Mayo v. Prometheus: Did the Supreme Court Clarify Bilski and the §101 Test?

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The Supreme Court has at last handed down its opinion in Mayo Collaborative Services v. Prometheus Laboratories, Inc. A unanimous Court invalidated Prometheus’s patents for optimizing the dosage of thiopurine drugs, holding that the claims merely “inform[ed] a relevant audience about certain laws of nature.” Mayo Collaborative Services v. Prometheus Labs., Inc., 566 U.S. __, slip op. at 11 (2012).

We wrote in January1 that this opinion would be the Court’s first opportunity to clarify § 101 since its decision in Bilski. This follow-up article attempts to analyze how Mayo clarified or modified § 101 analysis, and what we can expect post-Mayo.

DEMISE OF THE MACHINE-OR-TRANSFORMATION TEST?

Mayo marks the first instance of a court invalidating a patent that passed the machine-or-transformation test. The claims included several steps that were found to be transformative by the Federal Circuit in upholding the validity of the patents, namely “administering” and “determining” steps. The Court dismissed these steps, stating that although they were “not themselves natural laws[,] neither [were] they sufficient to transform the nature of the claim.” Mayo, slip op. at 9. The “administering” step was considered “irrelevant,” as it simply referred to a pre-existing audience, namely the doctors who administer thiopurine drugs. A “wherein” clause was found to simply describe the relevant law of nature, i.e. the optimal dosage range of thiopurine drugs, and suggest that doctors consider this optimal range while treating a patient. The “determining” step was considered to be insufficiently inventive, as it simply told “doctors to engage in well-understood, routine, conventional activity.” And, finally, the Court found that the steps taken together “add[] nothing to the laws of nature that is not already present when the steps are considered separately.”

In the few short years since the Federal Circuit confirmed that the machine-or-transformation test was the sole, governing test for determining patent eligibility of a process incorporating a fundamental principle (i.e. a law of nature, natural phenomena or abstract idea), In re Bilski, 454 F.3d 943, 956 (Fed. Cir. 2008), the test has already been downgraded twice by the Supreme Court.

First, in Bilski, the Court stated that while the machine-or-transformation test was a “useful and important clue” for analyzing patent eligibility, it was “not the sole test.” Bilski v. Kappos, 130 S. Ct. 3218, 3227 (2010). Still, post-Bilski, lower courts continued to analyze claims under § 101 using the machine-or-transformation test with this rough pattern: if a process satisfied the machine-or-transformation test, then it claimed patentable subject matter; if it failed the test, then it may still be patent eligible as long as it does not merely claim a law of nature, physical phenomena or abstract idea.

Now, in Mayo, the machine-or-transformation test has taken a further hit: even if a claimed process satisfies the test, it still may not claim patentable subject matter. The Court explained that “in stating that the ‘machine-or-transformation test’ is an ‘important or useful clue’ to patentability, we have neither said nor implied that the test trumps the ‘law of nature’ exclusion.” Mayo, slip op. at 19. Thus, post-Mayo, even a patent that passes the machine-or-transformation test may still be unpatentable for claiming a fundamental principle.

Consequently, we have to ask whether it would be more efficient to just dispense with the machine-or-transformation test, and proceed directly to the ultimate question of whether a claim covers a fundamental principle? And if so, is there a test that could help with that analysis?

PATENTABILITY UNDER § 101 AND/OR §§ 102 AND 103?

Given the demise of the machine-or-transformation test’s reliability, which courts have long employed to determine patent eligibility of claims incorporating laws of nature, natural phenomena, or abstract ideas, what guidance has the Court provided in its wake?

On the one hand, the Court acknowledges (as it long has) that the analysis of § 101 is distinct from that of the later sections in the title. Mayo, slip op. at 21 (“The relevant [precedential] cases rest their holdings upon section 101, not later sections.”); accord Diamond v. Diehr, 450 U.S. 175, 188-89 (1981) (“The ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter”). As Justice Breyer explains, “to shift the patent-eligibility inquiry entirely to . . . sections [102, 103, or 112] risks creating significantly greater uncertainty, while assuming that those sections can do work that they are not equipped to do.” Id.

On the other hand, without going so far as to state that novelty or nonobviousness should be considered when determining patent eligibility (although several Justices did admit during oral argument that a robust § 101 threshold that includes a peek at §§ 102 and 103 is tempting), the Court hints at doing so when criticizing the “transformative” steps in Prometheus’s claimed methods as being conventional, obvious, routine, and well-understood. See id. at 8 (“[]the question before us is whether the claims . . . add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes”); id. at 10 (“[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
Indeed, post-Mayo lower courts may have to assess the state of the art when analyzing § 101 patent eligibility (an inquiry that was distinguished from §§ 102 and 103 during oral argument in Mayo as being an easier, not fact-dependent inquiry) to determine if “significantly more” “inventive concepts” or elements are claimed.

**IMPACT ON MYRIAD AND BEYOND**

While the patents in Mayo were limited to methods that claimed a law of nature, this opinion will impact § 101 analysis for patents claiming other fundamental principles and involving other types of claims. For instance, method claims often relate to “abstract ideas,” such as business methods or mathematical algorithms embodied in software. Mayo could have a significant impact on patents claiming such abstract ideas if inventive, unconventional, non-routine or not well-understood elements or concepts must be claimed in order to make a business method or mathematical formula patent eligible.

Meanwhile, the next opportunity for the Federal Circuit to shape post-Mayo § 101 law will likely be Association for Molecular Pathology v. Myriad Genetics Inc., which the Supreme Court remanded to the Federal Circuit in light of its opinion in Mayo. While method claims involving abstract ideas (analyzed using the machine-or-transformation test) were previously at issue in Myriad, only matter claims involving laws of nature were raised on appeal.

The compositions at issue in Myriad are DNA fragments, which are isolated from native human DNA, that code for naturally-occurring genes associated with a predisposition to breast and ovarian cancers. While native DNA (obviously) exists in native, isolated DNA does not; it must be synthesized as an isolate or excised from native DNA using well-established techniques, which requires breaking the covalent bonds anchoring the fragment to the DNA chain, resulting in a chemically distinct product.

The district court found Myriad’s claimed DNA isolates to be patent ineligible because, *inter alia*, their genetic function was “not markedly different” to that of native DNA. The Federal Circuit, less than a year ago in its July 2011 opinion, disagreed and held that Myriad’s DNA isolates were patent eligible because their chemical structure was markedly different from that of native DNA.

**ENDNOTES**