were confusing to both patients and physicians, leaving them unsure as to whether or not they were at increased risk of developing cancer. At one point Dr. Ostrer suggested a collaborative study with Myriad to help clear the confusion on "variants of unknown significance," but Myriad was not open to collaboration (ACLU plaintiff statements).

Dr. Arupa Ganguly, a geneticist and clinical pathologist, was the Co-Director of the Genetic Diagnostic Laboratory at the University of Pennsylvania and joined the lawsuit because the legalities of patents block critical research. She had been offering breast cancer susceptibility testing with a different and less expensive test than Myriad's test. Her clinic did not charge Myriad's rates in part because health insurance would not reimburse at those rates. Myriad aggressively enforced its patents to create exclusivity, and Dr. Ganguly and the University of Pennsylvania's Genetic Diagnostic Laboratory received a threatening cease-and-desist letter from Myriad on the basis of patent infringement (ACLU plaintiff statements). This essentially

forced Dr. Ganguly to change the entire direction of her research and she is no longer involved in breast cancer research. Her negative experiences dampened her desire to develop other genetic tests for fear of infringing on patents, ultimately taking its toll on patients. Her case is a prime example of the chilling effects of patents (Simoncelli).

In the end, the court granted standing to only one plaintiff, Dr. Ostrer, of the twenty plaintiffs initially listed. In law, a party must have sufficient legal interest in the dispute and demonstrate harm from the law or action challenged. The court requires standing so it can be confident that the dispute will be argued adequately on both sides. The standing requirement prevents citizens from filing frivolous lawsuits. The court found that most of the plaintiffs did not have standing because Myriad had never threatened them with a lawsuit, or they had not indicated their actions would change if the Court found in their favor. The court believed the idea of having breast cancer survivors as plaintiffs was absurd (Hansen). Even though Myriad had clearly threatened to sue Dr. Ganguly, she was not granted standing because she could not honestly say she would resume *BRCA* testing if the courts dissolved Myriad's patents. Dr. Ganguly had already changed directions and her lab was no longer set up for *BRCA* research. On the other hand, when the court posed this question to Dr. Ostrer, he stated he *would* resume his research and testing on *BRCA* genes (Simoncelli).

The ACLU knew it faced an uphill battle with legal standing for its plaintiffs because standing was more restrictive in the context of patents, but it deliberately approached this case like a civil rights case and not as a patent case. According to Hansen, if this had been a First, Fourth, or Fourteenth Amendment case or a Title VI case (one of the federal civil rights statutes), then all of the ACLU's clients would have been granted standing. When the ACLU first filed the case, many patent bloggers from the Patent Bar predicted it would lose on standing and the court

would never get to the merits of the issue. Even though the Supreme Court decided several years before that standing rules in patent cases should be the same as standing rules in other cases (for example, First Amendment cases), the Federal Circuit did not follow this ruling. Hansen believes the Federal Circuit Court would have liked to have thrown out the ACLU's only plaintiff who was found to have standing, but the court was more interested in defeating them on the merits of the case. He maintains, "They were so eager to express their view that patents were patentable that they bent their own, even more restrictive standing rules in order to rule against us on merit" (Hansen).

VI. Federal District Court of the Southern District of New York

The ACLU filed the case in the Federal District Court of the Southern District of New York. Judge Robert W. Sweet was appointed to be a District Court Judge in 1978 and was the judge assigned to the case. By coincidence, Judge Sweet's law clerk, Herman Yue, received his Ph.D. in Molecular Biology from Berkeley. Yue was a geneticist as well as a lawyer so he understood the implications of the science and turned out to be invaluable to Judge Sweet. Yue had even once applied for a patent himself. Judge Sweet confirmed that the case was assigned to him on a completely random basis, based upon a computer algorithm (Sweet).

In March 2010, Judge Sweet and the U.S. District Court struck down Myriad's patents on *BRCA* genes. Judge Sweet, in his opinion, declared "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body, nor the information it encodes. Therefore, the patents at issue directed to 'isolated DNA' containing sequences found

in nature are unsustainable as a matter of law and are deemed unpatentable under 35 U.S.C.§101" (S.D.N.Y. March 29, 2010 District Court Opinion).

