Per Curiam

SUPREME COURT OF THE UNITED STATES

No. 04–607

LABORATORY CORPORATION OF AMERICA HOLDINGS, DBA LABCORP, PETITIONER *v.* METABOLITE LABORATORIES, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

[June 22, 2006]

PER CURIAM.

The writ of certiorari is dismissed as improvidently granted.

THE CHIEF JUSTICE took no part in the consideration or decision of this case.

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JUSTICE BREYER, with whom JUSTICE STEVENS and JUSTICE SOUTER join, dissenting.

This case involves a patent that claims a process for helping to diagnose deficiencies of two vitamins, folate and cobalamin. The process consists of using any test (whether patented or unpatented) to measure the level in a body fluid of an amino acid called homocysteine and then noticing whether its level is elevated above the norm; if so, a vitamin deficiency is likely.

The lower courts held that the patent claim is valid. They also found the petitioner, Laboratory Corporation of America Holdings (LabCorp), liable for inducing infringement of the claim when it encouraged doctors to order diagnostic tests for measuring homocysteine. The courts assessed damages. And they enjoined LabCorp from using any tests that would lead the doctors it serves to find a vitamin deficiency by taking account of elevated homocysteine levels.

We granted certiorari in this case to determine whether the patent claim is invalid on the ground that it improperly seeks to "claim a monopoly over a basic scientific relationship," Pet. for Cert. i, namely, the relationship between homocysteine and vitamin deficiency. The Court has dismissed the writ as improvidently granted. In my

view, we should not dismiss the writ. The question presented is not unusually difficult. We have the authority to decide it. We said that we would do so. The parties and *amici* have fully briefed the question. And those who engage in medical research, who practice medicine, and who as patients depend upon proper health care, might well benefit from this Court's authoritative answer.

I

A

The relevant principle of law "[e]xclude[s] from . . . patent protection . . . laws of nature, natural phenomena, and abstract ideas." *Diamond* v. *Diehr,* 450 U. S. 175, 185 (1981). This principle finds its roots in both English and American law. See, *e.g.*, *Neilson* v. *Harford*, Webster's Patent Cases 295, 371 (1841); *Le Roy* v. *Tatham,* 14 How. 156. 175 (1853); *O'Reilly* v. *Morse*, 15 How. 62 (1854); *The Telephone Cases,* 126 U. S. 1 (1888). The principle means that Einstein could not have "patent[ed] his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Diamond* v. *Chakrabarty*, 447 U. S. 303, 309 (1980). Neither can one patent "a novel and useful mathematical formula," *Parker* v. *Flook*, 437 U. S. 584, 585 (1978), the motive power of electromagnetism or steam, *Morse, supra,* at 116, "the heat of the sun, electricity, or the qualities of metals," *Funk Brothers Seed Co.* v. *Kalo Inoculant Co.,* 333 U. S. 127, 130 (1948).

The justification for the principle does not lie in any claim that "laws of nature" are obvious, or that their discovery is easy, or that they are not useful. To the contrary, research into such matters may be costly and time-consuming; monetary incentives may matter; and the fruits of those incentives and that research may prove of great benefit to the human race. Rather, the reason for the exclusion is that sometimes *too much* patent protection can impede rather than "promote the Progress of

Science and useful Arts," the constitutional objective of patent and copyright protection. U. S. Const., Art. I, §8, cl. 8.

The problem arises from the fact that patents do not only encourage research by providing monetary incentives for invention. Sometimes their presence can discourage research by impeding the free exchange of information, for example by forcing researchers to avoid the use of potentially patented ideas, by leading them to conduct costly and time-consuming searches of existing or pending patents, by requiring complex licensing arrangements, and by raising the costs of using the patented information, sometimes prohibitively so.

Patent law seeks to avoid the dangers of overprotection just as surely as it seeks to avoid the diminished incentive to invent that underprotection can threaten. One way in which patent law seeks to sail between these opposing and risky shoals is through rules that bring certain types of invention and discovery within the scope of patentability while excluding others. And scholars have noted that "patent law['s] exclu[sion of] fundamental scientific (including mathematical) and technological principles," (like copyright's exclusion of "ideas") is a rule of the latter variety. W. Landes & R. Posner, The Economic Structure of Intellectual Property Law 305 (2003). That rule reflects "both . . . the enormous potential for rent seeking that would be created if property rights could be obtained in [those basic principles] and . . . the enormous transaction costs that would be imposed on would-be users." *Id.*, at 305–306; cf. *Nichols* v. *Universal Pictures Corp.*, 45 F. 2d 119, 122 (CA2 1930) (L. Hand, J.).

