Nos. 2014-1139, -1142, -1144

United States Court of Appeals for the Federal Circuit

ARIOSA DIAGNOSTICS, INC., NATERA, INC. and VERINATA HEALTH, INC.,
Plaintiffs-Appellees,
and
DNA DIAGNOSTICS CENTER, INC.,
Counterclaim Defendant-Appellee,
and
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiff,
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. 3:11-06391-SI, 3:12-cv-00132-SI, and 3:12-cv-00865-SI, Judge Susan Y. Illston.

BRIEF OF *AMICUS CURIAE* SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION SUPPORT OF APPELLANT AND IN FAVOR OF REVERSAL

William L. Respess
Sheppard Mullin Richter & Hampton LLP
12275 El Camino Real, Suite 200
San Diego, California 92130-2006
(858) 720-8900

Attorneys for Amicus Curiae

Nos. 2014-1139, -1142, -1144

United States Court of Appeals for the Federal Circuit

ARIOSA DIAGNOSTICS, INC., NATERA, INC. and VERINATA HEALTH, INC.,
Plaintiffs-Appellees,
and
DNA DIAGNOSTICS CENTER, INC.,
Counterclaim Defendant-Appellee,
and
THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY,
Plaintiff,
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. 3:11-06391-SI, 3:12-cv-00132-SI, and 3:12-cv-00865-SI, Judge Susan Y. Illston.

BRIEF OF *AMICUS CURIAE* SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION SUPPORT OF APPELLANT AND IN FAVOR OF REVERSAL

William L. Respess
Sheppard Mullin Richter & Hampton LLP
12275 El Camino Real, Suite 200
San Diego, California 92130-2006
(858) 720-8900

Attorneys for Amicus Curiae

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* San Diego Intellectual Property Law Association certifies the following:

1. The full name of every party or amicus represented by me is:
   San Diego Intellectual Property Law Association
2. The name of the real party in interest (if the party name in the caption is not the real party in interest) represented by me is:
   San Diego Intellectual Property Law Association
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 curiae* now represented by me in the trial court or agency or are expected to appear in this court are:
   William L. Respess
   Sheppard Mullin Richter & Hampton LLP
   12275 El Camino Real, Suite 200
   San Diego, CA 92130-2006
   (858) 720-8900

Dated: January 28, 2014

/s/ *William L. Respess*
William L. Respess

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

I. STATEMENT OF INTEREST OF AMICUS CURIAE.

The San Diego Intellectual Property Law Association (SDIPLA) is an association of attorneys in San Diego, California practicing in all areas of intellectual property law. SDIPLA members include attorneys employed by corporations, universities, and the government and attorneys in private practice. SDIPLA members represent both owners and users of intellectual property. A primary concern of the SDIPLA is that the law applicable to intellectual property be developed in a way that enhances the ability of the clients of its members to conduct their businesses with reasonable certainty concerning the predictability of the treatment of patent applications filed by them on inventions made by them or their employees and the validity and scope of patents owned by them or others affecting their businesses.

The *amicus curiae* has no stake in any of the parties to this litigation or the result of this case, other than its interest in seeking correct and consistent interpretation of the law affecting intellectual property. However, its members are concerned by the troubling nature of the decision by the holding of the District Court in this case. The results of its holding could not be clearer. For all practical purposes no patent could be granted for diagnostic applications of a newly discovered disease marker that are based on known methodologies for performing diagnostic tests. Taken in isolation that decision might not have far reaching

effect. However, recently published guidelines concerning patent examination practice for evaluating claims for compliance with the patent eligibility requirements of §101 demonstrate that the Office is intending to apply a similar standard to that of the district Court in this case. See Examination Guidelines and Training Materials published at http://www.uspto.gov/patents/law/exam/examguide.jsp. See also Evaluating Subject Matter Eligibility Under 35 USC §101: August 2012 Update published at http://www.uspto.gov/patents/law/exam/101_training_aug2012.pdf.

