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Federal Circuit Reaffirms (Again) Gene Patents in *Myriad*

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Advisory

On August 16, 2012, biotechnology patent owners breathed a short sigh of relief, as the US Court of Appeals for the Federal Circuit issued the highly anticipated decision in *Association for Molecular Pathology v. Myriad Genetics*, finding that DNA sequences are indeed eligible for patent protection. However, not all biotech innovators will be happy with the *Myriad* decision since certain diagnostic method claims were again struck down as ineligible for patent protection. Additionally, one of the three judges on the panel dissented on the patentability of isolated DNA, arguing, "extracting a gene is akin to snapping a leaf from a tree." The final word on this subject may need to come from the Supreme Court.

The *Myriad* case had been on the Supreme Court docket briefly last year but was sent back down to Federal Circuit for reconsideration in view of the Supreme Court decision earlier in its term in *Mayo Collaborative Services v. Prometheus Laboratories*. In *Mayo*, the Supreme Court held that diagnostic claims essentially claiming a natural principle are not patent eligible under § 101 of the Patent Act.

On remand, in a 2-1 decision, the Federal Circuit upheld Myriad's "isolated DNA" claims and the method claim directed to screening potential cancer therapeutics, but also held that certain method claims directed to "analyzing" or "comparing" gene sequences are not patent eligible subject matter under § 101 in view of *Mayo*. Judge Lourie, writing for the majority, clarified that the issue is "patent *eligibility*, not *patentability*," and that policy questions – such as whether DNA warrants special treatment under the patent laws – are best left to Congress.

In finding isolated DNA to be patent-eligible subject matter, Judge Lourie noted that the Supreme Court precedents in *Chakrabarty* and *Funk Brothers*, and not *Mayo*, controlled patent eligibility for composition claims. The Federal Circuit essentially followed its earlier logic in distinguishing these claims: isolated DNA molecules are not found in nature, are man-made and the product of human ingenuity. Both Judges Lourie and Moore drew a distinction between products of nature and products of man that "follow[], as all materials do, laws of nature." In her concurring opinion, Judge Moore indicated that the chemical difference between the *in situ* gene and the isolated gene was not by itself sufficient to justify protection, but that change in combination with the "enlargement of the range of . . . utility" derived from the isolation" led to patent eligibility. Judge Moore also appeared to place considerable weight on the USPTO's long-standing practice of granting patents on such subject matter.

In a dissenting opinion, Judge Bryson disagreed with the majority on this issue of patent eligibility for genes. He concluded that the *Mayo* decision handed down by the Supreme Court earlier this year was instructive because the Court found that the method claim at issue in the *Mayo* case was not directed to patent-eligible subject matter because it contributed nothing "inventive" to the law of nature. Judge Bryson likewise concluded that Myriad's claims to isolated DNA were not patentable because Myriad had not done "enough" to distinguish the alleged invention from a similar product of nature. He dismissed the act of isolating the DNA from the *in situ* gene as merely a matter of breaking covalent bonds.

Upon reconsideration of the method claims also at issue in this case, the three judge panel came to the same conclusions it had previously – albeit by different logic to take into account the Supreme Court's reasoning in the

Mayo case. With regard to the method of comparing or analyzing claims, the Court held that there was no putatively transformative step to make each claim something other than a claim to a natural law, and that the methods were simply directed to the abstract mental process of comparing two sequences.

By contrast, the Federal Circuit judges again found the claimed method for screening of therapeutics to be patentable subject matter, holding that even though a method includes known steps it can be sufficiently transformative if the steps are to create novel, *i.e.*, transformed, subject matter. The fact that the claim includes the steps of determining and comparing the cells growth rates "does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell – patent-eligible subject matter."

The Federal Circuit's application of the *Mayo* case to Myriad's claims on diagnostic methods provides little guidance on how to draft such diagnostic claims to secure allowance – and survive future patentability challenges. It is clear that the claims must recite something "transformative." However, what constitutes a transformation in a diagnostic method remains to be elucidated.

Moreover, the discussion of patentability for DNA sequences is far from being over. Should parties appeal in the next 90 days, the Supreme Court could again grant certiorari or there could be an *en banc* rehearing by the full Federal Circuit. Nutter attorneys will continue to keep you informed regarding the developments in this area.

This advisory was prepared by Nutter's Intellectual Property practice. For more information, please contact your Nutter attorney at 617.439.2000.

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