SAN FRANCISCO BAY AREA INTELLECTUAL PROPERTY
AMERICAN INN OF COURT

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February 2006 Meeting Announcement:

Natural Phenomena or Natural Objections?

The February 2006 program will present a moot court of the *LabCorp v. Metabolite* case, set to be argued in the Supreme Court on March 21, 2006. The claimed invention at issue is a method for detecting a specific vitamin deficiency, consisting of assaying a body fluid for an elevated level of an amino acid and correlating that elevated level with a vitamine deficiency. LabCorp asserts that the patent claims a natural phenomenon or a "basic scientific fact" and, as such, seeks to encompass nonpatentable subject matter.

Panelists:	**Martin C. Fliesler**	*Fliesler Meyer*
	Mark Lemley	*Stanford Law School, Keker & Van Nest*
	Corynne McSherry	*Electronic Frontier Foundation*
	Heather Mewes	*Fenwick & West*
	Robert A. Morrill	*Sidley Austin Brown & Wood*
	Gene Paige	*Keker & Van Nest*
	David V. Sanker	*Boalt Hall School of Law*
	Claude M. Stern	*Quinn Emanuel*
	Hon. Bernard Zimmerman	*United States District Court*

Time and Location: **Wednesday, February 15, 2006 at 6:00pm**
Courtroom of The Honorable Magistrate Judge Bernard Zimmerman
United States Federal Building
Courtroom G, 15th Floor
450 Golden Gate Avenue
San Francisco, California

Dinner to Follow at: California Culinary Academy
625 Polk Street (between Turk and Eddy)

c/o Joshua M. Masur, Mayer Brown Rowe & Maw LLP, Two Palo Alto Square, 3000 El Camino Real, Suite 300, Palo Alto, California 94306-2112
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No. 04-607

IN THE
Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (doing business as LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR PETITIONER

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QUESTION PRESENTED

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.

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioner in this case is Laboratory Corporation of America Holdings (doing business as LabCorp) ("LabCorp"). LabCorp has no parent corporations, and no publicly held company owns ten percent or more of its stock.

Respondents are Metabolite Laboratories, Inc. and Competitive Technologies, Inc.

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BRIEF FOR PETITIONER

OPINIONS BELOW

The opinion of the Federal Circuit is reported at 370 F.3d 1354 and is reproduced at page 1a of the appendix to the petition ("Pet. App."). The order of the District Court denying LabCorp's motion for judgment as a matter of law or a new trial is unreported and is reproduced at Pet. App. 34a.

JURISDICTION

The judgment of the Federal Circuit was entered on June 8, 2004. On August 5, 2004, the Federal Circuit denied a timely filed petition for rehearing or rehearing en banc. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutes are set forth in the appendix to this brief.

INTRODUCTION

The Court has granted certiorari to answer this question: whether a vaguely worded patent claim "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." Pet. i. The answer to the question is no. As construed by the Federal Circuit, the patent claim at issue is infringed whenever any doctor tests a patient for a level of homocysteine, a basic amino acid—regardless of how or why the test is performed—and then thinks in his or her mind that the result may signify a vitamin deficiency. The result has been millions of dollars in damages and an injunction prohibiting homocysteine testing by LabCorp for *any* reason and by *any* method.

Upholding this patent claim would allow an effective monopoly over a scientific principle, in contravention of this Court's settled precedents. Correlations, like all natural phenomena and laws of nature, belong in the public domain because they are "the basic tools of scientific and technological work." *Gottschalk* v. *Benson*, 409 U.S. 63, 67-68 (1972). Allowing a vaguely worded "correlating" claim to confer an almost unbounded private property right over doctors' thought processes and both past and future inventions would hinder both the practice of medicine and the goals of innovation and scientific progress that the patent laws were intended to promote. The judgment below should be reversed.

STATEMENT OF THE CASE

The Patent. Homocysteine is an amino acid found naturally in the human body.[1] For decades, it has been

[1] This brief uses the terms "total homocysteine" and "homocysteine" interchangeably. Total homocysteine consists of four components: homocysteine-cysteine mixed disulfide, homocysteine-albumin, free homocysteine, and the similarly spelled

known that elevated levels of homocysteine are linked to various medical conditions. For example, as far back as 1969 Dr. Kilmer S. McCully discovered that elevated homocysteine is connected to heart disease. *See* J.A. 239-245, 344-349. Elevated homocysteine has also been connected with other conditions, including renal disease, dehydration, vitamin B_6 deficiency, inborn enzyme deficiencies, hypothyroidism, lupus, and decreased cognitive function. *See*, ***e.g.***, J.A. 250-251, 336-337, 339, 355-356. One of the respondents in this case has itself noted that elevated levels are associated with Alzheimer's disease, chronic fatigue syndrome, and rheumatoid arthritis. *See* J.A. 316.

This case arises because it is also a scientific fact that elevated levels of homocysteine are associated with deficiencies in two basic vitamins: cobalamin (Vitamin B_{12}) and folate (folic acid). The case involves U.S. Patent 4,940,658 (the "Patent"), whose three inventors (the "patentees") claim to have been the first to discover that scientific fact. As the patent specification recites, the patentees claim to have "discovered that an elevated level of total homocysteine in tissues of warmblooded animals correlates 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 (Patent, col. 4, lns. 16-23). *See* S.A. 12 (Patent, col. 5, lns. 64-66) ("It has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue."); J.A. 100, 108. The patentees based their scientific

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homocys***tine***. J.A. 198, 262. The patent at issue likewise uses the terms interchangeably. *See*, ***e.g.***, S.A. 12 (Patent, col. 5, lns. 57, 64, 67; col. 6, lns. 3, 7, 48) ("S.A." refers to the Supplemental Appendix filed pursuant to S. Ct. R. 33.1(c), which contains the patent.).

discovery on a study of hospital patients. *See* S.A. 14-15 (Patent, cols. 10-12).[2]

In November 1986, the patentees filed the application that would become the Patent. Most of the claims of the Patent (Claims 1-12 and related claims) relate to a new method for testing (assaying) for total homocysteine. This method (referred to below as the "GCMS" method) employs mass spectrometry and requires the performance of several detailed steps, which are recited in the patent claims. *See* S.A. 30 (Patent, col. 41, lns. 1-57). Notably, these claims are not at issue in this appeal. For, as explained below, LabCorp has paid and continues to pay royalties whenever it uses this patented GCMS method.

This appeal, by contrast, involves only Claim 13 of the Patent, which is a separate and independent claim.[3] That claim recites, *in its entirety*:

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[2] LabCorp has argued that the patentees were not the first to have discovered this fact, and that the discovery was in any event obvious in light of prior studies. It had been known well before the filing of their patent application that elevated homocysteine—as measured by levels of two of the four *components* of total homocysteine comprising about 30% of the total—was associated with cobalamin and folate deficiencies. *See* J.A. 318-319, 321-322, 326, 198. Nevertheless, the patentees insisted that they advanced the state of scientific knowledge by being the first to discover that *total* homocysteine is likewise linked to these deficiencies. The Federal Circuit held that this seemingly trivial difference sufficed to render Claim 13 non-obvious. Pet. App. 20a.

[3] Each claim of a patent is capable of being separately infringed. *See, e.g.*, *Intervet Am., Inc.* v. *Kee-Vet Lab., Inc.*, 887 F.2d 1050, 1055 (Fed. Cir. 1989). Claim 13 is the only claim now at issue in the case. *See* Pet. App. 21a-23a (finding no present case or controversy regarding Claim 18, whose validity LabCorp had sought to challenge).

> 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.

S.A. 30 (Patent, col. 41, lns. 58-65) (emphases added).

Claim 13 is thus a "method" or "process" claim consisting of only two steps. *First*, one must assay a body fluid for total homocysteine. It does not matter what assay method is used, because Claim 13 applies no matter how one tests for homocysteine. *Second*, one must "correlat[e]" an elevated level of total homocysteine with a deficiency of cobalamin or folate. The term "correlating" is not further defined in the Patent, and nothing in the claim or the specification says precisely what it means to "correlate" a homocysteine level with vitamin deficiencies. Further, although Claim 13 expressly covers only correlation of "elevated" levels of total homocysteine, the Federal Circuit has now construed it to cover all test results, elevated or not. Pet. App. 11a-13a.

In the patent application as originally filed, Claim 13 had recited only "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals by assaying body fluids for the presence of elevated levels of total homocysteine." J.A. 288 (amendment text removed). The Patent Examiner rejected that proposed claim for, among other things, failing to "distinctly claim the subject matter which [the] applicant regards as the invention." J.A. 274. He explained that "Claim 13 should recite discrete, sequential process steps, for example, obtaining a sample, contacting the sample, etc. The final step should be clearly related to the preamble of the claim." *Id*. The Examiner also found that Claim 13 was unpatentable in light of prior art, because "[i]t would have been obvious for one of ordinary skill in the art to determine cobalamin 'or' folate deficiency

indirectly by measuring homocysteine and methylmalonate levels * * *." J.A. 276.[4]

But while they made other changes, the applicants did not amend Claim 13. The Examiner again rejected the proposed claim as anticipated by the prior art. *See* J.A. 285. He also noted that

> [i]n the absence of a correlation step, the preamble of claim 13 merely recites an intended use of the invention. The claim lacks a positive limitation of correlating to a particular condition and has only one method step recited. Applicants admit on pages 12 and 13 of the specification that assays for homocysteine are known.

Id. This time, the applicants amended Claim 13 to add the second step of "correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin and folate." J.A. 288. That claim was allowed. Yet while Claim 13 refers to the process of "correlating" elevated homocysteine levels with vitamin deficiencies, the Patent says nothing about how a practitioner is to accomplish that step.

LabCorp Licenses The Patented Testing Method. Respondent Competitive Technologies, Inc. ("CTI"), through a predecessor, acquired rights to the Patent before it issued. CTI granted respondent Metabolite Laboratories, Inc. ("Metabolite") a non-exclusive license to the Patent, including the right to sub-license. *See* J.A. 224, 296-297. Metabolite agreed to pay CTI a royalty equal to 6% of the amount charged for assays performed by Metabolite in accordance with the Patent. J.A. 226, 227.

LabCorp is the second-largest clinical reference laboratory in the United States. It performs tests to assist health care providers in diagnosing and treating their patients but does not itself diagnose or treat patients. *See* J.A. 358-359. In

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[4] Methylmalonate is another substance involved in different claims of the Patent not at issue here.

January 1991, Metabolite sublicensed the patent to Roche Biomedical Laboratories ("Roche"), LabCorp's predecessor. That agreement (the "Agreement") granted LabCorp (formerly Roche) a sublicense "for the practice of Licensed Assays in the United States." J.A. 302. "Licensed Assays" were defined as including, among other things, "assays of homocysteine using methods and materials falling within the claims of [the Patent]." J.A. 301. In return, LabCorp agreed to pay Metabolite a total of 27.5% of the revenue for the tests: 6% to CTI, the patent holder, and 21.5% to Metabolite, CTI's licensee. *See* J.A. 303, 227.

The Agreement also specifically provided that LabCorp could terminate it with respect to any "Licensed Assay" of homocysteine if "a more cost effective commercial alternative is available that does not infringe a valid and enforceable claim of the [Patent]." J.A. 305. Thus, if an assay does not infringe a "valid and enforceable claim" of the Patent, the Agreement specifically provides that LabCorp does not have to pay royalties for that assay.

LabCorp began performing "licensed assays" in 1992 and paid royalties under the Agreement. The royalties, however, were paid not because of Claim 13—which recites no particular testing method—but because LabCorp used (and still uses) the patented *GCMS method* when conducting some total homocysteine tests. In particular, LabCorp still uses the GCMS method when conducting a separate "panel test" that assays for total homocysteine along with three other substances, and LabCorp therefore pays royalties for the panel tests. J.A. 163.

