U.S. Supreme Court Issues Decision on Patent Eligibility of DNA Sequences

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On June 13, 2013, the U.S. Supreme Court ruled unanimously in Association for Molecular Pathology v. Myriad Genetics, 569 U.S. ___ (2013) (“Myriad”) on the question of whether isolated DNA is patent eligible. The Court held that isolated genomic DNA is not eligible for patenting under Section 101 of the patent statute, but that "synthetic" cDNA is eligible. What is the significance of this decision and where do biotechnology companies and researchers go from here?

Reversal of Thirty Years of Patent Office Policy

Since the early 1980s, the U.S. Patent and Trademark Office (“USPTO”) has granted thousands of patents claiming isolated DNA. It was the USPTO’s policy that a particular gene could be patentable if it was isolated from its natural state and purified from other molecules naturally associated with it. However, in Myriad, the Supreme Court held that naturally occurring DNA is not eligible for patenting just because it has been isolated — it remains a product of nature which has long been excluded from patent eligibility.

This distinction is significant because the Court is trying to draw a line between products of nature and man-made products. The Court has said that synthetic or modified DNA is different enough to be considered man-made, but isolating a naturally occurring sequence is not. The Court is taking a more stringent approach to what is considered unpatentable natural products or phenomena even though the decision runs counter to 30 years of USPTO policy.

Navigating the Biotechnology Patent Landscape

Although Myriad is a landmark decision, it is important to understand its scope. The Supreme Court held that naturally occurring DNA cannot be patented just because it has been isolated. But the Court also held that DNA that has been modified from its naturally occurring form may still be patented. To this end, the Court held that cDNA, which is synthetically created DNA that contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins, is patentable. The Court also was careful to qualify its holding by noting that the case does not apply to methods of using DNA, new applications of knowledge about naturally occurring genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Even though isolated naturally occurring DNA is not patentable, it still will be possible for companies to obtain patents on key elements for making and using gene-based inventions.

However, one tricky aspect of trying to navigate the area of patenting methods of using DNA or new applications of knowledge about naturally occurring genes relates to another Supreme Court case from last year. In Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012) (“Mayo”), the Court held that certain diagnostic methods were not patentable because they involved routine conventional steps (e.g., administering a known drug and analyzing a blood sample) coupled with what the Court viewed as an
unpatentable law of nature (e.g., adjusting dosage based on observed metabolite concentrations in the blood sample). The Court held that the process by which the drug is metabolized in the body is a natural process, and so the relationship between the amounts of metabolites and the effectiveness of drug dose is a law of nature. Merely observing the relationship, without adding anything else, was not enough to make the claims patentable. *Mayo* has had an impact on diagnostic methods patents that involve correlations between diseases and certain biomarkers (like specific proteins or gene mutations).

The bottom line is that it's still possible to obtain patents relating to methods of using DNA or new applications of knowledge about naturally occurring genes, but *Mayo*, now in combination with *Myriad*, has made it more challenging to show that the methods involve additional elements that take the claims beyond what could be construed to be a combination of a natural principle with conventional methods or reagents. It's tricky — if claims are too broad, they may be struck down; but if they are too narrow, they may not adequately protect the claimed method from copycats.

**Impact on the Biotechnology Industry and Academic Research**

Although the full impact of *Myriad* remains to be seen, some in the biotechnology industry are concerned that any decision restricting the patenting of DNA will remove important incentives for creating biotechnology-based applications. Others point to the fact that because the Supreme Court has affirmed that synthetic DNA can be patented, and was careful to exclude many key components of biotechnology-based inventions, this decision may strengthen the incentives for investing in research in this area. For example, Myriad Genetics has patents with different types of claims covering different aspects of its technology and its cDNA claims were upheld, which is probably why the price of its stock initially soared after this decision was released.

If you have a company with a business model based solely on the sale or use of naturally occurring genes, then, of course, *Myriad* is going to be a big problem for you. Most biotechnology companies these days are not based on a single patent around an isolated naturally occurring DNA sequence. Even for companies that have relied on patent claims to isolated naturally occurring DNA (like Amgen's blockbuster anemia treatment based on the human protein erythropoietin), these companies also generally have patents covering either the types of synthetic DNA the Supreme Court said are patentable, or to the types of technology the Court explicitly carved out of its decision, such as methods of using DNA and new applications of knowledge about naturally occurring genes. In fact, most genetic patents acquired during the last decade have been for synthetic sequences, so some in the industry view synthetic DNA as the most commercially important form of DNA used in biotechnology. For example, agricultural biotechnology companies work with plant DNA, but most of the time they are modifying or combining naturally occurring genes in new ways, such as to make better seeds. It's not that you can't patent DNA sequences, it's how you go about doing it.

Researchers may now have more freedom to engage in whole-genome sequencing because they won't have to worry about a slew of isolated DNA patents for covering individual sequences. However, some have speculated that because early-stage research on newly discovered DNA sequences cannot be patented, it may encourage companies to be more secretive about those early-stage discoveries. In fact, Myriad Genetics has already developed a proprietary database of DNA sequence variants and related clinical information pertaining to the breast cancer genes BRCA-1 and BRCA-2, and some fear that there will be pressure toward keeping potentially valuable inventions secret (i.e., as a trade secret rather than pursuing patent protection through which the invention ultimately is publicly disclosed). While maybe not within universities, where the goal of sharing and disseminating discoveries interacts with the drive for commercialization and technology transfer, but certainly within companies, particularly in the diagnostics field in light of *Mayo*, we may see increased reliance on trade secret protection.
Striking a Balance Between the Public Interest and Promoting Innovation

If you have to spend a significant amount of time, effort, and money developing something new and getting it into the marketplace, only to have someone else copy it and produce a competing product with relatively minimal outlay of their own, that creates a disincentive to be the lead innovator. You have to recoup those costs before you can make a profit. In the biotechnology and pharmaceutical fields, that initial development is particularly challenging. Some studies indicate that for every 5,000 to 10,000 experimental compounds considered, only one will gain FDA approval, and getting to that point takes 10 to 15 years of research and development costing over $1 billion. The few successes have to make up for the many failures.

Because innovation is important to the advancement of society, we want to provide an incentive to innovate. One of the purposes of the patent system is to promote innovation. It's right there in the U.S. Constitution (Article I, Section 8, Clause 8). It says that Congress has the power to provide inventors with the exclusive right to their discoveries for a limited time to promote progress. The reference to a limited time is the trade-off. As a society, we also want to encourage the dissemination of knowledge for the public good. In exchange for a period of time in which you can keep others from practicing your invention, you agree to disclose your invention in enough detail so that at the end of that period of time, the invention is freely available to the public. It's a balancing act.

Ultimately, that type of balancing act is at the heart of the Myriad decision. What is the best way to promote progress? In Myriad, the Supreme Court has decided that progress is best served if isolated, naturally occurring DNA is always freely available to the public, while synthetic DNA can be eligible for the limited time protections offered under the Constitution.

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