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IN THIS ISSUE

Joseph E. Kovarik and Ben Roxborough report on the ramifications of two seminal Supreme Court decisions in the area of patent law dealing with patent eligibility. The recent confusion as to what is patentable under 35 USC §101 has created havoc for patent prosecutors and litigators, and threatens the viability of already issued patents.

The Patent Ineligibility Tsunami: The Impact of the *Mayo* and *Alice* Decisions on the Future of Innovation

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Introduction

No two decisions in the last decade have impacted patent practice more than the Supreme Court's *Mayo* and *Alice* decisions. Since *Alice* was issued in July 2014, 67 percent of all lower court cases—dealing with the defense of patent ineligibility under section 101—have invalidated the patent-in-suit.[1] The *Mayo* decision in March 2012 sparked the demise of broad patents in the life sciences, especially those in the diagnostic arena. The *Alice* decision did much the same for software patents. The patent ineligibility defense, therefore, has culled patents primarily in these industries—eroding significant pillars of the modern American economy.[2] Indeed, what was once a complete rarity in both patent prosecution and litigation practices just five years ago, has now become a critical concern. While there are some hopeful signs that the patent ineligibility tsunami wave may be waning, its potential devastation to existing patent portfolios has yet to be fully appreciated.

Section 101: The *Mayo* and *Alice* Decisions

Section 101 of Title 35 U.S.C. sets forth what is patent eligible and provides that, "[w]hoever *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." Traditionally, the test has been applied as a broad filter—with narrowly tailored judicial exceptions, i.e., laws of nature, natural phenomena, and abstract ideas are patent ineligible. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014).

In *Alice*, for example, the Supreme Court examined patent claims that recited a method for mitigating settlement risk using shadow credit records held by a third-party intermediary (a 'clearing house'). The Court held that the claims were drawn to an "abstract idea" because the use of a third-party intermediary was considered a building block of "fundamental economic practice." *Id.* at 2356. Evidence used to support this conclusion was predicated on well-known articles and treatises.[3] The Court further likened the use of an intermediary to that of hedging, also being an abstract idea beyond the scope of §101. *Id.* Merely using a computer was deemed insufficient to confer patentable status to an invention, with the Court stating that the process claims "amount[ed] to nothing significantly more than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer." *Id.*

In *Mayo*, the patents concerned the use of thiopurine drugs for the treatment of

[1] Robert R. Sachs, *Alice Brings A Mix Of Gifts For 2016 Holidays*, Bilskiblog: http://www.bilskiblog.com/blog/2016/12/alice-brings-a-mix-of-gifts-for-2016-holidays.html (last visited December 30, 2016).

[2] Robert Carlson, *Estimating the biotech sector's contribution to the US economy*, Nature Biotechnology 34, 247–255 (2016)

[3] See, e.g., Yadav, *The Problematic Case of Clearinghouses in Complex Markets*, 101 Geo. L. J. 387, 406-412 (2013); J. Hull, *Risk Management and Financial Institutions* 103-104 (3d ed. 2012).

autoimmune diseases. *Mayo Collaborative Services v. Prometheus Laboratories, Inc*., 132 S. Ct. 1289 (2012). Doctors knew that such drugs could be helpful in treating Crohn's disease and that the drugs' toxicity or effectiveness could be measured relative to how thiopurine metabolized in the body. Going one step further, however, the patentee discovered the optimal ratio of thiopurine drugs that could be used for individual patients based on the levels of metabolites in the blood after the drugs were administered. In short, the patented invention devised a method to personalize the use of thiopurine drugs to guard against toxicity. The crux of the patent was directed to three steps: (1) an administering step, (2) a determining step, and (3) a "wherein" step that merely provided context.

