THE *MAYO* FRAMEWORK IS BAD FOR YOUR HEALTH

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INTRODUCTION

Although the doctrine of patent eligibility formally arises out of § 101 of the Patent Statute,[1] in fact the relationship between the literal language of the statute and the contours of the doctrine as we know it today is highly attenuated at best. As a practical matter, patent eligibility is a creature of judge-made law, invented by the Supreme Court to screen out subject matter the Court has deemed better left unpatented, regardless of whether it might otherwise satisfy other requirements of patentability more grounded in the statute, such as utility, novelty, and nonobviousness.[2] The Court views patent eligibility as an important, and perhaps primary, doctrinal tool for advancing compelling policy objectives and has in recent years focused an inordinate amount of attention to refining and expanding its reach.[3]

The Court's recent reinvigoration of the doctrine is having a major impact on the availability of patent protection in some important areas of innovation, most particularly those involving software-implemented—but otherwise non-technological—processes, biotechnology, and healthcare. With respect to computer-implemented processes, the effect of the intervention appears to be in-line with the intent of the Supreme Court. The Justices have expressed skepticism toward patents on innovations that seem non-technological at heart, and lower courts have repeatedly invalidated patents of this type under the new patent eligibility jurisprudence.[4]

With respect to biotechnology and healthcare, however, the doctrinal shift has likely raised the bar for patentability to a much greater degree than anticipated or desired by the Court. In its recent patent eligibility decisions, most notably *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[5] the Court has emphasized that while natural phenomena are the fun-

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1 35 U.S.C. § 101 (2012).

2 *Id.* §§ 101-103.

3 The Supreme Court has decided eight patent eligibility cases since 1972. *See infra* Part I. In contrast, since 1976 the Supreme Court has decided only one case addressing the nonobviousness requirement, which many would consider to be the fundamental criterion of patentability. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007).

4 *See infra* Part II.

5 132 S. Ct. 1289 (2012).

damental building blocks of future research and innovation—and as such should not be patentable per se—it is equally important to ensure that the threshold to patent eligibility is not raised to a height that would impinge upon the ability of innovators to secure effective patent protection for practical applications of these natural phenomena.[6] Unfortunately, due to the unnecessarily expansive language employed by Justice Breyer in *Mayo*, it has become increasingly apparent that subject matter eligibility threatens the availability of patent protection for some of the most innovative and meritorious applications of natural phenomena in the realm of biotechnology and the life sciences, threatening the availability of the next generation of medical innovation.[7]

This Article begins in Part I by providing a brief historical retrospective of the development of the patent eligibility doctrine, which occurred in two waves of Supreme Court decisions: between 1972 and 1981 and from 2006 to the present. Part II delves into the related questions of: (1) what are the Supreme Court's policy objectives for the recent reinvigoration of the patent eligibility doctrine; and (2) has it achieved those objectives? Part III discusses three important out-standing questions regarding the application of the new test for patent eligibility: (1) what constitutes a natural phenomenon; (2) what constitutes an inventive step; and (3) what, if any, role does preemption play in the analysis? Part IV provides four examples of recent lower court decisions that have applied the new test, often referred to as the *Mayo* Framework, in a literal manner. This application has resulted in the invalidation of claims directed towards processes that would have easily passed patent eligibility muster prior to the most recent wave of Supreme Court decisions. The Article concludes by suggesting that the Supreme Court should revisit the question of patent eligibility and re-articulate the standard in a manner better-suited to ensure the availability of meaningful patent protection for the next generation of innovation, particularly in the life sciences. If the Court fails to do so, Congress should seriously consider addressing the problem through an amendment of the statute.

I. A BRIEF HISTORY OF PATENT ELIGIBILITY DOCTRINE

A. *The First Wave (1972-1981)*

The first wave of Supreme Court decisions addressing patent eligibility occurred between 1972 and 1981 and essentially gave birth to the doctrine as we know it today. The coming-of-age of two new and revolutionary technologies, computer programming and biotechnology, and an increasing

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6 *Id.* at 1293-94; *see infra* Part II.

7 *See infra* Parts II-IV.

need for intellectual property that could incentivize the commercial development of these technologies prompted these decisions.[8] Although patents are the form of intellectual property most often associated with technological innovation, in the 1970s it was unclear whether computer programs and engineered biological systems (including recombinant DNA and genetically modified microorganisms) fell within the realm of patentable subject matter.

In this first wave of decisions, the Court set forth the parameters of patent eligibility in broad terms, which remain in place today as a formal matter. The language of § 101, which the courts point to as the statutory basis for the doctrine, states simply that patent protection is available for any new and useful process, machine, composition of matter, or article of manufacture.[9] But in the first wave of decisions, the Court repeatedly emphasized that certain fundamental principles, often referred to as patent ineligible concepts, are explicitly excluded from the realm of potentially patentable subject matter—despite no mention of these concepts in the statute.[10] These judge-made exclusions have appeared under different designations through the years, but recently the Court seems to have settled on "abstract ideas, laws of nature, and natural phenomena."[11] To date, the courts have tended to use the terms "law of nature" and "natural phenomenon" interchangeably, and case law does not appear to assign different definitions to the terms. This Article refers to both concepts simply as "natural phenomena." Under this simplified nomenclature, there are essentially two distinct categories of patent ineligible concepts: natural phenomena and abstract ideas.

The first wave of decisions provided little in the way of explicit definition for these two concepts. The Court held that certain mathematical algorithms embodied in computer programs fell within the abstract idea exclusion.[12] In dicta, the Court indicated that naturally occurring substances—including naturally occurring living organisms, plants and minerals—are natural phenomena, as are fundamental principles of nature such as $E = mc^2$ and the law of gravity.[13] While inventors cannot patent these fundamental principles per se, the Court has repeatedly cautioned against an overly stringent interpretation of the prohibition against patenting these concepts, noting that most patent-eligible inventions typically embody practical applications of ineligible concepts.[14] In one of the most oft-quoted statements in patent law, the Court has emphasized that "anything under the sun that is

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8 *See, e.g.*, Parker v. Flook, 437 U.S. 584, 587-88 (1978).

9 35 U.S.C. § 101 (2012).

10 *See* Diamond v. Diehr, 450 U.S. 175, 201 (1981) (Stevens, J., dissenting) (stating that the Court has previously held that mathematical procedures that can be conducted in old computers are not patentable processes).

11 *Mayo*, 132 S. Ct. at 1293.

12 *E.g.*, Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972).

13 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

14 *See id.* at 308-09.

made by man" is eligible for patent protection,[15] an expansive statement of the scope of patentable subject matter that the Federal Circuit embraced and ran with over the next two decades, ultimately resulting in the second wave of patent eligibility decisions intended to rein in the scope of patentable subject matter.

Three of the four patent eligibility cases decided during the first wave specifically addressed the eligibility of computer programs, ultimately concluding that at least some computer programs are patentable, at least if the computer program is sufficiently tethered to technological innovation. The first two decisions, *Gottschalk v. Benson*[16] and *Parker v. Flook*,[17] decided in 1972 and 1978, respectively, found that the claims at issue in those cases represented little more than attempts to patent the mathematical algorithms underlying the computer programs, and thus constituted impermissible attempts to patent abstract ideas.[18] After *Flook*, the prospect for patent protection of software seemed doubtful at best, and thoughts turned increasingly to enlistment of copyright as an alternative form of protection for software.[19] However, the situation changed in 1981 when the Court issued its landmark decision in *Diamond v. Diehr*,[20] upholding the patent eligibility of the computer program at issue in that case.[21]

Significantly, *Diehr* did not purport to overrule *Benson* and *Flook*. Many, however, would argue that it is difficult—if not impossible—to reconcile the outcomes in *Diehr* and *Flook*, given the similarity of the computer programs at issue in the respective cases. In retrospect, the critical distinction appears to be that the *Diehr* computer program applied to the curing of rubber, which seemed more "technological" and concrete than the arguably more abstract computer program at issue in *Flook*. As a practical matter, *Diehr* was an extremely important decision because it signaled that some computer programs are patent eligible, at least if the computer program is tied to a concrete application bearing some degree of similarity to the sorts of conventional technologies that have been traditionally afforded patent protection.

The Court took up the question of patent eligibility in the context of biotechnology once during this first wave in *Diamond v. Chakrabarty*,[22] and responded with a ringing endorsement for an expansive and permissive

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15 *Id.* at 309 (quoting S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)) (internal quotation marks omitted).

16 409 U.S. 63 (1972).

17 437 U.S. 584 (1978).

18 *Parker*, 437 U.S. at 594; *Gottschalk*, 409 U.S. at 71-72.

19 *See* Pamela Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 DUKE L.J. 663, 692-93 (1984).

20 450 U.S. 175 (1981).

21 *Id.* at 192-93.

22 447 U.S. 303 (1980).

interpretation of the scope of patent-eligible subject matter.[23] The subject matter at issue in *Chakrabarty* was a genetically modified living organism, for which the U.S. Patent and Trademark Office ("PTO") denied patent protection based on its view that living organisms cannot be patented.[24] A narrowly divided Supreme Court overturned the PTO's decision, holding that no prohibition against patenting living organisms exists, so long as the organism is "made by man," i.e., the product of genetic engineering rather than natural occurrence.[25] *Chakrabarty* paved the way for patenting not only genetically modified organisms, but also a host of related biotechnological innovations such as engineered DNA and monoclonal antibodies, and is widely attributed as a significant milestone in the growth of biotechnology as a major industry in the United States. More generally, the decision signaled the Court's endorsement of a patent system that accommodates new technologies as they develop, even in the absence of explicit Congressional directive with respect to the technology.

The first wave ended with the *Diehr* decision in 1981, leaving unresolved some important questions as to the scope of patent-eligible subject matter. For example, how far along the spectrum between abstract (*Benson* and *Flook*) and technological (*Diehr*) must a computer program lie in order to constitute patent-eligible subject matter? How much human intervention is necessary to render a natural product patent eligible, particularly in the context of biotechnology? DNA manipulation and modification lies at the heart of biotechnology, and the patent eligibility of the resulting DNA was a question of profound importance in that industry. In particular, biotechnology provided tools for isolating meaningful quantities of copies of naturally occurring DNA, with tremendous potential practical applications. Would these newly isolated DNA molecules be eligible for patent protection post-*Chakrabarty*? Significantly, the first-wave decisions provided no example of a patent ineligible claim in the realm of biotechnology, or, more generally, involving an attempt to patent a natural phenomenon.

B. *The Second Wave (2006-2014)*

After the first wave of patent eligibility decisions, the Supreme Court took a twenty-five year hiatus, during which it left the development of the contours of patent eligibility in the hands of the newly launched U.S. Court of Appeals for the Federal Circuit (which coincidentally came into being the year after the Supreme Court decided *Diehr*).[26] During those twenty-five

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23 *Id.* at 315-16.

24 *Id.* at 305-06.

25 *Id.* at 309.

