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The U.S. Supreme Court Raises the Threshold for Patentable Subject Matter

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Many (if not all) inventions arise from the *application* of a known or newly discovered natural phenomenon, law of nature or abstract idea. It has been long established, however, that mere natural phenomena, laws of nature or abstract ideas are not *themselves* eligible for patent protection. Two recent cases before the U.S. Supreme Court draw attention to the question of the patentability of claims to methods of medical treatment and claims to isolated DNA sequences that incorporate natural phenomena.

In the first case, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,[1] a unanimous U.S. Supreme Court ruled that steps directed generally to (1) administering a specific drug to a patient and (2) determining the level of metabolites of that drug in the patient in the claims of two patents that otherwise recited only a natural phenomena were not significant enough to transform the unpatentable laws of nature into patent-eligible applications of those laws. Justice Breyer, writing for the *Mayo* Court, stated 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,"[2] and that such "[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,"[3] thus adding considerations of novelty,[4] and perhaps even obviousness,[5] to the question of whether the claims constitute patentable subject matter under §101 of the Patent Act.[6]

In the second case, *Association for Molecular Pathology v. Myriad Genetics Inc.*,[7] the Court remanded to the U.S. Court of Appeals for the Federal Circuit the challenge to the patentability under §101 of claims to isolated and purified DNA for reconsideration in light of the Court's decision in *Mayo*. The Federal Circuit[8] had previously found the composition claims to isolated DNA molecules and method claims for screening potential cancer therapeutics via changes in cell growth rates to be patentable subject matter, in part because the claimed isolated DNA molecules, as portions of much larger native DNA, are distinct chemical compositions that do not exist in nature.

Section 101 of the Patent Act states that:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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[1] Slip Opinion No. 10-1150, March 20, 2012, 566 U.S. ___ (2012).

[2] Slip Opinion at 4.

[3] Slip Opinion at 10, quoting Parker v. Flook, 437 U.S. 584, 590 (1978).

[4] See 35 U.S.C. § 102.

[5] See 35 U.S.C. § 103.

[6] 35 U.S.C. § 101.

[7] U.S., No. 11-725, remanded 3/26/2012.

[8] Association for Molecular Biology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011).

While §101 itself requires the four subject matter areas to be "new," there is nothing stated about obviousness. The Court stated in *Mayo* that the prohibition against obtaining patent protection for natural phenomena, laws of nature or abstract ideas is "an important implicit exception"[9] to the broad language of this provision of the Patent Act. The Court reasoned that upholding the patents at issue in this case risks tying up too much future use of the underlying natural laws by others, thereby inhibiting, rather than promoting, science and further discoveries.

The patents at issue[10] in *Mayo* each contain claims directed to some variation of methods of "optimizing therapeutic efficacy" for, and/or "reducing toxicity associated with," "treatment of an immune-mediated gastrointestinal disorder," "comprising (a) *administering*[11] a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and (b) *determining* a level of 6-thioguanine" and/or "6-methyl-mercaptopurine" in the subject "*wherein* the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and *wherein* the level of 6-thioguanine greater than about 400 pmol" and/or "the level of 6-methyl-mercaptopurine greater than 7000 pmol" "per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." Immune-mediated gastrointestinal disorders include Crohn's disease and ulcerative colitis. The drugs used to treat patients having these diseases include thiopurine drugs, specifically 6-Mercaptopurine (6-MP) and a pro-drug, azathioprine (AZA) which is converted to 6-MP. Once administered, 6-MP can be enzymatically converted to various metabolites and their nucleotides. However, not all patients metabolize 6-MP in the same way or to the same degree. In some patients, the kind and degree of conversion can be fatally toxic while in certain other patients, the drug is rendered ineffective. Determining the appropriate dosage for any given patient had been difficult.

The inventors discovered the correlation between the level of certain metabolites in the blood of a patient who had received 6-MP and the efficacy of the treatment. They filed for and obtained two patents, which were exclusively licensed to Prometheus Laboratories, Inc. (Prometheus). Prometheus for a time sold diagnostic kits for use in practicing the claimed methods to Mayo Clinic Rochester and Mayo Collaborative Services (collectively, Mayo) until Mayo decided to use and sell its own test using a somewhat different metabolite level to determine toxicity. Prometheus sued for patent infringement. The District Court ruled in Mayo's favor, finding the Prometheus patents to be invalid because the correlation between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages is a natural phenomenon. Prometheus appealed.

