MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, ET AL., PETITIONERS v. PROMETHEUS LABORATORIES, INC.

SUPREME COURT OF THE UNITED STATES

132 S. Ct. 1289

December 7, 2011, Argued
March 20, 2012, Decided

SYLLABUS

Although 'laws of nature, natural phenomena, and abstract ideas" are not patentable subject matter under § 101 of the Patent Act, *Diamond v. Diehr*, 450 U.S. 175, 185, 101 S. Ct. 1048, 67 L. Ed. 2d 155, "an *application* of a law of nature . . . to a known structure or process may [deserve] patent protection." *id.*, at 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155. But to transform an unpatentable law of nature into a patent- eligible application of such a law, a patent must do more than simply state the law of nature while adding the words "apply it." See, *e.g., Gottschalk v. Benson*, 409 U.S. 63, 71-72, 93 S. Ct. 253, 34 L. Ed. 2d 273. It must limit its reach to a particular, inventive application of the law.

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the two patents at issue, which concern the use of thiopurine drugs to treat autoimmune diseases. When ingested, the body metabolizes the drugs, producing metabolites in the bloodstream. Because patients metabolize these drugs differently, doctors have found it difficult to determine whether a particular patient's dose is too high, risking harmful side effects, or too low, and so likely ineffective. the patent claims here set forth processes embodying researchers' findings that identify correlations between metabolite levels and likely harm or ineffectiveness with precision. Each claim recites (1) an "administering" step -- instructing a doctor to administer the drug to his patient -- (2) a "determining" step -- telling the doctor to measure the resulting metabolite levels in the patient's blood -- and (3) a "wherein" step -- describing the metabolite concentrations above which there is a likelihood of harmful side-effects and below which it is likely that the drug dosage is ineffective, and informing the doctor that metabolite concentrations above or below these thresholds "indicate a need" to decrease or increase (respectively) the drug dosage.

Petitioners Mayo Collaborative Services and Mayo Clinic Rochester (Mayo) bought and used diagnostic tests based on Prometheus' patents. But in 2004 Mayo announced that it intended to sell and market its own, somewhat different, diagnostic test. Prometheus sued Mayo contending that Mayo's test infringed its patents. The District Court found that the test infringed the patients but granted summary judgment to Mayo, reasoning that the processes claimed by the patents effectively claim natural laws or natural phenomena -- namely, the correlations between thiopurine metabolite levels and the toxicity and efficiency of thiopurine drugs -- and therefore are not patentable. The Federal Circuit reversed, finding the processes to be patent eligible under the Circuit's "machine or transformation test." On remand from this court for reconsideration in light of *Bilski v. Kappos*, 561 U.S. ___, 130 S. Ct. 3218, 177 L. Ed. 2d 792, which clarified that the "machine or transformation test" is not a definitive test of patent eligibility, *id.*, at ___ - ___, 130 S. Ct. 3218, 177 L. Ed. 2d 792 the Federal Circuit reaffirmed its earlier conclusion.

Held: Prometheus' process is not patent eligible, pp. 8-24.

JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

> "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." 35 U.S.C. § 101.

The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond* v. *Diehr*, 450 U.S. 175, 185, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (1981); see also *Bilski* v. *Kappos*, 561 U.S. ___, ___, 130 S. Ct. 3218, 3222, 177 L. Ed. 2d 792, 797 (2010); *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (1980); *Le Roy* v. *Tatham*, 55 U.S. 156, 14 How. 156, 175, 14 L. Ed. 367 (1853); *O'Reilly* v. *Morse*, 56 U.S. 62, 15 How. 62, 112-120, 14 L. Ed. 601 (1854); cf. *Neilson*

v. *Harford*, Webster's Patent Cases 295, 371 (1841) (English case discussing same). Thus, the Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that E=mc2; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, *supra*, at 309, 100 S. Ct. 2204, 65 L. Ed. 2d 144 (quoting *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130, 68 S. Ct. 440, 92 L. Ed. 588, 1948 Dec. Comm'r Pat. 671 (1948)).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk* v. *Benson*, 409 U.S. 63, 67, 93 S. Ct. 253, 34 L. Ed. 2d 273 (1972). And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in *Diehr* the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" 450 U.S., at 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (quoting *Parker* v. *Flook*, 437 U.S. 584, 590, 98 S. Ct. 2522, 57 L. Ed. 2d 451 (1978)). It added that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, *supra*, at 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155. And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph Co.* v. *Radio Corp. of America*, 306 U.S. 86, 59 S. Ct. 427, 83 L. Ed. 506, 1939 Dec. Comm'r Pat. 857 (1939):

> "'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'" 450 U.S., at 188, 101 S. Ct. 1048, 67 L. Ed. 2d 155 (quoting *Mackay Radio*, *supra*, at 94, 59 S. Ct. 427, 83 L. Ed. 506, 1939 Dec. Comm'r Pat. 857).

