



# Intellectual Property NewsFlash

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## Medical Method Held Not Patentable

### Recent Appeals Decision finds Medical Procedure is not Patentable Subject Matter, Citing *In re Bilski*

by John R. Harris

A recent decision from the Court of Appeals for the Federal Circuit (CAFC) has raised serious questions about how to patent processes or methods for diagnosing or treating diseases. The case is *Classen Immunotherapies, Inc. v. Biogen IDEC et al.*, Case No. 2006-1634, -1649 (Fed. Cir. Dec. 19, 2008) (nonprecedential). The patent involved in the case was U.S. Patent No. 5,723,283 (“the ‘283 Patent”) entitled “Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae,” owned by Classen Immunotherapies, Inc., a company based in Maryland.



Classen Immunotherapies had sued a number of pharmaceutical and other health-care companies for patent infringement in Maryland including GlaxoSmithKline, Merck & Co., Chiron Corporation, and various Kaiser-Permanente entities. The defendants in the case obtained a summary judgment from the district court in Maryland that the claims of the ‘283 Patent were invalid under 35 U.S.C. § 101, which is known as the “patentable subject matter” requirement for patentability. This part of the patent laws states that “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 and requirements of this title [Title 35, U.S.C.]”

Over the years, the case law interpreting this statute has explored the extent to which a process or an improvement to a process may be considered patentable subject matter. Many patents have been issued by the U.S. Patent & Trademark Office for various types of processes (also called procedures, methods, etc.). These so-called “method patents” or “process patents” cover a wide range of technological fields, including computer software, materials processing, chemistry and chemical manufacture, business methods, as well as medical and surgical procedures.

Claim 1 of the ‘283 Patent involved a method for determining the effect of an immunization schedule:

A method of determining whether an immunization schedule affects the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals, relative to a control group of mammals, which comprises:

immunizing mammals in the treatment group of mammals with one or more doses of one or more immunogens, according to said immunization schedule, and

comparing the incidence, prevalence, frequency or severity of said chronic immune-mediated disorder or the level of a marker of such a disorder, in the treatment group, with that in the control group.

Note that the claim in the patent did not involve any specific type of immunization – just the effect of an immunization schedule. Note also that the last step of the process (“comparing ...”) arguably does not result in any specific recited benefit or utility to the treatment group.

The case did not involve the patentability of the method under the criteria of novelty and nonobviousness, which are more frequently the source of a challenge to patentability of an invention. The U.S. Patent Office considered those issues to some degree when deciding to grant the patent in 1998. There were no questions about novelty or nonobviousness mentioned by the CAFC in its opinion.

In finding claim 1 unpatentable, the CAFC simply said that:

In light of our decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), we affirm the district court’s grant of summary judgment that these claims are invalid under 35 U.S.C. § 101. Dr. Classen’s claims are neither “tied to a particular machine or apparatus” nor do they “transform[] a particular article into a different state or thing.” *Bilski*, 545 F.3d at 954. Therefore we affirm.

This was the extent of the opinion – one short paragraph. But the message from the court was clear: the reasoning of the *In re Bilski* case applies to claims of this nature. (*In re Bernard L. Bilski and Rand A. Warsaw*, Case No. 2007-1130, October 30, 2008). In that case, the CAFC held in an *en banc* decision that, in order to constitute patentable subject matter, a process must satisfy either one (or both) of the following tests: (1) the process must be tied to a particular machine or apparatus, and/or (2) the process must physically transform an article into a different state or thing. These tests are called the “machine-or-transformation” test, although in actuality two separate tests are involved. (For more information about the *In re Bilski* decision, see the [October 2008 MMM Intellectual Property NewsFlash](#), “New Appeals Decision Will Affect Computer and Process Patents - Case Summary of *In re Bilski* Decision: Patentable Processes Must Involve Physical Transformation or Be Tied to a Particular Machine.”)



The *Classen* decision was designated by the CAFC as “nonprecedential.” Prior to December 1, 2006, the CAFC was fairly harsh in prohibiting the citation of nonprecedential opinions in arguments and briefs before the court. Under the current rules of practice before the CAFC (namely, Rule 32.1), parties may now cite a nonprecedential opinion in briefs and arguments. But it is not clear what effect or influence such nonprecedential opinions will have on lower courts or on the CAFC itself. The designation of the decision as nonprecedential might be viewed as a signal to the community that the court is not through with the question of the patentability of medical procedures, and perhaps has significant misgivings about the ruling or its effect.

According to CAFC Practice Rule 32.1(b), an opinion or order which is designated as nonprecedential is one determined by the panel issuing it as not adding significantly to the body of law. In the *Classen* case, this suggests that the deciding panel of three judges believed that the language of the claim was so clearly nontransformative or tied to a particular machine that the issue was not worth significant discussion. The troubling part of the case is the implicit extension of the *In re Bilski* reasoning to medical procedures patents, and the failure to discuss and consider the transformative effect of immunization of mammals from a prior susceptible state to a later, immunized, and arguably less disease-susceptible state. But the claim stopped with the “comparing...” step and did not include any further steps that could be viewed as transformative.

