

# OBVIOUSNESS IS OBVIOUSLY IN *MAYO*: HOW *ARIOSA* REVEALS *MAYO*'S TRUE REQUIREMENT

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## INTRODUCTION

The purpose of this note is to explore the recent U.S. Court of Appeals for the Federal Circuit's decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,<sup>1</sup> a case that has left the future patentability of numerous medical diagnostic technologies uncertain and the prospect of investing in innovation in the life sciences industry unappealing.<sup>2</sup> The decision marks yet another controversial

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<sup>1</sup> 788 F.3d 1371 (Fed. Cir. 2015).

<sup>2</sup> See Eric J. Marandett & Irina Oberman Khagi, *Ariosa V. [sic] Sequenom Signals Trouble Ahead for Life Sciences*, LAW360, [www.law360.com/articles/718236/ariosa-v-sequenom-signals-trouble-ahead-for-life-sciences](http://www.law360.com/articles/718236/ariosa-v-sequenom-signals-trouble-ahead-for-life-sciences) (last visited Apr. 14, 2016). Marandett and Oberman Khagi note that the standard suggested by *Ariosa* "puts at risk such inventions as immunodiagnostics, molecular diagnostics, and method patents directed to therapeutic uses of antibodies,

milestone in the U.S. court system's path to establishing what qualifies as patent-eligible subject matter under 35 U.S.C. § 101.<sup>3</sup>

This note argues that the framework for a § 101 analysis established under *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*,<sup>4</sup> requires a court to perform an obviousness analysis when assessing patent validity, that the application of such framework to *Ariosa* was improperly performed, and that *Ariosa* was the ideal opportunity to formally import an obviousness analysis requirement into *Mayo*. Section II will provide a history of the *Ariosa* case, from the conception of the questionably-patentable material to the more recent denials of a motion to re-hear the case en banc before the Federal Circuit and of a petition for certiorari before the Supreme Court, and will briefly introduce the controversial claims in U.S. Patent 6,258,540,<sup>5</sup> the patent covering the “Non-Invasive Prenatal Diagnosis” technology at the heart of

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vaccines, gene therapy, and biologics and biosimilars.” *Id.* Patent protection is intended to provide “monetary incentives that lead to creation, invention, and discovery,” while balancing a possible impediment on invention through issues such as “raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements.” *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012).

<sup>3</sup> 35 U.S.C. § 101 (1952). “The [*Ariosa*] decision adds to a spate of recent cases marking a shift in the law on patentable subject matter, a trend that started with the Supreme Court decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and continued more recently in *Alice Corp. v. CLS Bank International*.” Jeffrey M. Jacobstein et al., *Federal Circuit Decision in Ariosa v. Sequenom Offers Further Clarification on the Scope of Patent-Eligible Subject Matter*, INTELL. PROP. & TECH. L. J. (Sept. 2015), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=632a2e1b-2216-449c-838b-d7428cf8d869>. See also Sue D. Nym, *Ariosa is a Good Example of Outcome-Driven § 101 Decisions*, IPWATCHDOG (Aug. 9, 2015), <http://www.ipwatchdog.com/2015/08/09/ariosa-is-a-good-example-of-outcome-driven-%24-101-decisions/id=60433/> (discussing a noticeable trend in § 101 decisions regarding early-outcome decision-making against patentability, and specifically noting that “[s]eemingly every new court decision addressing subject matter eligibility under 35 U.S.C. § 101 progressively weakens the patent system . . . each case seems to present a new low in terms of the depth and quality of analysis.”); see also Devlin Hartline, *Federal Circuit Should Reconsider Ariosa v. Sequenom: The Panel Decision Threatens Modern Innovation*, IPWATCHDOG (Aug. 30, 2015), <http://www.ipwatchdog.com/2015/08/30/federal-circuit-should-reconsider-ariosa-v-sequenom-the-panel-decision-threatens-modern-innovation/id=61171/> (noting that current § 101 jurisprudence is a “mess”).

<sup>4</sup> 566 U.S. 66 (2012).

<sup>5</sup> Non-Invasive Prenatal Diagnosis, U.S. Patent No. 6,258,540 (filed Mar. 4, 1998) (issued July 10, 2001) [hereinafter ‘540 Patent].

the *Ariosa* litigation. Section III will discuss legal precedent indicative of a requirement to perform a 35 U.S.C. § 103<sup>6</sup> obviousness test, including the background case law on which *Mayo* is based, and will also highlight evidence of obviousness analysis throughout cases such as *Ariosa*. Section IV will address the implications of importing obviousness for *Ariosa* as well as other leading cases in patent law, specifically addressing issues with obviousness in *Ariosa*. Section V concludes the note, briefly discussing how *Ariosa* was the case for the Supreme Court to narrow *Mayo*'s broad language and should serve as a basis for a legislative fix to § 101.

#### HISTORY AND BACKGROUND

The *Ariosa* case rests on the patentability of U.S. Patent 6,258,540 (“540 Patent”), originally filed in March of 1998 and titled “Non-Invasive Prenatal Diagnosis.”<sup>7</sup> Generally, in the United States there are five requirements that any invention must meet to be patented: the invention must be comprised of patent-eligible subject matter, must be useful, novel, non-obvious, and enabled through a specification.<sup>8</sup> Set forth in § 101, patent-eligible subject matter requires that an invention be within an area that is qualified for patent protection, generally “includ[ing] anything under the sun that is made by man,”<sup>9</sup> but excluding inventions that fall within the traditionally barred categories of (1) laws of nature, (2) natural phenomena, and (3) abstract ideas.<sup>10</sup> Section

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<sup>6</sup> 35 U.S.C. § 103 (1952).

<sup>7</sup> 540 Patent, *supra* note 5.

<sup>8</sup> 35 U.S.C. § 101; 35 U.S.C.A. § 102 (West, Westlaw through P.L. 112–211 approved 12/18/12); 35 U.S.C. 103; 35 U.S.C.A. § 112 (West, Westlaw through P.L. 112–29 approved 9/16/11). “The claimed subject matter must be useful, novel, and not obvious. In addition, the patent application must describe, enable, and set forth the best mode of carrying out the invention. These latter requirements must be satisfied before issuance of the patent, for exclusive patent rights are given in exchange for disclosing the invention to the public.” *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736 (2002) (citations omitted).

<sup>9</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). § 101 specifically lists as patent-eligible a “process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101.

<sup>10</sup> *See Chakrabarty*, 447 U.S. at 309. “Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’” *Id.* (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

101 also requires utility, a relatively low threshold to satisfy, which requires an invention be “capable of providing some identifiable benefit.”<sup>11</sup> Next, under 35 U.S.C. § 102,<sup>12</sup> an invention must be new in that it is not previously described in existing “prior art.”<sup>13</sup> Then, obviousness under 35 U.S.C. § 103 requires that a “person having ordinary skill in the art to which the claimed invention pertains” find that, in light of prior art, the invention is not already known.<sup>14</sup> In other words, obviousness requires an examination of whether “a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and [whether] the skilled artisan would have had a reasonable expectation of success in doing so.”<sup>15</sup> Finally, the invention must be accompanied by a written description with enough particularity so as to enable an individual skilled in the art to make, use, and understand the invention.<sup>16</sup>

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<sup>11</sup> *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366 (Fed. Cir. 1999). In *Juicy Whip*, the U.S. Court of Appeals for the Federal Circuit reversed a lower court’s decision that invalidated a patent on a “post-mix” beverage dispenser for lack of utility, and recognized that even inventions that alter a product to make it look like another product satisfy the requirement of utility. *Id.* at 1367–68. *See also* *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (stating that “[t]o violate § 101 the claimed device must be totally incapable of achieving a useful result.”).

<sup>12</sup> 35 U.S.C.A § 102.

<sup>13</sup> *Id.* § 102(a). “[P]rior art” is a legal phrase used to describe evidence that your invention is already known, and can include a printed publication, or something in public use, on sale, or described in another patent. *Id.* § 102(a)(1), (2).

