New Court Ruling May Alter the Legal Landscape for Gene Patents

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INTRODUCTION

Does permitting the patenting of genes help or hurt scientific innovation? In the traditional pharmaceutical industry, patents are widely seen as the economic cornerstone for drug development. Without them, companies argue, nothing would protect the value of their huge investments, and the incentive for progress would evaporate. Who would spend hundreds of billions of dollars to develop a product that anyone else could copy and profit from?

Patent protection in the field of genetics, however, raises a number of new questions. Whereas traditional drugs are synthesized in laboratories, genes are products of nature. Genes are not created by scientists; rather, they are discovered. Do patents promote a race to discovery or a race to lock up access to natural substances that exist independently of human intervention?

The patenting of genes has tremendous economic and clinical implications. Genomics likely represents the future of much of medicine. Patent protection for genes, or the lack of it, will determine the financial structure under which this new branch of biomedical science evolves. It will shape the fortunes of companies seeking to develop products, of researchers in academia and industry, and of investors. Of even greater significance, it may determine the medical benefits that patients ultimately receive.

This past March, a federal court in New York issued a ruling that could dramatically change the legal landscape for gene patents. In the case of Association for Molecular Technology v. U.S. Patent and Trademark Office, Judge Robert Sweet struck down several patents for genes associated with susceptibility to breast and ovarian cancer. He found that they protect information, not inventions, and therefore fail to meet the criteria for patent validity. The ruling would negate most existing patents on genes and prevent the approval of future ones.

The suit was brought by the American Civil Liberties Union (ACLU) along with several researchers, scientific organizations, and women who carry the genes. It targeted the patent-holders as additional defendants. These include a small biotechnology company, Myriad Genetics, Inc., and the University of Utah. The proceeding is commonly referred to as the Myriad Genetics case.

The decision is certain to be appealed, and there is a good chance it will go all the way to the Supreme Court. The case will be closely watched as it proceeds. A ruling by the high court could establish the first clear legal guidelines on patents related to human genes.

In the October 2009 issue of P&T, this column described the Myriad Genetics case after it had been filed.2 The outcome of the case, which is considered here, was a surprise to many. It gives new life to the movement to invalidate all patents on human genes.

PATENTS AND GENES

Patents prevent anyone but the patent-holder from manufacturing, using, or distributing discoveries and inventions for 20 years from the date of filing. However, only certain kinds of discoveries and inventions are eligible to be patented. To qualify, they must be useful, non-obvious, and novel. They must also represent an original design or process rather than an abstract concept or an item commonly found in nature. The Patent and Trademark Office (PTO) makes an initial determination as to whether these criteria have been met. A favorable decision can be challenged in court, where patents are often overturned.

Patents related to genetics received their first legal test about 30 years ago, when the PTO granted protection to a bioengineered microorganism. In 1980, the Supreme Court upheld the PTO’s action in the case of Diamond v. Chakrabarty,2 declaring that new life forms are novel enough to be patentable. Although this ruling settled the question of whether manufactured genes can receive patent protection, it did not address the patentability of genes that occur naturally, including those found in humans. Future courts were left to decide whether the substance of our genetic makeup could be subject to exclusive private ownership.

In the absence of definitive legal guidance, the PTO has routinely issued patents for human DNA sequences that constitute genes since 1992. Its reasoning is that the material has been purified from its natural form through human intervention. This is sufficient to transform it from a product of nature to a human invention. Since the PTO first took this position, technology has advanced to permit rapid isolation of genes. Today, an estimated 20% of the human genome is subject to patents.3

THE MYRIAD GENETICS DECISION

The ACLU initially filed the Myriad case on behalf of a woman who took a Myriad screening test to determine whether she carried mutated BRCA1 and BRCA2 genes, which indicate a heightened risk of breast and ovarian cancer. The result was positive, and she sought a second opinion regarding the implications. However, the patents blocked anyone other than Myriad Genetics from analyzing the same gene sequences. The ACLU and other organizations that joined as plaintiffs sought a broad court ruling that would invalidate not only the Myriad patents but also all patents on human genes.
On March 29, the plaintiffs received the ruling they wanted. The court found that the act of isolating a DNA sequence does not make the sequence novel. It represents the same underlying information concerning a series of nucleic acid bases that is contained in naturally occurring DNA. Unlike pharmaceutical chemicals, genes are important not as physical structures but as carriers of information. In the words of Judge Sweet, Myriad’s isolated DNA is not an invention but, rather, “… the physical embodiment of the laws of nature—that those that define the construction of the human body.”

