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Expert Analysis

Moving Forward on Patentable Subject Matter After 'Bilski'

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On Nov. 9, 2009, the Supreme Court heard oral argument in *Bilski v. Kappos*, which is the appeal of the decision by the Court of Appeals for the Federal Circuit (CAFC) that ostensibly clarified, or at least established, until the Supreme Court weighs in, that the proper test for patentable subject matter is the "machine or transformation" test. Given the number of times in recent years that the U.S. Supreme Court has refined and rejected standards set by the CAFC, the patent bar and inventors alike are eagerly waiting to see if and how the landscape of patent law will shift again after *Bilski* is decided.

That *Bilski* was argued early in this term of the Supreme Court is a secret to no one. Yet recently, in *Prometheus v. Mayo Collaborative Services*, the Federal Circuit decided to further develop the law under the machine or transformation test rather than wait for the Supreme Court to weigh in on the appropriate standard. The juxtaposition of *Bilski* and *Prometheus* demonstrates the far reaching implications of the question of what is patentable subject matter for a diverse set of industries.

The invention in *Bilski* was directed to managing the consumption risk costs of a commodity.[1] Thus, the claimed invention was what has casually been referred to as a "business method." By contrast, in *Prometheus*, the invention was directed to a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder.[2] It could thus be called a "medical (not business) or treatment method." Yet both cases required an analysis of what type of invention can be patented. Because these two cases are representative of two such diverse industries—the financial/ software/ Internet and pharmaceutical/ medical devices/ biotechnology industries—all attorneys who counsel innovative clients should follow closely the developments of the contours of what is patentable subject matter.

Scope as Defined by Congress

Congress has defined the scope of what is patentable as follows:

> 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 of this title.[3]

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Unfortunately, Congress defined the term "process" to mean a "process, art or method."[4] Thus, by using the word process to define a process, Congress left it to the courts to decide what is a "process" within the meaning of the patent laws.

Although Congress did not artfully define what is a process, when given the opportunity to rein in the scope of patentable processes, Congress declined to do so. In 1999, Congress enacted a business method defense (prior use) to patent infringement, which provided that when an infringer used the same method more than one year prior to the effective filing date of the patent at issue there would be no liability.[5] Thus, Congress implicitly suggested that it believed that at least some methods of doing business were and should continue to be patentable.

Machine or Transformation

Over the past few decades the pendulum reflecting patentable subject matter, and thus what are patentable processes, has swung very liberally, with courts often pointing to the Supreme Court's citation to Congress' intent to include within the scope of patentable subject matter "anything under the sun that is made by man."[6] Indeed, at one time, the only perceived limit on what was patentable subject matter was to exclude laws of nature, natural phenomena and abstract ideas.[7] And even then, although the non-patent eligible subject matter could not form the basis of a patent claim, the application of a law of nature or mathematical formula was recognized as being a possible basis for patent protection.[8]

The broad pronouncements about the far reaches of what constitutes patentable subject matter were made when both the biotechnology and computer industries were in their infancy. However, beginning about a decade ago, when each of these industries started its own accelerated growth and began to provide opportunities for great financial windfalls to those with new and innovative ideas, obtaining and respecting patent positions became smart business practice. As the bioinformatics industry grows at the intersection of these two areas (e.g., pharmacogenomics and systems biology), the need to understand how and when to obtain a strong patent position will only further grow.

Under the current Federal Circuit standard in *Bilski*, a claimed process is directed to patentable subject matter if: (1) it is drawn to a particular machine or apparatus; or (2) it transforms a particular article into a different state or thing.[9] This test has become known as the machine or transformation test and as the Federal Circuit clarified, "the use of a specific machine or transformation of an article must impose meaningful limits on the claim's scope to impart patent-eligibility…[and] the involvement of the machine or transformation

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in the claimed process must not merely be insignificant extra-solution activity."[10]

Bilski failed this test. The claims were directed to a method of hedging risk and required initiating a first series of transactions, identifying market participants and initiating a second series of transactions, none tied to a computer. Consequently, the Federal Circuit held that the invention was not patentable because it was directed to "a non-transformative process that encompasses a purely mental process of performing requisite mathematical calculations without the aid of a computer or any other device, mentally identifying those transactions that the calculations have revealed would hedge each other's risks, and performing the post-solution step of consummating those transactions"[11]

'Prometheus'

In *Prometheus*, the claimed method was for optimizing therapeutic efficacy and required: (a) administering a drug providing 6-thioguanine to a person having a specific disorder and (b) determining the level of 6-thioguanine in the person, wherein a level less than a specified level indicates a need to increase the amount of drug and wherein a level greater than a specified level indicates a need to decrease the amount of drug. Thus, the method was for calibrating the proper dosage of thiopurine drugs. As with *Bilski*, in the broadest claim there was no requirement of a computer apparatus.

