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Section 101 Requires Something More . . . But How Much More?

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Since the inception of the modern patent code in 1952, the question of whether an invention meets subject matter eligibility requirements under 35 U.S.C. § 101 ("Section 101") has rarely been difficult or contentious. Section 101 requires that patents only be awarded for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." Courts created several well-accepted exceptions to patentable subject matter: laws of nature, physical phenomena, and abstract ideas. Until recently, these exceptions were narrowly interpreted as a "low hurdle" that a patent applicant must overcome. This is no longer the case, and Section 101 has reached an unprecedented prominence in patent prosecution, reexamination, and litigation.

This article explores recent changes in Section 101 jurisprudence. In examining these changes, we trace the legal standard applied to inventions utilizing a law of nature, abstract idea, or natural phenomenon to survive Section 101. We conclude that the "low hurdle" has become substantially higher.

I. From "Something More" to an "Inventive Concept": The Supreme Court's Analysis of Inventions Under Section 101

A. The "Patent Eligibility Trilogy"

A trio of seminal Supreme Court decisions, known as the "Supreme Court Trilogy" or "Patent Eligibility Trilogy," first defined the requirement that "something more" was needed to transform patent claims directed towards the use of an algorithm, law of nature or abstract idea from non-patentable subject matter into patentable subject matter. In *Gottschalk v. Benson*[1] and *Parker v. Flook*,[2] the first two cases in the trilogy, the Court held that claims covering algorithms by themselves were not patent eligible under Section 101. In *Gottschalk*, the Court found unpatentable claims for an algorithm used to convert binary code decimal numbers to equivalent pre-binary numbers.[3] The Court's finding ultimately rested on its view that Gottschalk's claims captured the only practical application of the algorithm in a generic digital computing environment that, without more specific context, would effectively permit patent protection over every use of the algorithm. In *Flook*, the Court similarly found a method for computing and updating an "alarm limit" for use in monitoring catalytic conversion processes to be unpatentable under Section 101.[4] The application claimed only the algorithm, failed to explain how to determine the underlying variables of the algorithm, and was silent on the catalytic conversion process.[5] Accordingly, the Court found the invention to be nothing more than a mathematical formula and thus ineligible subject matter under Section 101.

In the third case of the trilogy, *Diamond v. Diehr*,[6] the claims at issue applied the Arrhenius equation, which is a mathematical formula describing the effect of temperature on reaction rates, to a process for curing rubber.[7] Prior art methods of molding cured rubber involved placing the uncured rubber inside a heated press for a particular time. Skilled artisans used the Arrhenius equation to calculate when to open the press and remove the cured, molded rubber.[8] At the time of invention, however, there was no way to obtain an accurate measure of the rubber's temperature without opening the press.[9] The invention solved this problem by using embedded thermocouples to constantly check the temperature and feed the measured values into a computer.[10] A computer then applied the Arrhenius equation to calculate when the press should be opened.[11] The Court found that Diehr's use of a mathematical equation in a computerized rubber press was meaningfully different from cases like *Parker v. Flook* that sought to preempt the use of mathematical equations in a generic computer environment.[12] Instead, Diehr's claims were eligible for patent protection because they were limited to specifically improving methods of curing rubber.[13]

The Court's reasoning in *Diehr* was a significant turning point in Section 101 jurisprudence. The Court created precedent that a physical machine or process using ineligible subject matter, an algorithm in *Diehr*, can transform the ineligible into eligible subject matter.[14] The patent community was given direction that judicial exceptions to patentability can become patentable when "performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing)."[15]

B. *Bilski v. Kappos*

The *Diehr* opinion served as the seminal case leading to the so-called "machine-or-transformation test" for determining the patent eligibility of processes containing one of the statutory exceptions to patentable subject matter.[16] For years, until the Supreme Court decided *Bilski v. Kappos*,[17] the machine-or-transformation test was a predictable way to analyze whether claims passed muster under Section 101. Starting with *Bilski*, Section 101 jurisprudence moved away from the use of a "rigid" test towards balancing tests requiring a more substantive analysis of the inventive qualities of the proposed innovation.

