Patent Law Update: Association for Molecular Pathology v. PTO

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Federal Circuit Hears Arguments in *Myriad Genetics* Case

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The Federal Circuit heard arguments July 20, 2012 in the long-running dispute between The Association for Molecular Pathology and Myriad Genetics, Inc. (*Myriad*), which the Supreme Court returned to the Federal Circuit for reconsideration in view of the Supreme Court's recent decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* In *Prometheus*, the Supreme Court held certain claims to methods of determining a dosage of a drug were not patent eligible subject matter, characterizing the claims as not significantly more than a law of nature and as too broadly preemptive of the natural law to be patent-eligible. The remand reopened the question of patent eligibility of Myriad's claims to isolated DNA encoding BRCA1 polypeptides and a method for screening potential cancer therapeutics.

BRCA1 is a cancer susceptibility gene which can be inherited. Women (and men) who inherit the gene have an increased chance of certain cancers, in particular breast cancer. Both the American Civil Liberties Union and the U.S. government are involved in the case, both taking positions that certain of Myriad's patent claims pre-empt important natural products and/or natural laws, preventing free public access.

Myriad argued that the holding in *Prometheus* is irrelevant to its isolated DNA claims. It further asserted that pre-emption is not a separate test for subject matter patentability but merely a proxy for the appropriate test. Myriad asserted that patentability of the DNA claims is controlled by the Supreme Court's 1980 decision in *Diamond v. Chakrabarty,* which found genetically engineered oil-eating microbes patent eligible and broadly held patent eligible anything under the sun that required the hand of man. Myriad hung its subject matter eligibility argument in favor of the method claim 20 on the patent-eligibility of the transformed eukaryotic host cell containing an altered BRCA1 gene.

Myriad also argued that method claim 20 was not properly before the court because it was not part of the Association for Molecular Pathology's (AMP) petition for certiorari. Judge Bryson pointed out the court's task was not limited by what the petitioners had included in their Supreme Court petition.

The AMP focused on "the stunning breadth" of the product claims. Judge Lourie quickly dismissed this as a different legal issue, one of scope of enablement and written description under §112, rather than subject matter eligibility under §101. Judge Moore was even sharper, quoting *Prometheus* as saying that breadth is not relevant; she advised AMP that its pre-emption argument "is a waste of time and space." AMP quickly moved on to discuss method claim 20, arguing that whether the method uses a product which may be patent eligible should not make a difference to patent eligibility of the method itself. Judge Moore was dubious, inquiring how that can be if the transformed cell used in the method is not "found in nature."

The U.S. limited its argument to the subject matter of claim 1, isolated DNA encoding BRCA1 polypeptides, which the U.S.

characterized as isolated but otherwise unmodified. The U.S. argument was also based on pre-emption. Although the U.S. indicated that it did not want the court to make a special rule just for DNA, it did argue that patent eligibility of a product should require more than what is incidental to its isolation. This would move the formerly bright line question for patent eligibility of a product—"is it found in nature?"—to "is it different from what is found in nature in a way that is not merely incidental to its isolation?"

Judge Bryson asked how Myriad's isolated DNA claims were different than claims to several presumably patent-ineligible examples, including a baseball bat made out of a tree trunk, coal mined from the earth, Michelangelo's David hewn from a block of marble, and a kidney cut out of a body. Myriad distinguished these examples by saying that it took substantial scientific ingenuity to decide exactly where to cut to isolate the BRCA1 gene from a human chromosome. Myriad did not point out that these examples involved only physical changes, whereas DNA is chemically changed when it is isolated from a chromosome. Past case law has consistently recognized a chemical change as a hallmark of subject matter eligibility.

Although the outcome of a case cannot necessarily be predicted from the demeanor and comments of its judges at oral argument, it appears that the Federal Circuit may reach the same outcome it had previously. This time it may couch its decision differently, using the language and concepts articulated by the Supreme Court in *Mayo*.

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