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U.S. Appeals Court Strikes Blow To Diagnostic Method Patents

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The Federal Circuit has issued its long-awaited decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, but the decision is not good news for those seeking to obtain or enforce U.S. patents on diagnostic methods. The appeals court affirmed the district court's finding that Sequenom's claims are invalid under 35 USC § 101, applying the analytical framework set forth in the U.S. Supreme Court's *Mayo* decision in a way that could have a ripple effect across the diagnostic and personalized medicine industry.

The Claims At Issue

The Sequenom patent at issue was U.S. Patent 6,258,540. The claimed technology relates to diagnostic methods for determining certain fetal characteristics such as gender and genetic defects, based on paternally inherited cell-free fetal DNA (cffDNA) found in maternal plasma and serum. The independent claims at issue in this appeal are set forth below.

> 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.
>
> 24. A method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises: removing all or substantially all nucleated and a nucleated cell populations from the blood sample, amplifying a paternally inherited nucleic acid from the remaining fluid and subjecting the amplified nucleic acid to a test for the paternally [sic] inherited fetal nucleic acid.
>
> 25. A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises obtaining a non-cellular fraction of the blood sample amplifying a paternally inherited nucleic acid from the non-cellular fraction and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

The Patent Eligibility Problem

The Federal Circuit decision was authored by Judge Reyna and joined by Judges Linn and Wallach. Judge Linn also filed a concurring opinion.

The court applied *Mayo*'s two-step framework for determining patent eligibility, considering first whether the claims are directed to a patent-ineligible concept, and, if they are, determining whether the additional claim elements "transform the nature of the claim" into a patent-eligible application of the natural phenomenon.

With regard to the first step, the court noted that the claims start and end with naturally occurring material (cffDNA). Thus, the court found them to be caught by the first step of the two-step *Mayo* framework, and require analysis under the second step.

With regard to the second step, the court considered whether the process steps recite additional features that are new and useful. However, instead of considering the process steps as a whole, and recognizing that amplifying a paternally inherited nucleic acid from a serum sample from a pregnant female was ***new***, and that detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample was ***new and useful***, the court found that the method steps did not support patent eligibility because they used conventional amplification and detection techniques. The court separately considered several dependent claims, but found none to add anything "inventive" to the claimed methods.

The court's conclusion indicates how it may analyze other diagnostic method claims for patent eligibility:

> 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.

Judge Linn's Concurrence

Judge Linn's concurring opinion places blame for the result here squarely on the shoulders of the Supreme Court and its decision in *Mayo*. Judge Linn urges the Court to reconsider the *Mayo* framework, and at least permit the consideration of "post-solution activity" when that activity is novel.

A Ripple Effect Across The Diagnostic Industry

While the contours of this decision have yet to be determined, it at least appears to leave room for patent eligibility where method claims recite novel laboratory techniques or reagents. However, it may make it more difficult to obtain patents related to diagnostic methods, personalized medicine, and other method claims that involve a "natural phenomenon." Even if the Supreme Court grants *certiorari*, it will be another year before we could have a different decision. While various groups are working on possible legislative solutions to the patent eligibility problem, it will take time to negotiate statutory language that is agreeable to all stakeholders, and even longer for any proposed legislation to make is way through Congress.

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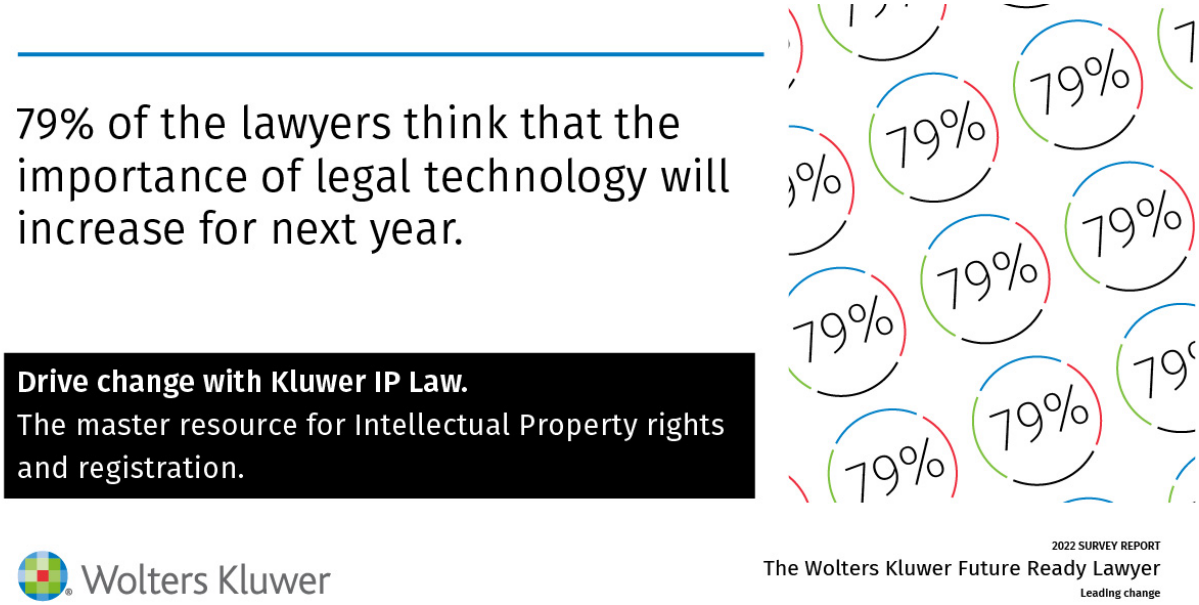

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