The defendants argued that the claim was not directed to patentable subject matter because it was directed to natural phenomena—the correlation between thiopurine drug metabolite levels and efficacy and toxicity. The district court agreed, holding that the administering and determining steps were merely data-gathering steps and the final step, which centered around noting what the result indicated and which the court labeled a "warning" step, was a mere mental step.[12] The district court also noted that the correlations were not patentable because they resulted from natural body phenomena.[13]

On appeal, the patent holder argued that both the machine and transformation tests were met. However, the Federal Circuit focused solely on the transformation test, and because that test was satisfied, it did not reach the machine test.

The Federal Circuit held that the transformation test was met by the claim because there was a transformation of the human body following the administration of a drug, and there were various chemical and physical changes of the drug's metabolites that enabled their concentrations to be determined.[14] The court summarized: "The asserted claims are in effect claims to methods of treatment, which are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition."[15]

The Federal Circuit also noted that upon administration, the drug undergoes a transformation and that reliance on natural processes was irrelevant for purposes of determining whether the subject matter was patentable.[16] Furthermore, the court noted that determining the level of the drug in the blood involves a transformation because those levels could not be determined by mere inspection.[17]

The Federal Circuit also took the opportunity to address the significance of having a data gathering step in a claim. As in this case, when the data is gathered as part of a protocol, that step did not render the protocol to be non-transformative. The Federal Circuit contrasted the present claims with those found in *In re Grams*.[18] In *Grams*, the claims required performing a clinical test and based on the test, determining if an abnormality existed. In contrasting the two cases, the court emphasized that in *Grams* the essence of the claimed process was the mathematical algorithm rather than any transformation of the tested individuals. The crucial difference being that the claims in *Grams* did not require the performance of clinical tests on individuals. Thus, whereas the data gathering steps of *Grams* were insignificant extra-solution activity, in *Prometheus*, they were part of a treatment regimen.

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Of course, given the language used by the Federal Circuit and the characterization of the claims as a method of treatment, on remand, *Prometheus* will now likely be confronted with a challenge under 35 U.S.C. §287(c)(1), which limits remedies against a medical practitioner for medical activity. (The Mayo Clinic is one of the defendants.)

Finally, the Federal Circuit also commented on the issue of a claim containing a mental step. The Federal Circuit agreed that claim contained a limitation that amounted to a mental step. Were the entire claim directed to a mental step, it would have been unpatentable. However, the court held that the inclusion of a subsequent mental step in a claim does not by itself negate the transformative nature of prior claims.

The Federal Circuit's holding in *Prometheus* that the claims were directed to patentable subject matter has at least two significant implications. First, it is a clear reminder that the scope of what may be considered a sufficient transformation is broad, and patent practitioners should lay the foundation for describing different transformations that are the result of newly developed inventive processes. Second, it establishes that the inventions that are directed to gathering and analyzing data can be patentable if part of a protocol. This suggests that the Patent Office will soon be faced with an increased number of longer process claims that include both data analysis and transformation steps.

Conclusion

The machine or transformation test is the current analysis that the courts and the Patent Office will take when considering whether subject matter is patentable. As both *Bilski* and *Prometheus* show, this question is not industry specific, but it is particularly important when an inventor is trying to obtain patent rights directed to processes. Because of the changing landscape, and the likelihood that whatever the Supreme Court does, there will remain unanswered questions about where the boundaries lie, the patent practitioner should always consider trying to claim processes both broadly and as tied to devices and/or causes one or more transformations.

Further, although many practitioners are waiting for the final word from the Supreme Court in *Bilski*, one should expect that shortly thereafter, there will be an increased number of continuation-in-part applications filed to include sufficient foundation for what will become the new standard for patentability, and an increased filing of reissue applications for those applications that already have the necessary foundation, but for which the claims do not already comply with what will become the new standard.

1. 545 F.3d 943 (Fed. Cir. 2008).
2. 2008-1403 Slip Opinion at p. 3 (Fed. Cir. Sept. 17, 2009).
3. 35 U.S.C. §101.
4. 35 U.S.C. §100(b).
5. 35 U.S.C. §273(a)(3) and (b)(1).
6. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).
7. *Diamond v. Diehr,* 450 U.S. 175, 185 (1981).
8. *Bilski*, 545 F.3d at 953.
9. Id.
10. Id. at 9.
11. Id. at 965.
12. *Prometheus* at *5.
13. Id.
14. Id. at 14-15.
15. Id. at 15.
16. Id. at 16.
17. Id. at 17.
18. 888 F.2d 835 (Fed. Cir. 1989).