Client Alert

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USPTO Begins to Apply *Myriad* to Pending Patent Applications

In *Ass'n For Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court held that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring." 133 S. Ct. 1207 (2013). Further, fragments that are "indistinguishable from natural DNA" are not statutory subject matter. *Id.*, 2119. The USPTO has begun acting on the Court's new definition of patentable subject matter regarding claims reciting DNA, and the Court's reasoning opens up new questions concerning the patentability of other natural products.

The Supreme Court based the decision on their observation that the inventors' contribution was information regarding the sequence and genomic location of the gene in question, which the Court characterized as the discovery of a natural phenomenon. On the other hand, the Court held that cDNA is statutory subject matter because the cDNA molecules are not naturally occurring. The Court did not rule on the patentability of methods of using the naturally occurring DNA, but such claims are believed to be subject to their earlier holding in *Mayo Collaborative Servs v. Prometheus Labs., Inc.,* 132 S. Ct. 1289 (2012).

The USPTO has now begun to apply the holding in *Myriad* by rejecting claims drawn to naturally occurring DNA. This dragnet has encompassed any claim seen as possibly comprising what the Supreme Court considered "naturally occurring DNA," including patent applications with allowed claims are being pulled from issue. In initial discussions with the USPTO, it appears that the USPTO is receptive to cDNA, recombinant DNA, DNA comprising heterologous DNA and labeled/modified DNA as being possibly exempt from rejections in view of *Myriad*.

The logical question at this point is how far the USPTO will expand their *Myriad* scrutiny. The Supreme Court supported their decision in *Myriad* by citing *Funk Brothers*, a 1948 case involving claims to a mixture of microbes, each of which was known to occur in nature, but which were not known to occur together in the particular mixture. The 1948 Court had held that even if the mixture was novel, claims that were limited only by combining unmodified natural products were not patentable. The *Myriad* decision opens the question of whether other compositions based on components unchanged from their natural state will be patentable. For example, will the USPTO apply *Myriad* to proteins, antisera, bacteria or other biological material that is arguably "naturally occurring"?

While the *Myriad* decision appears to provide some guidance concerning how the new standards apply to DNA sequences, it raises new uncertainty concerning other natural products. The decision leaves open the question of what options an applicant has to avoid Myriad-based rejections for claims that include a "naturally occurring" biological material in a composition.

The lawyers of Hunton & Williams LLP are available to assist patent applicants in their efforts to address issues arising from the Myriad decision, while also counseling clients on how to proactively avoid any potential problems associated with the Court's decision.

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