

**Keywords:** patentable subject matter; transformation; method of treatment

**General:** The Federal Circuit holds that “method of treatment” claims are patentable under the *Bilski* machine-or-transformation test because the administration of a drug to a person results in a transformation of a human body.

*Prometheus Labs. Inc. v. Mayo Collaborative Services*  
92 U.S.P.Q.2d 1075 (Fed. Cir. 2009)  
Decided September 16, 2009

## I. Facts

Prometheus is the sole exclusive licensee of the ‘623 and ‘302 patents, which are generally directed to calibration of proper dosages of thiopurine drugs for treatment of various autoimmune diseases. Following administration, these drugs are broken down by the body into various metabolites. As various patients may metabolize such drugs differently, issues of non-responsiveness and drug toxicity may arise in some cases. The patents at issue claim methods for optimizing therapeutic efficacy of such drugs by administering a drug to a subject and determining the level of the drug in the subject. Claim 1 of the ‘623 patent is representative:

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.

Prometheus marketed a clinical test that used the technology covered by the patents at issue. Mayo purchased and used the Prometheus tests for some time, but then announced its intention to develop and sell its own test. Mayo’s test measured the same metabolites, but used different threshold levels to determine toxicity.

Following Mayo’s announcement, Prometheus sued Mayo for infringement of the patents. The district court granted summary judgment of infringement to Prometheus. In its opinion, the district court construed the term “indicates a need” to mean “a warning that an adjustment in dosage may be required.” The court also held that this construction did not require that a doctor actually adjust the dosage in view of such warning.

Subsequently, Mayo moved for summary judgment of invalidity, arguing that the claims recited unpatentable subject matter under 35 U.S.C. § 101. In particular, Mayo argued that the patents

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improperly claimed natural phenomena (i.e., correlations between drug metabolite levels and efficacy/toxicity) and that the claims wholly preempt use of the natural phenomena.

The district court granted summary judgment to Mayo on the invalidity issue. The district court reasoned that, as construed in the summary judgment order of infringement, the claims included three steps: (1) administer the drug, (2) determine metabolite levels, and (3) be warned that an adjustment in dosage may be required. The district court also held that the “administering” and “determining” steps are merely necessary data-gathering steps for use of the correlations, and that the “warning” step is only a mental step in that the measured metabolite levels themselves “warn” the doctor of a potential need to adjust dosage levels. On this basis, the district court concluded that the claims recite the correlations between particular concentrations of the recited metabolites and efficacy/toxicity in patients.

The district court also found that these correlations were natural phenomenon—resulting from natural body processes—and that the inventors merely observed the relationship between metabolite levels and therapeutic efficacy and toxicity. Consequently, the district court concluded that because the claims cover the correlations themselves, the claims wholly-preempt use of the correlations. Prometheus appealed the district court’s grant of summary judgment of invalidity under 35 U.S.C. § 101.

## II. Issue

Did the district court err in holding that the claims were not directed to statutory subject matter and in granting summary judgment of invalidity to Mayo?

## III. Discussion

Yes. According to the test articulated by the Federal Circuit in *Bilski*, a method is patent-eligible under 35 U.S.C. § 101 if it is tied to a particular machine or apparatus, or if it transforms a particular article into a different state or thing. Further, the *Bilski* court held that, to impart patent-eligibility, “the use of a specific machine or transformation of an article must impose meaningful limits on the claim’s scope,” and “the involvement of the machine or transformation in the claimed process must not merely be insignificant extra-solution activity.” Rather, “[t]his transformation must be central to the purpose of the claimed process.”

While refusing to address many of the contentions advanced by Prometheus in support of the patent-eligibility of the claims at issue, the Federal Circuit found that each of the administering and determining steps is transformative. Particularly, the Federal Circuit concluded that “the transformation is of the human body following administration of the drug and the various chemical and physical changes of the drug’s metabolites that enable their concentrations to be determined.” The Federal Circuit further noted that the 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.”

With respect to the administration step, the Federal Circuit noted that administered drugs do not pass through a human body without affecting the body, and that this transformation (i.e., the effect on the body) is “the entire purpose” of administering the drugs. Regarding the determining step, the court concluded: (1) that the metabolite levels could not be determined by mere inspection; (2) that some form of manipulation (e.g., high pressure liquid chromatography) is required to extract the metabolites from a bodily sample to determine their concentration; (3) that this manipulation results in a transformation of the bodily sample; and (4) that this transformation is central to the

purpose of the claims because the determining step is a significant part of the claimed method of treatment.

Because these steps are transformative and central to the claims, the court held that the administering and determining steps are not merely data-gathering steps or insignificant extra-solution activity. Further, although agreeing that the “wherein” clauses are mental steps, the Federal Circuit noted that the presence of such mental steps does not negate the transformative nature of the other steps in the claims. Consequently, the Federal Circuit held that the claimed methods satisfy all of the requirements under *Bilski’s* transformation prong for subject matter eligibility under 35 U.S.C. § 101.