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Sequenom Requests Rehearing En Banc

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Earlier this summer, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the Federal Circuit affirmed a decision by the District Court for the Northern District of California granting summary judgment of invalidity of the asserted claims of U.S. Patent No. [6,258,540](#) (see "[Ariosa Diagnostics, Inc. v. Sequenom, Inc. \(Fed. Cir. 2015\)](#)"). Last week, Sequenom filed a [petition for rehearing en banc](#), arguing that the panel's decision in June was inconsistent with the Supreme Court's decisions in *Diamond v. Diehr*, 450 U.S. 175 (1981), *Mayo v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), and *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013), and that the panel's decision poses a threat to patent protection in multiple fields of invention.

Sequenom begins by asserting that the panel's decision raises the following question of exceptional importance:

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?

According to Sequenom:

The panel decision in this case reads recent Supreme Court precedent to create an existential threat to patent protection for an array of meritorious inventions. It avowedly holds that "groundbreaking" new diagnostic methods that "make[] a significant contribution to the medical field" are ineligible for a patent whenever they (1) incorporate the discovery of a natural phenomenon, and (2) the techniques involved in putting that discovery to its first practical use were individually known beforehand. See Op. 10, 16. In other words, the person who

first discovers a natural phenomenon can never obtain a patent on any practical application of that new knowledge, however surprising or revolutionary the results, unless the steps she teaches to use it are independently novel.

Sequenom notes that although the individual techniques involved in the claimed methods were known, "no one had been practicing them in the combination disclosed in the patent," and moreover, that "the material the patent taught the world how to test *had previously been discarded as waste*" (emphasis in petition).

As discussed in the petition, the inventors (Drs. Dennis Lo and James Wainscoat) discovered that cell-free fetal DNA (cffDNA) was circulating in the blood of pregnant mothers, and that this knowledge could be used to create a maternal blood test for certain fetal genetic traits and abnormalities. The petition states that the discovery of cffDNA in maternal blood "was a profound breakthrough," noting that "their *Lancet* article describing it has since been cited about a thousand times."

As for the claimed invention, Sequenom states that:

The patent specifically claimed a method of (1) fractionating a pregnant mother's blood, (2) amplifying the genetic material in the serum/plasma, and (3) identifying paternally inherited material as a means of testing for fetal characteristics or medical conditions. It is undisputed that no one was previously practicing these steps in combination because they were in fact discarding the relevant materials as waste. The techniques involved were known, but their combination as taught in the '540 patent was anything but conventional; indeed, the convention was essentially the opposite [internal citations omitted].

However, the Federal Circuit panel that heard the appeal (Circuit Judges Reyna, Linn, and Wallach) determined that the asserted claims failed the two-step test for patent eligibility set forth in *Mayo*.

According to Sequenom:

The panel's core reasoning was that, "[f]or process claims that encompass natural phenomenon, the process steps . . . must be new and useful." And because researchers already knew how to (1) fractionate blood; (2) amplify DNA in serum or plasma; and (3) detect characteristics in amplified DNA, the method impermissibly added only "well-understood, routine, and conventional activity" to the natural phenomenon Lo and Wainscoat discovered [internal citations omitted].

In arguing for rehearing *en banc*, Sequenom contends that:

The panel's decision misinterprets *Mayo* both by failing to read that decision in light of the key Supreme Court precedent that *Mayo* endorses and by reaching a result the Supreme Court has twice disavowed in recent opinions. Neither *Mayo's* holding, nor

even its dicta, compel the panel's conclusion -- a conclusion that threatens dire consequences for biomedicine as a field and patent law as a whole.

In the first of two reasons why the Federal Circuit should grant rehearing *en banc*, Sequenom argues that "[t]he panel's decision misinterprets *Mayo* by ignoring *Diehr* and *Myriad* to reach a consequence that *Mayo* quite clearly did not intend." With respect to *Diehr*, Sequenom notes that each of the techniques recited in the claimed method was already known and practiced, but they were not practiced *in combination*. Sequenom argues that the claimed method in the '540 patent "is just like that in *Diehr*, and not at all like that in *Mayo*," adding that "[t]he natural phenomenon Drs. Lo and Wainscoat discovered motivated them to teach a new method that *no one* was practicing, and whose combined steps were in fact the opposite of the 'conventional' approach, even if each individual technique involved was 'well-understood' on its own" (emphasis in petition).

Sequenom also argues that:

[T]he panel's difficulty in reconciling existing Supreme Court precedent is reflected in the fact that its ruling does not even *mention Diehr*, and -- perhaps more importantly -- makes no effort at all to address whether the combination of steps taught in the '540 patent was "routine" activity at the time of the patent. This is accordingly the simplest basis on which the full Court can intervene to prevent the bizarre result of "excluding a meritorious invention from the patent protection it deserves" based on an over-reading of *Mayo* that will take many other deserving inventions down with it [emphasis in petition].

While asserting that "*Mayo* clearly suggested that 'a new way of using an existing drug' would be eligible for patent protection under §101," Sequenom observes that "under the panel's test, that cannot be true: The drug is known, the means of administering it are known, and the only new insight is the (unpatentable) natural law that the drug treats a disease no one previously knew it treated." According to Sequenom, "[t]he test *Diehr* sets out solves this problem by showing exactly why such applications remain perfectly patentable -- they would in combination be non-routine and non-conventional uses of known techniques to accomplish new results that are motivated by an insight about the natural world."

As for the second reason why the Federal Circuit should grant rehearing *en banc*, Sequenom states that:

The full Court's intervention is particularly necessary because, if this Court does not step in and draw this line, the 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 also argues that "the problem goes well beyond diagnostics or even medicine: If combining conventional techniques in an unconventional fashion, motivated by a discovery about nature's laws, is unpatentable subject matter, it is hard to see how *any* process claim can survive" (emphasis in petition). The petition also suggests that following the panel decision, the only way protect a "field-changing invention" like that of the '540 patent will be to keep it a secret for as long as possible, which Sequenom contends "benefits no one, especially in fields like medicine where collaborative sharing of basic research is so fundamental to progress and the timely development of life-saving interventions."

Gazing into the crystal ball, Sequenom suggests that:
[T]hose seeking new vaccines, new uses for existing drugs, new noninvasive tests, or other biomedical innovations will quite likely conclude that the game is no longer worth the candle. And who could blame them: They could revolutionize their field, teach their colleagues a method that is the diametric opposite of the conventional wisdom, create a practical test that confers enormous medical benefits on society, have their research cited close to a thousand times, and yet still be denied a patent because their previously unknown method relies on too fundamental a discovery *they made* about the natural world [emphasis in petition].

Sequenom argues that "[n]othing requires this anomalous result," adding that "[t]his patent is radically different from those recently rejected under §101 because it claims a combination of steps that *no one* in the field was previously practicing and does not purport to (and did not in fact) preempt all uses of the natural discovery that motivated it" (emphasis in petition). Sequenom concludes by stating that "[t]he full Court should take this opportunity to protect patent law's fundamental principles from being eroded by results neither the Supreme Court nor Congress could possibly have intended."