<sup>14</sup> 35 U.S.C § 103 (1952). According to Robert P. Merges and John F. Duffy, this standard considers “whether a development is a significant enough technical advance to merit the award of a patent. . . . [I]f an idea is so obvious that people in the field would develop it without much effort, then the incentives provided by the patent system may be unnecessary to generate the idea.” ROBERT P. MERGES & JOHN F. DUFFY, *PATENT LAW AND POLICY: CASES AND MATERIALS* 606, 608 (6th ed. 2013).

<sup>15</sup> *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007).

<sup>16</sup> *See* 35 U.S.C.A. § 112 (West, Westlaw through P.L. 112–29 approved 9/16/11). Accompanying the specification describing the invention is “one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” *Id.* § 112(b). The Supreme Court has recognized that claim interpretation, in light of the specification, is a question of law for a court to decide, while infringement of a claim is a question of fact to be submitted to a jury. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 377 (1996).

*Lo's Discovery*

As of 1998, methods for detecting fetal sex and abnormalities used invasive techniques, such as amniocentesis and chorionic villus sampling.<sup>17</sup> Amniocentesis, still commonly used today, involves using a needle to take a sample of the amniotic fluid surrounding an unborn fetus for chromosomal testing, and is typically performed between fourteen and twenty weeks of a pregnancy.<sup>18</sup> Amniocentesis is approximately 99% accurate, but also carries risks of miscarriage, and can be painful for the mother.<sup>19</sup> Similarly, chorionic villus sampling entails the use of a needle or catheter to obtain a sample of the chorionic villi tissue found in the placenta for chromosomal testing, and can be performed between ten and thirteen weeks of a pregnancy, but has a higher risk of miscarriage than amniocentesis and may even result in a false positive.<sup>20</sup> As a result, there was a need in the industry for a non-invasive, effective, cost-efficient, and safer method of detecting birth defects, such as Down's Syndrome.<sup>21</sup>

In 1996, Y.M. Dennis Lo, one of the inventors of the '540 Patent technology, began working on such a method when he deduced from a series of medical articles that deoxyribonucleic acid ("DNA") from a fetus may be present in the mother's blood outside of fetal cells.<sup>22</sup> Lo had recently earned a degree from the University of Cambridge and two professional Doctoral degrees from the University of Oxford, and, at the time of the discovery, had been serving as a lecturer and honorary consultant at the University of Oxford Clinical School.<sup>23</sup> Through laboratory testing involving the use of different types of polymerase chain reactions ("PCR"), Lo

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<sup>17</sup> '540 Patent, *supra* note 5.

<sup>18</sup> *Amniocentesis*, AM. PREGNANCY ASS'N, <http://americanpregnancy.org/prenatal-testing/amniocentesis/> (last visited Apr. 8, 2017).

<sup>19</sup> *Id.* According to the American Pregnancy Association, "[a]lthough amniocentesis is considered to be a safe procedure, it is recognized as an invasive diagnostic test that does pose potential risks. . . . The risk of miscarriage ranges from 1 in 400 to 1 in 200." *Id.* Further, "[m]iscarriages can occur because of infection in the uterus, water breaking, or labor being induced prematurely." *Id.*

<sup>20</sup> *Chorionic Villus Sampling: CVS*, AM. PREGNANCY ASS'N, <http://americanpregnancy.org/prenatal-testing/chorionic-villus-sampling/> (last visited Apr. 8, 2017).

<sup>21</sup> *See* '540 Patent, *supra* note 5 (describing risky, time-consuming, and expensive methods currently used).

<sup>22</sup> CAMBRIDGE UNIV. PRESS, *THE PCR REVOLUTION: BASIC TECHNOLOGIES AND APPLICATIONS* 244 (Stephen A. Bustin ed., 2010).

<sup>23</sup> *Academic Profiles: Dennis Lo: Professor*, DEP'T OF CHEMICAL PATHOLOGY: THE CHINESE U. OF H.K., <http://www.cuhk.edu.hk/med/cpy/Research/DennisLo.htm> (last visited Apr. 29, 2016).

identified that substantial portions of cell-free fetal DNA were present in maternal blood in substantially higher concentrations than other types of DNA that were known to be present in blood at the time.<sup>24</sup>

Competing non-invasive methods of detection being researched at the time of Lo's discoveries focused on the use of fetal cells present in the mother's blood or whole cells from the fetus, but proved to be time-consuming or expensive.<sup>25</sup> Blood sampling techniques involved taking a mother's blood and spinning the blood in a centrifuge to obtain blood cells separated from the blood plasma,<sup>26</sup> where the blood plasma was then discarded by researchers in favor of analyzing the blood cells alone for detection of fetal sex and abnormalities.<sup>27</sup> In contrast to competing technologies, Lo examined the discarded blood plasma and discovered the presence of cell-free fetal DNA ("cffDNA"), or DNA existing outside of a human cell, that could be analyzed and used for detection.<sup>28</sup>

Polymerase chain reaction is a method of DNA amplification in which DNA is replicated numerous times to provide billions of copies of the DNA, making even a tiny sample of DNA enough for analysis by a scientist.<sup>29</sup> The process was invented in the 1980's,<sup>30</sup> and by 1996, had become a technique that could be used by any laboratory to reproduce data pertaining to DNA.<sup>31</sup> Precisely because the PCR process is simple, inexpensive, and easy to perform, Lo chose to use this amplification method as a step in his inventive process in order to produce larger samples of the cffDNA

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<sup>24</sup> See CAMBRIDGE UNIV. PRESS, *supra* note 22 (describing Lo's laboratory experiences).

<sup>25</sup> See '540 Patent, *supra* note 5 (describing competing technologies).

<sup>26</sup> See Dr. Khezar Hayat, *Difference Between Plasma and Serum*, MEDIMOON (July 3, 2012), <http://medimoon.com/2012/07/difference-between-plasma-and-serum/> (describing blood plasma as the liquid portion of the blood, containing clotting factors, which holds the red blood cells in suspension throughout the body).

<sup>27</sup> See '540 Patent, *supra* note 5 (describing competing technologies).

<sup>28</sup> See *generally id.* (describing the claimed invention). Blood serum, composed of blood plasma without any clotting factors, was also found to contain cffDNA, indicating that cffDNA is present throughout the blood and is not tied to the clotting process. *Id.*

<sup>29</sup> See *generally Polymerase Chain Reaction (PCR)*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/probe/docs/techpcr/> (last visited Feb. 21, 2017) (describing how polymerase chain reaction works).

<sup>30</sup> *Id.*

<sup>31</sup> See '540 Patent, *supra* note 5 (describing polymerase chain reaction and amplification).

found in maternal blood plasma for testing, while keeping the overall costs of the test to a minimum.<sup>32</sup>

Soon after Lo and his colleague, James Wainscoat, paired the cffDNA discovery with PCR amplification, a patent application was filed in March of 1998. After spending three years in patent prosecution the '540 patent was granted on July 10, 2001, listing Lo and Wainscoat as co-inventors of the technology and Isis Innovation, Ltd. as the patent holder.<sup>33</sup> Isis Innovation, Ltd., the technology transfer subsidiary of the University of Oxford,<sup>34</sup> ultimately licensed the technology to Sequenom, Inc. ("Sequenom"), a biotechnology research company based in California.<sup>35</sup> The commercial embodiment of the technology soon after went on sale, named the "MaterniT21" test.<sup>36</sup>

As Lo's discovery of cffDNA in maternal blood spread throughout the scientific community, competing technologies featuring the discovery began entering the marketplace, including the Harmony Test.<sup>37</sup> The Harmony Test, produced by molecular diagnostics research company, Ariosa Diagnostics, Inc. ("Ariosa"),<sup>38</sup> is a prenatal diagnostic tool that involves analyzing specific human DNA to predict the chance of trisomy 21, 18, and 13 in a fetus.<sup>39</sup> The Harmony Test relies on similar principles and

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<sup>32</sup> See *id.* (describing competing technologies).