In *Bilski*, the Supreme Court addressed an invention related to the long-known abstract method of risk hedging. The Court found that the invention at issue failed to transform an abstract idea to patent-eligible subject matter. Specifically, the Court noted that an abstract idea claimed generally and

described using broad, general examples is not worthy of patent protection.[18] Just as in *Flook*, where limiting an algorithm to one claimed field of use did not render the invention patent eligible, the Court in *Bilski* held that the claims limiting the abstract idea of hedging to the narrow field of energy markets did not render Bilski's invention patent eligible.[19] The Court needed "something more" to transform a process of hedging into a patent-eligible invention.[20]

Bilski was important for at least two reasons. First, *Bilski* relegated the long-used machine-or-transformation test from the determinative test for patentability under Section 101 to a "useful and important clue."[21] Second, instead of a strict application of the machine-or-transformation test, the Court, in light of the Patent Eligibility Trilogy, elaborated that the ultimate question was not whether the ineligible matter was part of a machine or a transformation, but whether granting the claims would effectively grant a monopoly over the abstract idea.[22]

C. *Mayo v. Prometheus*

The Supreme Court's next Section 101 decision was in the life sciences, a technology field that often utilizes or relates to the body's natural processes. In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court found a diagnostic test measuring metabolite levels in a patient's blood following drug administration to claim patent-ineligible subject matter because it used the natural laws of human drug metabolism without "something more."[23] The claimed invention was characterized as having three steps: (1) administering the drug to a subject, (2) determining metabolite levels, and (3) being warned that an adjustment in dosage may be required.[24] The parties agreed that the first two steps were routinely practiced prior to the date of patenting. Additionally, there was little question that the third step, which involved correlating the metabolite levels with the patient's overall health, is directed to the natural law of drug metabolism. Thus, the issue was whether the first two steps (which were in the prior art) added enough to the third step (which comprised a natural law) such that the invention as a whole was not ineligible under Section 101.

The Court's ruling established a two-step framework for distinguishing claims directed to the patent-ineligible subject matter of laws of nature, natural phenomena, and abstract ideas from those that satisfied Section 101. The first step is to determine whether a claim is directed to a patent-ineligible concept such as an abstract idea, a mathematical formula, or a law of nature.[25] If the first step is answered in the affirmative, the second step is to consider whether the additional elements recited in the claim "transform the nature of the claim" into a patent-eligible application by reciting an "inventive concept" that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."[26]

The Court applied this two-step analysis to the claimed inventions in *Mayo* and found that the correlation step between metabolite concentrations in the blood and the likelihood of drug effectiveness was directed to an ineligible law of nature. Thus, in contrast to the machine-or-transformation analysis, which might have found machines measuring metabolite concentrations to satisfy Section 101, the Court examined the inventive quality of the features applying the ineligible subject matter. The Court first opined that "the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm" are laws of nature and thus unpatentable unless "the patent claims *add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws*."[27] The Court further concluded that the first two steps, which had long been practiced in the prior art, were "not genuine applications" of the natural law for the purpose of passing Section 101. The Court explained that "the steps in the claimed processes (aside from the natural laws themselves) involve *well-understood, routine, conventional activity* previously engaged in by researchers in the field,"[28] and therefore were "not sufficient to transform unpatentable natural correlations into patentable applications of those regularities."[29] Although the Court did not articulate exactly what could transform a natural law into a patent-eligible application of that law, the Court emphasized that the addition of well-understood, routine, conventional activity at a "high level of generality" was not enough.[30]

Mayo signified a distinct change in what "more" is needed to satisfy Section 101. The earlier machine-or-transformation analysis, looking for applications of ineligible subject matter to man-made technology, now required an evaluation of whether said machine or transformation reached beyond well-understood, routine and conventional activity recited at a high level of generality to an "inventive concept." With added contours to Section 101's bar to patentability, practitioners and innovators alike were eager for further clarification from the Court.

D. *Association for Molecular Pathology v. Myriad Genetics*

Association for Molecular Pathology v. Myriad Genetics, Inc.[31] gave the Court an opportunity to further clarify Section 101's boundaries. In *Myriad*, the Supreme Court addressed whether isolated segments of naturally occurring genomic DNA and man-made cDNA were patent eligible under Section 101.

Myriad presented a relatively simple factual background. Myriad Genetics, Inc. ("Myriad") obtained a number of patents concerning the BRCA1 and BRCA2 genes, which are associated with an increased risk of breast cancer. Myriad's patents contained claims directed to isolated genes, diagnostic methods utilizing the BRCA genes to screen for risk of cancer, and methods to identify drug candidates. The gene patents at issue were composition claims directed to isolated segments of human DNA as well as man-made cDNA, which is synthetic DNA wherein the portions that do not encode for protein synthesis (exons) are removed in the lab.

The Supreme Court found that only claims directed towards isolated cDNA, and not those directed towards isolated genomic DNA, passed muster under Section 101. The Court explained that the claims directed to isolated DNA were ineligible because: "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes … [n]or did Myriad create or alter the genetic structure of DNA."[32] By

contrast, the Court found that cDNA, wherein the non-protein coding exons have been removed from the strand, is patent-eligible subject matter because it is not naturally occurring, i.e., not a product of nature.

