No. 04-607

In the Supreme Court of the United States

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

This Court granted the petition for a writ of certiorari limited to question three as presented in the petition, which asks: Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to "correlat[e]" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

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INTEREST OF THE UNITED STATES

This case concerns the written description, enablement, and definiteness requirements of the Patent Act, and the question presented might also be construed to ask whether claimed inventions that would monopolize basic scientific relationships are patentable subject matter. The United States Patent and Trademark Office (PTO), which is "responsible for the granting and issuing of patents," 35 U.S.C. 2(a)(1), has an interest in the resolution of such questions. At the invitation of the Court, the United States filed a brief as amicus curiae at the petition stage of this case.

STATEMENT

1. Deficiencies in two B vitamins, cobalamin and folate, can cause serious illnesses. Once detected, however, a deficiency can be treated with vitamin supplements. Scientific researchers at University Patents

Inc., the predecessor of respondent Competitive Technologies, Inc. (CTI), determined that elevated levels of total homocysteine, an amino acid, are closely associated with deficiencies in cobalamin or folate. The researchers applied for and received a patent on methods for assaying samples of body fluids or tissues to determine total homocysteine levels, as well as methods for diagnosing cobalamin or folate deficiency based on elevated total homocysteine levels. Pet. App. 2a-3a. The patent claim at issue here, claim 13 of United States Patent No. 4,940,658 (the '658 patent), identifies:

> 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.

Pet. App. 3a; Supp. App. (S.A.) 30.

CTI licensed the '658 patent to respondent Metabolite Laboratories, Inc., which in turn sub-licensed the patent to the predecessor-in-interest of petitioner Laboratory Corporation of America Holdings. Physicians ordered total homocysteine assays from petitioner, which initially performed the assays under its sub-license by using an assay method set forth in the patent. In 1998, however, petitioner began using a different assay method and stopped paying royalties to Metabolite. Respondents then filed suit against petitioner for inducing patent infringement by the physicians, contributory infringement, and breach of contract. Pet. App. 3a-4a.

2. The district court submitted the case to a jury, which found claim 13 of the '658 patent valid; found petitioner liable for induced infringement, contributory infringement, and breach of contract; and found that petitioner's infringement was willful. The jury assessed damages of approximately $1 million for infringement and $3.7 million for breach of contract. The district court entered judgment based on the jury verdict, denied petitioner's motion for judgment as a matter of law, and doubled the jury's infringement award based on the finding of willfulness. See Pet. App. 3a-4a, 34a-39a. The court permanently enjoined petitioner from performing "any homocysteine-only test." *Id.* at 36a (citation omitted).

3. a. The Federal Circuit affirmed. Pet. App. 1a-27a. Noting that the parties focused "solely on * * * the correlating step" of claim 13, the court of appeals stressed that it did "not address the assaying step." *Id.* at 13a & n.1. "In essence," the court held, "'correlating' means to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both * * *, and also to relate the absence of an elevated total homocysteine level to a deficiency in neither." *Id.* at 12a.

Because "[t]he record shows that physicians order assays and correlate the results of those assays," the court of appeals held that physicians who ordered assays from petitioner after petitioner stopped making royalty payments directly infringed the patent. Pet. App. 13a. The court further concluded that substantial evidence supports the jury's finding that petitioner intended to induce such infringement because petitioner provided total homocysteine assays to physicians and encouraged the use of such assays to detect cobalamin and folate

deficiency. *Id.* at 14a-15a. Because it upheld the finding of induced infringement, the court of appeals did not review the jury's finding of contributory infringement. *Id.* at 15a.

The court of appeals rejected petitioner's contentions that claim 13 is invalid on various grounds—*viz*, indefiniteness, lack of written description, non-enablement, anticipation, and obviousness. Pet. App. 15a-21a. Because "[a] patent issued from [PTO] bears the presumption of validity under 35 U.S.C. § 282," the court explained that "[a]n accused infringer * * * must prove patent invalidity under the clear and convincing evidentiary standard." *Id.* at 15a.

In the Federal Circuit's view, petitioner did not overcome the presumption of validity. Because claim 13 has a discernible meaning, the court held that it is not indefinite. Pet. App. 16a. The court concluded that the patent specification provides an adequate written description because "[t]he record is replete with evidentiary support that * * * persons of ordinary skill in the art * * * understood from the specification that the '658 patent inventors possessed the 'correlating' step at the time they filed the patent application." *Id.* at 17a.

Similarly, the court determined that the patent specification enabled the invention by disclosing all of the necessary steps. Pet. App. 17a-18a. The court explained that "the correlating step is well within the knowledge of one of skill in this art" because it is "a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." *Id.* at 18a. And because the prior art in the record did not specifically disclose that total homocysteine is correlated with cobalamin or folate deficiency, the court further concluded that claim 13 was neither anticipated by the prior art nor obvious.

Id. at 18a-20a. Finally, the court held that the district court's injunction barring petitioner from performing "any homocysteine-only test" is not overbroad because it "simply addresses [petitioner's] specific acts constituting indirect infringement." *Id.* at 26a-27a (citation omitted).

b. Judge Schall concurred in part and dissented in part. Pet. App. 28a-33a. He "agree[d] with the majority's conclusions with respect to validity" of claim 13, but concluded that the claim is infringed only when a test reveals elevated levels of total homocysteine, not when it reveals normal or low levels. *Id.* at 28a, 30a.