The published guidelines make it clear that the Patent and Trademark office intends to follow the same rigid standard for patent eligibility as that used by the District Court. For example, in one illustrative example, a method for detecting a presumable novel marker for rheumatoid arthritis using an antibody to the marker is not considered patent eligible unless the claim is restricted to detection using a specified antibody. See Subject Matter Eligibility Under 35 USC §101: August 2012 Update, pp. 54-62.

Amicus curiae submit this brief by motion for leave to file pursuant to Federal Circuit Rule 29(b). This brief was authored by counsel for *amicus curiae* and approved by its Boards of Directors. No party or its counsel authored this brief in whole or in part nor contributed money to support drafting or submission

of this brief nor has any party other than the *amicus curiae* or its counsel contributed money used to fund preparation or submission of this brief.

II. *AMICIUS CURIAE'S* STATEMENT OF THE QUESTIONS THE COURT SHOULD CONSIDER.

In reviewing the decision of the Court below, *Amici* request this Court to consider the following questions:

1. Does a claim to a diagnostic use of a known process or known composition of matter that is statutorily patent eligible under 35 U.S.C. §101 become nonstatutory when the use is a new use of the known process or known composition of matter for the limited purpose of detection of a product of nature or natural phenomenon?
2. Is it relevant to the question of statutory patent eligibility of the claim of question 1 that the claimed process satisfies the machine-or-transformation test for statutory patent eligibility of a process?
3. Can a claim to a new diagnostic use of a known process or known composition of matter that is statutory patent eligible under 35 U.S.C. §101 be deemed preemptive of a product of nature or natural phenomenon when the new use of the known process or known composition of matter is limited to the detection of the product of nature or natural phenomenon?

III. BACKGROUND AND SUMMARY OF ARGUMENT.

A. Background.

This case requires the Court to once again determine whether particular claims, and particularly process claims, satisfy the eligibility standards required of under 35 U.SC. §101 as articulated by the Supreme Court when those claims attempt in some fashion to exploit laws of nature, natural phenomena or abstract ideas. The claims of the patent before the Court in this case, U.S. 6,258,540 (the "´540 patent") are very straightforward and have been previously construed by a panel of the Court in a prior appeal in which Sequenom, Inc., appellant in both this case and the prior appeal, unsuccessfully sought reversal of a decision of the District Court denying it a preliminary injunction.[1]

Using Claim 1 of the patent as representative of the invention, as did the Court in its earlier consideration of the denial of the preliminary injunction, the claimed invention is a method of noninvasively detecting a particular fetal gene of paternal origin carried by the fetus in the blood of a pregnant woman involving amplifying extracellular fetal genetic material present in plasma or serum derived from whole maternal blood and detecting the amplified gene of interest.[2] Both of

---

[1] See *Aria Diagnostics, Inc. v. Sequenom, Inc.,* 726 F.3d 1296 (Fed. Cir. 2013).

[2] Claim 1 of the patent reads: "A method for detecting a paternally inherited nucleic acid of fetal origin performed on a serum of 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."

the parties and the District Court agree that noninvasive detection of a gene of paternal origin can be diagnostically important with respect to the health status of the fetus.

This Court's decision with respect to Sequenom's appeal was not an affirmance of the decision of the District court. Instead, the Court reversed the decision of the District Court based on its faulty construction of the claims of the patent and remanded the matter with instructions that the lower court evaluate the various defenses raised by the defendant, Aria Diagnostics, Inc., including the defense that the claims were not patent eligible under §101, particularly in light of the decision of the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. ___, 133 S.Ct. 2107, 186 L.ED. 124 (2013). In its instructions this Court noted that the Supreme Court in *Myriad* had held that claims directed to isolated DNA were not eligible, but that claims directed to cDNA were patent eligible. *Aria Diagnostics, Inc. v. Sequenom, Inc.,* 726 F.3d at 1304.

On remand, the parties brought cross motions for summary judgment under Section 101, Sequenom seeking a judgment that the process claims of the patent were drawn to eligible subject matter and Ariosa[3] seeking a judgment that the claims were not patent eligible. Even though a "process" is among the classes of invention made eligible for patenting under §101, the District Court denied

[3] Aria is now known as "Ariosa Diagnostics, Inc." and hereinafter will be referred to as "Ariosa."

