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Myriad Uncertainties Re: U.S. Supreme Court Ruling

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Angelina Jolie recently disclosed her decision to undergo a double mastectomy after testing positive for a genetic mutation to the BRCA1 gene that meant her risk of developing breast cancer could be as high as 87%. Jolie's decision illuminates a developing question in patent law: should human genes and diagnostic testing of genes be patentable? The U.S. Supreme Court recently answered that question, ruling that human genes cannot be patented. The Supreme Court's decision impacts diagnostics, personalized medicine, and biotechnology companies, and opens new genetic testing options.

In its unanimous June 13, 2013, decision in ***Association for Molecular Pathology v. Myriad Genetics*****,** the Supreme Court ruled patent claims controlled by Myriad covering the isolated DNA sequences of BRCA1 and BRCA2, two human genes linked to breast and ovarian cancer, were not eligible for patent protection. The Supreme Court's decision has profound public policy and patent law implications, and is the final word in the Myriad case that has been working its way up and down the court system for the past four years.

The Supreme Court decided to hear the Myriad case for the second time in late 2012, and heard oral arguments before a packed courthouse on April 15, 2013. Myriad argued the claimed genes were patentable as products of human ingenuity because Myriad isolated the genes by cleaving them from flanking DNA. Myriad also asserted that gene patents are essential to incentivize research innovation and bring life-saving products to market. In opposition, the American Civil Liberties Union and the Public Patent Foundation, on behalf of the plaintiffs, asserted that Myriad merely uncovered a functional use of specific human genes, which are patent-ineligible natural products. The U.S. government also participated and encouraged the Supreme Court to find the claims to human genes should not be patentable, while claims to DNA sequences not found in nature, such as complementary DNA (cDNA), could be patented.

In its unanimous decision, the Supreme Court ruled that naturally occurring DNA molecules are products of nature, even when isolated, and therefore not patent-eligible. However, the Supreme Court also found that cDNA, which is artificially synthesized from the genetic template, is patent-eligible. The impact of the Supreme Court decision will be widespread in terms of patenting: **more than 40% of the human genome is currently covered by patents, including almost 3000 patents directed to isolated DNA molecules like the Myriad patents. The validity of these patents is now called into question.**

The Supreme Court decision is a blow to biotech companies that hold gene patents, but could be a boon to the diagnostics industry by opening new avenues for research and genetic testing. Many diagnostics industry experts believe the decision removes obstacles so genetic testing will become more widespread and affordable. Several diagnostic companies, including Quest Diagnostics, Gene By Gene, Ambry Genetics, and GeneDx, have announced that they will begin pursuing cancer-diagnostic tests using the BRCA genes to compete with Myriad's offerings. Despite the Supreme Court's ruling, Myriad asserts that its 24 patents and more than 500 enforceable claims provide "strong patent protection" for its tests. Only time and further legal challenges will determine the true scope of the Supreme Court's ruling.

Wall Street is watching the case as Myriad's stock price dropped nearly 25% in the seven trading days following the Supreme Court ruling, while other genetics and diagnostic companies have rallied on the decision. From a public policy standpoint, the case's impact on innovation is controversial: does patent protection encourage innovation? Or would industry growth result if companies could offer competing tests for any gene? The aftershocks of the Supreme Court decision will be felt for many years.

The Myriad case is a landmark in gene patenting. The case extends beyond isolated genes and will have far-reaching implications for the patent system, the IVD industry, investors, and patients for years to come. If you are still looking for summer reading material, you should put the Supreme Court's decision on your must-read list.

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