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Expert Analysis

Trends in Patents and Trade Secrets Change Landscape of Innovation

“It is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.”

—*Ariosa v. Sequenom*
2015 U.S. App. LEXIS 20842
(Fed. Cir. 2015) (en banc)



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The above quote by Judge Alan Lourie of the U.S. Court of Appeals for the Federal Circuit artfully captures what some would say is a disturbing trend, narrowing the scope of patentable subject matter, which has seen many otherwise valuable and groundbreaking inventions dedicated to the public and denied patent protection. In the wake of this trend, alternative forms of intellectual property (IP) protection are becoming more appealing. If the trend continues and the pendulum continues to swing away from patent protection, then the incentive to innovate will be disrupted and public access to cutting edge technological innovation will be stunted.

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The ability to protect IP is fundamental to the incentive to innovate and a key component to competition. IP, however, is not one-size-fits-all. There are different types of IP that

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are available, depending on what you are looking to protect. This article focuses on two types of IP relevant to high tech and life sciences innovation—patents and trade secrets. In particular, this article addresses the recent trends in patent and trade secret law and how, as Judge Lourie opined, those trends may be changing the landscape of innovation.

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areas of innovation, they have remarkably different public impacts. Patents are publicly facing and require public disclosure of information describing and teaching the patented technology. The public benefits from that information and, in exchange, the inventor or inventors receive a government-granted monopoly for a finite period of time. Trade secrets, on the other hand, are by necessity private. Like the Coca-Cola formula, the public may have the benefit of the ultimate product, but they are not entitled to the information behind it. Unlike the impact of patents, the public cannot use the substance of trade secrets to perpetuate innovation.

There has been significant recent activity in three prominent governmental bodies impacting patent and trade secret laws: The Supreme Court has addressed, and narrowed, the scope of patentable subject matter under 35 U.S.C. §101; the Federal Circuit has applied that scope, despite its own expressed disagreement with the result; and Congress has recently passed the Defend Trade Secrets Act of 2016 (DTSA, signed into law on May 11, 2016), which provides civil federal trade secret protection. This activity portrays a narrowing scope of patent

protection and a growing availability of a more predictable trade secret enforcement regime.

Patent Eligibility

There are three core requirements for obtaining a United States patent, codified in Title 35 of the U.S. Code. First, the purported invention must be useful, or satisfy the “utility” requirement of §101. Second, it must be new, or satisfy the “novelty” requirement of §102. And third, it must be non-obvious under §103.

The utility requirement also serves a gatekeeping function for what constitutes patentable subject matter. While there are no explicit statutory prohibitions on patentable subject matter, there are some well-developed judicially-created exclusions: “laws of nature, natural phenomena, and abstract ideas.” *Diamond v. Diehr*, 450 U.S. 175 (1981). The Supreme Court justified these restrictions with reference to fundamental laws that were discovered but still unpatentable: “Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (quoting *Funk Bros. v. Kalo*, 333 U.S. 127 (1948)). Thus, an inventor attempting to patent something novel, non-obvious, and with clear utility, like Einstein’s equation, may be rebuffed if his or her invention falls into one of the three excluded categories.

The tremendous impact of §101 on otherwise patentable material underscores the importance of clearly defining the scope of the exclusions. The prevailing test for whether a claimed invention is directed to patentable subject matter is set forth in the Supreme Court’s opinion in *Mayo v.*

Prometheus, 132 S. Ct. 1289 (2012). In that case, the Court prescribed a two-part test: (1) determine whether the claims at issue are directed to a patent-ineligible concept. If they are, (2) consider the elements of each claim both individually and as an ordered combination to determine whether additional elements transform the nature of the claim into a patent-eligible application.

The Supreme Court acknowledged that the application of this test is not without risk, stating “that too broad an interpretation of this exclusionary principle could eviscerate patent law.” *Mayo v. Prometheus*, 132 S. Ct. 1289 (2012). Unfortunately, several Federal Circuit jurists assert that this is exactly what has happened.

In *Mayo* and three other major decisions between 2010 and 2014, the Supreme Court has narrowed the scope of patentable subject matter by expanding the apparent reach of the exclusions. Two of the cases, *Bilski v. Kappos*, 561 U.S. 593 (2010) and *Alice Corp. v. CLS Bank Int’l*, 132 S. Ct. 2347 (2014), addressed and expanded the scope of “abstract ideas.” Sandwiched between those decisions, *Mayo* (2012) and *Ass’n for Molecular Pathology v. Myriad*, 133 S. Ct. 2107 (2013), expanded the scope of “laws of nature.” Taken together, the application of these cases has dramatically increased the scope of the exclusions from §101, resulting in substantial threats to patents involving computer-implemented systems and methods, diagnostic techniques, and claims drawn to genetic material.

A recent Federal Circuit case, *Ariosa Diagnostics v. Sequenom*, encapsulates the difficulty created by the current trend in the scope of patentable subject matter and sets the stage for, perhaps, further

Supreme Court clarification. The challenged claims in *Ariosa* cover a diagnostic method for identifying fetal abnormalities using paternally inherited, cell-free fetal DNA (cffDNA), discovered in maternal plasma and serum. Prior to the work done by the inventors, maternal blood serum and plasma were discarded from diagnostic techniques.

