

Bilski's impact on medical method patents

The *Bilski* court held that abstract ideas cannot be patented, but recent months have provided clear indications that medical treatments and methods are patentable. However, patent applicants and practitioners should not allow this to distract them from the other requirements for patenting; all claims must still pass the novelty, obviousness and disclosure requirements

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On 28th June 2010 the Supreme Court issued its long-awaited *Bilski v Kappos* opinion on the patentability of methods. Initially, there was a great deal of uncertainty as to how the ruling would apply to medical treatments and diagnostic methods, but the past few months have provided clear indications that such treatments and methods are patentable.

In the *Bilski* opinion, the court seemed able to agree only that the *Bilski* claims at issue (for hedging by commodities buyers and sellers against the risk of price changes in the energy market) constituted unpatentable subject matter. The court issued the narrow finding that the claims at issue constituted attempts to patent abstract ideas and did not use the so-called "machine-or-transformation" test espoused by the Federal Circuit in the same case. Notably, the court seemed in unanimous agreement that the machine-or-transformation test is not the sole test for patent eligibility under Section 101 of the Patent Act; in fact, the majority

expressly stated that a process need not be tied to a machine or transformation in order to be patentable. The court also narrowly determined that business method claims *per se* are not ineligible to be patentable subject matter.

However, the focal point of the decision is the finding that abstract ideas in themselves are not patentable. The court reaffirmed its prior case law that one cannot patent a mathematical formula, an abstract idea or an algorithm. The application of a law of nature or mathematical formula to a known structure or process may be patentable, but one cannot circumvent the prohibition by attempting to limit the use of the formula or idea to a particular technological environment or by adding insignificant post-solution activity.

However, the court provided no firm guidance or bright-line test for abstractness. In fact, in his concurrence Justice Stevens noted that the court "never provides a satisfying account of what constitutes an unpatentable abstract idea". Attempts to circumvent the abstract idea issue (eg, by trying to limit a method to a particular subject-matter area) are likely to run into arguments that the claims are mere "field-of-use" restrictions or merely add insignificant post-solution activity.

Fortunately, guidance has been provided by both the US Patent and Trademark Office (PTO) and the US Court of Appeals for the Federal Circuit, which hears appeals of patent cases. The PTO has issued interim guidance establishing the machine-or-transformation test as a "safe harbor", while the Federal Circuit recently upheld the patentability of medical treatment claims in light of *Bilski*.

PTO machine-or-transformation safe harbour

While the machine-or-transformation test

is no longer the sole test to be used for determining the patentability of method claims, it will continue to constitute a vital element of PTO practice. It will provide some certainty to patent applicants and effectively act as a safe harbour.

On 27th July 2010 the PTO published its “Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v Kappos*” (Fed Reg 43922). In general, the PTO will continue using the machine-or-transformation test as a tool for determining whether the claimed invention is a patentable process. If a claimed method meets the test, the method will be considered likely to be patentable unless there is a clear indication that the method is directed to an abstract idea. Conversely, if the claimed method does not meet the test, the PTO examiner will reject the claim under Section 101 unless there is a clear indication that the method is not directed to an abstract idea.

The PTO established four factors to be considered by examiners in determining whether method claims are directed to abstract ideas.

Particular machine or apparatus

Examiners should consider whether the method involves or is executed by a particular machine or apparatus. If so, the claims are more likely to be considered patentable subject matter. Sub-factors include the degree to which the machine in the claim can be specifically identified (ie, not any and all machines); the issue of whether the machine or apparatus is integral to implementation of the steps of the method; and the extent to which the machine or apparatus imposes meaningful limits on the execution of the claimed method steps. Thus, if the machine or apparatus contributes only nominally or insignificantly to the execution

of the method (eg, for a data-gathering step), the method is unlikely to be considered patent eligible.

Transformation of a particular article

Examiners should consider whether the performance of the method results in or involves the transformation of a particular article. If so, the method is more likely to be considered patentable subject matter. Sub-factors include the particularity or generality of the transformation; the issue of whether the article can be specifically identified; the nature of the transformation; the nature of the article transformed; and the extent to which the transformation imposes meaningful limits on the execution of the claimed method steps. Thus, if the transformation contributes only nominally or insignificantly to the execution of the method (eg, for a data-gathering step), the method is unlikely to be considered patent eligible.

Application of law of nature

Examiners should consider whether the performance of the method involves the application of a law of nature, even in the absence of a particular machine or transformation. If so, the claims are less likely to be drawn to an abstract idea. Sub-factors include the particularity or generality of the application; whether the application solely involves subjective determinations (eg, ways to think about the law of nature); and whether its involvement is merely extra-solution activity or a field-of-use limitation.

General concept

Examiners should also consider whether there is a general concept (principle, theory, plan or scheme) involved. If so, the claims are unlikely to be considered patentable subject matter. A large number of sub-



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factors may be considered, including the issue of whether use of the concept would be pre-empted in other fields; the extent to which the claim covers both known and unknown uses of the concept; the extent to which the claim effectively covers all possible solutions to a particular problem; whether the concept is disembodied and not instantiated; and the mechanisms by which the steps are implemented.