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*; Oxford University Innovation, U. OF OXFORD, <https://innovation.ox.ac.uk> (last visited Feb. 20, 2017).

<sup>35</sup> *Sequenom Purchases Non-Invasive Prenatal Testing Intellectual Property from Oxford University Innovation*, U. OF OXFORD (Oct. 7, 2014), <https://innovation.ox.ac.uk/news/sequenom-purchases-noninvasive-prenatal-testing-intellectual-property-isis-innovation/>.

<sup>36</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015), (describing Lo and Wainscoat's discovery).

<sup>37</sup> See '540 Patent, *supra* note 5 (describing competing technologies).

<sup>38</sup> *About the Company*, HARMONY PRENATAL TEST, <http://www.ariosadx.com/about-us/> (last visited Feb. 21, 2017).

<sup>39</sup> *Id.*; Trisomy 21, also called Down Syndrome, occurs when an individual possesses a full or partial extra copy of chromosome twenty-one, where chromosomes are structures contained inside of the nucleus of human cells that carry human genetic coding. *What is Down Syndrome?*, NAT'L DOWN SYNDROME SOC'Y, <http://www.ndss.org/Down-Syndrome/What-Is-Down-Syndrome> (last visited Feb. 23, 2017). Individuals with Down Syndrome may have mild to moderate cognitive delays, low muscle tone, small stature, an upward slant of the eyes, and a single deep crease in the middle of their palms. *Id.* Trisomy 18, called Edwards Syndrome, occurs when a baby has three copies of chromosome eighteen, which results in numerous abnormalities as well as a very low chance of surviving birth. *What is Trisomy 18?*, TRISOMY 18 FOUND., <http://www.trisomy18.org/what-is-trisomy-18/> (last visited Feb. 23, 2017). Similarly, Trisomy 13, or Patau Syndrome, occurs when an individual has three copies of chromosome 13, and results

concepts as used in Lo's technology, wherein fetal cfDNA samples from maternal blood are examined to foresee birth defects.<sup>40</sup>

### *Litigation Arises*

In anticipation of a potential infringement lawsuit, Ariosa filed a declaratory judgment action in December 2011 seeking a court ruling that the Harmony Test did not infringe the claims of the '540 patent.<sup>41</sup> More specifically, at issue were claims 1, 2, 4, 5, 8, 19–22, 24, and 25.<sup>42</sup> The independent claims, 1, 24, and 25, cover the bulk of the patented invention and are complimented by dependent claims 2, 4, 5, 8, 19, 20, 21, and 22 that seek to narrow the subject matter covered in the patent, including limiting the DNA detection method and the chromosome to be analyzed.<sup>43</sup> For example, claim 21 adds the steps necessary to prepare a maternal blood sample for testing using the method of claim 1.<sup>44</sup>

In response to the declaratory judgment action, Sequenom counterclaimed claiming infringement of the '540 patent, and filed

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in immediate complications that cause more than 90% of infants with Trisomy 13 to die in their first year. *Trisomy 13*, MEDLINEPLUS, <https://medlineplus.gov/ency/article/001660.htm> (last visited Feb. 23, 2017).

<sup>40</sup> See *How Harmony Prenatal Test Works*, HARMONY PRENATAL TEST, <http://www.ariosadx.com/expecting-parents/technology/> (last visited Feb. 23, 2017) (describing the analysis performed by the Harmony Test).

<sup>41</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 942 (N.D. Cal. 2013) (describing the procedural background of the case).

<sup>42</sup> See *id.* (noting the claims at issue).

<sup>43</sup> Claim 1 provides “[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.” ‘540 Patent, *supra* note 5. Claim 24 states “[a] method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises: removing all or substantially all nucleated and anucleated [sic] cell populations from the blood sample, amplifying a paternally inherited nucleic acid from the remaining fluid and subjecting the amplified nucleic acid to a test for the Paternally inherited fetal nucleic acid.” *Id.* Finally, claim 25 provides “[a] method for performing a prenatal diagnosis on a maternal blood sample, which method comprises obtaining a non-cellular fraction of the blood sample amplifying a paternally inherited nucleic acid from the non-cellular fraction and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.” *Id.*

<sup>44</sup> Claim 21 reads “[a] method of performing a prenatal diagnosis, which method comprises the steps of: (i) providing a maternal blood sample; (ii) separating the sample into a cellular and a non-cellular fraction; (iii) detecting the presence of a nucleic acid of foetal [sic] origin in the non-cellular fraction according to the method of claim 1; (iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal [sic] nucleic acid.” *Id.*

a motion for a preliminary injunction to enjoin Ariosa from making, using, or selling the Harmony Prenatal Test.<sup>45</sup> After Sequenom's motion for a preliminary injunction was denied by the U.S. District Court for the Northern District of California, Sequenom successfully appealed the Court's order, resulting in the Federal Circuit vacating and remanding the case with instructions<sup>46</sup> for the lower District Court to examine subject matter eligibility under § 101 in light of the Supreme Court's 2013 decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*<sup>47</sup> In *Myriad*, the Supreme Court held invalid patent claims that covered the isolation of specific genes from the rest of a DNA strand on the basis that the genes simply existed in nature and isolating the genes did not render them patent-eligible.<sup>48</sup> However, the Supreme Court did uphold other claims in Myriad's patent covering cDNA, or "complimentary DNA," that was synthetically created for a specific purpose, finding that the cDNA was not a product of nature and therefore patent-eligible under § 101.<sup>49</sup>

Upon remand of *Ariosa* and careful consideration of seven Supreme Court decisions on subject matter eligibility under § 101, the District Court returned a verdict in favor of Ariosa, following the framework for the § 101 analysis established in *Mayo*.<sup>50</sup> In *Mayo*, the Supreme Court invalidated patent claims outlining a process of detecting metabolite levels in patients, where the levels of metabolites formed in a patient indicated the likelihood that a dosage of thiopurine, a therapeutic drug used to treat autoimmune diseases such as Crohn's Disease, would be helpful or harmful to the patient.<sup>51</sup> The Court recognized that specific analysis must be applied when considering subject matter eligibility of patents that seek to claim natural phenomena, laws of nature, and abstract ideas, where a court must first "determine whether claims are directed to a patent-ineligible concept."<sup>52</sup> If they are directed at

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<sup>45</sup> See *Ariosa*, 19 F. Supp. 3d at 942 (describing the procedural background of the case).

<sup>46</sup> See *id.* (describing the instructions on remand).

<sup>47</sup> 133 S. Ct. 2107 (2013).

<sup>48</sup> See *id.* at 2117 (discussing how separating the genes from surrounding genetic material is not an act of invention).

<sup>49</sup> See *id.* at 2119 (describing cDNA).

<sup>50</sup> See generally *Ariosa*, 19 F. Supp. 3d at 942 (finding in favor of Ariosa and that the '540 patent contained patent-ineligible subject matter).

<sup>51</sup> See *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 72 (2012) (describing the patent claims at issue).

