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***Bilski's* Impact on Biotechnology and Medical Diagnostic Claims**

On June 28, 2010, the U.S. Supreme Court handed down its eagerly awaited decision in *In re Bilski*. While the decision deals directly with business method and software patents, at its essence, *Bilski* broadly addresses the eligibility of patent subject matter under 35 U.S.C. §101. As now enunciated by the Supreme Court, patent subject matter eligibility will not be determined solely by the “machine-or transformation” test.



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The rationale that the Supreme Court articulates for subject matter eligibility in the business method context may be applied just as well to claims drawn to biotechnological and medical processes. *Bilski* clarifies that “machine or transformation” is not the exclusive test for evaluating patent eligibility and provides guidance on application of this test, in combination with other criteria, for determining patentable subject matter for the life sciences arena.

Post-*Bilski* Recommendations

Clients should be aware that process claims may be prone to challenges on the basis of 35 U.S.C. §101, not only by examiners in the course of prosecution but also by accused infringers or potential and existing licensees for issued patents.

Although the holding clearly establishes that “machine-or-transformation” is not the sole test for deciding whether an invention is a patent eligible process, the Court has not rejected this test and it should be considered when preparing a patent application.

Going forward, a process or method patent application should include claims that either recite a nexus between the process and a machine, or emphasize a transformation step. The application should also provide a clear link between the process or method and a useful, concrete, and tangible result. Diagnostic process claims might

include a description of the end result of the process like a diagnosis of a particular disease, recommendation of alternative courses of action based on the result, or determination of a particular treatment protocol. Pending applications should be reviewed to determine whether a continuation filing could shore up claims that now may be potentially suspect in view of *Bilski*. Allowed applications and issued patents should be reviewed, particularly with regards to the machine-or-transformation test. Consideration should be given to potential reissue and/or continuation filing strategies, particularly if such patents might be asserted in the near future.

The application of the “abstract ideas” analysis (the Court found the *Bilski* patent claims invalid as being directed to “abstract ideas”) raises the possibility that if patent claims fail the machine-or-transformation test, all is not lost. The Court suggests that claims may still be patentable if they survive the “abstract ideas” analysis. In the future, it will be helpful for a patentee or patent owner to:

- Assess whether the claims meet the requirements of the machine-or-transformation test
- Formulate a rationale for why the subject matter is patent-eligible (i.e., is not an “abstract idea”)

In regard to the latter, consideration should be given to cast the claimed subject matter

in terms that appropriately interject concepts to move the technology further away from abstract ideas alone (e.g., administration, transformation, or determination concepts).

The “Machine or Transformation” Test

Previously, the Court of Appeals for the Federal Circuit (CAFC) adopted the “machine or transformation” test for patent eligibility.

Under this test, a process would meet the requirements for patentability if it is:

- Tied to a particular machine or apparatus or
- Transforms a particular article into a different state or thing.

The CAFC noted that a claim that recites a fundamental principle and pre-empts substantially all uses of that fundamental principle is not patentable. To impart patent-eligibility, “the use of a specific machine-or-transformation of an article must impose meaningful limits on the claim’s scope.”

Unpatentable subject matter cannot be made patentable by insignificant post-solution or extra-solution activity. The transformation of an article “must be central to the purpose of the claimed process.” Further, in most cases, mere “gathering data would not constitute a transformation of any article.”

The CAFC characterized the *Bilski* claimed subject matter as 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.” The CAFC also held that the claim would effectively pre-empt any application of the fundamental concept of hedging and mathematical calculations inherent in hedging: “while the claimed process contains physical steps (initiating, identifying), it does not involve transforming an article into a different state or thing.” Thus, the CAFC held the *Bilski* claimed subject matter unpatentable, and the *Bilski* patent therefore invalid. *Bilski* thus appealed the decision of the CAFC to the U.S. Supreme Court.

Prometheus: Medical Application of the “Machine or Transformation” Test

While *Bilski* was under consideration by the U.S. Supreme Court, the CAFC provided further guidance in application of the “machine or transformation” test to medical methods. In this precedential opinion, the CAFC held that claims to “a method of optimizing therapeutic efficacy for treatment of a disease” can constitute patentable subject matter under 35 U.S.C. 101. (*Prometheus Laboratories Inc. v. Mayo Collaborative Services*, Fed. Cir. No. 2008-1403 on September 16, 2009).

