Federal Circuit Holds Claims to Isolated DNA Molecules Patent-Eligible

August 16, 2012

In July of 2011, in Myriad I, the Federal Circuit Court of Appeals held as follows regarding the appeal from the Section 101 "patent eligibility" rulings made by the Southern District of New York court:

1. The Court of Appeals reversed the district court's decision that Myriad's composition claims to "isolated" DNA molecules cover patent-ineligible products of nature under § 101, because the molecules as claimed do not exist in nature.
2. The Court also reversed the district court's decision that Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates is directed to a patent-ineligible scientific principle.
3. The Court affirmed the district court's decision that Myriad's method claims directed to "comparing" or "analyzing" DNA sequences are patent ineligible; because such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.

An appeal to the Supreme Court was taken and the petition for certiorari was granted on March 26, 2012. However, the Supreme Court vacated the Federal Circuit's decision and remanded the case to the Court of Appeal for further consideration in light of its decision in Mayo Collaborative Services v. Prometheus, Inc., 132 S. Ct. 1289 (2012).

On August 16, 2012, in Myriad II, the Federal Circuit again held as follows regarding the appeal from the Section 101 "patent eligibility" rulings made by the Southern District of New York court:

1. The Court of Appeals reversed the district court's decision that Myriad's composition claims to "isolated" DNA molecules cover patent-ineligible products of nature under § 101 since the molecules as claimed do not exist in nature.
2. The Court also reversed the district court's decision that Myriad's method claim to screening potential cancer therapeutics via changes in cell growth rates is directed to a patent-ineligible scientific principle.
3. The Court affirmed the district court's decision that Myriad's method claims directed to "comparing" or "analyzing" DNA sequences are patent ineligible; because such claims include no transformative steps and cover only patent-ineligible abstract, mental steps.

Regarding the impact of the Mayo decision from the Supreme Court, Judge Lourie writing in the majority opinion stated the following regarding the DNA claims:

The Supreme Court in Mayo **focused on its concern that permitting patents on particular subject matter would prevent use by others of, in** Mayo**, the correlation recited in the method claims. Plaintiffs argue here that they are preempted from using the patented DNA molecules. The answer to that concern is that permitting patents on isolated genes does not preempt a law of nature.** A composition of matter is not a law of nature.

Regarding some of Myriad's method claims and the impact of the Mayo decision Judge Lourie stated the following:

We turn next to Myriad's challenged method claims. This court in its now- vacated decision of July 29, 2011, had held method claims 1 of the '999, '001, and '441 patents, as well as method claims 1 and 2 of the '857 patent—all of which consist of analyzing and comparing certain DNA sequences**—not to be patent-eligible subject matter on the ground that they claim only abstract mental processes. In light of the Supreme Court's decision in** Mayo**, we reaffirm that prior holding. The Court made clear that such**

diagnostic methods in that case essentially claim natural laws **that are not eligible for patent.**

Judge Moore, concurring (in part) with the majority opinion, reviewed the history of the patentability of purified natural products (e.g., Vitamin B-12, adrenaline) and stated the following in support of the Section 101 patentability of isolated DNA:

The Patent Office has, for more than a decade, affirmatively stated its belief that isolated DNA is patentable for the same reasons as isolated vitamins or hormones. There is no indication from Congress that this view is wrong; to the contrary, it appears Congress also believes DNA is patentable. This long-term policy of protecting isolated DNA molecules has resulted in an explosion of innovation in the biotechnology industry, an industry which, unlike the financial services industry or even the software industry, depends on patents to survive. Holding isolated DNA not patentable would destroy long settled industry expectations for no reason other than a gut feeling that DNA is too close to nature to be patentable, an arbitrary decision based on a judge-made exception. I believe that isolated DNA fragments, which have both chemical changes from the naturally occurring genomic DNA as well as new utility, are "the kind of 'discoveries' that the statute was enacted to protect." I therefore decline to extend the "laws of nature" exception to include isolated DNA sequences.

Judge Bryson, concurring (in part) and dissenting in part, stated the following;

I concur with the portions of this court's judgment that are directed to the patentability of the cDNA claims, and the patentability of the method claims. I respectfully dissent from the court's holding that Myriad's BRCA gene claims and its claims to gene fragments are patent-eligible.

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We are therefore required to decide whether the process of isolating genetic material from a human DNA molecule makes the isolated genetic material a patentable invention. The court concludes that it does; I conclude that it does not.

Regarding the impact of the Mayo decision on this case, Judge Bryson stated the following:

Just as a patent involving a law of nature must have an "inventive concept" that does "significantly more than simply describe . . . natural relations," Mayo**, 132 S. Ct. at 1294, 1297, a patent involving a product of nature should have an inventive concept that involves more than merely incidental changes to the naturally occurring product. In cases such as this one, in which the applicant claims a composition of matter that is nearly identical to a product of nature, it is appropriate to ask whether the applicant has done "enough" to distinguish his alleged invention from the similar product of nature. Has the applicant made an "inventive" contribution to the product of nature? Does the claimed composition involve more than "well-understood, routine, conventional" elements? Here, the answer to those questions is no.**

It is expected that this case will again go before the Supreme Court for a final determination of the Section 101 patent eligibility issues discussed above.

Click here to view the Decision.

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