SUMMARY OF ARGUMENT

The patent specification at issue here satisfies the enablement, written description, and definiteness requirements of 35 U.S.C. 112. The specification adequately enables and describes the claimed method by explaining how it works and how to perform it, and by including examples demonstrating that the patent applicants had performed the method. The claim is also sufficiently definite because its bounds are marked with precision, such that a person skilled in the art would understand whether any given method infringed the claim. Although petitioner contends (Pet. 24-25) that the specification does not adequately describe the claim's "correlating" step, the court of appeals construed that step to be "a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." Pet. App. 18a.

Petitioner's contention (Pet. 23) that holding claim 13 valid would mean that "parties could claim patent monopolies over basic scientific facts" confuses the Section 112 disclosure and drafting requirements with the Pat-

ent Act's separate limitations on the subject matter eligible for patent protection. Although laws of nature, natural phenomena, and abstract ideas are not patentable under 35 U.S.C. 101, petitioner did not contend in the lower courts that the patent claim is invalid under Section 101. Nor does the question presented in this Court fairly include that question. Instead, the question presented, construed in light of the arguments set forth in the body of the petition and in the courts below, asserts only that a *consequence* of affirming the jury's verdict on the Section 112 issues would be to grant a monopoly over a scientific relationship. Any such consequence, however, would flow from petitioner's failure to raise a Section 101 claim, not from any error in applying Section 112.

If the Court nonetheless concludes that the question presented fairly encompasses a Section 101 challenge, a remand would be appropriate. The court of appeals' claim construction, the jury's findings, and the relief awarded all suggest that *any* use of a total homocysteine assay infringes claim 13, because doctors who review such assays can be presumed to perform mental correlations of the results with cobalamin or folate deficiencies or the absence thereof, even if they ordered the assays for a different reason. So construed, claim 13 appears impermissibly to encompass all "substantial practical application[s]" of the natural relationship that can be identified by reference to the limited record presently before the Court. *Gottschalk* v. *Benson*, 409 U.S. 63, 71-72 (1972). Because petitioner did not raise a Section 101 challenge in the lower courts, however, respondents had no opportunity to create a full record on that issue. A remand for further evidentiary proceedings would

therefore be appropriate if the Court reached the Section 101 issue.

Claim 13 also appears to be invalid as anticipated by the prior art under 35 U.S.C. 102. The court of appeals' determination that any use of a total homocysteine assay infringes the patent appears to have the effect of impermissibly removing existing assay methods from the public domain. Like the Section 101 issue, however, that question is not fairly included in the question presented.

ARGUMENT

A. THE PATENT SPECIFICATION SATISFIES THE REQUIREMENTS OF 35 U.S.C. 112 BY DESCRIBING, ENABLING, AND CLAIMING THE METHOD

The question presented asks (Pet. i) whether a patent claim "setting forth an indefinite, undescribed, and non-enabling step" is invalid. That question refers to Section 112 of the Patent Act, which requires that a patent specification contain "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same." 35 U.S.C. 112. Further, "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *Ibid.*

Section 112 thus imposes three relevant requirements. First, the specification must contain a written description of the invention. Second, the specification must enable a person skilled in the art to make and use the invention. Third, the patent claim must identify with definiteness the exact scope of the claimed invention. Because the '658 patent was issued by PTO, it is "pre-

sumed valid." 35 U.S.C. 282. Petitioner's arguments under Section 112 do not overcome that presumption.

1. a. The enablement and written description requirements are related but distinct. "The enablement requirement is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel Corp.* v. *Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003); accord PTO, *Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement* (*PTO 112 Guidelines*), 66 Fed. Reg. 1099, 1103 (2001); see *Tyler* v. *City of Boston*, 74 U.S. (7 Wall.) 327, 330 (1868) (construing analogous requirement in earlier patent statute to require that a patent "state the component parts of the new manufacture claimed with clearness and precision, and not leave the person attempting to use the discovery to find it out 'by experiment'"). Enablement is an essential aspect of the basic *quid pro quo* that underlies a patent grant, because it ensures that the invention is immediately added to the storehouse of public knowledge and that the public will receive unlimited use of the invention after patent protection expires. See *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 480-481 (1974); *Evans* v. *Eaton*, 20 U.S. (7 Wheat.) 356, 433-434 (1822).

In addition to enabling the invention, the specification must contain a "written description of the invention," 35 U.S.C. 112, that "convey[s] to a person of skill in the art that the patentee had possession of the claimed invention at the time of the application, *i.e.,* that the patentee invented what is claimed." *LizardTech, Inc.* v. *Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005); see Pet. App. 17a; *PTO 112 Guidelines*, 66 Fed. Reg. at 1104. "An applicant shows posses-

sion of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." *PTO 112 Guidelines*, 66 Fed. Reg. at 1104. Demonstrating that an invention has been reduced to practice is one such way of showing possession, *id.* at 1104, 1107-1108 n.6, although an invention need not have been reduced to practice in order for it to be patentable, *Pfaff* v. *Wells Elec., Inc.*, 525 U.S. 55, 60-61 (1998). In addition to ensuring that the claimant has invented and possessed the claimed subject matter, the written description requirement helps to prevent inventors from later asserting that they invented more than they in fact did. See *Moba, B.V.* v. *Diamond Automation, Inc.*, 325 F.3d 1306, 1319 (Fed. Cir.), cert. denied, 540 U.S. 982 (2003); *Vas-Cath, Inc.* v. *Mahurkar*, 935 F.2d 1555, 1561, 1563 (Fed. Cir. 1991); see generally *Evans*, 20 U.S. (7 Wheat) at 434-435.

