THE MOSSOFF-NOONAN "23 PROFESSORS" AMICUS BRIEF IN THE *SEQUENOM* CASE ON THE ROAD TO THE SUPREME COURT[*]

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The case at the Federal Circuit is styled as *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* This paper is an excerpt from the *Brief of Twenty-Three Law Professors in Support of Appellant's Petition for Rehearing En Banc* in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015). Footnotes in the original brief have been integrated into the text as shown in brackets.

The petition was denied (with concurring and dissenting opinions) on December 2, 2015. A petition for *certiorari* is due March 1, 2016 (unless extended).

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SUMMARY OF ARGUMENT

The panel decision exceeded the scope of the Supreme Court's § 101 jurisprudence in distinguishing patents claiming laws of nature, natural phenomena, and abstract ideas from patents claiming patent-eligible applications of those concepts. *Ariosa Diagnostics, Inc. v. Sequenom, Inc*., 788 F.3d 1371 (Fed. Cir. 2015). As the Supreme Court recognized in *Bilski v. Kappos*, 561 U.S. 591 (2010), Section 101 is a "dynamic provision designed to encompass new and unforeseen inventions." *Id.* at 605. Since the parties and other *amici* address the legal infirmities and technological errors in the panel's decision, *amici* here offer two further insights as to how the panel decision undermines the essential function of the patent system in promoting new innovation. First, development and commercialization of prenatal genetic diagnostic tests is exactly the type of twenty-first-century innovation the patent system is designed to promote as a historically "unforeseen invention." *Id.* at 605. Second, the panel's analysis is not even "a sufficient basis for evaluating processes similar to those in the Industrial Revolution," because if applied consistently it would call into question nineteenth-century patented innovation the Supreme Court deemed valid. *Id.* at 605.

ARGUMENT

I. The Panel Decision Undermines Twenty-First-Century Innovation That The Patent System Is Designed To Promote And Protect

The panel's decision contravenes the *Bilski* Court's injunction that § 101 tests should not impede the progress of future innovation. The massive research and development into new technological applications of genetic diagnostic testing methods exemplifies the "progress of . . . useful Arts" the patent system is intended to promote and secure to its creators. [U.S. Const. art. 1, § 8, cl. 8.]
As the close relationship between genetic variation (and mutational injury) and disease has become more clear as a result of massive research and development (R&D) expenditures, the value of genetic diagnostic tools has increased exponentially. Experts now estimate that 60-70% of all medical treatment decisions are based on the results of diagnostic tests.[The Importance Of Diagnostics, http://www.biomerieux.com/en/importance-diagnostics (last visited Aug. 18, 2015).] Such tests have immense benefits for patient care and greatly reduce associated costs (including decreasing hospitalization and avoiding unnecessary treatment). [Roche, Annual Report 2014, 33 (2015), available at http://www.roche.com/gb14e.pdf.]

The economics of innovative diagnostic tests reflect exactly the economic justification for the patent system: the cost of applying a genetic diagnostic test is relatively low, but the ex ante R&D cost is enormous and is not reflected in the marginal cost of the medical test itself. According to one study, the average cost to develop and commercialize a diagnostic testing technology in the United States is between $50-75 million and can exceed $100 million for developing and commercializing novel diagnostic technologies. [*Mystery Solved! What is the cost to develop and launch a Diagnostic?*, Diaceutics Group, http://www.diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic (last visited Aug. 18, 2015).] Screening for diseases with complex genetic interactions, like diabetes, heart disease, and cancer, require even greater investments. As the *Bilski* Court recognized, the patent system exists to promote new inventions on the frontier of human technological knowledge like genetic testing methods, which by necessity require massive R&D expenditures that can only be recouped via the protections offered by property rights in this innovation.

The panel decision contravenes this insight by the Supreme Court because it threatens to preclude many genetic and other diagnostic tests from the ambit of patent protection. It disincentivizes making the massive R&D investments required to create this new innovation in the twenty-first century. This is neither hyperbole nor conjecture. For example, Accelerate Diagnostics recently warned its investors that it "incurred significant costs in connection with the development and commercialization of [its] [diagnostic testing] technology" and "[i]f we are unable to effectively protect our . . . intellectual property, our business would be harmed." [Accelerate Diagnostics, *2014 Annual Report*, 23 (2015), available at http://ir.axdx.com/secfiling.cfm?filingID=1000096-15-20&CIK=727207.]

