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LEGAL ALERT

April 4, 2012

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Will the Myriad Gene Patent Claims Be Found to Have "Added Enough?"

by Chuck Hauff, Bill Mulholland and Jeremy Kapteyn

On Monday, March 26, 2012, the U.S. Supreme Court sent the *Myriad* gene patent case back to the Federal Circuit in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 US ____ (2012). The prior Federal Circuit decision, issued by a divided panel in July of 2011, generally upheld the patentability of genes and genetic methods. Late last year, a petition for certiorari was filed before the Supreme Court. *Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office*, 653 F.3d 1329 (Fed. Cir. 2011), *petition for cert. filed sub nom*, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (Dec. 7, 2011) No. 11-725. Monday's decision granted certiorari and summarily vacated that prior decision, remanding the case back to the Federal Circuit for further consideration in light of *Prometheus*.

The patent claims at issue in the *Myriad* case fall into three general categories: 1) compositions of isolated DNA; 2) methods of screening for potential cancer

therapeutics; and 3) diagnostic methods, generally relating to identifying potential genetic alterations in the BRCA1 'breast cancer gene;' the methods directed to analyzing human samples for the presence of certain mutations, or comparing human tumor samples against non-tumor samples for the presence of alterations.

The District Court found that those claims comprised non-patentable subject matter. Compositions of isolated DNA were deemed to fall within the judicially created "products of nature" exception under 35 U.S.C. §101. The court reasoned that isolated DNA molecules were not markedly different from native DNA. The method claims were found to cover DNA sequence analyses or comparisons by essentially any method and thus, to be so broad in reach that they covered mental processes, independent of any physical transformation.

The Federal Circuit opinion was fractured. The majority opinion was written by Judge Alan Lourie. A concurring opinion by Judge Kimberly Moore joined certain aspects of the majority opinion (including the conclusion that human gene cDNAs are patentable) and merely concurred-in-part with other aspects. Judge William Bryson's opinion concurred-in-part and dissented-in-part with the majority opinion. Together, Judge Lourie and Judge Moore held that the claims directed to DNA molecules (isolated genomic DNAs) and screening were patentable subject matter, but that the diagnostic methods did not constitute patentable subject matter.

As noted in our previous alert, the Supreme Court's analysis in *Prometheus* focused heavily on assessing whether the claims improperly tie up future uses of laws of nature. Specifically, the Court set forth a two-part rubric – "inhibiting future innovation" and "monopolizing natural phenomena" – which now become prisms through which lower courts must assess such questions of patent eligibility to ensure that the claims "add enough" to the natural law or correlation in order to delineate patentable subject matter. Notably, the divided Federal Circuit's *Myriad*

decision addressed these themes.

DNA has been routinely patented in the United States. Isolation and purification of a natural substance was *the* key metric by which such patentability questions were judged. For more than a decade, Patent Office policy recited that "[a]n isolated and purified DNA molecule that has the same sequences as a naturally occurring gene is eligible for a patent because…that DNA molecule does not occur in that isolated form in nature…" 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). It is estimated more than 2,600 patents have been issued which claim isolated DNA.

Rather than rely on the purification argument traditionally used to support the patentability of natural products, the majority in the Federal Circuit's *Myriad* decision delved significantly into the chemistry of nucleic acids in assessing the underlying "products of nature" doctrine. It found that the breaking of chemical bonds that occurs in the course of isolation of the claimed DNA was necessary and sufficient to distinguish the isolated DNA from native DNA; i.e., that it was sufficiently *transformative* to delineate patentable subject matter.

The majority articulated what it saw as the Supreme Court's test:

> The distinction, therefore, between a product of nature and a human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. Specifically, the Supreme Court has drawn a line between compositions that, even if combined or altered in a manner not found in nature, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics. *Id. Hartranft, 121 U.S. at 615; see also Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931).

The claimed isolated DNA molecules were found to meet this test, not simply due to mere isolation from associated cellular and chromatin material, but because of a more nuanced understanding of the underlying chemistry of genomic DNA:

> It is undisputed that Myriad's claimed isolated DNAs exist in a distinctive chemical form -- as distinctive chemical molecules -- from DNAs in the human body, i.e., native DNA. Native DNA exists in the body as one of forty-six large, contiguous DNA molecules. Each DNA molecule is itself an integral part of a larger structural complex, a chromosome. In each chromosome, the DNA molecule is packaged around histone proteins into a structure called chromatin, which in turn is packaged into the chromosomal structure…
>
> 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. For example, the BRCA1 gene in its native state resides on chromosome 17, a DNA molecule of around eighty million nucleotides…In contrast, isolated BRCA1…consists of just 80,000 or so nucleotides…Accordingly, BRCA1 [in its isolated state is] not the same molecules as DNA as it exists in the body; 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*. (Emphasis added).

