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***Mayo Collaborative Services v. Prometheus Labs., Inc.:* U.S. Supreme Court Finds Prometheus Method Claims Unpatentable as Laws of Nature**

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In an opinion published today, the Supreme Court unanimously held that claims directed to the relationship between the concentrations of blood metabolites and response to a therapeutic drug in two patents owned by Prometheus Laboratories, Inc. were unpatentable, stating that they "effectively claim the underlying laws of nature themselves." This is a reversal of the Federal Circuit's decision which held that the claims did indeed encompass patentable subject matter.

Prometheus Laboratories, Inc. (Prometheus) is the sole licensee of two patents (U.S. Patent Nos. 6,355,623 and 6,680,302) claiming methods for determining optimal dosages of thiopurine drugs used to treat gastrointestinal and non-gastrointestinal autoimmune diseases. The patents generally claim methods reciting the steps of: (a) administering a thiopurine drug to a subject, and (b) determining the levels of the drug or the drug's metabolites in red blood cells in the subject. The measured metabolite levels are then compared to pre-determined metabolite levels, wherein measured metabolite levels in the patient that are outside the pre-determined range indicate a need to increase or decrease the level of drug to be administered so as to minimize toxicity and maximize treatment efficacy.

The Court sought to determine whether the claims did more than merely describe laws of nature. It asked specifically, "do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws?" The Court generally focused its analysis on two specific cases: *Diamond v. Diehr*, 450 U.S. 175 (1981) (granting claims which encompassed natural phenomena) and *Parker v. Flook*, 437 U.S. 854 (1978) (invalidating claims encompassing natural phenomena). In

analogizing the Prometheus claims to those in *Flook*, the Court stated that the steps recited in the claimed method "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field" and thus, the claims encompassed non-patentable subject matter.

The general message conveyed by the Court seems to be two-fold. First, if "the steps in [a] claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field," the claim likely encompasses non-patentable subject matter. And second, they demonstrated general concern 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." How this message affects the thousands of existing patents in the field of personal medicine remains to be seen. However, going forward, patent practitioners would be wise to revisit this ruling when drafting claims to medical diagnostic methods.

We will provide a more detailed analysis of this decision in a future edition of *snippets*.

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