August 27, 2012

In yet another turn in the ever-winding road of patent-eligible subject matter disputes, the Court of Appeals for the Federal Circuit has issued its opinion in the highly anticipated case *Association for Molecular Pathology (AMP) and ACLU v. USPTO and Myriad Genetics*, Slip Op. 10-1406 (Fed. Cir. 2012). To the relief of many, the court ruled that composition claims to "isolated" DNA molecules are patent-eligible products of nature because they represent a nonnaturally occurring composition of matter. In contrast, the court reiterated its view that claims to methods of "comparing" or "analyzing" DNA sequences are not patent-eligible because such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.

The technology in question covered isolated breast cancer susceptibility genes ("BRCA") and associated diagnostic methods with patent claims directed to: 1) compositions of isolated DNA molecules; 2) methods of comparing DNA sequences; and 3) methods of screening potential cancer therapeutics. For each of these claim types, the court was asked to determine which, if any, are patent-eligible under 35 U.S.C. §101.

Composition claims are patent-eligible. In answering the question regarding compositions of isolated DNA, the court relied on the well-established Supreme Court *Chakrabarty*[1] and *Funk Brothers*[2] decisions to hold that isolated DNA molecules are "obtained in the laboratory and are man-made, the product of human ingenuity" and that the "challenged claims are drawn to patent-eligible subject matter because the claims cover molecules that are markedly different—have a distinctive chemical structure and identity—from those found in nature." Specifically, the court noted that the isolated DNAs at issue are each in a distinctive chemical form, are free standing portions of larger natural DNA molecules, and have chemical bonds severed. The court additionally made a point of stating that this holding was in line with the long history of accepting isolated DNA molecules as patent-eligible and that to make a dramatic change that would upset the longstanding system should be left to Congress.

Method claims may be patent-eligible. Turning to the method claims, the court clearly had the recently decided *Prometheus*[3] decision in mind and reached different conclusions. For the method of screening cancer therapeutics, the court concluded that a claim directed to growing transformed cancer cells followed by measuring the respective growth rates are patent-eligible because the claim at issue recites more than an abstract mental step of comparing numbers and goes further by applying certain steps to transformed cells that are man-made. According to the court, the fact that claim includes "steps of determining the cells' growth rates and comparing growth rates does not change the fact that the claim is based on a man-made, non-naturally occurring transformed cell," which is by definition patent-eligible subject matter.

In contrast, the court held that claims directly solely to analyzing and comparing naturally occurring DNA sequences are not patent-eligible because such claims amount to abstract mental processes. The claim at issue is to a method for screening a tumor sample by comparing a BRCA1 gene from a tumor sample to a BRCA1 gene from a non-tumor sample where a difference in sequence indicates an alteration in the tumor sample. The court deemed this comparison not patent-eligible because the claim "recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences" and limiting the comparison to particular genes, such as BRCA, or to particular alterations of genes "fails to render the claimed process patent-eligible."

Take home point. The court's *Myriad* decision is a welcomed guidepost to practitioners wrestling with patentable subject matter questions because the decision solidifies issues surrounding composition of matter claims while clarifying that method claims with a transformative step involving man-made products are patent-eligible. The court has also seemingly opened the door to considering that sample processing, extracting, or sequencing steps might be sufficiently transformative. Looking ahead, practitioners trying to add such steps to claims may want to weigh carefully the value of such claims against the ability to assert them against an

opponent in litigation. n

Notes

1 447 U.S. 303 (1979).

2 333 U.S. 127 (1948).

3 566 U.S. ___ (2012).

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