LabCorp Switches Methods For Homocysteine-Only Tests. Although elevated homocysteine has been linked to various medical conditions, a test result showing elevated homocysteine levels, standing alone, is of limited practical utility to physicians screening for a vitamin deficiency. That is because homocysteine may be elevated in cases of cobalamin *or* folate deficiency, *or* as the result of other conditions,

and a test *only* for homocysteine therefore cannot itself diagnose or distinguish between vitamin deficiencies. *See* S.A. 12 (Patent, col. 5, lns. 64-66). The patent specification itself notes that it is unsafe to diagnose and treat a cobalamin or folate deficiency based on just an elevated homocysteine result, due to the risk that the prescribed vitamin was not actually deficient in the patient's system: "[t]he use of folic acid to treat cobalamin [deficiency] is extremely dangerous." S.A. 10 (Patent, col. 1, lns. 46-55). Indeed, in 1992 one of the patentees himself wrote to LabCorp advising that it was not good medical practice to use levels of a single metabolite—such as homocysteine—to diagnose cobalamin or folate deficiencies. J.A. 299-300. Thus, when a doctor is interested in homocysteine levels in connection with possible vitamin deficiencies, the doctor will order the royalty-bearing *panel* test, which tests for homocysteine along with other metabolites and thus indicates which vitamin may be deficient. *See* J.A. 235-236.

"Homocysteine-only" (or "single homocysteine") tests *are* helpful, however, in screening patients for risk of heart disease. As noted, the association between elevated homocysteine and risk of heart disease has been known since at least 1969. Knowledge of this scientific fact became more widespread by the 1990s. Because using homocysteine levels alone to screen for heart-disease risk does not create a risk of misdiagnosis, doctors did not have to use a panel test for that purpose and could instead test solely for homocysteine. Thus, the increasing attention to the relationship between homocysteine and cardiovascular disease resulted in an increase in demand for homocysteine-only tests. *See* J.A. 168. In 1994, in response to this increasing demand, LabCorp began offering such a test, which it initially performed using the GCMS method of the Patent. J.A. 136. LabCorp paid royalties on homocysteine-only tests it performed using the patented method. J.A. 137.

As more studies were published linking the risk of elevated homocysteine with heart disease, however, demand for the homocysteine-only test "seemed to skyrocket" to the point where LabCorp "couldn't keep up with the work" using the GCMS method of the Patent. J.A. 168. In May 1998, LabCorp entered into a research agreement with Abbott Laboratories to test Abbott's new immunoassay method for testing for homocysteine. Abbott's method was far faster and less labor-intensive than the GCMS method identified in Claims 1-12 of the Patent—a crucial advance in light of the increased demand for homocysteine-only tests. Whereas the GCMS method took "upwards of 18 hours to turn out a result," the Abbott method reduced that time "to a matter of minutes." J.A. 167.

Beginning in August 1998, LabCorp stopped using the licensed GCMS method for homocysteine-only blood tests and began using Abbott's method. On November 2, 1998, LabCorp notified Metabolite that it had begun using the Abbott method for homocysteine-only assays of blood samples, and therefore that it would no longer pay royalties for such assays. J.A. 237. LabCorp did not terminate the Agreement with regard to other tests, however, because it continued to use the licensed method—and to pay royalties—to perform the panel test and homocysteine-only assays on urine samples. J.A. 136-137.

Even though LabCorp no longer used the GCMS method for homocysteine-only blood tests, respondents nevertheless contended that LabCorp infringed Claim 13 and breached the associated Agreement *regardless* of the method used for the tests. Respondents' theory is that, unless a license is granted and a royalty paid, every one of the thousands of doctors who orders one of the millions of homocysteine tests performed for patients nationwide necessarily infringes Claim 13 because each doctor looks at the test result and allegedly performs the patented "correlating" step by *thinking* that the result indicates the existence or non-existence of a vitamin

deficiency. Under that theory, the direct infringers are the doctors who allegedly "correlate" test results in their minds. But rather than sue doctors, respondents sued LabCorp—which committed no direct infringement—on the theory that LabCorp contributes to or induces doctors' infringement by performing homocysteine tests for them and by allegedly informing them of the basic medical fact that elevated homocysteine is associated with vitamin deficiencies.

The District Court Proceedings. In May 1999, respondents sued LabCorp in the District Court for the District of Colorado. CTI, the patent holder, brought claims for infringement and contributory infringement of the Patent. Metabolite, the licensee, brought corresponding claims for breach of the Agreement.

The District Court held proceedings to construe the relevant claims of the Patent, as required under *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). In the course of construing the "correlating" step of Claim 13, the court remarked that

> [a]n invention is not just an idea, it is not just a mental discovery. It must combine the idea with the means of putting it into practice and producing the desired result. And so until the discovery is put into a practical form, there is no invention. There is no valid patent. * * * The Supreme Court, way back when, in [*T.H. Symington Co.* v. *National Malleable Castings Co.*, 250 U.S. 383 (1919)], said "A conception of the mind, not represented in some physical form, is not an invention." So if one takes the statement, which may very well be a wonderful new conception, that if there is an elevated level of total homocysteine and * * * that elevated level can be correlated in said body fluid with deficiency of cobalamin or folate, that is certainly a new idea, something original. But what is the * * * practical form of that? What are the actual steps? What are the discrete, sequential steps for putting into practice this new statement?

J.A. 46-47.[5]

Accordingly, in construing the claim term "correlating," the court held that " '[c]orrelating' is a verb, and must * * * comprise a discrete, sequential process step" as the Examiner had earlier required. J.A. 60. As the court later reiterated at trial, "[b]asically, what my ruling was is that you can't patent an idea. You have to patent an act or the test * * *." J.A. 131. The court also adopted a dictionary definition of "correlating" as meaning "to establish a mutual or reciprocal relationship between." J.A. 60. But although the court made clear that correlating had to be a discrete, active step beyond the mental concept that elevated homocysteine is associated with vitamin deficiencies, the court provided no further guidance as to how a practitioner is to perform the "correlating"—*i.e.*, how one is to actively "establish" a "relationship" between a test result and a vitamin deficiency.[6]

The District Court then granted summary judgment to LabCorp on direct infringement, J.A. 16, because LabCorp, although it performed tests for doctors, did not "correlate" any results, whatever that may mean. But the court denied summary judgment on other issues and set the case for trial.

The case was tried to a jury beginning in November 2001. LabCorp moved for judgment as a matter of law at the close of the evidence. In connection with that motion, the court noted that "part of the argument" was "whether you really

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[5] *See also* J.A. 51 (trial court direction to "[t]ell me what practical steps are done to do [the correlating]? Because we know from the case law that there must be a practical form. Can't be just a mental conception. So what do you do? No. 1, No. 2, No. 3, No. 4. What do you do to correlate?").

[6] The court also construed other terms of Claim 13. For example, the term "elevated" was construed as "raised above the normal range," and the term "deficiency" was construed as "a shortage of a substance necessary to health." J.A. 59.

can patent an idea * * * rather than a method." J.A. 174. *See also* J.A. 173 (trial court statement that "it's difficult to think you can patent an idea, rather than a test. And that's what I'm afraid some of these patents do, is try to patent an idea."). But the court nevertheless denied the motion. J.A. 29 (R. 239).

The jury returned a verdict against LabCorp for contributory and induced infringement. And while the trial evidence demonstrated that fewer than 20% of test results showed *elevated* homocysteine levels (as seemingly required to satisfy the limitations of Claim 13), Pet. App. 32a-33a, the jury nonetheless awarded damages to respondents based on *every* one of the 351,458 homocysteine-only tests LabCorp performed via the Abbott method during the relevant period. This amounted to $1,019,365 to CTI for the infringement and $3,652,724 to Metabolite for the corresponding breach of contract. *See id*. at 34a; *see also* J.A. 271-272, 175-176 (explaining calculation). The jury also found LabCorp's infringement to be willful, and found the patent valid.

LabCorp renewed its JMOL motion, but the District Court denied that motion a year later. Pet. App. 34a. The court also doubled the $1,019,365 in patent damages in light of the finding of willful infringement, resulting in a total damage award of $6,297,665.87 including prejudgment interest. *Id*. at 38a. The court further awarded CTI attorneys' fees in an amount to be determined. *Id*. at 36a. And the court enjoined LabCorp from performing "*any* homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method." *Id*. at 36a-37a (emphasis added). Eight months later, the District Court awarded more than $1.1 million in attorneys' fees and costs against LabCorp, based on the earlier finding of willful infringement, raising the total monetary award to more than $7,400,000. In addition, LabCorp tendered almost $2,000,000 more to secure a stay of the injunction pending the Federal Circuit appeal. *See* J.A. 41 (R. 318) (Jan. 13, 2003 order staying injunction).

The Court Of Appeals' Decision. The Federal Circuit affirmed. The court first rejected LabCorp's argument that the "correlating" step of Claim 13 should be construed to require, at a minimum, that a doctor actually confirm that a patient with elevated homocysteine is in fact suffering from a vitamin deficiency, as shown by actual physical symptoms. LabCorp explained that the Patent itself notes that some people with elevated homocysteine do *not* suffer from vitamin deficiencies, and that the patentees themselves had determined such deficiencies in their patients by looking at their symptoms. Thus, because respondents presented no evidence that doctors who look at the results of homocysteine-only tests ever confirm the existence of vitamin deficiencies, LabCorp argued that the doctors did not infringe and that LabCorp did not induce or contribute to infringement.

The court rejected this argument, holding that Claim 13

> does not require a further association between the level of total homocysteine and [physical symptoms]. *The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies*.

Pet. App. 8a (emphasis added). *See also id*. at 12a ("the claim language does not require a confirmatory step linking these conditions to diagnosed or apparent symptoms"). As the court later held in connection with examining the patent's validity, "[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 other words, the court held that a doctor infringes the Patent merely by looking at a test result and *thinking* in his or her mind that there is an "association of homocysteine levels with vitamin deficiencies." *Id*. at 8a. Once the doctor has thought about this basic scientific association after looking at a homocysteine test result, he or she has performed the patented "correlating." According to the court, no further steps—such as confirming that the patient actually *has* a vita-

min deficiency—are required to infringe. This is consistent with the view of the patentees, who testified that the entire "correlating" process "takes place in the mind of the physician." J.A. 110. *See also* J.A. 111, 137-141, 155-157.

The court also rejected LabCorp's related argument that if Claim 13 were construed as broadly as respondents contended, it would be invalid. The court largely relied on its claim construction, Pet. App. 16a, in which it had held that the "correlating" step merely requires a doctor to look at a test result and think about the naturally occurring association with vitamin deficiencies. The court, however, ignored LabCorp's express argument that

> [i]f 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," without any explanation of the testing or correlation processes. 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, 185 (1981) ("[e]xcluded from * * * patent protection are laws of nature, natural phenomena, and abstract ideas"); Chisum on Patents § 1.03[6].

LabCorp Ct. App. Br. 41. *See also* LabCorp Ct. App. Reply Br. 3 ("[W]ere the Court to uphold this vague 'test plus correlate' claim, anyone would improperly be able to patent basic scientific facts rather than any actual novel testing method.").

The Federal Circuit also expanded the patent even further than its literal reach. Claim 13 covers only the assaying and correlation of "an *elevated* level of total homocysteine." S.A. 30 (Patent, col. 41, ln. 63) (emphasis added). But the panel majority held that the patent is infringed even by test results that are *not* elevated—more than 80% of all results. Pet.

App. 12a-13a. Judge Schall dissented on this point, because in his view "[i]f the patient's homocysteine levels are not 'elevated,' by the plain language of the claim, there is no 'correlating' to be done." *Id*. at 31a.

