2014-1139, -1144

United States Court of Appeals for the Federal Circuit

ARIOSA DIAGNOSTICS, INC., and NATERA, INC.,

Plaintiffs-Appellees,

and

DNA DIAGNOSTICS CENTER, INC.,

Counterclaim Defendant-Appellee,

v.

SEQUENOM, INC., and
SEQUENOM CENTER FOR MOLECULAR MEDICINE, LLC,

Defendants-Appellants,

and

ISIS INNOVATION LIMITED,

Defendant.

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

BRIEF OF THE BIOINDUSTRY ASSOCIATION AS *AMICUS CURIAE* SUPPORTING PETITION FOR REHEARING *EN BANC*

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United States Court of Appeals
for the Federal Circuit

Ariosa Diagnostics, Inc v. Sequenom, Inc.
Nos. 2014-1139, -1144

CERTIFICATE OF INTEREST

Counsel for the *Amicus Curiae*, BioIndustry Association, certifies the following:

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

   BioIndustry Association ("BIA")

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 me are:

   None

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

   Before this Court, BIA is represented by Nutter McClennen & Fish LLP (Konstantin Linnik, Lana A. Gladstein, and Isaac Hubner), 155 Seaport Boulevard, Boston, MA 02210.

Dated: August 27, 2015

/s/ Konstantin M. Linnik
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ABBREVIATION	MEANING
AIA	The America Invents Act of 2011
EPO	European Patent Office
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

I. STATEMENT OF INTEREST OF *AMICUS CURIAE*

The BioIndustry Association ("BIA") is a United Kingdom trade association of over 300 member organizations working in research and development ("R&D") and manufacturing in the bioscience sector.[1] BIA members include emerging and established biotechnology companies, pharmaceutical companies, academic research and philanthropic organizations. BIA members are responsible for over ninety per cent of biotechnology-based medicines currently in clinical development in the UK; they are at the forefront of innovative scientific developments targeting areas of unmet medical need.

The issues raised in this case are of great importance to BIA. The majority of BIA's members are small and medium size enterprises. For these enterprises, the ability to raise R&D funding or attract larger companies to collaborate heavily depends on the strength of their intellectual property, primarily patents. Lack of patent protection severely hinders their ability to bring to life new and improved treatments and, in many cases, makes it impossible.

Many BIA members operate, or plan to operate, directly or indirectly in the United States, and thereby create jobs in the United States. Not surprisingly, startups and fledging businesses rely on the US market projections for securing R&D funding,

[1] BIA has no commercial interest in the parties to this action and none of the parties is a member of BIA. Pursuant to Fed. Cir. R. 35(g) BIA is contemporaneously filing a motion for leave to file this brief.

as the US accounts for 47% of the global biotechnology market.[2, 3] According to the USPTO, approximately 50% of all US patent applications are filed by foreign entities.[4]

BIA members believe that a strong, clear, and effective patent system is vital to innovation and healthcare not just in Europe and the US, but globally. BIA members are concerned that the panel decision, if left unchanged, jeopardizes the future of much-needed diagnostics and life-saving medicines.

II. REASONS FOR GRANTING REHEARING EN BANC

Harmonized, clear, and predictable regulatory and legal frameworks are essential for biomedical innovation. The panel's interpretation of the Supreme Court's precedent puts the US patentable subject matter eligibility standard at odds with those of other industrial nations. It is a setback in long-standing efforts to harmonize patents laws. Moreover, foreign and multinational companies would be additionally disadvantaged because, as a practical matter, in the absence of patent protection in the US, their inventions would not be protectable as trade secrets. These companies would be forced to choose between patent protection in the rest of the world (except the US) or trade secret protection everywhere. As a result, the unintended consequence of the *Sequenom* decision may be an exodus of investment and businesses

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[2] Evaluate Pharma, *Pharmaceutical & Biotech Sales Analysis by Country,* May 2014, at 2 http://info.evaluategroup.com/rs/evaluatepharmaltd/images/EvaluatePharma%20-%20Pharmaceutical%20%26%20Biotech%20Sales%20Analysis%20by%20Country%20-%20Report.pdf

[3] All references to websites throughout this brief were last visited on August 24, 2015.

[4] *See U.S. Patent Statistics, Calendar Years 1963-2014* http://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.pdf

from the US market or the life science industry in general. For these reasons, the *amicus curiae,* BIA, respectfully urges the Court to review the panel decision *en banc*.

A. The Panel Decision Is at Odds With Accepted Patent-Eligibility Standards

The panel used the Supreme Court's two-step approach, enunciated in *Mayo v. Prometheus Laboratories*, 132 S. Ct. 1289 (2012), for determining whether Sequenom's claims are directed to patent-ineligible subject matter. Judge Linn characterized the panel's holding as an unintended consequence of *Mayo*. *See* Conc. Op. at 2. This Court is in the best position to build on the general framework outlined by the Supreme Court in *Mayo* and *Association for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013), and to apply that framework to the unique facts presented in this case so as to avoid "unintended consequences."