See also *Funk Brothers*, *supra*, at 130, 68 S. Ct. 440, 92 L. Ed. 588, 1948 Dec. Comm'r Pat. 671 ("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").

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, *e.g.*, *Benson*, *supra*, at 71-72, 93 S. Ct. 253, 34 L. Ed. 2d 273.

The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The 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. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook*, *supra*, at 593, 98 S. Ct. 2522, 57 L. Ed. 2d 451. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. *Morse*, *supra*, at 112-120, 15 How. 62, 14 L. Ed. 601; *Benson*, *supra*, at 71-72, 93 S. Ct. 253, 34 L. Ed. 2d 273 . And they insist that a process that focuses upon the use of a natural law also contain 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. *Flook*, *supra*, at 594, 98 S. Ct. 2522, 57 L. Ed. 2d 451; see also *Bilski*, *supra*, at ___, 130 S. Ct. 3218, 3225, 177 L. Ed. 2d 792, 801 ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant post solution activity'" (quoting *Diehr*, *supra*, at 191-192, 101 S. Ct. 1048, 67 L. Ed. 2d 155)).

We find that the process claims at issue here do not satisfy these conditions. In particular, 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. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

. . .

Prometheus' patents set forth laws of nature-namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that *if* the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per 8x108 red blood cells, *then* the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body-entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do 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? We believe that the answer to this question is no.

A

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

. . .

A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are *Diehr* and *Flook*, two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. The *Diehr* process (held patent eligible) set forth a method for molding raw, uncured rubber into various cured, molded products. The process used a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. It consisted in effect of the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold opening time, and (3) configuring the computer so that at the appropriate moment it would signal "a device" to open the press. *Diehr*, 450 U.S., at 177-179, 101 S. Ct. 1048, 67 L. Ed. 2d 155.

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.*, at 187, 101 S. Ct. 1048, 67 L. Ed. 2d 155. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Ibid.* These other steps apparently added to the formula something that in terms of patent law's objectives had significance-they transformed the process into an inventive application of the formula.

The process in *Flook* (held not patentable) provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons. Certain operating conditions (such as temperature, pressure, and flow rates), which are continuously monitored during the conversion process, signal inefficiency or danger when they exceed certain "alarm limits." The claimed process amounted to an improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, *e.g.*, the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm limit values. 437 U. S., at 585-587, 98 S. Ct. 2522, 57 L. Ed. 2d 451.

The Court, as in *Diehr*, pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it characterized the claimed process as doing nothing other than "provid[ing] a[n] unpatentable formula for computing an

updated alarm limit." *Flook*, *supra*, at 586, 98 S. Ct. 2522, 57 L. Ed. 2d 451. Unlike the process in *Diehr*, it did not "explain how the variables used in the formula were to be selected, nor did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit." *Diehr*, *supra*, at 192, n. 14, 101 S. Ct. 1048, 67 L. Ed. 2d 155; see also *Flook*, 437 U.S., at 586, 98 S. Ct. 2522, 57 L. Ed. 2d 451. And so the other steps in the process did not limit the claim to a particular application. Moreover, "[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring alarming'" 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. *Id.*, at 594, 98 S. Ct. 2522, 57 L. Ed. 2d 451. "[P]ost solution activity" that is purely "conventional or obvious," the Court wrote, "can[not] transform an unpatentable principle into a patentable process." *Id.*, at 589, 590, 98 S. Ct. 2522, 57 L. Ed. 2d 451.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions 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. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in *Diehr* was not so characterized; that in *Flook* was characterized in roughly this way.

. . .

Finally, in *Benson* the Court considered the patentability of a mathematical process for converting binary coded decimal numerals into pure binary numbers on a general purpose digital computer. The claims "purported to cover any use of the claimed method in a general purpose digital computer of any type." 409 U. S., at 64, 65, 93 S. Ct. 253, 34 L. Ed. 2d 273. The Court recognized that "'a novel and useful structure created with the aid of knowledge of scientific truth'" might be patentable. *Id.*, at 67, 93 S. Ct. 253, 34 L. Ed. 2d 273 (quoting *Mackay Radio*, 306 U.S., at 94, 59 S. Ct. 427, 83 L. Ed. 506, 1939 Dec. Comm'r Pat. 857). But it held that simply implementing a mathematical principle on a physical machine, namely a computer, was not a patentable application of that principle. For the mathematical formula had "no substantial practical application except in connection with a digital computer." *Benson*, *supra*, at 71, 93 S. Ct. 253, 34 L. Ed. 2d 273. 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."

3

The Court has repeatedly emphasized this last mentioned concern, a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. Thus, in *Morse* the Court set aside as unpatentable Samuel Morse's general claim for "'the use of the motive power of the electric or galvanic current . . . however developed, for making or printing intelligible characters, letters, or signs, at any distances,'" 56 U.S. 62.

. . .

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson*, *supra*, at 67, 93 S. Ct. 253, 34 L. Ed. 2d 273. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify.

* * *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered.