



PHARMACEUTICALS EXPORT PROMOTION COUNCIL
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Dated: 20th June, 2011

Supreme Court Grants Cert. In Mayo v. Prometheus

Today, in what may be an ominous turn for biotech IP law, the Supreme Court granted cert. for the second time in Mayo Collaborative Services v. Prometheus Labs., Inc, Supreme Court No. 10-1150. Post-Bilski, the Supreme Court granted cert., vacated and remanded the Fed. Cir.'s decision, rendered December 17, 2010, (related posts are archived under "patentable subject matter") that reaffirmed that claims involving methods of medical treatment coupled with determining the levels of metabolites of the administered drugs were directed to patentable subject matter, and were not directed to abstract ideas or phenomena of nature. 628 F.3d 1347 (Fed. Cir. 2010).

Is it pay-back time? In the decision below, the Fed. Cir. pointedly in fn. 2, declined to give weight to the "Metabolite Labs. dissent," 548 U.S. 124) in which Justices Breyer, Souter and Stevens would have found claims to an assay for cobalamin deficiency patent-ineligible as involving "natural correlations and data-gathering steps." The Prometheus claims are not without vulnerable points. The Fed. Cir. agreed that the steps recited comparing the determined level of the metabolite to a benchmark level and concluding that a need exists to increase or decrease the amount of the drug administered were mental steps and not per se patentable. The Fed. Cir. also held that the first steps of the claims – the administering and determining steps – were not merely data gathering steps, but were central to the claimed method of optimizing therapeutic efficacy of the treatment.

While two of the three Justices who wrote the Metabolite dissent have retired, the Court clearly feels that there are issues here that need resolution. However, it is difficult to see how "methods of medical treatment" could remain patentable subject matter if these claims are held not to be. While processes are s. 101 patentable subject matter, John L. White's Chemical Patent Practice (1993) felt it necessary to include a section "Process of Treating Humans." Paragraph three



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begins:

“Claims to the treatment of humans medicinally are now allowed. Ex parte Timmis (POBA 1959) 123 USPQ 581 (treatment of chronic myeloid leukemia). The fact the claimed process for modifying a function of the human body (combating the clotting of blood) involves a mental determination of the amount administered is not a bar to patentability where that portion is an incidental feature of the process. Ex parte Campbell et al., (POBA 1952) 99 USPA 51.”

These decisions are from the nineteen fifties not the eighteen fifties! In Prometheus, the Fed. Cir. explicitly noted that claims to methods of medical treatment are patentable subject matter. Are modern medicine and IP law about to part ways?

Source: Patents4Life