<sup>52</sup> *Ariosa Diagnostics, Inc., v. Sequenom, Inc.*, 788 F.3d 1371, 1380 (Fed. Cir. 2015) (citing *Mayo*, 566 U.S. at 77).

such, then,

[To be patentable,] a process that focuses upon the use of a natural law [a natural phenomenon or an abstract idea] [must] contain other elements or a combination of elements, sometimes referred to as an “inventive concept,” [as] sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law [natural phenomenon, or abstract idea] itself.<sup>53</sup>

In identifying the requirement of “inventive concept,” the Supreme Court was concerned with “upholding patents that claim processes that too broadly preempt the use of a natural law” and protecting against patents that “simply state the law of nature while adding the words ‘apply it.’”<sup>54</sup> Ultimately, the Supreme Court found that the patent claims pertained directly to laws of nature, and that additional steps in the claims consisted of “well-understood, routine, conventional activity already engaged in by the scientific community.”<sup>55</sup> Therefore, the patent claims insufficiently transformed stated correlations between metabolite levels into a patent-eligible process that applied the correlations and as such, were invalidated.<sup>56</sup>

Likewise, the *Ariosa* District Court found that the independent claims of the ‘540 patent were not patent-eligible subject matter because “cffDNA is a natural phenomenon and the claims of the ‘540 patent merely add well-understood, routine, conventional activity in the field to that natural phenomenon.”<sup>57</sup> In the majority opinion of *Ariosa*, Judge Illston noted that neither the cffDNA, nor its discovery, was patentable, and while the ‘540 patent did not seek to claim the cffDNA, the central issue in the case was whether the steps of the claimed methods in the ‘540 patent were sufficient to render the claims patentable under *Mayo*.<sup>58</sup> The Court agreed with *Ariosa* that the process of amplification of DNA in blood was well known by the time of the discovery of the cffDNA presence in

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<sup>53</sup> *Mayo*, 566 U.S. at 72–73. This “inventive concept” is truly § 103 obviousness, as argued in this note.

<sup>54</sup> *Id.* at 72. “[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.” *Id.* at 71. “[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.” *Id.*

<sup>55</sup> *Id.* at 79–80.

<sup>56</sup> *See id.* at 79 (describing the failure of the claims to add anything significant to natural phenomenon).

<sup>57</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 948 (N.D. Cal. 2013).

<sup>58</sup> *See id.* (noting that the parties agreed that cffDNA is a natural phenomenon).

maternal blood plasma, and as such was not enough of an “inventive step” to support claim validity.<sup>59</sup>

Almost two years later, the Federal Circuit issued a decision on an appeal by Sequenom, affirming the lower court’s decision and again finding that the ‘540 patent’s method claims were invalid under § 101.<sup>60</sup> Judge Reyna noted that “the claimed method begins and ends with a naturally occurring phenomenon” and thus proceeded to the second portion of the *Mayo* analysis wherein the added method steps to apply the natural phenomenon need to be “new and useful.”<sup>61</sup> Analogizing the facts of *Ariosa* with those in *Mayo*, the Federal Circuit felt that the ‘540 patent’s claims amounted “to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA,” and as such this method was not sufficiently “new and useful” to adequately transform the patent-ineligible subject matter.<sup>62</sup>

More recently, in December 2015, a petition to rehear *Ariosa* en banc was denied by the Federal Circuit in large part due to the Court’s desire to adhere to the Supreme Court’s framework for § 101 subject matter eligibility inquiries as established in *Mayo*.<sup>63</sup> Notably, the three opinions contained in the order, from Judges Lourie (joined by Moore), Dyk, and Newman, reflect a desire and need for Supreme Court direction on how *Mayo* should be applied.<sup>64</sup> Judge Lourie discusses how there are certainly patentable aspects of the claims that “rely on or operate by, but do not recite, a natural phenomenon or law” that require “physical . . .

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<sup>59</sup> See *id.* at 949 (describing the Court’s findings).

<sup>60</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.* 788 F.3d 1371, 1373 (Fed. Cir. 2015) (noting the results of the appeal). The Federal Circuit has exclusive appellate jurisdiction under 28 U.S.C. § 1295(a)(1) for appeals of civil actions arising under an Act of Congress relating to patents. 28 U.S.C. § 1295(a)(1) (West, Westlaw through P.L. 112–29 approved 9/16/11).

<sup>61</sup> See *Ariosa*, 788 F.3d at 1376 (applying the *Mayo* framework to the ‘540 patent).

<sup>62</sup> *Id.* at 1377.

<sup>63</sup> See generally *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (discussing adherence to *Mayo* in order to find the ‘540 patent invalid).

<sup>64</sup> Indeed, Judge Dyk writes that “further illumination as to the scope of *Mayo* would be beneficial” and that “further guidance must come from the Supreme Court.” *Id.* at 1287. Judge Newman agrees “with my colleagues that this case is wrongly decided. . . . I do not share their view that this incorrect decision is required by Supreme Court precedent.” *Id.* at 1293. Judge Lourie closes her opinion by noting that “it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps, or that they claim abstract concepts.” *Id.* at 1287.

steps requiring human intervention,” and that the use of the claimed techniques for maternal blood cffDNA were “not routine and conventional,” but then goes on to cite the need to adhere to *Mayo* and finds a lack of innovation.<sup>65</sup> To the contrary, Judge Newman entirely distinguishes *Mayo* from the *Ariosa* facts, writing that *Mayo* should not apply whatsoever to invalidate the ‘540 patent’s claims and applauds the significance of Lo’s discovery in prenatal testing.<sup>66</sup>

In an attempt to propose a narrower application of the *Mayo* framework, Judge Dyk in his concurring opinion both praises and criticizes *Mayo*, noting that the framework is “an essential ingredient of a healthy patent system” that screens out patents that involve well known and longstanding abstract ideas or laws of nature that do not warrant novelty.<sup>67</sup> However, in one limited scope, “*Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from the creativity and novelty of the discovery of the law itself,” as is often the case in the development of diagnostic and therapeutic technologies.<sup>68</sup> As such, Judge Dyk proposed that to be patent-eligible under § 101, a claimed invention must be both “narrow in scope and actually reduced to practice” wherein “the claim should be invalid unless narrowly tailored to the particular application of the law [of nature] that has been developed.”<sup>69</sup> Thus, under this proposed analysis, the ‘540 patent would qualify as patent-eligible subject matter under § 101, but likely still invalid under the remaining requirements of patentability, as the claims themselves are very broad.<sup>70</sup>

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<sup>65</sup> See generally *id.* at 1284–87 (Judge Lourie’s concurring opinion).

<sup>66</sup> See generally *id.* at 1293–94 (Judge Newman’s dissenting opinion).

<sup>67</sup> See generally *Ariosa*, 809 F.3d at 1287–92 (Judge Dyk’s concurring opinion).

<sup>68</sup> *Id.* at 1289.

<sup>69</sup> *Id.* at 1291. Judge Dyk writes that “[l]imiting patentees to narrow applications they have actually developed and reduced to practice would be in keeping with *Mayo*’s commandment that ‘simply appending conventional steps, specified at a high level of generality, to laws of nature . . . cannot make those laws, phenomena, and ideas patentable.’” *Id.* at 1291–92 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 82 (2012)).

<sup>70</sup> See *Ariosa*, 809 F.3d at 1293 (noting that “the major defect is not that the claims lack inventive concept but rather that they are overbroad.”); see also *id.* at 1286 (“The claims might be indefinite or too broad. . .”).

In March 2016, a petition for a writ of certiorari to the Supreme Court was filed.<sup>71</sup> Given the amount of amicus curiae briefs filed expressing concern from numerous Intellectual Property legal scholars and research institutions, as well as the size of the industries that could have been negatively impacted by the *Ariosa* decision, a petition and grant were expected, but denied in June 2016.<sup>72</sup>

#### OBVIOUSNESS IS THE KEY

Through examining obviousness and subject matter eligibility over the past sixty years, this section of the note argues that the latter portion of the *Mayo* framework requires a patent validity reviewer to engage in an obviousness analysis under § 103 to justify subject matter eligibility under § 101. This section follows with an examination of more recent cases that demonstrate obviousness, and specifically includes a discussion of the aspects of obviousness analysis that the *Ariosa* court engaged in. Leading Supreme Court cases that have shaped patent litigation and serve as the foundation for *Mayo* are indicative of a requirement for obviousness considerations, and the judicial opinions drafted throughout the *Ariosa* litigation touch upon various factual areas that would be considered in such analysis. Yet, the opinions lack a full consideration of all four components of obviousness and at times appear to conflate the subjective and objective case facts surrounding the '540 patent. Let's review.

#### *Mayo Requires Obviousness Analysis*

The obviousness requirement as set forth in § 103 holds that a claimed invention is invalid “if the differences between the claimed invention and the prior art are such that the claimed invention as

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<sup>71</sup> Petition for a Writ of Certiorari at \*i, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 2016 WL 1105544 (2016) (No. 15–1182). The petition offers a question presented asking “[w]hether a novel method is patent-eligible where: (1) a researcher is the first to discover a natural phenomenon; (2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and (3) he thereby achieves a previously impossible result without preempting other uses of the discovery?” *Id.*

<sup>72</sup> See Paul Cole, *Guest Post: Ariosa v Sequenom -- A Path to the Supreme Court?*, PAT. DOCS, <http://www.patentdocs.org/2015/12/guest-post-ariosa-v-sequenom-a-path-to-the-supreme-court.html> (last visited Apr. 29, 2016) (noting “[t]he weight of concern expressed by institutions, the academic community and industry and their collective willingness to expend time and effort in explaining their concerns.”).

a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains.”<sup>73</sup> In *Graham v. John Deere Co. of Kansas City*,<sup>74</sup> the Supreme Court interpreted § 103 to involve factual inquiries in three major areas; (1) the prior art, (2) the comparison between the prior art and the patent claims, and (3) the level of sophistication required in the relevant art.<sup>75</sup> *Graham* still operates as a leading case today, and modern U.S. Patent and Trademark Office (“USPTO”) guidelines provide “[e]xemplary rationales that may support a conclusion of obviousness,” including “[s]ome teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.”<sup>76</sup> In considering “teaching, suggestion, or motivation” evidence, the prior art is examined to determine whether one or more of the cited art documents provides reasoning as to why one skilled in the art

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<sup>73</sup> 35 U.S.C. § 103 (1952).

<sup>74</sup> 383 U.S. 1 (1966). *Graham* is a significant case in patent law since it was the first major decision given by the Supreme Court, following the ratification of the Patent Act of 1952, on patentability in light of § 103. *Id.* at 3. The decision resulted in the invalidation of the patents involved in two sets of litigation; an infringement suit between William Graham and John Deere Co. over a device designed to absorb shock from the shanks of chisel plows, and declaratory judgment and infringement actions between Calmar, Inc. and Cook Chemical over a finger-operated sprayer with a “hold-down” cap of the type commonly seen on insecticide bottles. *Id.* at 3–4. On the *Graham* facts, the Court recognized that a person having ordinary skill in the prior art “would immediately see that the thing to do [to improve shock absorption] was what Graham did,” and found “no nonobvious facets in the [patent] arrangement,” thus resulting in invalidity. *Id.* at 25–26. On the facts of *Cook Chemical*, the Court found that the invention “rests upon exceedingly small and quite non-technical mechanical differences in a device which was old in the art” under a 1953 patent; as such, the limited claims of the patent were evident from the prior art and therefore obvious. *Id.* at 36–37.

<sup>75</sup> *Id.* at 17.

<sup>76</sup> *Examples of Basic Requirements of a Prima Facie Case of Obviousness [R-08.2012]*, U.S. PAT. & TRADEMARK OFF., <http://www.uspto.gov/web/offices/pac/mpep/s2143.html> (last visited Apr. 9, 2017). Other exemplary rationales include: “(A) [c]ombining prior art elements according to known methods to yield predictable results; (B) [s]imple substitution of one known element for another to obtain predictable results; (C) [u]se of known technique to improve similar devices (methods, or products) in the same way; (D) [a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) ‘[o]bvious to try’ – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; [and] (F) [k]nown work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art.” *Id.*

would combine art documents to create the invention claimed in the patent; a teaching towards prior art combination is indicative of obviousness, and conversely, a teaching away is indicative of non-obviousness.<sup>77</sup> A teaching, suggestion, or motivation is one consideration to be made in an “expansive and flexible” determination of obviousness.<sup>78</sup> For example, in *U.S. v. Adams*,<sup>79</sup> a patent on a “wet” battery that contained water (rather than acid) and electrodes comprising magnesium and cuprous chloride survived a challenge for obviousness after the Court recognized that two teachings of the prior art would “deter any investigation [by one skilled in the art] into such a combination as is used by Adams,” noting that “known disadvantages in old devices which would naturally discourage the search for new inventions may be taken into account in determining obviousness.”<sup>80</sup>

The Supreme Court in *Graham* also recognized secondary considerations that could provide further insight into obviousness, namely commercial success of the invention, satisfaction of long-felt but unsolved needs, failure of others to solve the problem at hand, and unexpected results.<sup>81</sup> Evidence that tends to establish any of the secondary factors leads to a finding that a proposed invention is not obvious based on the reasoning that demand for the invention would have led others to develop the invention, but failed to successfully do so.<sup>82</sup> Consideration of secondary factors

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<sup>77</sup> See *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (“[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its element was, independently, known in the prior art”). “[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 418–19.

<sup>78</sup> *Id.* at 415. In *KSR*, the Supreme Court rejected the Federal Circuit’s strict adherence to “teaching, suggestion, or motivation” as a reason to reverse a District Court’s finding that a patent on a position-adjustable pedal assembly with an electronic pedal position sensor was obvious. *Id.* at 419.

<sup>79</sup> 383 U.S. 39 (1966).

<sup>80</sup> *Id.* at 42–43, 51–52.

<sup>81</sup> See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17–18 (1966). “Such inquiries may lend a helping hand to the judiciary which. . . [Helps] to resist the temptation to read into the prior art the teachings of the invention in issue.” *Id.* at 36. The goal of noting secondary considerations is to prevent “judicial hunches” that result in fact finders constructing a selective version of the facts that confirms the hunch. In *re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig.*, 676 F.3d 1063, 1079 (Fed. Cir. 2012).

<sup>82</sup> Other secondary considerations include skepticism by experts, praise by

has become increasingly important in recent litigation, and in some cases failure to consider secondary considerations has warranted vacating a court's decision.<sup>83</sup> In *Rambus Inc. v. Rea*,<sup>84</sup> the Federal Circuit vacated in part and remanded a decision by the Board of Patent Appeals & Interferences ("Board") that found various claims on a method of data transfer in computer memory circuits invalid for obviousness on the basis that the Board failed to properly consider objective evidence of non-obviousness.<sup>85</sup>

Obviousness is a blend of subjective, fact-based inquiry of the first three *Graham* elements and an objective analysis of secondary factors that examine the relevant art generally.<sup>86</sup> But how does all of this connect to *Mayo*? The language of *Mayo* features the requirement that the application of a law of nature, natural phenomenon, or abstract idea be composed of an element or elements featuring some sort of "inventiveness," which is a concept tracing back to *Funk Bros. Seed Co. v. Kalo Inoculant Co.*<sup>87</sup> In *Funk Bros.*, the Supreme Court invalidated a patent covering a mixture of naturally occurring strains of rhizobia, a bacterium that aids plants with affixing nitrogen from the air to the soil, due

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others, recognition of a problem, and copying of the invention by competitors. *What Are Secondary Considerations?*, THE PATENTABILITY BLOG (Feb. 1, 2005), <http://patentability.blogspot.com/2005/02/what-are-secondary-considerations.html>.

<sup>83</sup> See, e.g., *Apple Inc. v. Int'l Trade Comm'n*, 725 F.3d 1356, 1365 (Fed. Cir. 2013) (vacated and remanded the lower court's decision for the failure to consider secondary considerations); Jason E. Stach & Jeffrey A. Freeman, *Time to Stop Thinking About Secondary Considerations as Secondary*, FINNEGAN (Jan.–Feb. 2014), <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=8468473-33d8-4795-b7a2-5c4372b63804>.

<sup>84</sup> 731 F.3d 1248 (Fed. Cir. 2013).

