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### **Are Isolated Genes Unpatentable? The U.S. Government Thinks So.**

In March 2010, the district court for the Southern District of New York held that “isolated DNA” does not qualify as patentable subject matter under 35 USC §101. *Ass’n for Molecular Pathology and ACLU v. USPTO and Myriad* (S.D.N.Y. 2010). While the decision was groundbreaking and un-nerving for biotechnology and pharmaceutical companies, the overall consensus in the patent community has been that the decision would be overturned in the pending appeal before the Court of Appeals for the Federal Circuit (“Federal Circuit”).

The consensus may be wrong, or at least wavering, in light of a friend-of-the-court brief (“amicus curiae” brief) filed on October 29<sup>th</sup> by the U.S. Department of Justice (“DOJ”). In the brief, the DOJ argues that isolated, but otherwise unmodified genomic DNA, is not a human-made invention, and therefore not patent-eligible subject matter. Brief of Amicus Curiae at 17-18, *Ass’n for Molecular Pathology et al. v. USPTO et al.*, Appeal from SDNY, case no. 09-CV-4515 (No. 2010-1406). The conclusions and opinions expressed by the DOJ in its brief represent a reverse of longstanding policy of the U.S. Federal Government.

It goes without saying that the new position of the Federal Government will have significant impact on industries related to biotechnology. Indeed, if the Federal Circuit adopts this new position, many companies and government agencies will be unable to obtain and/or maintain patents that claim isolated genes. As such, it is expected that many biotechnology and pharmaceutical companies will also file briefs with the court in an effort to persuade the Federal Circuit to maintain the status quo, *i.e.*, that isolated genes are patent eligible material.

While the battle carries on in court, we encourage all of our clients in the biotechnology and pharmaceutical fields to continue documenting inventions and seek counsel concerning their intellectual property needs.

Link to Amicus brief (courtesy of Patentlyo.com and The New York Times):  
<http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf>

Addressee  
Date  
Page 2