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Expert Analysis

Patents for Computer and Life Science Technologies Making a Comeback?

In recent years, the U.S. Supreme Court has significantly shifted its attention in patent cases to the law regarding patent-eligible subject matter under 35 U.S.C. §101, making it more difficult to obtain and enforce patent protection for computer- and life-science-related technologies. Section 101 precludes patent protection for particular subject matters—i.e., laws of nature, natural phenomena and abstract ideas—and the Supreme Court's precedent has extended this exclusion to many cutting-edge technologies. Stakeholders have become alarmed that patent protection for foundational technologies is in jeopardy. Their concern is well founded.

Very few courts have upheld the validity of patent claims directed to computer-related technologies since the Supreme Court's shift. In fact, many district court judges have dismissed cases based on patent ineligibility even before the claim language has been construed or any facts considered. Similarly, life science patents have been held invalid



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as covering laws of nature or natural phenomena.

Such a trend could have serious implications on America's ability to be competitive in the global marketplace at a time when high-tech and biotech advances constitute major areas of innovation. However, two recent Federal Circuit cases (*Rapid Management Litigation* and *McRO*) suggest there may be reasonable boundaries on the court's principles for excluding patent protection. These recent decisions provide clues on how to draft claims that can survive a §101 challenge thereby allowing stakeholders to obtain and enforce patent claims that comport with the Supreme Court's jurisprudence under §101.

Supreme Court Takes Action

In 2012, the Supreme Court took up the issue of patent eligibility in *Mayo Collaborative Servs. v. Prometheus*

Labs., 132 S. Ct. 1289 (2012). It was a time when the court had—a few years earlier—held that certain patent claims to business methods were not patent-eligible because they were directed to an abstract idea. See *Bilski v. Kappos*, 561 U.S. 593 (2010). Now the court was seeing additional problems with patents and patent litigants. First,

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many patent suits were originating with non-producing entities who made aggressive patent licensing and litigation threats a part of their business model. Second, it was a time when many commentators questioned the quality of patents being granted by the U.S. Patent and Trademark Office.

The *Mayo* case addressed claims directed to a patient taking a specified amount of medication based on the concentration of metabolites found in the patient's body. The question presented to the court was whether these claims are patent-eligible under 35 U.S.C. §101.¹

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Reasoning that the connection between metabolite level and the necessary amount of medication involved a law of nature, the Supreme Court ruled that these claims were not patent-eligible. Specifically because the claims were directed to “well-understood, routine, conventional activity previously engaged in by researchers in the field” with the simple further instruction to apply it, the claims were held not patent-eligible. Significantly more than simply reciting a natural law and adding the words “apply it” must be claimed to be patent-eligible.

Less than a year later, the Supreme Court addressed patent eligibility in *Myriad Ass’n for Molecular Pathology v. Myriad Genetics*, 133 S. Ct. 2107 (2013). The patentee in *Myriad* asserted claims directed to certain isolated naturally occurring DNA sequences known as BRCA1 and BRCA2 and methods of using the sequences to diagnose breast cancer. The court held those claims invalid as patent-ineligible. However, in dicta, the Supreme Court left open the door to patents directed to “new applications of knowledge” stating that such applications of knowledge could be patent-eligible.

The following year, the Supreme Court clarified the principle set out in *Mayo* with a two-step test to analyze patent claims for compliance with 35 U.S.C. §101 in *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014). The first step of this test inquired whether the claim at issue is “directed to” one of the exceptions to patent eligibility, such as an abstract idea. If so, then step two would determine whether the claims—both their individual elements and as a whole—contain

an “inventive concept” sufficient to “transform the nature of the claim” into a patent-eligible application.”

Using this two-step test, the court held that “if a patent’s recitation of a computer amounts to a mere instruction to ‘implement’ an abstract idea ‘on a computer,’ that addition cannot impart patent eligibility.” The *Alice* ruling had a significant impact on computer-related patents, putting the industry on notice that it can no longer rely on patent protection for methods of doing business by using a general purpose computer.

Fallout for Industries

Both the high-tech and life sciences industries have been seriously affected by these holdings.

Since the *Alice* decision in June 2014, there have been 137 computer-implemented method patents that have been invalidated by the district courts. Of those 137 invalidated patents, 44 were invalidated pursuant to a motion to dismiss on the pleadings, 48 were invalidated pursuant to a motion for summary judgment, and 45 were invalidated by a district court judge after conducting a trial. Thus, of the high-tech patents asserted in litigation, 57 percent have been found invalid as directed to patent-ineligible subject matter.² Further, 75 percent of these decisions were affirmed by the Federal Circuit.³

Post-*Alice*, the major question for those in the high-tech industry has been whether the courts might use *Alice* to strike down the entire class of patents as patent-ineligible for merely reciting process steps implemented on a computer. The Supreme Court decisions have raised similar concerns among life sciences companies that

rely heavily on patent protection to justify commercial development of a new product. The holdings have clouded the validity of thousands of already-granted U.S. patents and materially affected the strategy companies follow to protect potential biologic product candidates.