Thus, the Court has recognized that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are . . . the basic tools of scientific and technological work." *Gottschalk* v. *Benson,* 409 U. S. 63, 67 (1972). It has treated fundamental scien-

tific principles as "part of the storehouse of knowledge" and manifestations of laws of nature as "free to all men and reserved exclusively to none." *Funk Bros.*, *supra*, at 130. And its doing so reflects a basic judgment that protection in such cases, despite its potentially positive incentive effects, would too often severely interfere with, or discourage, development and the further spread of useful knowledge itself.

B

In the 1980s three university doctors, after conducting research into vitamin deficiencies, found a correlation between high levels of homocysteine in the blood and deficiencies of two essential vitamins, folate (folic acid) and cobalamin (vitamin B_{12}). They also developed more accurate methods for testing body fluids for homocysteine, using gas chromatography and mass spectrometry. They published their findings in 1985. They obtained a patent. And that patent eventually found its commercial way into the hands of Competitive Technologies, Inc. (CTI), and its licensee Metabolite Laboratories, Inc. (Metabolite), the respondents here.

The patent contains several claims that cover the researchers' new methods for testing homocysteine levels using gas chromatography and mass spectrometry. Supp. App. 30. In 1991, LabCorp (in fact, a corporate predecessor) took a license from Metabolite permitting it to use the tests described in the patent in return for 27.5% of related revenues. Their agreement permitted LabCorp to terminate the arrangement if "a more cost effective commercial alternative is available *that does not infringe a valid and enforceable claim* of" the patent. App. 305 (emphasis added).

Until 1998, LabCorp used the patented tests and paid royalties. By that time, however, growing recognition that elevated homocysteine levels might predict risk of heart

disease led to increased testing demand. Other companies began to produce alternative testing procedures. And LabCorp decided to use one of these other procedures—a test devised by Abbott Laboratories that LabCorp concluded was "far superior." *Id.,* at 167 (testimony of Peter Wentz).

LabCorp continued to pay royalties to respondents whenever it used the patented tests. But it concluded that Abbott's test did not fall within the patent's protective scope. And LabCorp consequently refused to pay royalties when it used the Abbott test. *Id.,* at 237 (payment eliminated due to "change in methodology").

In response, respondents brought this suit against LabCorp for patent infringement and breach of the license agreement. They did not claim that LabCorp's use of the Abbott test infringed the patent's claims describing methods for testing for homocysteine. Instead, respondents relied on a broader claim not limited to those tests, namely claim 13, the sole claim at issue here. That claim—set forth below in its entirety—seeks patent protection for:

> "A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> "assaying a body fluid for an elevated level of total homocysteine; and
>
> "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." Supp. App. 30.

Claim 13, respondents argued, created a protected monopoly over the process of "correlating" test results and potential vitamin deficiencies. The parties agreed that the words "assaying a body fluid" refer to the use of any test at all, whether patented or not patented, that determines whether a body fluid has an "elevated level of total homocysteine." And at trial, the inventors testified that claim

13's "correlating" step consists simply of a physician's recognizing that a test that shows an elevated homocysteine level—by that very fact—shows the patient likely has a cobalamin or folate deficiency. App. 108–111 (testimony of Dr. Sally Stabler); *id.,* at 131–148 (testimony of Robert Allen). They added that, because the natural relationship between homocysteine and vitamin deficiency was now well known, such "correlating" would occur automatically in the mind of any competent physician. *Id.,* at 137–138 (same).

On this understanding of the claim, respondents argued, LabCorp was liable for inducing doctors to infringe. More specifically, LabCorp would conduct homocysteine tests and report the results measured in micromoles (millionths of a mole) per liter (symbolized μmol/L). Doctors, because of their training, would know that a normal homocysteine range in blood is between 7 and 22 μmol/L (and in urine between 1 and 20 μmol/L), Supp. App. 14, and would know that an elevated homocysteine level is correlated with a vitamin deficiency. Hence, in reviewing the test results, doctors would look at the μmol/L measure and automatically reach a conclusion about whether or not a person was suffering from a vitamin deficiency. Claim 13 therefore covered *every* homocysteine test that a doctor reviewed. And since LabCorp had advertised its tests and educated doctors about the correlation, LabCorp should be liable for actively inducing the doctors' infringing acts. See 35 U. S. C. §271(b).