II. The Panel's Analysis Contradicts § 101 Jurisprudence As Evidenced By How It Cast Doubts on Validity of Classic Method Patents

In *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court recognized that "too broad an interpretation of this exclusionary principle [regarding laws of nature, natural phenomena and abstract ideas] could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." [*Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289, 1293 (2012).] Reflecting similar concerns, the *Bilski* Court rejected a § 101 test developed for assessing nineteenth-century process patents because it failed in properly "determining the patentability of inventions in the Information Age" today. [*Bilski*, 561 U.S. at 605.

The Court further warned that "[a] categorical rule denying patent protection for 'inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law." *Id.* (citing *Diamond v. Chakrabarty*, 447, U.S. 303, 315 (1980)).]

These admonitions by the Supreme Court directly apply to this case, because not only does the panel decision threaten an entire field of twenty-first-century inventive activity, it would also cast serious doubt about classic nineteenth-century patented innovation either validly issued under the patent laws or sustained by the Supreme Court. There are too many historical patents and Supreme Court decisions to discuss them all within the constraints of this brief, [*see* Michael Risch, *Nothing is Patentable*, FLORIDA L. REV. F. (2015), available at http://ssrn.com/abstract=2642361 (noting classic patents called into doubt).
[1] U.S. Patent No. X00001 (issued July 31, 1790),] and thus we will identify only a few exemplars, including the first patent issued in 1790 on a method for making potash.[U.S. Patent No. X00001 (issued July 31, 1790).]

Many judges and scholars cite to *O'Reilly v. Morse*, 56 U.S. 62 (1853), because the Supreme Court famously invalidated Claim 8 of Morse's patent, but many today may not remember that the *Morse* Court explicitly affirmed the validity of the first seven claims in Morse's patent. [*See Morse*, 56 U.S. at 112 ("We perceive no well-founded objection . . . to his right to a patent for the first seven inventions set forth in the specification of his claims.").] This is important, because Claim 1 recited a method of operating an electro-magnetic telegraph that could be invalid under the panel's application of *Mayo*. Claim 1 is not quoted in Chief Justice Roger Taney's opinion in *Morse*, and so to understand this point, it is necessary to quote the relevant language from the claim:

> First. . . . what I specially claim as my invention and improvement, is making use of the motive power of magnetism, when developed by the action of such current or currents substantially as set forth in the foregoing description of the first principal part of my invention, as means of operating or giving motion to machinery which may be used to imprint signals upon paper or other suitable material, or to produce sounds in any desired manner, for the purpose of telegraphic communication at any distances.
> [U.S. Reissue Patent No. 117 (issued June 13, 1848).]

Under the panel's interpretation of step one of the *Mayo* test, this claim begins with patent ineligible natural phenomenon ("the motive power of magnetism") and ends with an abstract idea ("communication at any distances"). According to the panel, the second step in the *Mayo* test then requires assessing whether the claim also recites merely "well-understood, routine, and conventional activity," [*Ariosa*, 788 F.3d at 1377,] and each remaining element in Morse's Claim 1 recites conventional activity for the art in his time. First, Morse acknowledges in his specification that "it had been essayed to use the currents of electricity or galvanism for telegraphic purposes" before his invention, and he even acknowledges later in Claim 1 that "[t]here are various known methods of producing motion by electro-magnetism." [U.S. Reissue Patent No. 117 (issued June 13, 1848).] Second, the steps he states in Claim 1 of "operating or giving motion to machinery," "imprinting signals upon paper or other suitable material," and "produc[ing] sounds," when assessed individually were undeniably routine and conventional in the 1830s when Morse invented his electro-magnetic telegraph. [For an historical analysis of the invention, patenting, commercialization and litigation of Morse's electro-magnetic telegraph, *see* Adam Mossoff, *O'Reilly v. Morse* (Aug. 18, 2014), available at http://ssrn.com/abstract=2448363.
[1] U.S. Patent No. 174,465 (issued Mar. 7, 1876).] Accordingly, the *Ariosa* panel's application of the *Mayo* test, if applied to Claim 1 of Morse's patent in the same way the panel applied it to Sequenom's patent, leads to the conclusion that Morse's Claim 1 is arguably unpatentable subject matter. But this directly contradicts the Supreme Court's analysis and decision in *Morse* that Claim 1 is valid.

