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LEGAL ALERT

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Isolated DNA Molecules Are Patentable Chemical Entities, and Patent-Eligible Diagnostic Methods Must Include Transformational Steps

In a vindicating win for the biotechnology industry, the Court of Appeals for the Federal Circuit in *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* (Fed. Cir. No. 2010-1406) on July 29, 2011, reversed the lower court and held that "isolated" DNA, including genes and sequence-specific probes for detecting breast and ovarian cancer, are patent-eligible subject matter, since these molecules are "markedly different" new chemical entities that do not exist in nature. The Federal Circuit further found Myriad's method claims for screening therapeutic candidates to be patent-eligible since the claims recite transformative steps, rather than merely mental comparisons between sequences, but found the diagnostic method claims to be too abstract.

The defendant Myriad's request to dismiss the case for a lack of standing was also rejected on the basis of plaintiff Dr. Ostrer's ability to practice the claimed invention. However, lawyers for Dr. Ostrer filed a letter with the court on the same day as the decision indicating that he may no longer have that capacity at his new academic position.

Next, it is likely that the parties will seek *en banc* review, to include revisiting the standing issue, and then *certiorari* review by U.S. Supreme Court. However, the reasoning in this decision is consistent with recent Federal Circuit and Supreme Court precedent for patenting of compositions and method claims, and provides some much-needed clarity in this area of patent law muddied at the district court level.

Composition Claims to "Isolated" DNA Molecules

Judge Lourie wrote for the majority, stating that based on Supreme Court decisions such as *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), and *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948), a line had been drawn between unpatentable compositions having similar characteristics to those found in nature, and patentable compositions that human intervention has given markedly distinctive characteristics. Applying this test for the purpose of patent eligibility under 35 U.S.C. § 101, the majority concluded that the composition claims to isolated BRCA1 and BRCA2 DNA molecules qualify as man-made patentable subject matter because they have a markedly different chemical identity and nature from genetic molecules that exist in nature.

In reaching this conclusion, Judge Lourie first distinguished "isolated" DNAs from native DNAs existing in the body, stating that "human intervention in cleaving or synthesizing a portion of a native chromosomal DNA imparts on that isolated DNA a distinctive chemical identity from that possessed by native DNA." Second, he stated that isolated DNA is more than just purified DNA; it is not only removed from its native cellular and chromosomal environment, but is also manipulated chemically to become markedly different through cleavage from its chemical combination with other genetic materials existing in the body. When cleaved, an isolated DNA molecule is not a purified form of a natural material, but a distinct chemical entity. Third, Judge Lourie stated that the unchanged informational content of the isolated DNAs, relied upon so heavily in the patent-eligible product of nature finding by the lower court, is irrelevant to the issue. It is the distinctive nature of DNA molecules as isolated compositions of matter that determines their patent eligibility, rather than their physiological use or benefit, according to Judge Lourie.

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Regarding the various hypothetical analogies for patent ineligibility (e.g., lithium mined from the earth, kidneys taken from a body, or a leaf plucked from a tree) raised by the plaintiffs and their supporting *amici* briefs, Judge Lourie stated that "[n]one of these examples presents a composition claim to a distinctive chemical identity from that of the native element, molecule, or structure," and noted that "isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect." This Federal Circuit decision comports with the longstanding practice of the USPTO, which has issued patents to isolated DNAs for almost thirty years. Changes to this longstanding practice to exclude DNA inventions must come from Congress, not the courts, said Judge Lourie.

Judge Moore joined the majority as to isolated DNAs, but questioned whether longer strands of DNA are an unpatentable category whose utility might simply serve the same as that in nature, namely, as a gene to encode a protein. Judge Bryson agreed as to the patentability of cDNA, but disagreed with Moore's length-based mechanism for distinction and Lourie's view of the marked differences in characteristics of isolated genomic DNA and fragments. It should be noted that among the fifteen claims and seven patents at issue, this case did not challenge other man-made recombinant DNA construct and host claims, which unquestionably meet the requirements of patent eligibility.

Process/Method Claims

The Federal Circuit again applied the "machine-or-transformation" test, recently approved by the Supreme Court in *Bilski v. Kappos*, 130 S. Ct. 3218 (2011), to unanimously rule on patent eligibility of the following method claims.

a) *Diagnostic Claims of "Comparing" and "Analyzing" DNA Sequences are Patent- Ineligible*

The Court held that Myriad's diagnostic claims of merely "comparing" and "analyzing" two DNA sequences are directed to an abstract mental process that does not include any transformative step, such as would have been attained by patent qualifying steps such as isolating, extracting, or sequencing. "Neither comparing nor analyzing means or implies 'extracting' or 'sequencing' DNA or otherwise 'processing' a human sample," according to Judge Lourie (*citing Prometheus Labs., Inc. v. Mayo Collaborative Servs*, 628 F.3d 1347 (Fed. Cir. 2010), *cert*. granted 2011 WL 973139 (June 20, 2011)). Therefore, these process claims were affirmed as patent-ineligible under § 101 for failure to satisfy the machine-or-transformation test.

The Court distinguished these claims from similar diagnostic claims which it recently found valid in the *Prometheus* case, because those claims included the transformational step of "determining" the sequence, which the Court said implied isolating and sequencing steps, rather than merely a comparative mental process.

b) *Screening Claims for Potential Cancer Therapeutics are Patent- Eligible*

In contrast, the Court found valid Myriad's screening claim for potential cancer therapeutics, which included the active terms "growing," "determining," and "comparing" as transformative steps that are "central to the purpose of the claimed process" and more than the abstract mental step of looking at and comparing two numbers (*citing Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010)). This claim was found to present functional and palpable applications in the field of biotechnology, and to qualify as patentable subject matter under § 101.

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Conclusions

This Federal Circuit decision on patenting of DNA and diagnostic and screening methods balances legal precedent and public policy upon the scale of scientific endeavor, essentially finding that chemical transformations of material are sufficient to confer patent eligibility. Patent law protection excludes that which is naturally occurring, a law of nature, or an abstract mental process. Of course, in addition to qualifying as patentable subject matter, the claims must also be novel and non-obvious and meet the written description requirements.

Patent applicants will benefit from ensuring that claims to diagnostic and related methods incorporate active transformational steps, such as extracting, isolating or amplifying the DNA, rather than merely observational comparisons. While appellate review of the *Myriad* case will undoubtedly follow, this decision is generally consistent with the expectations of those in the biotechnology industry and supports the continued development of useful diagnostic tools and therapeutics based on patent protection.

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If you have any questions about this Legal Alert, please feel free to contact any of the attorneys listed below or the Sutherland attorney with whom you regularly work.

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