The Patent Eligibility Battle for Life Sciences Companies in a Changing Landscape

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Over the last few years, the United States Supreme Court has changed the landscape of patent eligibility with its decisions in *Mayo Collaborative Servs v Prometheus Labs, Inc.* 132 S. Ct. 1289 (2012) and *Alice Corp Pty Ltd v CLS Bank Int'l*, 134 S. Ct. 2347 (2014). While patent eligibility was not a primary focus in the life sciences area, the Supreme Court decisions and their progeny have sent shock waves through the life sciences field. Numerous biotech and diagnostic patents have been found to be ineligible under the threshold patent statute. This article addresses the changing landscape and key court decisions, suggests new avenues for companies to navigate the changed landscape and provides practical suggestions for companies in protecting and enforcing patents in the life sciences area.

United States Code 35. U.S.C. § 101 informs practitioners on what it takes for an invention to pass the threshold test of patentability. Considering all of the controversy that it invites, it may surprise some that patent eligibility is addressed in just one sentence: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” Interpretation of this section has changed significantly as the Supreme Court and the Court of Appeals for the Federal Circuit (Federal Circuit) decide complex patent infringement issues involving patent eligibility. Patent eligibility, once deemed a gatekeeper in name only, has now become one of the most prominent defenses to patent infringement.

In many ways, life science patent disputes have formed the foundation of the current patent eligibility landscape. Cases like *Mayo* and *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) are nearly synonymous with the term “patent eligibility.” In perhaps the first recent disruptive patentability case, the Supreme Court, in *Mayo* held that claims for methods of detecting a correlation between a metabolite, and the likelihood of a drug response, were not patentable. In invalidating the patent in question, the Court found that its claims did not recite anything “significantly more” than a natural law. The following year, in *Myriad* the Court held that claims to an isolated nucleic acid that encodes BRCA1 and BRCA2 genes, were patent-eligible. However, the Court held that the claims to an isolated nucleic acid that encodes BRCA1 and BRCA2 genes, were not patent-eligible because they were directed to a natural product. The *Myriad* decision reversed *Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980) which had long held that isolated biological materials, which were otherwise not found in nature, were patentable.

In view of these decisions, both courts and the United States Patent Office (USPTO) use a two pronged test that combines the logic in *Mayo* and *Myriad*: (1) is the patent claim directed to a judicial exception and (2) is there any element or combination in the claims that amount to “significantly more” than the judicial exception.

Post *Mayo* and *Myriad*, the Federal Circuit addressed the “significantly more” standard created in *Mayo in Myriad Genetics et. al. v. Ambry Genetics Corp.*, 774 F.3d 755 (Fed. Cir. 2014). The Court evaluated Myriad’s nucleotide primers for amplifying BRCA1 and BRCA2 genes, and methods of comparing BRCA genotypes to diagnose breast cancer, and held that neither sets of claims were patent eligible. First, it found that since Myriad’s primers shared sequences, as well as a base-pairing function, with those of naturally occurring nucleic acids they were not
patent-eligible. Second, applying the two-pronged Mayo test, it determined that the method claims were directed to an abstract idea of comparing and determining the existence of alterations, with the absence of “significantly more.”

Myriad Genetics gives patent attorneys direction when drafting and prosecuting patents and litigants guidance when assessing claims. Even if the invention appears to be directed to an abstract idea, there is a chance at patentability if a patentee can show something significant that the invention adds to the idea. These cases have also formed the foundation of the Supreme Court’s Alice v. CLS Bank International, 134 S. Ct. 2347 (2014) decision that is now also referenced to denote the two step patentability test used in almost every forum of patentability dispute.

Key Developments Post Mayo and Myriad

Courts have applied the Mayo and Alice tests to determine patentability in countless disputes in the life sciences space. Each application of the test has given courts new opportunities to clarify the Mayo and Alice tests for different applications.

In Ariosa Diagnostics v. Sequenom, Inc., 788 F.3d 1371, 1373 (Fed. Cir. 2015), the claims at issue were directed to a method of using cell-free fetal DNA (cfDNA) circulating in maternal plasma to diagnose fetal abnormalities. The method included 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.

The Federal Circuit held that the patent failed the two step Mayo test. First, the Court determined that the claims were directed to patent-ineligible subject matter, because the “method begins and ends with a natural phenomenon.” Second, it held that the claimed method does not “transform” the naturally occurring phenomenon into a patent-eligible application. The Court emphasized that the process steps for encompassing a natural phenomenon must be “new and useful” to transform the phenomenon into one that’s patent eligible. The patentee’s petition for rehearing en banc, as well as a petition to the Supreme Court, were both denied.

Nevertheless, in a rare bright spot, in Rapid Litigation Management Ltd. v. CellzDirect, Inc, 827 F.3d 1042 (Fed. Cir. 2016), the Federal Circuit overturned the District Court’s finding of patent ineligibility. The patents-in-suit related to a method of preserving hepatocytes. The District Court, applying the Mayo test, found the patents directed to a law of nature, in that the cells were able to survive freeze-thaw cycles, and thus lacked an inventive concept. The Federal Circuit on the other hand held that the patent was not directed to a law of nature, but instead, a “new and useful laboratory technique.” Further, the Court found that, even if the patent was directed to a law of nature, it possessed an inventive concept. The Court proffered some guidance, stating that “patent-eligibility does not turn on ease of execution or obviousness of application.” Thus, while pre-emption is not the test for eligibility, a lack of pre-emption can show that a natural law is not being monopolized and can indicate the possibly of patentable subject matter.

