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The *Myriad* Decision: Has the Dust Settled Yet?

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Legal Update

Six months ago, the United States Supreme Court shook up the biotechnology industry by ruling that genetic sequences are not patent eligible "simply because they have been isolated." *AMP v. Myriad Genetics*, 569 U.S. 12-398 (June 13, 2013). While providing little practical guidance, the Court succeeded in raising many new questions at the core of biotechnology patenting. For example, what characteristics are required to make natural nucleic acids patent eligible? What about other natural products, such as stem cells, polypeptides, antibodies, purified enzymes, and hormones?

The U.S. Patent and Trademark Office (USPTO) is still developing comprehensive guidance for applying *Myriad*. Based on preliminary guidance and current USPTO practice, *Myriad* is being applied strictly to nucleic acids, but generally not to other natural products. For now, sequence variations (*e.g.*, 95% or greater identity) or point mutations may not be enough to make a natural nucleic acid patent eligible. *See, e.g.*, *Prosecution History of USSN 13/350,372*. On the other hand, "isolation" is still apparently sufficient to make other natural products, for example polypeptides, patent eligible. *See, e.g., Prosecution History of USSN 13/543,049*. This may change, however, with the USPTO's comprehensive guidance, which is expected soon. In the meantime, *Myriad*-based rejections may vary by examiner due to a lack of clear standards.

A number of pending lawsuits should provide insight into the standards for patent eligibility under *Myriad*. *Myriad* only invalidated claims to isolated, natural nucleic acids, leaving Myriad's claims to *diagnostic methods* and *synthetic, non-natural nucleic acids* apparently untouched. On the basis of these claims, Myriad filed suit against Ambry, Gene-by-Gene, Quest Diagnostics, GeneDx, Invitae, and LabCorp. Therefore, at least for now, *Myriad* has not eliminated *genetic diagnostic patents*. But, questions remain on how diagnostic methods, and synthetic sequences, based on natural nucleic acid sequences will be analyzed after *Myriad*. For example, will all *synthetic nucleic acid compositions* be patent eligible, including those with naturally occurring sequence information, or will *non-natural sequence information* also be required?

There are also pending cases which should provide insight into whether *Myriad* applies to other natural products. Although legal precedent would seem to dictate that "isolation" makes natural compounds such as polypeptides and small molecules patent eligible, that precedent also applied to nucleic acids but failed under the *Myriad* analysis. The *Consumer Watchdog v. WARF* appeal to the Federal Circuit should provide some answers to the question of patent eligibility of purified *stem cells*. Similarly, the *St. Jude* suits against *Xcovery (Civil Action No. 3:13-cv-01143, M.D. Tenn.)* and *Novartis (Civil Action No. 2:13-cv-02802, W.D. Tenn.)* should provide some answers to the question of patent eligibility for *isolated cDNA, polypeptide, and antibody natural products*. If *Myriad* requires more than "isolation" for other natural products, where will it draw the line? For example, would a protein require a non-natural sequence for patent eligibility, or would chemical modification of a natural structure be sufficient?

While *Myriad's* full impact is still being determined, and the public debate on limiting patents continues, it is already clear that *Myriad* has fundamentally changed biotechnology patenting. Given the current political climate, further developments will probably come from the USPTO, and from courts' application of *Myriad*, rather than new legislation. Nutter will continue to keep you updated as the USPTO guidance and case law regarding *Myriad*

develop.

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

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