In a decision issued prior to the Supreme Court’s ruling in *Bilski v. Kappos*, the Federal Circuit reversed the district court’s determination that Prometheus’ asserted claims were directed to non-statutory subject matter. See *Prometheus Laboratories, Inc. v. Mayo Collaborative Services (2009)* (Prometheus I). In Prometheus I, the Federal Circuit panel relied on its own rationale in *In re Bilski* to conclude that Prometheus’ asserted claims met the machine-or-transformation test, which the Federal Circuit characterized as the “definitive test for determining the patentability of a process under § 101.” In *Bilski*, however, the Supreme Court ruled that though the machine-or-transformation test can serve as a “useful and important clue” and “an investigative tool,” it is not the “sole” test for determining the patent eligibility of process claims. Accordingly, on the day after handing down the *Bilski* decision, the Supreme Court vacated and remanded Prometheus I for reconsideration in light of *Bilski*.

In an opinion that largely mirrors its previous decision in Prometheus I, the Federal Circuit last month reaffirmed the ultimate conclusion that Prometheus’ claims are directed to patent eligible subject matter under 35 U.S.C. § 101. See *Prometheus Laboratories, Inc. v. Mayo Collaborative Services (2010)* (Prometheus II).

The asserted claims in *Prometheus I and II* are directed to methods that seek to optimize the therapeutic efficacy of thiopurine drugs such as 6-MP and AZA while minimizing their toxic side effects. The claimed methods typically include two distinct steps: (a) “administering” a thiopurine drug that can be metabolized in a subject, and (b) “determining” the levels of the drug’s metabolites in the subject. The measured metabolite levels can then be compared to pre-determined metabolite levels, “wherein” the measured metabolite levels “indicate a need” to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize treatment efficacy. Several of the asserted claims recite only the “determining” step.

On remand, the Federal Circuit limited briefing to the effect of *Bilski* on the Federal Circuit’s previous ruling in Prometheus I. Regarding *Bilski*, Prometheus argued that the Supreme Court did not overrule the long-established view that claims that satisfy the machine-or-transformation test necessarily satisfy Section 101. Rather, *Bilski* only stands for the proposition that claims that do *not* satisfy the machine-or-transformation test are *not* necessarily non-patentable. Mayo, on the other hand, argued that the Supreme Court reaffirmed that “preemption” is the controlling standard for Section 101. That is, claims that wholly preempt all practical use of naturally occurring correlations (e.g., between metabolite levels and drug efficacy or toxicity) are invalid.

The Federal Circuit disagreed with Mayo that the Supreme Court’s *Bilski* decision dictated a wholly different analysis or result. Rather, because the “administering” and “determining” steps are both transformative within the meaning of the machine-or-transformation test (albeit as an “investigative tool” rather than as a “definitive” test), the Federal
Circuit arrived at the identical “clear and compelling conclusion” as in *Prometheus I* that the asserted claims comply with Section 101. Regarding the “administering” step, the transformation is of the human body and its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs’ metabolites that enable their concentrations to be determined. “The fact that the change of the administered drug into its metabolites relies on natural processes does not disqualify the administering step from the realm of patentability” as administering the drug itself is not a natural process. Regarding the “determining” step, the Federal Circuit reaffirmed that “[s]ome form of manipulation, such as the high pressure liquid chromatography method…, is necessary to extract the metabolites from a bodily sample and determine their concentration.” Though Mayo further argued that each of these are merely data-gathering steps for use of the correlations, the Federal Circuit concluded that the transformations are central to the method of treatment because measuring the levels of metabolites of administered drugs is what enables dosage adjustments to optimize efficacy or reduce toxicity during a course of treatment. Finally, the Federal Circuit reaffirmed that though the final “wherein” clauses of the asserted claims are mental steps that are not patent-eligible on their own, a subsequent mental step does not, by itself, negate the transformative nature of prior steps.

In *Prometheus II*, the Federal Circuit also concluded that the *Bilski* decision did not undermine its previous preemption analysis. As before, the Federal Circuit held that Prometheus’ claims are drawn to a particular application of a naturally occurring phenomenon and not to a law of nature itself. That is, the claimed steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites. As such, the asserted claims do not preempt all uses of the natural correlation between metabolite levels and drug efficacy or toxicity, but rather utilize them in a series of specific steps. See also *Diamond v. Diehr* (“Their process admittedly employs a well-known mathematical equation, but they do not seek to preempt the use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.”).

Like *Bilski*, the decision by the Federal Circuit in *Prometheus II* does little to shed light on the bounds of patent-eligible subject matter, especially with regards to business methods *per se*. Nonetheless, because the Federal Circuit continues to rely on the machine-or-transformation test as a “useful and important clue” in determining compliance with 35 U.S.C. § 101, applicants who draft claims to meet this test may continue to have a safe harbor.

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