LabCorp had also challenged the finding of contributory infringement on the ground that there are substantial *non*-infringing uses for homocysteine-only tests—most importantly, to assess for risk of heart disease. The Federal Circuit, however, did not reach that issue. Instead, it held that LabCorp could be held liable for induced infringement because certain of LabCorp's educational and informational materials state the basic medical fact "that elevated total homocysteine correlates to cobalamin/folate deficiency." *Id*. at 15a. According to the court, the alleged dissemination of this scientific fact to doctors constituted intent to induce infringement because LabCorp thereby "promote[d] total homocysteine assays for detecting cobalamin/folate deficiency." *Id*.[7] The court thus upheld the damages and injunction against *all* total homocysteine tests performed by LabCorp—regardless of the reason the tests were performed—specifically crediting the testimony of one of the patentees that "it would be *malpractice* for a doctor to receive a total homocysteine assay without determining cobalamin/ folate deficiency." *Id*. at 14a (emphasis added).

Having affirmed on infringement and validity, the Federal Circuit upheld the jury's finding that LabCorp had breached the Agreement by failing to pay royalties on homocysteine-only tests conducted via the Abbott method. The court held that LabCorp's non-payment constituted a material breach of

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[7] The court was incorrect as a factual matter. The evidence cited by the court merely referred doctors to the *panel* test (on which LabCorp continues to pay royalties) when screening for vitamin deficiencies, or discussed elevated homocysteine as a risk factor for *heart disease*. *See* Pet. 10 n.5; J.A. 266-267, 268-269, 263-265, 252-254, 246-251.

the Agreement, which in turn constituted a wrongful termination of it. *Id*. at 23a-24a. The court thus rejected LabCorp's arguments that the Agreement was not breached because Claim 13 was invalid and/or not infringed, and therefore that no royalties were owed for tests performed by the Abbott method. *See* LabCorp Ct. App. Br. 36-38.

The court also affirmed the District Court's award of enhanced damages based on the jury's finding of willful infringement. Pet. App. 26a. And it affirmed the injunction prohibiting LabCorp from performing homocysteine-only tests under any testing method. *Id*. at 27a.[8]

Proceedings In This Court. After the Federal Circuit denied LabCorp's petition for rehearing, this petition followed. This Court invited the Solicitor General to express the views of the United States on a specific query: whether Claim 13, as construed by the Federal Circuit, is invalid "because one cannot patent 'laws of nature, natural phenomena, and abstract ideas.' " 125 S. Ct. 1413 (citing *Diehr*, 450 U.S. at 185). The Solicitor General's response stopped short of directly answering the Court's question, instead recommending against certiorari on non-jurisdictional, prudential grounds pertaining to the manner in which that issue was raised below and in the petition. LabCorp's submission in response to the Solicitor General's filing explained, among other things, that the issue identified by the Court was presented in Question 3 and the body of the petition, and is properly before the Court. *See* Supplemental Brief for Petitioner in Response to Brief for the United States. This

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[8] LabCorp separately appealed the attorneys' fees judgment to the Federal Circuit, which summarily affirmed that judgment in light of its merits ruling. LabCorp filed a separate petition for certiorari seeking review of the attorneys' fees award, which is docketed as No. 04-1579. Both parties agreed that that petition should be held pending a decision in this case, and the petition in No. 04-1579 presently remains pending.

Court then granted certiorari, limited to Question 3 as presented in the petition. 126 S. Ct. 601.[9]

SUMMARY OF ARGUMENT

As construed by the Federal Circuit, Claim 13 violates this Court's longstanding rule barring patents on "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. No less than Einstein's famous formula $E=mc^2$ or Newton's description of the laws of gravity, the discovery of a natural relationship between homocysteine and vitamin deficiencies is a "manifestation[] of laws of nature, free to all men and reserved exclusively to none." *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Respondents cannot effectively assert proprietorship over this basic scientific fact.

Claim 13 involves no actual invention beyond the scientific discovery it recites. It is well-settled that one cannot transform an invalid process into a valid one merely by grafting insignificant post-solution activity onto an otherwise unpatentable scientific principle. Here, Claim 13 has been interpreted to require *no* post-solution activity whatsoever—simply *thinking* about the scientific correlation will infringe. And the claim involves only the trivial pre-solution activity of obtaining the input for the correlation by conducting a homocysteine test by *any* method—whether patented, previously known, or yet to be discovered. If Claim 13 passes muster, the prohibition against patenting scientific principles would be eviscerated. For a competent drafter could effectively patent almost *every* natural correlation through a similar "test and correlate" claim.

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[9] As explained in the supplemental brief, the issue identified by the Court was fairly included in Question 3, respondents did not object to its consideration as required by S. Ct. R. 15.2, and the issue was raised below. In any event, the issue is always open to consideration by the Court. *See infra* n.11.

Nor is Claim 13 legitimate simply because it recites that the correlation can be used to detect vitamin deficiencies. This Court has repeatedly invalidated patents on scientific principles that similarly purported to be limited to specific uses. And in any event, as construed by the Federal Circuit Claim 13 has a prohibited preemptive sweep. The court held that *every* doctor who orders a homocysteine test and looks at the result—regardless of how or why the test is done—automatically engages in the patented "correlating" step. This holding improperly allowed respondents to monopolize *all* homocysteine testing by any method whatsoever.

Claim 13 likewise fails the requirements that a patent must distinctly, fully, and clearly describe the subject matter of the "invention" so as to enable a skilled practitioner to know exactly what has been invented. *See* 35 U.S.C. § 112. Claim 13 and its specification describe no more than an unpatentable scientific principle, rather than any invention. If the correlating step consists of something more than thinking about a scientific fact—as it must for Claim 13 to be valid—whatever more it consists of is found nowhere in the Patent. The Patent describes and enables only one particular method of homocysteine testing, yet the Federal Circuit improperly allowed the patentees to use the vaguely drawn Claim 13 to monopolize testing techniques that the Patent does not describe, that the patentees do not purport to have discovered, and on which they were expressly denied a patent.

Allowing such a patent on a basic medical correlation would have grave implications in the medical field and beyond. Respondents have claimed a monopoly over *all* homocysteine tests, including more efficient and effective methods than the one disclosed in the Patent. The Federal Circuit has furthermore found liability for induced infringement based on the dissemination to doctors of a basic medical fact used for patient care. If Claim 13 is upheld, any person who discovers a new correlation useful in medicine will gain the right to demand royalties from people who think

or tell others about it, thereby discouraging researchers from developing new testing methods and chilling medical practice, future discovery, and scientific discourse. Nor are the implications limited to medicine. Correlations are elemental tools of all science, and as such are free to all and patentable by none. They are too valuable, too necessary for future invention, to be kept outside the public domain.

For these reasons, the Court should hold Claim 13 invalid, and reverse the judgment against LabCorp in its entirety.

ARGUMENT

I. AS CONSTRUED BY THE FEDERAL CIRCUIT, CLAIM 13 VIOLATES THE PROHIBITION ON PATENTING "LAWS OF NATURE, NATURAL PHENOMENA, AND ABSTRACT IDEAS."

A. Claim 13 Involves No Inventive Process Or Device Beyond The Natural Phenomenon It Recites.

"[E]xcluded from * * * patent protection are laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. As this Court held more than 150 years ago, "the discovery of a principle in natural philosophy or physical science, is not patentable." *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 116 (1853). "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. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known." *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156, 175 (1852).

Since its landmark decision in *Morse*, the Court has never retreated from the rule that "a scientific truth, or the mathematical expression of it, is not a patentable invention." *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).[10] "He who discovers a hitherto unknown

[10] More recently, the Court has described the issue as implicating "patentable subject matter" under 35 U.S.C. § 101, which

phenomenon of nature has no claim to a monopoly of it which the law recognizes." *Funk Bros.*, 333 U.S at 130. *See also Diehr*, 450 U.S. at 182; *Flook*, 437 U.S. at 589; *Benson*, 409 U.S. at 67-68. As the Court has explained:

> [A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of * * * nature, free to all men and reserved exclusively to none."

Diamond v. *Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting *Funk Bros.*, 333 U.S. at 130). Protecting the public against such unwarranted patent monopolies is so important that the Court will consider the patentability issue even where, unlike here, it is not even raised by the parties. *See Hill* v. *Wooster*, 132 U.S. 693, 698 (1890) (even where parties "ignore" it, "neither the Circuit Court nor this court can overlook the question of patentability").[11]

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provides that patents will be granted for "any new and useful process, machine, manufacture, or composition of matter." *See*, *e.g.*, *Diehr*, 450 U.S. at 181. But the "plain language of Section 101 does not answer the question" of patentability, *Parker* v. *Flook*, 437 U.S. 584, 588 (1978), and that issue is also encompassed by other sections of the Patent Act, including Section 112, which likewise depends on the existence of a patentable "invention." *See infra* at 32-42.

[11] *See also Slawson* v. *Grand St. R.R.*, 107 U.S. 649, 652 (1883) ("the question whether [the] invention is patentable or not is always open to the consideration of the court, whether the point is raised by the answer or not"); *Smithkline Beecham Corp.* v. *Apotex Corp.*, 403 F.3d 1331, 1353-54 (Fed. Cir. 2005) (Gajarsa, J., concurring) (issue is always open to consideration given the "centrality of patentable subject matter" and the "significant public policy interest in removing invalid patents from the public arena") (and cases cited therein).

As construed by the Federal Circuit, Claim 13 runs afoul of this venerable rule. At the "heart" of the claim is the scientific fact that homocysteine levels bear a natural relationship to cobalamin or folate deficiencies. *See* J.A. 281 (statement of patentees in prosecution history that "[t]he heart of these claims is the concept that total homocysteine is elevated in patients with cobalamin and folic acid deficiency"). Whether that fact is characterized as a natural phenomenon, law of nature, or abstract principle, it is the "established rule" that such a scientific fact "cannot be the subject of a patent." *Flook*, 437 U.S. at 589. *See* Robert A. Kreiss, *Patent Protection for Computer Programs and Mathematical Algorithms: The Constitutional Limits on Patentable Subject Matter*, 29 N.M. L. Rev. 31, 67 n.251 (1999) ("The existence of statistical correlations between a particular biological test and a particular genetic or biological condition is another example of a law of nature."). "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." *Benson*, 409 U.S. at 67.

In *Funk Bros.*, 333 U.S. at 130, the Court invalidated a patent that was based on nothing more than the discovery of the natural "qualities" of certain bacteria. So too here, "[t]he qualities of [homocysteine], like the heat of the sun, electricity, or the qualities of metal, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id*. The scientific correlation recited in the Patent simply "reveals a relationship that has always existed." *Flook*, 437 U.S. at 593 n.15. Although they claim to have discovered that pre-existing relationship, the patentees surely did not *invent* it. As with "a new mineral discovered in the earth or a new plant found in the wild," *Diehr*, 450 U.S. at 185, the discoverers of the natural association between homocysteine and vitamin deficiencies " 'ha[ve] no claim to a monopoly of it which the law recognizes.' " *Flook*, 437 U.S. at 591 (quoting *Funk Bros.*, 333 U.S. at 130).

Like other patent claims invalidated by this Court, Claim 13 involves no inventive process or device beyond the scientific principle it recites.[12] The Federal Circuit has held that Claim 13 can be infringed simply by *thinking* about the unpatentable scientific fact that homocysteine levels are associated with deficiencies in two basic vitamins. "The correlating step is simply a conclusion that a cobalamin/ folate deficiency exists *vel non* based on the assaying step." Pet. App. 18a. *See also id*. at 8a ("The claim only requires association of homocysteine levels with vitamin deficiencies. It requires no further correlation to confirm the relationship to vitamin deficiencies."). According to the Federal Circuit, once a doctor has reflexively thought about this basic scientific association after looking at a homocysteine test result, the doctor has performed the patented "correlating" step. This is consistent with the patentees' trial testimony that the entire "correlating" process "takes place in the mind of the physician." J.A. 110. *See also* J.A. 111 ("Everything is done in the physician's mind."); J.A. 155-157.

