

December 4, 2012

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.

This content is provided for general informational purposes only, and your access or use of the content does not create an attorney-client relationship between you or your organization and Cooley LLP, Cooley (UK) LLP, or any other affiliated practice or entity (collectively referred to as "Cooley"). By accessing this content, you agree that the information provided does not constitute legal or other professional advice. This content is not a substitute for obtaining legal advice from a qualified attorney licensed in your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our <u>legal notices</u>.

Key Contacts

Dr. Michael Tuscan Washington, DC

mtuscan@cooley.com +1 202 842 7802 Dr. Matthew Langer New York mlanger@cooley.com +1 212 479 6280

This information is a general description of the law; it is not intended to provide specific legal advice nor is it intended to create an attorney-client relationship with Cooley LLP. Before taking any action on this information you should seek professional counsel.

Copyright © 2023 Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304; Cooley (UK) LLP, 22 Bishopsgate, London, UK EC2N 4BQ. Permission is granted to make and redistribute, without charge, copies of this entire document provided that such copies are complete and unaltered and identify Cooley LLP as the author. All other rights reserved.