The jury found LabCorp liable on this theory. The District Court calculated damages based on unpaid royalties for some 350,000 homocysteine tests performed by LabCorp using the Abbott method. The court also enjoined LabCorp from performing "any homocysteine-only test, including, without limitation homocysteine-only tests via the Abbott method." App. to Pet. for Cert. 36a–37a (internal quotation marks omitted).

LabCorp appealed. It argued to the Federal Circuit that the trial court was wrong to construe claim 13 so broadly that infringement took place "every time a physician does nothing more than look at a patient's homocysteine level." Corrected Brief for Appellant in No. 03–1120 (CA Fed.), p. 28 (hereinafter Brief for Appellant). Indeed, if so construed (rather than construed, say, to cover only *patented* tests), then claim 13 was "invalid for indefiniteness, lack of written description, non-enablement, anticipation, and obviousness." *Id.*, at 38. LabCorp told the Federal Circuit:

> "If the Court were to uphold this vague claim, anyone could obtain a patent on any scientific correlation—that there is a link between fact A and fact B—merely by drafting a patent claiming no more than 'test for fact A and correlate with fact B' . . . . Claim 13 does no more than that. If it is upheld, CTI would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own. The law is settled that no such claim should be allowed. *See, e.g., Diamond* v. *Diehr,* 450 U. S. 175 (1981); . . . Chisum on Patents §1.03[6]." *Id.*, at 41.

The Federal Circuit rejected LabCorp's arguments. It agreed with the District Court that claim 13's "correlating" step simply means "relating total homocysteine levels to cobalamin or folate deficiency, a deficiency in both, or a deficiency in neither." 370 F. 3d 1354, 1363 (2004). That meaning, it said, is "discernable and clear"; it is definite, it is described in writing, and it would enable virtually anyone to follow the instruction it gives. And that is sufficient. *Id.*, at 1366–1367. The Court did not address LabCorp's argument that, *if so construed*, claim 13 must be struck down as an improper effort to obtain patent protection for a law of nature.

Moreover, the Circuit concluded, because any competent

doctor reviewing test results would automatically correlate those results with the presence or absence of a vitamin deficiency, virtually every doctor who ordered and read the tests was a direct infringer. And because LabCorp "publishes . . . Continuing Medical Education articles" and other pieces, which urge doctors to conduct the relevant tests and to reach a conclusion about whether a patient is suffering from a vitamin deficiency based upon the test results, LabCorp induces infringement. *Id.*, at 1365. Finally, the court rejected LabCorp's challenge to the injunction. *Id.*, at 1372.

LabCorp filed a petition for certiorari. Question Three of the petition asks "[w]hether a method patent . . . directing a party simply to 'correlate' test results can validly claim a monopoly over a basic scientific relationship . . . such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result." Pet. for Cert. i. After calling for and receiving the views of the Solicitor General, 543 U. S. 1185 (2005), we granted the petition, limited to Question Three.

II

The question before us is whether claim 13, as construed and applied in the way I have described in Part I–B, is invalid in light of the "law of nature" principle, described in Part I–A. I believe that we should answer that question. There is a technical procedural reason for not doing so, namely, that LabCorp did not refer in the lower courts to §101 of the Patent Act, which sets forth subject matter that is patentable, and within the bounds of which the "law of nature" principle most comfortably fits. See 35 U. S. C. §101 (patent may be obtained for "any new and useful process, machine, manufacture, or composition of matter"); *Flook,* 437 U. S., at 588–589. There is also a practical reason for not doing so, namely, that we might benefit from the views of the Federal Circuit, which did

not directly consider the question. See, *e.g.*, *United States* v. *Bestfoods,* 524 U. S. 51, 72–73 (1998).

Nonetheless, stronger considerations argue for our reaching a decision. For one thing, the technical procedural objection is tenuous. LabCorp argued the essence of its present claim below. It told the Federal Circuit that claim 13 as construed by the District Court was too "vague" because that construction would allow "anyone" to "obtain a patent on any scientific correlation;" it would permit the respondents "improperly [to] gain a monopoly over a basic scientific fact" despite "settled" law "that no such claim should be allowed." Brief for Appellant 41 (citing *Diehr,* 450 U. S., at 1185; 1 D. Chisum, Patents §1.03[6]) (2006 ed.) (hereinafter Chisum). LabCorp explicitly stated in its petition for certiorari that, "if the Court allows the Federal Circuit opinion to stand . . . [respondents] would improperly gain monopolies over basic scientific facts rather than any novel inventions of their own." Pet. for Cert. 25 (citing *Diehr*, *supra; Gottschalk,* 409 U. S. 63; *Funk Bros.,* 333 U. S. 127; *Mackay Radio & Telegraph Co.* v. *Radio Corp. of America,* 306 U. S. 86 (1939)). And after considering the Solicitor General's advice not to hear the case (primarily based upon LabCorp's failure to refer to 35 U. S. C. §101), we rejected that advice, thereby "necessarily consider[ing] and reject[ing] that contention as a basis for denying review." *United States* v. *Williams,* 504 U. S. 36, 40 (1992).

