



What Subject Matter Is Patent-Eligible?

KEY COURT RULINGS FOCUS ON BUSINESS METHODS, GENETIC MATTER

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A threshold question in U.S. patent law is, “Whether the subject matter of a claim in a pending patent application or issued patent is directed to patentable subject matter?”

Just a few years ago the answer to that question seemed simple, “Yes, if the claimed subject matter came from the ‘hand of man.’” However, recent case law involving business method patents and patents claiming genes have placed the issue in the forefront of patent law. This brief article is intended to highlight and summarize this issue for the non-patent practitioner.

U.S. patent law is governed by 35 U.S.C. § 100, et seq. Whether the subject matter of an invention is patent-eligible is addressed by 35 U.S.C. § 101. Pursuant to § 101, an invention is patentable if it falls within one of four categories of invention: processes, machines, manufactures, or compositions of matter. The drafters of § 101 intended the scope of “patentable subject matter” to be interpreted broadly. Historically, the Supreme Court has interpreted § 101 to have only three specific exceptions to patentable subject matter — “laws of nature, physical phenomena, and abstract ideas.”

Recently two highly publicized cases, *Bilski v. Kappos* and *Association for Molecular Pathology v. USPTO*, have addressed this issue in the context of business method patents and patents directed to genes. These two cases, discussed below, have set forth



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the legal guidelines that federal courts and the U.S. Patent & Trademark Office (PTO) should use when determining this issue.

The *Bilski* Case

For patent lawyers and owners of business method patents, the Supreme Court’s *Bilski v. Kappos* decision (130 S. Ct. 3218 (2010)) regarding the patentability of business methods was one of the most anticipated decisions of 2010.

In the *Bilski* case, the Supreme Court explored two general questions: (1) what is the proper test for determining the patentability of a process, and (2) whether business methods should be categorically excluded from patentable processes. Specifically at issue, was whether the *Bilski* business method was a patentable process under § 101.

The *Bilski* patent application claimed a business method for explaining how buy-

ers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes. Before reaching the Supreme Court, the PTO rejected the *Bilski* patent application as not patentable under § 101 because it “is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application”

The PTO’s decision was then appealed to the Federal Circuit, which affirmed the PTO’s decision. As part of the Federal Circuit’s en banc decision, the court rejected its prior test for determining whether a process is patentable (whether an invention produces a “useful, concrete, and tangible result,” which was developed by the Supreme Court in *State Street Bank*), and instead set forth a new and sole test, for determining whether a process is patentable. That is the “machine-or-transformation” test, which states “a claimed process is patent eligible if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing.”

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The Supreme Court considered whether the Federal Circuit's "machine-or-transformation" test should be the sole test for determining patentability of a process and found that it was not. The Court concluded that if it were the sole test, then that would violate statutory interpretation principles because, for example, the ordinary meaning of "process" does not require tying to a machine or transformation of an article. Nevertheless, the Supreme Court found "the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101."

The Supreme Court also found that business methods should not be categorically excluded from "processes" under § 101. Since § 101 is only the threshold test for patentability, the Court said "even if a particular business method fits into the statutory definition of a 'process,' that does not mean that the application claiming that method should be granted. In order to receive patent protection, any claimed invention must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112."

Even though the Supreme Court found the Federal Circuit's test is not the exclusive patentability test for processes and business methods, and business methods are not categorically outside of § 101, it affirmed the Federal Circuit's decision that the claims of the *Bilski* patent application were not patentable under § 101 because "it claims an abstract idea," the concept of hedging risk. The Court reasoned that "allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea."

Following *Bilski*, owners of business method patents can rest assured, for now, that business methods are not categorically unpatentable and that to determine the patentability of a business method, the Federal Circuit's "machine-or-transformation" test is not the exclusive test.

The Myriad Case

The Federal Circuit Court of Appeals recently addressed a controversial issue in biotechnology: Whether an isolated gene constitutes patent-eligible subject matter. Since the first human gene was patented in 1982, the PTO has granted thousands of "gene patents"—*i.e.*, a biological patent on a specific, isolated DNA sequence, or the process to make or use the DNA sequence.

DNA is the complex molecule that governs heredity. Heredity and physiological activity are driven by the order or "sequence" of DNA's repeating subunits. Natural or "native" DNA can be separated into "isolated" DNA by laboratory techniques to create a separate, free-standing portion of an original DNA molecule.

In *Association for Molecular Pathology v. USPTO* ("*Myriad*"), 99 U.S.P.Q.2D (BNA) 1398 (Fed. Cir. July 29, 2011), the Federal Circuit reversed a contentious decision by the Southern District of New York, and held that the two isolated DNA sequences at issue constituted patent-eligible subject matter.

First, the Federal Circuit held that the isolated DNA molecules themselves were patent-eligible under § 101 because the new DNA was "markedly different" from native DNA. Moreover, the new DNA possessed a "distinctive chemical identity" from native DNA attributable to the laboratory tech-

niques that created the isolated DNA segments. Second, the Federal Circuit affirmed the ineligibility of a method for "comparing" or "analyzing" DNA because this step was an abstract mental process that could "be accomplished by mere inspection alone" rather than human intervention or manipulation. Lastly, the Federal Circuit reversed the ineligibility of the method of screening for cancer therapeutics because its "growing" and "determining" steps were "inherently transformative" due to the physical manipulation of the cells.

As it stands, the *Myriad* decision will likely have a far-reaching impact in the biotechnology field. *Myriad* appears to establish a patent eligibility standard—*i.e.*, DNA sequences will be patent-eligible if isolated into new, distinct DNA sequences—which may increase the willingness of pharmaceutical companies to increase investments in genetic treatments and therapeutics. *Myriad*, however, is an appellate decision, so it is likely that a cert. petition will be filed for the Supreme Court to clarify the standard of patent-eligibility for human genetic material.

Conclusion

In light of these recent decisions, the subject of "patent-eligible subject matter" under 35 U.S.C. § 101 is evolving. Both business method patents and DNA patents are not per se patent-ineligible. As the decisions stand now and under any test that the court may adopt in the future to determine an invention's patent-eligibility, patent drafters and litigators alike should pay careful attention to the chosen language in a patent's claims and description to avoid enveloping one of the three § 101 exceptions. ■