As explained below, the correlating step is in fact wholly undefined in both the claim itself and the specification. *See infra* at 32-42. But one thing is certain: the breadth given Claim 13 by the Federal Circuit renders it invalid. To be sure, "a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm." *Flook*, 437 U.S. at 590. But a valid process patent must claim something more than thinking about a natural

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[12] *See*, *e.g.*, *Funk Bros.*, 333 U.S. at 131 (invalidating attempt to patent specific combination of mutually non-inhibitive bacteria strains because the patentee had discovered only the bacteria's "qualities of non-inhibition" which "is no more than discovery of the handiwork of nature and hence is not patentable"); *Benson*, 409 U.S. at 71 (rejecting patent on use of algorithm to convert binary-coded decimal numerals into pure binary numerals because its "practical effect" would be to "patent an idea").

phenomenon or law of nature. A patent claim that amounts to nothing more than thinking about a scientific fact is indistinguishable from patenting the fact itself, and "a scientific truth * * * is not a patentable invention." *Mackay*, 306 U.S. at 94. The scientific principle that homocysteine levels are associated with vitamin deficiencies is "free to all men and reserved exclusively to none." *Funk Bros.*, 333 U.S. at 130. Nobody can gain the legal right to prevent others from simply thinking about such a principle, or to demand a license fee for the privilege of doing so.

There is nothing of any significance to Claim 13 beyond the recognition of an unpatentable scientific fact. The Federal Circuit held that the *only* thing that Claim 13 requires beyond thinking about the natural relationship between homocysteine and vitamin deficiencies is that a test first be performed—*any* test by *any* method. This includes all homocysteine testing methods known before the Patent application was filed, and also all methods that might later be conceived. This trivial step of ascertaining the input for the correlation cannot render the claim valid. For this Court has made clear that one cannot circumvent the patentability rule by grafting insignificant activity onto unpatentable scientific principles.

For example, in *Flook* the Court invalidated a process patent that incorporated an algorithm, even though the process included a step in which the algorithm was used to calculate something known as an "alarm limit." The patentees had argued that the patent was valid because of "specific 'post-solution' activity—the adjustment of the alarm limit to the figure computed according to the formula." 437 U.S. at 590. The Court rejected this argument: "The notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance." *Id*. Otherwise, "[a] competent draftsman could attach some form of post-solution activity to almost any mathematical formula; the Pythagorean theorem would not have been patentable, or

partially patentable, because a patent application contained a final step indicating that the formula, when solved, could be usefully applied to existing surveying techniques." *Id*. Subsequently, in *Diehr*, the Court reiterated this holding that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." 450 U.S. at 191-192. As the Court held, "a mathematical formula does not become patentable subject matter merely by including in the claim for the formula token postsolution activity such as the type claimed in *Flook*." *Id*. at 192 n.14.

Here, Claim 13 has been construed to involve *no* post-solution activity of any kind—merely thinking about a scientific correlation is enough to infringe—and only the trivial *pre*-solution activity of conducting a homocysteine test by *any* method, whether patented or not. This kind of token activity cannot transform Claim 13 into a patentable invention, because the correlation itself embodies the notion that a homocysteine level somehow be observed. *Every* correlation or equation requires that an input variable be ascertained in some manner. Allowing someone to transform an invalid patent claim into a valid one simply by adding that insignificant step would "allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection." *Diehr*, 450 U.S. at 192. As the Federal Circuit once held in invalidating a patent claiming a similar but far more detailed method of diagnosis using an algorithm that "correlated" parameters from clinical tests, "[t]he presence of a physical step in the claim to derive data for the algorithm will not render the claim statutory." *In re Grams*, 888 F.2d 835, 840 (Fed. Cir. 1989). *See also In re Christensen*, 478 F.2d 1392, 1394 (C.C.P.A. 1973) ("Given that the method of solving a mathematical equation may not be the subject of patent protection, it follows that the addition of the old and necessary antecedent steps of establishing val-

ues for the variables in the equation cannot convert the unpatentable method into patentable subject matter.").[13]

Indeed, if Claim 13 were valid, a competent patent drafter could render *any* correlation patentable through just such legerdemain. Einstein (a former patent clerk himself) could have prevented anyone from applying his famous equation $E=mc^2$—an equation is, after all, just a kind of correlation—simply by patenting a Method for Determining Energy Associated With Mass, consisting of "determining mass times the speed of light squared and correlating with energy." *But see Chakrabarty*, 447 U.S. at 309 ("Einstein could not patent his celebrated law that $E=mc^2$"). Pythagoras could likewise have obtained the prohibited patent on a Method for Determining Length of Hypotenuse of a Right Triangle consisting of "measuring the two small sides of a right triangle and correlating the squares of those sides with the square of the hypotenuse." *But see Flook*, 417 U.S. at 590 ("the Pythagorean theorem would not have been patentable, or partially patentable"). Such a rule would make patentability "depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for 'ideas' or phenomena of nature." *Id*. at 593.

The present-day implications of such a holding are limitless—and dangerous. Anyone who discovers a new medical correlation could stifle medical treatment through a similar "test plus correlate" claim. To take a hypothetical example,

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[13] The Federal Circuit later held that the analysis in *Grams* was "unhelpful" in a case involving an algorithm because the analysis "did not ascertain if the end result of the claimed process was useful, concrete, and tangible." *AT&T Corp.* v. *Excel Communications, Inc.*, 172 F.3d 1352, 1360 (Fed. Cir.), *cert. denied*, 528 U.S. 946 (1999). The *Grams* analysis, however, is both helpful and correct in this context, because this Court's precedents establish that merely specifying an ultimate end use for a scientific fact does not permit a patent on thinking about the fact. *See infra* at 27-29.

someone who discovers that elevated cholesterol is linked to Alzheimer's disease could patent a method consisting of "test for cholesterol and correlate with risk of Alzheimer's disease," and thereby gain the legal right to prevent doctors from thinking about that correlation when diagnosing and treating patients. And that patentee could prevent *all* cholesterol testing no matter how or why a test is performed—even if it is performed for the established purpose of screening for heart-disease risk or through previously known or newly discovered methods—on the ground that every doctor looking at a result will necessarily perform the patented "correlating" with Alzheimer's disease once that scientific fact is known. Likewise, the first person to discover a correlation between blood type and a particular condition could effectively monopolize all blood type testing in a similar manner.

That is what happened here: respondents won an injunction against *all* homocysteine-only tests, even though the tests were performed for the traditional purpose of screening for heart disease risk rather than diagnosing vitamin deficiencies, and even though they were performed via a new and more efficient method than the one disclosed in the Patent. The prohibition against patenting scientific facts exists precisely to prevent private parties from gaining such legal control over "the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67.

B. Claim 13 Does Not Recite Any Transformative Process, Nor Does Its Described Use Render The Claim Valid.

In *Diehr*, the Court held that a patent on "a physical and chemical process for molding precision synthetic rubber products" was valid, because the process "involve[d] the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing." *Diehr*, 450 U.S. at 184. As the Court explained there, " '[t]ransformation and reduction of an article to a different state or thing is the clue

to the patentability of a process claim that does not include particular machines.' " *Id*. (citations omitted).

Claim 13 recites no such transformative method. The correlating step occurs in the mind, and the assaying step does not direct a practitioner to transform anything.[14] Indeed, Claim 13 says nothing about how the assay is to be performed and covers any conceivable test. Thus, although various assaying methods could involve some sort of transformation, Claim 13 recites *no testing method at all*. There are similarly many different ways to measure mass or energy, some of which might be patentable on their own, but that would not have allowed Einstein to patent a method claiming no more than "determine mass times the speed of light squared and correlate with energy." The Patent *does* claim a specific testing method—*in Claims 1-12*—and LabCorp continues to pay royalties when it uses that method.

Nor is Claim 13 saved by the fact that its preamble notes a practical use of the correlation—detecting vitamin deficiencies. For one thing, the Federal Circuit's construction

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[14] Although the Court need not consider the issue, Claim 13 also fails the traditional "mental steps" doctrine under which "processes involving mental operations were considered unpatentable." *Diehr*, 450 U.S. at 195 (Stevens, J., dissenting). *See*, *e.g.*, *In re Abrams*, 188 F.2d 165, 168-170 (C.C.P.A. 1951); *cf.* Donald S. Chisum, *The Patentability of Algorithms*, 47 U. Pitt. L. Rev. 959, 967-968 (1986) (noting doctrine's development from transformation cases). The doctrine also prohibited process claims consisting of both physical and mental steps if the claim's novel element was found only in the mental step. *See Diehr*, 450 U.S. at 195 (Stevens, J. dissenting); *Abrams*, 188 F.2d at 168. Here, Claim 13's only allegedly novel element is the "correlating" requirement—a purely mental step that makes the patent invalid under that doctrine. Although the Court of Customs and Patent Appeals ultimately moved away from the mental steps doctrine, *see In re Prater*, 415 F.2d 1378 (C.C.P.A. 1968), this Court has never explicitly considered the doctrine on the merits.

makes clear that this preamble is no limitation at all because "[t]he correlating step is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." Pet. App. 18a. In other words, any practitioner will necessarily infringe *every* time he or she looks at a test result. But regardless, this Court has repeatedly held that an otherwise invalid claim is not rendered valid merely because it recites a particular use of a law of nature or natural phenomenon. A law of nature is unpatentable "regardless of whether the patent is intended to cover all uses of [the law] or only limited uses." *Diehr*, 450 U.S. at 192 n.14. That is why in *Morse*, 56 U.S. at 112, the Court invalidated a patent claim based on the natural phenomenon of electromagnetism, even though the claim was limited to using electromagnetism for transmitting information at a distance. The claims invalidated in *Flook* similarly limited application of the unpatentable algorithm to a particular use—updating alarm limits—but that did not save them. 437 U.S. at 593-595. *See also id*. at 590 n.11 (noting that patent claim invalidated in *Benson* contemplated a "specific end use"). Simply noting that the correlation between homocysteine levels and vitamin deficiencies can be used to detect vitamin deficiencies—which is all that Claim 13 does—is "comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel." *Id*. at 595.

Because specifying one practical use for a scientific correlation does not render a patent claim valid, it is ultimately immaterial whether Claim 13 preempts every "substantial practical application" of the correlation—a factor the Court has considered in determining patentability. *Benson*, 409 U.S. at 71. But as construed by the Federal Circuit, Claim 13 does have a prohibited preemptive sweep. The scientific principle that elevated homocysteine is associated with vitamin deficiencies is substantially covered by Claim 13, because anyone who mentally applies that principle to a test result has necessarily infringed the patent.

In *Benson*, which involved a binary conversion algorithm, the Court held that the patent would effectively preempt the algorithm even though the patent was limited to digital computers. *Id*. Here, the preemption of the correlation between homocysteine levels and vitamin deficiencies is even more far-reaching. Claim 13 covers every total homocysteine test no matter how it is performed, thereby preventing LabCorp from utilizing the new and more efficient Abbott testing method, as well as any prior art testing methods. *See*, *e.g.*, J.A. 112 (testimony of CTI's president that Claim 13 covers "every single homocysteine test done in the United States," including those utilizing the Abbott method). It covers any "correlating" of test results, vaguely defined by the Federal Circuit (although not the Patent) as any "association of homocysteine levels with vitamin deficiencies." Pet. App. 8a. This includes the purely mental association allegedly undertaken by doctors today, but also presumably would include any "correlating" done by a machine or other process. And it covers all homocysteine tests, no matter why they are performed, on the view that every doctor necessarily "correlates" test results with possible vitamin deficiencies.

The staggering breadth of this claim further demonstrates its invalidity. There is no way to design or engineer around the claim by developing a better or more efficient homocysteine test or by avoiding the patented correlating process. Because the claim covers doctors' thought processes, it is effectively impossible to avoid infringing by not thinking about the scientific fact once the fact is known. Indeed, the Federal Circuit credited respondents' testimony that it would be "malpractice" for any doctor *not* to perform the patented "correlating" step. Pet. App. 14a. *See also* J.A. 106. Moreover, as one of the patentees testified, even *patients* can infringe if they are aware of the scientific principle, request a test, and then "correlate" the results of the tests in their own minds. *See* J.A. 157-158. And under the theory of indirect infringement applied below, anyone who informs doctors about the existence of the basic scientific fact that

homocysteine levels are associated with cobalamin or folate deficiencies could be guilty of inducing infringement.

