FEDERAL CIRCUIT REAFFIRMS PATENT ELIGIBILITY OF ISOLATED DNA MOLECULES

BY: PAUL M. RIVARD

On August 16, 2012, the U.S. Court of Appeals for the Federal Circuit issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* ("*Myriad II*") following a remand from the U.S. Supreme Court. The Supreme Court asked the appellate court to reconsider its July 2011 panel decision ("*Myriad I*") following the high court's ruling in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* ("Mayo"). In Mayo, the Supreme Court held certain claims to methods of determining a dosage of a drug were not patent-eligible because they impermissibly preempted a natural law. The remand reopened the question of patent eligibility of Myriad's claims to isolated DNA encoding BRCA1 polypeptides and methods for screening potential cancer therapeutics. Individuals who inherit the BRCA1 gene have an increased chance of developing certain cancers, most notably breast cancer.

Myriad II reaffirmed *Myriad I* in all respects. The court again reversed the lower court's ruling that claims to "isolated" DNA molecules cover patent-ineligible products of nature under § 101, noting that the molecules as claimed do not exist in nature. The *Myriad II* panel also reversed the district court's decision that claims involving screening potential cancer therapeutics via changes in cell growth rates were directed to a patent-ineligible scientific principle, as these methods involve transformative steps. The court, however, agreed with the district court that claims involving "comparing" or "analyzing" DNA sequences were patent-ineligible methods embracing only abstract, mental steps.

The court made clear at the outset that the appeal was not about whether individuals suspected of having an increased risk of developing breast cancer are entitled to a second opinion, whether the patentee acted improperly in its licensing or enforcement policies, whether it is desirable for one company to hold a patent covering a lifesaving test, or whether the claims at issue are novel, nonobvious, or overly broad. The *Myriad II* panel expressed that any restrictions on patents on medical methods or novel biological molecules is a policy matter for Congress to decide.

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Writing for the majority, Judge Lourie tackled the Supreme Court's concerns articulated in *Mayo* of a patent foreclosing further research on a scientific principle. Judge Lourie found that such concerns were inapplicable to the isolated DNA claims at issue. He explained "permitting patents on isolated genes does not preempt a law of nature. A composition of matter is not a law of nature."

Next, addressing the claims involving analyzing and comparing DNA sequences, the majority agreed the claims were patent-ineligible methods involving only abstract mental processes. The majority said

MORE ▸

[**FEDERAL CIRCUIT**, FROM PAGE 9]

the Supreme "Court made clear that such diagnostic methods . . . essentially claim natural laws that are not eligible for patent."

Judge Moore concurred-in-part and wrote separately to emphasize the importance of the decades-long policy of permitting patents on isolated DNA molecules, a policy which founded and has become the lifeblood of the biotechnology industry. Judge Moore said that "isolated DNA fragments, which have both chemical changes from the naturally occurring genomic DNA as well as new utility, are the kind of 'discoveries' that the statute was enacted to protect."

Judge Bryson agreed with the majority on the patent-eligibility of the claims directed to cDNA and the patent-ineligibility of the claims involving "comparing" or "analyzing" DNA sequences. Dissenting-in-part, Judge Bryson would have affirmed the lower court's ruling that the claims to the isolated BRCA gene are patent-ineligible. Pointing to the Supreme Court's *Mayo* decision, Judge Bryson believed the isolated DNA material involved no "more than merely incidental changes to the naturally occurring product" and no "inventive' contribution" to the product of nature.

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While *Myriad II* may be welcome news for a biotechnology industry that was recently dealt a harsh blow by the Supreme Court in *Mayo*, the battle may not be over yet. The Supreme Court has taken up a number of patent eligibility questions as of late and may have the final word on this one as well. ■

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