

PRESENTED AT

11th Annual Advanced Patent Law Institute

March 10-11, 2016

Alexandria, Virginia

***Sequenom* and Section 101 Challenges in
Diagnostics and Personalized Medicine**

Adam Mossoff

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2014-1139, 2014-1144

ARIOSIA DIAGNOSTICS, INC., NATERA, INC.,
Plaintiffs-Appellees,
DNA DIAGNOSTICS CENTER, INC.,
Counterclaim Defendant-Appellees,
v.
SEQUENOM, INC., SEQUENOM CENTER FOR MOLECULAR
MEDICINE, LLC,
Defendants-Appellants,
and
ISIS INNOVATION LIMITED,
Defendant.

Appeal from the United States District Court for the Northern
District of California in case Nos. 3:11-cv-06391-SI, 3:12-cv-
00132-SI, Judge Susan Y. Illston.

BRIEF OF TWENTY-THREE LAW PROFESSORS IN SUPPORT OF
APPELLANT'S PETITION FOR REHEARING EN BANC

Adam Mossoff
George Mason University
School of Law
3301 Fairfax Drive
Arlington, VA 22201
(703) 993-9577
Professor of Law

Kevin E. Noonan
McDonnell Boehnen
Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, IL 60606
(312) 913-0001
Counsel for Amicus Curiae

A full list of the Amici is included at the end of the brief.

CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rules 28(a)(1) and 47.4(a), counsel for *amicus curiae* state the following:

1. The full names of every party or *amicus* represented by us is:

Twenty-three Law Professors Specializing in Patent Law and Policy

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by us is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by us is:

None.

4. The names of all law firms and the partners or associates that appeared for any of the parties or *amicus* now represented by us in the trial court or agency or in a prior proceeding in this case or are expected to appear in this Court are:

Kevin E. Noonan of McDonnell Boehnen Hulbert & Berghoff LLP

Dated: August 27, 2015

/s/ Kevin E. Noonan

Kevin E. Noonan

McDonnell Boehnen

Hulbert & Berghoff LLP

300 South Wacker Drive

Chicago, IL 60606

TABLE OF CONTENTS

	PAGE
INTEREST OF AMICUS CURIAE	1
SUMMARY OF ARGUMENT	1
ARGUMENT	2
I. The Panel Decision Undermines Twenty-First-Century Innovation That The Patent System Is Designed To Promote and Protect.....	2
II. The Panel’s Analysis Contradicts § 101 Jurisprudence As Evidenced By How It Cast Doubts on Validity of Classic Method Patents.....	4
CONCLUSION	10

TABLE OF AUTHORITIES

CASES	PAGE(S)
<i>Ariosa Diagnostics, Inc. v. Sequenom Inc.</i> , 788 F.3d 1371 (Fed. Cir. 2015)	1, 6
<i>Bilski v. Kappos</i> , 561 U.S. 593 (2010).....	1, 2, 5, 10
<i>Dolbear v. American Bell Telephone Company</i> , 126 U.S. 1 (1888).....	7
<i>Mayo Collaborative Services v. Prometheus Laboratories, Inc.</i> , 132 S. Ct. 1289 (2012).....	4
<i>O'Reilly v. Morse</i> , 56 U.S. 62 (1853).....	5, 6
<i>Wisconsin v. Pelican Ins. Co.</i> , 127 U.S. 265 (1888).....	9
STATUTES	
U.S. CONST. art. 1, § 8 , cl. 8	2
OTHER AUTHORITIES	
Accelerate Diagnostics, <i>2014 Annual Report</i> (2015), available at http://ir.axdx.com/secfiling.cfm?filingID=1000096-15-20&CIK=727207	4
CHRISTOPHER BEAUCHAMP, <i>INVENTED BY LAW: ALEXANDER GRAHAM BELL AND THE PATENT THAT CHANGED AMERICA</i> (2014).....	8
Justin Hughes, <i>Copyright and Incomplete Historiographies: Of Piracy, Propertization, and Thomas Jefferson</i> , 79 S. CAL. L. REV. 993 (2006).....	9

Neal Katyal & Paul Clement, <i>On the Meaning of “Natural Born Citizen,”</i> 128 HARV. L. REV. F. 161 (2015)	9
Adam Mossoff, <i>O’Reilly v. Morse</i> (Aug. 18, 2014), available at http://ssrn.com/abstract=2448363	7
Adam Mossoff, <i>Who Cares What Thomas Jefferson Thought About Patents? Reevaluating the Patent “Privilege” in Historical Context</i> , 92 CORNELL L. REV. 93 (2007).....	9
<i>Mystery Solved! What is the cost to develop and launch a Diagnostic?</i> , Diaceutics Group, http://www.diaceutics.com/mystery-solved-what-cost-develop-and-launch-diagnostic (last visited Aug. 18, 2015).....	3
Henry M. Payntor, <i>The First Patent</i> (rev., 1998), available at http://www.me.utexas.edu/~longoria/paynter/hmp/The_First_Patent.html	8
Michael Risch, <i>Nothing is Patentable</i> , FLORIDA L. REV. F. (2015), available at http://ssrn.com/abstract=2642361	5
Roche, <i>Annual Report 2014</i> , (2015), available at http://www.roche.com/gb14e.pdf	3
THE IMPORTANCE OF DIAGNOSTICS, http://www.biomerieux.com/en/importance-diagnostics (last visited Aug. 18, 2015).	3
U.S. Patent No. X00001 (issued July 31, 1790)	5, 8
U.S. Reissue Patent No. 117 (issued June 13, 1848).....	6, 7
U.S. Patent No. 174,465 (issued Mar. 7, 1876).....	7

INTEREST OF THE AMICUS CURIAE¹

The *amicus curiae* are twenty-three law professors who teach and write on patent law and policy, and are thus concerned with the integrity of the legal system that secures innovation to its creators and to the companies that commercialize it in the marketplace. Although *amici* may differ amongst themselves on other aspects of modern patent law and policy, they are united in their professional opinion that this court should grant rehearing *en banc* because the panel decision's application of § 101 undermines the function of the patent system to promote and to legally secure twenty-first-century innovation. They have no stake in the parties or in the outcome of the case.

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.² 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

¹ No party's counsel authored this brief in whole or part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than amici, their members, or counsel contributed money intended to fund preparing or submitting the brief. Fed. R. App. P. 29(c)(5).

² *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

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.³

As the close relationship between genetic variation (and mutational injury) and disease has become more clear as a result of massive research and

³ U.S. CONST. art. 1, § 8, cl. 8.

Also available as part of the eCourse

[Patent Eligibility: Section 101 Challenges and the New USPTO Guidelines](#)

First appeared as part of the conference materials for the

11th Annual Advanced Patent Law Institute session

"*Sequenom* and Section 101 Challenges in Diagnostics and Personalized Medicine"