Sequenom's motion and granted the motion of Ariosa, after an analysis of Supreme Court precedent relating to the subject matter eligibility of patent claims that have held that "laws of nature, natural phenomena and abstract ideas" are not themselves patent eligible.[4]

Even though the District Court's opinion clearly indicates that it was basing its decision that the claims of the ´540 patent were not patent eligible under §101 based on these authorities, in granting Ariosa's motion for judgment and denying Sequenom's, it misconstrued them when it held that "the only inventive concept contained in the patent is the discovery of cffDNA, which is not patentable."[5] For reasons that we will develop more fully below, the decision of the District Court, clearly misapplies the holdings of the Supreme Court relating to subject matter patentability of claims implicating products of nature and natural phenomena upon which it purports to rely and should be reversed and remanded for a determination of the other issues raised by the litigants.

B. Summary of Argument.

It is true, as the District Court found, that the inventors were the first to recognize that cffDNA is present in the blood of a pregnant woman. It is also true that the presence of cffDNA in maternal blood is a natural phenomenon. However,

---

[4] *Diamond v. Diehr*, 450 U.S. 175, 185, 101 S.Ct. 1048, 67 L.Ed.2d 155 (1981).

[5] According to the brief of the Appellants, at page 2, the term "cffDNA" is intended to refer to cell-free fetal DNA.

it is abundantly clear from the inspection of claim 1 and the other independent claims are not claims to the natural phenomenon. None of them claim maternal blood or even cffDNA. Instead, in our view, when properly construed the independent claims of the patent are, in substance, claims to a process which can and should be viewed as either or both of claims to a new use of a known process (amplification and detection of DNA) and/or to a new use of an old composition of matter (either plasma or serum obtained from the fractionation of maternal blood) to detect a previously unknown target, a cffDNA in maternal blood. As such, the claims are patent eligible claims to a patent eligible process under §101 as that section is illuminated by 35 U.S.C. §100(b) which reads:

> "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." (Emphasis by underlining added).

Our analysis of the applicable law starts with the observation that both (i) the process of DNA amplification and (ii) a composition of matter comprising plasma or sera derived from blood, are clearly subject matter eligible under §101 for patenting and could be patented were they otherwise novel and unobvious under 35 USC §§102 and 103 extant at the time of the filing of the application resulting in the ´540 patent were they not restricted to a process for detecting a cffDNA of

paternal origin.[6] In that regard, and as the Court is surely aware, numerous patents have been granted on DNA amplification, among which is U.S. 4,683,195. Claim 1and other claims of that patent claim a process of detecting a nucleic acid by amplifying the nucleic acid and then detecting the amplified DNA. These patents have been extensively litigated without challenge, or without a successful challenge at least, to the patent eligibility of the claims.[7]

It is decades old and fundamental patent law doctrine that addition of a limitation to a patent eligible claim actually makes the claim narrower in scope. That doctrine is eviscerated if a diagnostic process which, when broadly claimed, would be patent eligible if the requirements of novelty and unobviousness were

---

[6] It is not essential to our argument that blood plasma or serum be considered patent eligible as a composition of matter under Section 101. However, in nature they are each a component of blood and must be obtained from blood by the intervention of man and in the form obtained they have properties different from blood which permits them to be used for purposes for which blood is unsatisfactory. It is undoubtedly the case that many persons wounded in battle under circumstances where typing and the administration of whole blood are impractical owe their lives to the invention of plasma. Further, we think it worth noting that other products found in natural products such as adrenalin and insulin have been found to be patentable after separation from the environment in which they occur naturally when they exhibit properties permitting uses for which the product in its natural form is not useful. See U.S. 730,176 (1903) for (adrenalin) and U.S. 1,469,994 (1923) for insulin. Accordingly, we think plasma and sera would have been patent eligible inventions.

[7] See, for example, *Applera v. Bio-Rad Lab Inc*., case no. 3.04-cv-01881 in the U.S. District Court for the District of Connecticut. The Court may also want to take notice of the fact that the inventor of amplification technology, Dr. Kary Mullis, was awarded the Nobel Prize for Chemistry for his efforts in 1993.

satisfied becomes ineligible for patenting when narrowed if that narrowing involves applying the process to the new use of detecting a hitherto unknown product of nature or natural phenomenon, in this case the presence of cffDNA of paternal origin in maternal blood.