The Court in *Myriad* emphasized that it was not ruling on the patent eligibility of *methods* for isolating genes, but instead was merely addressing the eligibility of genes themselves.[33] The majority suggested that an innovative method of manipulating genes might merit patent protection, but also noted that, in *Myriad* and much like the technology in *Mayo*, the methods used by the patentees "'were well understood, widely used, and fairly uniform insofar as any scientist engaged in the search for a gene would likely have utilized a similar approach.'"[34] As such, the methods added to the composition claims failed to add an "inventive" dimension sufficient to transform the composition claims covering naturally occurring genomic DNA segments into a patent-eligible invention.

Although the Court again emphasized that transformation of a claim comprising a product of nature—or other ineligible subject matter—into a patent-eligible invention requires the addition of something "inventive," there was little clarification as to what that is. The 2014 decision in *Alice Corp. Pty. Ltd. v. CLS Bank International*,[35] the most recent Supreme Court opinion on Section 101 eligibility, gave the Court an opportunity to examine "inventive" aspects of patents directed to the abstract idea of intermediated settlement.

E. *Alice Corp. v. CLS Bank International*

Just one year after deciding *Myriad*, the Supreme Court revisited Section 101 in *Alice*. The patents in *Alice* were directed to methods for facilitating the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. The concept of using a third party to mitigate settlement risk is known as an intermediated settlement or escrow, and has been practiced in finance for centuries.

The Court held that the claims were directed to nothing more than abstract ideas and were thus invalid. Applying the two-step *Mayo* test, the Court first found that the claimed method of using an intermediated settlement to facilitate transactions was an abstract idea, and thus was ineligible for protection.[36] The Court then emphasized that, under *Mayo* and other subject-matter precedent, simply adding conventional steps to a method that is already well known in the art does not provide the "inventive concept" required for patent protection.[37] Similarly, the Court held that claims directed towards an abstract concept implemented by known technologies are not inventive, and thus, do not deserve patent protection: "wholly generic computer implementation is not generally the sort of 'additional featur[e]' that provides any 'practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself.'"[38] As the inventions claimed in *Alice* did not add more than a generic computer to an abstract idea, the Court found that they failed to meet the second step of the *Mayo* test.

The Court explained that, because the "[inventors] do not, for example, purport to improve the functioning of the computer itself" or "effect an improvement in any other technology or technical field," the application of an abstract idea to a generic computer was not enough to overcome Section 101's requirements.[39] Quoting *Mayo*, the Court stated that "'[s]imply appending conventional steps, specified at a high level of generality,' [is] not '*enough*' to supply an 'inventive concept,'"[40] found the claims to cover unpatentable subject matter, and again reinforced its requirement that "something more" is needed to transform an invention using an abstract idea, law of nature or natural phenomenon into patent-eligible subject matter, but added very limited guidance as to what "something more" means and what level of specificity is required to satisfy Section 101.

Some commentators have criticized the *Alice* decision as the beginning of the end of high technology commercial innovation, arguing that the vague but seemingly stringent eligibility standard announced by the Court will deter investment and innovation in these areas. There are similar concerns, for example, in the biotech and medical diagnostic fields. It remains to be seen what the ultimate effect of *Alice* and its predecessors will be, but the Federal Circuit case of *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,[41] suggests that the Supreme Court's amorphous requirement of an "inventive concept" has left the lower courts with inadequate guidance for evaluating patents that relate to an abstract idea, natural law, or natural phenomenon.

II. *Ariosa Diagnostics v. Sequenom*: The Supreme Court's Next Section 101 Case?

Ariosa illustrates the challenges faced by the Federal Circuit and the lower courts in applying the Supreme Court's recent Section 101 precedent.

The inventors in *Ariosa* obtained U.S. Patent No. 6,258,540 ("the '540 patent") covering a method of analyzing cell-free fetal DNA ("cffDNA") isolated and amplified from maternal serum to perform a non-invasive, prenatal diagnosis of sex determination, blood type, genetic disorders, and pre-eclampsia. This was the first time cffDNA had been isolated from maternal serum; previously it had to be derived from a fetus in utero.[42] The medical community lauded the invention as a breakthrough in prenatal diagnostics, as previous techniques required invasive methods, which presented risks to the patient and were often time-consuming and expensive.[43] The '540 patent contained independent claims related to general methods of synthesizing cffDNA found in maternal serum, as well as narrower claims related to the use of a technique known as a polymerase chain reaction ("PCR") to amplify isolated cffDNA found in maternal serum.[44]

The '540 patent was eventually licensed to Sequenom, Inc. ("Sequenom"), which ended up in litigation over the '540 patent with its competitor Ariosa.[45] The district court found the '540 patent to claim ineligible subject matter under Section 101,[46] and the Federal Circuit affirmed. The Federal Circuit applied the Supreme Court's two-part test for assessing subject-matter eligibility, namely, that inventions premised on abstract ideas, natural laws, or natural phenomenon require an additional "inventive concept" to be eligible for patenting. Applying this understanding of the Supreme Court's teachings regarding diagnostic claims predicated on abstract ideas or natural phenomena, the Federal Circuit stated:

> It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon. 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. The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.[47]

The Federal Circuit then opined that the methods the applicants used to detect and amplify cffDNA were well-understood, routine, and conventional at the time of patenting.[48] Because the Federal Circuit held that the method steps were well understood, conventional, and routine—including the claims directed towards PCR—it concluded that the method of detecting paternally inherited cffDNA was not eligible for patenting.

