132 S.Ct. 1289, 182 L.Ed.2d 321, 80 USLW 4225, 101 U.S.P.Q.2d 1961, 12 Cal. Daily Op. Serv. 3236, 2012 Daily Journal D.A.R. 3618, 23 Fla. L. Weekly Fed. S 189
(Cite as: 132 S.Ct. 1289)

Supreme Court of the United States
MAYO COLLABORATIVE SERVICES, dba Mayo Medical Laboratories, et al., Petitioners
v.
PROMETHEUS LABORATORIES, INC.

No. 10–1150.
Argued Dec. 7, 2011.
Decided March 20, 2012.

Background: Licensee of patents claiming methods for calibrating proper dosage of thiopurine drugs to treat autoimmune diseases filed infringement suit. The United States District Court for the Southern District of California, John A. Houston, J., 2008 WL 878910, granted summary judgment of invalidity of patents. Licensee appealed. The United States Court of Appeals for the Federal Circuit, 581 F.3d 1336, reversed. The Supreme Court granted certiorari, vacated the Court of Appeals decision, and remanded for reconsideration. On remand, the Court of Appeals, Lourie, Circuit Judge, 628 F.3d 1347, again reversed. Certiorari was granted.

Holding: The Supreme Court, Justice Breyer, held that patents effectively claimed the underlying laws of nature themselves, and thus were invalid.

Reversed.

West Headnotes

[1] Patents 291 6

291 Patents
291I Subjects of Patents
291k4 Arts
291k6 k. Principles or laws of nature. Most Cited Cases

Patents 291 16.2

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.2 k. Ideas and abstract principles. Most Cited Cases

Patents 291 16.3

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.3 k. Natural or scientific phenomena or principles. Most Cited Cases

Laws of nature, natural phenomena, and abstract ideas are not patentable. 35 U.S.C.A. § 101.

[2] Patents 291 6

291 Patents
291I Subjects of Patents
291k4 Arts
291k6 k. Principles or laws of nature. Most Cited Cases

Patents 291 16.2

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.2 k. Ideas and abstract principles. Most Cited Cases

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Patents 291 16.3

291 Patents
291II Patentability
291II(A) Invention; Obviousness
291k16.3 k. Natural or scientific phenomena or principles. Most Cited Cases

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. 35 U.S.C.A. § 101.

[3] Patents 291 7.12

291 Patents
291I Subjects of Patents
291k4 Arts
291k7.12 k. Law of nature. Most Cited Cases

To transform unpatentable law of nature into patent-eligible application of such law, one must do more than simply state the law of nature while adding the words "apply it." 35 U.S.C.A. § 101.

[4] Patents 291 7.12

291 Patents
291I Subjects of Patents
291k4 Arts
291k7.12 k. Law of nature. Most Cited Cases

Patented process that focuses upon use of natural law must also contain other elements or combination of elements, sometimes referred to as "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. 35 U.S.C.A. § 101.

[5] Patents 291 7.14

291 Patents
291I Subjects of Patents
291k4 Arts
291k7.14 k. Particular processes or methods as constituting invention. Most Cited Cases

Patent claims covering processes that helped doctors who used thiopurine drugs to treat patients with autoimmune diseases determine whether given dosage level was too low or too high, and purporting to apply natural laws describing relationships between concentration in the blood of certain thiopurine metabolites and likelihood that drug dosage would be ineffective or induce harmful side-effects, did not transform unpatentable natural laws into patent-eligible applications of those laws; steps in claimed processes, apart from natural laws themselves, involved well-understood, routine, conventional activity previously engaged in by researchers in the field. 35 U.S.C.A. § 101.

[6] Patents 291 6

291 Patents
291I Subjects of Patents
291k4 Arts
291k6 k. Principles or laws of nature. Most Cited Cases

Prohibition against patenting abstract ideas cannot be circumvented by attempting to limit use of the formula to a particular technological environment. 35 U.S.C.A. § 101.

[7] Patents 291 6

291 Patents
291I Subjects of Patents

132 S.Ct. 1289, 182 L.Ed.2d 321, 80 USLW 4225, 101 U.S.P.Q.2d 1961, 12 Cal. Daily Op. Serv. 3236, 2012 Daily Journal D.A.R. 3618, 23 Fla. L. Weekly Fed. S 189
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291k4 Arts
291k6 k. Principles or laws of nature. Most Cited Cases

Purely conventional or obvious pre-solution activity is normally not sufficient to transform unpatentable law of nature into patent-eligible application of such a law. 35 U.S.C.A. § 101.

Patents 291 328(2)

291 Patents
291XIII Decisions on the Validity, Construction, and Infringement of Particular Patents
291k328 Patents Enumerated
291k328(2) k. Original utility. Most Cited Cases

6,355,623, 6,680,302. Invalid.

***1290** *Syllabus* [FN*]

FN* The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States v. Detroit Timber & Lumber Co.,* 200 U.S. 321, 337, 26 S.Ct. 282, 50 L.Ed. 499.

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. 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***1291** 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 patents 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 efficacy of thiopurine drugs—and therefore are not patentable. The Federal Circuit reversed, finding the processes to

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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. 593, 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. at 3226–3227, the Federal Circuit reaffirmed its earlier conclusion.

