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DePaul Journal of Art, Technology & Intellectual Property Law

Volume 26
Issue 1 *Fall 2015*

Article 5

Ariosa Diagnostics, Inc. v. Sequenom, Inc.

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ARIOSA DIAGNOSTICS, INC. V. SEQUENOM, INC.

I. INTRODUCTION

Sequenom is a California based company specializing in developing molecular technologies including NIPTs (Non-Invasive Prenatal Genetic Testing), and laboratory developed tests for genetic diseases and cancer.[1] At issue here is Sequenom's patent regarding the methodology and usage of cffDNA.

In 1996, Dr. Dennis Lo and Dr. James Wainscoat, researchers for Sequenom, discovered a new type of DNA in the blood stream of an expecting mother called cell free fetal DNA, or cffDNA.[2] cffDNA is freely circulating fetal DNA located within the plasma of the maternal blood stream.[3] A particular type of fetal DNA, paternal cffDNA, allows for the early detection of certain features of the fetus such as its sex, paternity and a variety of genetic and chromosomal diseases.[4] In 2001, Drs. Lo and Wainscoat had acquired a patent relating to its discovery and methods of use (the 540 patent).[5]

The 540 patent does not relate to the discovery of cffDNA, but instead illustrates the methods used to amplify cffDNA to detectable levels.[6] It also includes techniques used in diagnosing genetic diseases in a fetus based on cffDNA inherited from the father.[7] After the cffDNA is extracted from the maternal plasma, Sequenom uses methods called polymerase chain reaction (PCR) and gel electrophoresis to amplify the cffDNA to detectable levels.[8]

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[1] Sequenom, *Sequenom: The Science of Interpreting the Genome* (2015), http://www.sequenom.com.

[2] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (2015).

[3] *Id.*

[4] Sequenom, *Sequenom: The Science of Interpreting the Genome* (2015), http://www.sequenom.com.

[5] *Ariosa*, 788F.3d at 1373.

[6] *Id.*

[7] *Id.*

[8] *Id.*

A. Ariosa Diagnostics & Appellees

Appellees Ariosa Diagnostics Inc., Natera, Inc., and Diagnostics Center Inc. are competitors of Sequenom who also specialize in the development and marketing of non-invasive tests used for the purpose of diagnosing fetal characteristics and paternity.[9] Sequenom's 540 patent negatively impacts Ariosa's ability to market and develop current and future non-invasive prenatal genetic tests. If the patent is allowed to stand, Ariosa would most likely have to cease to market all current and future tests in development that use the same methods in the 540 patent or risk litigation. Ariosa could also come to an agreement with Sequenom to license Sequenom's patent for Ariosa's use. Both options would place a financial burden on Ariosa which did not previously exist and could potentially harm the future of the company's research and development wing.

B. Substantive & Procedural History

Initially, Sequenom sent letters to each of the appellees alleging patent infringement.[10] In response, each appellee asserted that there was no patent infringement in declaratory judgments.[11] Sequenom then filed a preliminary injunction against Ariosa to enjoin them from selling their Harmony Prenatal Test, a DNA based blood test that detects the presence of certain chromosomal anomalies signaling disease in a baby.[12] In July 2012, the district court denied Sequenom's motion for a preliminary injunction and held that "there was a substantial question over whether the subject matter of the asserted claims was directed to eligible subject matter."[13] Sequenom then appealed to the federal court of appeals.[14]

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[9] *Id.* at 1374.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*
[14] *Id.*

In August 2013, the federal court of appeals vacated and remanded the case in order for the subject matter eligibility to be examined under Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 133 S.Ct. 2107, 2117 (2013)."[15] Both parties then filed for summary judgment.[16] Sequenom appealed the district court ruling in favor of Ariosa which stated that cffDNA was a naturally occurring phenomenon and Sequenom did not contribute enough to this naturally occurring phenomenon to deem it eligible under 35 U.S.C § 101.[17] The court emphasized that Sequenom used PCR and gel electrophoresis, which were routine methods, and applied them to the naturally occurring phenomenon of cffDNA.[18] These very steps, the court reasoned, made Sequenom's claims patent ineligible.[19]

II. LEGAL ANALYSIS

In its analysis of the issue, the court re-iterated a two-part test established in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012), which laid out the framework for determining what a patent eligible concept would look like.

