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CAN PATENT PROTECTIONS TRAMPLE CIVIL LIBERTIES? THE ACLU CHALLENGES THE PATENTABILITY OF BREAST CANCER GENES

by ANN WEILBAECHER

A landmark lawsuit headed by the American Civil Liberties Union (ACLU) challenges the constitutionality and validity of patents on two human genes linked to inherited breast and ovarian cancer, BRCA1 and BRCA2.¹ According to the ACLU, gene patents “undermine the free exchange of information and scientific freedom, bodily integrity, and women’s health.”² The ACLU argues that the contested gene patents create a monopoly that illegally

limits women's health care options, interferes with diagnostic testing, and stifles research.³

The defendants argue that without intellectual property protection, companies will not make the necessary financial investments to validate genetic tests for diseases, which can cost millions of dollars.⁴ The defendants contend that "the patent system has worked exactly as it was designed to do" by rewarding the defendants' landmark discoveries and encouraging life-saving research.⁵

The ACLU's suit organized over 150,000 scientists, physicians, activists and cancer patients as plaintiffs in the District Court for the Southern District of New York.⁶ The defendants include the University of Utah Research Foundation, which owns the patents, Myriad Genetics, the exclusive licensee, and the U.S. Patent and Trademark Office (USPTO).⁷ If successful, this lawsuit could have widespread effects not only on the validity of the BRCA1 and BRCA2 patents, but also on gene patents in general.⁸

THE MYRIAD GENETICS CONTROVERSY

Approximately 12 percent of women develop breast cancer during their lives, and approximately 1.4 percent of women develop ovarian cancer.⁹ Women who carry inherited mutations on their BRCA1 and BRCA2 genes face a higher risk of breast cancer (from 40 to 85 percent) as well as a heightened risk of ovarian cancer (from 15 to 40 percent).¹⁰ Diagnostic tests can determine if a woman has a mutation on these genes, enabling her to take potentially life-saving preventative measures such as removing her breasts or ovaries.¹¹

Since the late 1990s, Myriad Genetics has held exclusive rights to the BRCA1 and BRCA2 gene patents and diagnostic tests.¹² Under current U.S. patent law, a gene patent owner has the exclusive right, for up to 20 years, to control the patented gene's use for research, diagnosis or treatment.¹³ The result is that Myriad Genetics is the only company that may legally conduct or authorize testing for the BRCA1 and BRCA2 genes.

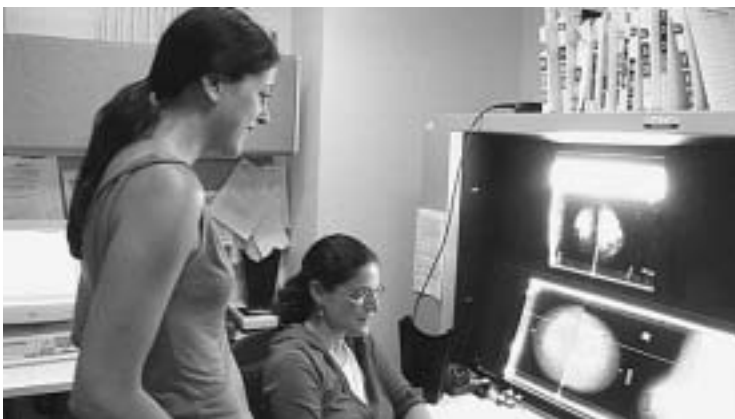
According to the defendants, the limited exclusivity offered by patents was the incentive that allowed the University of Utah and Myriad Genetics to develop these diagnostic tools that "[have] helped thousands of women . . . take steps to reduce their risk of breast and ovarian cancer."¹⁴

The ACLU, however, argues that this exclusivity has thwarted research and access to diagnostic testing.¹⁵ Because Myriad Genetics has chosen to enforce their licenses strictly, women who want to receive testing for these susceptibility genes must go through Myriad Genetics, which charges more than \$3,000 for the diagnostic test, known as the “BRACAnalysis”.¹⁶

