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PATENTS

Catching Fire: The Odds of Patent Eligibility For Life Sciences Patents Are No Longer in Favor

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The bounds of patent eligibility set forth in 35 U.S.C. § 101 have long been understood to end at laws of nature, natural phenomena and abstract ideas.[1] *In the past few years, the Supreme Court has shed new light on these exceptions, raising the bar for patent eligibility and, in turn, creating a groundswell of Section 101 challenges and ensuing rulings invalidating patents on this basis. At the outset, the majority of such challenges involved patents directed to business methods and other software-based technology. However, determinations of patent ineligibility are increasingly appearing in the life sciences realm. Unless and until the Supreme Court heeds the calls from the Federal Circuit judiciary to modify the framework of Section 101 analysis to account for inventions which apply conventional processes to certain types of new discoveries, many life science patents are at risk of being invalidated as patent ineligible, and, as Judge Lourie warns, "a crisis of patent law and medical innovation may be upon us."*[2]

[1] *See* Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014).

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I. Recent U.S. Supreme Court Decisions on Section 101

A New Framework for Patent Eligibilty Under Mayo

In *Mayo Collaborative Services v. Prometheus Laboratories Inc.*, the U.S. Supreme Court established a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from patents that are applications of those concepts and, thus, patent eligible.[3] First, a court must determine whether the claims are directed to a law of nature or other similarly patent-ineligible concept.[4] If so, courts must then consider whether additional elements add "significance" so as to "transform" the claimed subject matter into an inventive concept.[5] The Supreme Court specified, however, that any "purely 'conventional or obvious' " steps are "not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law."[6]

Alice Sparks a Change in Section 101 Jurisprudence

In *Alice*, the Supreme Court reiterated the two-step test set forth in *Mayo* for determining patent eligibility, this time focusing on claims allegedly directed to abstract ideas.[7] The court characterized the second step

[2] Ariosa Diagnostics, Inc. v. Sequenom, Inc., Nos. 2014-1139, 2014-1144, Lourie concurrence at 4 (Fed. Cir. Dec. 2, 2015) (denying rehearing en banc).
[3] 132 S. Ct. 1289, 1297-98 (2012).
[4] *See Mayo*, 132 S. Ct. at 1297.
[5] *Id.* at 1298, 1299.
[6] *Id.* (quoting Parker v. Flook, 437 U.S. 584, 590 (1978)).
[7] *Alice*, 134 S. Ct. at 2357-58.

as a search for an ''inventive concept,'' *i.e.*, an element or combination of elements ''sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.''[8] In other words, in order to transform an abstract idea into a patentable invention, the claims must add more than mere instructions to apply the abstract idea.[9]

As of August 2015, 69 percent of Section 101 motions to dismiss post-*Alice* are reported to have been fully or partially granted.[10] The majority of such motions have concerned business method and other computer-based patents.[11] That *Alice* has had such an impact on this area is not surprising, given that *Alice* itself concerned a computer-based scheme for mitigating settlement risk in financial exchanges.[12] However, the effects of *Alice* are now extending beyond software and business method patents to medical diagnostic inventions and other areas in the life sciences realm.

II. The Fire Spreads Beyond Computer-Based Patents

Federal Circuit Scorches Medical Diagnostics Patents

The Federal Circuit first applied *Alice* to life sciences patents in December 2014 in *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litigation*.[13] After discovering that mutations of the BRCA1 and BRCA2 genes can increase the risk of certain breast and ovarian cancers, Plaintiff-Appellant Myriad Genetics Inc., obtained both composition of matter claims reciting specific primers used to target this genetic sequence and method claims reciting techniques by which the particular gene could be compared against a patient's genetic sequence.

