

## Intellectual Property Client Service Group

To: Our Clients and Friends

March 26, 2012

### Supreme Court Defines The Boundary Between Patentable Subject Matter And Non-Patentable “Laws Of Nature”

In a unanimous decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Court held that a process of determining proper drug dosage was not patentable, because it did not provide sufficient “inventive concept” above and beyond the underlying law of nature.

Prometheus was the exclusive licensee of a patent (“Prometheus patent”) that claimed a process for determining the proper dosage of thiopurine drugs for the treatment of certain diseases. If the dose is too high, toxicity results. If the dose is too low, efficacy suffers. To determine whether a dose is too high or too low, the concentration of a metabolite of the drug (i.e., a composition produced by the body when the drug is metabolized) may be determined and compared to certain standards. The claims of the Prometheus patent recite an administering step (the drug is administered to a patient), a determining step (the concentration of the metabolite is determined) and a “wherein” step describing the metabolite concentration below which there is “a need to increase the amount of said drug administered,” and a metabolite concentration above which there is “a need to decrease the amount of said drug subsequently administered.”

Mayo sparked the underlying dispute by announcing that it intended to begin marketing and selling its own version of the test. Prometheus sued for patent infringement. The District Court found the Prometheus patent invalid because it claimed unpatentable natural phenomena: the relationship between “concentrations of certain metabolites in the blood and the likelihood that a dosage of the thiopurine drug will prove ineffective or cause harm.” Relying upon a “machine or transformation” test to identify patentable subject matter, the Federal Circuit reversed.

Supreme Court precedent has held that while laws of nature are not patentable under 35 U.S.C. §101, the application of a law of nature can be patentable. For an application of a law of nature to be patentable, however, “one must do more than simply state the law of nature while adding the words “apply it.” The relevant question, therefore, is whether 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.”

To determine whether the Prometheus patent added “enough” to the underlying law of nature, the Court considered three principles: 1) patent eligibility should take into account the principles underlying the prohibition of patents on natural laws, and should not depend entirely on the skill of the individual drafting the claim, 2) courts should not uphold patents that “claim processes that too broadly preempt the use of a natural law,” and 3) a process patent that is based on a natural law must contain an additional “inventive concept,” such that the resulting patent does not amount to a patent on the natural law itself. The Court described the first step of the Prometheus patent claims, administration of the drugs, as a simple reference to the relevant audience. The second step, determining the level of metabolites in the bloodstream of the patient, was well-understood, routine and conventional activity for scientists in the field. The “wherein” step, the relationship of metabolite levels to dosage of thiopurine, was merely a description of the natural laws, “at most adding a suggestion that [the doctor] should take those laws into account when treating his patient.”

The Court held that the steps in the claimed processes consisted of “instructions [that] 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.” Furthermore, allowing such a patent to stand would “risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”

The United States (“Government”) filed an *amicus curiae* brief in *Prometheus*, arguing that almost any step beyond the mere recitation of a law of nature should be sufficient to create patentable subject matter. The Government asserted that the other sections of the Patent Act, namely the novelty, non-obviousness, and written description requirements, are sufficient to screen for patentability. The Court acknowledged that the § 101 patentable subject matter inquiry may overlap with other sections of the Patent Act, but was not willing to adopt the Government’s position. The Court worried that “to shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.”

In conclusion, the Court maintained that “an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” But, the application of the law of nature must be “significant,” and include other elements that constitute an “inventive concept” separate from the natural law itself. This decision thus emphasizes the importance of distinguishing claimed processes involving the application of a natural law from the underlying natural law itself. If a claimed process does not add “enough” to the underlying natural law, the process will be deemed unpatentable subject matter.

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