Published on *The National Law Review* https://natlawreview.com

Federal Circuit Invalidates Sequenom's Fetal DNA Prenatal Diagnosis Patent as Not Patent Eligible

Article By:

Intellectual Property Department Barnes Thornburg

Citing the Supreme Court's Mayo opinion and the Myriad decision, the Federal Court affirmed the District Court Summary Judgment that U.S. Patent 6,258,540 was invalid under 35 U.S.C. §101 (*Ariosa Diagnostics, Inc. v. Sequenom, Inc.*) (Decision).

> Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art. (Page 13, Decision)

This decision goes beyond the Mayo and Myriad holdings. The "methods themselves" refers to the laboratory techniques used to accomplish the claimed methods, not to the claimed methods.

Method claims were to a noninvasive prenatal diagnostic test based on detection of paternally inherited "cell-free fetal DNA (cffDNA)" in maternal blood samples. This paternal DNA was previously not known to be present, or detectable in maternal blood, and was not present in nature at levels suitable for diagnosis. The test is useful for example, to detect fetuses at risk for X-chromosome linked genetic disorders, e.g. some forms of muscular dystrophy and hemophilia. The invention was to amplify the cffDNA to levels useful for diagnosis, and to detect paternal markers. In nature, paternal DNA is not amplified in maternal blood.

The court makes it more difficult to patent innovation in biotechnology. For example, detection and application of diagnostic biomarkers to develop the personalized medicine sought after by the public, depends on many "conventional and routine" laboratory techniques to accomplish the diagnosis. The court's decision predicts that laboratory techniques used for biological inventions themselves have to be novel and patentable.

Although acknowledging that claims at issue were method claims, which are "generally eligible subject matter" (page 8, Decision) and that claims should be considered as a whole, the court pronounced that the claimed method begins and ends with a natural phenomenon, therefore is not

patent eligible.

The court did not consider that the method per se does not exist in nature, and is not a natural phenomenon or an abstract idea, but stated “the claims are directed to naturally occurring phenomenon,” referring to the cffDNA.

The court considered moot, one argument for patent eligibility, that claims do not preempt a natural product, nature phenomenon, or abstract idea.

Although claims on appeal were “method claims,” the court focused on the composition, cffDNA.

> The district court agreed with Ariosa’s argument that the claims of the ‘540 patent were directed to the natural phenomenon of paternity inherited cffDNA. (Page 7, Decision)

Therefore Sequenom’s arguments that there was no preemption failed.

> While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. (Page 14, Decision)

The court considered the contribution of man to the invention to be “discovery regarding cffDNA” and agreed that the detection of cffDNA in pregnant women’s blood "is a positive and valuable contribution to science.” (Page 16, Decision)

The court acknowledged that there are many advantages of the cffDNA diagnosis over prior art prenatal diagnosis such as amniocentesis and chorionic villus sampling, e.g. there is no risk to the fetus and costs are lower. However, the court concluded “even such valuable contributions can fall short of statutory patentable subject matter.”

National Law Review, Volume V, Number 168