A. Background on Mayo v. Prometheus

Mayo was also a patent infringement case encompassing a technique to calculate the optimum dose of drugs administered to patients with autoimmune disease in order to limit its harmful side effects.[20] The respondent brought action against its competitors alleging patent infringement on this basis.[21] The court devised a two-pronged test to define whether a particular concept is eligible for patenting.[22]

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[15] *Id.* at 1375.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] *Mayo Collaborative Servs. v. Prometheus Labs.*, Inc., 132 S. Ct. 1289 (2012).
[21] *Mayo*, 132 S. Ct. at 1290, 1291.
[22] *Id.*

In the first part of this test, the court asked if the claim is directed to a patent ineligible concept.[23] "Phenomena of nature, mental processes and abstract, intellectual concepts are not patentable because they are basic tools of scientific and technological work."[24] The court articulated that a patent involving these concepts may create a type of monopoly that would work to stifle innovation, rather than promote it.[25]

The second prong asks whether the concept contains any conventional steps that would not deem it sufficiently "inventive".[26] A patent focusing on a natural phenomenon must contain additional components so that it is not merely replicating a law of nature.[27]

B. Background on Diamond v. Diehr

Although, the court in *Ariosa* relied heavily on the *Mayo* case, *Mayo* was heavily distinguished from *Diehr*.[28] In *Diehr*, the respondents filed claim to patent the process of creating cured products from raw, uncured synthetic rubber.[29] A part of this process involved the use of mathematical equations and a programed computer.[30] The court held the process patent eligible on the basis that the patent claim did not preempt the use of any one individual step, but the combination of steps as a whole in order to achieve the same result.[31] The court also held when taken together, all the steps as one process are patent eligible even though the individual steps in the process were not new, original, or patent eligible themselves.[32]

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[23] *Mayo*, 132 S. Ct. at 1293, 1294.
[24] *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).
[25] *Mayo*.132 S. Ct. at 1296.
[26] *Id.* at 1294.
[27] *Id.*
[28] *Diamond v. Diehr*, 101 S. Ct. 1048 (1981).
[29] *Id.* at 177.
[30] *Id.*
[31] *Id.* at 188.
[32] *Id.* at 187.

C. Application of Mayo Test

The court in the present case reasoned that the patented method started and ended with a natural phenomenon, therefore, the patent was directed towards a naturally occurring phenomenon.[33] The court supported this reasoning by looking into the description of the invention notes which stated the surprising discovery of a high concentration of fetal DNA located in maternal DNA and plasma.[34] Thus, the claim was directed towards a naturally occurring phenomenon.[35]

Since the patented method involved a naturally occurring phenomenon, the court moved on to the second prong of the test. In the second prong, the court looked at whether the claim contained an inventive concept sufficient to "transform" the naturally occurring phenomenon into a patent eligible application.[36]

The court concluded that the claim did not include any aspects that were sufficiently "inventive" in order to deem it eligible for patenting.[37] These aspects when concerning a claim of a certain method, the court reasoned, must be "new and useful".[38]

D. Judge Linn's Independent Concurrence

Judge Linn's concurrence recognized that this decision was possibly an unintended consequence of the broad two-part test set out in *Mayo*.[39] He stated that although he did not agree with the outcome of this particular case, the precedent set in *Mayo* nonetheless bound him to his decision.[40] Judge Linn indicated that the 540 patent should have been eligible.[41] Although amplification

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[33] *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1376 (2015).
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] *Id.* at 1377.
[38] *Parker v. Flook*, 437 U.S. 584, 591 (1978) ("The process itself, not merely the mathematical algorithm, must be new and useful.").
[39] Ariosa, 788 F.3d at 1380.
[40] *Id.*
[41] *Id.* at 1381.