If Claim 13 is upheld, the only solution for practitioners and testing companies is not to test for homocysteine at all—thereby depriving patients of needed medical services—or to pay respondents a license fee for the privilege of thinking about a basic scientific fact. Moreover, since correlations are at the heart of most medical diagnoses, doctors and testing companies would forever be saddled with the specter of patent infringement liability—even for existing testing methods—as each newly discovered correlation becomes a private property right removed from the public domain.[15]

It is of no moment whether the patentees discovered a correlation that has practical utility. Although the import of their marginal contribution to scientific knowledge has been disputed, *see supra* n.2, "a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery." *Funk Bros.*, 333 U.S. at 131-132. *See also Brenner* v. *Manson*, 383 U.S. 519, 528-529 (1966) (utility is only a "starting point" in examining patent validity). Einstein's equation is extra-ordinarily useful and required Nobel-prize-caliber ingenuity to discover, but that fact would not have allowed him to effectively patent the equation through a "test plus correlate" claim. *See also Morse*, 56 U.S. at 112 (invalidating attempt to patent use of electromagnetism for sending information at

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[15] Permitting respondents to claim proprietary dominion over homocysteine assays known to the public even before the Patent application was filed is especially pernicious because it flouts the traditional rule that "matter once in the public domain must remain in the public domain." *Kewanee Oil Co.* v. *Bicron Corp.*, 416 U.S. 470, 484 (1974). "Congress may not authorize the issuance of patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available." *Graham* v. *John Deere Co.*, 383 U.S. 1, 6 (1966).

a distance notwithstanding utility of claimed invention). As the Court explained in *Funk Bros.*, even though an "application of [a] newly-discovered natural principle * * * may well have been an important commercial advance," that does not make it patentable where, as here, it was merely a "simple step" to create the patented product or process "once nature's secret * * * was discovered." 333 U.S. at 132.

"The process itself, not merely the mathematical algorithm, must be new and useful." *Flook*, 437 U.S. at 591. The claims at issue in *Flook* were invalid not simply because they contained an algorithm. Rather, they were invalid because the claims as a whole did not disclose anything inventive beyond the algorithm itself. "[T]he discovery of [a natural] phenomenon cannot support a patent unless there is some other inventive concept in its application." *Id*. at 594.[16] In *Diehr*, the Court clarified that "claims must be considered as a whole" and emphasized that scientific principles and other prior art elements should not be ignored in determining whether an overall process is patentable. 450 U.S. at 188-189. Thus, the *Diehr* Court explained that *Flook* "did not hold * * * that the mathematical algorithm could not be considered at all." *Id*. at 189 n.12. Here, when Claim 13 is considered *as a whole*, it has no inventive concept—indeed no concept at all—beyond recognition of a scientific principle.

There is a longstanding and key distinction between a potentially useful scientific *discovery* and a patentable *invention*.[17] The Patent claims a specific method for homo-

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[16] A natural phenomenon, even if newly discovered, is "treated as though it were a familiar part of the prior art." *Id*. at 592. *See also Tilghman* v. *Proctor*, 102 U.S. 707, 724 (1880); *Morse*, 56 U.S. at 115.

[17] *See Morton* v. *New York Eye Infirmary*, 17 F. Cas. 879, 881 (C.C.S.D.N.Y. 1862) ("A discovery of a new principle, force, or law operating, or which can be made to operate, on matter, will not entitle the discoverer to a patent. It is only where the explorer has

cysteine testing in Claims 1-12. Those claims are unchallenged, and LabCorp pays royalties when it uses that patented method. But Claim 13, as construed by the Federal Circuit, is nothing more than a prohibited patent on a natural phenomenon, law of nature, or abstract principle. The patentees may have discovered a scientific principle, but they *invented* nothing that is disclosed in Claim 13.

II. CLAIM 13 FAILS THE DEFINITENESS, ENABLEMENT, AND WRITTEN DESCRIPTION REQUIREMENTS OF THE PATENT LAWS.

For largely the same reasons, Claim 13 also fails the requirements that a patent must distinctly, fully, and clearly describe the subject matter of the "invention" so as to enable a skilled practitioner to know exactly what has been invented. *See* 35 U.S.C. § 112.[18] Claim 13 and its corresponding specification do no more than state a scientific fact. There is no further explanation anywhere in the Patent of what it means to "correlat[e]" homocysteine test results, beyond recognizing the scientific principle that elevated homocysteine levels are associated with cobalamin and folate

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gone beyond the mere domain of discovery, and has laid hold of the new principle, force, or law, and connected it with some particular medium or mechanical contrivance by which, or through which, it acts on the material world, that he can secure the exclusive control of it under the patent laws. * * * It is then an invention, although it embraces a discovery.").

[18] Among other things, Section 112 contains (1) a "definiteness" requirement that the claims "point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention;" (2) an "enablement" requirement that the specification describe "the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art * * * to make and use the same;" and (3) a requirement of a "written description of the invention and of the manner and process of making and using it." 35 U.S.C. § 112 ¶¶ 1, 2.

deficiencies. More is required to satisfy the disclosure requirements of Section 112—a patentee must fully describe and enable an actual "invention." As Judge Giles Rich noted long ago, "[m]eritorious though the scientific principles disclosed may be, and regardless of how much they may reveal to other workers in the field, they fall short of the point which must be reached to entitle one to a patent. That point is not reached until it is possible to comply with the provision in section 112 of the statute * * *." *Application of Joliot*, 270 F.2d 954, 958 (C.C.P.A. 1959) (Rich, J. concurring). Claim 13 merely recites a scientific principle and therefore falls short of satisfying Section 112.[19]

A. To Meet The Disclosure Requirements, A Patent Must Describe More Than A Scientific Principle.

A patentee is, and always has been, required to provide a detailed public disclosure as a condition of receiving a monopoly on an invention.[20] And this Court has steadfastly confirmed the importance of fully complying with these disclosure requirements. As the Court explained long ago, a patent is valid only if the specification "enables arti[s]ans to make and use" the invention and "put[s] the public in possession of what the party claims as his own invention."

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[19] Each of the provisions of Section 112 requires that the patentee sufficiently describe its "invention," which necessarily requires one to determine whether there is in fact any invention apart from an unpatentable scientific principle. *Cf. In re Ziegler*, 992 F.2d 1197, 1201 (Fed. Cir. 1993) ("If the application fails as a matter of fact to satisfy 35 U.S.C. § 101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. § 112.").

[20] *See* Patent Act of 1790, ch. 7, § 2, 1 Stat. 109; Patent Act of 1793, ch. 11, § 3, 1 Stat. 318; Patent Act of 1836, ch. 357, § 6, 5 Stat. 117; Patent Act of 1870, ch. 230, § 26, 16 Stat. 198; Patent Act of 1952, ch. 950, § 112, 66 Stat. 798.

Evans v. *Eaton*, 20 U.S. (7 Wheat.) 356, 433-434 (1822).[21] More recently, the Court has noted that "[t]he disclosure required by the Patent Act is 'the quid pro quo of the right to exclude.' " *J.E.M. AG Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 142 (2001) (citation omitted). *See also Universal Oil Prods. Co.* v. *Globe Oil & Refining Co.*, 322 U.S. 471, 484 (1944) (same). A patent must make it clear for the patent holder to "know what he owns" and for the public to "know what he does not" own. *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki, Co., Ltd.*, 535 U.S. 722, 730-731 (2002). *See Markman*, 517 U.S. at 373 ("[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.' ") (citation omitted). The requirements of Section 112 ensure that "exclusive patent rights are given in exchange for disclosing the invention to the public," which encourages others "to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo*, 535 U.S. at 736, 731.

Requiring the disclosure to express the claimed invention with "accuracy, precision, and care" serves important purposes. *Merrill*, 94 U.S. at 573. The patent monopoly "is a property right; and like any property right, its boundaries should be clear." *Festo*, 535 U.S. at 730. *See also Motion*

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[21] *See also Merrill* v. *Yeomans*, 94 U.S. 568, 574 (1876) ("[N]othing can be more just and fair, both to the patentee and to the public than that the former should understand, and correctly describe, just what he has invented, and for what he claims a patent."); *Seymour* v. *Osborne*, 78 U.S. (11 Wall.) 516, 540 (1870) (inventor must fully "explain the principle by which the invention may be distinguished from others of like kind"); *Brooks* v. *Fiske*, 56 U.S. (15 How.) 212, 215 (1853) (disclosure "warn[s] an innocent purchaser * * * of his infringement" and "tak[es] from the inventor the means of practising upon the credulity or fears of other persons, by pretending that his invention was different from its ostensible objects").

Picture Patents Co. v. *Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) (patent claims and specification "so mark where the progress claimed by the patent begins and where it ends that they have been aptly likened to the description in a deed, which sets the bounds to the grant which it contains"). Only if the public knows the exact "metes and bounds" of the monopoly can the patent system avoid "block[ing] off whole areas of scientific development." *Brenner*, 383 U.S. at 534-535. Thus, the claims and specification "determine not only what is protected, but also what is free for use to all." *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989). A patent must possess "that precision and clearness of statement with which one who proposes to secure a monopoly at the expense of the public ought to describe the thing which no one but himself can use or enjoy, without paying him for the privilege of doing so." *Merrill*, 94 U.S. at 570.

As Judge Rich indicated in *Joliot*, the patentability and disclosure requirements are connected, since a claim that recites a scientific principle without any inventive application of it fails both. This Court's decision in *Morse* is instructive. Samuel Morse's patent included detailed claims describing a telegraph machine, as well as a broader eighth claim that sought to patent the use of "electro-magnetism, however developed for marking or printing intelligible characters, signs, or letters at any distances." 56 U.S. at 112. The Court permitted the telegraph claims, but rejected the eighth claim as "too broad, and not warranted by law." *Id*. at 113. To uphold that claim, the Court reasoned, would improperly allow Morse to preempt every invention that used electricity to send messages without regard to the "process or machinery [by which] the result is accomplished." *Id*. This would have meant rewarding Morse with a patent monopoly for a function of electromagnetism—"a manner and process which he has not described and indeed had not invented, and therefore could not describe when he obtained his patent." *Id*.

Because Morse did not describe or invent every manner of using electricity to send messages, the eighth claim would have improperly permitted Morse to preempt related discoveries that do not use "any part of the process or combination set forth in [his] specification." *Id*. Thus, merely reciting a useful result of a scientific principle, without claiming a specific novel application of it, contravenes both the patentability and disclosure requirements. *See* 1 Donald S. Chisum, *Chisum on Patents*, OV-7 (2005) (*Morse* "established the principle of undue patent breadth; an inventor of one means of achieving a useful result can claim only that means, not all possible means of achieving the result.").

Upholding Claim 13 would likewise endow its patentees with a pervasive monopoly without regard to the limited nature of what they actually described and invented. The patentees disclosed and described a specific method for testing for total homocysteine, and those claims—like Morse's telegraph claims—are unchallenged. But also like Morse, the patentees went further and sought to patent a basic scientific principle—the correlation between homocysteine levels and vitamin deficiencies. The result has been what *Morse* forbids: the patentees have used the broad Claim 13 to effectively gain a monopoly over *all* homocysteine tests, no matter how or why they are performed. *See also Wyeth* v. *Stone*, 30 F. Cas. 723, 727 (C.C.D. Mass. 1840) (Story, J.) (rejecting "claim for an art or principle in the abstract, and not for any particular method or machinery" because "[a] claim broader than the actual invention of the patentee is, for that very reason, upon the principles of the common law, utterly void, and the patent is a nullity").

