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On August 16, 2012, the United States Court of Appeals for the Federal Circuit issued its opinion in *Association for Molecular Pathology (AMP) and ACLU v. USPTO and Myriad Genetics*. To the relief of many in the biotech community, the appellate court ruled that composition claims to "isolated" DNA molecules are patent-eligible products of nature because they represent a nonnaturally occurring composition of matter. In contrast, the court reiterated its view that claims to methods of "comparing" or "analyzing" DNA sequences are not patent-eligible because such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.

The Federal Circuit's decision is not the end of the road for the gene patentability saga. On September 24, 2012, AMP, filed a petition for *writ of certiorari* to the United States Supreme Court on three questions:

1. Are human genes patentable?
2. Did the court of appeals err in upholding a method claim by Myriad that is irreconcilable with the Supreme Court's ruling in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,* 132 S. Ct. 1289 (2012)?
3. Did the court of appeals err in adopting a new and inflexible rule, contrary to normal standing rules and the Supreme Court's decision in *MedImmune, Inc. v. Genentech, Inc.,* 549 U.S. 118 (2007), that petitioners who have been indisputably deterred by Myriad's "active enforcement" of its patent rights nonetheless lack standing to challenge those patents absent evidence that they have been personally threatened with an infringement action?

On Friday, November 30, 2012, the Supreme Court granted *certiorari* to address the single issue: "Are human genes patentable?"

The Federal Circuit's opinion in the *Myriad* decision was a welcomed guidepost to practitioners wrestling with patentable subject matter and solidified that composition of matter claims to isolated gene sequences (*i.e.,* isolated DNA molecules) are patent-eligible subject matter. While the Supreme Court has chosen not to address questions 2 (method claims) and 3 (standing issues), indicating agreement with that part of the *Myriad* opinion, the fact that the Supreme Court has granted *certiorari* on the singular issue of patentability raises uncertainty regarding the Federal Circuit's opinion that isolated gene sequences are patent-eligible subject matter.

Practitioners will need to wait for further guidance from the Supreme Court, which will likely come before the end of the current term in June 2013. In the meantime, human genes in the form of isolated DNA and other nucleic acid molecules remain patent-eligible.

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