The Supreme Court could not have intended a general exclusion denying patent protection to meritorious inventions merely because they are based on a discovery of something that occurs in nature. Unquestionably, *Mayo* and *Myriad* prescribe that patent protection is not available if the inventor "claims" a law of nature, a natural phenomenon, or an abstract idea. *See, e.g., Mayo*, 132 S. Ct. 1289, 1297 (2012). It is also clear that the claim language is not to be interpreted literally, instead, the Supreme Court instructs one to look at the substance of what the inventor attempts to claim. *Id.* One needs to determine whether the inventor has added "significantly more" to

the claims, "enough" to transform a patent-ineligible discovery into a patent-eligible application of that discovery. *Id.* at 1294.

It is critical, therefore, to delineate with clarity when a patent-ineligible discovery becomes sufficiently transformed. A sweeping interpretation requiring the inventor to come up with an "inventive concept" beyond a novel application of the discovery itself will lead to unfortunate results, as in the case here, where even an acknowledged ground-breaking meritorious invention is denied patent protection merely because it originates from a discovery of a natural phenomenon.

A direct comparison with other jurisdictions may be instructive. Similarly to the US, laws of nature and natural phenomena are not patentable in Europe,[5] yet patent-eligibility determinations for the same inventions result in drastically different outcomes there. It begs the question: "Does the problem lie with the analytical framework (or lack thereof) rather than the merits of the inventions?"

Consider European patent EP 994 963 ("EP '963"), the counterpart of Sequenom's US Patent 6,258,540 ("the '540 patent"). EP '963 was examined and

[5] Article 52(2) of the European Patent Convention states: "(2) The following in particular shall not be regarded as inventions…: (a) discoveries, scientific theories and mathematical methods..." While Art. 53(c) also excludes "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body," this exclusion does not apply to diagnostic methods practiced on samples *ex vivo*, such as Sequenom's method. *See* http://documents.epo.org/projects/babylon/eponet.nsf/0/00E0CD7FD461C0D5C1257C060050C376/$File/EPC_15th_edition_2013.pdf, at 110. Likewise, the UK patent statute excludes from the term invention "a discovery, scientific theory or mathematical method." *See* UK Patent Act 1977, Section 1(2)(a) at http://www.legislation.gov.uk/ukpga/1977/37.

granted by the EPO. As can be seen from the table below, European claim 4 of Sequenom's EP '963 is substantially identical to US claim 1 of the '540 patent:

EP '963 patent	**US '540 patent**
1. A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of foetal origin in the sample, wherein said nucleic acid is a paternally inherited sequence which is not possessed by said pregnant female.	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.
4. A method according to [claim 1], wherein said detecting comprises amplifying said nucleic acid.	

Notably, EP '963 was challenged, but survived a third-party opposition and an appeal of that decision at the EPO. Subject-matter eligibility was not at issue, and the EPO twice affirmed the claims as novel and inventive. *See Decision of the Boards of Appeal of The EPO,* Case No. T 0146/07 - 3.3.08 (December 13, 2011) (attached hereto as Addendum A).

The EPO has long-recognized that when an idea or concept underlying the claimed subject-matter resides in a discovery, it does not necessarily mean the claimed

subject-matter is a discovery as such.[6] The EPO Guidelines issued in 2012 differentiate a mere discovery from a practical application of that discovery as follows:

> ***If a new property of a known material or article is found out, that is mere discovery and unpatentable*** because discovery as such has no technical effect and is therefore not an invention within the meaning of Art. 52(1). ***If, however, that property is put to practical use, then this constitutes an invention which may be patentable.*** For example, the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable. To find a previously unrecognized substance occurring in nature is also mere discovery and therefore unpatentable. ***However, if a substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect.***

EPO Guidelines for Examination http://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm (emphasis added). The opposite outcomes in the application of patent eligibility standards in the US and Europe, while not peculiar to the present case, reflect a fundamental difference in the two analytical approaches seemingly designed for the same purpose, to exclude "mere discoveries" from being patented. The "significantly more" requirement enunciated in *Mayo* and *Myriad* has no equivalent in the patent laws of other industrialized countries and, to be useful and instructive, requires a more developed analytical framework.

B. The Panel Decision Frustrates Long-Term Harmonization Efforts

The newly emerged disparity of patent eligibility standards frustrates decades-long efforts to harmonize IP laws across the world. Such efforts are rooted in

[6] G2/88, OJ 1990, 93, http://archive.epo.org/epo/pubs/oj1990/p093_185.pdf

international treaties and foundational to the United States' ongoing efforts to promote a modern innovation economy, consistent with the Constitutional directive "[t]o promote the Progress of Science and useful Arts." *U.S. Const.* art. I, § 8, cl. 8.

