



Intellectual Property Alert: Supreme Court to Weigh In on Gene Patents

By **Paul M. Rivard**

On April 15, 2013, the U.S. Supreme Court heard arguments in *Association for Molecular Pathology (AMP) v. Myriad Genetics, Inc.* At issue is the eligibility of Myriad's patent claims to isolated DNA encoding BRCA1 polypeptides. Individuals who inherit a mutated BRCA1 gene have an increased chance of developing certain cancers, particularly breast and ovarian cancers. The U.S. Court of Appeals for the Federal Circuit ruled that Myriad's claims to isolated DNA molecules qualify as patent-eligible compositions of matter under 35 U.S.C. § 101.

AMP's Arguments

Counsel for AMP argued that DNA claims should not be permitted if they embody a naturally-occurring sequence, regardless of whether the molecule is derived from biological matter or prepared synthetically. AMP urged that patent protection should be available for DNA only when a scientist creates sequences that would not otherwise be found in biological organisms.

During the arguments, several justices questioned AMP on what incentives for innovation would exist if the Court struck down patent claims covering isolated DNA. Justice Kennedy appeared to be skeptical that scientific curiosity and Nobel prizes, as AMP posited, would provide the needed incentive to attract investment dollars.

AMP also argued that, for patent-eligibility purposes, it is not enough to isolate something from nature. Rather, according to AMP, a material must be sufficiently manipulated such that it has a different function than that of the natural material. Justice Kagan did not appear convinced, pointing out that the degree to which something differs from the prior art should go to the question of obviousness rather than eligibility.

Myriad's Arguments

Counsel for Myriad argued that an isolated DNA molecule is markedly different from what exists in nature, and that the invention importantly enables physicians to determine whether a woman has an increased likelihood of developing breast cancer. Myriad asked the justices to respect the U.S. Patent and Trademark Office's expertise and carefully considered 2001 examination guidelines, which recognize isolated DNA is eligible for patenting. Counsel also pointed to a biotech industry that has thrived under this longstanding practice.

Myriad suggested the Court should view isolated DNA like a baseball bat carved from a tree rather than a plant uprooted from the ground. But some of the justices expressed concerns over whether isolated DNA was too close to nature's handiwork, with Justice Sotomayor questioning how one can patent a sequential numbering series that occurs in nature, and Chief Justice Roberts characterizing the invention as mere "snipping" from naturally occurring material.

Solicitor General's Arguments

The Department of Justice argued (as friend-of-the-Court) that isolated DNA should not be eligible for patenting, but that synthetically-made complementary DNA (cDNA) should be patent-eligible. As pointed out by Justice Alito during arguments, the federal government has changed its stance on this question, and there is currently a fracture within the Executive Branch as the U.S. Patent and Trademark continues its longstanding practice of permitting patents on isolated DNA.

Overall, the justices seemed more receptive to allowing claims on cDNA. Justice Breyer noted the differences between the molecular structures of naturally occurring DNA and cDNA are readily identifiable. One possible outcome is that the Court will adopt this middle-ground position advanced by the Department of Justice.

The Court is expected to issue its ruling later in 2013.

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