CLIENT ALERT

What *Sequenom* Means for Biotech Patents: Even New Methods of Using Natural Phenomena May Not Be Patentable, Absent More

Jun.17.2015

On June 12, 2015, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the U.S. Court of Appeals for the Federal Circuit invalidated Sequenom's patent claiming methods of detecting paternally-inherited fetal DNA in a mother's blood serum or plasma, affirming the district court's decision. The decision highlights that discoveries to new, even "revolutionary," methods of detecting and analyzing naturally occurring phenomena may be ineligible for patent protection under 35 U.S.C. § 101 absent some additional contribution to the state of the art. In so holding, the court considered and rejected arguments by Sequenom that (1) limited preemption of the natural phenomenon by the claims at issue rendered the claims patent eligible; and (2) that a new application of already known steps or processes to a newly discovered natural phenomenon is itself patent eligible.

The court's decision suggests that to qualify as patentable subject matter, method or process claims to a new application of a natural phenomenon must include a step distinct from the natural phenomenon that is itself patent eligible under the Patent Act.

Until further guidance is provided by Congress or the courts, method or process claims to new applications of natural phenomena are likely to be found valid only if at least one of the method steps are novel, independently patentable subject matter. These may include novel and non-obvious laboratory techniques, modified protein or genetic sequences, transformed cells, or other novel and non-obvious contributions to the existing state of the relevant biotechnical art. Exactly what the necessary additional patentable subject matter is required after *Sequenom* remains to be seen.

The *Sequenom* court invalidated the method claims of U.S. Patent No. 6,258,540 (the '540 patent). The claims of the '540 patent were directed towards a method for detecting paternally inherited cell-free fetal DNA (cffDNA), which is naturally present in the maternal plasma and serum of pregnant women, and diagnosis of fetal characteristics based on the detection and analysis of the naturally occurring cffDNA.

According to the court, the patent specification and patent application filings made clear that the only novel, inventive aspect of the claimed invention was the inventors' discovery of cffDNA in maternal plasma and serum. Previously, researchers had discarded this portion of maternal blood samples as medical waste, irrelevant to the creation of tests for fetal characteristics such as genetic abnormalities or gender. Sequenom's MaterniT21 test, commercializing the invention claimed in the '540 patent, offers "an alternative to prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques that took samples from the fetus or placenta."

The parties agreed "that the ['540] patent does not claim cffDNA or paternally inherited cffDNA," but rather "claims certain methods of using cffDNA." Representative claim 1 of the '540 patent reads:

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

The court evaluated this and all of the claims at issue under the two-step framework of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289 (2012). Citing the specification at length, the court concluded that "the claims at issue [were] directed to a patent ineligible concept": naturally occurring cffDNA found in the blood stream of a pregnant woman. Applying the second step of the *Mayo* framework, the *Sequenom* court also concluded that the claims at issue did not "contain an additional inventive concept, sufficient to 'transform' the claimed naturally occurring phenomenon into a patent eligible application."

Notably, the court clarified that under *Mayo*, "[f]or process claims that encompass natural phenomenon," such as the ccfDNA that was the subject to the Sequenom patent, "the process steps are the additional features that must be new and useful." The court specifically rejected the patentee's arguments "that the claimed methods are patent eligible applications of a natural phenomenon," reasoning that the claims amounted to no more than a direction to apply well-known techniques to a natural phenomenon. The court did so despite agreeing that Sequenom's invention "revolutionized prenatal care."

The court also rejected Sequenom's argument that the claims were patent eligible because of the limited scope of preemption of the natural phenomenon, *i.e.*, that the claimed methods embodied only narrow and specific uses of cffDNA. The court explained that, "[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility."

In rejecting the patentee's two primary arguments, the court in essence required that at least one additional step of a process applied to a natural phenomenon must itself be independently patentable, inventive, and novel. That requirement applies regardless of the extent to which the method or process covered by the patent claims effect a preemption of the natural phenomenon.

Whether such a broad and expansive reading of *Mayo* will withstand further scrutiny remains to be seen. In a concurring opinion, Judge Linn seemed to welcome review of the "perhaps unintended" result of interpreting *Mayo's* "broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain." Sequenom has indicated it is considering its options for further appeal.

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