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Breaking the Chains of Prometheus: Practical Claim Drafting

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In Greek mythology, Prometheus stole fire from Zeus to give to mankind. It seems that Zeus is now reclaiming some of that fire in the guise of *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, No. 10-1150 (U.S. Mar. 20, 2012), the Supreme Court's latest decision addressing patent-eligible subject matter. But a practical analysis of *Prometheus* reveals strategies one can use in drafting patent claims to keep those claims burning.

The claims at issue in *Prometheus* involved diagnostic- and therapeutic-type processes. The representative claim considered by the *Prometheus* Court was directed to a method of "optimizing therapeutic efficacy" for treating a particular disorder. It included an administering step, which instructed a doctor to give a certain drug to patients suffering from the disorder; a determining step, which instructed the doctor to measure the level of resulting metabolites in the patients' blood following administration; and two wherein clauses that defined the relevant ranges of metabolite concentration that corresponded to drug efficacy and toxicity.

The Court held these claims to comprise only ineligible subject matter, because they involved nothing more than the application of an unpatentable law of nature through well-known, conventional means. Specifically, the claims simply defined the natural relationship between metabolite concentration in the blood and the probability that the metabolite will either be therapeutically effective or harmful to the patient. The application of that relationship set forth in the claimed administering and determining steps, was stated to recite only processes that were already well known in medicine. As the Court put it, "the claims inform a relevant audience about certain laws of nature; any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community . . . and are insufficient to transform unpatentable natural correlations into patentable applications of those regularities."

The U.S. Patent & Trademark Office ("PTO") then issued preliminary guidance on March 21, 2012 to its Patent Examiners in light of *Prometheus*, instructing Examiners to reject claims that amount to "a monopoly on the law of nature, natural phenomenon, or abstract idea **itself**" (emphasis in original). Further, a claim that includes a law of nature also needs to include other elements, or combinations thereof, that amount to "significantly **more than** a law of nature . . . with conventional steps specified at a high level of generality" (emphasis in original).

What does this mean for patent practitioners and the innovation community? Setting aside debates such as whether Prometheus's key patent claimed merely a "law of nature" or whether the Court confused subject matter eligibility and novelty, there may still be patentable subject matter achievable through careful claim drafting when preparing and prosecuting patent applications that include subject matter

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similar to that at issue in *Prometheus*. Set forth below are a few claim drafting suggestions that may be useful, subject to further judicial decisions that provide additional guidance.

First, describe and claim inventions practically, or, put simply, as the inventions would be used in commerce. Patent applications often include broad claims that are designed to encompass as much protection as possible. However, such patent applications should also include narrower claims that target the invention as it is specifically contemplated to be practiced. For Prometheus, such a claim might have also recited subsequently administering a specific dose of the drug based on the results of the blood level determining measurement(s). This may require consideration of additional issues, such as joint/divided infringement, but doing so may favorably alter the patentable subject matter analysis to yield patentable claims.

Second, consider affirmatively setting forth points of novelty, rather than inferentially referring to them in a wherein clause. Prometheus's claims appear to have failed in part because the active elements of the claim, such as the determining step, that set forth the application of the natural law were found to be well known and conventional in the art. The wherein clauses contained possible points of novelty, but the Court did not consider these to be a significant limitation and therefore dismissed it in the subject matter analysis as "at most adding a suggestion that [a doctor] should take those [natural] laws into account when treating his patient." On the other hand, this drafting tactic alone may not be sufficient to show patentable subject matter where only this affirmatively recited feature provides a patentable distinction after treating the "law of nature" as prior art.

Third, pursue claims that capture actors in the real world. Claiming so broadly to capture the entire world's population as it relates to the natural law is likely a problematic position. Draft claims to target a specific actor or group of actors, or a specific application in the real world. In other words, per the PTO's preliminary guidance, give the natural law some context with other feature(s). For example, in *Diamond v. Diehr*, 450 U.S. 175 (1981), the claims invoked an unpatentable mathematical equation, but applied that equation in the context of a specific rubber-molding application. These claims were upheld because they claimed a specific application of a mathematical equation, rather than attempting to claim all applications of the equation.

Fourth, include a transformative element in your diagnostic (and other) claims. While the *Prometheus* Court found that any transformation present in Prometheus's claims was not enough to trump the "law of nature" exclusion, the PTO has now specifically instructed Examiners to continue following *Bilski v. Kappos*, 130 S. Ct. 3218 (2010) even in view of *Prometheus*. Thus, arguments based on the machine-or-transformation test should still be useful to claim allowance and for now the lower courts are still likely to look to this earlier Supreme Court-approved test as an important factor in resolving the patent eligibility of certain subject matter.

Although many analysts and pundits fear that *Prometheus* is a death knell for the patentability of many inventions, particularly in the medical and pharmaceutical fields, the claims at issue may have been analyzed differently and upheld if they had been drafted just a little differently. So as you think about how best to claim your invention, consider how careful claim drafting that includes the practical suggestions above might help keep the inventive fires burning and unbound from the rock of *Prometheus*.

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