Another prominent and more commonly cited example of a patentable invention is Claim 5 of Alexander Graham Bell's patent on the telephone, [U.S. Patent No. 174,465 (issued Mar. 7, 1876),] which was affirmed by the Supreme Court in *Dolbear v. American Bell Telephone Company*, 126 U.S. 1 (1888). Claim 5 recites:

> The method of and apparatus for transmitting vocal or other sounds telegraphically . . . by causing electrical undulations, similar in form to the vibrations of the air accompanying the said vocal or other sounds.

Again, applying the *Ariosa* panel's analysis to Claim 5 in Bell's patent leads to the same conclusion reached for Claim 1 of Morse's patent. First, under *Mayo* step one, Claim 5 begins and ends with "vocal and other sounds," and concerns generally the mere transmission of those sounds by electrical undulations. These concepts are natural phenomena, and thus are patent ineligible *per se*. The claim also does not recite anything significantly more than the ineligible concepts

themselves that was not routine, well-understood and conventional, because telegraphic transmission and electrical undulation had been long known in the art. [*See* CHRISTOPHER BEAUCHAMP, INVENTED BY LAW: ALEXANDER GRAHAM BELL AND THE PATENT THAT CHANGED AMERICA 58-85 (2014) (recounting claims of many prior and existing uses of electrical currents in telegraphic communication).] Again, contrary to the Supreme Court's own analysis and decision in 1888, the *Ariosa* panel's analysis leads to the logical conclusion that Bell's famous Claim 5 is unpatentable subject matter.

Perhaps most surprising is that the first U.S. patent ever granted would be invalid under the panel's application of the *Mayo* two-step test. The first patent issued in 1790 to Samuel Hopkins for his method of making potash. [U.S. Patent No. X00001 (granted July 31, 1790).] This method involved well-known steps such as burning and dissolving ash, and Hopkins' "inventive" contribution was in the timing and specific order of the steps. [*See* Henry M. Payntor, *The First Patent* (rev., 1998), available at http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html.] Both of these aspects of Hopkins' patent considered individually would be deemed basic facts or concepts of conventional human activity, and under the *Ariosa* panel's application of the *Mayo* test are arguably unpatentable subject matter.

This is significant because Hopkins' patent was signed by Thomas Jefferson as Secretary of State and as a member of the committee created under the 1790 Patent Act who reviewed Hopkins' application. Jefferson was both a drafter of some of the early patent laws and has long been known for his views that patents should be severely restricted in their issuance to inventors. [*See* Adam Mossoff, *Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent "Privilege" in Historical Context*, 92 CORNELL L. REV. 93, 959-63 (2007); *see also* Justin Hughes, *Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson*, 79 S. CAL. L. REV. 993, 1026-34 (2006) (discussing Jefferson's contradictory views on the legitimacy of patents and copyrights).] Moreover, Hopkins' patent was issued under the 1790 Patent Act, which was drafted by many of the original Framers of the Constitution who were then serving in Congress. Justices and constitutional scholars recognize legislation from the First Congress as having significant import as to the meaning of the Constitution. [*See, e.g.*, *Wisconsin v. Pelican Ins. Co.*, 127 U.S. 265, 297 (1888) (quoting 1789 Judiciary Act as primary evidence of meaning of Article III, § 2); Neal Katyal & Paul Clement, *On the Meaning of "Natural Born Citizen,"* 128 HARV. L. REV. F. 161, 161 (2015) ("The Supreme Court has long recognized that two particularly useful sources in understanding constitutional terms are British

common law and enactments of the First Congress.").] This includes the Copyright and Patent Clause's authorization for Congress to secure an "exclusive Right" to "Inventors" for their "Discoveries" in order to advance the "progress of . . . useful Arts." Thus, when a contemporary court reaches a decision that calls into question a patent validly issued under the 1790 Patent Act and signed by Jefferson himself, it is cause to question whether this court has applied the law correctly.

As has been made clear, the panel decision not only contradicts the *Bilski* Court's injunction that § 101 is a "dynamic provision designed to encompass new and unforeseen inventions," *Bilski*, 561 U.S. at 605, such as the revolutionary genetic diagnostic testing methods made possible by the modern biotech revolution, it also casts doubt on classic patented innovation validly issued or upheld by the Supreme Court. This suggests that the *Ariosa* panel has misapplied § 101 jurisprudence and that the error is significant enough to warrant *en banc* consideration.

CONCLUSION

Amici urge this court to grant rehearing of this matter *en banc* and reverse the panel decision.