Judge Sweet later declared that this case was one of the most challenging and meaningful cases he has heard; he believed from the beginning there was a real possibility the case would make it to the Supreme Court. Judge Sweet attended the Supreme Court proceedings and was very pleased with the outcome of the case. He thought that the underlying issue, although he did not deal with it in his opinion, was how best to advance scientific knowledge. "Does scientific knowledge advance best through a process such as patenting or does it advance best through the free exchange of information?" Judge Sweet also used the case to overturn the legal doctrine established in the 1911 decision of *Parke-Davis v Mulford*, in which Judge Learned Hand allowed the patenting of biological substances isolated from nature (Sweet).

When the ACLU filed the case in district court, it sued both Myriad and the U.S. government. Chris Hansen felt that at some level, it was not fair to just sue Myriad. Myriad had applied for and been granted a patent by the federal government; therefore, Myriad was simply exercising the authority the federal government had given it. The ACLU did not realize how unusual it was to sue the government to invalidate a federal patent. In fact, no one had ever done it. From the perspective of a civil rights lawyer, it seemed perfectly logical to sue the governmental entity charged with a wrong. However, that is not the way patent law has customarily been adjudicated in court. This brought controversy and caused ripples in the Patent Bar. A patent blogger actually called for the ACLU legal team to be disbarred for filing such a frivolous case. Ultimately, the District Court dismissed the USPTO, not because it was wrongly sued but because it was unnecessary to the case. The court did not need the involvement of the patent office for it to invalidate these patents (Hansen).

VII. Federal Circuit Appeals Court

All patent case appeals must go to the Court of Appeals for the Federal Circuit, established by Congress in 1982. The theory is that patent law is too complicated for those without a scientific background so the government established a specialized court with judges who can understand the science. However, the District Court with Judge Sweet and his geneticist law clerk appear to have understood the issues at least as well, if not better than the Court of Appeals did. As expected, Myriad appealed the case to the Federal Circuit Court (Hansen).

In July 2011, the United States Court of Appeals for the Federal Circuit upheld Myriad's patents, declaring that human genes are, in fact, patentable. Judge Alan Lourie wrote in his majority opinion, "The isolated DNA molecules before us are not found in nature. They are obtained in the laboratory and are man-made, the product of human ingenuity" (*Association for Molecular Pathology v. U.S. Patent & Trademark Office*, *653 F. 3d 1329 Fed. Cir.2011).* The ACLU expected to lose the case in Federal Circuit Court because of the long entrenched pro-patent stance of the court. It lost 2-1. Chris Hansen, however, points out that in his eyes they actually lost 1.51 – 1.49. Judge William Bryson ruled for ACLU on the central issue of the case - the patentability of human genes, on the basis that "the genetic coding material …is the same, structurally and functionally, in both the native (BRCA) gene and the isolated form of the gene" *(Association for Molecular Pathology V. U.S. Patent & Trademark Office, 653 F. 3d 1329 Fed. Cir.2011).* Judge Lourie, a prior chemist put on the court because of his expertise, ruled against ACLU on the patentability of human genes. Hansen paraphrases Judge Lourie's comments, "The question of whether human genes are patentable or not is purely a question of chemistry. Biology is irrelevant" (Hansen). Chris Hansen believes the absurdity of

that statement actually helped ACLU when the case was heard before the Supreme Court because it illustrated how one can become caught up and trapped in his or her own expertise. The first question Judge Lourie asked during oral argument was, "Isn't it true that when a gene is isolated, you break a covalent bond?" Chris Hansen related this story at the November 2013 Science, Technology, and Society symposium at Harvard University. At that point, Hansen maintained that he had learned a fair amount of genetics over the three years that the ACLU was putting the case together, but he had no idea what a covalent bond was. He conceded he "bluffed his way through it." The opinion of the third judge in the Federal Circuit Court, Judge Kimberly Moore, was the reason Hansen professes that ACLU actually lost 1.51 – 1.49. This judge indicated that she did *not* regard human genes as patentable, but since the USPTO had been allowing gene patenting for over twenty years, she was going to "let it slide." Judge Moore preferred to remain with the status quo due to the huge investments by the biotechnology industry that rested on patents. Hansen was so incensed by Moore's comment that he jokingly told his colleagues that he wanted to include in his brief, "Well, we had racially segregated schools for forty years and we didn't just let that slide!" (Hansen)

The ACLU lost on the issue of including the federal government as part of the lawsuit when the District Court severed the USPTO from the case. It did not matter in the District Court because Judge Sweet invalidated the patents and the court did not need the patent office to be a part of the lawsuit. The ACLU was then faced with another decision that could make or break the entire initiative – should the ACLU appeal the decision to dismiss the federal government from the case? The ACLU decided not to cross appeal. This worked to the ACLU's favor shortly after that when the U.S. government switched sides between the time the case left the District Court and went to the Court of Appeals. When the case got to the Federal Circuit Court,

the Solicitor General, the federal government's highest ranking litigator, indicated that the U.S. government's position was that genes should not be patentable. Chris Hansen speculates that Francis Collins, the head of the National Institutes of Health (NIH) may have played a substantial role in turning around the government's position. Francis Collins had been publicly opposed to gene patents for years. Undeterred, however, the USPTO continued to issue patents on human genes and made it known that it disagreed with the federal government's position (Hansen).