26 *History of the Federal Judiciary*, FED. JUD. CTR., http://www.fjc.gov/history/home.nsf/page/index.html (last visited May 9, 2016).

years, the Federal Circuit oversaw a significant expansion of the scope of subject matter recognized as eligible for patent protection. Two particularly important Federal Circuit decisions in this regard were *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*[27] and *AT&T Corp. v. Excel Communications, Inc.*,[28] decided in 1998 and 1999, respectively.[29] *State Street Bank* was a particularly influential Federal Circuit decision, holding that methods of doing business could be eligible for patent protection, which contradicted a previously widely held assumption that business methods were not patentable.[30] In *AT&T Corp.* the Federal Circuit held that a computer program fell "comfortably" within the scope of patentable subject matter because it applied an abstract idea (the "Boolean principle") "to produce a useful, concrete, tangible result without pre-empting other uses of the mathematical principle."[31] This "useful, concrete, and tangible" test, which became the de facto standard for patent eligibility, arguably eliminated patent eligibility as a meaningful restriction on the scope of patent-eligible subject matter by essentially collapsing the tests for patent eligibility and utility.[32]

The ensuing expansion of the effective range of patent-eligible subject matter in the 1990s and early 2000s led to the issuance of patents directed towards inventions bearing less and less relation to what many would consider "technological" innovation. This expansion included a host of patents directed towards financial methods and other "business methods," some computer implemented, and thus, arguably at least, "technological" in nature, but many lacking any tether to computers or technology.[33] These business-method patents came under increasing criticism, based in part on a perception that companies would develop these methods even in the absence of patent protection.[34] Moreover, critics felt a general discomfort with patents directed towards innovations that, while perhaps novel and nonobvious, seemed to have little to do with technology.[35] The Supreme Court later pointed to *State Street Bank* and *AT&T Corp.* as significant milestones in the expansion of patent eligibility that ultimately prompted the Supreme Court to intervene in the second wave of cases discussed below.[36]

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27 149 F.3d 1368 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

28 172 F.3d 1352 (Fed. Cir. 1999), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

29 *AT&T Corp.*, 172 F.3d at 1352; *State St. Bank & Tr.*, 149 F.3d at 1368.

30 *State St. Bank*, 149 F.3d at 1375-77.

31 *AT&T Corp.*, 172 F.3d at 1358.

32 DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1255 (Fed. Cir. 2014) ("At one time, a computer-implemented invention was considered patent-eligible so long as it produced a 'useful, concrete and tangible result.'" (quoting *State St. Bank & Tr.*, 149 F.3d at 1373)).

33 *See* Bilksi v. Kappos, 561 U.S. 593, 659-60 (2010) (Breyer, J., concurring).

34 *See id.* at 626 (Stevens, J., concurring).

35 *See id.* at 617.

36 *Id.* at 659 (Breyer, J., concurring) ("Indeed, the introduction of the 'useful, concrete and tangible result' approach to patentability, associated with the Federal Circuit's *State Street* decision, preceded

At around the same time, a backlash against many patents in the biotechnology realm also began to take shape. Patents claiming isolated forms of naturally occurring DNA sequences were a particular source of concern, but more generally, commentators sensed that genes and other fundamental building blocks of biotechnological research faced the danger of being unduly tied up by patents. Professors Heller and Eisenberg popularized the "patent thicket" theory, which postulated that a thicket of patents on genetic sequences and other research tools threatened to impede biotechnological research and medical innovation.[37] Patents relating to genes and genetic testing were a particular focus of concern, based on a fear that these patents might block the development of life-saving genetic tests or even prevent patients from learning about their own personal genetic makeup.[38] While the Federal Circuit never directly addressed the patent eligibility of isolated DNA, it did issue decisions upholding the patentability of isolated DNA sequences.[39] Further, the PTO took the position that isolated DNA sequences were man-made in the *Chakrabarty* sense, and hence eligible for patent protection.[40]

In 2006, presumably in response to this expansive reinterpretation of the scope of patent-eligible subject matter, and the resulting backlash, the Supreme Court reengaged with patent eligibility. The result was a second wave of decisions that has sent shockwaves through much of the patent community, particularly those involved in areas of innovation relating to business methods, computer programs, biotechnology, and medicine. Between 2006 and 2014 the Supreme Court granted certiorari in five patent eligibility cases, two involving business methods and the other three involving biotechnology.[41] Significantly, all three of the biotechnology cases related to diagnostic testing, an area of biotechnology where many believed patents might negatively impact innovation and access.[42] More particularly,

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the granting of patents that 'ranged from the somewhat ridiculous to the truly absurd.'" (quoting *In re* Bilski, 545 F.3d 943, 1004 (Fed. Cir. 2008) (en banc), *aff'd sub nom.* Bilski v. Kappos, 561 U.S. 593 (2010))).

37 *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698-99 (1998).

38 *See* SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH & SOC'Y, U.S. DEP'T OF HEALTH & HUMAN SERVS., GENE PATENTS AND LICENSING PRACTICES AND THEIR IMPACT ON PATIENT ACCESS TO GENETIC TESTS 38 (2010).

39 *See, e.g.*, Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991).

40 Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001); Cherylyn A.P. Esoy, Comment, *The PTO's 2001 Revised Utility Examination Guidelines for Gene Patent Applications: Has the PTO Exceeded the Scope of Authority Delineated by the Court's Interpretation of a "Useful" Invention?*, 33 SETON HALL L. REV. 127, 138-39 (2002).

41 *See* Lisa Larrimore Ouellette et al., *Supreme Court Patent Cases*, WRITTEN DESCRIPTION: PATENT & IP BLOG, http://writtendescription.blogspot.com/p/patents-scotus.html (last visited May 9, 2016).

42 *But see* Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization, and Utilization of Innovative Genetic Diagnostic Tests* 10-11 (Ctr. for the Prot. of Intellectual

the three biotechnology cases all involved inventions based on the discovery of some clinically relevant biomarker in human patients, thus seeming to implicate the practice of medicine and the ability of a person to know and understand their own genetic and physiological makeup.

The case that initially kicked off the second wave was *Laboratory Corp. of America Holdings* (*LabCorp*) *v. Metabolite Laboratories, Inc*.[43] The patent at issue in *LabCorp* concerned the correlation between the level of an amino acid (homocysteine) in a person's blood and the presence of a vitamin deficiency.[44] It claimed methods of diagnosing the existence of certain vitamin deficiencies by testing for the level of metabolite present in a person's blood, using the correlation.[45] The Supreme Court granted certiorari to address the patent eligibility of the claims, but ultimately dismissed the case without deciding it,[46] presumably because after granting certiorari the Justices realized that the lower courts had not addressed the issue of patent eligibility. However, Justice Breyer penned an extremely influential dissenting opinion, joined by two other Justices, expressing his belief that the Court should have decided the case in a manner that invalidated the patent claim for lack of patent eligibility, and arguing more broadly that patents on this sort of fundamental discovery threatened to impede more than promote progress in science and medicine.[47] Even though the Supreme Court did not decide *LabCorp*, Breyer's dissent informed the patent community that the previously moribund patent eligibility doctrine was once again in play—and that the Justices appeared eager and ready to decide a case in which the issue of patent eligibility was properly presented for review.

Put on notice that the Supreme Court was poised to intervene, and no doubt cognizant of growing concerns regarding the expansion of patent-eligible subject matter, the Federal Circuit took action in 2008 by addressing the issue of patent eligibility en banc in *In re Bilski*.[48] In *Bilski*, the court essentially replaced the "useful, concrete, and tangible result" with the stricter "machine-or-transformation" test.[49] Some amici urged the Federal Circuit to adopt a "technological arts test" for patent eligibility, but the court declined, concerned that "the contours of such a test . . . would be unclear because the meanings of the terms 'technological arts' and 'tech-

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Prop., Policy Brief, July 2014), http://cpip.gmu.edu/wp-content/uploads/2014/04/Holman-Critical-Role-of-Patents-in-Genetic-Diagnostic-Tests.pdf.

43 548 U.S. 124 (2006) (per curiam).

44 *Id.* at 125 (Breyer, J., dissenting).

45 *Id.*

46 *Id.* (majority opinion) (dismissing the writ as improvidently granted).

47 *Id.* at 125, 127-28, 131-32 (Breyer, J., dissenting).

48 545 F.3d 943 (Fed. Cir. 2008) (en banc) (abrogating both *State Street Bank* and *AT&T Corp.* by replacing the "useful, concrete and tangible result" inquiry with the "machine-or-transformation" test), *aff'd sub nom.* Bilski v. Kappos, 561 U.S. 593 (2010).

49 *Id*. at 959-60.

nology' are both ambiguous and ever-changing."[50] The Federal Circuit further noted that "no such test has ever been explicitly adopted by the Supreme Court."[51]

While the Federal Circuit stopped short of announcing a per se prohibition against patents on non-technological innovations, the machine-or-transformation test appeared to limit patent eligibility to processes that incorporated some quantum of technology, either by being "tied to a particular machine or apparatus" or transformed into a different state or thing.[52] While this standard seemed to deny patent eligibility to innovative processes lacking any connection to technology, practitioners generally thought that under the machine-or-transformation test, a computer-implemented process could be patent eligible by virtue of the involvement of the computer, even if the inventive concept did not involve any innovation in computer technology. As the Federal Circuit stated in 2014, after the en banc *In re Bilski* decision but prior to the subsequent Supreme Court intervention, computer-implemented inventions "crossed the eligibility threshold by virtue of being in the technological realm, the historical arena for patented inventions," even if the innovative aspect of the process was non-technological in nature.[53]

However, the Supreme Court was not satisfied with the Federal Circuit's attempt to address the issue of patent eligibility in *In re Bilski*, and in a second wave of decisions, the Court decided four patent eligibility cases between 2010 and 2014. Two of the four, *Bilski v. Kappos*[54]—the case affirming *In re Bilski*—and *Alice Corp. v. CLS Bank International*,[55] dealt with the patent eligibility of what many would characterize as "business methods."[56] In the case of *Bilski*, the claims were directed towards methods of hedging risk in commodity trading.[57] Unlike many patented business

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50 *Id.* at 960.

51 *Id.*

52 *Id.* at 954-56 (concluding that a patent-eligible process must either be "tied to a particular machine or apparatus" or transformed into a different state or thing, i.e., the "machine-or-transformation test").

53 DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1255 (Fed. Cir. 2014) (citing *id.* at 954-56).

54 561 U.S. 593 (2010).

55 134 S. Ct. 2347 (2014).

56 *See Bilski*, 561 U.S. at 594-95.

57 *Id.* at 599. An illustrative claim recites the steps of:

> (a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;
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> (b) identifying market participants for said commodity having a counter-risk position to said consumers; and
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> (c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

methods, such as the financial processes claimed in *State Street Bank*, the *Bilski* claims were not limited to computer-implemented processes, and as such the claims lacked any explicit technological hook.[58] Although Justice Stevens filed a concurring opinion in *Bilski* on behalf of himself and three other Justices—arguing that patentable subject matter should be limited to technological innovation and that methods of doing business are not patentable subject matter[59]—the majority rejected the notion of a blanket prohibition against patenting business methods, expressing concerns as to how the term "business method" might be defined in the future.[60] Nonetheless, the majority opinion found that while the patent statute "appears to leave open the possibility of some business-method patents, it does not suggest broad patentability of such claimed inventions."[61] Furthermore, the manner in which the majority applied the test for patent eligibility to Bilski's claims intimated that, to the extent that it might still exist, the scope of patent protection available for business methods is narrow indeed.

In *Alice*, the claims at issue were directed towards a "computer-implemented scheme for mitigating 'settlement risk' (*i.e.*, the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary."[62] Even though the claims all explicitly recited the use of a computer, and thus had a technological element lacking in the *Bilski* claims, the Supreme Court found that this computer involvement was insufficient to render the claims patent eligible.[63] Although Justice Stevens retired shortly after writing his concurring opinion in *Bilski*,[64] the remaining three Justices from that opinion filed a concurring opinion in *Alice* "adher[ing] to the view that any 'claim that merely describes a method of doing business does not qualify as a 'process' under § 101.'"[65] While the majority still refused to go so far as to declare a blanket prohibition against the patenting of business methods, *Alice* makes clear that the mere involvement of technology will not render a process patent eligible if the underlying point of invention is deemed too "abstract."[66]

The other two patent eligibility cases decided during the second wave, *Mayo v. Prometheus* and *Ass'n for Molecular Pathology v. Myriad Genet-*

Id. (quoting Joint Appendix at 19-20, *Bilski*, 561 U.S. 593 (No. 08-964)) (internal quotation marks omitted).

58 *See id.* at 615-16 (Stevens, J., concurring).

59 *Id.* at 614.

60 *Id.* at 608-09 (majority opinion).

61 *Id.* at 608.