As the court of appeals explained, the enablement and written description requirements are considered from the perspective of one skilled in the art. Pet. App. 17a, 18a; see, *e.g.*, *Tilghman* v. *Proctor*, 102 U.S. 707, 728 (1880); *Loom Co.* v. *Higgins*, 105 U.S. 580, 585-586 (1881). In this case, the parties agreed, and the jury was instructed, that such a person would have "a medical degree and experience in researching the amino acid homocysteine and its relationship to diseases." Pet. App. 7a (citation omitted).

b. Especially from the perspective of such a person, the patent specification easily satisfies the enablement and written description requirements by explaining precisely how to perform the claimed method and demonstrating that the applicants had in fact performed it.

The specification explains that "[i]t has now been discovered that an elevated level of total homocysteine in tissues of warmblooded animals correlates both with cobalamin deficiency and with folic acid deficiency; an animal with elevated levels of total homocysteine is likely to have one or both deficiencies." S.A. 11. The specification goes on to disclose both how to assay for total homocysteine and how to correlate elevated levels of total homocysteine with deficiencies in the B vitamins. See, *e.g.*, S.A. 12-14.

The specification explains that "[s]uitable assays for this purpose include any assays capable of determining levels of homocysteine in body tissues, preferably body fluids." S.A. 12. Although petitioner erroneously contends (Pet. 23) that "[n]either the claim nor the specification says anything about how one is to conduct the assay," the specification describes "several different known assays suitable for use in determining levels of homocysteine in urine or blood," S.A. 12, as well as a new assay method claimed in the '658 patent, S.A. 12-14. The specification also includes two detailed examples that describe how the applicants measured homocysteine using different assay methods. See S.A. 15-20. Thus, the specification leaves no doubt that the applicants had undertaken the assay step, and it simultaneously enables others skilled in the art to undertake that step by showing them how to do so.

The same is true of the correlation step. The specification discloses that "[t]he normal range for homocysteine in human serum is from about 7 to about 22 μmol/liter, and in human urine is from about 1 to about 20 μmol/liter. Homocysteine levels above these ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication." S.A. 14.

The specification then provides an example of tests conducted by the applicants in which total homocysteine levels were elevated above normal levels for 99% of the patients with cobalamin deficiency and 95% of those with folate deficiency. S.A. 28.

Petitioner therefore errs in contending (Pet. 24-25) that the specification does not "describe what a practitioner must do to perform the active 'correlating' step." As the court of appeals construed the claim, "[t]he correlating step is a simple conclusion that a cobalamin/ folate deficiency exists *vel non* based on the assaying step." Pet. App. 18a; see *id.* at 8a ("The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship.").

Although petitioner protests (Pet. 24) that "[a]ll the patent tells a prospective practitioner is that a person with an elevated homocysteine level *may* have a vitamin deficiency," the mere fact that the claimed detecting method may not always be accurate does not render it invalid under Section 112. The written description and enablement inquiries focus on the disclosure and possession of the invention, not the extent of its utility. And notwithstanding petitioner's criticisms, moreover, the patent claim appears to have substantial utility. The court of appeals explained that the claimed method predicts cobalamin or folate deficiency "relatively accurately." Pet. App. 11a; see S.A. 28.

c. In any event, the written description and enablement issues in this case are primarily factual. This Court long ago stated that analogous requirements in the Patent Act of 1793, ch. 11, 1 Stat. 318, were "matter[s] of fact for the jury, and not of law for the decision of the Court." *Evans*, 20 U.S. (7 Wheat.) at 428.

Under the modern patent statutes, the Federal Circuit treats the adequacy of a written description as a question of fact and enablement as a question of law based on subsidiary findings of fact. *Moba*, 325 F.3d at 1319, 1321; Pet. App. 4a-5a.

Here, the jury found that the specification satisfied both the enablement and written description requirements, J.A. 396-397, the district court denied petitioner's motion for judgment as a matter of law, Pet. App. 34a-35a, and the Federal Circuit affirmed based in part on its review of the record, see, *e.g.*, *id.* at 17a ("The record is replete with evidentiary support that * * * persons of ordinary skill in the art * * * understood from the specification that the '658 patent inventors possessed the 'correlating' step."). This Court does not ordinarily disturb such fact-specific determinations, see generally *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949), and there is no reason to upset the jury's verdict on the enablement and written description questions here.[1]

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[1] There is some disagreement among the Federal Circuit's decisions regarding whether the written description requirement is satisfied by evidence the inventor possessed the invention, or whether some further description of the invention may be required in some circumstances. See, *e.g.*, *Enzo Biochem, Inc.* v. *Gen-Probe Inc.*, 323 F.3d 956, 969 (Fed. Cir. 2002). PTO has interpreted the written description requirement to focus solely on possession, see *PTO 112 Guidelines*, 66 Fed. Reg. at 1102, 1104, and the Federal Circuit's recent cases appear to adopt that view, see, *e.g.*, *LizardTech*, 424 F.3d at 1345; *Pandrol USA, LP* v. *Airboss Ry. Prods., Inc.*, 424 F.3d 1161, 1165 (Fed. Cir. 2005); Pet. App. 17a. Any disagreement on that point is not relevant here, however, because the specification clearly describes the claimed method, its allegedly novel aspects, and the extent to which it differs from the prior art disclosed in the specification, and thus satisfies either standard. See S.A. 10-14; pp. 10-11, *supra*.