Despite the fact that the government switched sides for the case in the Federal Circuit Court, the court upheld Myriad's patent claims on DNA molecules. The ACLU decided to appeal to the United States Supreme Court. The Supreme Court vacated the Court of Appeals' finding in March 2012, and remanded the case back to the Federal Circuit, instructing the Court of Appeals to reconsider the ruling taking into account the *Mayo Collaborative Services v. Prometheus Laboratories* decision that the Supreme Court had announced the prior week. In Mayo, the Supreme Court unanimously struck down a medical diagnostics patent covering the relationship between drug dosing and levels of specific metabolites in the blood. Justice Stephen Breyer, in speaking for the Court, held that the relationship between drug doses and metabolites was "not patentable because it constituted a law of nature" (*Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 566 U.S_132 S. Ct. 1289 2012). When the Court of Appeals reconsidered the Myriad case in light of Mayo, the same three judges on August 16, 2012 once again ruled 2-1 upholding Myriad's claims on DNA molecules, stating that isolated DNA is, in fact, patentable. (The court also unanimously upheld one method claim on using *BRCA* assays in discovering drugs to treat cancer and invalidated five broad method claims for detecting mutations in *BRCA* genes).

VIII. United States Supreme Court

By the time the Myriad case wound its way to the Supreme Court, many predicted the ACLU might win; however, this was not always the case. Early on, most researchers and medical geneticists predicted the ACLU would not stand a chance of winning such a case. A majority of legal scholars were supportive in the sense that they agreed that gene patenting was a relevant issue and that patents on human genes were wrong as a matter of law and policy. However, these same scholars believed the chances of winning a legal challenge in this arena were infinitesimal (Hansen). The United States Patent and Trademark Office (USPTO) had been issuing gene patents since the late 1970s, the biotech industry had grown up around this practice, and the Patent Bar was committed to maintaining the status quo. Several had tried and failed to challenge this policy through a formal comment process with the USPTO back in the early 2000s, when patent examination guidelines for utility and for written description were being revised. Legislation to end gene patenting had been introduced and gone nowhere. Medical researchers had dealt with the headaches of gene patents for so long that they assumed gene patenting was too entrenched to change (Simoncelli). Hansen was undeterred with the naysayers and negativity because he maintained all along that gene patenting was wrong. Simoncelli and Hansen did discuss whether or not they were going to actually make the law worse if they lost the case, but decided the risk was minimal because the law could not get much worse. They were passionate about taking the case on to challenge gene patenting (Simoncelli). It was fortunate that the ACLU remained steadfast in its commitment because there were not many organizations that could have developed the case the way the ACLU did.

Simoncelli herself initially thought the odds of winning the case were under fifty percent, although Hansen was more optimistic. Simoncelli envisioned they would more than likely lose due to long-standing deference to the USPTO; there was a precedent of more than twenty years of allowing these patents. Nevertheless, in Simoncelli's mind, "even if they lost the case, they could win." Despite the uphill battle they faced, she felt it was essential to bring the issue of gene patenting to the forefront (Simoncelli).

The Supreme Court accepts approximately one percent of the cases before it, but the ACLU anticipated that it was likely it would hear this case. The case had appeal because it dealt with breast cancer and the human body. When drafting the "question presented" to go before the Supreme Court, the ACLU made a deliberate choice to simplify the question down to four words. According to Chris Hansen, typical questions go along the lines of, "Given the position of the Federal Circuit in Smith V. Jones, in the absence of…, and the alternatives of…" Lawyers typically want to spin the question presented. The ACLU elected to present one of the shortest questions ever presented: "Are human genes patentable?" Four words! Hansen and Simonceilli strategically simplified the question because intuitively they felt that if the Supreme Court thought about the case the way Tania Simoncelli first presented it to Hansen, they would ultimately prevail. They wanted the Supreme Court to consider the case from a common sense point of view rather than strictly from the viewpoint of patent law or genetics (Hansen).