The decision relied heavily on a federal appeals court ruling in a case involving a patent on a method for hedging risks in commodities trading, In re Bilski. That decision found the patent to be invalid because it covered an abstract principle rather than a specific process. The court reasoned that the method did not involve an actual invention or a transformative step for turning a naturally occurring substance into something else. The Bilski decision has been appealed to the Supreme Court, and the result will be watched closely. If it is overturned, the Myriad holding could meet a similar fate.

**PATENTS AND BIOMEDICAL INNOVATION**

Beyond the legal technicalities, gene patents raise the larger question of whether ownership of genetic information promotes or stifles biomedical innovation. The ACLU believes that patents on human genes inhibit research, and it has called the Myriad case “one of the most important legal battles in the history of biotechnology.” On the other side, Lila Feisee, Director of Federal Government Relations and Intellectual Property at the Biotechnology Industry Organization (BIO), fears that without patent protection, companies will not be able to raise the investment capital needed to develop new tests and treatments.

Many researchers and clinicians side with the ACLU’s position. A report issued this past April by a research team at Duke University concluded that granting exclusive licenses for individual genes, which occurs when a patent is issued, could slow down or even prevent the advance of genomic medicine. It cited a number of examples of reduced access to tests for a range of conditions, including Alzheimer’s disease, hearing loss, and cystic fibrosis.

Patent claims have constrained several medical centers in offering genetic tests. For example, Baylor College of Medicine stopped offering a test for the gene associated with Duchenne muscular dystrophy after it received a warning letter from the gene’s patent-holder. The problem is particularly acute when tests involve multiple genes that are subject to different patents. Emory University School of Medicine developed a test that can detect chromosomal abnormalities across the entire genome, but it risks violating patents if it reports the results to the patients’ physicians. It has chosen to disclose the results anyway, citing its ethical obligations, but it acknowledges a legal risk. Some academic researchers have faced similar impediments, although not to the same degree.

On the other hand, commercialization of genomics requires tremendous financial investments. Investors will only take the risk in return for the promise of large returns. Would these returns be possible without patent protection? Many in the industry think they would not. Outside investment is particularly important for small start-up companies that have formed the foundation of the biotechnology industry to date.

**THE NEXT ROUND**

The ultimate status of gene patents will have profound consequences for the business of biotechnology, and it presents a substantial challenge to the law. Resolving the legal issues will require a fundamental rethinking of the role of intellectual property. What are the boundaries between human invention and observation of nature? How much of a transformation is needed before a natural substance is recognized as an invention? The Supreme Court’s decision in Bilsky will provide some guidance, but questions will almost certainly remain.

If gene patents are upheld, will the point be reached when the entire human genome is subject to private ownership? New technologies will almost certainly make the isolation of DNA sequences increasingly easy to accomplish, leading to a more rapid pace of gene patent claims. Would this fragmentation limit future research or would it open the floodgates for new infusions of investment capital?

Looking further down the road, what will happen when the gene patents that have been granted start to expire?

The patents at issue in the Myriad case will last until 2045 or 2053. Will the protected portions of the human genome then revert to the public domain, or will entrepreneurs find new ways to lay claim to pieces of it? New patents related to the same gene sequences might be permitted based on newly identified uses for the genes or new processes for analyzing them.

It is clear that resolving these issues is crucial to unleashing the full potential of genomics. It is also likely that the fewer intellectual property claims researchers and clinicians have to navigate, the easier their paths will be.

The future of genomics depends to a large extent on the effectiveness of the legal system at balancing the competing interests in order to smooth that path.

**REFERENCES**

1. No. 09 Civ. 4515 (SDNY, March 29, 2010).
6. 545 F.3d 943 (Fed. Cir. 2008).