62 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2351-52 (2014).

63 *Id.* at 2359-60.

64 Jan Wolfe, *Supreme Court Decides Bilski: Stevens and Allies Try to Ban "Business Method" Patents, but Fail to Get Fifth Vote*, PRIOR ART (June 28, 2010), http://thepriorart.typepad.com/the_prior_art/2010/06/supreme-court-decides-bilski.html.

65 *Alice*, 134 S. Ct. at 2360 (Sotomayor, J., concurring) (quoting *Bilski*, 561 U.S. at 614).

66 *Id.* at 2352 (majority opinion).

ics, Inc.,[67] both relate to biotechnology, and more particularly to methods of diagnostic testing.[68] *Mayo*, decided in 2012, involved patents claiming methods of using a diagnostic test to calibrate the optimal dosage of certain autoimmune disease drugs to the physiology of an individual patient.[69] The claimed invention utilized the discovery of a correlation between the level of drug metabolite in a patient's blood and the desirability of increasing or decreasing the amount of drug administered to the patient.[70]

In *Mayo*, the Supreme Court characterized the correlation between drug metabolite level and optimal drug dosage as a patent-ineligible, natural phenomenon, and held that the claims did not incorporate sufficient additional "inventive concept" to cross the patent-eligibility threshold.[71] Justice Breyer emphasized the critical role he saw for the patent eligibility doctrine in preventing patents from tying up the fundamental building blocks of science and technological innovation.[72] At the same time, he recognized the danger that an overly restrictive view of patent eligibility would deny patent protection to truly worthwhile inventions.[73] He stated in *Mayo* that the decision should not threaten the availability of patent protection for drug method-of-treatment claims.[74] Unfortunately, as discussed in more detail below, Justice Breyer's unnecessarily broad language seems to be having exactly the opposite effect, denying patent protection for truly meritorious inventions that might not adequately develop without the patent incentive.[75]

Myriad, the other second wave biotechnology decision, involves patents directed towards isolated DNA molecules that the Court believed to be potentially relevant to diagnostic testing.[76] The American Civil Liberties Union ("ACLU") and others initially brought the lawsuit based on concerns that these patent claims threatened the availability of, and access to, genetic diagnostic tests relating to breast cancer.[77] The Court held the challenged patent claims, which recite isolated DNA molecules having the genetic sequence of naturally occurring genomic DNA, patent ineligible based on the Court's perception that the chemical structure of these isolated molecules

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67 133 S. Ct. 2107 (2013).

68 *Id.* at 2114; Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1295 (2012).

69 *Mayo*, 132 S. Ct. at 1295-96; *see also* Holman, *supra* note 42, at 3.

70 *Mayo*, 132 S. Ct. at 1295.

71 *Id.* at 1294.

72 *See id.* at 1303.

73 *Id.* at 1293 ("[T]oo broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.").

74 *See id.* at 1302.

75 *See infra* Part II.

76 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2114 (2013). The Court assumed that "isolation [of the claimed DNA] is necessary to conduct genetic testing." *Id.*

77 *See The Fight to Take Back Our Genes*, ACLU, https://www.aclu.org/feature/fight-take-back-our-genes (last visited May 9, 2016).

was substantially identical to their naturally occurring counterpart.[78] Although the case arose out of concerns regarding genetic testing, the Court decided *Myriad* in a manner which implicated the patentability of a host of non-DNA inventions based on natural products.[79] As of yet, *Myriad* has not had as much of an impact on biotechnology patenting as *Mayo*, but it has resulted in a change in practice at the PTO and a subsequent rejection of natural, product-related claims that the PTO would have previously deemed patent eligible.

C. *The* Mayo *Framework for Assessing Patent Eligibility*

The second wave of patent eligibility decisions has resulted in a test for patent eligibility that the patent community has come to refer to as the "*Mayo* Framework."[80] The *Mayo* Framework purports to follow principles set forth in the first wave of patent-eligibility decisions, and it attempts to provide guidance in distinguishing between a claim that merely recites a patent-ineligible concept, as opposed to a potentially patentable claim that recites the application of a patent-ineligible concept.[81] The *Mayo* Framework comprises two steps. In Step I, the court "determine[s] whether the claims at issue are directed to [a] patent-ineligible concept[]."[82] If the answer is yes, the court proceeds to Step II, in which the court asks, "[W]hat else is there in the claims before us?"[83] The claim is patent eligible if, and only if, there is "enough" of the "what else" in the claims to meet some threshold.[84]

The Supreme Court has left it to the lower courts to grapple with the critical question of how much "what else" is "enough" to cross over the threshold and into the realm of patent eligibility. It has provided little in the way of concrete guidance, characterizing Step II as a search for an "'inventive concept'—*i.e.*, an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[85] The Court has also empha-

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78 *Myriad*, 133 S. Ct. at 2117. The author filed an amicus brief in the Federal Circuit explaining substantial differences in chemical structure, but the courts did not adopt this view. Brief of *Amicus Curiae* Law Professor Christopher M. Holman in Support of Neither Party at 8, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303 (Fed. Cir. 2012) (No. 2010-1406), 2012 WL 2884112, at 8.

79 *See Myriad*, 133 S. Ct. at 2119-20.

80 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) (citing Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289 (2012)).

81 *Id.* at 2355.

82 *Id.*

83 *Id.* (quoting *Mayo*, 132 S. Ct. at 1297) (internal quotation marks omitted).

84 *See id.*

85 *Id.* (alteration in original) (quoting *Mayo*, 132 S. Ct. at 1294).

sized that the patent-eligibility analysis must "consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application."[86]

II. IS THE SUPREME COURT ACHIEVING WHAT IT SET OUT TO ACCOMPLISH IN THE SECOND WAVE?

The Supreme Court's preoccupation with patent eligibility since 2010 is no doubt based on a hope that reinvigoration of the doctrine can address an ill-advised expansion of the scope of patentable subject matter that has occurred under the Federal Circuit's watch. In particular, the Court is now leveraging prohibitions against the patenting of "abstract ideas" and "natural phenomena"—which played little if any meaningful role in policing patentability in the years preceding the second wave—to achieve two distinct policy objectives. The first of these objectives is to dramatically scale back, if not completely eliminate, the availability of patent protection for innovations that are fundamentally non-technological in nature. The second is to limit the scope of patent protection available to the fundamental building blocks of research and innovation, particularly in the arena of biological sciences and health care, while maintaining adequate patent protection for the innovative applications of these building blocks. This Section of the Article argues that while the Court appears to have achieved its first objective, it has overshot on the second, creating a patent-eligibility standard for biological innovations that threatens to unduly limit the availability of effective patent protection for important and innovative applications of biological discoveries, particularly drugs and diagnostics.

A. *Non-Technological Innovations*

Historically, patents have generally been thought of as a form of intellectual property reserved for technological innovations. In keeping with this general understanding, the PTO has a long-standing practice of requiring training in some area of technology as a prerequisite to representing clients before the PTO as patent agents/attorneys.[87] Some non-technological innovations might be amenable to other forms of intellectual property, such as trade secret or copyright, but in many cases, these sorts of innovations are

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86 *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1298, 1297).

87 OFFICE OF ENROLLMENT & DISCIPLINE, U.S. PATENT & TRADEMARK OFFICE, GENERAL REQUIREMENTS BULLETIN FOR ADMISSION TO THE EXAMINATION FOR REGISTRATION TO PRACTICE IN PATENT CASES BEFORE THE UNITED STATES PATENT AND TRADEMARK OFFICE 4 (2015).

simply not protectable. For example, a firm that develops and implements an innovative approach to conducting business would have generally been unable to prevent others from copying that approach unless they could manage to maintain it as a secret—that is until decisions like *State Street Bank* and *AT&T Corp.* in the late 1990s opened the door to the patenting of business methods.

In *State Street Bank* and *AT&T Corp.* the Federal Circuit seemed to disavow any technological requirement for patentability, requiring a change in PTO examination standards[88] and precipitating a flood of patent applications with claims directed towards increasingly non-technological innovations, many of which ultimately issued as patents.[89] As these patents became known to the general public and asserted against activities that previously were assumed to be outside the realm of patentable subject matter, criticism of non-technological patents mounted.[90] In the second wave of decisions, the Supreme Court seems to have internalized this concern and sought to address it by prescribing a more robust application of the long-standing prohibition against the patenting of abstract ideas.

The Court's antipathy towards the extension of patent protection to non-technological innovations appeared front and center in *Bilski*. The case arose out of a patent examiner's decision explicitly finding that Bilski's claims were patent ineligible for not being directed towards a technological invention.[91] On appeal, although the en banc Federal Circuit declined to go so far as to declare a technological requirement for patent eligibility, the court did establish a machine-or-transformation requirement for patent eligibility.[92] As a practical matter, this requirement strongly disfavored the patenting of non-technological inventions, if not effectively barring them.[93]

When *Bilski* reached the Supreme Court the Justices came very close to creating an explicit technological requirement for patent eligibility, with four of the nine expressing the opinion that patent eligibility should be limited to technological inventions.[94] While the other five Justices were not

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88 *See* AT&T Corp. v. Excel Commc'ns, Inc., 172 F.3d 1352, 1357 (Fed. Cir. 1999), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008); State St. Bank & Tr. Co. v. Signature Fin. Grp., Inc., 149 F.3d 1368, 1373 (Fed. Cir. 1998), *abrogated by In re* Bilski, 545 F.3d 943 (Fed. Cir. 2008).

89 *See* Scott Feldman, *Patent Law Gets Saner*, MIT TECH. REV. (Aug. 15, 2007), https://www.technologyreview.com/s/408441/patent-law-gets-saner/; James Turner, *Has the US Patent System Gone Too Far?*, CHRISTIAN SCI. MONITOR (Mar. 12, 2009), http://www.csmonitor.com /Technology/Tech-Culture/2009/0312/has-the-us-patent-system-gone-too-far.

90 *See, e.g.*, Michael Barclay, *Bilski v. Kappos: The Supreme Court Declines to Prohibit Business Method Patents*, ELECTRONIC FRONTIER FOUND. (June 29, 2010), https://www.eff.org/deeplinks/ 2010/06/bilski-v-kappos-supreme-court-declines-prohibit.

91 Bilski v. Kappos, 561 U.S. 593, 599-600 (2010) ("The patent examiner rejected petitioners' application, explaining that . . . ['']the invention is not directed to the technological arts.'").

92 *See id.* at 611-12.

93 *See infra* Part I.

94 *See Bilski*, 561 U.S. at 657 (Stevens, J., concurring).

willing to go quite this far, their majority opinion voiced clear skepticism toward patenting of non-technological inventions, observing that while the patent statute "appears to leave open the possibility of some business-method patents, it does not suggest broad patentability of such claimed inventions."[95] Significantly, the majority explicitly pointed out that *Bilski* had not decided whether business methods were patent eligible, but rather had simply left the question unresolved.[96] One of the key policy considerations that seems to have driven *Bilski* was the Court's perception that companies are likely to develop non-technological inventions, particularly methods of doing business, even without the patent incentive.[97] Therefore, patents on these sorts of innovations threatened to impede rather than promote their development and implementation.[98]

In *Alice*, the Court went further and clarified that in order to be patent eligible, a process cannot merely incorporate a technological feature, such as a computer-implemented step, but instead the nature of the innovation itself must be technological.[99] Under *Alice*, limiting the scope of a claim to computer-implemented embodiments of a claimed process does not render the claim patent eligible if the point of innovation is itself not technological.[100] *Alice* appears to stand for the proposition that the involvement of a computer will only render a claim patent eligible if the underlying innovation lies within the realm of computer technology.[101] That is, the innovation must improve the functionality of the computer itself, rather than merely use a computer to implement a non-technological innovation.[102]

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95 *Id.* at 608 (majority opinion).