Some partial comfort might be drawn from the fact that the claim in the ‘283 Patent was clearly **not directed to immunizing mammals** – it was directed to the notion of “determining whether an immunization schedule affects the ... disorder.” This claim thus clearly lacked any readily identifiable transformative effect, as the potential beneficial effort of the alleged invention is assessment of an immunization schedule, not facilitation of a treatment itself.

Perhaps (and this is the author’s speculation), the *Classen* invention would have more likely survived the subject-matter validity challenge if it included steps designed to be transformative on the state of mammals from unimmunized to immunized. Or perhaps (and again speculation), had the inventor further studied the various markers recited in the claim and determined some modification of the immunization schedule, and had that modification resulted in a measurable improvement in the disease incidence of the treatment group of mammals, the patentable subject matter challenge would have been a closer question.

The claims in the *Classen* case are similar to those addressed in a 2006 U.S. Supreme Court decision of *Laboratory Corp. of America (LabCorp) v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006). That case revolved around claim 13 of Metabolite’s U.S. Patent No. 4,940,658:

13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
  - assaying a body fluid for an elevated level of total homocysteine; and
  - correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

The question presented in that case was as follows: Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to “correlat[e]” test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor

necessarily infringes the patent merely by thinking about the relationship after looking at a test result? The Supreme Court did not reach this question on the merits and dismissed a petition for certiorari on procedural grounds. But three justices in a dissenting opinion, led by Justice Breyer, would have heard the case and would have found the patent invalid:

There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a “natural phenomenon.” . . . [The claimed] process instructs the user to (1) obtain test results and (2) think about them. . . . At most, respondents have simply described the natural law at issue in the abstract patent language of a “process.” But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge.

The dissent in the *LabCorp* case also took shots at the *State Street Bank* decision that started the business method patent craze, and arguably influenced the CAFC to some degree in its *In re Bilski* ruling.

These rulings raise questions about the viability of patents that involve medical procedures and patents that are not tied closely to particular machines (such as particular medical devices) or clearly result in some kind of tangible, visible, measurable transformation. One particular question from the *Classen* case is whether a patient (a mammal) that receives immunizations according to a schedule would not be considered a transformation of an article (a mammal) from one state (unimmunized) to another state (immunized)? Is a mammal or other biological entity not considered an “article” that can be transformed by a method? But note carefully – the claim did not recite that any animals in the treatment group were transformed by the immunization.

Moreover, certain medical diagnosis procedures, such as early diagnosis of cancer by detection of tumor markers, are not clearly “tied to a particular machine or apparatus” nor do they “transform a particular article into a different state or thing.” There are hundreds of patents directed to these procedures. Will diagnosis procedure patents be held invalid based on the *LabCorp*, *Classen*, and *In re Bilski* cases?

Another case working its way through the CAFC may provide some more answers soon. The case of *Prometheus Laboratories, Inc. v. Mayo Collaborative Services and Mayo Clinic Rochester*, Case No. 2008-1403 (CAFC), involves the following medical treatment procedure claim:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining a level of 6-thioguanine or 6-methyl-mercaptopurine in said subject having said immune-mediated gastrointestinal disorder,

wherein a level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein a level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells or a level of 6-methyl-mercaptopurine greater than about 7000 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug.

Note that this claim recites “determining a level” of a substance as its final step, which does not immediately seem to involve either a distinct transformation or a particular machine.

The district court in this case relied heavily upon the dissent in the *LabCorp* case in finding no patentable subject matter. The American Intellectual Property Law Association (AIPLA) has filed an *amicus* brief in this case urging the CAFC to not proscribe patents for the entire field of biomedical diagnostic tools. It is widely accepted that such tools are very important in medicine and that the courts should not remove the incentives to innovate in this area. (The case is still in the briefing stage as of this writing.)



It is apparent that the Supreme Court and the CAFC are in a mood to more closely scrutinize any kind of process patent for patentable subject matter. Claims of already-issued patents that do not readily satisfy the “machine-or-transformation” test are now at greater risk of being held invalid if an attempt is made to enforce them. Companies in the medical procedures fields that are seeking patents may want to re-examine their patent filings and, in the right case, file amended claim sets or reissue applications.

If you have questions about the *Classen* decision, the *LabCorp* decision, the *In re Bilski* decision, medical procedures or diagnostics patents, medical devices patents, patent application writing, patent enforceability, or other issues involved in the patent system, please contact either of the following attorneys:

**John R. Harris**, Author and Editor ([jrh@mmmlaw.com](mailto:jrh@mmmlaw.com)) 404.504.7720

**Ping Wang, M.D.**, Partner, Editor ([pwang@mmmlaw.com](mailto:pwang@mmmlaw.com)) 202.842.0217

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1600 Atlanta Financial Center - 3343 Peachtree Road, NE - Atlanta GA 30326 - 404.233.7000

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