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## Federal Circuit Addresses Patentability Of “Personalized Medicine” Claims

**Holds that claims requiring assay of specimen satisfy *Bilski*'s “machine or transformation” test even if they do not recite particular assay method or instrument**

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In its first precedential opinion applying the “machine or transformation” test of *In re Bilski* to claims directed to methods of treating patients, the Federal Circuit held that steps implicitly requiring the assay of specimens are sufficiently transformative even if they do not require use of any particular instrument or assay method.

The patents at issue in *Prometheus Laboratories v. Mayo Collaborative Services* concerned methods for optimizing the dosage of certain drugs based on the results of blood tests. Some claims incorporated the step of administering the recited drugs to patients, but others omitted any such requirement and were directed to interpreting the results of unspecified tests that measured the amount of metabolite in the bloodstream. Exemplary claims of both types from U.S. Patent 6,355,623 are reproduced below:

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 the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

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

46. A method of optimizing therapeutic efficacy and reducing toxicity associated with treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) determining the level of 6-thioguanine or 6-methylmercaptopurine in a subject administered a drug selected from the group consisting of 6-mercaptopurine, azathioprine, 6-thioguanine, and 6-methylmercaptopurine, said subject having said immune-mediated gastrointestinal disorder;

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

The district court held the claims invalid as having been drawn to unpatentable subject matter under 35 U.S.C. § 101, writing that they “recite a natural phenomenon—the correlations between thiopurine drug metabolite levels and therapeutic efficacy and/or toxicity—and . . . ‘wholly pre-empt’ use of said correlations.” Its decision referred to a 2006 dissent from the Supreme Court’s dismissal of certiorari in the *Lab Corp. v. Metabolite* case, in which Justice Breyer, joined by Justices Stevens and Souter, wrote that diagnostic claims to correlating homocysteine levels in the blood with vitamin deficiency were unpatentable under § 101 as drawn to a “natural phenomenon.”

After the district court’s judgment that Prometheus’ claims were invalid, the Federal Circuit issued its en banc opinion in *Bilski*, articulating what it characterized as the “definitive test” for patent-eligibility of processes under § 101. The court held that patentability is limited to claims that are “tied to a particular machine or apparatus” or that transform “a particular article into a different state or thing.” Further explaining this “machine-or-transformation” test, *Bilski* also required that the machine or transformation impose meaningful limits on the

claims' scope, be central to the purpose of the claimed process (not merely "insignificant extra-resolution activity"), and not preempt substantially all uses of a fundamental principle.<sup>1</sup>

Although the claims at issue in *Bilski* were of the type commonly known as "business methods," the Federal Circuit's decision set forth a general rule of patent-eligibility applicable to all fields of art. Accordingly, the decision raised questions (and created some apprehension) in other areas, including medical diagnostics and personalized medicine, in which patents are sometimes (as in the *Prometheus* case) drawn to methods of making decisions based on acquired data. Uncertainty existed if claims not expressly limited to use of a particular assay or instrument would be unpatentable under *Bilski* as not "tied to a particular machine or apparatus" and not operating to "transform[] a particular article into a different state or thing." The importance of this issue is perhaps suggested by the submission of *amicus* briefs in *Prometheus* by Novartis, Myriad Genetics, the Biotechnology Industry Organization (BIO), and others.

Reversing the district court's judgment of invalidity, the Federal Circuit held that *Prometheus*' claims were drawn to patentable subject matter under § 101, rejecting Mayo's arguments (which had been accepted by the district court) that they were directed to correlations that are natural phenomena, with the "administering" and "determining" elements mere data-gathering steps that could not confer patentability.

With respect to claims that recited the administration of specified drugs, the Federal Circuit held that such activities are transformative of the human body and thus satisfy *Bilski*'s requirement of a "transformation" of matter:

[T]he methods of treatment claimed in the patents in suit squarely fall within the realm of patentable subject matter because they

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<sup>1</sup> The Supreme Court granted cert in *Bilski*; oral argument is scheduled for November 9, 2009.

"transform an article into a different state or thing," and this transformation is "central to the purpose of the claimed process." The transformation is 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 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. (emphasis added; citations omitted)

As can be seen from this explanation, the decision squarely holds that method-of-treatment claims are *per se* eligible for patent protection under § 101 when they require administration of a "defined group of drugs."

The court further held, with respect to claims that did *not* include the administration of drugs (such as claim 46 above), that the step of "determining" the amount of drug or metabolite in the blood was sufficiently transformative because it requires the transformation of a specimen and provides information that cannot be determined by mere inspection. It explained that omission of a step reciting administration of a drug

[D]oes not diminish the patentability of the claimed methods because the determining step, which is present in each of the asserted claims, is also transformative and central to the claimed methods. Determining the levels of [drug metabolites] in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection.

Because the court concluded that the claims satisfied the "transformation" test of *Bilski*, it did not address their compliance with the alternative "machine" test.

Reaching the next part of the *Bilski* standard, which asks if the machine or transformation is central to the claimed purpose, the Federal Circuit

determined that the transformative steps of “administering” the drug or “determining” its level in the blood were “central to the claims rather than merely insignificant extra-solution activity” because they were not “merely” for the purpose of gathering data, but instead part of a transformative treatment protocol. In this regard, it rejected the proposition that the additional recitation of mental steps (using the result of the blood test to adjust the dose of drug) that are themselves not patent-eligible negated the transformative nature of the prior steps and thereby defeated patentability of the claims as a whole.

The Federal Circuit’s discussion of *Lab Corp.* was limited to a footnote, which stated that the dissent in that case was not precedent. Although the court further stated that the claims at issue in that case were different, it did not expressly distinguish them from those of the *Prometheus* patents or explain what differences, if any, would be of importance to the § 101 inquiry. For reference, the claim at issue in the *Lab Corp.* case reads as follows:

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. [U.S. Patent 4,940,658]

Similar to claim 46 of the *Prometheus* patent, that claim includes a “determining” step (here called “assaying”) and a mental-process step, but does not require the administration of any specific drug. Unlike claim 46, which recites in its preamble that the claimed method is one of “optimizing therapeutic efficacy,” the claim in *Lab Corp.* does not recite in its preamble any necessary action, such as correcting the vitamin

deficiency by administering a supplement. It remains to be seen if such difference is of significance to the question of patentability, but the *Prometheus* opinion suggests, with its statement that “[t]he invention’s purpose to treat the human body is made clear in the specification and the preambles of the asserted claims,” that this difference may be significant. (And of course, a construction of the preamble of claim 46 as a limitation could have a substantial effect on the question of infringement.)

Because the district court’s judgment of invalidity rested only on § 101, the Federal Circuit did not address other potential grounds of invalidity, such as noncompliance with the requirements of § 112 or obviousness in light of the prior art. Absent settlement by the parties or modification of the Federal Circuit’s decision in further appellate litigation (reconsideration at the Federal Circuit or review by the Supreme Court), those issues will presumably be litigated on remand.

### Case citations:

*In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008)

*Laboratory Corp. of Am. v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting from dismissal of certiorari)

*Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 2008-1403 (Fed. Cir. Sept. 16, 2009)