It is also noteworthy that the process of the claims of the 540 patent clearly satisfies the machine-or-transformation test frequently used to evaluate whether a process claim is patent eligible under Section 101. Although it declined to endorse the test as the sole indicator of process claim patent eligibility, the Supreme Court did hold that the test retains vitality as "a useful and important clue…for determining whether some claimed inventions are processes under §101." *Bilski v. Kappos,* 561 U.S. ___, 130 S.Ct. 3218, 3227 (2010).

The process of the ´540 patent requires substantial manipulation of the natural phenomenon involved here. Thus, the maternal blood containing cffDNA of paternal origin must be fractionated to obtain maternal plasma or serum and the plasma for serum further processed to separate the cffDNA and the separated DNA manipulated in the final steps of the actual amplification process. All of these manipulations are, as the Court held in *Bilski*, yet further clues to the patentability of the claims justifying recognition of the patent eligibility of the ´540 patent claims.

Amicus curiae submits that the clarification of the law of patent eligibility of processes that would result by adopting a rule that a claim to a process which is a new use of a process, machine, manufacture or composition of matter that itself would be patent eligible under §101would greatly ease the determination of patent eligibility in the patentability examination conducted in the Patent and Trademark Office and the review of validity challenges in the District Courts. We further submit that adoption of this rule is also consistent with existing Supreme Court precedent.

Our analysis of that precedent follows next but before undertaking it we think it important to point out that the District Court, in particular reliance on *Parker v. Flook,* 437 U.S. 584 (1978) and on *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* 132 S.Ct. 1289, 1300 (2012) insists that a process claim containing a law of nature must recite substantially more innovation than "conventional steps, specified at a high level of generality" to be patentable. The District Court, however, does not provide helpful insight with respect to the additional innovation necessary for patentability. Furthermore, the rigid application of language from *Flook* and *Mayo* stands in stark contrast to the observation in *Diamond v. Diehr,* 450 U.S. 175, 187 (1981) that "[it] is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be patentable." For reasons we shall discuss

below, consideration of the most pertinent Supreme Court authority in the context of the facts of the cases they were deciding demonstrates that a claim to a new use of a known process or composition of matter that applies a law of nature or natural phenomenon without claiming it has the requisite innovation to satisfy the exacting requirements imposed by the Supreme Court. We turn now to an analysis of Supreme Court precedent.

IV. ARGUMENT: THE DEVELOPMENT OF THE LAW RELEVANT TO CLAIMS IMPLICATING LAWS OF NATURE, NATURAL PHENOMENA AND ABSTRACT IDEAS AND ITS APPLICATION TO THE 540 CLAIMS.

1. *Cochrane v. Deener,* 94 U.S. 780 (1876). *Cochrane* was decided in an era when there was doubt that a process not tied to a specific machine was patentable, the Court firmly resolved that doubt by affirming the validity of a patented process that the patentee claimed was "not limited to any special arrangement of machinery." *Id.* at 785. In its decision the court provided a definition of a patent eligible process that currency today in determining patent eligibility. Thus, the Court said:

> "A process is a mode of treatment of certaqin materials to produce a given result. It is an act, or series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery." (Emphasis added). *Id.* at 788.

Even though §101 itself and cases like *Cochrane* and its progeny suggest that patent eligibility is broadly available, the Court long ago attached an important

limitation on the patentability of "inventions" which, though not specifically expressed in §101. That limitation is that, notwithstanding the plain language of §101, laws of nature, natural phenomena and abstract ideas *per se* should be available to all and, therefore, are not patentable in any form. See, for example, *Bilski,* 130 S. Ct. at 3225.

The Court established this exception long before the enactment of §101, and at least as long ago as 1852 in *Le Roy v. Tatham*, 55 U.S. 156 (1852), holding:

> "[A] principle is not patentable. A principle, in the abstract, is a fundamental truth; an original cause, a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Id.* at 174-75.

