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Myriad's Breast Cancer Test Patents Not Patent Eligible

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Following a 2013 decision in which the **Supreme Court invalidated Myriad Genetics, Inc.'s patents on human genes**, the Federal Circuit this month went a step further, **and held that Myriad's breast cancer test patents are also patent ineligible under Section 101**. *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patient Patent Litigation*, (Fed. Cir., Dec. 17, 2014). The Federal Circuit's decision calls into question broad categories of patents in biotechnology, life sciences, and related fields involving uses and methods of natural materials. In the 2013 Supreme Court case, the Court invalidated claims of Myriad's '282 patent directed to isolated DNA strands, including typical strands and mutations that are correlated to an increased likelihood of developing certain breast or ovarian

cancers. The Supreme Court held that the claims directed to the isolated DNA were patent ineligible because the isolated DNA strands were naturally occurring and a natural phenomenon.

In this new Federal Circuit opinion, the court addressed the validity of different claims of the same '282 patent and related patents, including composition of matter and method claims. The composition of matter claims were directed at synthetically replicated primers that contained the identical DNA sequences of the naturally occurring DNA strands that the Supreme Court found to be patent ineligible in the earlier case. The Federal Circuit held the composition of matter claims invalid on the same grounds, explaining that "neither naturally occurring compositions of matter, nor synthetically created compositions that are structurally identical to the naturally occurring compositions, are patent eligible."

The method claims were directed to screening for alterations of the BRCA1 genes, and involved comparison of the subject's gene sequence to that of a typical or "wild-type" gene. The Federal Circuit held that the method claims were patent ineligible under Alice in that: (1) they were unpatentable "abstract ideas" comprised of comparing two gene sequences; and (2) the claims did not add any "inventive concept," but recited routine and conventional steps that were already well known by scientists involved in making and analyzing such comparisons. This case could have broad implications for the validity of a wide range of patents involving natural materials, synthetic replications, or methods for analyzing, comparing, or manipulating those materials.

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