2. While the enablement and written description requirements focus on the content of the patent specification, the definiteness requirement directs that the patent claim must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. 112. "It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.'" *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370, 373 (1996) (quoting *McClain* v. *Ortmayer*, 141 U.S. 419, 424 (1891)); see *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 731 (2002).

Because the patent claim defines the scope of the patent grant, *Markman*, 517 U.S. at 373, compliance with the definiteness requirement turns on whether the claim makes "[t]he limits of the patent" known. *General Elec. Co.* v. *Wabash Appliance Corp.,* 304 U.S. 364, 369 (1938); accord *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 232, 236 (1942). In assessing definiteness, a claim must be read in light of the specification and the knowledge of a person skilled in the art. *Carnegie Steel Co.* v. *Cambria Iron Co.*, 185 U.S. 403, 432, 437 (1902). Thus, "[t]he test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Miles Labs., Inc.* v. *Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993), cert. denied, 510 U.S. 1100 (1994).[2]

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[2] Although *General Electric*, *United Carbon*, and *Carnegie Steel* interpreted the definiteness requirement of the Patent Act of 1870, ch. 230, 16 Stat. 198, the modern version of Section 112 "is not materially different from the 1870 Act with regard to claiming." *Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.,* 520 U.S. 17, 26 (1997). Accord-

Especially when read by a person skilled in the art in light of the specification, claim 13 satisfies the definiteness requirement because it marks the boundaries of the patent claim with precision. The claim is infringed only if a person "assay[s] a body fluid for an elevated level of total homocysteine," and then "correlat[es] an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate." S.A. 30. Although that language is undeniably sweeping, it is not unclear. As the court of appeals held, "[t]he claim * * * provides that if the assay discloses 'an elevated level of total homocysteine,' the physician determines whether there is a cobalamin or folate deficiency by 'correlating,' i.e., comparing the elevated level with the normal homocysteine level." Pet. App. 12a (quoting S.A. 30); see p. 11, *supra*.

3. Petitioner argues (Pet. 23) that if claim 13 satisfied the enablement, written description, and definiteness requirements, "parties could claim patent monopolies over basic scientific facts rather than any novel inventions." That argument confuses the Section 112 disclosure and drafting requirements with the Patent Act's separate limitations on the subject matter eligible for patent protection. This Court has long held that under 35 U.S.C. 101, "laws of nature, natural phenomena, and abstract ideas" may not be patented. *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981). But that limitation under Section 101 is entirely separate and distinct from the requirements of Section 112. Cf. pp. 17-27, *infra*.

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ingly, those precedents apply with full force to the current definiteness requirement.

B. WHETHER THE PATENT CLAIM IS INVALID BECAUSE IT CLAIMS A LAW OF NATURE, NATURAL PHENOMENON, OR ABSTRACT IDEA IS NOT FAIRLY INCLUDED IN THE QUESTION PRESENTED

Although the patent claim as construed by the courts below may be invalid under the rule that natural phenomena may not be patented (see pp. 17-27, *infra*), that issue is not fairly included in the question presented. Under this Court's Rule 14.1(a), "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." The question presented here asserts (Pet. i) that the patent claim includes a step that is not sufficiently enabled, described, or definite. Although it also asks (*ibid.*) whether such a patent claim "can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result," that portion of the question is not fairly read as an independent assertion that claim 13 violates Section 101 by claiming unpatentable subject matter. To the contrary, that passage appears on its face to be mere argument regarding the alleged consequences of upholding the claim against petitioner's Section 112 challenge.

The body of the petition supports that interpretation. The relevant argument heading states that "A Patent That Simply Claims A Scientific 'Correlation'—Without More—Is Indefinite, Insufficiently Described, and Non-Enabling." Pet. 23 (emphasis omitted). The heading does not assert that the claim is invalid under the natural-phenomenon doctrine of Section 101. The text of the petition (Pet. 23-26) then focuses on the Section 112 issues. Although it argues (Pet. 25) that "[i]f the Federal Circuit decision is not corrected, [respondent]

CTI and others like it would improperly gain monopolies over basic scientific facts," that contention, like the corresponding portion of the question presented, appears to be argument regarding the consequences of upholding the court of appeals' Section 112 rulings—not a stand-alone claim of invalidity based on Section 101, which is not even cited in the petition.[3] Because the petition, fairly read, challenges the patent claim's validity only on grounds *other than* failure to comply with Section 101, the claim's validity under that Section is not properly before this Court. See, *e.g.*, *Yee* v. *City of Escondido*, 503 U.S. 519, 537 (1992); *Albertson's, Inc.* v. *Kirkingburg*, 527 U.S. 555, 563 n.9 (1999); see also Gov't Cert. Br. 16-17.

