Supreme Court to Rule on Patentability of Human Genes

by Guest Contributor and John Conley and Dan Vorhaus

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The Supreme Court today granted a writ of *certiorari* (meaning they agreed to hear the appeal) in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc., et al.*, the famous case centered on patents covering two human genes: BRCA1 and BRCA2.

Of note is that the Court limited its grant of the appeal to the first of the three questions posed by the petitioners/plaintiffs: "*Are human genes patentable?*"

What that means is that the Court has declined to take up other questions presented about method claims and about standing to sue. As a result, the Federal Circuit's prior holding that the bulk of Myriad's challenged diagnostic method patents are invalid is now a final decision. This comes as no surprise given the Supreme Court's recent and decisive opinion tightening the criteria for medical method patents in *Prometheus v. Mayo*, handed down earlier this year.

Instead, the Court will address - and will *only* address - the central point of disagreement in the 2-1 decision of the Court of Appeals for the Federal Circuit of August 16, 2012. In that ruling, Judges Lourie and Moore were in the majority, upholding their previous 2011 ruling that isolated DNA molecules are patentable subject matter. Judge Bryson dissented with that part of the ruling, and the Solicitor General has twice (here and here) filed briefs in the case that track closely to Judge Bryson's dissent.

By granting the appeal, the Supreme Court is now poised to finally address the key point of contention in a series of lengthy and contradictory rulings that began in 2010 with a ruling from a US Federal District Court and continued through the the Court of Appeals for the Federal Circuit (which hears appeals of all US patent cases). It is expected that the Supreme Court will hand down its ruling in *Myriad* by June 2013.

As for the substance of that ruling, while there will be plenty of speculation about what the Supreme Court's decision to grant *certiorari* portends for the future of gene patents, all we know for certain is that four justices (the minimum number needed to grant *certiorari* in any case) have something that they want to say about the matter. We do not know what any individual justice might want to say, or even whether the other five justices want to say anything at all.

Perhaps, the Court will reverse the Federal Circuit's prior holdings and find Myriad's gene patents invalid. Or perhaps, the Court will affirm the Federal Circuit, and in so doing clarify the law surrounding product patents, including gene patents. Come next summer we will finally have our answer (at which point we can all move on to the next controversy in genetic testing).