In reversing the Federal Circuit's decision, the Supreme Court held that steps (1)-(3) were ***not*** considered significant enough so to transform the invention into one that should gain patent protection under 35 U.S.C. § 101. The first two steps were dismissed as something that a doctor would typically do—i.e., as "nothing more [than] well understood, routine, conventional activity previously engaged in by scientists who work in the field." *Id.* at 1297. And the third step was described as the equivalent to "Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant." *Id.* In sum, because the patent claims were directed to a natural law, and because the claims failed to add significantly more, the patented claims were held invalid under section 101.

The Legal Test for Section 101

As drawn from the above cases, the modern framework for determining patent eligibility requires a two-step analysis. *First*, a court determines "whether the claims at issue are directed to one of those patent ineligible concepts"—i.e., whether the claims are directed to laws of nature, natural phenomena, or abstract ideas. *Alice*, 134 S. Ct. at 2355. *Second*, a court determines whether the claims include an additional element or a combination of elements that constitute 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." *Id.*

While simple to articulate, the test has presented problems for patent prosecutors and litigators alike.

The Implications of the *Mayo* and *Alice* Decisions on Patent Prosecutors and Litigators

For patent prosecutors, the implications of the *Mayo* and *Alice* decisions have been significant. In the absence of clear and consistent guidance from the USPTO as to how the two-step framework is to be applied, traversing rejections becomes a crapshoot. For example, what is an "abstract idea?" And what constitutes something that is "significantly more" than an abstract idea? The second question folds upon the first—

leading to nothing more than a conclusory analysis.

The USPTO's several issued guidelines to determine the scope of the Supreme Court's *Mayo* and *Alice* decisions have provided only piecemealed and confusing directions. Since July 2014, there have been four substantive memoranda issued (plus many more updates). Between the months of May and October 2016, the USPTO issued monthly updates to examiners (and the public). This was unprecedented for the USPTO—highlighting the difficulties that the Supreme Court's decisions pose for both the agency itself and patent prosecutors.

Such uncertainly has created a groundswell for legislative change by patent bodies such as the American Intellectual Property Law Association (AIPLA) and the Intellectual Property Owners (IPO), along with companies such as Microsoft, Proctor & Gamble Co., Qualcomm, GlaxoSmithKline, Lockheed Martin and Novartis to name but a few. But while the need for legislative changes to section 101 has gained momentum, they ignore that the exceptions to section 101 are judicially imposed. Legislative change would thus need to focus on the Court's judicially imposed exceptions; not necessarily the section itself.

For patent litigators, the ramifications of the *Mayo* and *Alice* decisions have been equally dramatic. In an unprecedented fashion, defendants are increasingly using motions to dismiss to entirely extinguish patent rights at the onset of litigation. And the success rates have been high.[4] In the first year following *Alice*, federal courts invalidated patents at an alarming rate—80 percent.[5] And while that percentage has dropped to 50 percent over the past year,[6] these figures are still extraordinary—particularly given the standards that purportedly safeguard non-moving parties in the Rule 12(b)(6) context.

In the pre-*Alice* landscape, not one federal court invalidated a patent based on section 101 grounds at the Rule 12(b)(6) stage. But in the post-*Alice* landscape, federal courts are now doing so routinely. The table below illustrates this phenomenon more clearly—depicting the fact that section 101 challenges, set in the Rule 12(b)(6) context, are even more extreme than other defenses because the Supreme Court has, as of yet, failed to invalidate patents at the same, nascent stage of litigation:

[4] Robert R. Sachs, *Alice Brings A Mix Of Gifts For 2016 Holidays*, Bilskiblog: http://www.bilskiblog.com/blog/2016/12/alice-brings-a-mix-of-gifts-for-2016-holidays.html (last visited December 30, 2016).