The absence of any Section 101 challenge from the petition is not surprising, because petitioner did not raise such a challenge in either of the lower courts, and neither of those courts addressed the issue. In the court of appeals, petitioner noted in passing that if its indefiniteness challenge were rejected, respondent CTI "would improperly gain a monopoly over a basic scientific fact rather than any novel invention of its own." Pet. Corr. C.A. Br. 41 (citing *Diehr*, 450 U.S. at 185). As in the petition, however, petitioner advanced that cursory argument solely in support of its Section 112 challenge, not as a separate ground for reversal under Section 101. See Gov't Cert. Br. 15-17.

This Court does not ordinarily review questions that were neither pressed nor passed upon below. See, *e.g.*, *Adarand Constructors, Inc.* v. *Mineta*, 534 U.S. 103, 109

[3] That contention is also wrong for the related reason that no matter how the Section 112 issue is resolved, other litigants will retain the right, which petitioner failed to exercise below, to make a non-patentable subject matter argument under Section 101.

(2001). Although respondents did not call the Court's attention to the waiver in their brief in opposition, they should not be faulted for failing to raise a waiver objection to an issue that was not fairly included in the question presented. Cf. Sup. Ct. R. 15.2 ("Any objection to consideration of a *question presented* * * * may be deemed waived unless called to the Court's attention in the brief in opposition.") (emphasis added). Accordingly, this case does not properly present any issue regarding the natural phenomenon doctrine.

C. THE PATENT CLAIM APPEARS TO CLAIM ALL SUBSTANTIAL PRACTICAL APPLICATIONS OF THE NATURAL RELATIONSHIP THAT ARE REVEALED BY THE LIMITED RECORD BEFORE THE COURT

If this Court were to conclude that the question presented fairly includes a challenge to the validity of claim 13 under Section 101, any such challenge would necessarily be limited to the question whether the patent impermissibly claims "a monopoly over a basic scientific relationship," Pet. i, because that is the only potentially relevant language in the question presented. As construed by the court of appeals, and on the limited record presently before the Court, claim 13 appears to run afoul of the rule that one cannot patent every "substantial practical application" of a law of nature, natural phenomenon, or abstract idea. *Gottschalk* v. *Benson*, 409 U.S. 63, 71-72 (1972). Because petitioner did not raise a Section 101 challenge in the courts below, however, respondents had no opportunity or incentive to introduce evidence on that issue in the district court, and accordingly a remand for further proceedings would be required in order to resolve that issue definitively.

1. a. The scope of patentable subject matter is generally quite broad. "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" if the other conditions for patentability, such as novelty, non-obviousness, and the Section 112 requirements are satisfied. 35 U.S.C. 101. Thus, this Court has noted that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'" *Diehr*, 450 U.S. at 182 (quoting S. Rep. No. 1979, 82d Cong., 2d Sess. 5 (1952), and H.R. Rep. No. 1923, 82d Cong., 2d Sess. 6 (1952)).

"Excluded from such patent protection," however, are "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185; accord, *e.g.*, *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker* v. *Flook*, 437 U.S. 584, 589 (1978); *Benson*, 409 U.S. at 67-68; *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948); *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939). "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1852); see *Rubber-Tip Pencil Co.* v. *Howard*, 87 U.S. (20 Wall.) 498, 507 (1874); *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 116 (1853). Instead, such "manifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." *Funk*, 333 U.S. at 130; see *Benson*, 409 U.S. at 67 ("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.").

Thus, "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter" under Section 101. *Chakrabarty*, 447 U.S. at 309. "Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Ibid*. Nor can one patent "a novel and useful mathematical formula," *Flook*, 437 U.S. at 585; electromagnetism or steam power, *Morse*, 56 U.S. (15 How.) at 113-114; or "[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals," *Funk*, 333 U.S. at 130; see *Le Roy*, 55 U.S. (14 How.) at 175.

b. Claim 13 *involves* such a natural phenomenon, because it asserts and relies on the existence of a naturally occurring correlation between elevated levels of total homocysteine and deficiencies in cobalamin or folate. The natural relationship between elevated total homocysteine and deficiencies in the B vitamins is an unpatentable "principle in natural philosophy or physical science," *Morse*, 56 U.S. (15 How.) at 116, just as the relationship between energy, mass, and the speed of light discovered by Einstein ($E=mc^2$), and the relationship between force of attraction, mass, and distance discovered by Newton (the law of gravity), are unpatentable natural phenomena. See *Chakrabarty*, 447 U.S. at 309. Insofar as the relationship is no more than an observable, naturally occurring fact of human physiology, it is also analogous to observations of the properties of bacterial strains and metals, which this Court has held to be unpatentable. See *Funk*, 333 U.S. at 130.

c. Determining whether claim 13 *involves* a phenomenon of nature is only the beginning of the inquiry, however, because "[i]t is now commonplace 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*, 450 U.S. at 187; accord *Flook*, 437 U.S. at 590 ("[A] process is not unpatentable simply because it contains a law of nature."); *Benson*, 409 U.S. at 67; *Funk*, 333 U.S. at 130. "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." *Diehr*, 450 U.S. at 188 (quoting *Mackay*, 306 U.S. at 94).

