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Ariosa Diagnostics, Inc. v. Sequenom, Inc.: How the Federal Judiciary Stripped a Breakthrough Invention of Patent Protection *By David A. Gass*

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* (12 June 2015), Federal Circuit Judge Linn wrote effusively about a groundbreaking prenatal testing invention that “effectuated a practical result and benefit not previously attained” and that was “deserving of patent protection.” He wrote this in an opinion concurring that Sequenom’s claimed invention was *ineligible* for patent protection under 35 USC §101. Who is responsible for such a seemingly anomalous result?

The Role of Congress

The United States Constitution empowers Congress to write patent laws to award inventors with patents “[t]o promote the Progress of Science and useful Arts.” Congress defined the types of inventions eligible for patent protection in 35 U.S.C. §101 broadly: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,” so long as other substantive requirements of the patent statute are met. Sequenom’s patent

claims were directed to a process, an eligible category under §101. Thus, Congress’ statute is not responsible for the anomalous result.

The Impact of the Supreme Court

Understanding the fate of Sequenom’s patent requires an understanding of the Supreme Court’s interpretation of §101. In a flurry of recent decisions finding inventions ineligible for patent protection, the Court has progressively turned the eligibility inquiry away from §101 as written by Congress, instead focusing on “judicial exceptions” of its own creation. “The Court’s precedents provide three specific exceptions to §101’s broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas.” *Bilski v. Kappos* (2010). In *Bilski*, the Court acknowledged that “these exceptions are not required by the statutory text.”

In grappling with controversial “business method” patents, the *Bilski* Court *rejected* a relatively bright-line test, known as the “Machine-or-Transformation test” (“MOT test”) for distinguishing patent-eligible

processes from the judicial exceptions. The *Bilski* Court rejected the MOT test as potentially being *too restrictive* -- imposing limits on eligible processes not justifiable by the plain language of §101. “[C]ourts should not read into the patent laws limitations and conditions which the legislature has not expressed.”

Mayo Collaborative Services v. Prometheus Laboratories (2012), involved a medical process invention for determining if a drug dose was safe and effective. Although the *Mayo* Court quoted §101 (the controlling statute), the Supreme Court devoted its entire legal analysis to construing the Court’s own *exceptions* to the statute, “in light of the Court’s precedents.” Because the MOT test was not a definitive test for patent-eligibility, a patent claim’s *satisfaction* of the test did not necessarily mean that claim was patent-eligible. After *Mayo*, the Court’s “law of nature” exclusion *trumped* the MOT test, and claims needed something more than passage of the MOT test to be eligible.

The *Mayo* Court also expanded the scope of its “natural law” exception. Whereas traditional “natural laws” generally were mathematical characterizations of the natural world, Prometheus’ “laws of nature” involved human administration of synthetic drugs: “relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a... drug will prove ineffective or cause harm.”

The Court revisited §101 in *Association for Molecular Pathology v. Myriad Genetics* (2013). Again, the Court quoted §101, but devoted its entire analysis to construing the Court’s “judicial exceptions.” The Court concluded that Myriad’s patent claims directed to isolated human DNA were not directed to an eligible “new and useful... composition of matter,” but were instead directed to ineligible “naturally occurring phenomena,” thus expanding its judicial exceptions to exclude some compositions of matter from patent eligibility.

Most recently, in *Alice Corp. v. CLS Bank International* (2014), the Supreme Court continued its pattern of



quoting §101 *pro forma*, but developing its exceptions, discerning from *Mayo* “a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts.” This framework searches for “additional elements” that “transform the nature of the claim into a patent-eligible application.” In the Court’s words, “a search for an “inventive concept” that is “sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.” (The claims to Alice’s computer-implemented scheme for mitigating risk in a financial transaction failed the Court’s “framework.”)

