Supreme Court Holds Prometheus Patent Claims Invalid

2012-03-22

The Supreme Court of the United States unanimously held that patent claims directed to optimizing treatment of an immune-related disorder by administering a drug and determining whether the level of a metabolite in a patient's blood was within a desired range were not directed to patentable subject matter and were hence invalid. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, --- U.S. --- (March 20, 2012.). According to the Court, "scientists already understood that the levels in a patient's blood of certain metabolites ... were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective." (Slip op. 4). The patent claims at issue were directed to what "those in the field did not know," the desired "level of -6-thioguanine in [a] subject having [an] immune-mediated gastrointestinal disorder." (Slip op. 5).

According to the Court, these 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 side effects." (Slip op. 3). The question before the Court was whether the other steps of the method claim, "administering" the drug and "determining" the resulting metabolite level, "add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws." (Slip op. 8, italics in original).

The Court held that the answer was "no." The Court concluded that "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" (Slip op. 4), and "that the patent claims at issue here effectively claim the underlying laws of nature themselves." (Slip op. 24).

Throughout its opinion, the Court emphasized that "laws of nature" are not patentable. Its apparent focus was on whether the way in which the "law of nature" was *applied* "contain[ed] other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself" (Slip op. 3). The Court also said that "[p]urely 'conventional or obvious' '[pre]solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." (Slip op. 10). Reviewing its prior decisions, the Court said that the multi-step rubber-curing process in *Diamond v. Diehr*, 450 U.S. 175 (1981) was patentable because it was "nowhere suggested that all of these steps, or at least the combination of those steps were in context obvious,

already in use, or purely conventional" (Slip op. 12) and that "[t]he other steps apparently added to the formula something that in terms of patent law's objective had significance - they transformed the process into an inventive application of the formula." (*Id.*). On the other hand, in *Parker v. Flook*, 437 U.S. 584 (1978), the steps in the claimed process (other than a formula or algorithm) were "all 'well known' to the point where, putting the formula to the side, there was no 'inventive concept' in the claimed application of the formula." (Slip op. 13). As for the process for converting binary-coded decimal numbers into pure binary numbers claimed in *Gottschalk v. Benson*, 409 U.S. 63 (1972), the Court held that the claims there "purported to cover any use of the claimed method in a general-purpose digital computer of any type," and that "the mathematical formula had 'no substantial practical application except in connection with a digital computer.' ... Hence the claim (like the claims before us) was overly broad; it did not differ significantly from a claim that just said 'apply the algorithm.'" (Slip op. 16).

Authors

James B. Lampert

RETIRED PARTNER

james.lampert@comcast.net

+1 617 526 6000

Mark C. Fleming

PARTNER

Co-Chair, Appellate and Supreme Court Litigation Practice

mark.fleming@wilmerhale.com

+1 617 526 6909