This chemical/structural distinction forms the basis of the majority's determination that the claimed DNA is not, as it is "in nature, . . . covalently bonded to such

other materials" but is sufficiently transformed into something "markedly different – hav[ing] a distinctive chemical identity and nature" from the DNA as found in human cells to be patentable subject matter. The method claims were also decided under a transformation rubric, and the Federal Circuit found that the diagnostic method claims at issue recited mere mental steps of comparing or analyzing, and thus were not patentable, while the screening method was found to satisfy a transformation because of the recited step of growing eukaryotic cells, among others.

But Judge Moore's concurring opinion points to at least one pitfall with this structure-based approach, because, as she notes, if deciding the case on a blank canvas, she "might conclude that an isolated DNA sequence that includes most or all of a gene is not patentable subject matter." This would be due to the fact that "[d]espite the literal chemical difference, the isolated full length gene does not clearly have a new utility and appears to simply serve the same ends devised by nature, namely to act as a gene encoding a protein sequence." But the utility of the sequences in this case are not the same. The utility of the native DNA within an organism is not the same as for the isolated DNA. Native DNA, of course, sets forth instructions for a cell, while the claimed BRCA1 sequence is utilized as an analytical tool for detecting the presence or absence of human gene sequences linked to an increased risk of breast cancer.

On remand, the question of whether isolated genes are patentable subject matter will likely be assessed differently under the *Prometheus standards* of "inhibiting future innovation" and "monopolizing natural phenomena." The Federal Circuit will need to analyze whether the claims to a composition of matter that is also embodied in genomic DNA found in nature *add enough* such that they cannot be found to disproportionately tie up the use of underlying products of nature; they cannot be said to inhibit the making of further discoveries in other fields, particularly those fields not contemplated by the

patentees. The Supreme Court stated that "to transform an unpatentable law of nature into a patent-eligible application of such a law, a patent must do more than simply state the law of nature while adding the words 'apply it.' … It must limit its reach to a particular inventive application of the law."

Curiously, it was this issue that divided the Federal Circuit. In his dissent from the majority opinions, Judge Bryson noted as follows: "In its simplest form the question in this case is whether an individual can obtain patent rights to a human gene. From a common-sense point of view, most observers answer, 'Of course not. Patents are for inventions. A human gene is not an invention.'"

Perhaps even more telling is Judge Bryson's view that extending patent protection to gene fragments and isolated human genes has significant and potentially far-reaching stifling effects. Specifically, as Judge Bryson noted, "if sustained the court's decision will likely have broadened consequences, such as preempting methods for whole genome sequencing even though Myriad's contribution to the field is not remotely consonant with such effects." As Judge Bryson reasoned in his dissent:

> Of course, Myriad is free to patent applications of its discovery. As the first party with knowledge of the sequences, Myriad was in an excellent position to claim applications of that knowledge… Yet some of Myriad's challenge compositions claims effectively preempt any attempt to sequence the BRCA genes including whole genome sequencing. In my view those claims encompass unpatentable subject matter and a contrary ruling is likely to have substantial effects on research and treatment in this important field.

The type of analysis employed by Bryson was prevalent in the Supreme Court's unanimous

decision. Specifically, the Supreme Court in *Prometheus* was clearly concerned with the breadth of the claims and the likelihood that the patents would foreclose more future invention than the underlying discovery could reasonably justify.

While the real world success of the biotechnology industry perhaps suggests otherwise, namely that science and industry are not being harmed by – but rather enhanced by – the issuance of such patents, the Federal Circuit may be challenged to explain that the Myriad patents "add enough" to constitute patentable subject matter and prevent a negative impact on future innovation. The Supreme Court's forceful unanimous decision in *Prometheus* likely means that the Federal Circuit will have to defend its majority position from the *Myriad* decision: that the claimed isolated genes are sufficiently "markedly different" from those of the human subject from which they originated to constitute patentable subject matter.

We will continue to monitor these matters.

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