The long-term, global trend towards patent law harmonization extends back over 130 years to the 1883 Paris Convention for the Protection of Industrial Property. The Paris Convention, which now covers 176 member countries including the US, ensures equal national treatment and priority rights for applicants from all member countries.[7]

Following the Paris Convention, harmonization continued and expanded, resulting in numerous treaties and international organizations with essentially universal membership. For example, the WIPO (an agency of the United Nations) was created in 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the world."[8] WIPO currently has 188 member states, administers 26 international treaties, including the Paris Convention and the 1970 Patent Cooperation Treaty (PCT), which provides a unified procedure for protecting inventions in each of its 148 contracting states.[9]

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[7] *See WIPO Summary of the Paris Convention for the Protection of Industrial Property* http://www.wipo.int/treaties/en/ip/paris/summary_paris.html and *WIPO-Administered Treaties* http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2.

[8] *WIPO Convention Establishing the World Intellectual Property Organization* http://www.wipo.int/treaties/en/text.jsp?file_id=283854.

[9] *See WIPO Member States* http://www.wipo.int/members/en/; *WIPO-Administered Treaties* http://www.wipo.int/treaties/en/; *PCT – The International Patent System*

Similarly, the 1995 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which is administered by the WTO and covers all 161 WTO member countries, is notable for introducing IP law directly into international trade and for setting down minimum and uniform standards for many forms of intellectual property protection across the industrialized world.[10]

The panel decision in this case also appears to be fundamentally incompatible with recent major legislation in the United States. The AIA, passed in 2011, was conceived as a major step in the harmonization efforts and pre-dates *Mayo* and *Myriad*. The AIA was the most significant and far-reaching IP legislative initiative since the US Patent Act of 1952.

Notably, the AIA made no changes to § 101 and preserved the *status quo* on patent eligibility, except adding "a human organism" as an exclusion to patent-eligible subject matter.[11] As stated by the USPTO, the AIA "pave[d] the way for greater patent harmonization … to ensure consistency and clarity of rights to the world's innovators." *See Harmonization: The Time is Now,* http://www.uspto.gov/learning-and-

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http://www.wipo.int/pct/en/; and *Summary of the Patent Cooperation Treaty (PCT) (1970)* http://www.wipo.int/treaties/en/registration/pct/summary_pct.html.

[10] *See WTO Overview: the TRIPS Agreement* https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm and *Members and Observers* https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

[11] "LIMITATION ON ISSUANCE OF PATENTS.

(a) LIMITATION.--Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism." PL112-29, September 16, 2011, 125 Stat. 284, Sec. 33.

resources/ip-policy/harmonization. This is not simply a legislative remit but an economic imperative.

The USPTO further emphasized that:

> as innovators seek to tap into global markets, it is ***imperative*** that the international patent system provide consistent, cost effective avenues to obtain ***reliable patent rights in multiple jurisdictions***. The passage of the AIA enables the USPTO to lead on a vision of the IP world in which ***national and regional patent systems are harmonized in pursuit of creating an optimal environment for technological innovation and diffusion***.

Id. (emphasis added). Thus, the panel decision threatens the innovativeness and competitiveness of the US economy, and as such cannot be what international treaties, Congress, and the Supreme Court intended.

C. Trade Secret Protection is Not a Viable Option for Foreign and Multinational Companies

The interplay of patent eligibility standards in the United States and other jurisdictions, and its effect on the availability of trade secret protection should be given particular attention. The increasing globalization and the growing size of the biotechnology market (the US represents 47% of the biotechnology market, *see* Footnote 2 *supra*) demand that innovators protect their inventions throughout the world. In this environment, foreign and multinational companies are uniquely disadvantaged by the *Sequenom* decision.

Procuring a patent in Europe, for example, like in the US, comes at the cost of public disclosure of the invention in the patent application publication. As a result of

publication, trade secret protection is forfeited everywhere in the world. A US-only applicant may file a patent application with a request for non-publication,[12] and if unsuccessful in obtaining a patent, may pursue protection via trade secrets. Foreign entities, on the other hand, do not have that option because such non-publication exception does not exist outside the US. Thus, if they obtain patents in their respective countries, but are refused a patent in the US, they will have neither patent nor trade secret protection in the US. Therefore, a consequence of the panel's decision in *Sequenom* is the *de facto* abolition of intellectual property protection in the United States for many foreign and multinational companies who were able to procure patents abroad.

Such an outcome is particularly troubling in the case of meritorious, life-saving inventions. The resulting lack of both patent and trade secret protection will drive investments away from the US market and will impede investment in the biotechnology industry as a whole.

III. CONCLUSION

For the foregoing reasons, BIA respectfully urges the Court to review the panel decision *en banc*.

[12] Under 35 U.S.C. § 122 (a)(2)(B)(i), "If an applicant makes a request upon filing, certifying that the invention disclosed in the application has not and will not be the subject of an application filed in another country, or under a multilateral international agreement, that requires publication of applications 18 months after filing, the application shall not be published… ."

Respectfully submitted,

Dated: August 27, 2015

/s/ Konstantin M. Linnik

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