



AMP v. USPTO (“The Myriad Case”): Status quo on gene patents . . . for now

Association for Molecular Pathology v. U.S. Patent & Trademark Office (“The Myriad Case”) is the first decision to specifically address whether DNA isolated from its natural state is patentable subject matter.¹ The Federal Circuit found that isolated DNA is patentable subject matter thereby reversing the decision of the district court. Although the decision focused on the subject matter patentability of isolated DNA, the case presented three issues: 1) standing of the plaintiffs, 2) subject matter patentability of isolated DNA, and 3) the subject matter patentability of method claims using isolated DNA.

The decision was unanimous in regards to 1) Dr. Harry Ostrer being the sole plaintiff with standing because he was the only plaintiff with “an actual and imminent injury,”² 2) cDNA is patentable because it does not exist in nature, and 3) method claims utilizing isolated DNA have subject matter patentability when the claim recites a transformative step but not when the claim can be completed solely by mental processes. With regard to the subject matter patentability of isolated DNA, such as isolated genes, all three judges in the panel provided their own opinions, summarized below. Because of the importance of the issue and the lack of judicial consensus on the law, this issue will likely be decided by the Supreme Court of the United States.

1. Subject Matter Patentability of Isolated DNA

The highest profile aspect of this case was the issue of subject matter patentability for isolated DNA. The panel split two to one whether isolated DNA in general was patentable subject matter. In the majority decision, written by Judge Lourie, the court found that isolated DNA is patentable subject matter due to its distinctive structural characteristic. Judge Lourie focused on the breaking of bonds from its natural state: “it has been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body.”³ Thus, the court viewed isolated DNA as a distinct chemical entity. The court also found that the informational content is irrelevant to the subject matter patentability of the composition, although the information content does inform obviousness questions. The court made the distinction between isolated DNA and purified DNA, reasoning that simple purification may not impart subject matter patentability whereas the characteristics of isolated DNA do impart subject matter patentability.

Judge Moore concurred in the judgment of the court, but provided her own reasoning. Judge Moore also made a distinction between short and long strands of DNA. In regards to short strands of isolated DNA, Judge Moore agreed with Judge Lourie that the isolated nature of the

¹ Brief for *amicus curiae* Kane Biotech Inc., *Ass’n for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406 (Fed. Cir. 2011) (Merchant & Gould filed an *amicus curiae* brief in this case in support of the defendants/appellants (supporting the subject matter patentability of isolated DNA)).

² *Ass’n. for Molecular Pathology v. U.S. Patent & Trademark Office*, No. 2010-1406, slip op. at 30 (Fed. Cir. 2011).

³ Slip Opinion at 42.



DNA made it distinct from its natural state. Further, Judge Moore emphasized the difference in the utility of isolated DNA from DNA in its natural state. Specifically, she reasoned that isolated DNA possesses a new utility that natural DNA does not. For instance, the ability of the isolated DNA to be used in diagnostic testing is important. She explained: “Diagnostic testing . . . is not a natural utility The claimed DNA does not serve the ends of nature originally provided. Instead, the isolated DNA sequences have markedly different properties which are directly responsible for their new and significant utility.”⁴

Judge Moore suggested that the issue of subject matter patentability of longer strands of DNA was a harder issue to decide. Although the longer strands were still distinct molecules, Judge Moore was not sure if the utility was much different than the natural state. She emphasized that this issue was not solely a legal question. Rather, Judge Moore felt that the courts should defer to Congress in terms of overturning the subject matter patentability of isolated DNA, especially in regards to longer strands of isolated DNA. She reasoned that a decision to abrogate gene patents *in toto* would overturn the settled expectations of the biotech industry and the USPTO's extended history of issuing patents to isolated DNA. Such a fundamental change is more of a policy decision that requires action by Congress. Thus, Judge Moore concluded that longer strands of isolated DNA were patentable subject matter until an act of Congress provides to the contrary.

Although Judge Bryson concurred with the majority that cDNA is not found in nature and is thus patentable subject matter, he concluded that isolated human genes are not patentable subject matter. Judge Bryson dissented by characterizing isolated DNA in this case as just a simple extraction of a natural genetic unit. He further characterized the issue as “whether the process of isolating genetic material from a human DNA molecule makes the isolated gene a patentable invention.”⁵ Further, Judge Bryson dismissed the structural differences between isolated genes in corresponding native genes. Specifically, he believed the structural differences to be irrelevant to the claim limitation, the function of the genes, and their utility.

2. Method Claims

The Federal Circuit was unanimous in affirming-in-part and reversing-in-part the subject patentability of the method claims at issue, consistent with *Bilski*.⁶ The court affirmed the non-patentability of method claims just reciting steps of “analyzing” and “comparing.” Thus, methods that can encompass abstract mental steps without a transformative step were found not to be patentable subject matter. The Federal Circuit also held that the active steps of “extracting” or “sequencing” could not be read into the claims into these claims. However, methods of “screening” and “determining” included transformative steps. Thus these claims were more than

⁴ *Id.* at 71.

⁵ *Id.* at 3 (Bryson, J., dissenting).

⁶ *Bilski v. Kappos*, 130 S. Ct. 3218 (2010).



just abstract mental steps. The court concluded that the transformative active step in the claim resulted in subject matter patentability.

3. Appeal

Both sides petitioned for a panel rehearing. The plaintiffs/appellees appealed the decision regarding standing (asserting that another physician and the American College of Medical Genetics should have standing) and the subject matter patentability of isolated DNA. That petition was denied.

Myriad also petitioned for a panel rehearing on the matter of standing. Dr. Ostrer, the lone plaintiff decided to have standing, left New York University and moved to Albert Einstein College of Medicine, so Myriad asserted that there was a question as to whether the facilities at Dr. Ostrer's new position allowed him to conduct the BRCA testing that would be required to infringe the claims. At this date, the appeal is still pending.

Interestingly, neither side petitioned for rehearing on the decision in regards to the method claims.

4. Summary

The Federal Circuit has upheld the status quo in the subject matter patentability of isolated DNA. However, this issue will almost assuredly be decided by the Supreme Court of the United States. From the beginning, it has been generally assumed that the ACLU representing the plaintiffs wished to take this case all the way to the Supreme Court to invalidate gene patents, not just the specific ones at issue in this case.