through PCR and gel electrophoresis were routine methods, using it to detect cffDNA was something which had never been done before.[42] Citing Diamond v. Diehr, Judge Linn reasoned that in *Mayo*, doctors had already been measuring metabolites, adjusting dosage and performing the subsequent steps for years in the exact same way the patent had claimed.[43] However, in the present case, these "routine" steps had never before been performed because the maternal plasma in which cffDNA is found was frequently discarded during blood samples.[4445]

III. FUTURE IMPLICATIONS

The implications of this decision will be far reaching. This ruling will no doubt have a grave impact for future biomarker patenting methods. With a possible increase in the denial of patenting biomarker detection methods, a disincentive for innovation may arise. The court's main goal here was to refrain from allowing a party to patent essential laws of nature and natural occurrences because it would inherently stifle innovation.[46] However, by interpreting the scope of the *Mayo* test broadly, the court has done the very thing they intended to prevent. Many biomarker detection methods utilize types of "routine" methods in some shape or form. If these techniques now come under heavy scrutiny by the courts, it may act as a disincentive for biotechnology companies to develop new detection methods in this field.

As future cases with similar facts are heard, courts will have to narrow down an already far-reaching two-part test. The broad language of the *Mayo* test leaves many questions regarding its scope and application. As patent infringement claims flood the courts, judges will have to further refine the over-inclusive

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[42] *Id.*

[43] *Id.* at 1380.

[44] *Id.* at 1380-1381.

[45] *See, Diamond v. Diehr*, 450 U.S. 175, 177 (U.S. 1981) (where the Supreme Court held that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well-known and in common use before the combination was made").

[46] *Ariosa*, 788 F.3d. at 1371.

vocabulary. Courts will have to define what makes a concept sufficiently "inventive" as to be eligible for patenting as well as what exactly constitutes an "abstract idea" or a "law of nature".

Judge Linn's concurrence offers some hope in that it recognizes there may be a potential problem with the court's broad language of the *Mayo* test. Even though Judge Linn concurred with the Court, he did make it a point to mention that he was bound by precedent.[47] This could potentially open up the door for the evolution of a similar train of thought in subsequent cases.

Sequenom has recently filed a petition for rehearing en banc along with many amici briefs for support, many of which were written by twenty-three law professors who teach and write about patent law.[48] Their main contention is the court's decision in *Ariosa* undermines the principles and notions the patent law system is designed to protect.[49] In support of this, they allege the court's decision was too general and broad and thus contradicts their own holding in Bilski v. Kappos, 561 U.S. 591 (2010), which stated that §101 is a "dynamic provision designed to encompass new and unforeseen inventions.[50] The application of *Mayo's* two-step test to already past legal patents would today render them invalid.[51] The brief also asserts that the decision stifles innovation by not allowing companies to recoup their investment.[52] Companies spend anywhere from $50-$70 million dollars in the research and development of genetic tests alone and if they cannot make up for that through patent protections of their products, it will threaten their financial stability.[53] This will result in the company ceasing to develop new innovative products for fear of not being compensated for their work.[54] Recently, Accelerated Diagnostics alerted its investors that if they are not able to sufficiently protect its intellectual property, they would incur

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[47] *Ariosa*, 788 F.3d at 1380.

[48] Brief of Amicus Curiae of Appellant at 1, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (2015) (No. 2014-1193).

[49] *Id.* at 1.

[50] *Id.* at 1-2.

[51] *Id.* at 2.

[52] *Id.* at 2-3.

[53] *Id.* at 3-4.

[54] *Id.* at 4.

heavy losses due to the significant costs that go into marketing and developing a product.[55]

IV. CONCLUSION

It is difficult to accurately predict the impact this decision will have because it was decided so recently. Time will only tell what the courts will make of this decision and whether they will adopt the overbroad test or work to narrow the Mayo test over the years to come. The courts may have their work cut out for them in trying to narrow and define certain language in the test. The court has made it clear that the only way to protect your invention is to keep it a secret for as long as possible. A small positive is Sequenom's petition for a rehearing en banc. The petition along with the amicus brief makes a very compelling argument against the broad, overarching *Mayo* test. In the meantime, the court's decision is quite ironic at best; in its attempt to promote innovation, a closer step was taken towards the suppression of creativity.

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[55] *Id.*

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