96 *Id.* at 612 ("[N]othing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past. It may be that the Court of Appeals thought it needed to make the machine-or-transformation test exclusive precisely because its case law had not adequately identified less extreme means of restricting business method patents, including (but not limited to) application of our opinions in *Benson*, *Flook*, and *Diehr*." (citation omitted)).

97 *Id.* at 651 (Stevens, J., concurring).

98 *Id.* at 608 (majority opinion) ("The Information Age empowers people with new capacities to perform statistical analyses and mathematical calculations with a speed and sophistication that enable the design of protocols for more efficient performance of a vast number of business tasks. If a high enough bar is not set when considering patent applications of this sort, patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change.").

99 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2350-51 (2014).

100 *Id.* at 2358 ("[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention.").

101 *See id.* at 2358-59.

102 *Id.* at 2359 (finding the patent ineligible claims recited a method wherein "the function performed by the computer at each step of the process is '[p]urely conventional'. . . . In short, each step does no more than require a generic computer to perform generic computer functions. . . . The method claims do not, for example, purport to improve the functioning of the computer itself. ('There is no specific or limiting recitation of . . . improved computer technology . . . '). Nor do they effect an improvement in any other technology or technical field." (citations omitted)).

The United States took this position in an amicus brief filed in *Alice*, arguing that when computers are used in "non-technological fields of human activity, it is all the more important that traditional limits on patent eligibility be rigorously enforced."[103] According to the United States' brief, the "ultimate inquiry [in assessing patent eligibility] is whether the claims are directed to an innovation in computing or other technical fields instead of to an abstract method of organizing economic concepts and relationships."[104] The brief argued that if the mere recitation of the generic use of a computer was sufficient to render a claim patent eligible, it would open the door to the patenting of "a wide range of non-technological human activities that have not traditionally been thought eligible for patenting," and which in the government's view should not be patentable.[105] The government's brief identified that one factor relevant to patent eligibility of a method claim reciting the use of the computer is "whether the invention involves an improvement in the functioning of the computer as a computer, *e.g.*, by making it more efficient."[106]

As a practical matter, lower courts have repeatedly invoked *Alice* to invalidate patent claims directed towards computer-implemented processes wherein the court deems the inventive concept of the invention to be non-technological in nature.[107] In contrast, even post-*Alice*, the Federal Circuit will uphold the patent eligibility of claims that "do not merely recite the performance of some business practice [on a computer] known from the pre-Internet world . . . [if] the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of [computers]."[108] Thus, while the *Alice* decision is highly un-

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103 Brief for the United States as Amicus Curiae in Support of Respondents at 16, *Alice*, 134 S. Ct. 2347 (No. 13-298), 2014 WL 828034, at 16.

104 *Id.* at 28-29.

105 *Id*. at 29-30.

106 *Id*. at 30.

107 *E.g.*, DDR Holdings, LLC v. Hotels.com, L.P., 773 F.3d 1245, 1256 (Fed. Cir. 2014). In citing to earlier Federal Circuit decisions where claims that recited various computer hardware elements were declared patent ineligible under *Alice*, the court explained that "these claims in substance were directed to nothing more than the performance of an abstract business practice on the Internet or using a conventional computer. Such claims are not patent-eligible." *Id.* The *DDR Holdings* court cited to *Ultramercial, Inc. v. Hulu, LLC*, 772 F.3d 709, 715-16 (Fed. Cir. 2014), *buySAFE, Inc. v. Google, Inc.*, 765 F.3d 1350, 1355 (Fed. Cir. 2014), and *Accenture Global Servs., GmbH v. Guidewire Software, Inc*., 728 F.3d 1336, 1344-45 (Fed. Cir. 2013), as examples of cases also involving claims reciting insufficient technological innovation. *DDR Holdings*, 773 F.3d at 1256; s*ee also* Planet Bingo, LLC v. VKGS, LLC, 576 F. App'x 1005 (Fed. Cir. 2014). In *Planet Bingo*, the Federal Circuit found that claims directed to a computerized bingo game "consist[] solely of mental steps which can be carried out by a human using pen and paper" and that, because the computer elements recited were purely generic and conventional, there were no meaningful limitations at step two of the *Mayo* test. *Id.* at 1007 (quoting Planet Bingo, LLC v. VKGS, LLC, 961 F. Supp. 2d 840, 851 (W.D. Mich. 2013)) (internal quotation marks omitted).

108 *DDR Holdings*, 773 F.3d at 1257; *see also* Cal. Inst. of Tech. v. Hughes Commc'ns Inc., 59 F. Supp. 3d 974, 994 (C.D. Cal. 2014) (upholding patent eligibility of claims "generally directed to abstract

popular in certain quarters, particularly among software patent prosecutors, it appears to be what the Supreme Court had intended: an efficient doctrinal tool for striking down patents directed towards fundamentally non-technological innovations, which the Justices, along with many other members of society, have deemed better left unpatented.

B. *Building Blocks*

During the first wave, the Court repeatedly emphasized that one of the primary policy rationales for denying patent protection to patent-ineligible concepts is that these concepts "are the basic tools of scientific and technological work."[109] This policy justification also figured prominently in the second wave of decisions, with the Court again emphasizing that "monopolization of th[ese] tools through the grant of a patent might tend to impede innovation more than it would tend to promote it."[110] *Mayo* particularly emphasized a concern that allowing patents that broadly claimed natural phenomena "would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."[111] The Court has seemed particularly concerned with maintaining access to the building blocks of biotechnology and human health care innovation, as evidenced by the fact that all three grants of certiorari in the second wave "natural phenomena" cases involved an aspect human physiology with significant medical implications.[112] The Court has also expressed a related concern, which is that patents directed towards these phenomena threaten to interfere with the ability of doctors to communicate with and treat their patients, and also for individuals to learn about their own health and genetic makeup.[113]

At the same time, the second wave decisions have repeatedly emphasized the importance of maintaining a patent-eligibility threshold that permits the patenting of innovative applications of natural phenomena. For example, in *Mayo* the Court recognized "that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at

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concepts, [because the] claims contain meaningful limitations that represent sufficiently inventive concepts, such as the irregular repetition of bits and the use of linear transform operations").

109 Gottschalk v. Benson, 409 U.S. 63, 67 (1972).

110 Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012).

111 *Id.* at 1294.

112 *See, e.g.*, *id.* at 1304-05.

113 *See id.* at 1302 ("[The patents] tie up the doctor's subsequent treatment decision . . . . And they threaten to inhibit the development of more refined treatment recommendations . . . ."); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2114 (2013) ("[Myriad's patents] solidified [Myriad's] position as the only entity providing BRCA testing.").

some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[114]

Significantly, it seems apparent that the Court assumed that its reinvigoration of patent eligibility, particularly with respect to biological natural phenomena, would not have the effect of excluding a substantial percentage of biotechnological innovations from patent protection. For example, in *Mayo* the Court indicated that it did not believe that its decision would negatively impact the availability of patent protection for new drugs and new methods of using drugs.[115] Similarly, in *Myriad* the Court seemed to assume that even though it had invalidated some of Myriad's gene patent claims, the possibility of meaningful protection remained for diagnostic methods directed toward the genes.[116]

Unfortunately, the manner in which the new patent eligibility standard, particularly as set forth in *Mayo*, is being applied to inventions relating to biotechnology and healthcare seems to be going much further than the Court intended. While the Court assumed that adequate protection would remain available for important applications of biological natural phenomena, with each new decision applying the *Mayo* Framework in the context of biotechnology and medicine, this protection seems less and less likely.[117] Ironically, some of Myriad's diagnostic-method claims that the Supreme Court assumed were patent eligible—and thus would provide adequate patent protection for Myriad even in the absence of the invalidated gene patent claims—were later declared patent ineligible by the Federal Circuit under the *Mayo* Framework.[118]

III. THREE IMPORTANT QUESTIONS RAISED BY THE *MAYO* FRAMEWORK

The two-part *Mayo* Framework leaves three questions with important implications for patenting in biotechnology largely unresolved. First, what constitutes a natural phenomenon? Second, what constitutes a sufficiently "inventive concept" to render a claim relating to a natural phenomenon patent eligible? And third, what is the role, if any, of preemption in patent eligibility analysis post-*Alice*?

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114 *Mayo*, 132 S. Ct. at 1293.

115 *Id.* at 1302 (distinguishing between the patent claims at issue in that case and a "typical patent on a new drug or a new way of using an existing drug").

116 *Myriad*, 133 S. Ct. at 2119-20.

117 *See infra* Part IV.

118 Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-based Hereditary Cancer Test Patent Litig.), 774 F.3d 755, 763-64 (Fed. Cir. 2014).

A. *What Constitutes a "Natural Phenomenon"?*

The fact that the Supreme Court has articulated a two-step test for patent eligibility implies that it intends the first step to serve some sort of gatekeeping function. In that case, some subset of patent claims that are not directed towards a patent ineligible concept must exist, given that the Supreme Court has specifically instructed that Part II of the test only comes into play if the answer to the question posed by Step I is "yes." With respect to biotechnology and the life sciences, in particular, if Step I is to perform any meaningful gatekeeping function there must exist some substantial category of inventions in this technological space that do not implicate natural phenomena. Conversely, if courts interpret the definition of natural phenomenon in a very expansive manner, such that virtually any invention in the life sciences inherently implicates a natural phenomenon, Step I will serve no meaningful gatekeeping function in the context of biotechnology. Unfortunately, it is looking more and more like this will be the case, due in large part to the expansive definition of natural phenomena adopted by the *Mayo* Court.[119]

The inclusion of natural phenomena in the list of patent ineligible concepts arose during the first wave of patent-eligibility decisions. In *Chakrabarty*, for example, the Court provided patent-ineligible examples such as "laws of nature, physical phenomena . . . . a new mineral discovered in the earth or a new plant found in the wild . . . [Einstein's] celebrated law that $E = mc^2$ . . . [and Newton's] law of gravity."[120] Standing on its own, a definition limited to similar examples would likely create little problem for biotechnology. After all, biotechnology is about creating synthetic biological products, not patenting pre-existing lifeforms.

Unfortunately, in the second wave, the Supreme Court seems to have embraced a much broader interpretation of the scope of patent-ineligible natural phenomena. In his *LabCorp* dissent, Justice Breyer concluded, "There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in [the claim at issue] is a 'natural phenomenon.'"[121] The Solicitor General took the same position in the amicus brief the government filed in connection with that case, which assumed that the "natural relationship between elevated total homocysteine and deficiencies in the B vitamins is an unpatentable 'principle in natural philosophy or physical science.'"[122] This conclusion seems plausible because the correlation does exist naturally in at least some individuals, independent of any

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119 *See infra* Part IV.

120 Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

121 Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc. (*LabCorp*), 548 U.S. 124, 135 (2006) (Breyer, J., dissenting).

122 Brief for the United States as Amicus Curiae at 19, *LabCorp*, 548 U.S. 124 (No. 04-607) (quoting O'Reilly v. Morse 56 U.S. (15 How.) 62, 116 (1853)).

human intervention. Unfortunately, the implication is that most newly invented diagnostic tests will fail Step I of the *Mayo* Framework because innovation in diagnostic testing typically arises out of the discovery of a naturally occurring correlation between a biomarker and a clinically relevant state or condition.[123] For example, the diagnostic tests at issue in the *Myriad* case were based on the discovery of a correlation between certain genetic variations in the BRCA genes and a propensity for cancer.[124]

Nevertheless, Step I could still perform a meaningful gatekeeping function in the area of personalized medicine and diagnostic testing if the definition of natural phenomena excluded correlations that do not occur naturally, but rather as a consequence of human intervention—for example, by administration of a synthetic, man-made drug to a patient. Regrettably, the Court in *Mayo* acquiesced to a very expansive interpretation of "natural phenomena" adopted by the courts in the decisions below, and this interpretation threatens to negate the gatekeeping function of Step I with regard to many, if not most, biotechnological innovations, effectively requiring analysis under Step II as a matter of course.