For another thing, I can find no good practical reason for refusing to decide the case. The relevant issue has been fully briefed and argued by the parties, the Government, and 20 *amici*. The record is comprehensive, allowing us to learn the precise nature of the patent claim, to consider the commercial and medical context (which the parties and *amici* have described in detail), and to become familiar with the arguments made in all courts. Neither the factual record nor the briefing suffers from any

significant gap. No party has identified any prejudice due to our answering the question. And there is no indication that LabCorp's failure to cite §101 reflected unfair gamesmanship.

Of course, further consideration by the Federal Circuit might help us reach a better decision. Lower court consideration almost always helps. But the thoroughness of the briefing leads me to conclude that the extra time, cost, and uncertainty that further proceedings would engender are not worth the potential benefit.

Finally, I believe that important considerations of the public interest—including that of clarifying the law in this area sooner rather than later—argue strongly for our deciding the question presented now. See Part IV, *infra.*

III

I turn to the merits. The researchers who obtained the present patent found that an elevated level of homocysteine in a warm-blooded animal is correlated with folate and cobalamin deficiencies. As construed by the Federal Circuit, claim 13 provides those researchers with control over doctors' efforts to use that correlation to diagnose vitamin deficiencies in a patient. Does the law permit such protection or does claim 13, in the circumstances, amount to an invalid effort to patent a "phenomenon of nature"?

I concede that the category of non-patentable "phenomena of nature," like the categories of "mental processes," and "abstract intellectual concepts," is not easy to define. See *Flook, supra*, at 589 ("The line between a patentable 'process' and an unpatentable 'principle' is not always clear"); cf. *Nichols*, 45 F. 2d, at 122 ("[W]e are as aware as anyone that the line [between copyrighted material and non-copyrightable ideas], wherever it is drawn, will seem arbitrary"). After all, many a patentable invention rests upon its inventor's knowledge of natural phenomena;

many "process" patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process. See generally 1 Chisum §1.03, at 78–295. Nor can one easily use such abstract categories directly to distinguish instances of likely beneficial, from likely harmful, forms of protection. Cf. FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, p. 1 (Oct. 2003) (hereinafter FTC) (collecting evidence that "issues of fixed cost recovery, alternative appropriability mechanisms, and relationships between initial and follow-on innovation" vary by industry); Burk & Lemley, Policy Levers in Patent Law, 89 Va. L. Rev. 1575, 1577–1589 (2003) ("Recent evidence has demonstrated that this complex relationship [between patents and innovation] is . . . industry-specific at each stage of the patent process").

But this case is not at the boundary. It does not require us to consider the precise scope of the "natural phenomenon" doctrine or any other difficult issue. In my view, claim 13 is invalid no matter how narrowly one reasonably interprets that doctrine.

There can be little doubt that the correlation between homocysteine and vitamin deficiency set forth in claim 13 is a "natural phenomenon." That is what the petitioners argue. It is what the Solicitor General has told us. Brief for United States as *Amicus Curiae* 19 (filed Dec. 23, 2005) ("The natural relationship between elevated homocysteine and deficiencies in the B vitamins is an unpatentable 'principle in natural philosophy or physical science'") (quoting *Morse*, 15 How., at 116)). Indeed, it is close to what the respondents concede. Brief for Respondents 31 ("The correlation between total homocysteine and deficiencies in cobalamin and folate that the Inventors discovered could be considered, standing alone, a 'natural phenomenon' in the literal sense: It is an observable aspect of biochemistry in at least some human populations").

The respondents argue, however, that the correlation is nonetheless patentable because claim 13 packages it in the form of a "process" for detecting vitamin deficiency, with discrete testing and correlating steps. They point to this Court's statements that a "process is not unpatentable simply because it contains a law of nature," *Flook*, 437 U. S., at 590; see also *Gottschalk*, 409 U. S., at 67, and that "an *application* of a law of nature . . . to a known . . . process may well be deserving of patent protection." *Diehr,* 450 U. S., at 187. They add that claim 13 is a patentable "application of a law of nature" because, considered as a whole, it (1) "entails a physical transformation of matter," namely, the alteration of a blood sample during whatever test is used, Brief for Respondents 33 (citing *Cochrane* v. *Deener,* 94 U. S. 780, 788 (1877); *Gottschalk, supra,* at 70), and because it (2) "produces a 'useful, concrete, and tangible result,'" namely, detection of a vitamin deficiency, Brief for Respondents 36 (citing *State Street Bank & Trust Co.* v. *Signature Financial Group, Inc.*, 149 F. 3d 1368, 1373 (CA Fed 1998)).