Additionally, the ACLU contends that because of this monopoly women do not have the option of receiving a second opinion or of having another lab perform the tests.¹⁷ Further, women who do not have insurance, or whose insurance does not cover the test, do not have access to this potentially life-saving diagnostic tool.¹⁸

In Europe, numerous research institutes and genetics societies have filed notices of opposition to Myriad’s patents on the BRCA1 and BRCA2 genes.¹⁹ In Canada, the government’s policy is to let labs infringe on Myriad’s patents, thus allowing multiple labs to conduct the tests at lower prices.²⁰

In the United States, the controversy received public attention last year in an Emmy-nominated documentary called “In the Family.”²¹ In this documentary, filmmaker Joanna Rudnick chronicles her own experience of making a difficult decision when faced with a positive test result for inherited mutations on her BRCA genes: risk dramatically increased odds of developing cancer, or have her breasts and ovaries removed as preventive measures.²² Her film documents the struggles she and others facing a similar decision encounter and explores the detrimental effects of one company having a monopoly on the BRCA1 and BRCA2 genes.²³



*Image of Filmmaker, Joanna Rudnick (standing), while filming “In the Family.”*²⁴

According to Rudnick, “every film screening I have, someone inevitably will ask me the question, ‘How can you patent a gene? Isn’t that a product of nature?’ It’s been interesting to see how little awareness there is in the general public about the fact that gene patenting is taking place.”²⁵

She comments, “I was very hopeful when I heard that the ACLU was taking on not only Myriad Genetics but also the U.S. Patent Office, really challenging that gene patents are products of nature.”²⁶

THE ETHICS OF PATENTING GENETIC MATERIAL

The ACLU lawsuit reinvigorates the public debate about the ethics of patenting material so intimately connected to life. In a famous interview on April 12, 1955, journalist Edward R. Murrow, asked the inventor of the polio vaccine, Dr. Jonas Salk, “Who owns the patent on this vaccine?” to which Dr. Salk responded, “Well, the people, I would say. There is no patent. Can you patent the sun?”²⁷

In a controversial New York Times opinion piece written in 2007, Michael Crichton, popular sci-fi writer and creator of television drama “ER,” decried the perils of patenting genes, claiming, “YOU, or someone you love, may die because of a gene patent.”²⁸ “Gene patents are now used to halt research, prevent medical testing and keep vital information from you and your doctor,” he asserted.²⁹

According to Jordan Paradise, Associate Professor at Seton Hall University School of Law, “the ACLU lawsuit is fundamentally asking, is this something that is patenting human life?”³⁰ She elaborates, “on the one extreme, there are people saying, you are patenting people and that’s akin to slavery.”³¹ She explains, however, that the moral and ethical arguments are not just about patenting the human body but whether these patents are driving up the cost of health care and whether people might not have access to certain information about themselves.³²

Proponents of gene patents, such as the Biotechnology Industry Organization (BIO), contend that restricting gene patents “would do far more harm than good to patients” because patenting and exclusive licensing practices are critical to fostering the development of important genetic tests.³³ BIO maintains that

gene patents also “create incentives to promote physician and patient education, broader insurance coverage, and improved compliance.”³⁴

THE ACLU LAWSUIT

The ACLU seeks nothing less than to invalidate all gene patents.³⁵ Dan Ravicher, the Executive Director of the Public Patent Foundation, states that it “is absolutely our intent that upon victory this will render invalid patents on many other genes. We just had to pick one case as our case.”³⁶

Dr. Alice Martin, a geneticist and patent lawyer in Chicago, expresses concern that the ACLU is trying to eliminate gene patents in general, rather than simply targeting the poor licensing practices of one company, Myriad Genetics.³⁷ “Don’t knock out the whole patent system because Myriad didn’t handle this properly,” she says.³⁸

The lawsuit claims that patents on the BRCA1 and BRCA2 genes and diagnostic tests are unconstitutional and invalid, violating legal principles that prohibit patents on products of nature.³⁹ “The foundational issue of being able to patent genetic sequences is really in direct conflict with over 150 years of Supreme Court precedent,” asserts Paradise.⁴⁰