The ACLU petitioned for certiorari on the standing issue when the case went to the Supreme Court, but that part of its petition was not granted. The organization decided to add the standing question for political reasons. Hansen had been offended that the lower court had not granted the plaintiffs standing, and contended that it was contrary to the Supreme Court's decision several years ago on standing in patent cases. In addition, he did not want the case to be

called Ostrer v. Myriad. He vowed to take the case to the Supreme Court with every single plaintiff still attached to it. If they had petitioned for certiorari without the standing question, then they likely would have had to re-title the case and Hansen was not willing to do that. There was important symbolism in making sure the Supreme Court knew who all the plaintiffs were, even if only one of them had been granted standing (Hansen).

By the time of the oral arguments, Chris Hansen had retired from the ACLU and Tania Simoncelli had left the ACLU to take a position with the FDA. Hansen came back out of retirement and Simoncelli took a leave of absence from her job to prepare for the Supreme Court case (Hansen and Simoncelli). Hansen had been approached by many lawyers offering to take over the oral arguments for him, but there was no way he was going to give up presenting the oral argument (Hansen).

The team invested a great deal of time on the briefs. Hansen is a firm believer that the brief should be a coherent narrative and sound like it is authored by one voice. He spent most of the time explaining genetics and what a gene was and how isolating a gene does not turn it into something else. His team also resurrected all the metaphors that they used in the lower courts and these turned out to be central to the case. Hansen's favorite metaphor related genes to gold. He declared, "If you take gold out of a mountain or stream, it is still gold. You have not transformed it. It is true that once you take it out of the mountain, you can use it in jewelry, so there is a new potential use for the gold. And it is true that inside the mountain gold does something different from what it does outside the mountain. Inside the mountain, it is helping to hold up the mountain; however, that doesn't make it patentable." The only problem with this metaphor is that gold is not a part of the body. When brainstorming human body metaphors, the team settled on a kidney. Hansen stressed, "Isolating DNA is no different from isolating a

kidney and no one would suggest that isolating a kidney was patentable. It is true that you can take it out of the body and put it in someone else's. It has a new use and it is also severed from the rest of the body (just as a gene is severed from the chromosome)." Hanson conceded that when he used the kidney metaphor in the Federal Circuit Court, one of the judges exclaimed, "Of course, a kidney is not patentable; it's an organ, not a gene!" Hansen never understood what he meant by that (Hansen STS).

Hansen went first during the oral arguments for the Supreme Court because the ACLU had lost the case in the Federal Circuit Court. The justices did not ask questions that he had not anticipated and it went relatively well. Hansen maintains the most interesting part was his opponent's response when Justice Kagan asked, "I understand that you believe a gene is patentable, is that correct?" Gregory Castanias, the lead attorney representing Myriad Genetics replied, "Yes." Justice Kagan then inquired, "Well is an entire chromosome patentable?" Castanias responded, "Well, that presents a different question. It may violate other aspects of the patent law, and, for example, you would have to consider…" Justice Kagan cut him off. "You are not answering my question." (He was violating the tenet that the first answer when asked a "yes/no" question by a judge, especially a Supreme Court Justice, is a "yes" or "no"). Finally, when pressed enough, the attorney asserted, "Yes, a chromosome is patentable." "So," Justice Kagan inquired, "is a kidney patentable?" He stammered, "Well, that depends on a lot of issues of patent law….," and she cut him off as he tried to duck the question. Finally, he shot back, "Yes, a kidney is patentable!" At that moment, Hansen sensed victory (Hansen STS).

The case was decided 9 - 0 in their favor, a unanimous decision. Justice Clarence Thomas, in writing for the court, noted, "A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated. It is an undisputed fact that

Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 gene. Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the criteria for patent eligibility" (*Association for Molecular Pathology et al v. Myriad Genetics, Inc. et al, No. 12-398, U.S. 2013).*

During the oral arguments, protesters gathered outside the Supreme Court to demonstrate their opposition to gene patenting, holding signs, "Your corporate greed is killing my friends" and "My genes are not your property." This case resonated strongly with the public as it had implications for the lives of millions of women. Breast cancer is an emotional topic and many individuals were gripped by the potential outcome of the case. The actress Angelina Jolie brought additional national attention to *BRCA* genes and the breast cancer cause when, during the Supreme Court case, she publicly announced in a May 14, 2013 op-ed piece in the *New York Times* that she had undergone a prophylactic double mastectomy after learning that she had tested positive for a *BRCA* mutation. Her editorial also brought attention to the fact that the cost of the *BRCA* test remained an obstacle for many women (Jolie 2013). The ACLU had declared all along that this was a case about civil rights and a case about real women; the outpouring of public interest in the case substantiated this.