The problem first arose in a district court decision in the *Mayo* case, in which the court determined that correlations in the human body involving non-naturally occurring, synthetic molecules constitute "natural phenomena."[125] While acknowledging that the drug metabolites recited in the claims did not occur naturally in the human body, the district court nevertheless characterized the correlation between the metabolites and optimal drug dosage as a patent-ineligible "work of nature" because the drugs "are converted *naturally* by enzymes within the patient's body to form an agent that is therapeutically active, [and thus] the correlation results from a natural body process."[126] In essence, the court concluded that the mere involvement of a natural process in the interaction between a man-made drug and the human body renders the interaction a "natural phenomenon."[127]

When the Federal Circuit accepted the case on appeal, this author filed an amicus brief on behalf of a group of law professors arguing that the interaction of the human body with a synthetic molecule, in particular a drug breakdown product, should not be considered a natural phenomenon because the interaction would never occur naturally, but instead only occurs

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123 Holman, *supra* note 42, at 4.

124 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2112 (2013); Holman, *supra* note 42, at 2.

125 Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 WL 878910, at *6 (S.D. Cal. Mar. 28, 2008), *rev'd*, 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012).

126 *Id.* at *7 (quoting Declaration of Dr. Richard Bloomfeld in Support of Prometheus Laboratories Inc.'s Motion for Summary Judgment of Infringement of Claim 7 of U.S. Patent No. 6,355,623, ¶ 23, at 4, *Mayo*, 2008 WL 878910 (No. 04cv1200 JAH (RBB))) (internal quotation marks omitted) (court mistakenly citing to Dr. Bruce Bostrom, Doc. No. 542, ¶ 15).

127 *Id.*

as the result of active, purposeful human intervention.[128] Though the court refers to these synthetic molecules as drug "metabolites," in fact,

> they are fundamentally different from naturally occurring metabolites, such as the homocysteine at issue in *LabCorp.* Metabolites like homocysteine occur naturally in the human body, independently of any human intervention. Drug metabolites, such as those recited in the claims at issue in this case, do not occur naturally, in the human body or otherwise, and are thus not properly considered natural phenomena.[129]

The brief went on to explain that under the district court's expansive interpretation of "natural phenomena," it was hard to imagine what sorts of inventions would remain patentable, pointing out that

> virtually every patented invention is based on some discovery involving the interaction of human ingenuity with the natural environment and natural processes. For example, an airplane operates by interacting with the air in a particular manner that results in flight. The air and its properties are natural phenomena, but surely that does not render the interaction of an airplane with the air a natural phenomenon. More to the point, what biological or pharmaceutical invention is not based on an interaction with natural biological processes? In particular, drugs operate by means of chemical interactions with naturally occurring proteins and other biomolecules in the body, according to the fundamentals laws of chemistry and biology. Simply interacting with natural processes does not render a *man-made* biological phenomenon a natural phenomenon, but that would seem to be the result if the rationale of the lower court were applied generally to other scenarios beyond the facts of this case.[130]

Regrettably, this explanation did not persuade the Federal Circuit, and in deciding the appeal, the court essentially assumed that the district court was correct in its characterization of the non-naturally occurring correlation as a natural phenomenon.[131] The Federal Circuit referred to the method claims as reciting an application of "*naturally occurring* correlations between metabolite levels and efficacy or toxicity," but it nonetheless reversed the district court, deciding that these "method claims recite a patent-eligible application."[132] The court reasoned that the asserted claims were not drawn "to a natural phenomenon" but instead were "drawn only to a particular application of that [natural] phenomenon."[133]

When the case reached the Supreme Court, this expansive interpretation of "natural phenomena" was again adopted, resulting in the reversal of the Federal Circuit's opinion and the rejection of Prometheus's patent claims. The Court provided little independent analysis as to why this non-

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128 Brief of *Amici Curiae* Interested Patent Law Professors in Support of Neither Party at 6, *Mayo*, 628 F.3d 1347 (No. 2008-1403) [hereinafter Law Professors as *Amici* in *Mayo*].

129 *Id.* at 11.

130 *Id.* at 12.

131 Prometheus Labs., Inc. v. Mayo Collaborative Servs. 628 F.3d 1347, 1355 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012).

132 *Id.* (emphasis added).

133 *Id.* at 1354.

naturally occurring correlation represented a natural phenomenon, simply concluding that "Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm."[134] The Court acknowledged the fact that "it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person," but went on to find that "the relation itself exists in principle apart from any human action[and is] a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes."[135]

B. *What Constitutes an "Inventive Step"?*

The *Mayo* Framework requires an inventive step beyond the mere recitation of a patent-ineligible, natural phenomenon, but questions remain as to what constitutes a sufficiently "inventive step?" In *Mayo,* the Court suggested that an inventive step is something that goes beyond that which is "well-understood, routine, [and] conventional,"[136] and the patent community has come to accept this explanation as the standard. As of yet, it is unclear how this standard compares to, and relates with, the nonobviousness requirement of 35 U.S.C. § 103, which is the traditional doctrinal mechanism for setting the inventive threshold for patentability.

One way to interpret the inventive step requirement would be to essentially treat any natural phenomenon implicated/embodied by a patent claim as a sort of pseudo prior art, and then ask whether the claimed subject matter would have been obvious given knowledge of that information. Some precedent exists for such an approach. In *Flook*, the Supreme Court took the position that in analyzing a claim for patent eligibility, any patent-ineligible concept embodied in the claim "is assumed to be within the prior art," and that the claim as a whole is patent eligible only if "there is some other inventive concept in its application."[137] *Flook* states that a patent-ineligible concept (in that case a mathematical algorithm, but presumably this methodology would also apply to a natural phenomenon) is to be "treated as though it were a familiar part of the prior art," regardless of whether "the algorithm was in fact known or unknown at the time of the claimed invention."[138]

Similarly, shortly after the Supreme Court granted certiorari in *LabCorp*, the Federal Circuit briefly flirted with the idea of treating patent-

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134 *Mayo*, 132 S. Ct. at 1296.

135 *Id*. at 1297.

136 *Id.* at 1298.

137 Parker v. Flook, 437 U.S. 584, 594 (1978).

138 *Id.* at 591-92 (citing Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

ineligible concepts as part of the prior art, not in the context of patent-eligibility analysis, but rather under the guise of § 103 and the nonobviousness requirement. The Federal Circuit presented this unconventional approach as dicta in *In re Comiskey*,[139] a 2007 panel decision addressing the patent eligibility of a method of "mandatory arbitration for unilateral and contractual documents claim."[140] The panel essentially held that the method constituted a patent ineligible abstract idea, and struck down those claims that were not explicitly tied to implementation by a computer for lack of patent eligibility.[141]

On the other hand, with respect to other claims that explicitly recited a computer implementation step, the court held that the inclusion of this step was sufficient to cross over the threshold into patent eligibility.[142] But the panel went on to rule that these computer-implemented claims appeared to do nothing more than add a modern, general-purpose computer or modern communication devices to an otherwise unpatentable mental process, and that such a "routine addition of modern electronics to an otherwise unpatentable invention typically creates a prima facie case of obviousness."[143] The panel remanded the case to the PTO to "determine in the first instance whether the addition of general purpose computers or modern communication devices to Comiskey's otherwise unpatentable mental process would have been non-obvious to a person of ordinary skill in the art."[144]

Comiskey caused a bit of an uproar in the patent community because the dicta threatened the patentability of many of the inventions that had been patented in the wake of *AT&T Corp.* and *State Street Bank*. In response to the uproar, the en banc Federal Circuit withdrew the original *Comiskey* opinion, replacing it with a superseding opinion that removed all reference to the idea of treating patent-ineligible concepts as prior art for purposes of nonobviousness analysis under § 103.[145] In the revised opinion, the court merely directed "the PTO to consider the § 101 question in the first instance" to do decide whether the computer-implemented claims recite patentable subject matter.[146]

In any event, a relatively stringent inventive step test, requiring something more than the application of "well-understood, routine, and conventional" technology to a newly identified natural phenomenon, could have devastating consequences for the patentability of some of the most important inventions in biotechnology, particularly if applied in conjunction

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139 499 F.3d 1365 (Fed. Cir. 2007), *revised and superseded en banc*, 554 F.3d 967 (Fed. Cir. 2009).

140 *Id.* at 1374.

141 *See id.* at 1378-79.

142 *Id.* at 1379-80.

143 *Id.* at 1380.

144 *Id.* at 1380-81.

145 *In re* Comiskey, 554 F.3d 967, 969 (Fed. Cir. 2009) (en banc).

146 *Id.* at 970.

with a broad definition of natural phenomena as described above.[147] For example, if the discovery of a correlation between a biomarker and a clinically significant state, e.g., a genetic variation and a propensity for cancer, is considered a natural phenomenon, what could be more conventional than to test for the presence of the biomarker? If the interaction between a synthetic chemical compound, e.g., a drug, with the human body in a manner that alleviates the effect of disease is a natural phenomenon, then what could be more conventional than to formulate the chemical compound into a drug and use it to treat patients affected with the disease? If these applications are insufficiently inventive under Step II of the *Mayo* Framework, they are generally patent ineligible, a conclusion which has very troubling implications for the patentability of drugs and diagnostics, two of the most important areas of innovation in human healthcare. As discussed below, these concerns are playing out in actual cases where courts are denying patent protection to meritorious inventions with a high potential for improving the human condition for a failure to satisfy the *Mayo* Framework.[148]

C. *What Is the Role of Preemption in the Analysis?*

During the first wave, the Supreme Court's articulation of patent eligibility as a distinct requirement of patentability appeared to stem from preemption concerns. A finding of patent eligibility seemed to hinge upon the extent to which the patent claim threatened to preempt all practical uses of a patent ineligible concept.[149] For example, in the first patent eligibility decision, *Benson*, the Court emphasized the fact that "[t]he mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."[150] Preemption of a patent ineligible concept appeared sufficient, and perhaps necessary, for a claim to be patent ineligible.

In *Flook*, the Court seemed to split over the question of whether preemption is in fact necessary for a finding of patent ineligibility. The claims at issue were limited to applications in the petrochemical and oil-refining industries, and thus posed no threat of preempting use of the underlying mathematical formula in other contexts.[151] In the decision below, the Court of Customs and Patent Appeals held the claims patent eligible because the claims did not "preempt the formula or algorithm contained there-

147 *See supra* Part II.

148 *See infra* Part IV.

149 *See, e.g.*, Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972).

150 *Id.*

151 Parker v. Flook, 437 U.S. 584, 586 (1978).

in," and hence were not patent ineligible under *Benson*.[152] In other words, the Court of Customs and Patent Appeals treated preemption as necessary for a finding of patent ineligibility. Three Justices writing a dissent in *Flook* agreed, finding the lower court's decision in this regard "wholly in conformity with basic principles of patent law."[153]

The *Flook* majority disagreed, however, and held that a finding of patent ineligibility does not apply solely to patent claims that wholly preempt a patent ineligible concept.[154] While acknowledging that the claims at issue in *Flook* did not seek to "wholly preempt the mathematical formula" due to the many uses of the formula outside the petrochemical and oil-refining industries that would remain in the public domain, the majority concluded nonetheless that the claims were patent ineligible because the only steps incorporated into the claim beyond the mathematical formula were "conventional or obvious."[155] In effect, the *Flook* majority applied a version of what the patent community now refers to as the "inventive step" test and held that preemption is not a prerequisite for a conclusion of patent eligibility.

