The Latest in The §101 Saga: Sequenom Petitions the Federal Circuit to Reconsider

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The Federal Circuit's *Ariosa v. Sequenom* decision issued earlier this summer marked the apex of the current trend to limit the scope of patent eligible inventions; the trend which is particularly troubling in the case of meritorious, life-saving inventions of new medical treatments and diagnostics.

I. Sequenom Files Petition for Rehearing En Banc

In its petition, filed with the Court of Appeals for the Federal Circuit on August 13, 2015, Sequenom argues that its case raises the following precedent-setting question:

Is a novel method patent-eligible under §101 where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates her to apply a new combination of previously known techniques to the phenomenon; and (3) she thereby achieves a previously unknown and impossible result?

Arguing that its patent claims were "*collateral damage in what is properly a war on frivolously broad claims directed to things like correlation tables and actual strands of human DNA*," Sequenom petitioned the Federal Circuit for an *en banc* review of its June 12 holding in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*. In that strikingly sweeping decision, a Federal Circuit panel invalidated U.S. Patent 6,258,540 (the '540 patent) on a diagnostic method as being directed to ineligible subject matter. Sequenom now warns that that panel's decision "reads recent Supreme Court precedent to create an existential threat to patent protection for an array of meritorious inventions" beyond those in the personalized medicine and diagnostics industries:

"If the full Federal Court does not step in and overturn its prior panel, the prior panel's rule threatens to swallow many more meritorious inventions along with this one. The core of nearly every major innovation is the discovery of a fact about the natural world that motivates inventors to combine existing techniques to achieve new practical results."

Sequenom predicts that two negative consequences will stem from the panel's decision: 1) researchers will be encouraged to keep their fundamental discoveries secret as long as possible, stymieing the progress and development of medical innovations; 2) the uncertainty engendered by the panel's test will discourage investment, as "*neither scientists nor venture*

capitalists will see much to gain in basic biomedical research."

II. Background of the Federal Circuit Panel Holding

The inventors of the '540 patent discovered that cell-free fetal DNA (cffDNA) was circulating in the blood of pregnant mothers and employed this knowledge to create maternal blood tests for fetal genetic traits and abnormalities. Claim 1 of the '540 patent covers:

> 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.*

While conceding that the discovery underlying the '540 patent was indeed ground-breaking, the panel nevertheless held that the claims failed the two-step *Mayo* framework under the earlier Supreme Court's holding in *Mayo v. Prometheus*. First, the invention was found to be directed to a patent-ineligible concept, reasoning that the method "begins and ends with naturally occurring phenomenon" (cffDNA in maternal blood and parentally inherited cffDNA). At step two, the panel examined whether the claims recite elements that amount to 'significantly more' than the judicial exception to 'transform' it into a patent eligible concept. Relying on *Mayo*, the panel stated that "for process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful." Since the intrinsic record indicated that the 'amplifying' and 'detecting' steps were well-understood in the art, they did not 'transform' the method claims into patent-eligible subject matter. The panel majority drew a parallel between the '540 patent and the claimed methods in *Mayo*, which were found to be appending conventional steps to a natural law (and therefore insufficient to supply an 'inventive concept').

Judge Linn separately argued in a concurring opinion that Sequenom's invention was nothing like the diagnostic in *Mayo*, as the latter claimed a set of steps that were already being performed by doctors. Nevertheless, he reluctantly joined the Court's opinion because the "Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though here no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers."

III. Sequenom's *En Banc* Request

Seeking an *en banc* rehearing now, Sequenom hopes that the full court will overturn the prior panel's ruling.

The petitioner (Sequenom) argues that the panel's ruling was inconsistent with the US Supreme Court decisions in *Diehr*, *Mayo*, and *Myriad.* The petitioner notes that according to *Diamond v. Diehr* "*a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.*" Sequenom then explains that the panel ignored the instruction of *Diehr* to consider the claims as a whole when determining the subject matter eligibility of process claims. Further, the fact that it was a discovery of a natural phenomenon that motivated the novel combination of steps should not foreclose patentability. Sequenom contends that the panel's ruling leads to an absurd result: a researcher can patent a useful diagnostic that combines existing techniques *only if he does not understand the natural phenomena underlying it*.

Next, Sequenom also argues that the Supreme Court *Mayo* ruling in 2013 in fact reaffirmed its 1981 holding in *Diehr* which held that a new combination of steps was patentable, even if the individual steps were known. Sequenom echoes the arguments made Judge Linn distinguishing the '540 invention from the *Mayo* diagnostic claims.

Finally, according to Sequenom, while the *Myriad* decision foreclosed claiming a natural phenomenon itself, that Supreme Court opinion also stated that "as the first party with knowledge of [a natural phenomenon], Myriad was in an excellent position to claim applications of that knowledge."

Sequenom concludes by arguing *en banc* review would be the perfect opportunity for the Federal Circuit to establish a "principled line in this difficult area that is consistent with Supreme Court precedent, continues to reject patents that purport to claim natural phenomena, and yet protects truly meritorious patents" from becoming innocent causalities in the § 101 battle.