It is also well established, however, that a patent applicant cannot validly patent a process that comprises every "substantial practical application" of a law of nature, because such a patent "would wholly pre-empt the [law of nature] and in practical effect would be a patent on the [law of nature] itself." *Benson*, 409 U.S. at 71-72; see PTO, *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility* (*Interim Subject Matter Eligibility Guidelines*), 1300 Off. Gaz. Pat. Office 142, 146 (Nov. 22, 2005) <http://www.uspto.gov/web/patents/patog/week47/OG/TOC.htm#ref13>. That "preemption" limitation is important because without it, "a competent draftsman [could] evade the recognized limitations on the type of subject matter eligible for patent protection." *Diehr*, 450 U.S. at 192; accord *Flook*, 437 U.S. at 590, 593.

2. If the question presented raises a Section 101 issue at all, it is whether claim 13 impermissibly asserts "a monopoly over a basic scientific relationship," because that is the only potentially relevant language in the text of the question presented. Pet. i. At most, that language can be read to raise the question whether claim 13 is invalid under the preemption rationale set forth in *Benson*, on the ground that it covers all substan-

tial practical applications of the asserted natural phenomenon. That language cannot plausibly be read to include other potential challenges to the validity of the patent claim under Section 101. It does not, for example, ask whether the claim sets forth an invalid but particularized application of the natural phenomenon, as opposed to claiming the entirety of the natural phenomenon.[4]

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[4] Under any reading of the question presented, therefore, it does not encompass the question whether a process patent that includes a transformative step satisfies Section 101 when the only "inventive" aspect of the patent is a newly discovered law of nature or natural phenomenon. See Gov't Cert. Br. 11-15 (discussing that issue); see also *id.* at 7-10. As the government explained in its brief at the petition stage (*id.* at 12-14), that question turns on the extent to which this Court's decision in *Diehr* is properly understood to limit the rationale set forth in *Flook*. That issue is not raised by the question on which the Court granted certiorari, because it asks only whether a patentee "can validly claim a *monopoly* over a basic scientific relationship" (Pet. i (emphasis added)), whereas the Court emphasized in both *Diehr* and *Flook* that those cases did *not* involve monopolization of a law of nature. *Diehr*, 450 U.S. at 187 (patentees "do not seek to pre-empt the use of that equation"); *Flook*, 437 U.S. at 589-590 (patentee "does not seek to 'wholly preempt the mathematical formula'") (quoting *Benson*, 409 U.S. at 72).

If the issue were before this Court, determining whether claim 13 constitutes a valid application of the natural phenomenon would require consideration of the claim "as a whole." *Diehr*, 450 U.S. at 188; accord *Flook*, 437 U.S. at 594 & n.16. PTO has issued interim guidelines instructing its examiners to determine that if a claim, taken as a whole, "provides a transformation or reduction of an article to a different state or thing," "the claim meets the statutory requirement of 35 U.S.C. Sec. 101." *Interim Subject Matter Eligibility Guidelines*, 1300 Off. Gaz. Pat. Office at 146. Claim 13 appears to satisfy that test because the various methods of assaying for total homocysteine that are described in the record entail significant physical or chemical alteration of a sample of blood or other bodily fluid. See, *e.g.*, S.A. 15-16, Pl. Tr. Exh. 205, Def. Tr. Exhs. JP and BT (describing such methods). PTO's guide-

a. As construed by the court of appeals, claim 13 is sweeping in its scope. The Federal Circuit determined that "[t]he claim only requires association of homocysteine levels with vitamin deficiencies." Pet. App. 8a. Under that holding, "correlate" means "to relate the presence of an elevated total homocysteine level to either a cobalamin or folate deficiency, or both * * *, and also to relate the absence of an elevated total homocysteine level to a deficiency in neither." *Id.* at 12a. According to the court of appeals, "[t]he claim simply says nothing about a confirmatory step or a further correlation beyond the stated relationship." *Id.* at 8a-9a; accord *id.* at 10a. Instead, "[t]he correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." *Id.* at 18a. In sum, the court of appeals held that anyone who thinks about the relationship between elevated total homocysteine and cobalamin or folate deficiency after obtaining the results of a total homocysteine assay infringes the patent claim.

The claim's breadth is further underscored by the jury's findings and the relief awarded, which suggest that doctors infringe the patent claim whenever they review the results of total homocysteine assays, regardless of the purpose for which they ordered the assays. The district court instructed the jury that it should find petitioner liable for contributory infringement if, among other things, the total homocysteine assays performed by petitioner were not "capable of substantial nonin-

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lines reflect its (and the Federal Circuit's) view that *Diehr* substantially limited the *Flook* Court's holding that a claimed method must contain some inventive aspect other than a natural phenomenon in order to be patentable under Section 101. Compare *Diehr*, 450 U.S. at 188-190, with *Flook*, 437 U.S. at 592-594; see Gov't Cert. Br. 11-14.

fringing use." J.A. 379. By finding petitioner liable for contributory infringement, the jury necessarily concluded that no substantial non-infringing uses of the total homocysteine assays had been proven on the trial record.