On appeal, the Federal Circuit first held that the ''primers'' claimed as compositions of matter were not protectable because they were ''structurally identical to the ends of DNA strands found in nature.''[14] The court next held the asserted method claims to be patent ineligible under *Alice*. Specifically, under step one, the court found that the method, which required screening for an altered BRCA1 gene by ''comparing'' the subject's sequence with a non-mutated version of the sequence, was an ineligible ''abstract mental process of 'comparing' and 'analyzing' two gene sequences.''[15] Under step two of the *Alice* test, the court found that the mechanism for the comparison involved only well-understood, routine, and conventional techniques; thus, it did not ''add 'enough' to make the claims as a whole patent-eligible.''[16] The court also made reference to the risk of preempting further discovery in the field, noting that ''[i]f the combination of certain routine steps were patent eligible, so too would different combinations of other routine steps.''[17]

The Federal Circuit again invalidated medical diagnostic method claims in *Ariosa Diagnostics Inc. v. Sequenom Inc.*in June 2015.[18] In *Ariosa*, the claims at issue involved methods of detecting paternally inherited fetal DNA (referred to as cell-free fetal DNA or cffDNA) in maternal blood samples and making a prenatal diagnosis based on such DNA.[19] Even though the court heralded the invention as having ''created an alternative for prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques that took samples from the fetus or placenta,'' the claims at issue were deemed patent ineligible under the *Mayo* framework.[20] First, the court found that the claimed methods were directed to ineligible subject matter since ''the existence of cffDNA in maternal blood is a natural phenomenon.'' [21] Next, the court concluded that ''the preparation and amplification of DNA sequences in plasma or serum were well-understood, routine, conventional activities'' and, thus, failed to add an inventive concept to the claimed natural phenomenon.[22] The court also rejected the patent owner's argument that alternative uses of cffDNA outside the scope of the claims demonstrated that the patent at issue was narrow and would not pose a preemption problem.[23] The court noted that ''[w]hile preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility.''[24]

District Courts Fan the Flames

District courts have also begun to use *Alice* as a mandate to invalidate other types of life sciences patents, even where preemption does not appear to be a concern. In *Celsis in Vitro Inc. v. CellzDirect Inc.*,[25] a district court in the Northern District of Illinois deemed processes for cryogenically freezing hepatocytes (a type of liver cell) patent-ineligible. The discovery at issue was that the cells could be frozen, thawed and refrozen without losing significant cell viability, which the court

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[8] *Id.* at 2355 (quoting *Mayo*, 132 S. Ct. at 1294).

[9] *See id.* at 2357.

[10] *See* Robert R. Sachs, *#AliceStorm in June: A Deeper Dive Into Court Trends, and New Data on Alice Inside the USPTO*, George Mason University School of Law, Center for the Protection of Intellectual Property (Aug. 10, 2015), http://cpip.gmu.edu/2015/08/10/alicestorm-in-june-a-deeper-dive-into-court-trends-and-new-data-on-alice-inside-the-uspto/; *see also* Edward L. Tulin & Kristen Voorhees, *Fast & Furious: Post-Alice Dismissals of Patent Infringement Cases Using Rule 12 Motions,* Bloomberg BNA, BNA's Patent, Trademark, & Copyright Journal 1 fig. 1 (Mar. 20, 2015) (reporting a complete or partial dismissal rate of 83%).

[11] *See Software Patents are Crumbling, Thanks to the Supreme Court*, Vox (updated Sept. 12, 2014), http://www.vox.com/2014/9/12/6138483/software-patents-are-crumbling-thanks-to-the-supreme-court; *see also* James Carroll et al., *After 'Alice': A Feedback Loop of Software Patent Invalidity*, Corporate Counsel (Sept. 3, 2015), http://www.corpcounsel.com/id=1202736364859/After-Alice-A-Feedback-Loop-of-Software-Patent-Invalidity (noting ''increased scrutiny of software and business method patents'').

[12] *See Alice*, 134 S. Ct. at 2351-52.

[13] 774 F.3d 755, 758-59 (Fed. Cir. 2014) [hereinafter *In re BRCA1*].

[14] *In re BRCA1*, 774 F.3d at 760.

[15] *Id.* at 763 (citation omitted).

[16] *Id.* at 764 (holding that there can be no inventive step where the claim elements other than those directed to the abstract idea ''do nothing more than spell out what practitioners already kn[ow]).