Three years later in *Diehr*, the Court seemed to again change course, with the majority in that case treating preemption as not only sufficient, but also necessary for a finding of patent ineligibility.[156] A four-Justice dissent objected to this approach, complaining that in *Flook* the majority had "rejected the argument that patent protection was available if the inventor did not claim a monopoly on every conceivable use of the algorithm," a statement that the dissent found inconsistent with the *Diehr* majority's assumption that preemption is a prerequisite for patent ineligibility.[157] The *Diehr* dissent specifically called out the inconsistency between the Court's treatment of preemption in *Flook* and *Diehr*, noting that the claims in *Flook* were patent ineligible even though they "did not cover every conceivable application of the formula."[158] In summary, at the close of the first wave of patent eligibility decisions, the Justices appeared conflicted as to the role of preemption in patent-eligibility analysis. The majority in *Diehr*, which was the last of these decisions and thus the Court's final word on the subject prior to the second wave, seemed to indicate that preemption is not only sufficient for a finding of patent eligibility, but also arguably a prerequi-

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152 *In re* Flook, 559 F.2d 21, 23 (C.C.P.A. 1977), *rev'd sub nom.* Parker v. Flook, 437 U.S. 584 (1978).

153 *Flook*, 437 U.S. at 599 (Stewart, J., dissenting).

154 *Id.* at 589-90 (majority opinion).

155 *Id.*

156 *See* Diamond v. Diehr, 450 U.S. 175, 191-93 (1981).

157 *Id.* at 215 (Stevens, J., dissenting).

158 *Id.* at 192 n.14 (majority opinion); *id.* at 205, 209-11, 216 (Stevens, J., dissenting).

site.[159] Moreover, in *Diehr* the issue of preemption seemed to be the key consideration in assessing the patent eligibility of the claims.[160]

At the beginning of the second wave, preemption seemed to remain an important consideration, if not the overriding concern, in patent eligibility jurisprudence. The United States also clearly took this position as evidenced in the amicus brief filed by the Solicitor General in *LabCorp*.[161] In its brief, the government took the position that "[i]f the question presented [in the petition for certiorari] raises a Section 101 issue at all, it is whether claim 13 impermissibly asserts 'a monopoly over a basic scientific relationship,'" i.e., whether the claim at issue preempts "all substantial practical applications of . . . [a] natural phenomenon."[162] Notably however, Breyer's dissent in *LabCorp* devotes little if any attention to the concept of preemption.[163]

In *Bilski*, the Court recognized the role of patent eligibility in addressing preemption concerns, opining that "[a]llowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."[164] However, the Court seemed to ignore the language in *Diehr* suggesting that preemption is necessary for a finding of patent ineligibility and instead reemphasized the Court's proposition from *Flook* "that limiting an abstract idea to one field . . . [does] not make the concept patentable."[165] The Court then proceeded to declare Bilski's claims patent ineligible,[166] even though the claims clearly could not preempt the abstract idea at issue in the case given that they were limited to particular applications of that concept involving commodities and energy markets.

In *Mayo*, the district court focused heavily on preemption in its patent eligibility analysis.[167] The alleged infringer in the case based its argument of patent ineligibility largely on a contention that

> the claims [at issue in the case] "wholly pre-empt" use of the correlation because the only practical use of the correlation is in drug treatment for gastrointestinal autoimmune diseases and non-gastrointestinal autoimmune diseases, and anyone seeking to employ the correla-

159 *See id.* at 187, 191-92 (majority opinion).

160 *See id.*

161 Brief for the United States as Amicus Curiae, *supra* note 122, at 17-21.

162 *Id.* at 20-21.

163 Lab. Corp. of Am. Holdings v. Metabolite Labs. Inc. (*LabCorp*), 548 U.S. 124, 125-39 (2006) (Breyer, J., dissenting).

164 Bilski v. Kappos, 561 U.S. 593, 611-12 (2010).

165 *Id.* at 612.

166 *Id.*

167 Prometheus Labs., Inc. v. Mayo Collaborative Servs., No. 04cv1200 JAH (RBB), 2008 WL 878910, at *10 (S.D. Cal. 2008) ("The case law is clear, if a claim that recites unpatentable subject matter 'wholly pre-empts' all practical use of the unpatentable subject matter, the claim is invalid under section 101." (quoting Gottschalk v. Benson, 409 U.S. 63, 71-72 (1972))), *rev'd*, 628 F.3d 1347 (Fed. Cir. 2010), *rev'd*, 132 S. Ct. 1289 (2012).

> tion must conduct the only active steps recited in the claims—administer the drug and determine metabolite levels.[168]

The patent owner attempted to counter this preemption argument by citing numerous examples of applications of the underlying natural phenomenon that the patent claims did not cover.[169] The district court sided with the defendant, however, and held the claims patent ineligible, doing so in a manner suggesting that it saw preemption as an extremely important consideration in the patent eligibility analysis, and perhaps even a necessary prerequisite for a finding of patent ineligibility.[170] Regarding the allegedly unpatented applications set forth by the patent owner, the court found that "the law does not require that every conceivable use be preempted to invalidate the claim. Rather, it is enough that the unpatentable subject matter recited in the claims has 'no substantial practical application' outside the context of the claims."[171]

On appeal, the Federal Circuit likewise focused its analysis largely on the issue of preemption, but in contrast to the district court, found that the claims did not preempt all uses of the natural phenomenon.[172] Instead, the Federal Circuit concluded that the claims recited "specific treatment steps" involving "a particular application of the natural correlations," and as such, "the claims do not preempt all uses of the natural correlations; they utilize them in a series of specific steps."[173]

When the Supreme Court decided *Mayo*, it gave some lip service to the idea of preemption, but essentially ignored the issue in its analysis of patent eligibility.[174] For example, the Court noted that the Federal Circuit had upheld the patent eligibility of the claims based on its "clear and compelling conclusion . . . that the . . . claims . . . do not encompass laws of nature or preempt natural correlations," and made no attempt to refute this conclusion.[175] Instead, the Supreme Court focused its analysis on the lack of "inventive step," and treated preemption as merely a policy concern that supported the "inventive step" requirement, rather than as an element of the test for patent ineligibility.[176]

Interestingly, in *Myriad*, the Court never even mentioned preemption in its analysis for patent eligibility. *Alice*, the Court's most recent decision, identified the *Mayo* Framework as setting the standard for patent eligibil-

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168 *Id.* at *11.
169 *Id.* at *11-13.
170 *Id.* at *11-12, *14.
171 *Id.* at *11 (quoting *Benson*, 409 U.S. at 71-72).
172 *Mayo*, 628 F.3d at 1355.
173 *Id.*
174 *See* Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1294 (2012).
175 *Id.* at 1296 (quoting *Mayo*, 628 F.3d at 1355) (internal quotation marks omitted).
176 *See id.* at 1294, 1302-03.

ity,[177] and the decision is notable for the absence of any reference to preemption as a consideration in the analysis of a claim for patent eligibility. Instead, *Alice* simply characterized preemption as a "concern that undergirds our § 101 jurisprudence" and which "drives [the] exclusionary principle" of patent eligibility, not a factor to consider in determining the patent eligibility of claims.[178]

IV. RECENT DECISIONS APPLYING THE *MAYO* FRAMEWORK IN THE CONTEXT OF BIOTECHNOLOGY AND MEDICINE

The effects of the recently heightened standard of patent eligibility are increasingly affecting the biotechnology and the life science industries, where courts are applying the *Mayo* Framework in a manner resulting in the invalidation of patent claims that would have clearly passed patent-eligibility muster prior to the second wave. The definitions of "natural phenomena" and "inventive concept" discussed above[179] appear to have played an important role in these decisions, and the deemphasized role of preemption in the analysis has likely also contributed. This Part reviews four recent decisions in the lower courts involving the invalidation of issued patent claims directed towards genetic diagnostics, drug methods of treatment, research tools, and medical devices, and it illustrates the impact the second wave is having on patenting in biotechnology and medicine.

A. Ariosa Diagnostics v. Sequenom

As discussed above, all three of the life-sciences, patent-eligibility cases of the second wave involved inventions relating to diagnostics and/or personalized medicine.[180] Thus not surprisingly, the newly heightened standard particularly threatens patents relating to diagnostics and personalized medicine.[181] The fears of the biotechnology community were realized on June 12, 2015, when the Federal Circuit issued its decision in *Ariosa Diagnostics, Inc. v. Sequenom, Inc*.[182]

The patent at issue in *Ariosa*, U.S. Patent No. 6,258,540 ("the '540 patent"), relates to methods of diagnosis that involve detecting the presence of a paternally inherited nucleic acid of fetal origin in a blood sample taken from a pregnant woman.[183] The invention arose out of the discovery that

177 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354-55, 2358 (2014).
178 *Id.* at 2354, 2358.
179 *See supra* Sections III.A, B.
180 *See supra* Section I.B.
181 Holman, *supra* note 42, at 3-4.
182 788 F.3d 1371 (Fed. Cir. 2015).
183 *See id.* at 1373-74.

cell-free fetal DNA ("cffDNA") is detectable in maternal serum or plasma samples.[184] Claim 1 of the '540 patent is illustrative, and recites:

> 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.[185]

The "invention enables non-invasive prenatal diagnosis, including for example sex determination, blood typing and other genotyping, and detection of pre-eclampsia in the mother."[186]

The district court invalidated the claims for a lack of patent eligibility,[187] and on appeal the Federal Circuit affirmed, in spite of the undisputed merits of Sequenom's invention.[188] For example, Judge Linn of the Federal Circuit found it "hard to deny that Sequenom's invention is truly meritorious," noting that earlier technologies for prenatal diagnoses required invasive methods, which "present[ed] a degree of risk to the mother and to the pregnancy."[189] Prior to the invention, the available "techniques [we]re time-consuming or require[d] expensive equipment."[190] Judge Linn pointed out that the Royal Society had lauded the inventors' discovery as "a paradigm shift in non-invasive prenatal diagnosis."[191] He further noted that the commercial embodiment of the invention, the MaterniT21 test, was the first commercially available non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and that it presented fewer risks and a more dependable rate of abnormality detection than other tests.[192]

In applying the *Mayo* Framework to Sequenom's claims, the Federal Circuit began by finding that the existence of paternally inherited cffDNA in maternal plasma is a natural phenomenon.[193] From this fact, the court concluded that the claims are directed to methods that "begin[] and end[]

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184 *Id.* at 1373.

185 *Id.* at 1373-74.

186 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 19 F. Supp. 3d 938, 941 (N.D. Cal. 2013) (quoting U.S. Patent No. 6,258,540 (filed Mar. 4, 1998)) (internal quotation marks omitted), *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).

187 *Id.* at 954.

188 *Ariosa*, 788 F.3d at 1380.

189 *Id.* at 1381 (Linn, J., concurring) (alteration in original) (quoting U.S. Patent No. 6,258,540 (filed Mar. 4, 1998)) (internal quotation marks omitted).

190 *Id.* (alteration in original) (quoting U.S. Patent No. 6,258,540 (filed Mar. 4, 1998)) (internal quotation marks omitted).

191 *Id.* (quoting Declaration of Dr. Mark I. Evans in Support of Sequenom, Inc.'s Motion for Preliminary Injunction ¶ 52, at 18, *Ariosa*, 19 F. Supp. 3d 938 (No. 3:11-cv-06391-SI), 2012 WL 7991505) (internal quotation marks omitted).