The breadth of Claim 13 even sweeps in *prior art* assays, on which the patentees were *denied* a patent. As initially filed, Claim 13 recited a method for detecting vitamin deficiencies by assaying for total homocysteine. The Patent Examiner rejected that language on the ground "that assays

for homocysteine [were] known" in the prior art. J.A. 285.[22] Yet as a result of Claim 13, which recites no assay method, LabCorp has been enjoined from performing "*any* homocysteine-only test, including without limitation homocysteine-only tests via the Abbott method." Pet. App. 36a-37a (emphasis added). Simply by adding a "correlating" step that recites nothing beyond a scientific fact, the patentees were able to gain what the Examiner said they could not: a monopoly over all homocysteine tests, both methods in the prior art and those—such as the more efficient Abbott method LabCorp sought to use—developed later. Moreover, because Claim 13 has been construed to cover any mental or other "association of homocysteine levels with vitamin deficiencies," *id*. at 8a, anyone who seeks to employ that scientific fact in an actual invention will find that effort preempted by Claim 13. As in *Morse*, upholding this overly broad and undescribed claim would "shut the door against the inventions of other persons, and enable the patentee to avail himself of any new discoveries * * * which scientific men might bring to light." *Risdon Iron & Locomotive Works* v. *Medart*, 158 U.S. 68, 74 (1895) (discussing *Morse*).[23]

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[22] The Patent itself notes that the prior art of the day included homocysteine assays, stating that "[t]here are several different known assays suitable for use in determining levels of homocysteine in urine or blood." *See* S.A. 12 (Patent, col. 6, lns. 6-7, 42).

[23] Indeed, under respondents' own theory, the patentees had no reason even to seek patent protection for the GCMS method recited in Claims 1-12, because Claim 13 covers any test by any method. *See Morse*, 56 U.S. at 119 ("[I]f the eighth claim can be maintained, there was no necessity for any specification, further than to say that he had discovered that, by using the motive power of electro-magnetism, he could print intelligible characters at a distance. We presume it will be admitted on all hands that no patent could have issued on such a specification.").

B. Claim 13 Is Indefinite.

In light of the background axiom that claims must do more than recite a natural phenomenon or law of nature, Claim 13 fails to meet the definiteness requirement, which requires that the claim "particularly point[ ] out and distinctly claim[ ] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112 ¶ 2. Indefiniteness focuses on the claim language itself, as construed in light of the specification. That each claim be definite is important because "it is the claim which measures the grant to the patentee." *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 336 U.S. 271, 277 (1949). Only if the limits of a claim are clearly defined will two important purposes of the patent laws be met: "protecting the public against extension of the scope of the patent," *Universal Oil Prods.*, 322 U.S. at 484-485, and "disclos[ing] to the public * * * how its infringement may be avoided," *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923).

Claim 13 fails to satisfy either of these purposes. It impermissibly extends the Patent's scope by sweeping in all methods of assaying for homocysteine that were known at the time of the patent application, as well as all assays yet to be invented—simply by using the overly broad and undefined term "correlating." Claim 13 also extends to all possible means of "correlating" test results with vitamin deficiencies, whether such means were known to the patentees or not even developed yet. Claims can secure processes "but never * * * the scientific explanation of their operation." *Markman*, 517 U.S. at 373 (citation omitted). *See De Forest Radio Co.* v. *General Elec. Co.*, 283 U.S. 664, 684-685 (1931) ("It is method and device which may be patented and not the scientific explanation of their operation."). A patent is indefinite when it includes such "an all-embracing claim, calculated by its wide generalizations and ambiguous language to discourage further invention in the same department of industry and to cover antecedent

inventions." *Carlton* v. *Bokee*, 84 U.S. (17 Wall.) 463, 472 (1873). Similarly, because the correlating step is undefined beyond simply thinking about a scientific principle, it does not disclose to the public how infringement may be avoided. Indeed, it has turned out to be *impossible* to avoid infringing without stopping homocysteine testing entirely.

The Federal Circuit found the claim sufficiently definite, based on its view that the dictionary definition of "correlating" clearly informs a skilled artisan that Claim 13 "only requires association of homocysteine levels with vitamin deficiencies." Pet. App. 16a, 8a. But that is no more than a recognition of the underlying scientific principle. Nothing in the claim, even when read in light of the specification, recites the further discrete, *active* process step that the District Court held was required to satisfy patentability concerns. *See* J.A. 60 (" '[c]orrelating' is a verb, and must * * * comprise a discrete, sequential process step"); *see also* J.A. 274 (initial rejection of Claim 13 by Examiner for failing to "recite discrete, sequential process steps"). The claim as construed says *nothing* at all about what it means to actively "correlate" a test result. The Federal Circuit relied on the accepted dictionary definition of "correlate" as meaning "to establish a mutual or reciprocal relationship between." Pet. App. 8a-12a. But nothing recited in the claim or disclosed in the specification tells a practitioner how to actively "establish" a "relationship" between a particular test result and a vitamin deficiency. At most, the Patent discloses that such a scientific relationship *exists*.[24]

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[24] LabCorp had suggested below that Claim 13, at a minimum, should be construed to require that a doctor actually diagnose a vitamin deficiency through physical symptoms—which would have led to a judgment of non-infringement since there is no evidence that doctors engage in such activity after ordering homocysteine-only tests. But the Federal Circuit rejected that construction as unsupported by the claim or the specification. Pet. App. 8a-12a.

More is required for a valid claim. The definiteness requirement is intended to prevent a "zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942). Here, because the "correlating" step includes no recitation of any active process beyond mental recognition of a scientific fact, there is no way for a practitioner to conform his or her conduct so as to remove the risk of infringement. "To sustain claims so indefinite as not to give the notice required by the statute would be in direct contravention of the public interest which Congress therein recognized and sought to protect." *Id*. at 233.

C. Claim 13 Is Non-Enabling And Insufficiently Described.

Claim 13 likewise fails to satisfy the enablement and written description requirements, under which a patent must 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 ¶ 1.[25] These requirements focus on the specification, which must enable another to make and use the full scope of the invention "with clearness and precision, and not leave the person attempting to use the discovery to find it out 'by experiment.' " *Tyler* v. *City of Boston,* 74 U.S. (7 Wall.) 327, 330 (1868). *See also Bene* v. *Jeantet*, 129 U.S. 683, 686 (1889) (specification must enable another to "use the invention without having to resort to experiments of his own to discover [its] ingredients"). Moreover, under the written description requirement, the specification must further "show that the inventor possessed the invention at the time of the original filing." Pet. App. 17a; 3 Donald S. Chisum, *Chisum*

[25] The written description and enablement requirements "usually rise and fall together." *LizardTech, Inc.* v. *Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005).

on Patents § 7.04. "[P]recision of description is essential." *Universal Oil Prods.*, 322 U.S. at 484.

Claim 13 violates these requirements. The Federal Circuit held that Claim 13 is enabled because the "correlating" step "is a simple conclusion that a cobalamin/folate deficiency exists *vel non* based on the assaying step." Pet. App. 18a. In other words, Claim 13 is infringed based on a passive and automatic recognition of an underlying scientific principle. As support for enablement of the correlating step, the court cited only three sentences in the specification stating the scientific fact that elevated levels of homocysteine are associated with cobalamin and folate deficiencies. *Id*. (citing Patent, col. 4, lns. 17-20, col. 5, lns. 64-66, col. 9, lns. 26-29). Likewise, the court found a sufficient written description on the ground that persons skilled in the art understood the dictionary meaning of "correlating." Pet. App. 17a.

These holdings eviscerate the enablement and written description requirements. If the scope of Claim 13's active correlating step is narrower than thinking about a scientific fact—as it must be for the claim to be both patentable and sufficiently disclosed—nothing in the specification says exactly what it includes or how to do it. *Cf. Enzo Biochem, Inc.* v. *Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999) ("Tossing out the mere germ of an idea does not constitute enabling disclosure."); *see also T.H. Symington*, 250 U.S. at 386. Both the District Court and the Patent Examiner correctly found that "correlating" under Claim 13 must be a discrete, active step. Yet nothing in the specification informs a skilled artisan what that step is, beyond the passive recognition of a scientific principle. That renders Claim 13 invalid. *See Universal Oil Prods.*, 322 U.S. at 484; *General Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938); *Gill* v. *Wells*, 89 U.S. (22 Wall.) 1, 25-26 (1874).

That the undescribed "correlating" step occurs after a generic "assaying" step further highlights the lack of enablement and insufficient written description. Claims 1-12 are directed

to a particular assay method and the specification teaches only that method. This is the only method of assaying that is enabled—and yet Claim 13 sweeps in *any* method, including those that have yet to be conceived and those that already existed in the prior art. The patentees may not describe only a particular assay method that can be used in connection with a known scientific relationship—here Claims 1-12—and then claim a monopoly over all assays that have that function. "A patent is not good for an effect, or the result of a certain process, as that would prohibit all other persons from making the same thing by any means whatsoever." *Le Roy*, 55 U.S. at 175. *See Holland Furniture Co.* v. *Perkins Glue Co.*, 277 U.S. 245, 257 (1928) ("the patentee may not by claiming a patent on the result or function" extend a patent to things or processes not described). The patentees' disclosure of one assay method recited in Claims 1-12 does not "authorize them to put under tribute the results of the brilliant discoveries made by others." *Consolidated Elec. Light Co.* v. *McKeesport Light Co.*, 159 U.S. 465, 474 (1895).[26]

Finding Claim 13 to be enabled and sufficiently described would "shut out any further efforts to discover a better specimen of that class than the patentee had employed, would be an unwarranted extension of his monopoly, and operate rather to discourage than to promote invention." *Id.* at 476. In sum, as construed by the Federal Circuit, Claim 13 is far broader than what the Patent actually enables and describes, and it is therefore invalid.

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[26] *See also University of Rochester* v. *G.D. Searle & Co.*, 358 F.3d 916, 929 n.9 (Fed. Cir.) (" 'one cannot describe what one has not conceived' ") (citation omitted), *cert denied*, 125 S. Ct. 629 (2004); *In re Borkowski*, 422 F.2d 904, 909 (C.C.P.A. 1970) ("a claim which is of such breadth that it reads on subject matter as to which the specification is not 'enabling' should be rejected under the first paragraph of § 112").

III. CLAIM 13 HINDERS RATHER THAN PROMOTES SCIENTIFIC AND TECHNOLOGICAL PROGRESS.

A patent is "a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts.' " *Precision Instrument Mfg. Co.* v. *Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945) (quoting U.S. Const. art. I, § 8, cl. 8). That special privilege, however, has never extended to natural phenomena, laws of nature, and abstract principles because "they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67. This case amply demonstrates the dangers of allowing someone to use a vague claim to patent the very act of thinking about a scientific principle. Allowing an effective monopoly over a basic tool of science hinders rather than promotes the goals of innovation embodied in the patent laws. The public interest requires invalidation of such a pernicious claim.[27]

Patents on scientific discoveries divorced from clearly defined and inventive applications impede research by "giv[ing] a single entity monopoly control of basic research discoveries that enable subsequent investigations across a broad scientific theory." Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, 66 Law

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[27] *See*, *e.g.*, *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 343 (1971) (" 'A patent by its very nature is affected with a public interest. * * * (It) is an exception to the general rule against monopolies and to the right to access to a free and open market. The far-reaching social and economic consequences of a patent, therefore, give the public a paramount interest in seeing that * * * such monopolies are kept within their legitimate scope.' ") (citation omitted); *Lear, Inc.* v. *Adkins*, 395 U.S. 653, 663-664 (1969) (" 'It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly * * *.' ") (citation omitted).

& Contemp. Probs. 289, 295-296 (2003). It is for this reason that the Court has consistently adhered to the rule that prohibits patents on "upstream" discoveries of scientific principles. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 Science 698 (1998). If an individual may effectively claim a private monopoly over science's most basic tools, others will be unable to wield those tools for the public good. That is why Samuel Morse could not preempt others from experimenting with different ways to use electromagnetism to send intelligible signals. And it is why respondents cannot prevent others from employing new homocysteine assays—such as the indisputably more efficient Abbott method—based on a patent claim that discloses no assay method at all.