In so concluding, the jury implicitly rejected petitioner's contention that many of the assays did not infringe because doctors ordered them for purposes other than diagnosing cobalamin or folate deficiency. Petitioner had argued that the assays were used primarily to diagnose other conditions, especially heart disease. See Pet. C.A. Br. 31-33. Respondents' witnesses countered that, whatever the motivation for the assay, it would be "malpractice" for a physician not to perform the correlation upon viewing a total homocysteine assay, and that the other conditions associated with elevated total homocysteine are treated with supplements of cobalamin or folate in any event. See Resp. C.A. Br. 32-33, 41-42, 45. The jury's verdict demonstrates that, like the court of appeals, it credited that testimony. See Pet. App. 14a (relying on testimony that "it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency").

Indeed, the jury evidently awarded damages based on *all* of the assays performed by petitioner, because it awarded the full amount requested by respondents for "all of the assays that were done." J.A. 175-176; see J.A. 396. The district court then permanently enjoined petitioner from performing "*any* homocysteine-only test, including without limitation homocysteine-only tests via [petitioner's preferred] method." Pet. App. 36a (emphasis added and citation omitted).

Although the court of appeals did not review the jury's contributory-infringement finding or damages

award, it affirmed the scope of the district court's injunction. Pet. App. 15a, 27a. The court specifically rejected petitioner's contention that "the injunction is too broad because it extends beyond the scope of the claims." *Id.* at 27a. "To the contrary," the court concluded, "the injunction simply addresses [petitioner's] specific acts constituting indirect infringement." *Ibid.* The court of appeals thereby appears to have concluded that *any* assay for total homocysteine would infringe claim 13, regardless of the reason a doctor ordered it, because any doctor reviewing a total homocysteine result would necessarily perform the correlation in his or her head.

b. In light of that broad claim construction and the jury's findings, on the record presently before the Court claim 13 appears to cover all substantial practical applications of the natural phenomenon. As has been demonstrated, however, the parties did not litigate that issue in the lower courts, and thus respondents had neither reason nor opportunity to introduce evidence to attempt to defeat a preemption challenge. Moreover, the relevance of the jury's findings on non-infringing uses for purposes of the contributory infringement issue is diluted by the fact that respondents bore the burden of proof on that issue, whereas petitioner bore the burden of proving invalidity by clear and convincing evidence. See J.A. 378, 379-380, 390.[5]

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[5] It is unclear, moreover, whether the inquiry into substantial non-infringing uses in the contributory infringement and damages contexts is the same as the inquiry into substantial practical applications for purposes of the preemption issue. It is at least conceivable, for example, that a substantial practical application could exist (and thus preclude a finding of preemption) but be irrelevant for purposes of contributory infringement and damages, because it would be a use

It is unclear, therefore, whether the record would have reflected the existence of one or more substantial practical applications of the correlation that are not covered by the patent if the preemption issue had been fully litigated below. It is possible, however, to hypothesize potential non-infringing applications that could perhaps be found to be substantial on an appropriate record.

i. Because the assay step of claim 13 is limited to assaying a "body fluid" (S.A. 30), researchers or physicians might be able to employ the correlation without infringing the patent merely by determining total homocysteine levels through a method other than an assay of body fluids. The specification states that "[i]t has now been discovered that an elevated level of total homocysteine in *tissues* of warmblooded animals correlates both with cobalamin deficiency and with folic acid deficiency." S.A. 11 (emphasis added). The specification further explains that "[s]uitable assays for this purpose include any assays capable of determining levels of homocysteine in body *tissues*, *preferably body fluids*." S.A. 12 (emphasis added).

It is unclear whether any feasible methods exist for determining homocysteine levels without assaying body fluids, or whether any such methods would constitute substantial applications of the correlation. The specification discloses "several different known assays suitable for use in determining levels of homocysteine in urine or blood," S.A. 12, but those are body fluids. The patent also claims a series of novel assay methods that are not by their terms limited to body fluids (and one of which expressly includes assays of a "body tissue"), see S.A.

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exclusively by persons other than doctors who order homocysteine assays from petitioner.

30, but the specification's examples all involve assays of body fluids, see S.A. 12-20.[6]

ii. It might also be argued that there are uses of the correlation that do not involve any measurements, and therefore are not preempted. For example, if a patient had a condition known to be associated with elevated total homocysteine and cobalamin or folate deficiency, a doctor might prescribe cobalamin or folate supplements with an eye toward both treating the vitamin deficiency and heading off potential health problems associated with elevated total homocysteine, such as heart disease.

Under the court of appeals' construction of the "correlating" step, administering cobalamin or folate supplements in such circumstances might constitute a use of the correlation that would not involve assaying for total homocysteine. If so, the question would be whether doctors engage in that thought process to such an extent that it comprises a substantial practical application of the correlation.

c. Thus, it is conceivable that, if a preemption challenge under Section 101 had been raised in the district court, the record would reflect additional information concerning the feasibility and relative significance of those or other possible non-infringing applications of the correlation asserted in claim 13. Accordingly, if this Court were to conclude that the Section 101 issue is properly presented, it should vacate and remand for

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[6] As noted above, the district court enjoined petitioner from performing "*any* homocysteine-only test," Pet. App. 36a (emphasis added and citation omitted), and the court of appeals affirmed that injunction, *id.* at 27a. See pp. 23-24, *supra*. If the only basis for rejecting a preemption challenge to claim 13 were the existence of homocysteine tests of tissues other than body fluids, the injunction would presumably have to be narrowed to exempt such tests.

further proceedings to determine whether all substantial practical applications of the correlation are claimed by the patent.[7]

3. Regardless of whether claim 13 preempts the natural phenomenon at issue here, many medical and diagnostic procedures are unquestionably patentable. For example, the first 12 claims in the '658 patent identify assay methods whose validity has never been challenged, in part because they provide novel ways of measuring substances in bodies. See S.A. 30.