Looking back, Chris Hansen related a few interesting points about the Supreme Court decision in Harvard's 2013 Science, Technology, and Society (STS) symposium. First, "it was not the Supreme Court's best work." (Hansen). Although the ACLU won the case with a unanimous decision, the decision does not give enough guidance to the lower courts about when something is or is not patentable. In previous decisions, the Supreme Court has given better guidance. Hansen noted that the Justices may have believed it was "patently obvious," so they did not need to define clear rules. Second, the Supreme Court declared that cDNA is patentable.

He suspects the ACLU won on genomic DNA (that is not patentable) because it seemed self-evident. He concedes they may have lost on cDNA (the Court determined that it is patent eligible) in part because both the government and Dr. Eric Lander from Harvard submitted briefs stating cDNA should be patentable, and that hurt their case. He emphasizes, "It is too soon to know how much the cDNA issue will matter as other patent law doctrines could well knock out the patentability of cDNA." Many scientists maintain there is a way to get around cDNA claims. According to Hanson, "It could be a harmless loss" (Hansen).

IX. Why did the ACLU prevail?

Hansen and Simoncelli are extremely proud of the fact that even though most predicted they would never succeed in a gene patenting case, they not only took this case all the way to the U.S. Supreme Court, but won decisively 9-0. Working with scientists is challenging for lawyers as most lawyers, according to Hansen, are not comfortable discussing science. It seemed incomprehensible to Hansen when he started this case that he would ever understand any part of genetics (Hansen), but he dedicated himself to learning all he could and became quite competent (Simoncelli). It was an incredibly rewarding experience for both Hansen and Simoncelli who were passionate about this case because it mattered to so many people. Their strength was in building a coalition because bringing a case like this to the Supreme Court is a collective effort, not the work of one person. Including diverse perspectives made their argument stronger (Hansen and Simoncelli).

Simoncelli and Hansen feel that ultimately they were able to reverse over twenty years of patent law precedent because they framed this case so broadly. At the heart of this case was a

relatively straightforward legal question: is isolated DNA patent-eligible under section 101 of the Patent Act? They intentionally did not limit their arguments strictly to this sphere. They sought to include a range of arguments as to the impacts that gene patents were having on research, data sharing, clinical practice, patient experience, and access to care. They viewed litigation as a vehicle for bringing to the forefront a comprehensive understanding of how improperly issued patents can actually harm people and stand in the way of innovation. The coalition of experts and plaintiffs that they assembled for the case reflected this broad framing. The plaintiffs included not only the geneticists who received cease-and-desist letters from Myriad Genetics, but genetic counselors who would have liked to provide their patients with more and better testing options, as well as individual women who were unable to access testing or were interested in a second opinion. They sought and obtained declarations not only from geneticists who could explain what was meant by isolating DNA, but also, for example, from Dr. Mary-Claire King from the University of Washington who originally demonstrated the existence of *BRCA1* by discovering linkage between markers on chromosome 17 and risk of breast cancer in 1990 (Simoncelli). Dr. King later described the high incidence of false negative results (12%) that were the result of Myriad's refusal to update its test for a period of several years (Walsh). An STS scholar provided a detailed account of the history of the discovery of the BRCA genes to make clear that Myriad did not deserve credit as the sole discoverer of these genes (Simoncelli). The Nobel Prize winning economist, Joseph Stiglitz, described gene patents as a classic example of how the social cost of patenting that arises from the restrictions of the use of knowledge and the granting of monopoly power can outweigh any benefits that arise from public disclosure. Stiglitz argued, "These are patents on basic scientific knowledge- the very instructions inside each of our cells that determine what proteins are produced…In the case of a genetic sequence,

one cannot build upon the knowledge without having 'access' to the genetic sequence" (Sticklitz, Declaration to U.S. District Court for the Southern District of New York).