Held: Prometheus' process is not patent eligible. Pp. 1296 – 1305.

(a) Because the laws of nature recited by Prometheus' patent claims—the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm—are not themselves patentable, the claimed processes are not patentable unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations. The three additional steps in the claimed processes here are not themselves natural laws but neither are they sufficient to transform the nature of the claims. The "administering" step simply identifies a group of people who will be interested in the correlations, namely, doctors who used thiopurine drugs to treat patients suffering from autoimmune disorders. Doctors had been using these drugs for this purpose long before these patents existed. And a "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.' " *Bilski, supra,* at ——, 130 S.Ct., at 3230. The "wherein" clauses simply tell a doctor about the relevant natural laws, adding, at most, a suggestion that they should consider the test results when making their treatment decisions. The "determining" step tells a doctor to measure patients' metabolite levels, through whatever process the doctor wishes to use. Because methods for making such determinations were well known in the art, this step simply tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists in the field. Such activity is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. *Parker v. Flook,* 437 U.S. 584, 590, 98 S.Ct. 2522, 57 L.Ed.2d 451. Finally, considering the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. Pp. 1296 – 1298.

(b) A more detailed consideration of the controlling precedents reinforces this conclusion. Pp. 1298 – 1303.

***1292** (1) *Diehr* and *Flook,* the cases most directly on point, both addressed processes using mathematical formulas that, like laws of nature, are not themselves patentable. In *Diehr,* the overall process was patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. 450 U.S., at 187, 101 S.Ct. 1048. These additional steps transformed the process into an inventive application of the formula. But in *Flook,* the additional steps of the process did not limit the claim to a particular application, and the particular chemical processes at issue 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. 437 U.S., at 594, 98 S.Ct. 2522. Here, the claim presents a case for patentability that is weaker than *Diehr* 's patent-eligible claim and no stronger than *Flook* 's unpatentable one. The three steps 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. Pp. 1298 – 1300.

(2) Further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena,

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and ideas patentable is provided in *O'Reilly v. Morse,* 15 How. 62, 114–115, 14 L.Ed. 601; *Neilson v. Harford,* Webster's Patent Cases 295, 371; *Bilski, supra,* at ——— – ———; and *Benson, supra,* at 64, 65, 67, 93 S.Ct. 253. Pp. 1300 – 1301.

(3) This Court has repeatedly emphasized a concern that patent law not inhibit future discovery by improperly tying up the use of laws of nature and the like. See, *e.g., Benson,* 409 U.S., at 67, 68, 93 S.Ct. 253. Rewarding with patents those who discover laws of nature might encourage their discovery. But because those laws and principles are "the basic tools of scientific and technological work," *id.,* at 67, 93 S.Ct. 253, there is a danger that granting patents that tie up their use will inhibit future innovation, a danger that becomes acute when a patented process is no more than a general instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. The patent claims at issue implicate this concern. In telling a doctor to measure metabolite levels and to consider the resulting measurements in light of the correlations they describe, they tie up his subsequent treatment decision regardless of whether he changes his dosage in the light of the inference he draws using the correlations. And they threaten to inhibit the development of more refined treatment recommendations that combine Prometheus' correlations with later discoveries. This reinforces the conclusion that the processes at issue are not patent eligible, while eliminating any temptation to depart from case law precedent. Pp. 1301 – 1303.

(c) Additional arguments supporting Prometheus' position—that the process is patent eligible because it passes the "machine or transformation test"; that, because the particular laws of nature that the claims embody are narrow and specific, the patents should be upheld; that the Court should not invalidate these patents under § 101 because the Patent Act's other validity requirements will screen out overly broad patents; and that a principle of law denying patent coverage here will discourage investment in discoveries of new diagnostic laws of nature—do not lead to a different conclusion. Pp. 1302 – 1305.

628 F.3d 1347, reversed.

BREYER, J., delivered the opinion for a unanimous Court.

***1293** Stephen M. Shapiro, Los Angeles, CA, for Petitioners.

Donald B. Verrilli, Jr., Solicitor General, for the United States, as amicus curiae, by special leave of the Court.

Richard P. Bress for Respondent.

Jonathan Singer, John Dragseth, Deanna Reichel, Fish & Richardson P.C., Minneapolis, MN, Stephen M. Shapiro, Counsel of Record, Timothy S. Bishop, Jeffrey W. Sarles, Mayer Brown LLP, Chicago, IL, Eugene Volokh, Los Angeles, CA, Joseph M. Colaiano, James A. Rogers, III, Mayo Clinic, Rochester, MN, Charles Rothfeld, Mayer Brown LLP, Washington, D.C., for Petitioners.

Richard P. Bress, Counsel of Record, J. Scott Ballenger, Maximilian A. Grant, Matthew J. Moore, Gabriel K. Bell, Latham & Watkins LLP, Washington, DC, for Respondent.

For U.S. Supreme Court briefs, See:2011 WL 5189089 (Resp.Brief)2011 WL 5562514 (Reply.Brief)

Justice BREYER delivered the opinion of the Court.

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

"Whoever invents or discovers any new and

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