Indeed, since 1852, the U.S. Supreme Court has found that laws of nature, products of nature, and abstract ideas are not patentable subject matter.⁴¹ Natural discoveries must remain “free to all men and reserved exclusively to none.”⁴²

However, the USPTO has granted gene patents since 1982.⁴³ A 2005 study published in *Science* found that around 20 percent of human genes are currently patented, corresponding to 4,382 of the 23,688 genes listed in the National Center for Biotechnology Information’s gene database.⁴⁴

While the USPTO has concluded that naturally occurring genes found in the body are not patentable, genetic sequences that have been “isolated and purified” are.⁴⁵ The USPTO’s rationale is twofold: (1) “the DNA molecule does not occur in that isolated form in nature;”⁴⁶ and (2) the purified state of synthetic DNA preparations “is different from the naturally occurring compound.”⁴⁷

According to patent law scholar and research fellow at New York University School of Law, Matthew Herder, the doctrine of isolation and purification goes back to a 1911 case, *Parke-Davis*.⁴⁸ In that case, Justice Learned Hand found that although adrenaline exists in the body, it does not exist in an isolated and purified form in a way that scientists can use.⁴⁹

The landmark Supreme Court case, *Diamond v. Chakrabarty*, further paved the way for living entities to be considered patentable subject matter.⁵⁰ In 1980, the Supreme Court, by a vote of 5-4, approved a patent on a genetically engineered bacterium that had been modified to dissolve oil spills.⁵¹ This was the first time a patent on a living organism was granted in the United States.⁵² The Court famously concluded that “anything under the sun that is made by man” is patentable.⁵³

Although the USPTO cites *Chakrabarty* and *Parke-Davis* as a rationale for allowing gene patents, neither of these cases deals with genetic sequences.⁵⁴ In fact, according to Paradise, no Supreme Court case has specifically addressed gene patents as patentable subject matter.⁵⁵

Scientists, advocates and scholars disagree whether the step of isolating and purifying a genetic sequence should be enough to constitute patentable subject matter.⁵⁶ According to the ACLU complaint, an “‘isolated and purified’ human gene performs the exact same function as a non-isolated and purified human gene in a person’s body.”⁵⁷

“This is simply not true,” asserts Martin.⁵⁸ “A gene acting outside the living state has a completely different function than in the body.”⁵⁹ Martin elaborates, “if I own the BCRA gene, I don’t own the gene in a human, because in a human, it is not isolated and purified, it is part of the circular DNA.”⁶⁰

In addition to genetic sequence claims, the ACLU is also challenging correlation claims, that is, patents on the process of correlating the presence of a mutated gene with an increased risk of a certain disease.⁶¹ The plaintiffs argue that the process of comparing the association between a particular genetic sequence and a disease should not be patentable because it involves laws of nature.⁶²

According to an amicus brief filed by the American Medical Association and four other medical organizations, “for a process [or correlation] claim that ap-

plies a law of nature to be patent eligible, it also must transform an article to a different state or thing, or use a particular machine.”⁶³ The amicus brief asserts, “Myriad’s correlation claims do not require a specific machine nor transform an article to a different state or thing.”⁶⁴

The validity of this “machine-or-transformation” test is currently before the Supreme Court in *Bilski v. Kappos*.⁶⁵ Although *Bilski* involves a process for hedging risk in commodities trading, the test might be applied to all process patents including genetic diagnostic processes.⁶⁶ According to Herder, the ACLU’s correlation claims thus could be impacted by the Supreme Court’s decision in *Bilski*.⁶⁷

GENE PATENTS VIOLATE THE FIRST AMENDMENT

In addition to challenging whether genes constitute patentable subject matter, the plaintiffs are the first to apply the First Amendment to a gene patent challenge.⁶⁸ The lawsuit claims that patents on the BRCA1 and BRCA2 genes limit research and the free flow of information, violating the First Amendment.⁶⁹ The plaintiffs argue that “providing a private company a monopoly that has the effect of inhibiting, even completely preventing scientific inquiry, into a field of knowledge is not permissible under the First Amendment.”⁷⁰