The *Prometheus* patent claims at issue (U.S. Patent Nos. 6,335,623 and 6,680,302) require:

- Administration of a drug to a subject
- Determination of the level of the drug’s metabolite in the subject
- Comparison of the level of the metabolite in the subject to a recited value indicative of the proper dosage

The district court held that the *Prometheus* claims were directed to unpatentable subject matter under 35 U.S.C. §101 and therefore invalid. It asserted that the claimed correlations between thiopurine drug metabolite levels and therapeutic efficacy and/or toxicity were a natural phenomenon and not patentable as the correlations were merely the result of natural body processes. Significantly, the district court reasoned that the steps of “administering” and “determining” were simply “data-gathering” steps.

The CAFC considered the issue on appeal and reversed the decision of the district court. The CAFC held that the method of treatment claims at issue were patentable because they “transform an article into a different state of thing” and because the “transformation is central to the purpose of the claimed process.” Thus, the method claims were found to satisfy the machine-or-transformation test. “The transformation is one of the human body following administration of a drug and the various chemical and physical changes of the drug’s metabolites

that enable their concentrations to be determined.”

The CAFC further held that the determination step is also transformative. “Determining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection. Some form of manipulation, such as the high pressure liquid chromatography method specified in several of the asserted dependent claims or other modification of the substance to be measured, is necessary to extract the metabolites for a bodily sample and determine their concentration.”

The CAFC then concluded “that the administering and determining steps gather useful data, it is also clear that the presence of those two steps in the claimed process is not ‘merely’ for the purpose of gathering data. Instead, the administering and determining steps are part of a treatment protocol, and they are transformative.”

The CAFC’s holding that methods of treatment claims “are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition” clarified that medical diagnostic claims can be patent eligible, even if there is no explicit recitation of a chemical or physical transformation. The holding provided some guidance regarding how to draft claims to a diagnostic method that recite either a step of administering a drug or a step of determining the amount of a drug or metabolite in the blood.

Patent-Eligible Subject Matter Analysis in *Bilski*

In the Supreme Court’s holding in *Bilski*, it affirmed the invalidity of the patent for failure to claim patent-eligible subject matter. However, the basis of the Supreme Court’s ruling was not a failure of the claims to satisfy the machine-or-transformation test. Rather, the Court found the patent claims invalid as being directed to “abstract ideas”, which are not patentable subject matter. Thus, the patent was disposed by the Court’s application of the well

established precedent that laws of nature, physical phenomena, and abstract ideas are not patentable.

In regard to the test for patent-eligible subject matter, while the machine-or-transformation test is a useful tool for determining patent eligible subject matter, this test *alone* is too restrictive for analyzing *all* patent-eligible subject matter. The Court expressed doubts on the appropriateness of using only the machine-or-transformation test not only for business methods but particularly for biomedical processes as well. The Court recognized that while machine-or-transformation may be sufficient for evaluating Industrial Age technology, it is less clear that a single test would be appropriate for Information Age or emerging technologies. Moreover, the Court intimated that application of this single test to analyze subject matter might lead to such “intricacy and refinement” that the overarching goal of issuing patents for inventions important to promoting societal benefit might be obscured. The Court may be suggesting that life sciences and medical technologies should be the beneficiary of new inquiries (i.e., new analyses).

The Supreme Court further elaborated that the patent laws should be flexible to accommodate future technologies, and essentially encouraged the courts to develop other criteria (i.e., tests) consistent with *Bilski* and the Patent Act.

Bilski now provides an express articulation that machine-or-transformation is not the sole test for deciding whether an invention is a patent eligible process. However, the Court did not articulate specific standards or tests applicable in determining whether a claimed method meets the statutory requirements for patentable subject matter under 35 U.S.C. §101. In fact, the Court appears to be inviting lower courts to formulate tests to be used in concert with the machine-or-transformation test. For those pursuing patents in life sciences, *Bilski* is encouraging in that the Supreme Court:

- Has recognized that a single test is not appropriate for evaluating patent-eligible subject matter
- Is encouraging further development of criteria consistent with the Patent Act to apply to emerging technologies

The CAFC’s decisions in the *Prometheus* case as well as *Classen Immunotherapies v. Biogen IDEC* (both vacated and remanded to the CAFC for consideration in view of *Bilski*) will likely further delineate the analysis of patent-eligible subject matter for life sciences technologies. Therefore, *Bilski’s* precise impact on biotechnology and medical diagnostic claims remains to be further elucidated by the CAFC, and possibly the U.S. Supreme Court.

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