[5] *Id.*

[6] *Id.*

STATUTORY DEFENSE	SUPREME COURT DISMISSING CASE AT RULE 12(b)(6) STAGE	FEDERAL CIRCUIT DISMISSING CASE AT RULE 12(b)(6) STAGE
§ 101 - Patent Eligibility	Never	**Yes**[7]
§ 112 - Enablement	Never	Never
§ 112 - Indefiniteness	Never	Never
§ 102 – Novelty	Never	Never
§ 103 – Obviousness	Never	Never

Indeed, despite the Supreme Court stating in dictum that §§ 101, 102 and 103 require "various factual determinations," courts have taken a liberal view of such guidance and have tended to treat section 101 as a pure question of law. *Cf. Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011) ("To receive patent protection a claimed invention must, among other things, fall within one of the express categories of patentable subject matter, §101, and be novel, §102, and nonobvious, §103 . . . In evaluating whether *these* and other statutory conditions have been met, PTO examiners must make various *factual determinations*.") (emphasis added.)

For example, in a case where the patentee discovered that 'junk' DNA could be used to locate genes in the coding region of a DNA sequence, the Federal Circuit upheld the dismissal of the claims as being patent ineligible at the Rule 12(b)(6)stage. While scientists in 1989 had not used "junk" DNA in this fashion previously, the Federal Circuit concluded that this type of activity was nevertheless "conventional" as a matter of law. *Genetic Techs. Ltd. v. Merial L.L.C.,* 818 F.3d 1369, 1372 (Fed. Cir. 2016).

Conclusion and the Years Ahead…

Recent cases in the past six months appear to have pulled back from the § 101 onslaught. *See, e.g. Enfish, LLC v. Microsoft Corp*., 822 F.3d 1327, 1337 (Fed. Cir. 2016) (Subject matter should not be "described at a 'high level' of abstraction and untethered from the language of the claims because doing so ensures that exceptions to 35 U.S.C. § 101 will swallow the rule."); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.,* 827 F.3d 1042, 1051 (Fed. Cir. 2016) ("Repeating a step that the art taught should be performed only once can hardly be considered routine or conventional. This is

[7] For the past 18 months, the Federal Circuit has been holding business method patents ineligible under section 101 at the Rule 12(b)(6) stage. *See OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362 (Fed. Cir. 2015).

true even though it was the inventor's discovery of something natural that led them to do so."); *Trading Technologies International, Inc. v. Cqg, Inc.,* No. 2016-1616 (Fed. Cir. Jan. 18, 2017)(the public interest in innovative advance is best served when close questions of eligibility are considered along with the understanding flowing from review of the patentability criteria of novelty, unobviousness, and enablement,..."). Recent district court decisions are also picking up on a more detailed analysis. *See Verint Systems Inc. v. Red Box Recorders Ltd.*, 2016 WL 7156768, at *1-2. (S.D.N.Y., Dec. 7 2016).

Each of these decisions demonstrate an analysis that is more than just conclusory. Each illustrates how the two-step framework can be applied in a way that goes beyond a facial analysis of section 101 in determining what is—and what isn't—patent eligible. Indeed, in *Verint*, Judge Katherine B. Forrest was highly critical of decisions that described an invention at "high level[s]" in a "few words"—calling the "current fad of ineligibility decisions [one that has] . . . gotten ahead of itself." *Id.* These decisions offer hope to American businesses that hold patents in these areas, but whether these decisions will be enough to drawback the tide from the post-Alice 101 tsunami is hard to predict. What is certain, however, is that until there is greater certainty in this area of the law, the American economy will remain impinged. There are literally thousands of patents issued over the past five years that are owned by software and biotech companies—all of which presently enjoy the presumption of validity. Any attempt to enforce such patents, however, will invariably expose them to an immediate and scary challenge under section 101 in the face of 12(b)(6) motions to dismiss. Assertion of patent rights in this environment may entail far too much risk for these established and important industries. Thus, the potential devastation to the patent landscape cannot be fully appreciated at present. The further development of the case law and/or legislative changes in the next year will provide interesting clues as to the extent of damage that the patent ineligibility tsunami of *Mayo* and *Alice* has wrought.

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