The Court expressly, and significantly, did go on to say that processes that utilize such natural agencies are patent eligible. In the Court's words, with reference to these natural agencies, "the invention is not in discovering them, but applying them to useful objects." *Id.* at 175. Plainly the claims of the 540 patent meet the standard enunciated in *Le Roy.*

2. *Funk Brothers Seed Co. v. Kalo Innoculant Co.*, 333 U.S. 127 (1948). *Funk Brothers* is another important case in the evolution of Supreme Court jurisprudence relating to patent eligibility. The patent in that case, the Court noted, was directed to a combination of mutually noninhibitive naturally occurring bacteria previously individually used to inoculate plants. The novelty of the invention lay in the discovery that the species were noninhibitive of each other. As

far as the Court was concerned, this discovery was of the "handiwork of nature." *Id.* at 131. Apart from that handiwork, the combination of bacteria did nothing that each species did not do individually and that the only advantage to the user was the ability to buy them in combination rather than individually. *Id.* at 132. The Court accordingly held that the claims to the aggregation were not patent eligible but pointedly observed: "If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." *Id.* at 130. *Amici* submit that the process claims of the 540 patent do just that.

As in *Funk Brothers*, a handiwork of nature, i.e., the presence of cffDNA in maternal blood, was discovered by the patentees. However, they did not seek to patent this phenomenon but instead patented a process which, as the record in this case clearly reflects and the district Court acknowledges, takes advantage of the knowledge of that natural phenomenon by applying it to a new and very useful end, the detection of a cffDNA of paternal origin in the maternal blood. Accordingly, patent eligibility of the claims in the present case is consistent with the holding in *Funk Brothers* even though the article claims considered by the Court were held not to be.

In *Funk Brothers,* the Court went beyond merely holding the claims before it to be unpatentable. It also cited three cases of its own with approval where applications of natural phenomena had been held to be patentable, the *Telephone*

Cases, 126 U.S. 1, 532-553 (1888); *De Forest Radio Co. v. General Electric Co.,* 283 U.S.665, 684-685(1931); and *Mackay Radio & Tel. Co. v. Radio Corp.,* 306 U.S. 86, 94 (1939). Significantly, it also cited a decision of the second circuit upholding a patent challenged on the grounds it claimed a natural process. See *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F.3d 453 (2d Cir. 1908). The patent involved in *Cameron* claimed a process for treating sewage using naturally occurring anaerobic and aerobic bacteria that was a substantial improvement over known methods of treating sewage using such bacteria. The improvement over the known process of treating sewage with such bacteria was to conduct the process while the sewage flowed slowly. The Second Circuit stated that it was "satisfied that Cameron was the first one to subject a flowing current of sewage to the action of anaërobes and aërobes…." Based on that it held that, while the process involved the agencies of nature, it was for a practical purpose and, therefore, was patentable under the standard enunciated in the *Telephone Cases*. *Id.* at 463.

It is clear that the invention, a process using "natural agencies", held to be patentable was in fact a new use of old process (sewage treatment with anaerobic and aerobic bacteria) involving using the bacteria to treat slow moving sewage. Clearly, therefore, finding the claims of the ´540 patent to be patent eligible is consistent with the patent eligibility criteria discussed in *Funk Brothers*, i.e., that a process that applies a law of nature to a new and useful end is patent eligible.

3. *Diamond v. Diehr,* 450 U.S. 175 (1981). The patent claims in Diamond involved a method for curing rubber in a mold in a precise manner. Because an ideal cure for molded rubber is affected by a number of variables, including thickness of the molded article, the temperature of the mold and the amount of time the article being molded is allowed to remain in the mold, it is sometimes the case that articles are cure for an insufficient time or cured for too long, in each case adversely affecting the properties of the molded article. See Diamond, 450 U.S. at 177. Accordingly, the prior art process for curing molded rubber articles calculated the cure time as the shortest amount of time in which all parts of the product will be cured. This led to over or under estimating the time for curing the product. *Id.*at 178.