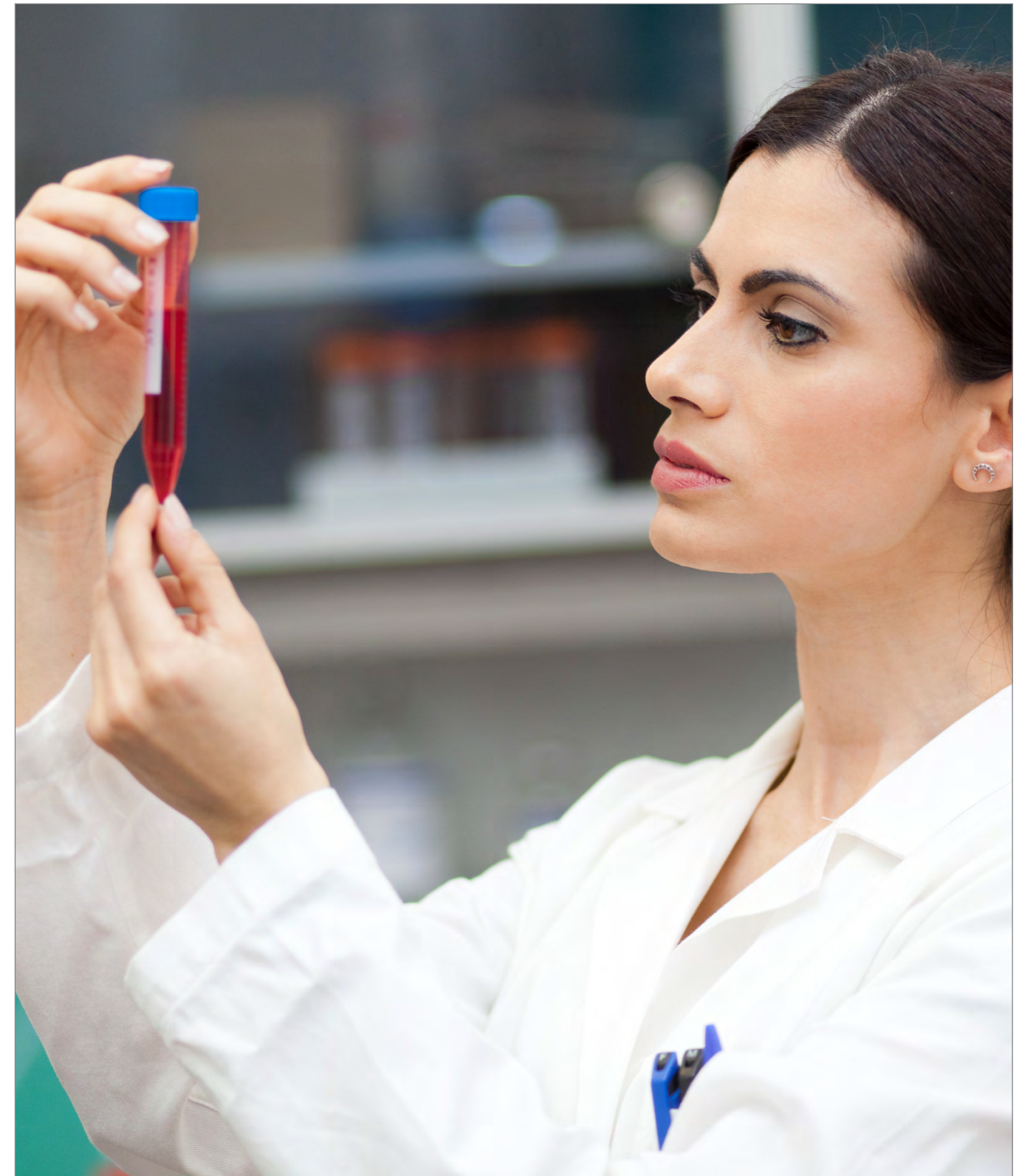
The Federal Circuit’s *Sequenom* decision

While decisions from *Bilski* to *Alice* have expanded the universe of ineligible subject matter, these decisions did not mandate that the Federal Circuit invalidate Sequenom’s fetal DNA testing patent.

The *Myriad* decision was not con-

trolling, because (as both parties acknowledged), Sequenom’s patent claims were not directed to isolated human fetal DNA (“cffDNA”), but rather, to *methods of using* the DNA. Nonetheless, the Federal Circuit implicated *Myriad* and triggered the *Mayo/Alice* “framework” -- accepting Ariosa’s characterization that the method claims of Sequenom’s patents were “directed to the natural phenomenon of paternally inherited cffDNA.”

Viewing the *Mayo/Alice* “framework” as a mandate, the Federal Circuit refused to give weight to evidence presented by the patentee that the patent *did not preempt* other scientists from using cffDNA. The Federal Circuit acknowledged that “The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability.” Nonetheless, instead of remanding the litigation to the district court, with instructions to weigh the parties’ evidence on the issue of preemption, the Federal Circuit concluded that “questions of preemption are inherent in and resolved by the [*Mayo/Alice*] §101 analysis. ...





While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility...” Even though the Supreme Court’s justification for its judicial exceptions is its concern about preemption, the Federal Circuit concluded that direct evidence adduced at the trial court on the issue of preemption was irrelevant.

Additionally, the Federal Circuit’s implementation of the *Mayo/Alice* “framework” is subject to criticism. Sequenom’s claims start with *maternal serum or plasma*, and end with *detecting* the paternally inherited fetal DNA, or *amplifying* that DNA.

Even though “detecting” and “amplifying” are process steps, i.e., *actions*, the Federal Circuit concluded that the claims failed the first part of the *Mayo/Alice* test because “The method ... begins and ends with a natural phenomenon [of cffDNA].” The court ultimately concluded that the claims failed the second element of the test as well, and were invalid.

Summary

The Supreme Court’s recent flurry of finding inventions ineligible for patent protection contributed mightily to the Federal Circuit’s invalidation of Sequenom’s patent. In 2010 the Court in *Bilski* construed §101 broad-

ly; and cautioned that courts should not read into the patent laws limitations and conditions (e.g., the MOT test) which the legislature has not expressed. By 2014, the Court had essentially stopped construing §101, and had created an eligibility “framework” that the legislature never expressed.

Rightly or wrongly, the Federal Circuit treated the *Mayo/Alice* “framework” as a new litmus test for eligibility. Even within that constraint, the Federal Circuit’s inaccurate application of the *Mayo/Alice* “framework,” and its refusal to accord weight to evidence on the issue of preemption, are ultimately responsible for the

patent on a “deserving invention” being invalidated. The Patentee Sequenom has requested rehearing, giving the Federal Circuit a chance to turn patent-eligibility jurisprudence back in the right direction.

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