On appeal, the Court of Appeals for the Federal Circuit overruled the District Court, finding the "administering" and "determining" steps to be transformative additions to the natural correlations. Mayo filed a petition for certiorari to the U.S. Supreme Court, which remanded the case to the Federal Circuit for reconsideration in light of its then recent decision in *Bilski v Kappos*,[12] concerning the patentability under §101 of the abstract idea embodied in claims to a process for hedging risks of price changes in, for example, the sale and purchase of commodities. In *Bilski*, the Supreme Court stated that determining whether the claimed invention transformed natural phenomena, laws of nature or abstract ideas is not definitive, but only an important and useful clue to patent eligibility. On remand, the Federal Circuit reaffirmed its earlier conclusion finding again in favor of Prometheus that the

[9] Slip Opinion at 1.

[10] U.S. Patents 6,355,623 and 6,680,302. The '302 patent is a continuation of the '623 patent and includes the same description.

[11] Emphasis added unless otherwise indicated.

[12] Bilski v. Kappos, 129 S. Ct. 2735 (2010).

claims did "not encompass laws of nature or preempt natural correlations."[13] Mayo again filed a petition for certiorari. The Supreme Court reversed.

The *Mayo* Court looked to past decisions concerning the patentability of claims that included natural laws or abstract ideas. Quoting often from several of its earlier decisions, the Court wrote that "'if there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end,'"[14] and that "'post-solution activity' that is purely 'conventional or obvious,' … 'cannot transform an unpatentable principle into a patentable process.'"[15]

The Court compared the claims of the two patents in issue to two of its earlier decisions as representative of opposite extremes where process claims containing abstract ideas or laws of nature had been found to be unpatentable in one case and patentable in the other. In the first decision, *Parker v. Flook*,[16] the Court characterized the claim as an attempt to patent a method of using an unpatentable algorithm by "identification of a limited category of useful, though conventional, post-solution applications."[17] In the second decision, *Diamond v. Diehr*,[18] the Court reached the opposite conclusion, finding patentable subject matter in claims involving a step-by-step method for "the transformation of an article, in this case raw uncured synthetic rubber, into a different state or thing."[19]

As applied to the Prometheus claims, the Court found that although it takes human action to administer the thiopurine drug, the correlation between the level of the claimed metabolites and the efficacy of the treatment is a natural process. There must be something of significance more than a description of the natural process and an instruction to apply it.[20] The question posed by the Court is whether the claims do significantly more than simply describing the natural relationship between the levels of metabolites and the need to increase or decrease subsequent dosages of the drug. The Court broke down a representative claim into three parts, the administering step, the determining step, and the two wherein clauses that recited the natural phenomena. The Court found the administering step to refer to the relevant "audience" of doctors and patients who treat and receive the drug, respectively. Critically, the Court also found that the administering step was well known, i.e., not new. The background sections of the patents in suit indicate that the thiopurine drugs were recognized treatments for the claimed patient group.[21] Referencing its earlier decisions in *Diehr* and *Bilski*, the Court stated that the "prohibition against patenting" natural laws and abstract ideas "cannot be circumvented by attempting to limit the use" of the natural law, phenomenon or abstract idea "to a particular technological environment."[22] The "determining" step was also dismissed as encompassing methods well known in the art. Again, the patents at issue stated that "[the] level of 6-MP metabolite can be determined by methods well known in the art."[23] The Court also considered whether the combination of steps when considered as a whole might add something worthy of patent protection,

[13] Slip Opinion at 8, quoting the Federal Circuit decision at 628 F.3d 1347, 1355 (2010).

[14] Slip Opinion at 2-3, quoting Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

[15] Slip Opinion at 13, quoting Parker v. Flook, 437 U.S. 584, at 589, 590 (1978).

[16] Parker v. Flook, 437 U.S. 584 (1978).

[17] *Id*. at 584, 594-95.

[18] Diamond v. Diehr, 450 U.S. 175 (1981).

[19] *Id*. at 184.

[20] Slip Opinion at 8 and 9.

[21] See U.S Patent 6,355,623, col. 1, lines 41-67 and U.S. Patent 6,680,302, col. 1, lines 43-67 and col. 2, lines 1-2.

[22] Slip Opinion at 9.