To avoid that result, the invention claimed a process wherein the temperature in the mold was continuously monitored, a practice apparently not carried out in the prior art. The temperature measurements obtained this way were fed to a computer which, using the Arrhenius equation to recalculate the cure time. When the recalculated time equaled the time required for curing, a signal was generated which caused the mold press to open. The claim to this process was rejected in the Patent and Trademark office as not being patent eligible because the

claim incorporated non statutory subject matter, the Arrhenius equation.[8] On appeal from the reversal of the Office decision by the Court of Customs and Patent Appeals, the Court affirmed the CCPA. In doing so it held that:

> "Arrhenius' Equation is not patentable in isolation, but when a process for curing rubber is devised which incorporates in it a more efficient solution of the equation, that process is at the very least not barred at the threshold by §101." *Id.* at 188.

Although not discussed by the Court, it should be noted that the claims in question were clearly in the form of a new use of a known process in which the old process, rubber molding, was modified by continuously monitoring the temperature in the mold and using the Arrhenius equation to determine when optimal curing had occurred. Thus the position of *Amicus curiae* concerning the patent eligibility of claims exploiting a practical use of a natural phenomenon or, as in *Diehr*, a mathematical abstraction in the form of a new use of an old process is entirely consistent with the result reached in *Diehr*.[9]

---

[8] In making this rejection, the Office relied on the holding in *Gottschalk v. Benson*, 409 U.S. 63 (1972).

[9] *Amicus curiae* argued above that it stands logic on its head to find a claim ineligible for patenting when it is a new use of an otherwise patentable process of composition of matter. The *Diehr* Court appears to share this view as it commented: "Our earlier opinions lend support to our present conclusion that a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula, computer program, or digital computer. *Id.* at 187.

4. *Mayo Collaborative Services v. Prometheus laboratories, Inc.*, 132 S.Ct. 1293 (2012). More recently in *Mayo*, the Court considered whether a method for treating Crohn's and related diseases was patent eligible. Claim 1 of the patent is representative of the claimed method which had two active steps, administering a prior art drug and measuring the level of certain metabolites resulting from the drug as it was broken down in the body. The claim also contained two "wherein" clauses relating to the significance of the measured level of metabolites. Thus, if the metabolite level was below a certain level, the drug dosage should be increased and if it was above a certain level the dosage should be decreased. The Court considered this relationship of the metabolite levels to be a natural law(s). *Id.* at 1296.

The Court, in its evaluation of the patent eligibility of the claim, appropriately we think, noted that the two active steps of the method were in fact known to the art. "Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels and efficacy and toxicity of thiopurine compounds." *Id.* at 1298. The claim did not require that a person practicing the method do anything which was not already known since the wherein clauses in the claim relating to the significance of the metabolite levels plainly do not add a further step or steps to the claimed process. Therefore, the claims in the patent reviewed in *Mayo*, unlike the claims of the ´540 patent or

the patent in *Cameron* discussed above, obviously do not embrace a new use of a known process or composition but are, instead, merely claims to the known process and inclusion in the claim of the instruction of the significance of the data obtained by the known process does not materially change the claim. Therefore, adopting the test of patent eligibility proposed by *Amicus curiae* does not conflict with the holding in *Mayo*.

5. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 2013. *Myriad* is the most recent case handed down by the Supreme Court. In *Myriad*, the Court considered the patentability of a number of claims directed to sequences of DNA corresponding to at least some portion of the DNA encoding the BRCA1 and BRCA2 proteins, genes of diagnostic significance with respect to the risk of a woman incurring breast cancer. In brief, the Court held that claims to genomic DNA were not patent eligible under §101 because, even though not known before the discovery that resulted in the patents considered by the Court, the genes encoding these proteins are products of nature. The Court reached this conclusion even though the DNA identified by Myriad were claimed as isolated forms of DNA. It did so because, in its view, the isolated gene sequences were insufficiently changed from their natural condition. By contrast, the Court also held that cDNA, because it does not exist in nature and can only be obtained by the intervention of man, is patentable. *Id.,* slip opinion at p. 17.

