Greenblum & Bernstein, P.L.C.
CLIENT ADVISORY
Recent Changes in Rules and Procedures

March 20, 2012

Supreme Court Rules Prometheus Patents Invalid

Dear Clients:

In a long-awaited decision, the United States Supreme Court ruled today, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (Case No. 10-1150), that claims for measuring patient drug levels and correlating those levels with a need to adjust dosage, is unpatentable subject matter tantamount to an attempt to patent a law of nature.

A representative claim from Prometheus's U.S. Patent No. 6,355,623, is provided in paraphrased form below:

> A method of optimizing a drug therapy comprising:
> (a) administering a drug to a subject; and
> (b) determining the level of a drug metabolite in the subject;
> wherein low levels of the metabolite indicate a need to increase dosage; and wherein high levels of the metabolite indicate a need to decrease dosage.

As can be seen, the claim requires administering the drug to a subject (which is known in the prior art), determining the blood level of the drug in the subject (also known in the prior art), and then establishing a correlation without actually requiring and adjustment to the dosage.

The District (trial level) Court had granted summary judgment of invalidity, holding that the Prometheus patents at issue effectively claim natural laws or natural phenomena, and as such were not patentable.

On appeal, however, the Federal Circuit reversed the lower court decision, stating that in addition to these natural correlations, the claimed processes specify the steps of (1) "administering a [thiopurine] drug" to a patient and (2) "determining the [resulting metabolite] level." The Federal Circuit explained that these steps involve the transformation of the human body or of blood taken from the body, thus, satisfying the "machine or transformation test," and therefore constituted patentable subject matter under §101.

Mayo requested and received Supreme Court review of the Federal Circuit decision.

In today's ruling, the Supreme Court noted that the patent claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful

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side-effects.

However, the Supreme Court held that the process claims at issue were not patentable because the steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. The Supreme Court further noted that "upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries."

With today's decision, the Supreme Court clarified what it means to attempt to patent laws of nature.

Should you have any questions or comments, please do not hesitate to contact us.

Best regards,

GREENBLUM & BERNSTEIN, P.L.C.