[23] See, for example, U.S Patent 6,355,623, col. 9, lines 13-14.

but found that "the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients."[24] Without offering much in the way of guidance as to what "something of significance" or "significantly more" might entail, the Court concluded that the steps are not sufficient to transform unpatentable natural correlations into patentable subject matter.[25]

While the Court admitted that its evaluation of the additional steps of "administering" and "determining" in this case sometimes overlap with the novelty inquiry under §102, the Court firmly rejected the U.S. Government's position that §101 should be construed broadly such that almost any step beyond a statement of a law of nature itself should transform the law of nature into a potentially patentable subject matter[26] and that concerns about the lack of novelty or obviousness of the claimed application of the law of nature are better addressed under §§102 and 103 of the Patent Act.[27] The Court wrote that such an approach would "make the 'law of nature' exception to §101 patentability a dead letter"[28] in part because §§102 and 103 are silent about treating laws of nature as prior art. The Court warned against interpreting the Patent Act in ways that make patent eligibility depend on the art of claim drafting without reference to the underlying principles supporting the prohibition. In other words, the Court's decision indicates that the Court believes that the Government's position would encourage applicants to submit claims that recite additional insignificant elements with the recitation of a law of nature, natural phenomenon or abstract idea to avoid the prohibitions inherent in §101, and that the requirements under §§102 and 103 may not be sufficient to prevent patenting a newly discovered law of nature, natural phenomenon or abstract idea never before publicly used, to anyone's knowledge, discussed in the literature, or otherwise falling within the specific definitions of prior art under §§102 and 103.

The Court deferred to Congress to address the competing concerns raised by several *amici*[29] concerning, on one hand, the risk to funding for needed research if a legal rule emerges that denies patent protection for inventions that use laws of nature and, on the other hand, the risk of inhibiting research and patient care if the basic tools of science are monopolized through the grant of patents that might impede innovation more than promote it. The Court stated that the patent laws are "general rules" that apply to many "different fields of human endeavor"[30] and reflect a balance between the competing considerations. The Court declined to weigh in on a policy that would provide increased protection for diagnostic laws of nature. Instead, the Court relied on its earlier decisions and its conclusions that there was nothing new about the additional steps in siding with the view that upholding the patent claims in this case would inhibit further research.

Concerns about the affect of the *Mayo v. Prometheus* decision on inventions that take advantage of natural phenomena may be addressed soon when the Federal Circuit reconsiders the claims in *Myriad Genetics*. The *Mayo* decision, however, could be limited to its facts. The two non-natural phenomena steps of administering and determining were both broadly written and admitted in the patents at issue to be well known in the art. Had any step been in itself new, the outcome may have been different. This addition to the Court's body of cases concerning patentable subject matter under §101 tells us

[24] Slip Opinion at 10.

[25] Slip Opinion at 11.

[26] Slip Opinion at 21, quoting Brief of the United States.

[27] 35 U.S.C. §§102 and 103 relating to the novelty and nonobviousness requirements of patentability, respectively.

[28] Slip Opinion at 21.

[29] "Friends of the court" independent of the parties who have an interest in the law created by the outcome of the decision and submit briefs in support of one position or another.

[30] Slip Opinion at 23.

that, going forward, claims that incorporate laws of nature, natural phenomena or abstract ideas, must include some additional elements or steps that at least in combination are not conventional, are not known and do not inhibit the use of the relevant natural law for future use by others. Although it may be helpful to limit the claims to specific uses of the natural law to avoid a determination that future use by others would be too severely curtailed, narrow limitations relating to the natural law or phenomenon alone would not appear to be sufficient. The claims at issue were specifically limited to a class of drugs and specifically identified metabolites, but those limitations were ultimately directed to the portion of the claim determined to recite the natural correlation. Therefore, any such specific limitations should be included in the additional, unconventional, novel elements of the claims. Claims found to be patentable in earlier decisions have integrated the abstract idea or law of nature into a structure or process that, when considered as a whole, performed a function the patent laws were designed to protect. Although not explicitly stated in the *Mayo* Court's decision, the power granted to Congress in the Constitution to "promote the Progress of Science and useful Arts"[31] that underlies the Patent Act may play a determining role in the Court's analysis of whether any given claim falls within the scope of patentable subject matter. If it adds nothing new and useful "of significance" to a field of endeavor, and is found to be more likely to inhibit rather than promote the progress of science, it may be doomed.

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[31] Article I, Section 8, Clause 8, U.S. Constitution.