<sup>85</sup> *Id.* at 1250, 1256. The Federal Circuit recognized that "objective evidence can establish that 'an invention appearing to have been obvious in light of the prior art was not.'" *Id.* at 1256 (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983)). Further, "[i]n some cases, that evidence is 'the most probative and cogent evidence in the record.'" *Rambus*, 731 F.3d at 1256 (quoting *Stratoflex*, 713 F.2d at 1538). Moreover, "[the evidence] helps 'turn back the clock and place the claims in the context that led to their invention.'" *Rambus*, 731 F.3d at 1256 (quoting *Mintz v. Dietz & Watson, Inc.*, 679 F.3d 1372, 1378 (Fed. Cir. 2012)).

<sup>86</sup> See also Gene Quinn, *Patentability Overview: Obviousness and Adequate Description*, IPWATCHDOG (June 9, 2012), <http://www.ipwatchdog.com/2012/06/09/patentability-overview-obviousness-and-adequate-description/id=25191/> (describing the obviousness requirement).

<sup>87</sup> 333 U.S. 127 (1948). Shortly after *Funk Bros.* was decided, the Patent Act of 1952 was enacted and codified the requirement for "invention" as 35 U.S.C. § 103, naming the standard "obviousness." See Honorable Giles S. Rich, *Why and How Section 103 Came to Be*, 14 FED. CIRCUIT B.J. 181, 190 (2004) (discussing the significant role of the concept of inventiveness in the drafting of 35 U.S.C. § 103).

to a lack of inventiveness independent of the discovery of any positive benefits derived from mixing various bacterium, and noted that the mixture was “hardly more than an advance in the packaging of the inoculants.”<sup>88</sup> *Funk Bros.* stands for the notion that the discovery itself of a law of nature, natural phenomenon, or abstract idea does not supply requisite inventiveness of an application of the discovery—the practical application of such discovery requires independent inventiveness to warrant patentability.<sup>89</sup> *Mayo’s* “routine, conventional activity”<sup>90</sup> is analogous to *Funk Bros.*’ “hardly more than an advance in the packaging;”<sup>91</sup> both reflect a lack of human ingenuity or contribution to science beyond the prior art—the heart of obviousness analysis—that would warrant a patent.

Even though *Funk Bros.* is often regarded as a product of nature case,<sup>92</sup> it continues to serve as controlling precedent for cases involving obviousness issues, even years after its conclusion.<sup>93</sup> In 1978, *Funk Bros.* was cited by the Supreme Court in *Parker v. Flook*,<sup>94</sup> a case resulting in the denial of a patent for an application of a mathematical algorithm, as the application contained “no patentable invention.”<sup>95</sup> In *Flook*, Justice Stevens echoes *Funk Bros.*, writing that “the discovery of . . . a [natural] phenomenon cannot support a patent unless there is some other inventive

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<sup>88</sup> *Funk Bros.*, 333 U.S. at 128–31.

<sup>89</sup> In *Funk Bros.*, Justice Douglas wrote that “[i]f 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. Further, the Supreme Court explained that “a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery.” *Id.* at 131. See Jeffrey A. Lefstin, *Inventive Application: A History*, 67 FLA. L. REV. 565, 629–30, 639–40 (2015) (noting connections between inventiveness and obviousness in *Funk Bros.*).

<sup>90</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 79 (2012).

<sup>91</sup> *Funk Bros.*, 333 U.S. at 131.

<sup>92</sup> The finding in favor of patentability in *Chakrabarty* was heavily reliant on distinctions with the facts in *Funk Bros.* See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (comparing the invention in *Chakrabarty* to that in *Funk Bros.*). Still today, *Chakrabarty* remains a pillar of subject matter eligibility. See, e.g., *Mayo*, 566 U.S. at 70–71 (examining case precedent, including *Chakrabarty*).

<sup>93</sup> See, e.g., Lefstin, *supra* note 89, at 638–40 (discussing how *Funk Bros.* was controlling precedent in *Armour Pharmaceutical Co. v. Richardson-Merrell, Inc.*).

<sup>94</sup> 437 U.S. 584 (1978). The claimed method in *Flook* involved regulating various operating conditions in a catalytic conversion process, entailing a three-step process beginning with the measurement of “the present value of the process variable (e.g., the temperature); an intermediate step which use[d] an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value.” *Id.* at 585.

<sup>95</sup> *Id.* at 594.

concept in its application.”<sup>96</sup> Sure enough, *Flook* was cited in *Mayo* as being “directly on point;”<sup>97</sup> thus, *Funk Bros.*’ “inventiveness” application has passed down to *Mayo* and is a clear source of *Mayo*’s “inventive concept” requirement.

Further consideration of *Flook* reveals that the Court “considered [the case] as if the principle or mathematical formula were well known.”<sup>98</sup> Directly after this decree, the Court addressed arguments that making such an assumption “improperly imports into § 101 the considerations of ‘inventiveness’ which are the proper concerns of §§ 102 and 103.”<sup>99</sup> First, the Court rejects that a “process” application automatically falls within patentable subject matter of § 101, as such an approach gives too much weight to a patent drafter’s writing and would be contrary to underlying patent policy.<sup>100</sup> Specifically, “[t]he rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of ‘discoveries’ that the statute was enacted to protect.”<sup>101</sup> Then, the Court rejected an assumption by the respondent that the fatal characteristic of the patent in question was the use of an un-patentable mathematical formula, finding instead that the patent failed due to a lack of a patentable “invention.”<sup>102</sup> In the very next paragraph, Justice Stevens addresses the “proper concerns” of § 102 and § 103 in discussing the patent in light of prior art.<sup>103</sup> Such analysis parallels that required by the first two components of *Graham*.

More recently, the Supreme Court repeated language similar to *Mayo*’s “routine, conventional activity” in *Myriad*, where the Court briefly discussed the processes used by *Myriad* to isolate DNA.<sup>104</sup> The Court noted that the processes “were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.”<sup>105</sup> Such language again mirrors *Graham*—here, the first and third

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<sup>96</sup> *Id.*

<sup>97</sup> *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 80 (2012).

<sup>98</sup> *Flook*, 437 U.S. at 592.

<sup>99</sup> *Id.*

<sup>100</sup> *See id.* at 593 (addressing the arguments).

<sup>101</sup> *Id.* (citation omitted).

<sup>102</sup> *See id.* at 594 (discussing the second argument).

<sup>103</sup> *See id.* at 592, 594 (addressing the lack of inventiveness in the calculation of alarm limits).

<sup>104</sup> *See Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–20 (2013) (in addressing a potential method claim for *Myriad*’s patents).

<sup>105</sup> *Id.*

components are examined.

Further cases involving an application of the *Mayo* framework reflect the judiciary engaging in analysis similar to what is required by *Graham*.<sup>106</sup> Between the District Court and Federal Circuit opinions on the ‘540 patent subject matter eligibility in *Ariosa*, three of the four *Graham* components are considered,<sup>107</sup> marking *Ariosa* as one of the strongest embodiments of obviousness analysis in an application of *Mayo*.

#### *Ariosa Considers Obviousness*

Judge Illston’s opinion in the 2013 Northern District of California Court’s decision indicates the Court’s consideration of the first, second, and fourth areas of *Graham*, namely, the prior art, differences between the present technology and the prior art, and the secondary industry factors.<sup>108</sup> After noting that the presence of cffDNA in maternal plasma or serum is a natural phenomenon, Judge Illston delved into discussion of the prior art offered by *Ariosa*, which included the specification of the ‘540 patent, prosecution history of the ‘540 patent, and of testimony by Sequenom’s expert.<sup>109</sup> Consideration was given to prior art such as “standard techniques” for preparation of serum of plasma from a maternal blood sample and also for the detection of fetal DNA in the maternal serum, as well as “traditional DNA diagnostics” prior to the invention.<sup>110</sup> In reaching its conclusion in favor of *Ariosa*, the Court stated, “the only inventive part of the patent is that the conventional techniques of DNA detection known at the time of the invention are applied to paternally inherited cffDNA as opposed to other types of DNA.”<sup>111</sup> This is a direct comparison between the prior art and the claimed invention, as required in *Graham*’s second inquiry. Judge Illston also touched upon the secondary

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<sup>106</sup> See, e.g., *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715–16 (Fed. Cir. 2014) (discussing how the claims involved in this case, on a method for the distribution of products over the Internet, fail to transform an abstract idea into patent-eligible subject matter).