Even though the isolated genomic DNA was not found to be patentable because, in the Court's view, it was a natural product, the Court took pains to point out that it was not holding that any invention based on knowledge of the genes was unpatentable, specifically noting that no method claims were before it. *Id.,* slip opinion at p. 17. The Court then went even further and cautioned "this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes." *Id*., slip opinion at p. 17. It then commented with approval on an observation by Judge Bryson of this Court in his opinion concurring in part and dissenting in part in this Court's judgment in *Association For Molecular Pathology v. United States*, 689 F.3d 1303, 1349 (2012) to the effect that "[as] the first party with knowledge of the … sequences, Myriad was in an excellent position to claim applications of that knowledge."

In his opinion Judge Bryson identified a number of claims in the patents of Myriad that met his criteria for patent eligible subject matter approvingly noted by the Supreme Court. Among these is claim 21 of U.S. 5,753,441 which claims a method of detecting a genetic alteration in the BRCA1 gene by hybridizing a probe to an RNA produced by that gene, a natural product or phenomenon, isolated from a human sample and detecting the resulting hybridization product. Significantly, the step of hybridizing a probe to an RNA isolated from a human sample to detect its presence involves nothing more than the use of conventional nucleic

hybridization technology. Therefore, claim 21 of the patent considered in Myriad clearly falls into the category of patent eligible subject matter under §101, as illuminated by §101(b), since it is directed to a new use of a known process, in this case the use of hybridization technology to detect a previously unknown natural product or natural phenomenon. Seen in that light, the endorsement of the patent eligibility of claim 21 by the Court clearly dictates that the same treatment should be accorded the claims of the ´540 patent.

V. CONCLUSION.

Amicus curiae, for the foregoing reasons, urge this Court to reverse the decision of the District Court and hold that a process claim which is directed to a new diagnostic use of a known process and/or known composition of matter that are otherwise eligible for patenting under §101 be itself considered patent eligible in the circumstance where the diagnosis is specifically directed to the detection of a previously unknown natural product or natural phenomenon of diagnostic significance. This should particularly be the result true in the case where the claimed process satisfies the machine-or-transformation test for patent eligibility of a process. This result is also consistent with long honored patent law doctrine that inclusion of an additional limitation in a claim actually narrows its scope and that as so narrowed the claim to the new use is not a claim to the product of nature or the natural phenomenon and not preemptive of it. The result is also not

inconsistent with the extensive jurisprudence developed by the Supreme Court concerning the patentability of processes that exploit knowledge of a previously unknown product of nature or natural phenomenon, for example, as it recently held in *Association of Molecular Pathology v. Myriad Genetics, Inc., supra.* Adoption of such a standard of patent eligibility will also do much to further and incentivize innovation to discover and exploit new diagnostic tools without restricting other applications of the product of nature or natural phenomenon such innovation reveals, all of which is to the substantial benefit of the public.

By: /s/*William L. Respess*
William L. Respess
Attorney for *Amicus Curiae*

United States Court of Appeals
for the Federal Circuit

Ariosa Diagnostics, Inc v. Sequenom, Inc.
Nos. 2014-1139, -1142, -1144

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by William L. Respess, counsel for Amicus Curiae, SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION, to print this document. I am an employee of Counsel Press.

On **January 28, 2014**, Counsel for Amicus Curiae has authorized me to electronically file the foregoing **Brief** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

David Isaac Gindler
Andrei Iancu
Amir Naini
Irell & Manella LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067
310-277-1010
dgindler@irell.com
aiancu@irell.com
anaini@irell.com
Counsel for Appellee
Ariosa Diagnostics, Inc.

Edward R. Reines
Derek C. Walter
Michele A. Guage
Weil, Gotshal & Manges LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
650-802-3000
edward.reines@weil.com
derek.walter@weil.com
michele.guage@weil.com
Counsel for Appellee
Verinata Health, Inc.

MICHAEL J. MALECEK
PETER E. ROOT
Aton Arbisser
KAYE SCHOLER LLP
Two Palo Alto Square, Suite 400
3000 El Camino Real
Palo Alto, California 94306
(650) 319-4500
michael.malecek@kayescholer.com
peter.root@kayescholer.com
aarbisser@kayescholer.com
Counsel for Appellants
Sequenom, Inc., et al.