In my view, however, the cases to which respondents refer do not support their claim. Neither *Cochrane* nor *Gottschalk* can help them because the process described in claim 13 is *not* a process for transforming blood or any other matter. Claim 13's process instructs the user to (1) obtain test results and (2) think about them. Why should it matter if the test results themselves were obtained through an unpatented procedure that involved the transformation of blood? Claim 13 is indifferent to that fact, for it tells the user to use any test at all. Indeed, to use virtually any natural phenomenon for virtually any useful purpose could well involve the use of empirical information obtained through an unpatented means that might have involved transforming matter. Neither *Cochrane* nor *Gottschalk* suggests that that fact renders the phenomenon patentable. See *Cochrane, supra*, at 785 (upholding

process for improving quality of flour by removing impurities with blasts of air); *Gottschalk, supra*, at 71–73 (rejecting process for converting numerals to binary form through mathematical formula).

Neither does the Federal Circuit's decision in *State Street Bank* help respondents. That case does say that a process is patentable if it produces a "useful, concrete, and tangible result." 149 F. 3d, at 1373. But this Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary. The Court, for example, has invalidated a claim to the use of electromagnetic current for transmitting messages over long distances even though it produces a result that seems "useful, concrete, and tangible." *Morse, supra*, at 16. Similarly the Court has invalidated a patent setting forth a system for triggering alarm limits in connection with catalytic conversion despite a similar utility, concreteness, and tangibility. *Flook, supra.* And the Court has invalidated a patent setting forth a process that transforms, for computer-programming purposes, decimal figures into binary figures—even though the result would seem useful, concrete, and at least arguably (within the computer's wiring system) tangible. *Gottschalk, supra*.

Even were I to assume (purely for argument's sake) that claim 13 meets certain general definitions of process patentability, however, it still fails the one at issue here: the requirement that it not amount to a simple natural correlation, *i.e.*, a "natural phenomenon." See *Flook, supra,* at 588, n. 9 (even assuming patent for improved catalytic converter system meets broad statutory definition of patentable "process," it is invalid under natural phenomenon doctrine); *Diehr,* 450 U. S., at 184–185 (explaining that, even if patent meets all other requirements, it must meet the natural phenomena requirement as well).

At most, respondents have simply described the natural

law at issue in the abstract patent language of a "process." But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge. Cf. *id.*, at 192 (warning against "allow[ing] a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection"). One might, of course, reduce the "process" to a series of steps, *e.g.*, Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce *any* process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable "natural phenomenon," and I can find nothing in claim 13 that adds anything more of significance.

IV

If I am correct in my conclusion in Part III that the patent is invalid, then special public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of healthcare while inhibiting its effective delivery. See Brief for American Clinical Laboratory Association as *Amicus Curiae* 8–13.

Even if Part III is wrong, however, it still would be valuable to decide this case. Our doing so would help diminish legal uncertainty in the area, affecting a "substantial

number of patent claims." See Brief for United States as *Amicus Curiae* 12–14 (filed Aug. 26, 2005). It would permit those in the medical profession better to understand the nature of their legal obligations. It would help Congress determine whether legislation is needed. Cf. 35 U. S. C. §287(c) (limiting liability of medical practitioners for performance of certain medical and surgical procedures).

In either event, a decision from this generalist Court could contribute to the important ongoing debate, among both specialists and generalists, as to whether the patent system, as currently administered and enforced, adequately reflects the "careful balance" that "the federal patent laws . . . embod[y]." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.,* 489 U. S. 141, 146 (1989). See also *eBay Inc.* v. *MercExchange, L. L. C.,* 547 U. S. ___, ___ (2006) (slip op., at 2) (KENNEDY, J., concurring); FTC, ch. 4, at 1–44; Pollack, The Multiple Unconstitutionality of Business Method Patents: Common Sense, Congressional Consideration, and Constitutional History, 28 Rutgers Computer & Technology L. J. 61 (2002); Pitofsky, Antitrust and Intellectual Property: Unresolved Issues at the Heart of the New Economy, 16 Berkeley Technology L. J. 535, 542–546 (2001).

For these reasons, I respectfully dissent.