<sup>107</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 949–51, 953–54 (N.D. Cal. 2013) (addressing prior art, the differences between the present technology and the prior art, and the secondary industry factors); see also *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377–79 (Fed. Cir. 2015) (addressing prior art, the differences between the present technology and the prior art, and the secondary industry factors).

<sup>108</sup> *Ariosa*, 19 F. Supp. 3d at 949–51, 953–54.

<sup>109</sup> See *id.* at 949–50 (noting the evidence presented by *Ariosa*).

<sup>110</sup> See *id.* at 949 (discussing the expert testimony given in this case).

<sup>111</sup> *Id.* at 950–51.

objective considerations of *Graham* in his consideration of preemption risks of the '540 patent, looking at the failure of others to develop commercially-viable methods of cffDNA detection.<sup>112</sup>

Following Judge Illston, the opinions from the Federal Circuit, collectively between *Ariosa's* appeal and subsequent denial to rehear *Ariosa* en banc, reflect components of an obviousness analysis. In the June 2015 decisions, Judge Reyna recited the myriad of facts considered by Judge Illston, highlighting how DNA amplification and detection were widely used in the field,<sup>113</sup> and engaged in a brief comparison of the claims of the '540 patent to the prior art.<sup>114</sup> He even noted Sequenom's argument that "before the '540 patent, *no one* was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA."<sup>115</sup> Further, Judge Reyna mentioned a secondary consideration wherein the discovery by Lo was praised by others.<sup>116</sup> Similarly, Judge Linn examined prior art in noting that "the maternal plasma used to be 'routinely discarded,' because . . . 'nobody thought that fetal cell-free DNA would be present.'"<sup>117</sup> Judge Linn took the secondary considerations' analysis one step further, building out a robust discussion of the invention's commercial success, long-felt but unresolved needs, failure of others, praise by others, and teaching away by others.<sup>118</sup> Judge Lourie's December

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<sup>112</sup> See *id.* at 953–54 (addressing Sequenom's argument that the claims of the '540 patent do not preempt all other uses of cffDNA, specifically discussing the commercial viability of competing technologies).

<sup>113</sup> See *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377–78 (Fed. Cir. 2015) (discussing the "standard techniques" used for preparation of maternal serum and DNA amplification).

<sup>114</sup> See *id.* at 1378. "For example, claim 2 identifies the poly-merase chain reaction as the amplification technique to be used in the detection method of claim 1. As noted above, this technique was well-understood, routine, and conventional in 1997, as specified by the patent itself." *Id.*

<sup>115</sup> *Id.* at 1379.

<sup>116</sup> See *id.* ("Lo and Wainscoat's contribution is that their 1997 *Lancet* publication has been cited over a thousand times.").

<sup>117</sup> *Id.* at 1381.

<sup>118</sup> See *Ariosa*, 788 F.3d at 1381. "Prior to the '540 patent, prenatal diagnoses required invasive methods, which 'present[ed] a degree of risk to the mother and to the pregnancy.' The available 'techniques [we]re time-consuming or require[d] expensive equipment.' Dr. Mark Evans testified that 'despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy.' In a ground-breaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as 'a paradigm shift in non-invasive prenatal diagnosis,' and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the *MaterniT21* test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies,

2015 decision, although spending much of the opinion elaborating as to background patent law, noted the specific prior art as well as the “innovative aspect of the claims appear[ing] to be the improvement in the method of determining fetal genetic characteristics or diagnosing abnormalities of fetal DNA, consisting of *use of the non-cellular fraction of fetal DNA*.”<sup>119</sup> Judge Lourie also noted that the prior art indicated that “amplification and detection of *cffDNA from maternal blood*, and use of these methods for prenatal diagnoses, were *not* routine and conventional.”<sup>120</sup>

#### IMPLICATIONS OF ESTABLISHING THE OBVIOUSNESS REQUIREMENT FOR § 101

What does importing a formal requirement for an examination of obviousness in the context of subject matter eligibility mean for *Ariosa*, as well as the greater context of patent law? This portion of the note will briefly explore the future of *Ariosa*, as well as consistency with *Myriad* and *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*.<sup>121</sup>

#### *Obviousness in Ariosa: Present, but Problematic*

Under the *Mayo* framework proposed by this note, *Ariosa* should be re-considered such that all elements of *Graham* are analyzed together in the same opinion to reach a conclusion on obviousness. While the District Court and Federal Circuit opinions engaged in

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such as Down’s syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests.” *Id.* (citations omitted).

<sup>119</sup> *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1286 (Fed. Cir. 2015).

<sup>120</sup> *Id.* Judge Lourie also wrote that “the finer filter of § 112 might be better suited to treating [claim issues] as questions of patentability,” which is further indicative of performing an obviousness analysis. *Id.*

<sup>121</sup> 134 S. Ct. 2347 (2014). In *Alice*, the Supreme Court found that patents on a computerized scheme for mitigating settlement risk (the risk that only one party to an agreed-upon financial exchange will satisfy its obligation) was invalid under the test set forth in *Mayo*, recognizing that mitigating settlement risk was an “abstract idea” and that directing a computer to implement the concept was insufficient to transform the patent-ineligible idea into a patent-eligible invention. *See id.* at 2353–54. *Alice* has had significant ramifications for patents, particularly for those in the software field. *See generally* Gene Quinn, *What Should We Do About Alice?*, IPWATCHDOG (Apr. 21, 2016), <http://www.ipwatchdog.com/2016/04/21/what-should-we-do-about-alice/id=68478/>

(discussing increases in successful patent challenges since *Alice*, as well as the uncertain future for patent law posed by the case).

parts of obviousness analysis by discussing facts in the *Ariosa* record pertaining to prior art and the “big picture” around prenatal diagnosis, each opinion on its own falls short of fully and properly analyzing all four components of *Graham*.

The June 2015 decision’s, by the Federal Circuit, opinions are problematic in that only if combined together may they reflect a more complete obviousness analysis, and also in that they at times fall short in how they consider certain aspects of *Ariosa*. First, Judge Reyna discussed DNA amplification’s wide use in science by 1997, but avoided subjective examination of the specific application of amplification to cffDNA found in maternal blood plasma or serum.<sup>122</sup> Judge Reyna divorced the steps involved in the ‘540 patent’s claims from the natural phenomenon and dismissed them as “routine[] and conventional” on their own and not in light of the natural phenomenon claimed in the ‘540 patent, instead only to general DNA, and in a manner conflicting with the second *Graham* inquiry.<sup>123</sup> Further inconsistent with obviousness analysis, Judge Reyna quickly dismissed the subjective teaching away that “no one was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA” as mere evidence of inventiveness of the discovery.<sup>124</sup> Among the various secondary considerations noted throughout the litigation, the opinion excluded all but Lo’s Lancet publication, which “alone” did not aid the ‘540 patent.<sup>125</sup>

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<sup>122</sup> See *Ariosa*, 788 F.3d at 1377 (discussing DNA amplification generally).

<sup>123</sup> See *id.* at 1377–78. “In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because 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.” *Diamond v. Diehr*, 450 U.S. 175, 188 (1981).

<sup>124</sup> *Ariosa*, 788 F.3d at 1379 (while a teaching away may be an indicator of obviousness and not absolute proof of obviousness, quickly dismissing a teaching away without considering it in context of the rest of the prior art, other teachings, or secondary considerations is improper under *Graham*. Moreover, Judge Reyna could have at least provided some reasoning as to why the teaching only pertains to the inventiveness of the discovery).

