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The Machine-Or-Transformation Test Reaffirmed As Useful And Important

In *Prometheus v. Mayo Collaborative* (2008-1403, Fed. Cir., Dec. 17, 2010)("*Prometheus II*"), the Federal Circuit has, on remand from the Supreme Court, again found Prometheus' claims directed to methods of treating the human body with medication to be patent-eligible subject matter. In August, the Federal Circuit noted that the Supreme Court had rejected the exclusive nature of the Machine-or-Transformation test, but *not* the wisdom behind it. *King Pharms. v. Eon* Labs, 616 F.3d 1267 (Fed. Cir., Aug. 2, 2010)(citing *Bilski v. Kappos*, 130 S. Ct. 3218 (U.S. 2010)("*Bilski II*")). Referencing its earlier decision in *Prometheus v. Mayo Collaborative*, 581 F.3d 1336 (Fed. Cir. 2009)("*Prometheus I")*, *vacated and remanded*, 130 S. Ct. 3543 (2010), the Federal Circuit noted in *King Pharmaceuticals* that "methods of treatment 'are always transformative when a defined group of drugs is administered to the body to ameliorate the effects of an undesired condition,' because such methods transform the human body." *King*, 616 F.3d at 1277. Thus, *Prometheus II* was almost a foregone conclusion. Though the result comes as no surprise to those who watch the Federal Circuit closely, the way the Federal Circuit reached its result does hold some interest.

Background

Prometheus, the sole and exclusive licensee of the litigated patents, claiming "a method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder," marketed a test package covered by the patents-in-suit. Mayo formerly purchased and used Prometheus' package but, in 2004, decided to venture out on its own, i.e., to infringe the patents. Prometheus filed suit in 2004, and in 2008 the district court granted Mayo summary judgment of invalidity based on a conclusion that the claims were directed to ineligible subject matter. On appeal, the Federal Circuit reversed and upheld validity under the Machine-or-Transformation test because, as indicated, the Court concluded that all methods of treatment of the human body are transformative. The Supreme Court issued its *Bilski* decision on June 28 and vacated and remanded *Prometheus I* on June 29.

The Machine-or-Transformation Test Remains Useful and Important

In taking another look at the facts in view of the Supreme Court's *Bilski II* decision, the Federal Circuit noted that patent eligibility turns on whether "asserted claims are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in *Benson* or *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*." (Slip op. at 13.) This is because "laws of nature, physical phenomena, and abstract ideas" are not patent eligible. Regarding the usefulness of the Machine-or-Transformation test, however, the Federal Circuit noted, as it had in *King*, that *Bilski* "did not disavow the Machine-or-Transformation test." Rather, the Machine-or-Transformation test remains a "useful and important clue, an investigative tool" in the analysis as to whether claimed subject matter is patent eligible.

Claims Directed to a Medical Treatment Are Transformative

In *Prometheus II*, the Federal Circuit determined that "neither the Supreme Court's *Bilski* decision nor the Court's GVR Order [vacating and remanding *Prometheus I*] compels a different outcome on remand, and [we therefore again] reverse the district court's judgment of invalidity under ? 101." As applied to the claims at issue, the Federal Circuit found that the Machine-or-Transformation test "leads to a clear and compelling conclusion, *viz*., that the present claims pass muster under ? 101." The Court determined that the claims "do not encompass laws of nature or preempt natural correlations," because the claims are directed to a specific method of treatment, where the claimed steps "involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs..." The claimed transformation was found to

satisfy the Machine-or-Transformation test because "[t]he transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes" of the drugs. Stated another way, the Court found that what "is clearly a transformation" is that "at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue." Even more generally, the Court quoted its own decision in *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008)("*Bilski I*")(affirmed by *Bilski II*), by asserting that "[i]t is virtually self-evident that a process for a chemical or physical transformation of *physical objects or substances* is patent-eligible subject matter."

Reference to *In re Abele*

You may recall that the Federal Circuit held in *Bilski I* that the so-called *Freeman-Walter-Abele* test for determining patent eligibility was inadequate. In a footnote, *Bilski I* stated that "portions [of prior decisions] relying solely on the *Freeman-Walter-Abele* test should no longer be relied on." Therefore, it came as a bit of a surprise that the Federal Circuit in *Prometheus II* compared the facts before it with those in *In re Abele,* 684 F.2d 902 (CCPA 1982), which held that a method of displaying X-ray attenuation data was patent eligible. The point of the comparison, however, is that a claim as a whole should be considered for patent eligibility; the recitation of algorithms and mental thoughts in a claim does not render ineligible an otherwise eligible claim. In holding the claims in *Prometheus II* patent eligible, the Federal Circuit determined that its current analysis "is consistent with *In re Abele."*

What This Means to You

Less than six months after *Bilski II*, it seems clear, as most predicted immediately in its wake, that the Supreme Court's decision was hardly seismic in its effects. *Prometheus II* now makes clear that even *Bilski I* and *Bilski II*, taken together, have hardly altered the basic modes of analysis of claims for patent eligibility. The determination of whether a claim is directed to patent-eligible subject matter questions whether a natural phenomenon is claimed, "the patenting of which would entirely preempt its use as in *Benson* or *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr.*" While not an exclusive test, the Machine-or-Transformation test remains important in making such a determination. Similarly, while it is improper to rely solely on the *Freeman-Walter-Abele* test, those cases, too, remain relevant touchstones.

More practically?- and of particular interest to the pharmaceutical industry?- *Prometheus II* makes crystal clear that methods of treatment of the human body with medication are indeed patent eligible. Whether you are a patent owner seeking to enforce your rights or a party accused of infringing the rights of others, we can help you assess the strength of the intellectual property at stake in view of this ever-developing body of law.