

IP Bulletin

Supreme Court Applies “Machine-or-Transformation Test” to Diagnostic Patents

On March 20, 2012, the Supreme Court unanimously ruled in *Mayo Collaborative Services v. Prometheus Laboratories Inc.* that a method for adjusting a drug dosage after observing a patient’s reaction to a drug administration was patent-ineligible subject matter under 35 U.S.C. § 101. The Supreme Court overturned the US Court of Appeals for the Federal Circuit and ruled that two patents owned by Prometheus are invalid because they covered naturally occurring phenomena.

Prometheus is the exclusive licensee of two patents that involve measuring the level of certain metabolites in the blood of patients taking thiopurine drugs for treatment of autoimmune diseases. The claimed method of invalidated claim 1 of US Patent No. 6,355,623 relates to optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder comprising administering a drug providing 6-thioguanine to a subject having an immune-mediated gastrointestinal disorder and determining the level of 6-thioguanine in the subject. The wherein clauses of claim 1 indicate that the levels of 6-thioguanine are indicative as to whether the dosage of the 6-thioguanine drug needs to be increased or decreased.

Prometheus sued Mayo for patent infringement and alleged that Mayo’s tests measuring 6-thioguanine infringe the patents. In 2009, the Federal Circuit overturned a lower court’s finding of patent ineligibility. The Federal Circuit held that the claims met the transformation prong of the machine-or-transformation test, which the Supreme Court held to be a valuable tool, but not determinative in *Bilski v. Kappos*. The machine-or-transformation test is a test of patent eligibility under which a claim to a process qualifies to be considered for patenting if it is implemented with a particular machine or else transforms an article from one thing or state to another.

On the day after the *Bilski* decision issued, the Supreme Court remanded two biotech cases in view of its decision, including the *Prometheus* case, to the Federal Circuit for reconsideration in light of the *Bilski* decision. On remand, the Federal Circuit confirmed the patentability of the disputed claims.

In its decision, the Supreme Court identified correlating 6-thioguanine levels and drug dosage levels to be an unpatentable law of nature. The Supreme Court believed the correlation between 6-thioguanine blood levels and its dosage to be a consequence of the metabolism of thiopurine compounds in the human body, in other words, a natural occurrence. The Supreme Court further opined that any physical and transformative elements of the invention were routine and insufficient to transform an unpatentable law of nature into patent-eligible subject matter.

It seems that the *Prometheus* decision is consistent with the Supreme Court’s previous holding in *Bilski*, with respect to the machine-or-transformation test as well as the recent Federal Circuit decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* In particular, the Federal Circuit held in *Myriad* that method claims directed to only “comparing” or “analyzing” DNA sequences are patent ineligible because they have no transformative steps and cover only patent-ineligible abstract, mental steps.

What ramifications does this decision have for diagnostic patents? Unfortunately, diagnostic gene patents were already under scrutiny in view of *Bilski* and *Myriad*. The *Prometheus* decision does not necessarily signal the end of personalized medicine patents. Rather, the decision affirms previous holdings regarding the importance of the machine-or-transformation test and further clarifies the nature of patent-eligible subject matter.

The US Patent and Trademark Office recently issued a memorandum to patent examiner as to how to apply the ruling to top ending patent applications.

For now, diagnostic companies may wish to ensure that their patent claims directed to methods involving “analyzing” or “comparing” samples include a transformation step that complies with the machine-or-transformation test.

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