Moreover, many diagnostic procedures that involve correlations may not monopolize all of the correlations' substantial practical applications. For example, claim 14 of the patent at issue here is identical to claim 13 except that it limits the assay step to assays undertaken according to a specified and novel method. See S.A. 30. Because that claim does not cover all substantial practical applications of the natural relationship—including the assays at issue in this case, which did not make use of the method identified in claim 14—its validity would not be jeopardized by a holding that claim 13 impermissibly preempts all substantial practical applications of the natural correlation.

Other patents that use the term "correlate" might also be construed to use that term more narrowly than the court of appeals construed it here. All else being

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[7] The Federal Circuit's predecessor held that *Benson* applies only to mathematical algorithms. See, *e.g.*, *In re Toma*, 575 F.2d 872, 877 (C.C.P.A. 1978). *Benson*'s rationale—that one may not patent an "idea," and that would be the practical effect of patenting all substantial practical applications of the idea, 409 U.S. at 71—refutes any attempt to cabin *Benson*'s holding to mathematical algorithms. See also *id.* at 67-69 (relying on cases involving natural phenomena other than mathematical algorithms).

equal, the more limits a claim is read to include, the more likely it is that the claim covers only some, but not all, substantial practical applications of any natural phenomena used in the claimed invention.

D. THE PATENT CLAIM IS INVALID UNDER 35 U.S.C. 102 IF IT CLAIMS ASSAY METHODS THAT WERE ALREADY INCLUDED IN THE PRIOR ART

The question presented does not ask whether claim 13 is invalid under 35 U.S.C. 102 because it was anticipated by the prior art, and that question is therefore not before this Court. We note, however, that claim 13, as construed by the court of appeals, appears to be invalid under Section 102 because the claim effectively prevents doctors from using previously known assay methods to measure total homocysteine for *any* purpose, even if the purpose was not to diagnose cobalamin or folate deficiency.

"[T]he stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public." *Aronson* v. *Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979). Thus, "§ 102 of the Patent Act * * * exclud[es] ideas that are in the public domain from patent protection," *Pfaff*, 525 U.S. at 64, by generally providing that no patent may issue on an invention previously known, used, or sold in this country, 35 U.S.C. 102(a), (b). See *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 148 (1989). That fundamental limitation on patentability is rooted in Article I, Section 8, Clause 8 of the Constitution, which this Court has construed to preclude "the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Bonito Boats*, 489 U.S. at 146

(quoting *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966)).

Although the court of appeals held that the prior art in the record did not specifically disclose the *correlation* between elevated total homocysteine and cobalamin or folate deficiency, Pet. App. 18a-20a, the patent specification acknowledges that methods of *assaying* for total homocysteine were known in the prior art and were used to screen for various medical conditions other than cobalamin or folate deficiency, see S.A. 12; p. 10, *supra*. As explained above, however, the lower courts enjoined petitioner from performing "any homocysteine-only test," Pet. App. 36a, and construed claim 13 in such a way that a doctor reviewing a total homocysteine assay cannot help but infringe the patent regardless of the purpose for which he or she ordered the assay. See pp. 22-24, *supra*.

So construed, claim 13 appears to remove methods of assaying for total homocysteine from the public domain, in violation of Section 102. "[I]f granting patent protection on the disputed claim would allow the patentee to exclude the public from practicing the prior art, then that claim is anticipated, regardless of whether it also covers subject matter not in the prior art." *Atlas Powder Co.* v. *Ireco Inc.*, 190 F.3d 1342, 1346 (Fed. Cir. 1999); accord *Schering Corp.* v. *Geneva Pharm., Inc.*, 339 F.3d 1373, 1379 (Fed. Cir. 2003). Although claim 13 might not be invalid as anticipated if the correlating step were construed to be less sweeping, or if the assay step were limited to novel assay methods, as construed by the

court of appeals the claim appears to remove the prior art from the public domain, in violation of Section 102.[8]

If the patent claim were held invalid, an anticipation rationale would be more administrable than a preemption rationale because it would rely on publicly known inventions, as opposed to requiring an inquiry into potential alternative applications that may not yet have been disclosed or discovered.

CONCLUSION

If this Court concludes that the question presented does not fairly include the question whether the patent claims all substantial practical applications of the natural correlation, the judgment of the court of appeals should be affirmed, or in the alternative the writ of certiorari should be dismissed as improvidently granted. If this Court concludes that the question presented does include that issue, the judgment of the court of appeals should be vacated and the case remanded for further proceedings.

Respectfully submitted.

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[8] The Patent Act specifies that "a new use of a known process" constitutes a "process" eligible for patent protection. 35 U.S.C. 100(b). Claim 13's apparent invalidity under Section 102 stems from its breadth, not from the mere fact that it applies known assay processes.

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