In a further development, in June 2018, the USPTO issued new guidance that suggests that patents on methods of treating disease should usually be considered patent-eligible. In its memo, the USPTO explained that examiners should apply the Federal Circuit’s ruling in Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int’l Ltd., 87 F.3d 117 (Fed. Cir. 2018) which held that its schizophrenia drug Fanapt is eligible for patenting under the Mayo test. In particular, the Court emphasized that method of treatment patents should be analyzed as a whole not just by looking at the parts dealing with natural phenomena. This guidance provides much needed relief for the life sciences industry and indicates that when patents cover methods of treatment involving practical applications of natural relationships, they should be considered patent eligible.

A New Layer to the Landscape

A more recent case Steven E. Berkheimer v HP INC., FKA Hewlett-Packard Company, 881 F. 3d 1360 (2018) adds yet another layer to the evolving Mayo/Alice framework. In Berkheimer the Federal Circuit raised the evidentiary requirements for patent ineligibility petitioners. Using the Alice analysis, the Court stated: “[f]irst, we determine whether the claims at issue are directed to” a patent ineligible concept. If so, “we 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.” Id. at 1365.

But, the Federal Circuit decided that “[t]he mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.” Id. at 1369. It went on to say: “[t]he question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence.” Id. at 1367. The Federal Circuit effectively raised the minimum requirement for patent invalidity.
It is no longer enough for a court, board, or examiner to conclude patent invalidity due to a plausible showing of “not significantly more.” The invalidator must see support for such an argument with clear and convincing evidence. This applies to both patent validity disputes, and patent prosecution. Indeed, the USPTO has instructed its patent examiners to provide evidence to substantiate their “not significantly more” arguments during the patent prosecution process. This may raise the acceptance rate for patents that otherwise would be rejected.

**Using Alternative Forums**

As the law and industry evolve, litigants are increasingly seeking resolution for their patentability disputes in new forums. Many disputes now take place in forums such as the PTAB and the ITC, which can offer streamlined processes that resolve faster than District Court litigation. Practitioners, particularly in the ever-evolving life sciences industry, should strategize to take advantage of the most appropriate forum given their differences and limitations.

**The Patent Trial and Appeals Board (PTAB)**

While the PTAB is an increasingly popular forum, practitioners should keep in mind key differences between the PTAB and the courts when planning patent infringement actions. A case in point is *Phigenix, Inc. v. ImmunoGen, Inc*, 845 F.3d 1168 (Fed. Cir. 2017). Phigenix initiated an Inter Partes Review (IPR) against ImmunoGen’s patent for an antibody maytansinoid conjugate before the PTAB and was ultimately unsuccessful. On appeal to the Federal Circuit, ImmunoGen filed a motion to dismiss based on Phigenix’s lack of standing which was granted.

While Phigenix’s original cause of action did not require a “case or controversy” and “injury in fact” because the PTAB is an Article I Tribunal, the Article III Federal Circuit where an appeal was sought does. Phigenix informed the PTAB that it brought the IPR to bolster the value of its patent portfolio -- a “cause of action” that does not rise to the level of standing required for an Article III court leading to dismissal based on standing. This case serves as a good reminder of forethought and procedural awareness in deciding between forums.

**The International Trade Commission (ITC)**

Although not as popular as the PTAB, the ITC is an increasingly utilized forum for life sciences patent disputes. This is possible because Section 337 of the Tariff act of 1930 specifies that:

“The importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer, or consignee, of articles that... are covered by the claims of a valid and enforceable United States patent” is “unlawful.” 19 U.S.C. §1337

In light of this prohibition, patent owners often bring claims against importers of goods that may infringe on patented inventions. While Section 337 of the Tariff act of 1930 does not create a cause of that encompasses patent eligibility, as with many patent matters, the issue of patent infringement may turn on patent eligibility in an ITC Section 337 hearing.

One of the most notable such examples is Administrative Law Judge (ALJ) Shaw’s analysis in the ITC investigation, *Certain Portable Electronic Devices and Components Thereof, (337-TA-994)*. ALJ Shaw evaluated whether the organizational methods, claimed in U.S. Patent No. 6,928,433, were patentable. Using the *Mayo/Alice* test, ALJ Shaw determined that the claim in question was “directed to the abstract idea of an organizational hierarchy,” and invalidated the patent. This shows that patent owners, engaging in any form of patent dispute must be aware of the implications of patent validity and also be aware of the forum’s ability to make a determination of patentability. It is possible to walk into an ITC investigation with a valid patent and leave without it.

**Looking Ahead**

As the jurisprudence continues to evolve, practitioners can be confident that there will be many more changes in the patent eligibility battle. Life science patents have formed the foundation of the patent eligibility landscape and they continue to significantly impact the law and industry as they have over the past decade. As we look forward at the changing patentability landscape, it is likely that practitioners will see life science patents at the forefront of the changes to come.


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