192 *Id.*

193 *Id.* at 1376 (majority opinion).

with a natural phenomenon," i.e., paternally inherited cffDNA.[194] The court found significance in the fact that "Sequenom does not contend that [the inventors] created or altered any of the genetic information encoded in the cffDNA, and it is undisputed that the location of the nucleic acids existed in nature before [the inventors] found them."[195] After concluding that the claims are directed to "matter that is naturally occurring," thereby satisfying Step I of the *Mayo* Framework, the court turned to Step II.[196]

In applying Step II, the court found that none of the additional elements recited in the claims introduced sufficient "inventive concept" to render the claims patent eligible.[197] In particular, while some of the challenged claims recite steps such as polymerase chain reaction ("PCR") for preparing, amplifying, and detecting DNA, the court held that all the recited techniques were "well-understood, conventional and routine" at the time of the invention, and thus failed to provide enough inventive concept to satisfy the *Mayo* standard.[198] In the words of the court:

> [A]ppending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art.[199]

Sequenom sought refuge in the preemption rationale for the doctrine, arguing that a claim is only patent ineligible if it preempts all uses of a natural phenomenon, and identifying numerous uses of cffDNA that did not fall within the scope of the claims.[200] While the district court agreed "that preemption is a consideration when performing a § 101 analysis," it rejected Sequenom's argument "that whether the claims preempt all uses of the natural phenomenon is dispositive of the analysis."[201] The district court ruled that a claim is patent ineligible if it preempts all "commercially viable" uses of a natural phenomenon, and is not saved by the existence of unpatented applications lacking the requisite commercial viability.[202] The court went on to conclude that Sequenom's claims covered all commercially viable means of testing for paternal cffDNA and thus, for patent eligibil-

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194 *Ariosa*, 788 F.3d at 1376.

195 *Id.*

196 *Id.*

197 *Id.*

198 *Id.* at 1377.

199 *Id.* at 1378.

200 *Ariosa*, 788 F.3d at 1378; Ariosa Diagnostics, Inc. v. Sequenom, Inc., 19 F. Supp. 3d 938, 953 (N.D. Cal. 2013), *aff'd*, 788 F.3d 1371 (Fed. Cir. 2015).

201 *Ariosa*, 19 F. Supp. 3d at 953 n.9.

202 *Id.* at 953.

ity purposes, preempted the use of the natural phenomenon.[203] The court was unclear as to exactly when the unpatented but commercially viable applications had to become available, stating simply that this type of method claim is patent ineligible unless, "at the time of the invention or at the time of issuance of the patent," there are available commercially viable alternatives for applying the claimed natural phenomenon.[204]

On appeal, the Federal Circuit appeared to distance itself from the district court's preemption analysis, and it offered no comment on the district court's reliance on a purported distinction between commercially viable and commercially non-viable uses for the purpose of deciding patent eligibility. Instead, the Federal Circuit seemed to treat the preemption analysis as outside the scope of the patent eligibility inquiry, relying solely on the *Mayo* Framework to arrive at the same patent-ineligible conclusion as the district court.[205] In discussing the relationship between preemption and patent eligibility, the Federal Circuit stated that, although

> [t]he Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability[,] . . . the absence of complete preemption does not demonstrate patent eligibility. . . . Where a patent's claims are deemed only to disclose patent ineligible subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.[206]

During the briefing stage of the appeal, Sequenom and some of its supporting amici urged the court to draw a distinction between natural phenomena based on whether or not their patenting would "interfere significantly with innovation in other fields now or in the future."[207] The court rejected this policy argument, however, holding that the Supreme Court cases "have not distinguished among different laws of nature or natural phenomenon according to whether or not the principles they embody are sufficiently narrow."[208]

In a thoughtful concurring opinion, Judge Linn complained that he had been compelled to join the court's opinion invalidating the claims only because he felt "bound by the sweeping language of the test set out" by the Supreme Court in *Mayo*.[209] Judge Linn expressed his opinion that Step II of the *Mayo* test is overly broad and was unnecessary to decide *Mayo*.[210] Further, the application of Step II's broad language in this case demonstrated the "perhaps unintended" consequence of "excluding a meritorious inven-

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203 *Id.* at 953-54.
204 *Id.* at 954.
205 *Ariosa*, 788 F.3d at 1379.
206 *Id.*
207 *Id.* at 1379.
208 *Id.*
209 *Id.* at 1380 (Linn, J., concurring).
210 *Id.*

tion from the patent protection it deserves and should have been entitled to retain."[211] According to Judge Linn, under "traditional," pre-*Mayo* standards of patentability, Sequenom's patent would have been valid, since the inventors had "effectuate[d] a practical result and benefit not previously attained."[212] His concurrence concludes with the following observation:

> But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.[213]

A recent article by this author expressed concern that if applied literally, *Mayo* threatens the availability of effective patent protection for many, if not most, innovations in diagnostics and personalized medicine.[214] The Federal Circuit's decision in *Ariosa* appears to have confirmed these fears. A number of concerned parties, including the Biotechnology Industry Organization ("BIO") and Pharmaceutical Research and Manufacturers of America ("PhRMA"), filed amicus briefs urging the Federal Circuit to rehear the case en banc, explaining the potentially devastating consequences for biotechnology and pharmaceuticals if the Federal Circuit applies this interpretation of *Mayo* broadly across the life sciences.[215] The Federal Circuit denied en banc rehearing, although four judges filed concurring and dissenting opinions all recognizing the policy concerns associated with the *Mayo* Framework as applied to inventions arising out of the life sciences.[216]

B. Endo Pharmaceuticals v. Actavis

As discussed above, the Supreme Court's *Mayo* decision adopted the lower courts' questionable conclusion that the interaction of a synthetic drug with the human body is a natural phenomenon.[217] The law professor amicus brief filed by the author when the Federal Circuit first heard *Mayo* warned that treating the interaction of a synthetic drug with the human body

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211 *Ariosa*, 788 F.3d at 1380 (Linn, J., concurring).

212 *Id.* at 1381 (quoting Le Roy v. Tatham, 63 U.S. (22 How.) 132, 135-36 (1859)) (internal quotation marks omitted).

213 *Id.*

214 Christopher M. Holman, *The Critical Role of Patents in the Development, Commercialization and Utilization of Innovative Genetic Diagnostic Tests and Personalized Medicine*, 21 B.U. J. SCI. & TECH. L. 297, 303 (2015).

215 The Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) as *Amici Curiae* Supporting Appellants and in Favor of en banc Reconsideration at 5-6, *Ariosa*, 788 F.3d 1371 (No. 2014-1139).

216 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1284 (Fed. Cir. 2015) (per curiam) (denying petition for rehearing case No. 2014-1139 en banc); *id.* at 1284-87 (Lourie and Moore, JJ., concurring); *id.* at 1287-93 (Dyk, J., concurring); *id.* at 1293 (Newman, J., dissenting).

217 *See supra* Part III.

as a natural phenomenon threatened the patent eligibility of pharmaceutical inventions in general.[218] After all, if patent eligibility requires an inventive step that goes beyond what is conventional and well-understood, it would seem that formulating a drug using routine methods, or administering the drug to a patient to take advantage of the interaction, might be insufficient for patent eligibility. Drug method-of-use claims would be particularly vulnerable. If courts characterize the therapeutic effect of a drug as a natural phenomenon and essentially treat the effect as part of the prior art, courts could easily hold that using the drug to treat a human patient is not sufficiently inventive to satisfy the *Mayo* Framework.

On November 17, 2015, this concern became a reality in *Endo Pharmaceuticals Inc. v. Actavis Inc*.[219] In this case, the district court adopted a magistrate judge's recommendation that found the drug method-of-use claims at issue in the case invalid based on the patent ineligibility of the claimed subject matter.[220] Shockingly, the court formed this opinion on a motion to dismiss under Rule 12(b)(6).[221] *Endo Pharmaceuticals* was an Abbreviated New Drug Application ("ANDA") litigation brought by Endo Pharmaceuticals against Actavis in connection with Actavis's attempt to market a generic version of Endo's Oxymorphone ER Tablets.[222] Representative claim 1 of the patent at issue in the case, U.S. Patent No. 8,808,737 ("the '737 patent"), recites:

> A method of treating pain in a renally impaired patient, comprising the steps of:
>
> a. providing a solid oral controlled release dosage form, comprising:
> i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and
> ii. a controlled release matrix;
> b. measuring a creatinine clearance rate of the patient and determining it to be (a) less than about 30 ml/min, (b) about 30 mL/min to about 50 mL/min, (c) about 51 mL/min to about 80 mL/min, or (d) above about 80 mL/min; and
> c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief;
>
> wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 nghr/mL.[223]

In applying Step I of the *Mayo* Framework, the magistrate judge accurately noted that the "*Mayo* court provided a broad definition for a law of

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218 Law Professors as *Amici* in *Mayo*, *supra* note 128, at 13-16.

219 No. 14-1381-RGA, 2015 WL 7253674 (D. Del. Nov. 17, 2015).

220 *Id.* at *2, *4.

221 *Id.* at *1-2, *4.

222 Endo Pharm. Inc. v. Actavis Inc., No. 14-1381-RGA, 2015 WL 5580488, at *2 (D. Del. Sept. 23, 2015), *recommendation adopted by* No. 14-1381-RGA, 2015 WL 7253674 (D. Del. Nov. 17, 2015).

223 U.S. Patent No. 8,808,737 (filed Aug. 19, 2014).

nature," and went on to conclude that "the connection between the severity of renal impairment and the bioavailability of oxymorphone" was the relevant natural law to which the claims are directed.[224] Moving to Step II of the *Mayo* Framework, the magistrate judge essentially determined that the "providing," "measuring," and "administering" steps were analogous to the steps in the claims held to be patent ineligible in *Mayo*, and thus did not "add enough" extra.[225]

The district court judge hearing the case adopted the magistrate judge's recommendation in its entirety and found the '737 patent to be "facially invalid," rejecting several of Endo's arguments in support of patent eligibility of its claims.[226] Of particular significance, Endo argued "that the Magistrate Judge's reliance on the similarities between the '737 patent's representative claim and the claim involved in [*Mayo*] was in error because the claim at issue in *Mayo* did not require that anyone act upon or apply the method in a tangible way, while Claim 1 of the '737 patent actually require[d] that the lower dose be administered."[227] Prior to this decision, some had held out hope that, even post-*Mayo*, a method of treatment claim that explicitly recited administration of the drug to a patient would remain patent eligible. The district court judge who decided *Endo*, however, rejected this notion, agreeing with the magistrate judge's conclusion that "limitations at issue in *Mayo* do in fact mirror the analogous limitations of Claim: 1 of the '737 patent."[228]

In reviewing the magistrate's recommendation, the court considered the following side-by-side comparison of the language of the *Mayo* and *Endo* claims. The *Mayo* claim language stated, "indicates a need to [increase/decrease] the amount of said drug subsequently administered to said subject" while the *Endo* claim language stated, "orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief."[229] The district court concluded that the "slight difference in phrasing is immaterial, because neither formulation provides any sort of 'inventive concept.'"[230]

The court further found Endo's argument that the '737 patent does not claim a law of a nature, but rather "a new and useful process," to be "thoroughly unconvincing."[231] The district court found that Endo had essentially admitted in its briefing that the '737 patent claimed a natural law based on the following statement: "[I]t is true that the claimed inventions relate to the

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224 *Endo Pharm.*, 2015 WL 5580488, at *6.

225 *Id*. at *6-7.

226 *Endo Pharm.*, 2015 WL 7253674, at *1, *4.

227 *Id.* at *1 (citation omitted).

228 *Id*. at *2.

229 *Id.* at *3 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1295 (2012)) (internal quotation marks omitted).

230 *Id*.

231 *Id.* (internal quotation marks omitted).

unexpected discovery that the bioavailability of oxymorphone is increased in patients with renal impairment."[232] This interpretation is troubling because while the patent statute explicitly states that a "discovery" can be patented, this court construed the patent owner's use of the term "discovery" as an admission that the "discovery" was a natural phenomenon.[233] If courts assume that all discoveries are natural phenomena, the availability of patent protection for innovation in the life sciences post-*Mayo* would appear to be extremely limited.