“We should care a lot about scientists’ ability to disseminate their knowledge,” asserts Herder.⁷¹ “People are raising concerns about whether the percentage of false positives or false negatives is higher than it would otherwise be if competitors were offering the services. And that’s a very real health care quality concern.”⁷² A 2006 study published in the *Journal of the American Medical Association* found that the Myriad diagnostic test missed mutations of 12% of the 300 people examined from high-risk families.⁷³

Rudnick points out that Myriad Genetics has a valuable repository of data on people who have tested positive or negative for BRCA1 and BRCA2.⁷⁴ “I believe they are no longer participating in registering that data in DNA databases. That makes me even more concerned that really important and potentially illuminating information may be out there but not shared with other scientists who are working on this.”⁷⁵

Rudnick also expressed concerns about Myriad's patents preventing women from obtaining a second opinion.⁷⁶ "If I'm going to take preventative measures and remove my body parts, I want a second opinion. It seemed to me there was nowhere else in medicine where you couldn't get a second opinion, and Myriad's monopoly was limiting that."⁷⁷

The ACLU recently survived its first hurdle— a motion to dismiss by the defendants.⁷⁸ On Nov. 1, 2009, Judge Robert W. Sweet denied the motion noting, "resolution of these issues will have far-reaching implications, not only for gene-based health care and the health of millions of women facing the specter of breast cancer, but also for the future course of biomedical research."⁷⁹

Whether the ACLU lawsuit will ultimately prevail remains to be seen. What is clear is that this lawsuit is reinvigorating the debate on a national scale of the ethics and constitutionality of "patenting life" and the need to ensure accessibility of genetic information and diagnostic tests to patients and researchers. Regardless of the outcome of the case, the ACLU has brought a once obscure concept of what constitutes patentable subject matter to the forefront of public debates.

NOTES

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3 Complaint, Ass'n. for Molecular Pathology v. U.S. Patent and Trademark Office, 09 Civ. 4515 ¶ 2 (S.D.N.Y. May 12, 2009).

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- 15 Complaint, *supra* note 5, ¶ 2.
- 16 *Id.* at ¶¶ 2, 92.
- 17 *Id.* at ¶¶ 2, 90.
- 18 *Id.* at ¶¶ 2, 93; ACLU, *supra* note 2, at 6.
- 19 *See* Jordan Paradise, *European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study of the Myriad Genetics' BRCA Patent Controversy*, 59 FOOD & DRUG LAW J. 133-138 (2004).
- 20 EDWARD RICHARD GOLD & JULIA CARBONE, MYRIAD GENETICS: IN THE EYE OF A POLICY STORM 29 (Int'l Expert Group on Biotechnology, Innovation and Intellectual Prop. ed., 2008).
- 21 *See* Kartemquin Films – Press Kit, <http://inthefamily.kartemquin.com/press> (last visited Nov. 20, 2009).
- 22 Kartemquin Films – The Film, <http://inthefamily.kartemquin.com/film> (last visited Nov. 20, 2009).
- 23 *Id.*
- 24 Grateful acknowledgement to Kartemquin Films for permission to reprint the picture from their website at <http://inthefamily.kartemquin.com/film>.
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- 32 *Id.*
- 33 Press Release, Biotechnology Indus. Org., BIO Disagrees with Recommendations of the Draft Report on Gene Patenting and Licensing (Oct. 12, 2009), *available at* <http://www.news-medical.net/news/20091012/BIO-disagrees-with-recommendations-of-the-draft-report-on-Gene-Patenting-and-Licensing.aspx>.
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- 40 Paradise, *supra* note 30.
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- 50 *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980); see also *Peeples*, *supra* note 1.
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- 56 See DRAFT REPORT, *supra* note 45, at 25-26; Schwartz, *supra* note 1.
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- 58 Martin, *supra* note 37.
- 59 *Id.*
- 60 *Id.*
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- 79 *Id.* at 2-3.