The U.S. Supreme Court opinion actually said nothing about the broader implications of public gene patents, research, access to testing, or patient care. However, Simoncelli argues that the case would never have made it to the Supreme Court if ACLU had not framed the issue as broadly as it did. The stage was set for the case in the U.S. District Court, and Judge Sweet described in his opinion the full range of public health concerns with regard to gene patenting. Also, because the ACLU framed the case broadly, it attracted an even wider range of stakeholders who joined as amici in the case. The amici included such diverse groups as medical associations and patient advocacy groups, environmental organizations, religious groups, and even some genetic diagnostic companies who chose to break away from the biotech industry's line on the issue. Simoncelli suspects that the broad framing of the case may have also influenced the U.S. government's decision to engage agencies other than the USPTO in its internal deliberations that resulted in the government switching sides in the case. The government changing sides was a pivotal moment in the case. The U.S. government's brief in the Federal Circuit specifically noted that the issue before the court turned on questions that implicate the expertise and responsibilities of a wide range of federal components, including not only the USPTO, but also the National Institute of Health (NIH), the anti-trust division of the Department of Justice (DOJ), the Centers for Disease Control (CDC), the Office of Science and Technology Policy (OSTP), the National Economic Council, and others (Simoncelli).

Another reason the ACLU ultimately prevailed, according to Tania Simoncelli, is that the team was able to adequately explain the scientific principles in the case. They needed to figure out how to explain enough of the science to make clear why the claims it was challenging were

so fundamentally wrong. The plaintiffs had to explain in simple terms what a gene is; what DNA is; what isolated DNA is; why is it isolated; why is isolated DNA virtually the same structurally and functionally as DNA in the body; why a patent on isolated DNA is going to, in effect, be a patent on the DNA itself; what Myriad did and did not do; and why what Myriad did is not an invention. It was a balancing act to explain these core arguments without adding "fuel to Myriad's attempt to make it all seem so complicated that it should be viewed as beyond the court's ability to decide it" (Simoncelli). That balancing act required experts and plaintiffs who were clear communicators, who were teachers of science with sufficient patience to work with the ACLU on this. It also required a commitment of the scientists and attorneys to understand one another. The experts devoted an extraordinary amount of time to work through these issues (Simoncelli).

The law, timing, and luck were also reasons why the ACLU and the other plaintiffs prevailed, according to Simoncelli. The law was truly on their side and they had a small team of lawyers who made it clear to the court that Myriad, in fact, did not invent anything, and that DNA in its isolated form is just as much a product of nature as the DNA in our bodies. Timing was critical in the sense that science had outpaced policy at that point and the $1,000 genome was on the horizon. That made Myriad's charge of almost $4,000 for sequencing and interpreting just two genes seem exorbitantly expensive. A number of multi-gene tests were entering the market, and researchers had increasing concerns about patents interfering with the development of these tests. Lastly, luck played a key role in that the ACLU filed the case in the Southern District of New York and randomly drew Judge Sweet who happened to have a clerk with a Ph.D. in molecular biology. The odds of drawing a judge who happened to have a law clerk with a scientific background in this field were extremely low. Judge Sweet took a keen

interest in the case and wrote a scientifically accurate and well-reasoned 153 page opinion, setting the stage for the ACLU's argument in the best possible way. This played a significant role in the outcome of the case (Simoncelli) and Judge Sweet later sat in the front row to watch the Supreme Court proceedings (Sweet).

Eight years elapsed between the time Simoncelli first brought up gene patenting with Hanson and the ruling by the Supreme Court. It was an enormous financial and emotional investment by scores of people. That investment led to several important legacies, perhaps none more important than raising the consciousness of the public as to the importance of the life sciences and the field of genetics in our everyday lives. The ACLU's ability to humanize the gene patenting issue took the debate out of the scientific arena and put it squarely into the public arena. The ACLU maintained all along that this issue mattered to real people and that individual genes, our genetic heritage, should not be owned by a corporation. This campaign is a shining example of how the public can be engaged in the debate of a scientific issue, even without knowing much about the science behind the issue. The lawsuit reminded all that our civil liberties must be given equal priority as science continues to develop new and exciting capabilities. Finally, the case reminds us that there are avenues for addressing the thorny issues that accompany any exciting new discovery and that these avenues can work, even against the longest of odds.

Possible Future Interviews:

Justice Kagan, United States Supreme Court

Dr. Francis Collins, Director of the NIH

Dr. Eric Lander, Founding Director of the Broad Institute

Myriad Genetics lawyers Brian Poissant, Laura Corruzi, and Gregory Castanias

Chris Mason, Assistant Professor of Physiology and Biophysics at Weill Cornell Medical College (May 2, 2014)

Randal Rader, Chief Justice of the Court of Appeals for the Federal Circuit

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Additional background information came from personal interview with Jorge Contreras, Law Professor at American University College of Law, Washington D.C. (specializing in intellectual property.