Even the dicta in *Myriad*, which left a faint hope alive that claims covering the application of natural phenomenon (and even isolated compounds) may be patent-eligible was dashed when a claim directed to an application of a natural phenomenon was struck down as patent-ineligible. See *Ariosa Diagnostics v. Sequenom*, 788 F.3d 1371, reh’g en banc denied, 809 F.3d 1282 (Fed. Cir. 2015) (per curiam), cert. denied, 136 S. Ct. 2511 (2016). The claims in *Ariosa* were directed to the specific application of extracting, amplifying and detecting paternal cell-free fetal DNA in maternal serum.

Although the Federal Circuit denied a rehearing in *Ariosa*, Judge Pauline Newman dissented, arguing that the Supreme Court’s precedent did not warrant invalidating the *Ariosa* claims. Relying on the Supreme Court’s interpretation of §101 based on preemption, Judge Newman reasoned that per *Myriad* “patenting of this new diagnostic method” was patent-eligible because it did not “preempt further study of this science.”

New Hope

For many, *Ariosa* has been a low point for patent eligibility. Recently, the Federal Circuit has showed signs of moving away from a restrictive reading and has instead moderated its view of § 101, providing new hope to patentees in both the life-sciences and high-tech fields. The Federal

Circuit has begun analyzing the first Alice step by focusing on whether the claimed subject matter preempts the claimed field to produce a more balanced legal framework for determining patent eligibility.

In one recent Federal Circuit case, *Rapid Litigation*, the claims at issue were directed to using a specific process for repeatedly freezing and thawing liver cells to produce a set of viable cells. See *Rapid Litig. Mgmt. v. Cellzdirect*, 827 F.3d 1042 (Fed. Cir. 2016). Although the district court found the claims invalid as claiming a law of nature, the Federal Circuit reversed stating that under step one of the two-step test, the claims are directed to more than just multiple cycles of freezing and thawing liver cells and thus do not preempt a law of nature.

When looking to the claim as a whole, the court stated: “The claims are directed to a new and useful method preserving hepatocyte cells. Indeed, the claims recite a ‘method of producing a desired preparation of multi-cryopreserved hepatocytes’” and that, according to the specification, “achieves a better way of preserving hepatocytes” than other known methods. Because the claims specifically recited the technical improvement, the Federal Circuit found other methods would not be preempted and thus found step one had been satisfied.

Similarly, the Federal Circuit in *McRO* clarified its stance on whether software-related inventions were eligible for protection, answering in the affirmative to the relief of many in the high-tech field. *McRO v. Bandai Namco Games Am.*, No. 15-1080, 2016 WL 4896481 (Fed. Cir. Sept. 13, 2016). Here too, the Federal Circuit found

that the claims were not directed to an abstract idea under step one of the test and therefore were patent-eligible.

McRO’s patent claims were directed to automating 3-D animation by using a particular set of rules which provided an advancement over known methods. As explained in the specification, 3-D animation uses multiple 3-D models of a character’s face to depict various facial expressions made during speech. Using prior methods, an animator had to manually determine how to morph the character’s

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face between the various 3-D models of facial expression.

Applying the two-step test as articulated in *Rapid Litigation*, the Federal Circuit found the claims required more than the abstract idea of using any rules-based approach to animate 3-D models. Indeed, the recited rules themselves had specific requirements that did not “preemp[t] all techniques for automating 3-D animation that rely on rules” and thus the claims were patent-eligible subject matter.

Post-Alice, Mayo and Myriad

Given the recent *Rapid Litigation* and *McRO* decisions, the Federal Circuit seems to have provided a more balanced framework to assess patent eligibility. The common theme running through both *Rapid Litigation*

and *McRO* is that the specification must explain the technical improvements which in turn must be specifically recited in the claims. In addition, as *McRO* points out, even generic claims may be patent-eligible so long as the claims specifically recite the necessary steps or rules and do not preempt all other techniques in the claimed field.

Finally, the court’s current focus on recitation of technical improvements and on consideration of what the claims are “directed to” may be a signal that the Federal Circuit may be gently shifting its focus to analyzing claims under other statutory provisions addressing novelty and enablement.



1. The patent laws of the United States define patent-eligible subject matter under §101 as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” Although expansive, the language of §101 is not limitless. The Supreme Court has read §101 as excluding from patent protection “laws of nature, natural phenomena, and abstract ideas.” *Diamond v. Diehr*, 450 U.S. 175 (1981). The reason for this exclusionary principle stems from a concern of preemption. See *Alice Corp. Pty. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014). Laws of nature (like gravity), natural phenomena (like the DNA sitting in our chromosomes), and abstract ideas (like mathematical algorithms) are the “building blocks of human ingenuity” and therefore may not be used by one for all purposes. *Id.* Monopolization of these tools by the grant of a patent might tend to impede innovation more than it would tend to promote it, thereby thwarting the primary object of the patent laws.

2. The statistics are based on research by LegalMetric, a legal research company, in a paper titled “Patent Eligibility Win Rates post-Alice to June 2016.”

3. The statistics are based on research by LegalMetric, in a paper titled “Percentage of Patent Ineligibility Decisions Affirmed June 2014 to October 2016.”