<sup>125</sup> See *id.* at 1379–80 (noting that Lo’s contribution as discussed in a 1997 publication was “cited over a thousand times.”). Additionally, Judge Reyna referenced the ineligibility of patents “directed to an application that starts and ends with a naturally occurring phenomenon.” *Id.* at 1378 (there is little to no support for an analysis about “starting and ending” with a natural phenomenon among the governing case precedent, and such language potentially opens the door to analysis about the state of the natural phenomenon at the beginning and

While Judge Linn's concurring opinion provided the most thorough discussion of objective secondary considerations of *Ariosa*, his subjective analysis of the prior art and dismissal of *Ariosa* appears to conflate subjectivity with objectivity, and may be a mistake of law.<sup>126</sup> Despite spending the majority of his opinion spelling out *Ariosa*'s dissimilarities with *Mayo* as well as praising *Ariosa*, Judge Linn simply stated that there was "no room to distinguish *Mayo* from [*Ariosa*]" and that he was "bound by the sweeping language" of *Mayo* without any further rationale as to why he was bound.<sup>127</sup> For example, Judge Linn discussed specific, subjective aspects of *Mayo* that led directly to a finding of obviousness, namely how "conventional activities" included the "very steps that doctors were already doing,"<sup>128</sup> but then decreed that the specific, subjective steps that *nobody* was taking in *Ariosa* were suddenly "conventional."<sup>129</sup> Hence, in the middle of his prior art analysis, Judge Linn backed out his initially subjective view of what was "conventional" to comport with the objective view of "conventional" as provided by Judge Reyna in the majority opinion.<sup>130</sup>

*Bringing Mayo Closer to Myriad, and What About Alice?*

While *Myriad* pertains to the first part of the *Mayo* framework in detailing what constitutes a natural phenomenon, law of nature, or abstract idea, *Myriad* also touched upon the

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end of the claimed method. For example, such analysis may include discussion of whether DNA that is copied and mass produced in a laboratory through human action actually constitutes a method "starting and ending" with a *naturally* occurring phenomenon. The "starting and ending" language may perhaps be an attempt at interpreting the word "transform," but such a rigid test for a word with many meanings appears to conflict with the Supreme Court's "flexible" approach described in *KSR*).

<sup>126</sup> A "mistake of law" occurs when a person makes one or more errors in understanding how the applicable law applies to past activity that is under analysis by a court. *Mistake of Law*, THE FREE DICTIONARY BY FARLEX: LEGAL DICTIONARY, <http://legal-dictionary.thefreedictionary.com/Mistake+of+Law> (last visited Apr. 9, 2017).

<sup>127</sup> *Ariosa*, 788 F.3d at 1380–81.

<sup>128</sup> *Id.* at 1380.

<sup>129</sup> *Id.* at 1381.

<sup>130</sup> Moreover, after stating that there was no room to distinguish *Mayo* from *Ariosa*, he then goes on to point out three ways in which the cases are different. Judge Linn hinted at subjective analysis of the invention by noting the teachings away of how "*no one*" was performing amplification on this particular DNA, how the maternal plasma was routinely discarded, and how amplification of cffDNA from maternal plasma had never been done before. *Id.*

obviousness analysis in the context of method claims covering such phenomenon and laws. At the end of Justice Thomas' majority opinion in *Myriad*, he noted that Myriad "could possibly" have sought a method patent, but that there were no method claims included in the patent reviewed in the litigation.<sup>131</sup> However, "the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents 'were [sic] well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.'"<sup>132</sup> This language, as well as the overtone of the paragraph, indicates that an imported obviousness analysis would result in a finding of obviousness: nevertheless, had method claims been included in the Myriad patents, a more in-depth consideration of the subjective and objective aspects of the claimed invention would have been required.

*Myriad* also noted that many of the unchallenged claims in Myriad's patents were on applications of the knowledge of natural phenomenon, and that "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge."<sup>133</sup> As Judge Dyk noted, "*Myriad* thus appeared to recognize that an inventive concept can sometimes come from discovery of an unknown natural phenomenon, not just from unconventional application of a phenomenon."<sup>134</sup> Indeed, this was a major point of clarification sought by Sequenom's petition for certiorari, given that Lo and Wainscoat discovered the presence of cffDNA in maternal blood serum.<sup>135</sup> However, given that discovery is strongly divorced from application of that discovery and the Supreme Court's desire to promote a "flexible" approach to obviousness while adhering to case precedent, it is unlikely that the Supreme Court will provide a strict answer on this issue: such a solution must come from Congress. At best, perhaps the inventiveness supplied by discovery can be given some consideration among the secondary considerations in an obviousness analysis, but likely is unable to

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<sup>131</sup> *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–20 (2013).

<sup>132</sup> *Id.*

<sup>133</sup> *Id.* at 2120.

<sup>134</sup> *Ariosa Diagnostics, Inc., v. Sequenom, Inc.*, 809 F.3d 1282, 1290 (Fed. Cir. 2015).

<sup>135</sup> See Petition for a Writ of Certiorari at \*i, *Sequenom, Inc. v. Ariosa Diagnostics, Inc.*, 2016 WL 1105544 (2016) (No. 15–1182) (showing that the question presented noted inventiveness from discovery).

be a stronger basis on which a claimed invention may be found obvious or nonobvious. For example, inventiveness of discovery may be folded into an obviousness analysis through consideration of “praise by others,” as in *Ariosa* where the Lancet article was widely cited and the discovery was highly regarded, wherein praise points in favor of non-obviousness.

Moreover, *Alice’s* finding on computer applications of natural phenomenon, laws of nature, and abstract ideas rests on the foundation that implementation of an un-patentable concept on a computer fails to add any sort of human ingenuity to that concept<sup>136</sup>; undeniably, this is precisely what the obviousness requirement protects against. Given the world’s widespread use of computers to more efficiently and accurately accomplish any given task, having a computer instead of a human “update[] the shadow records in real time,”<sup>137</sup> and “instruct[] the relevant financial institutions to carry out the ‘permitted’ transactions in accordance with the updated shadow records,”<sup>138</sup> would likely be obvious. As an application of the *Mayo* framework, *Alice* further reinforces the notion that *Mayo* requires an obviousness analysis. However, given the concerns that *Alice* has for software patents, perhaps formally importing the obviousness analysis may aid in the protection of software that had, up until *Alice*, traditionally been patent-eligible.<sup>139</sup>

#### CONCLUSION

The evidence of obviousness analysis that has passed throughout the case precedent serving as the foundation of *Mayo*, consistent use of language implicating *Graham* throughout post-*Mayo* litigation, and the fact that “invention” was quite literally renamed to “obviousness” in 1952 lead to the conclusion that the *Mayo* framework should be understood to require a § 103 obviousness analysis to determine whether, when seeking to patent an application of a natural phenomenon, law of nature, or abstract idea, a claimed invention possesses enough of an

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<sup>136</sup> See generally *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2360 (2014) (discussing the holdings of the Court).

<sup>137</sup> *Id.* at 2352.

<sup>138</sup> *Id.*

<sup>139</sup> See also Gene Quinn, *A Software Patent Setback: Alice v. CLS Bank*, IPWATCHDOG (Jan. 9, 2015), <http://www.ipwatchdog.com/2015/01/09/a-software-patent-setback-alice-v-cls-bank/id=53460/> (containing a robust discussion of *Alice’s* impact on software applications).

“inventive concept” to transform that invention into subject matter-eligible material. By such a standard, when applying *Mayo*, a court should engage in analysis of all four *Graham* considerations together before reaching a conclusion on obviousness, wherein a finding of obviousness results in subject matter ineligibility. Unfortunately, the Supreme Court has passed on a massive opportunity to use *Ariosa* to repair the *Mayo* language, and we must now turn to Congress or wait for the Supreme Court to consider future § 101 cases. Perhaps a *prima facie* case of obviousness should be required for initial § 101 purposes, somehow working alongside the long-established standard of clear and convincing evidence to overcome the presumption of patent validity. Perhaps instead, Congress should carve out an exception for life science technologies, and create a new rule for diagnostics, to prevent the evisceration of such an important field of innovation.

