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On Remand, Federal Circuit Maintains Previous Holding That Isolated DNA Is Patent-Eligible But Methods Of Comparing Or Analyzing Isolated DNA Are Patent-Ineligible

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(August 16, 2012) On August 16, 2012, the Federal Circuit released its highly anticipated decision in *Ass'n for Molecular Pathology v. USPTO and Myriad Genetics,* No. 2010-1406 (Fed. Cir. August 16, 2012) ("*Myriad*"), on remand from the U.S. Supreme Court, concerning the patent-eligibility of isolated DNA under 35 U.S.C. § 101.

The patents at issue in *Myriad* relate to isolated gene sequences and diagnostic methods of identifying genetic mutations in those sequences. The patents include three categories of claims: (i) composition claims directed to isolated DNA molecules, (ii) method claims directed to identifying cancer-predisposing mutations by analyzing or comparing a patient's DNA sequence to a normal sequence; and (iii) a method claim directed to screening potential cancer therapies based upon changes in the growth rates of transformed cells.

On summary judgment at the District Court level, all of the claims were held to be patent-ineligible. In the original decision on appeal, the Federal Circuit reversed-in-part, finding the composition claims at issue to be patent-eligible, but agreeing that the method claims relating to analyzing or comparing certain DNA sequences were patent-ineligible on the ground that they claim only abstract mental processes. As to the method claim relating to screening cancer therapies based upon changes in cell growth rates, the Federal Circuit found this claim to be patent-eligible, because in addition to the comparing and analyzing steps, it also recited the steps of growing transformed cells and determining those growth rates. The Federal Circuit concluded that these steps were transformative and that therefore this claim was patent-eligible.

Supreme Court granted certiorari, vacated the decision, and remanded the case to the Federal Circuit to be considered in light of its decision in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012) ("*Mayo*"), which, as previously reported by ARE, found patent claims directed to diagnosing and/or treating a disease to be an unpatentable law of nature under 35 U.S.C. § 101.

On remand, the Federal Circuit largely followed its prior decision, noting that "the principal claims of the patents before us on remand related to isolated DNA molecules,"

and that "*Mayo* does not control the question of patent-eligibility of such claims." (Slip op. at 38).

Specifically, the Federal Circuit concluded that the composition claims were patent-eligible, because "each of the claimed molecules represents a nonnaturally occurring composition of matter." (*Id.* at 7). Citing to the early Supreme Court decisions of *Chakrabarty* and *Funk Brothers*, the Court explained that the claimed isolated DNA molecules "are obtained in the laboratory and are man-made" and "have a markedly different chemical structure compared to native DNAs." (*Id.* at 39, 50). The Court further noted that "[w]hile they are prepared from products of nature, so is every other composition of matter." (*Id.* at 39, 42-43). Finally, in applying *Mayo* to the composition claims, the Federal Circuit concluded that "permitting patents on isolated genes does not preempt a law of nature," because isolated genes, as compositions of matter, are "not a law of nature" but rather "products of man." (*Id.* at 51-52).

However, as it did previously, the Federal Circuit again found that the set of method claims directed to "comparing" or "analyzing" DNA sequences was patent-ineligible, because these claims include no transformative steps and are directed to abstract, mental steps. (*Id.* at 8, 55).

Finally, the Federal Circuit also found that the method claim to screening potential cancer therapeutics based upon changes in cell growth was patent-eligible. The Federal Circuit had previously come to the same conclusion based on the fact that the claim required certain transformative steps, but revisited its earlier decision in light of *Mayo*, which held that "certain transformative steps are not necessarily sufficient under § 101 if the recited steps only rely on natural laws." (*Id.* at 8, 55-56). The Federal Circuit concluded that this claim is patent-eligible, because it recites a screening method based on the use of transformed, non-naturally occurring cells, and therefore the "claim includes more than the abstract mental step of looking at two numbers and 'comparing' two host cell's growth rates." (*Id.* at 60).

Of note, in its decision, the Federal Circuit emphasized that the sole issue before it was "patent eligibility [under 35 U.S.C. § 101], not patentability [i.e., which would involve a consideration of whether the claims are novel or nonobvious]." (*Id.* at 37-38).

The Court further noted that "in the context of discussing what this case is not about, that patents on life-saving material and processes, involving large amounts of risky investment, would seem to be precisely the types of subject matter that should be subject to the incentives of exclusive rights. But disapproving of patents on medical methods and novel biological molecules are policy questions best left to Congress, and other general questions relating to patentability and use of patents are issues not before us." (*Id.* at 38).

Each member of the Court wrote separate opinions, with the opinion of the court authored by Judge Lourie, with Judge Moore concurring-in-part and Judge Bryson dissenting-in-part. In dissent, Judge Bryson argued that a gene isolated from the human body should not be

patent-eligible.

Please continue to monitor our website for further developments on patent-eligible subject matter.

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Mr. Macedo is also the author of The Corporate Insider's Guide to U.S. Patent Practice, published by Oxford University Press in 2009, and, along with Anthony F. LoCicero, was counsel on the amicus submission submitted by the New York Intellectual Property Law Association to the Supreme Court in *Mayo v. Prometheus*.