[17] *Id.* at 764 n.4.

[18] 788 F.3d 1371, 1373 (Fed. Cir. 2015).

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

[20] *Id.* at 1373.

[21] *Id.* at 1376.

[22] *Id.* at 1377-78.

[23] *See id*. at 1378-79.

[24] *Id*. at 1379.

[25] 83 F. Supp. 3d 774, 776 (N.D. Ill. 2015).

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deemed to be an ineligible law of nature.[26] Under step two of the *Alice* test, since the claimed freezing process was ''well-understood,'' the district court characterized it as merely a ''straightforward application of the truth that hepatocytes are inherently capable of surviving multiple freeze-thaw cycles.''[27] Of note, the court found the subject matter ineligible despite acknowledging that other parties were able to work around the patent by using a different mechanism—and in fact had done so already.[28]

Using similar reasoning, the District of Minnesota, in *Genetic Veterinary Sciences Inc. v. Canine EIC Genetics LLC*,[29] found a patent related to the identification of a mutation in dogs associated with Exercise-Induced Collapse (''EIC'') invalid under *Alice*.[30] The court determined that the claims were directed to patent-ineligible natural law because the claims ''serve[] the overarching purpose of 'determining whether a dog has or is susceptible to developing' EIC.''[31] In addition, because each claim employed conventional techniques to test susceptibility to EIC, the patent failed step two and was thus held to be invalid.[32] Once again, that the claims were narrowly tailored to detailed processes did not save them from patent-ineligibility.[33]

A district court in the Western District of Wisconsin, however, arrived at a different result when applying the *Alice* test to claimed methods for drug screening in *Ameritox Ltd. v. Millennium Health LLC*.[34] In this case, the court considered two patents: one directed to a method for drug screening via urine sample and one directed to a similar method via a sample of any biological material. In a stark contrast to other courts' rulings, this court found patent claims directed to testing a urine sample patent eligible because the application of conventional procedures to a urine analysis was itself unconventional.[35] Specifically, the court relied upon the fact that the particular combination of steps at issue produced a ''new and useful result'' to a known problem in the field.[36] In effect, the court deemed the claims patent eligible because the invention provided a ''novel'' solution.[37] The court also found the second patent directed to all biological samples—rather than only to urine—to be invalid under Section 101 because such claims were ''speculative'' and likely to ''preempt similar discoveries with respect to other biological samples.''[38]

III. Federal Circuit Justices Call for An Overhaul

While the determination of patent eligibility in *Ameritox* appears to conflict with the Federal Circuit's analysis in *In re BRCA1* and *Ariosa*, which was decided soon after *Ameritox*, future modifications to the 101 analysis may lead the law in the direction of the *Ameritox* ruling. Indeed, many Federal Circuit judges have voiced concerns with the current doctrine and have called for the U.S. Supreme Court's *Mayo*/*Alice* framework to be adjusted.

In his concurrence to the majority opinion in *Ariosa*, Judge Linn stated that he joined the majority's opinion on invalidity only because he was ''bound by the sweeping language of the test set out in *Mayo*,'' and opined that this test ''exclud[ed] a meritorious invention from the patent protection it deserves and should have been entitled to retain.''[39] Of particular concern to him was that ''[t]he Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish *Mayo* from this case, even though [in *Ariosa*] *no one* was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers.''[40]

In addition, when the Federal Circuit denied the petition to rehear *Ariosa en banc*, several judges penned opinions criticizing the framework which led to this result. Judge Lourie, joined by Judge Moore, wrote that under the current standard for Section 101 analysis, ''the whole category of diagnostic claims is at risk'' and that ''it is unsound to have a rule that takes inventions of this nature out of the realm of patent-eligibility on grounds that they only claim a natural phenomenon plus conventional steps.''[41] Judge Lourie also pointed to notable differences between the circumstances in *Mayo* and *Ariosa*: whereas the '' 'conventional activities' in *Mayo* were the very steps that doctors were already doing,''[42] in *Ariosa*, ''it is undisputed that before this invention, the amplification and detection of cffDNA from maternal blood, and use of these methods for prenatal diagnoses, were not routine and conventional.''[43] As a result, Judge Lourie suggested changing the Section 101 framework to avoid having to ''divorce the additional steps from the asserted natural phenomenon to arrive at a conclusion that they add nothing innovative to the process.''[44]

