

CAFC DETERMINES THAT DNA SEQUENCES ARE PATENTABLE (August 2011)

On July 29, 2011, the Court of Appeals for the Federal Circuit (CAFC) determined that claims for isolated DNA are eligible for patenting. The decision was rendered in the case of *Association for Molecular Pathology ("AMP") v. U.S. Patent and Trademark Office ("Myriad")* case). Myriad owns patents directed to isolated gene sequences for BRCA1/BRCA2 and certain mutations associated with a predisposition for developing breast and ovarian cancer. Myriad is the only provider of BRCA1/BRCA2 testing in the U.S. The patents prevent other testing labs from conducting screens for isolated BRCA1/BRCA2. AMP members wanted to conduct these assays in their own testing labs but were fearful that Myriad would sue them for patent infringement. Therefore, AMP, on behalf of its members, filed suit against Myriad to invalidate the Myriad patents. They alleged that DNA, as a product of nature, is not patentable.

The Court's opinion was based upon the USPTO's 30 year policy that isolated DNA is patentable and the differences between isolated DNA not found in the body and native DNA found in the body. The Court determined that isolated DNA is different from native DNA. For example, the *BRCA1* gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides. Isolated DNA, in contrast, is a free-standing portion of a native DNA molecule, frequently a single gene. Isolated DNA has been cleaved (*i.e.*, had covalent bonds in its backbone chemically severed) or synthesized to consist of just a fraction of a naturally occurring DNA molecule. *BRCA1* with introns (non-coding nucleotides) consists of just 80,000 or so nucleotides and without introns, *BRCA1 shrinks* to just around 5,500 nucleotides. Based upon these differences, the Court found that the isolated DNA claims are patentable subject matter because they cover molecules (isolated DNA) that are markedly different (have a distinctive chemical identity and nature) from native DNA.