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Isolated Genes Remain Patentable
Federal Circuit Revisits Issue in Light of Supreme Court's *Mayo* Ruling

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In a very important decision for the biotech industry, the Court of Appeals for the Federal Circuit recently reaffirmed its holding that patent claims directed to isolated genes and a method that uses the genes to screen for breast cancer risk are patent eligible.

In contrast, claims directed to methods of analyzing or comparing a patient's sequence of a BRCA1 gene or BRCA1 RNA with a wild-type sequence to reveal cancer-predisposing mutations are patent ineligible (see *Assn. for Molecular Pathology v. U.S. Patent and Trademark Office,* a.k.a., *ACLU v. Myriad Genetics*).

Since this holding mirrored the Federal Circuit's previous decision in this case, the Supreme Court's recent ruling in *Mayo* did not alter the Federal Circuit's earlier conclusion (see *Assn. for Molecular Pathology v. U.S. Patent and Trademark Office and Mayo Collaborative Services v. Prometheus Laboratories, Inc.*).

In *Mayo*, the Supreme Court held this past March that patent claims reciting diagnostic methods that "essentially claim natural laws" by adding routine steps are patent ineligible (*Assn. for Molecular Pathology*).

In view of this holding, the Supreme Court vacated and remanded the Federal Circuit's previous decision in the present case, forcing the Federal Circuit to reconsider whether the following groups of claims are patent eligible in view of *Mayo*: (1) claims directed to two isolatedtgenes, BRCA1 and BRCA2, (2) claims directed to a method for screening potential cancer therapeutics by monitoring cell growth rates of transformed cells containing an altered BRCA1 gene, and (3) claims directed to methods of comparing a patient's sequence of a BRCA1 gene or BRCA1 RNA with the wild-type sequence to reveal mutations that may predispose the patient to cancer.

Although the district court held that all three groups of claims were patent ineligible, the Federal Circuit affirmed and has now reaffirmed, in view of *Mayo*, that the first and second groups are, in fact, patent eligible. This conclusion survived the *Mayo* decision, because the Federal Circuit held that *Mayo* was inapplicable to the first group of claims, which recite new compositions of matter.

For such compositions, the Federal Circuit stated that the question is whether "they claim patent-ineligible products of nature". Since the isolated molecules "are not found in nature" because "[t]hey are obtained in the laboratory and are man-made", the claims reciting them are patent eligible.

The second group also is patent eligible, according to the Federal Circuit, because the "man-made" nucleic acid molecules play a central role in the claimed method. The method has three basic steps: growing a transformed eukaryotic host cell containing an altered BRCA1 gene in the presence of a compound suspected of being a cancer therapeutic, growing the transformed eukaryotic host cell in the absence of the compound, and comparing the rates of growth of the two host cells.

The first step is the key to patent eligibility, because the Federal Circuit stated that "we once again, even in light of *Mayo*, arrive at the same conclusion because at the heart of claim 20 is a transformed cell, which is made by man, in contrast to a natural material".

Based on similar reasoning, the Federal Circuit held that the third group of claims is patent ineligible because the claimed methods do not rely on the growth of a man-made material. Instead, the third group of claims recite "methods of 'analyzing' or 'comparing' a patient's BRCA sequence with the normal, or wild- type, sequence to identify the presence of cancer-predisposing mutations". A claim reciting the comparison of these two natural, unmodified specimens is not patent eligible "because they claim only abstract mental processes".

Therefore, for all three groups of claims, the Federal Circuit's decision regarding patent eligibility hinged on the finding that the isolated genes are not "found in nature". This conclusion, however, did not garner the approval of one of the judges on the three-judge panel. The dissenting judge argued that extracting

a gene is like "snapping a leaf from a tree", an action that does not render the leaf a patent-eligible "human-made invention".

This logic complies with *Mayo*, according to the dissent, because "[j]ust as a patent involving a law of nature must have an 'inventive concept' that does 'significantly more than simply describe . . . natural relations,' . . . a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product". Interestingly, the dissent explicitly noted that *Mayo* "does not decide this case", but that its "analysis is nonetheless instructive".

Disregarding *Mayo's* holding as completely inapplicable, the majority discounted the dissent's argument by asserting that "[a]ll new chemical or biological molecules, whether made by synthesis or decomposition, are made from natural materials" and, as a result, "are different from natural materials, even if they are ultimately derived from them".

This reasoning closely follows that of the Supreme Court's landmark *Chakrabarty* decision, which held that "[t]he relevant distinction for purposes of [patent eligibility] is . . . between

products of nature . . . and human-made inventions" (*Diamond v. Chakrabarty*). Therefore, the claimed man-made genes are patentable and *Mayo* does not apply, according to the majority.

These divergent views indicate that it is not easy to distill overarching principles of patent eligibility of DNA/RNA from *Mayo* and *Chakrabarty*. As a result, these issues could be further settled by the Supreme Court if the Court accepts the petition for writ of certiorari filed by the ACLU on September 24, 2012.

Even if the natural versus unnatural origin issue is settled, this case does not shed much light on the scope of protection that method claims directed to diagnostic testing and personalized methods will receive in view of *Mayo*.

The analysis concerning the third group of claims in the present case offers little insight, because the claims simply recite the comparison of two naturally occurring materials without requiring any transformative steps. Patent applicants are advised to clearly include novel molecules or physical steps, such as sample isolation and laboratory testing, for their diagnostic testing claims to be patent eligible.