Any incentives to develop new and better homocysteine testing methods are much diminished if every such method is already embraced within Claim 13's broad and undefined scope. Allowing respondents both "to preempt the future before it has arrived," *Fiers* v. *Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993), and to recapture past inventions in the scope of their patent monopoly will suppress improvements in assay techniques by denying their future inventors due "reward for [their] inventions," *Universal Oil Prods.*, 322 U.S. at 484. *See* Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* 5-6 (2003) (patent that "contains claims that are likely overly broad" may cause a "competitor to forgo R&D in the areas that the patent improperly covers").

The problem is even more acute because infringement of Claim 13 occurs automatically whenever a doctor merely looks at a result and reflexively thinks about a scientific principle. According to respondents and the Federal Circuit, Claim 13 covers all homocysteine tests regardless of why they were ordered in the first place, because it would be "malpractice" for a doctor *not* to think about that principle

when treating patients. Pet. App. 14a. If each medical correlation becomes subject to patenting in the same manner, doctors will face potential liability for merely employing the latest medical knowledge, and testing companies will continually face the specter that even existing testing methods could fall under the sway of new correlation patents. The resulting ever-increasing thicket of overlapping patents would prove tortuous to navigate, necessarily leading to a decrease in testing and treatment. *Cf*. Mildred K. Cho, ***et al.***, *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. Molecular Diagnostics, No. 1, at 5 (Feb. 2003) (noting extent to which patent claims have deterred laboratories from performing clinical tests).

The ultimate victims are the patients whose health—and often lives—depend on access to basic medical knowledge. The public health is threatened when private parties are given the legal right to prevent others from thinking about scientific principles needed for sound medical treatment, or to demand tribute for that privilege. Homocysteine testing itself is a critical component of medical practice due mainly to the increased recognition of the connection between homocysteine and heart disease. Indeed, respondent CTI itself once estimated that homocysteine tests could become as common as cholesterol tests, with hundreds of millions performed each year. *See* J.A. 312-314, 315-317; *see also* CTI, Homocysteine Assay, http://www.competitivetech.net/technologies.htm#Homo (estimating growth to as many as 500 million assays). It was to meet this demand that LabCorp sought and found a testing method that was much better than the one disclosed in the Patent. Yet under the decision below, each of the thousands of doctors who orders and then looks at one of those millions of test results is infringing Claim 13 unless CTI is paid a royalty. There is no doubt that fully disclosed and truly novel medical testing devices or methods warrant protection. Such patents also allow others to develop still better inventions in the field—as the patent laws contemplate. But nobody should be able to gain the legal

right to prevent doctors from simply *thinking* about a basic scientific principle in treating patients.

Nor are the dangers limited to this case. Correlations and equations are the basic tools of all science and medicine—ranging from Einstein's and Newton's celebrated discoveries to the more modest one at issue here. If Claim 13 is upheld, anyone who claims to be the first to discover a correlation can patent it—and thereby demand a royalty from anyone who even thinks about it—through a similar claim. This would include medical correlations. *See supra* at 25-26. But it also would include other correlations in diverse areas ranging from physics to the social sciences and beyond. For example, someone who discovers that being a first-born child, or having been read to as an infant, correlates with future educational achievement could effectively patent those correlations and prevent schools or parents from thinking about them when deciding proper educational placements or services. One who discovered that barometric pressure correlates with likelihood of rain could have patented that correlation and prevented weather reporters and others from thinking about it. The consequences are endless.

Upholding Claim 13 will have an even more far-reaching effect in light of the theory of induced infringement applied below. LabCorp, which committed no direct infringement, was found to have intended to "induce" infringement because its "publications state that elevated total homocysteine correlates to cobalamin/folate deficiency and that this deficiency can be treated with vitamin supplements." Pet. App. 15a. *See also id*. ("[A] reasonable jury could find intent to induce infringement because LabCorp's articles state that elevated total homocysteine correlates to cobalamin/folate deficiency."). In other words, the Federal Circuit held that LabCorp actively induced infringement by informing doctors about a basic medical fact. Under this reasoning, *every* distribution of information regarding the natural relationship could induce infringement, by encouraging doctors and patients to

screen for homocysteine and to mentally "correlate" the results. For example, an advisory from the American Heart Association has recommended homocysteine screening for certain populations, explaining that if elevated levels are found "it is important to check the vitamin status owing to the inverse relationships reported between homocyst(e)ine and blood levels of folate, B_6, and B_{12}." J.A. 356. Public health advocates, publishers of medical textbooks, and others who simply pass along information about a patented correlation are similarly vulnerable because the obvious intent of distributing this information is to cause physicians to order assays and "correlate" the results.

The intellectual property laws should be construed to avoid such interference with the free flow of truthful information about scientific and medical discoveries. In the copyright area, the Court has noted that First Amendment free speech protections underlie the doctrine that prohibits copyrights over ideas as distinguished from specific expressions of them. *See Harper & Row Publishers, Inc.* v. *Nation Enters.*, 471 U.S. 539, 560 (1985). So too here, the patent laws should not allow parties to gain private property rights over scientific principles, and thereby prevent others from thinking about or disseminating such information.

It would be unimaginable for the government to prohibit doctors from thinking about a scientific fact necessary for sound medical practice, to prohibit others from informing them of that fact, or to penalize such acts monetarily. The courts should not visit that same result by way of the patent laws on doctors and the testing companies that serve them. Like the idea/expression dichotomy of copyright law, the rule against patenting scientific principles protects the free use and exchange of ideas by ensuring that patents are granted only for valid and fully disclosed applications of scientific principles, and not for claims (like Claim 13) that contain no inventive application beyond the principle itself.

IV. THE JUDGMENT SHOULD BE REVERSED.

As noted in the petition, the invalidity of Claim 13 requires reversal of the entire judgment against LabCorp, including the infringement and corresponding breach of contract damages, the injunction, and the attorneys' fees. *See* Pet. 19-20 n.12. Without a valid claim, there can be no induced or contributory infringement. Thus, the award of infringement damages and the associated injunction must be reversed. *See*, *e.g.*, *Eaton Corp.* v. *Rockwell Int'l Corp.*, 323 F.3d 1332, 1346 (Fed. Cir. 2003).[28] The same is true of the enhanced damages based on allegedly willful infringement, and the attorneys' fees and costs at issue in No. 04-1579. *See*, *e.g.*, *Roton Barrier, Inc.* v. *Stanley Works*, 79 F.3d 1112, 1127 (Fed. Cir. 1996). The breach of contract damages likewise fall as well. The Agreement specifically provides that LabCorp could terminate it with regard to any assay, and therefore would not owe royalties, if "a more cost effective commercial alternative is available that does not infringe a *valid and enforceable claim* of the [Patent]." J.A. 305 (emphasis added). Because Claim 13 is *not* valid and enforceable, there was no breach of any obligation to pay royalties based on that claim.[29]

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[28] Regardless of the validity of Claim 13, the injunction should be vacated in light of whatever standard the Court announces in *eBay, Inc.* v. *MercExchange, L.L.C.*, No. 05-130, in which the Court has granted certiorari to determine when injunctions are warranted in patent cases like this one.

[29] Even without this contractual provision, Metabolite could not command LabCorp to pay royalties based on an invalid patent claim. *See Lear*, 395 U.S. at 674 (if patent is invalid, licensee "must be permitted to avoid the payment of all royalties" based on the patent). A contrary holding would be "inconsistent with the aims of federal patent policy." *Id*. at 673.

CONCLUSION

For the foregoing reasons, the judgment should be reversed.

Respectfully submitted,

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APPENDIX

PERTINENT STATUTORY PROVISIONS

35 U.S.C. § 101 provides:

§ 101. Inventions patentable

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

* * * *

35 U.S.C. § 112 provides in pertinent part:

§ 112. Specification

The specification shall 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 which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

* * * *

35 U.S.C. § 271 provides in pertinent part:

§ 271. Infringement of patent

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

No. 04-607

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (D/B/A LABCORP),

Petitioner,

v.

METABOLITE LABORATORIES, INC. AND COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF FOR RESPONDENTS

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QUESTION PRESENTED

The third question presented in the petition, and the sole question on which this Court granted certiorari, is:

"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."

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

All parties to the proceeding below are listed in the caption.

Respondents Metabolite Laboratories, Inc. and Competitive Technologies, Inc. have no parent corporations and no publicly held company owns ten percent or more of their stock.

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BRIEF FOR RESPONDENTS

Respondents Metabolite Laboratories, Inc. and Competitive Technologies, Inc. respectfully submit that the judgment of the court of appeals should be affirmed; in the alternative, the writ of certiorari should be dismissed.

STATUTORY PROVISIONS INVOLVED

In addition to the excerpts of 35 U.S.C. §§ 101, 112 & 271 appended to petitioner's brief, the following pertinent statutes and rules are excerpted in the appendix to this brief: 35 U.S.C. §§ 100, 102, 103 & 282, Fed. R. Civ. P. 8(c), and Patent Act of 1870, ch. 230, § 61.

STATEMENT OF THE CASE

After a trial, the jury found that U.S. Patent No. 4,940,658 is valid, and awarded damages against petitioner for willfully infringing it and for breaching the agreement under which petitioner licensed it. The district court sustained the jury's findings, and the court of appeals affirmed.

A. The Invention

1. At issue in this case is a patented diagnostic method for detecting deficiencies of two vitamins, namely cobalamin (cbl or vitamin B_{12}) and folate (folic acid). Deficiencies in either cobalamin or folate can produce hematologic and neurologic abnormalities that can be incapacitating and even life-threatening. They are easily treated by simply administering supplements of the needed vitamin—but only if the diagnosis is accurate and the treatment is timely. S.A. 10; C.A. App. 4050-4052, 4093-4095, 4136-4137, 4443-4446, 4453-4455, 4464-4467, 4472-4474, 8610-8611, 8719-8720, 8727-8728, 8734-8735.

The diagnostic method at issue was invented by three medical school professors, Drs. Sally P. Stabler and Robert

H. Allen of the University of Colorado and the late Dr. John Lindenbaum of Columbia University (collectively, "the Inventors"). J.A. 85-86, 114, 154-155; C.A. App. 8584-8609, 4089-4090. The Inventors did not set out to invent a new method for diagnosing cobalamin and folate deficiencies (J.A. 92) since the old methods were thought to be quite good. When the Inventors began their work in the mid-1980s, leading textbooks taught (and it was widely believed) that cobalamin and folate deficiencies were easy to diagnose based on the presence and degree of anemia and enlarged red blood cells. In addition, confirmatory tests were available for directly measuring the concentration of cobalamin and folate in blood serum. It was thought that only extremely low concentrations indicated a significant deficiency. S.A. 10-11; J.A. 114-119, 206-209; C.A. App. 8791-8801, 8803-8832, 8834-8844; Pl. Tr. Exh. 88.

2. Cobalamin and folate are utilized in several complex metabolic pathways in the human body. In the 1980s the general outline of these pathways was understood, but perturbations in the pathways were not. S.A. 3; J.A. 90-96, 178-183. As part of their research, the Inventors sought to study "what's going on when you perturb these pathways." J.A. 92. Using a new gas chromatography/mass spectrometry method that they had invented, the Inventors analyzed hundreds of blood serum samples including samples from patients who were known to be cobalamin or folate deficient. The results were surprising in several ways.[1] Most important for this litigation, cobalamin and folate deficient patients tended to have elevated levels of an amino acid called homocysteine. J.A. 98-99, 200-203; S.A. 27-28. [2]

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[1] For example, to everyone's surprise an amino acid called methionine was not decreased in cobalamin deficient patients. J.A. 92-95, 181-183, 199; C.A. App. 8626-8634.

[2] Total homocysteine was elevated in 99% of the patients who had B_{12} deficiency and 95% of the patients who had folate

Homocysteine may exist in a free form or in one of three complex forms. Each free form or complex form is referred to as a species. "Total homocysteine" means the *total* of at least four individual species. J.A. 96-98, 197-198, 146; S.A. 12-13; J.A. 262. This point is occasionally unclear, because the medical literature uses the single word "homocysteine" sometimes as short-hand for *total* homocysteine, and sometimes as a reference to one or more of the four *species* of total homocysteine. The context must thus be reviewed to determine what was meant by the word "homocysteine." C.A. App. 4223. Moreover, the least abundant (J.A. 97; C.A. App. 4221, 4289) of the four species of total homocysteine is very close in spelling to homocysteine; it is "homocystine." Levels of the single species homocystine, however, are not indicative of levels of total homocysteine. C.A. App. 5324-5325, 10061.