Judge Dyk's concurrence to the rehearing denial in *Ariosa* advocated a modification to the *Mayo*/*Alice* framework for inventions stemming from a discovery of something new in nature.[45] According to Judge Dyk, ''*Mayo* did not fully take into account the fact that an inventive concept can come not just from creative, unconventional application of a natural law, but also from

[26] *See Celsis*, 83 F. Supp. 3d at 783-85.
[27] *Id.* at 783-84.
[28] *Id.* at 785 (noting that the patent does ''not lock up [a] natural law in its entirety'').
[29] 101 F. Supp. 3d 833 (D. Minn. 2015).
[30] *Genetic Veterinary*, 101 F. Supp. 3d at 838-39.
[31] *Id.* at 843 (citation omitted).
[32] *See id.* at 843-44.
[33] *See id.* at 847-48.
[34] 88 F. Supp. 3d 885 (W.D. Wis. 2015).
[35] *See Ameritox*, 88 F. Supp. 3d at 911-12.
[36] *Id.* at 911 (noting that the claimed invention ''contain[s] an inventive concept because the process described seeks to implement a novel solution to a pre-existing problem in the field'').
[37] *Id.* at 911-12.
[38] *Id.* at 917 (''[I]t is the very combination of integers in the [urine] patent that supplies the inventive concept to that invention.'').
[39] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1380 (Fed. Cir. 2015).
[40] *Id.* at 1381 (emphasis in original).
[41] Ariosa Diagnostics, Inc. v. Sequenom, Inc., Nos. 2014-1139, 2014-1144, Lourie concurrence at 4, 7 (Fed. Cir. Dec. 2, 2015) (denying rehearing en banc).
[42] *Ariosa*, 788 F.3d at 1380-81.
[43] Ariosa Diagnostics Inc. v. Sequenom Inc., Nos. 2014-1139, 2014-1144, Lourie concurrence at 6 (Fed. Cir. Dec. 2, 2015) (denying rehearing en banc).
[44] *Id.*
[45] *See id.*, Dyk concurrence at 5.

the creativity and novelty of the discovery of the law itself.''[46] This is ''especially true'' in the life sciences, ''where development of useful new diagnostic and therapeutic methods is driven by investigation of complex biological systems.''[47] Under his proposed approach, if the breadth of the claim is ''sufficiently limited to a specific application of the new law of nature discovered by the patent applicant,'' then ''the novelty of the discovery should be enough to supply the necessary inventive concept.''[48] Judge Dyk closed his concurrence with the hope that a future case will provide the Supreme Court with the appropriate opportunity to revisit the *Mayo*/*Alice* framework.[49]

Judge Newman authored a dissent to the *Ariosa* rehearing decision, focusing on the very differences between *Mayo* and *Ariosa* discussed by the concurrences, but maintaining that such differences required the opposite result even under the existing *Mayo* framework because the claimed method, the diagnostic knowledge and the benefit implemented by the method were all previously unknown.[50]

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The many discussions surrounding the *Mayo*/*Alice* framework in *Ariosa* demonstrate that at least five members of the Federal Circuit judiciary believe that patent eligibility determinations for inventions based on new discoveries should turn on whether the claimed implementation of such discovery is novel and not merely on whether individual steps had been used before in other contexts. Nevertheless, until the *Mayo*/*Alice* is framework is modified, many life sciences patents remain at great risk of being invalidated as patent ineligible.

[46] *Id.* at 6-7.
[47] *Id.* at 7.
[48] *Id*. at 9.
[49] *See id*. at 9.

[50] *Id.*, Newman dissent at 1-2.

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