Judge Linn's concurring opinion points to the continuing debate over the Supreme Court's new test. He explained that:

> In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.[49]

In Judge Linn's view, there is tension between the *Mayo* test and the Court's pronouncement in *Diehr* that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made."[50] Judge Linn's concerns might be addressed sooner rather than later, as Sequenom has filed a petition for rehearing en banc before the Federal Circuit and will likely file a petition for certiorari with the Supreme Court if the en banc petition is denied.

III. Conclusion

The Supreme Court's "inventive concept" test has made Section 101 a more robust limitation on patentability. Challenges to patentability under Section 101 present powerful defenses to accused infringers and pose new obstacles to patentees seeking to enforce their patents. The precise contours of Section 101 are an issue that the courts and the Patent and Trademark Office will continue to define for years to come.

(Endnotes)

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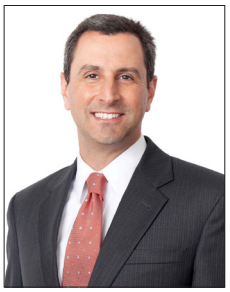

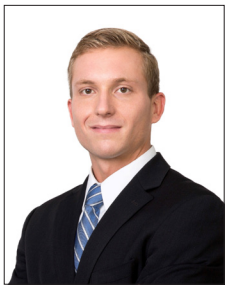

1 409 U.S. 63 (1972).
2 437 U.S. 584 (1978).
3 *Gottschalk*, 409 U.S. at 71-72.
4 *Flook*, 437 U.S. at 594-95.
5 *Id*. at 586.
6 450 U.S. 175 (1981).
7 *Id*. at 177-78.
8 *Id*.
9 *Id*.
10 *Id*. at 178.
11 *Id*. at 179.
12 *Id*. at 187.
13 *Id*. at 192-93.
14 *Id*. at 187.
15 *Id*. at 192-93.
16 The machine-or-transformation test holds that a claim to a process passes Section 101 if: (1) it is implemented by a particular machine in a non-conventional and non-trivial manner or (2) transforms an article from one state to another. *In re Bilski*, 545 F.3d 943, 961 (Fed. Cir. 2008).
17 561 U.S. 593, 130 S. Ct. 3218 (2010).
18 *Id*. at 3231.
19 *Id*.
20 *Id*.
21 *Id*. at 3227.
22 *Id*. at 3230-31.
23 566 U.S. 10, 132 S. Ct. 1289, 1294, 1305 (2012).
24 *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04cv1200, 2008 WL 878910, at *6 (S.D. Cal. Mar. 28, 2008).
25 *See Mayo*, 132 S. Ct. at 1297.
26 *Id*. at 1294.
27 *Id*. at 1296-97 (emphasis added (except words "enough" and "apply" italicized in original)).
28 *Id*. at 1294 (emphasis added).
29 *Id*. at 1298.
30 *Id*. at 1300-01 (emphasis added) ("Other cases offer further support for the view that simply appending conventional steps specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." (emphasis added)). *Id*. at 1300.
31 569 U.S. __, 133 S. Ct. 2107 (2013).
32 *Id*. at 2116.
33 *Id*. at 2119-20.
34 *Id*. at 2119-20 (quoting *Association for Molecular Pathology v. United States Patent and Trademark Office*, 702 F. Supp. 2d 181, 202-03 (S.D.N.Y. 2010)).
35 573 U.S. __, 134 S. Ct. 2347 (2014).
36 *Id*. at 2357.
37 *Id*. at 2359-60.
38 *Id*. 2358 (quoting *Mayo*, 132 S. Ct. at 1297).
39 *Id*. at 2359.
40 *Id*. at 2357 (quoting *Mayo*, 132 S. Ct. at 1300, 1297, 1294 (emphasis in original)).
41 788 F. 3d 1371 (Fed. Cir. 2015).
42 *Id*. at 1373.
43 *Id*. at 1381 (Linn, J., concurring).
44 *Id*. at 1373-74.
45 In response to letters from Sequenom threatening claims of infringement, Ariosa filed a declaratory judgment action alleging non-infringement of the '540 patent. Sequenom counterclaimed, alleging infringement. *Id*. at 1374.
46 *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 954 (N.D. Cal. 2013).
47 *Ariosa*, 788 F.3d at 1376.
48 *Id*. at 1377-78.
49 *Id*. at 1380.
50 *Diehr*, 450 U.S. at 188.