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U.S. Supreme Court Hears Oral Arguments in Myriad Gene Patent Case

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On April 15, 2013, the U.S. Supreme Court will hear oral arguments in one of the most controversial and publicized biotech patent cases, the “ACLU/Myriad” gene patenting case (formally, *The Association For Molecular Pathology, et al. v. USPTO et al.*). While it is nearly impossible to predict the outcome of a Supreme Court case from the oral arguments, the questions the Justices ask (or don’t ask) and the parties’ responses may at least provide an indication of the issues that the Court will focus on when it renders its decision.

Are Human Genes Patentable?

The Supreme Court granted certiorari to address the fundamental, threshold question of the patent-eligibility of human genes. The specific Myriad patent claims at issue are directed to “isolated DNA” molecules that embody the BRCA1 mutation associated with an aggressive form of breast cancer. The Federal Circuit has upheld the patent-eligibility of these claims twice (before and after the U.S. Supreme Court decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*). The Court’s decision to take up this case for review has been seen by many as a sign that the Court disagrees.

The Court will evaluate Myriad’s patent claims under the “product of nature” exception to 35 USC § 101, which holds that a patent cannot be granted on a naturally-occurring product. The Court has been presented with three ways to resolve this issue:

- The ACLU would have the Court decide that human DNA sequences cannot be patented because they encompass naturally-occurring human genes, or embody the same genetic information as human genes.
- Myriad would have the Court decide that any “isolated” DNA molecules can be patented, because they are distinct from products of nature on that basis.
- The U.S. Solicitor General has urged the Court to decide that claims that might encompass human genes should not be patent-eligible, but claims that are directed to DNA sequences that are not found in nature (such as Myriad’s cDNA claims) could be patented, even if they contain the same “genetic information” as a human gene.

The Federal Circuit Decisions

The Federal Circuit twice upheld Myriad’s “isolated DNA” claims in fractured decisions. Each

time, Judge Lourie wrote an opinion in support of the majority decision, which was joined by Judge Moore, Judge Moore wrote a concurring opinion, and Judge Bryson dissented.

Judge Lourie's opinion emphasized the "isolated" nature of the claimed DNA, and the fact that covalent bonds in the naturally-occurring genomic DNA sequence must be broken in order to obtain "isolated" DNA.

Judge Moore was less certain that isolated DNA is sufficiently distinguished from naturally-occurring DNA to satisfy 35 USC § 101, but was persuaded by the USPTO's long-standing practice of granting patents on isolated DNA, and the significant investment-backed expectations of the biotechnology industry.

Judge Bryson disagreed with respect to claims that might encompass human genes, but agreed that claims that are directed to DNA sequences that are not found in nature (e.g., the cDNA claims) can be patented.

Looking Ahead

This decision will be of great interest to the biotech community, and is likely to impact fields beyond the genetic screening market. For example, the Court's decision could impact the ability to patent a synthetic version of any substance found in nature, such as antibiotics, antigens useful in vaccines, peptide drugs, oil-eating bacteria, enzymes, etc. A decision that restricts the patent-eligibility of DNA sequences also could further undermine the ability to obtain patent protection for diagnostic methods and personalized medicine, which has become more difficult in the wake of the Supreme Court decision in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*.

Update: Please see my article on [PharmaPatentsBlog](#) for my summary of the oral arguments.

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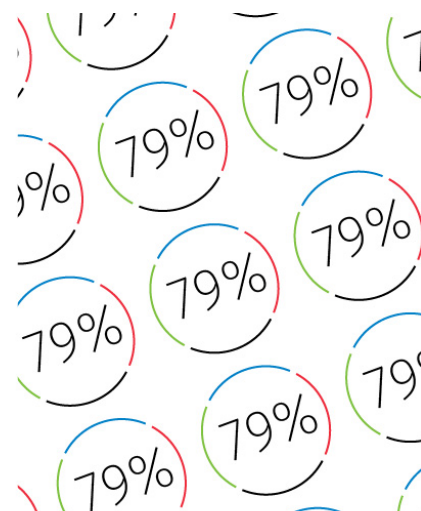
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