The district court granted summary judgment of invalidity and determined that Sequenom’s patent claims were directed to patent-ineligible subject matter under §101. On appeal, the Federal Circuit panel categorized the claimed method as “a groundbreaking invention,” “a new way that revolutionized prenatal care” and “an advantageous result...deserving of patent protection.” *Ariosa v. Sequenom*, 788 F.3d 1371 (Fed. Cir. 2015). Nonetheless, applying the two-part *Mayo* test, the panel affirmed the grant of summary judgment, and excluded from the scope of patentable subject matter as a natural phenomenon. *Id.* at 1379-80. Sequenom petitioned for rehearing en banc.

The Federal Circuit, in a per curiam order, denied Sequenom’s petition because, as Judge Lourie stated, the court could find “no principled basis to distinguish this case from *Mayo*, by which we are bound.” *Ariosa v. Sequenom*, 2015 U.S. App. LEXIS 20842 (Fed. Cir. 2015) (en banc). Judge Lourie, in a concurrence on behalf of himself and Judge Kimberly Moore, further wrote, as stated above, that “[i]t is said that the whole category of diagnostic claims is at risk. It is also said that a crisis of patent law and medical innovation may be upon us, and there seems to be some truth in that concern.” *Id.* Sequenom filed a petition for a

writ of certiorari to the Supreme Court, which is currently pending.

Trade Secrets as Alternative

As patents covering certain technologies, become increasingly difficult to uphold, Congress has taken a large step toward increasing the desirability of trade secret protection as an alternative through passage of the DTSA. As described above, the DTSA provides for federal private civil causes of action for trade secret misappropriation and confers subject matter jurisdiction in the federal district courts.

The subject trade secrets are designed to protect confidential corporate assets, maintain business ethics and prevent unfair competition. See Elizabeth A. Rowe & Sharon K. Sandeen, *Cases and Materials on Trade Secret Law 13* (Thomson Reuters 2012). A company that withholds its innovations from the public and elects not to file a patent application can guard that information as a trade secret.

The DTSA adopts an expansive definition of “trade secret,” which provides for protection of “financial, business, scientific, technical, economic, or engineering information...” DTSA §2(b)(1) and includes a list of examples that covers “methods, techniques, processes, procedures, programs, or codes...” Id. To qualify as a trade secret, the information must also derive “economic value, actual or potential, from not being generally known to, and not being readily ascertainable through proper means by, another person who can obtain economic value from the disclosure or use” of it. Id. Moreover, a party seeking to maintain a trade secret must take “reasonable measures to keep such information secret...”

Id. If trade secrets are acquired by “improper means,” the district courts are empowered to grant injunctions, damages, and even seize property, in “extraordinary circumstances.” DTSA §2(b)(3).

A Case Study—‘Myriad’

One of the four recent cases on the scope of patentable subject matter, *Ass’n for Molecular Pathology v. Myriad*, provides an interesting study of the alternative path of trade secret protection. The patent holder in that case, Myriad Genetics, is a biotechnology company that pioneered

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genetic testing for the BRCA-1 and BRCA-2 genes, which are linked to several forms of cancer risk. Myriad is reported to have responded to the loss of several of its patent claims in a §101 challenge, by moving toward the use of trade secret protection. See “Myriad’s Trade Secret Trump Card: The Myriad Database of Genetic Variants,” *PharmaPatents* (July 18, 2013), <https://www.pharmapatentsblog.com/2013/07/18/the-myriad-database-of-genetic-variants/>.

In so doing, although Myriad cannot keep others from innovating in this area, Myriad maintains a competitive advantage based on

its extensive genetic data collection, which it guards as a trade secret. This collection allows Myriad to “report definitive findings to over 97% of its patients” while competitors report the same findings for only 70-75 percent of patients.

While the transition from patent protection to trade secret protection for its newly-discovered genetic mutation data may preserve the financial benefit to Myriad, the public is not permitted to benefit from this information in the context of cancer research and/or improved diagnostics. This is but one example of why practitioners and innovators alike contend that a broad-based shift from patents to trade secrets does not serve the public interest.

The Path Forward

As Sequenom awaits a decision on its certiorari petition, there is little evidence that Congress has publicly taken an interest in this issue. While it could rewrite § 101, or even abolish it, as suggested by David Kappos, former head of the U.S. Patent and Trademark Office, See “Kappos Calls for Abolition of Section 101 of Patent Act,” *Law360* (April 12, 2016), <http://www.law360.com/articles/783604/kappos-calls-for-abolition-of-section-101-of-patent-act>, the most immediate solution would be for the Supreme Court to clarify and narrow the scope of the judicially-created exclusions from patentable subject matter. Many believe, however, that given the Supreme Court’s recent and decisive activity in this area, it is unlikely.

Only time will tell.