William Paul Schuck, Esq.
Bartko, Zankel, Bunzel & Miller
Suite 800
One Embarcadero Center
San Francisco, CA 94111
415-956-1900
pschuck@bzbm.com
Counsel for Appellee
Natera, Inc.

Paper copies will also be mailed to the above counsel at the time paper copies are sent to the Court.

Upon acceptance by the Court of the e-filed document, six paper copies will be filed with the Court, via Federal Express, within the time provided in the Court's rules.

January 28, 2014

/s/ John C. Kruesi, Jr.
John C. Kruesi, Jr.
Counsel Press

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).

__X__ The brief contains 5,172 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii),or

____ The brief uses a monospaced typeface and contains _____ lines of text, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

__X__ The brief has been prepared in a proportionally spaced typeface using MS Word 2013 in a 14 point Times New Roman font or

____ The brief has been prepared in a monospaced typeface using _____ _____in a ___ characters per inch_____ font.

January 28, 2014

/s/*William L. Respess*
William L. Respess
Attorney for *Amicus Curiae*

United States Court of Appeals
for the Federal Circuit

Ariosa Diagnostics, Inc v. Sequenom, Inc.
Nos. 2014-1139, -1142, -1144

CERTIFICATE OF INTEREST

Counsel for *amicus curiae* San Diego Intellectual Property Law Association certifies the following:

1. The full name of every party or amicus represented by me is:
   San Diego Intellectual Property Law Association
2. The name of the real party in interest (if the party name in the caption is not the real party in interest) represented by me is:
   San Diego Intellectual Property Law Association
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 curiae* now represented by me in the trial court or agency or are expected to appear in this court are:
   William L. Respess
   Sheppard Mullin Richter & Hampton LLP
   12275 El Camino Real, Suite 200
   San Diego, CA 92130-2006
   (858) 720-8900

Dated: January 28, 2014

/s/ *William L. Respess*
William L. Respess

United States Court of Appeals
for the Federal Circuit

Ariosa Diagnostics, Inc v. Sequenom, Inc.
Nos. 2014-1139, -1142, -1144

CERTIFICATE OF SERVICE

I, John C. Kruesi, Jr., being duly sworn according to law and being over the age of 18, upon my oath depose and say that:

Counsel Press was retained by William L. Respess, counsel for Amicus Curiae, SAN DIEGO INTELLECTUAL PROPERTY LAW ASSOCIATION, to print this document. I am an employee of Counsel Press.

On **January 28, 2014**, Counsel for Amicus Curiae has authorized me to electronically file the foregoing **Certificate of Interest** with the Clerk of Court using the CM/ECF System, which will serve via e-mail notice of such filing to any of the following counsel registered as CM/ECF users:

David Isaac Gindler
Andrei Iancu
Amir Naini
Irell & Manella LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067
310-277-1010
dgindler@irell.com
aiancu@irell.com
anaini@irell.com
Counsel for Appellee
Ariosa Diagnostics, Inc.

Edward R. Reines
Derek C. Walter
Michele A. Guage
Weil, Gotshal & Manges LLP
201 Redwood Shores Parkway
Redwood Shores, CA 94065
650-802-3000
edward.reines@weil.com
derek.walter@weil.com
michele.guage@weil.com
Counsel for Appellee
Verinata Health, Inc.

MICHAEL J. MALECEK
PETER E. ROOT
Aton Arbisser
KAYE SCHOLER LLP
Two Palo Alto Square, Suite 400
3000 El Camino Real
Palo Alto, California 94306
(650) 319-4500
michael.malecek@kayescholer.com
peter.root@kayescholer.com
aarbisser@kayescholer.com
Counsel for Appellants
Sequenom, Inc., et al.

William Paul Schuck, Esq.
Bartko, Zankel, Bunzel & Miller
Suite 800
One Embarcadero Center
San Francisco, CA 94111
415-956-1900
pschuck@bzbm.com
Counsel for Appellee
Natera, Inc.

January 28, 2014

/s/John C. Kruesi, Jr.
John C. Kruesi, Jr.
Counsel Press