Medical Treatment and Diagnostic Procedures – Patent Eligible?

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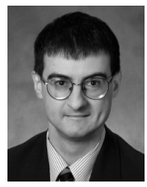

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The patent-eligibility of particular methods has been the topic of recent debate, with the focus centering on the future of so-called business method patents. Like many business methods, certain medical treatment or diagnostic techniques do not require the use of a specific machine. Resolving the patentability issues surrounding business methods therefore promises to impact the patent-eligibility of medical method patents as well.

Under the Patent Act, there are four categories of patentable inventions: processes (*e.g.*, methods), machines, manufactures, and compositions of matter. Significantly, laws of nature, physical phenomena, and abstract ideas are not patentable subject matter. (It should not be overlooked that patent-eligibility is merely one gatekeeper to receiving a patent—an invention must still satisfy other requirements such as novelty and non-obviousness.)

Many expected the Supreme Court to provide much-needed guidance on how to determine whether a method is patent-eligible in the recent *Bilski v. Kappos* case. The patent application in *Bilski* related to a procedure that allows energy traders to minimize or hedge the risks resulting from fluctuations in market demand. The invention was defined as a series of steps that did not require the use of a specific system or machine. The Patent Office characterized the method as simply the abstract idea of hedging and rejected the claims as unpatentable subject matter—the examiner essentially objected because the method was not implemented on a specific apparatus. The Federal Circuit affirmed and decided that a "machine-or-transformation test" is the exclusive test for determining whether a process is patent-eligible. This test requires analyzing whether the method is tied to a particular machine or apparatus, or whether the method transforms physical matter. A method is not patent-eligible if neither prong is met.

Nearly eight months after hearing oral arguments, the Supreme Court issued its opinion on the *Bilski* appeal in June. *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). Considering the length of time the Court took to render its decision, its opinion was rather anticlimactic, with the Court disappointing those who had hoped for clear guidance on the patent-eligibility of business methods (and potentially other methods). In fact, the Court refused to categorically exclude business methods from patent-eligibility. The Court also rejected the Federal Circuit's bright line machine-or-transformation test, holding instead that there is not one particular test that must be applied to the exclusion of others when determining the patent eligibility of a method. On the other hand, the Court did not prohibit using the machine-or-transformation test as part of the patent-eligibility analysis. The Court instead referred to the test as "an important and useful clue" for what constitutes a potentially patentable method. To determine patent eligibility for a method, the Court ultimately instructed courts to consider whether the method is directed to an abstract idea, law of nature, or physical phenomenon, none of which are patent-eligible. For example, the concept of hedging risk, the alleged invention in *Bilski*, is an unpatentable abstract idea. A math formula used to convert decimals to binary code is also an unpatentable abstract idea. By comparison, a procedure for molding uncured rubber into cured products that includes the use of a math formula to complete some of the steps is a patent-eligible ***application*** of the formula (rather than a claim to the formula itself).

We are now left to ponder the consequences of the *Bilski* decision on the patent-eligibility of medical methods. In fact, the Court specifically instructed the Federal Circuit to reconsider two recent decisions addressing whether certain medical methods are patent-eligible in light of *Bilski*. One case, *Prometheus Laboratories v. Mayo Collaborative Services*, involves methods for calibrating the dosage of certain drugs used for treating autoimmune diseases. Treating autoimmune diseases with these drugs was not a new idea, but non-responsiveness and toxicity were known issues. To that end, the method in *Prometheus* was intended to optimize therapeutic efficiency while minimizing toxic side effects. The steps of the method—a drug administration step followed by a step of determining drug levels and adjusting the amount of the drug based on those levels—are not tied to the use of a specific device. Nevertheless, the Federal Circuit had decided that the machine-or-transformation test was met because the method transforms "the human body following administration of a drug." In fact, the court went so far as stating that methods of treatment "are ***always*** transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition" because such methods transform the human body and are therefore patent-eligible. The court further declared the machine-or-transformation test to be the "definitive" (*i.e.*, exclusive) test for deciding whether a process is patent-eligible. This conclusion was erroneous based on the Supreme Court's holding in *Bilski* that the machine-or-transformation test is ***not*** the exclusive means for determining the patent-eligibility of a process or method.

The other case remanded by the Supreme Court, *Classen Immunotherapies v. Biogen IDEC*, involves a method for selecting vaccine regimens by comparing two vaccination schedules and identifying the one less likely to cause chronic autoimmune disorders. The district court remarked that the correlation between immunization schedules and the incidence of immune mediated disorders was simply a natural phenomenon. The court then determined that the method was only a general inquiry of whether the proposed correlation between an immunization schedule and the incidence of chronic disorders existed, and therefore the inventors were attempting to patent a natural phenomenon. In contrast to the *Prometheus* case, the Federal Circuit in *Classen* affirmed the district court's decision and noted that the claimed method failed to meet the machine-or-transformation test.

The Federal Circuit's first post-*Bilski* decision commenting on the patent-eligibility of medical methods sheds light on how those methods will be scrutinized going forward. In *King Pharmaceuticals v. Eon Labs*, 2010 U.S. App. LEXIS 15947 (Fed. Cir. Aug. 2, 2010), the Federal Circuit remarked that "while the Supreme Court in *Bilski* made clear that our machine-or-transformation test is not the exclusive test for patentability … it also made clear that the test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are" patent-eligible. In other words, the Federal Circuit intends to stick to its guns and revert to the machine-or-transformation test, albeit not with the stated intent of excluding other tests. It is therefore likely that the Federal Circuit will continue to consider treatment methods that require administering drugs to ameliorate the effects of a condition—as in the *Prometheus* case—to be patent-eligible because they transform the human body. On the other hand, the Federal Circuit is likely to overrule courts that hold other methods as patent-ineligible merely because an administration step is missing. In those situations, courts will need to determine whether other indicia of patent-eligibility or ineligibility are present, including whether a method is an abstract idea, law of nature, or physical phenomena (all patent-ineligible) or whether a method is a practical application of an abstract idea, law of nature, or physical phenomena (all of which would be patent-eligible).

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