Endo also made a policy argument "that the reasoning employed by the Magistrate Judge's Report and Recommendation would in effect invalidate all pharmaceutical method-of-treatment patents using an existing, well-known compound."[234] The district court responded, "[T]his case is hardly the poster child for [such] a policy argument," and it speculated that patent protection would still be available for method-of-use claims that are directed towards an invention embodying "creative steps or inventive leaps aside from the discovery of a natural law."[235]

It is important to note that the Endo claim is not a straightforward method-of-treatment claim, e.g., "a method of treating disease X by administering drug Y," and does not necessarily indicate that the magistrate judge would have ruled such a claim patent ineligible. The decision explicitly points out that "oxymorphone is 'widely used' for acute and chronic pain relief, thus showing that the utilization of oxymorphone is not the invention."[236] Perhaps the magistrate judge was implying that, in a case where the "invention" is the discovery of a new pharmaceutical agent for the treatment of some medical condition, a method-of-treatment claim could still be patent eligible under *Mayo*. But if the discovery that a chemical compound has therapeutic effect on a patient is to be treated as a natural phenomenon, which appears to be the case under the rationale of this decision, how successful will a pharmaceutical company be in arguing that use of that chemical compound for its therapeutic effect constitutes a sufficient "inventive leap" to satisfy the *Mayo* Framework?

C. Celsis In Vitro v. Cellzdirect

Celsis In Vitro, Inc. v. Cellzdirect, Inc.[237] provides another example of a district court decision wherein application of the *Mayo* Framework result-

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232 *Endo Pharm.*, 2015 WL 7253674, at *3 (alteration in original) (internal quotation marks omitted).

233 35 U.S.C. § 100(a) (2012) ("The term 'invention' means invention or discovery.").

234 *Endo Pharm.*, 2015 WL 7253674, at *1.

235 *Id*. at *4.

236 Endo Pharm. Inc. v. Actavis Inc., No. 14-1381-RGA, 2015 WL 5580488, at *6 (D. Del. Sept. 23, 2015), *recommendation adopted by* No. 14-1381-RGA, 2015 WL 7253674 (D. Del. Nov. 17, 2015).

237 83 F. Supp. 3d 774 (N.D. Ill. 2015).

ed in the invalidation of patent claims directed towards what appears to be a meritorious invention that would not have raised patent-eligibility concerns prior to the second wave.[238] The patent at issue, U.S. Patent No. 7,604,929 ("the '929 patent"), is directed towards processes for cryogenically freezing hepatocytes (a type of liver cell).[239] Hepatocytes are useful research tools, particularly in drug development, and can also be used for a variety of diagnostic and treatment purposes.[240] Prior to the invention, however, researchers and physicians could not easily access viable hepatocytes because of their erratic availability and short lifespan.[241] Researchers attempted cryopreservation, but found that freezing significantly decreased cell viability.[242] According to the district court decision, the "[p]revailing wisdom therefore [prior to the invention] taught that cells could be frozen only once and then had to be used or discarded. That severely limited the creation of the pooled hepatocyte products desired by researchers."[243]

Working in opposition to this prevailing wisdom, the inventors of the '929 patent developed for the first time a method for freezing and refreezing hepatocytes without losing significant cell viability, thus dramatically improving the availability of useful hepatocyte pools for drug testing and other research and treatment purposes.[244] The claims at issue in the case are directed towards a method of producing a preparation of cryopreserved hepatocytes capable of being frozen and thawed multiple times without a significant loss of viability, comprising the following steps: (1) previously frozen cells are thawed; (2) nonviable cells are separated from viable ones using a "density gradient fractionation;" and then (3) viable cells are cryopreserved for later use.[245]

The district court invalidated the claims, finding them to encompass patent-ineligible subject matter.[246] In applying the first step of the *Mayo* Framework, the district court found that the "patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles."[247] As to Step II, the court held that the claimed method lacked sufficient "inventive concept" because certain claimed elements such as the freezing of cells and the use of density gradient fractionation were "well-understood" and "conventional."[248]

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238 *See id.* at 783-84.

239 U.S. Patent No. 7,604,929 (filed Oct. 9, 2009).

240 *Celsis In Vitro*, 83 F. Supp. 3d at 777 (citing '929 Patent col. 5 l. 26-27).

241 *Id*. (citing '929 Patent col. 3 l. 49-52).

242 *Id.* (citing '929 Patent col. 3 l. 5-8).

243 *Id*. at 777-78 (citation omitted).

244 '929 Patent col. 3 l. 61 to col. 4 l. 6.

245 *Id.* col. 19 l. 56 to col. 20 l. 20.

246 *Celsis In Vitro*, 83 F. Supp. 3d at 783.

247 *Id*.

248 *Id*. at 782-83.

The district court acknowledged that, unlike the claims at issue in *Mayo*, the claims in this case did not "lock up the natural law in its entirety."[249] In fact, the defendant in this case had successfully designed around the patent claims "by using a different mechanism for sorting viable from nonviable cells."[250] Nonetheless, the court cited a recently decided Federal Circuit case, *University of Utah v. Ambry Genetics Corp.*,[251] for the proposition that the preemptive nature of a patent claim is "not ameliorated by virtue of the fact that there might have been other routine ways to get around the patent."[252] The court reasoned that "if one were allowed to own a slice of the preemptive pie, that would pave the way for multiple others to claim the rest of that pie. Such a result would clearly run counter to the teaching and purpose of *Mayo* and *Alice*."[253]

In effect, the court seems to have rejected the notion that preemption plays any role in patent eligibility analysis, since it suggests that any patent claim that covers any fraction of the potential applications of a patent ineligible concept is invalid because of the possibility that other inventors will, in the aggregate, patent the remaining applications, i.e., the remainder of the metaphorical pie. It is difficult to see how this reasoning is consistent with repeated admonitions by the Supreme Court that lower courts should administer the test for patent eligibility in a manner that does not prevent the patenting of an inventive application of a patent ineligible concept.

D. Exergen v. Thermomedics

Exergen Corp. v. Thermomedics, Inc.[254] provides yet another example in which the court recognizes the groundbreaking nature of a claimed method, but then proceeds to rule the claims at issue patent ineligible under the *Mayo* Framework.[255] A representative claim, Claim 51 of U.S. Patent No. 7,787,938, recites a "method of detecting human body temperature comprising: measuring temperature of a region of skin of the forehead; and processing the measured temperature to provide a body temperature approximation based on heat flow from an internal body temperature to ambient temperature."[256] The invention was motivated by a desire to provide a means for measuring human body temperature at a site on the body that is

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249 *Id*. at 785.

250 *Id.*

251 Univ. of Utah Research Found. v. Ambry Genetics Corp. (*In re* BRCA1- and BRCA2-based Hereditary Cancer Test Patent Litig.), 774 F.3d 755 (Fed. Cir. 2014).

252 *Celsis In Vitro*, 83 F. Supp. 3d at 785 (citing *Ambry*, 774 F.3d at 764 n.4) (internal quotation marks omitted).

253 *Id.*

254 No. 13-11243-DJC, 2015 WL 5579800 (D. Mass. Sept. 15, 2015).

255 *Id.* at *5-6.

256 *Id*. at *2.

"less invasive than regions targeted by earlier thermometers, such as the eardrum or rectum."[257] Prior to the invention, a "high-accuracy forehead thermometer had . . . not been available due to the challenges presented by the forehead's exposure to varying ambient air temperatures."[258]

Applying Step I of the Framework, the court found it beyond dispute that all of the claims at issue were directed towards patent-ineligible concepts.[259] The court did not explicitly identify these concepts, but suggested that they involved the "heat flow from an internal body temperature to ambient temperature" and "mathematical models of natural thermodynamic relationships."[260] Moving to Step II, the court took an approach similar to the court in *Endo*, essentially finding that the processing and measuring elements recited in the claims were analogous to the "determining" step in the *Mayo* claims, thus lacking in the necessary inventive concept to cross the patent eligibility threshold.[261]

The court readily acknowledged the groundbreaking nature of the invention, providing a significant advance in healthcare in a manner that ran entirely counter to the prevailing conventional wisdom.[262] For example, the court referenced a 1996 study from the Thermoregulation Research Laboratory at UCSF warning the medical community of the dangers of using skin temperature as a substitute for traditional core-temperature monitoring sites, and reporting a "poor correlation" between skin temperature and core temperature.[263] Similarly, the court noted that "the American Society for Testing and Materials, an international organization that develops technical standards, concluded in its 2003 and 2009 standards for infrared thermometers that skin temperature could not be independently correlated with core body temperature."[264] In fact, the inventor had to spend "years conducting clinical trials of Exergen's forehead thermometer to overcome skepticism among medical professionals who believed that measuring temperature at the forehead could not lead to accurate estimates of core body temperature."[265] Nevertheless, the court concluded,

> No matter how novel the concept of measuring body temperature from forehead skin temperature or how valuable the contribution to the medical community, this idea as set forth in

257 *Id.* at *1.
258 *Id.*
259 *Id.* at *4.
260 *Exergen*, 2015 WL 5579800, at *4 (internal quotation marks omitted).
261 *Id*. at *5-6.
262 *Id.*
263 *Id.* at *5.
264 *Id.*
265 *Id.*

> the asserted claims is fundamentally a discovery of a natural relationship between skin temperature and body temperature. . . . [and hence] not eligible for patent protection.[266]

CONCLUSION

The Federal Circuit recently denied a petition for en banc rehearing of *Ariosa*.[267] The decision to deny included two concurring opinions, filed on behalf of three judges on the court, who agreed with Judge Linn's concurrence in the original panel decision that although invalidation of the claims was not required by "policy or statute," it was unfortunately dictated by the broad language of *Mayo*.[268] Judge Newman filed a dissent expressing her belief that the court could still interpret language of *Mayo* in a manner that would have retained patent eligibility for Sequenom's claims.[269] But as is so often the case, the rest of the judges on the court do not seem to share Judge Newman's views, apparently feeling bound by *Mayo* to impose a standard of patent eligibility that will deny patent protection for a host of meritorious inventions relating to biotechnology and the life sciences.

If *Mayo* indeed ties the lower court's hands, relief will have to come from the Supreme Court or Congress. On March 21, 2016, Sequenom filed a petition for writ of certiorari, so perhaps the Supreme Court will take up the issue of patent eligibility once again, and hopefully the Court will recognize the problems with the *Mayo* Framework as it is currently being interpreted and applied.[270] In his concurring opinion to the decision to deny en banc rehearing, Judge Dyk proposed an interesting modification to the current test for patent eligibility. His proposal would maintain the availability of some patent protection for inventions that embody the application of a newly discovered natural phenomena—as opposed to the arguably previously known natural phenomena at issue in *Mayo*—even in the absence of any additional "inventive" elements beyond the discovery of the natural phenomenon.[271] The scope of protection envisioned under his approach would be significantly narrowed relative to the standard in place before *Mayo*; it would be limited to applications actually reduced to practice by the inventor.

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266 *Exergen*, 2015 WL 5579800, at *6 ("Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." (quoting Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117 (2013)) (internal quotation marks omitted)).

267 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282 (Fed. Cir. 2015) (per curiam).

268 *See id.* at 1284-87 (Lourie and Moore, JJ., concurring); *id.* at 1287-93 (Dyk, J., concurring).

269 *Id.* at 1293-94 (Newman, J., dissenting).

270 Petition for a Writ of Certiorari, Sequenom, Inc. v. Ariosa Diagnostics, Inc., No. 15-1182 (U.S. Mar. 21, 2016), 2016 WL 1105544.

271 *Ariosa*, 809 F.3d at 1291-92 (Dyk, J., concurring).

Judge Dyk's proposal to introduce an "actually reduced to practice" requirement to patentability[272] raises a host of concerns of their own, but these go beyond the scope of this Article. Nonetheless, his proposal illustrates the willingness of some on the Federal Circuit to work with the Supreme Court to arrive at a standard for patent eligibility that is more in line with good policy—and indeed with the Supreme Court's intent—which presumably is not to broadly deny patent protection to some of the most important inventions to arise out of life sciences research. Optimally, this standard would address the Court's concerns involving the potential for preemption of the building blocks of future innovation, while at the same time maintaining the availability of adequate protection for meritorious innovations in biotechnology and the health sciences.

272 *Id.* at 1291.