IV. *Amici* Express Support for Court's Rehearing

On August 27, 12 *amicus curiae* briefs were filed in support of Sequenom's petition to the full court for rehearing *en banc*. The briefs can be accessed via PatentDocs.com and through the links below. The following parties have filed the briefs, and their key arguments:

1. **BioIndustry Association (BIA)** -- brief

BIA is represented in this matter by Konstantin Linnik, Lana Gladstein and Isaac Hubner of the US law firm Nutter McClennen & Fish LLP.

- The panel decision is at odds with accepted patent-eligibility standards
- The panel decision frustrates long-term harmonization efforts
- Trade secret protection is not a viable option for foreign and multinational companies

2. **Biotechnology Industry Organization (BIO)** and **Pharmaceutical Research and Manufacturers of America (PhRMA)** (joint) -- brief

- The panel decision has exacerbated uncertainty as to the availability of effective patent protection for biotechnological innovation
- This court should clarify the contours of the *Mayo* framework
- A coherent articulation of the policy basis for the patent eligibility requirement is necessary for development of the doctrine in a manner consistent with the overarching objectives of the patent system

3. **Coalition for 21st Century Medicine (C21)** -- brief

- The biotechnology industry desperately needs the full federal circuit's guidance on what constitutes patent-eligible subject matter under *Mayo* and *Myriad*
- Recent Supreme Court case law excludes relatively little subject matter from patent eligibility under 35 U.S.C. §101
- The *Ariosa* panel decision exemplifies the improper expansion of the supreme court's narrow holding in *Mayo*:
- The majority failed to correctly define the subject matter of the claims
- The majority wrongly suggests all diagnostic claims are *prima facie* patent ineligible
- The majority improperly conflates the patent eligibility test of *Mayo* with traditional obviousness analysis

4. **Intellectual Property Owners Association (IPO)** -- brief

- The *en banc* court should clarify that a claimed invention must be analyzed as a whole to determine its patent eligibility
- The *en banc* court should hold that evidence of a lack of undue preemption supports a finding of patent eligibility

5. **Twenty-three Law Professors** (joint) -- brief

- The panel decision undermines twenty-first-century innovation that the patent system is designed to promote and protect
- The panel's analysis contradicts § 101 jurisprudence as evidenced by how it casts doubts on validity of classic method patents

6. **Novartis** -- brief

- The panel decision impermissibly narrows the eligibility test for method claims by failing to consider the "claims as a whole"
- The panel decision conflicts with the broader patent law by construing patent-eligibility more restrictively than patentability
- The panel decision improperly converts the judicial exceptions into "moving targets," creating needless uncertainty and undermining the objectives of the patent system

7. **Wisconsin Alumni Research Foundation (WARF)**, **Marshfield Clinic**, and **MCIS** (joint) -- brief

- The goal of the two-step *Mayo/Alice* framework is to ensure that patentees cannot effectively monopolize natural phenomena, laws of nature, and abstract ideas—no more and no less
- Where an inventor claims only an application that makes practical use of a natural phenomenon, the claims do not monopolize the natural phenomenon itself and are patent-eligible under Section 101
- The panel's analysis of *Mayo/Alice* Step Two was mistaken because isolation, amplification, and analysis of cffDNA in maternal fluids were not conventional

8. **New York Intellectual Property Law Association (NYIPLA)** -- brief

- This case presents a fundamental issue that should be reheard *en banc*
- Reheard en banc the *Mayo* framework does not moot preemption

9. **Jyant Technologies** -- brief

- The panel's decision contravenes precedent and ignores the purpose of the patent clause
- The panel's rationale casts doubt on the patentability of numerous types of inventions

10. **Amarantus Bioscience Holdings**, **Personalis** and **Population Diagnostics** (joint) -- brief

- The lower courts and the USPTO need better guidelines on how to

determine patent-eligible subject matter
- The Supreme Court has consistently required considering the claims as a whole
- Failure to consider each claim as a whole leads to arbitrary and inconsistent results
- This court has addressed similar improper abstraction in other contexts and has required focus on the claims and specification
- Excessive abstraction in *Alice*'s first step makes the second step a foregone conclusion

11. **Jeffrey Lefstin and Peter Menell (law professors)** -- brief

- This case presents vitally important issues at a critical juncture in the development of patent-eligibility law
- *Mayo* does not condition patent-eligibility on unconventional application
- *Mayo* and *Alice* prohibit dissection of claims into old and new components
- The panel's rule invalidates claims that *Mayo* deemed patent-eligible

12. **Paul Gilbert Cole** (law professor) -- brief

- This decision is likely to be followed by the USPTO for its examination guidance and if wrongly decided may adversely affect many pharmaceutical and biotechnology applicants
- The amplification product was misclassified as a natural phenomenon and not as a non-natural composition of matter contributing to eligibility as a manufacture under § 101
- Contrary to *Mayo* the Panel Opinion provides precedent for establishing ineligibility by considering features merely individually and ignoring or giving insufficient weight to their "ordered combination"
- The Panel Opinion disregarded the acknowledged new and beneficial results of the ordered combination as evidence of invention and hence relevant to § 101 eligibility
- When broadly interpreted the two-part test raises issues of compliance with TRIPS

A decision in this case is expected later this year, and may be appealed to the US Supreme Court.