The PTO's interim guidance gives several examples of general concepts which are now considered *prima facie* unpatentable subject matter:

- Basic economic practices or theories (eg, insurance or financial transactions).
- Basic legal theories (eg, dispute resolution or contracts).
- Mathematical concepts (eg, algorithms).
- Mental activity (eg, forming a judgement, observation, evaluation or opinion).
- Interpersonal interactions or relationships (eg, dating).
- Teaching concepts.
- Instructions on how business should be conducted.

If the factors indicate that the claimed method is directed to an abstract idea, the claim will be rejected under Section 101. The applicant will then have the opportunity to explain why the claimed method is not directed to an abstract idea.

While it remains to be seen how this interim guidance will be put into practice, it provides some structure for patent applicants. In view of the PTO interim guidance, most patent applicants will wisely draft at least some of their claims with an eye on meeting the machine-or-transformation test. Of course, applicants may push the envelope by including broader, more abstract claims, but anyone doing so should expect to have a fight on their hands.

In the biotech and medical world, where a particular device or instrument is involved, it should be included or identified in the claims – if not specifically as an element of the claim, then at least in terms of its capacity to be used with particular types of instrument or device. Where the method is being carried out in or with the assistance of a computer or computing device, prior guidance from the PTO on acceptable claim language should be followed. For example, one or more of the method steps may need to cite the fact that the step is being carried out using a processor or microprocessor in a computing device. Alternatively, these claims may be

rephrased as machine-based claims (eg, a machine for evaluating testing results, comprising a microprocessor coupled to a memory) wherein the microprocessor is programmed to evaluate test results by the method steps.

The transformation prong of this safe harbour can also be of use to the medical and biotech community, as was proved by the Federal Circuit's decision in *Prometheus Laboratories v Mayo Collaborative Services*.

Federal Circuit decision in *Prometheus Labs v Mayo*

Immediately after its *Bilski* decision, the Supreme Court granted certiorari, summarily vacated the lower court decisions and remanded two pending appeals back to the Federal Circuit for further consideration in light of the *Bilski* ruling. The first case remanded was *Prometheus Laboratories v Mayo Collaborative Services*, in which the Mayo Clinic was challenging two Prometheus patents claiming an iterative three-step dosing method. In general, the claimed method at issue involved the following steps:

- Administering a drug to a subject.
- Determining the level of the drug in the subject.
- Deciding whether the next dose to be administered should be the same, higher or lower, based on a comparison of the level of the drug in the subject with predetermined thresholds.

The Federal Circuit had held the method was patentable under the previous machine-or-transformation test, stating that the administration of the drug transformed an article into a different state or thing.

The second case to have been remanded to the Court of Appeals of the Federal Circuit in light of *Bilski* was *Classen Immunotherapies v Biogen IDEC*, a case involving claims to a method of determining whether an immunisation schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals relative to a control group. The base claim had two steps:

- Immunising mammals in the treatment group with one or more doses of one or more immunogens according to an immunisation schedule.
- Comparing the incidence, prevalence, frequency or severity of the immune-mediated disorder in the treatment group with that in the control group.

The Federal Circuit had summarily held that the claims were unpatentable under the previous machine-or-transformation test.

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While the patent community is still awaiting a decision on the *Classen* remand, a decision in the *Prometheus Labs* case was issued on December 17 2010, upholding the patentability of the medical treatment methods, even in light of *Bilski*. The Federal Court confirmed that the machine-or-transformation test, although not the sole test, was still a valuable tool that could be used to test patentability. It further held that the transformation prong of the machine-or-transformation test was satisfied by the “administering” and “determining” steps of several claims. The administering step caused the transformation of the human body and its components following the administration of a specific class of drug. The determining step involved a transformation in the various chemical and physical changes in the drugs' metabolites in the body, which enabled their concentrations to be determined.

Importantly, the court noted that these steps were not merely data-gathering steps or insignificant extra-solution activity, but were central parts of the treatment regimes. Likewise, the presence of mental steps in the claims, which would not be patentable on their own, did not negate the transformative nature of the prior administering and determining steps.

Most interesting was the Federal Circuit's apparent adoption of what might be considered a relatively bright-line test (albeit not explicitly so). In this regard, the court stated that claims to methods of treatment are “always transformative when one of a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition”. If this statement holds in the future, then any methods that administer a particular drug to the body for treatment should be assured of being patent eligible.

However, even if the initial subject matter threshold is easily passed, this does not mean that the claimed invention will ultimately be patentable. The claims must still pass the novelty (Section 102), obviousness (Section 103) and disclosure (Section 112) requirements. In fact, a tightening of the latter requirements in the United States has been seen in the area of gene patents, although everyone's attention has been focused on the threshold issue of whether human genes are patentable subject matter. Although the *Bilski* decision is important, patent applicants and practitioners should not allow it to distract them from the other requirements for patenting. ■

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