To measure total homocysteine, blood or other body fluid must be transformed by freeing the homocysteine molecules from the proteins and other compounds to which they are chemically bound. The end result is a sample that is chemically altered. J.A. 262 ("Determination of total Hcy in plasma/serum requires the reduction of the disulfide bond between [homocysteine] and other thiols or albumin"); J.A. 247. The Inventors were the first to study the relationship between total homocysteine and deficiencies of cobalamin and folate. In fact, they were the first to even measure

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deficiency. Thus the "false negatives," *i.e.*, no total homocysteine elevation notwithstanding the presence of a B_{12} or folate deficiency, were only 1% and 5%, respectively. The relationship was also reciprocal. Only two of fifty subjects without B_{12} or folate deficiency had elevated total homocysteine. Thus the "false positives," *i.e.*, total homocysteine elevation notwithstanding the absence of B_{12} or folate deficiency, were only 4%. J.A. 202-203; S.A. 27-28.

total homocysteine in patients with known cobalamin or folate deficiencies. J.A. 98-99, 111, 146-147.

The Inventors conducted extensive laboratory and clinical studies with their new diagnostic methods. They found that B_{12} and folate deficiencies were much more common than previously realized, and in ways that were difficult to recognize as deficiencies in B_{12} or folate. Many B_{12} or folate deficient patients did not have anemia or enlarged red blood cells, and their serum vitamin levels were often only slightly low, or even normal, as measured by the so-called confirmatory tests. The Inventors' work showed that the textbooks and the conventional wisdom were wrong. J.A. 119-121, 210-213, 216-219, 223. Consequently, millions of patients were being misdiagnosed and left untreated, especially in the senior population. S.A. 11, 14-15, 27, 29; C.A. App. 8846-8871, 4124-4132, 4524-4535, 8653-8683, 8846-8871, 8879-8884.

3. The Inventors published their findings in five different peer-reviewed journals (C.A. App. 8644-8652, 8665-8673, 8676-8683, 8885-8895, 8899-8907, 8617-8623), including *The New England Journal of Medicine*. J.A. 211-213; C.A. App. 8862-8871. Initially, the medical community was uninterested in, and even skeptical about, the need for the new tests because the old diagnostic methods were thought to be more than adequate. C.A. App. 4090-4092, 8612-8616, 4119-4120, 8639-8643, 4515, 8857-8861. In the issue of *The New England Journal of Medicine* in which the Inventors' article appeared, for example, a leading scientist and textbook author in the field, Dr. William Beck (J.A. 209; C.A. App. 8834-8844), observed in an accompanying editorial that "one need not be an obdurate skeptic to notice the [Inventors'] reliance on new diagnostic tests that gave abnormal results (many in patients with no known disease) when the results of more traditional tests were normal." J.A. 215. Dr. Beck went on to conclude that "[a]lthough these findings are provocative and encouraging, we do need con-

firmatory data." *Ibid.* Although the Inventors' total homocysteine test for B_{12} and folate deficiency was first published in 1985 (C.A. App. 8639-8643), it was not presented in a medical textbook until late 1992. C.A. App. 4533-4535, 8932-8942.

Eventually, however, the Inventors' papers and the principles they described became well-accepted and frequently referenced. C.A. App. 4531, 8909-8912. They have appeared in every edition of every textbook in the field since the mid-1990s. A few years after his cautious editorial in *The New England Journal of Medicine*, Dr. Beck referred to the Inventors' techniques and findings as "diagnostically essential" and providing "a new diagnostic standard against which other procedures are henceforth to be compared and evaluated." J.A. 221-222

The Inventors' method satisfied every requirement for a desirable clinical diagnostic tool. J.A. 83-89, 177. Physicians for the first time could detect deficiencies of B_{12} or folate by employing a two-step method: (1) assaying for total homocysteine; and (2) correlating the results with B_{12} and folate status. An elevated level of total homocysteine was strong evidence for the presence of a deficiency of one or both vitamins, while a normal level of total homocysteine was strong evidence for the absence of deficiency of either vitamin.

B. The Patent

1. In the original patent application, claim 13 (which is the only claim at issue in this Court) recited "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals by assaying body fluids for the presence of elevated levels of total homocysteine." J.A. 288. The PTO examiner rejected this claim as originally drafted, explaining:

> In the absence of a *correlation step*, the preamble of claim 13 merely recites an intended use of the in-

> vention. The claim lacks a positive limitation for *correlating* to a particular condition and has only one method step recited.

J.A. 285 (emphases added). In response, the Inventors added a discrete, sequential "correlating" step that limits the inventive method to detecting the condition of cobalamin or folate deficiency, as recited in the preamble:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals [by] comprising the steps of:
>
> assaying a body fluid[s] for [the presence of] an elevated level[s] of total homocysteine[.]; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

J.A. 288; *see also* Pet. App. 9a (summarizing prosecution history and recognizing that the preamble "restates that the invention detects vitamin deficiency"). With that amendment, claim 13 issued. C.A. App. 4546-4551.

2. The Inventors' universities obtain patents on faculty inventions under the Bayh-Dole Act, 35 U.S.C. §§ 200 *et seq.* C.A. App. 4375. They assigned the '658 patent to the predecessor of respondent Competitive Technologies, Inc. ("CTI"), a company that licenses to industry the technological developments of colleges and universities. The University of Colorado also established respondent Metabolite Laboratories, Inc. to practice the invention because, in light of initial skepticism in the medical community, the laboratory test industry initially showed little interest in offering this new diagnostic method. C.A. App. 4370-4371. CTI granted a patent license to Metabolite, where the Inventors developed proprietary expertise to make their invention

available to practicing physicians. C.A. App. 4551-4559, 9818-9830, 8962-8971.[3]

As the superiority of the diagnostic method invented by the Inventors became clear, the laboratory test industry—including petitioner's predecessor—became interested. J.A. 301-311. Metabolite gave petitioner's predecessor a sublicense to the '658 patent along with a license to the extensive know-how that Metabolite had developed in practicing the invention. C.A. App. 4605-4632, 9026-9110. Petitioner later succeeded to this business and received an assignment of the patent sublicense and know-how license. C.A. App. 4654, 9185-9186.[4]

For six years, petitioner and its predecessor paid royalties to respondents for every homocysteine assay it performed. Then, Abbott Laboratories—which had published articles referencing and teaching the patented invention (J.A. 187-188; C.A. App. 4656-4659, 9798-9805, 9290-9335)—introduced a new, automated total homocysteine assay kit.

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[3] Typically, a physician seeking a diagnosis orders a patient test; blood is drawn from a patient and shipped to a testing laboratory; the laboratory performs the test and reports the results to the physician; and the physician utilizes the results. C.A. App. 4140-4145.

[4] Under the assigned agreement, petitioner pays a 6% royalty to CTI for the patent sublicense and a separate 21.5% royalty to Metabolite for the know-how license on homocysteine assays (which also gives petitioner a *royalty-free* license to use Metabolite's trade-secret technology for potentially more than a hundred other assays). J.A. 124-126, 301-311; C.A. App. 4375, 4558-4578, 8943-8979, 8983-8984, 4598-4605. Eight of petitioner's large competitors, comprising much of the laboratory test industry, are also sublicensed under the '658 patent and pay royalties to CTI, although they do not use Metabolite's proprietary know-how and do not pay the separate royalty to Metabolite. C.A. App. 4370-4371, 4566-4573. None of these other licensees has ever asserted that the patent is invalid. C.A. App. 4382.

Petitioner decided that by using the Abbott kit it could avoid paying royalties to respondents. C.A. App. 5000, 5030. Petitioner continued to perform total homocysteine assays for the purpose of diagnosing cobalamin and folate deficiencies, but discontinued making royalty payments. *See* Pet. App. 3a.

C. The Litigation

1. CTI sued petitioner for infringement, inducing infringement and contributory infringement of the patent. Metabolite sued petitioner for breaching the license agreement. In its answer, petitioner admitted that it performed total homocysteine assays and "communicated [the test results] to the physician along with information from which these results may be correlated with the presence or absence of deficiencies of cobalamin or folate." J.A. 65. Petitioner asserted that "[t]he '658 patent is invalid, unenforceable, and/or void for failure to comply with 35 U.S.C. §§ 102, 103, and 112." J.A. 66. In particular, petitioner alleged that claim 13 is invalid as anticipated under Section 102, as obvious under Section 103, and for insufficient written description and nonenablement under Section 112. *Ibid.*; *see also* J.A. 75-78. Petitioner did not cite 35 U.S.C. § 101 in its answer or anywhere else in the voluminous pleadings and discovery exchanged in the district court, nor did it assert that claim 13 recites unpatentable subject matter. *See* U.S. Br. 16.

The jury was instructed on each of the invalidity defenses on which petitioner presented evidence at trial. *See* J.A. 380-384 (obviousness); 384-385 (anticipation); 385-386 (indefiniteness); 387-388 (enablement and sufficiency of the written description). The special verdict form had a space for the jury to determine the validity of claim 13 under each theory presented by petitioner: "Invalid for Nonenablement"; "Invalid for Insufficient Written Description"; "Invalid for Indefiniteness"; "Invalid for Obviousness"; and "Invalid for Anticipation." J.A. 397. The jury rejected each and every

one of these theories of invalidity. J.A. 396.[5] Nowhere in the jury instructions or the special verdict form is there any mention of Section 101 or subject matter patentability—for the simple reason that petitioner had never raised any such issues.

The jury also found that petitioner had engaged in both induced infringement and contributory infringement of the '658 patent, and that this infringement was willful. J.A. 396. The jury further found that petitioner had breached its license agreement with Metabolite by failing to pay royalties thereunder. J.A. 395-396.

The district court sustained the jury's findings of validity, infringement, and breach of contract. Pet. App. 34a-39a. It entered judgment against petitioner in the amount of approximately $5 million. J.A. 400-401.

2. The court of appeals affirmed the district court's construction of the "correlating" step of claim 13 as "includ[ing] both a mutual relationship between the presence of an elevated level of homocysteine and a vitamin deficiency and a reciprocal relationship between the absence of an elevated level of homocysteine and no vitamin deficiency." Pet. App. 12a. The court expressly did "not address the assaying step" of claim 13, because there was no dispute that petitioner performed that step. *Id.* at 13a n.1.[6] The court also "affirm[ed]

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[5] Petitioner's counsel described the jury as "a very impressive jury, very well educated." J.A. 83. The district court stated that "[y]ou couldn't have a brighter jury" (J.A. 175) and described the jury as "probably the most attentive, hard-working jury I've ever had." J.A. 176.

[6] Judge Schall dissented from the majority's affirmance of the district court's construction of the correlating step. Pet. App. 28a-33a. That issue was raised in the second question presented in the petition, which the Court did not grant. Judge Schall "agree[d] with the majority's conclusions with respect to validity." *Id.* at 28a.

the finding of indirect infringement based on the inducement analysis," and "decline[d] to consider contributory infringement." Pet. App. 15a.

As in the district court, petitioner made its panoply of invalidity arguments. Pet. App. 16a (petitioner "argue[d] that claim 13 is invalid on grounds of indefiniteness, lack of written description and enablement, anticipation, and obviousness"). The court of appeals considered and rejected each. *See id.* at 16a-21a. The court of appeals did *not* consider or decide whether the patent claims unpatentable subject matter under 35 U.S.C. § 101, again for the simple reason that petitioner presented no such issue to the court.

3. The petition for a writ of certiorari presented three questions, involving (a) the evidentiary standard for willful infringement, (b) the construction of the "correlating" step, and (c) Section 112-based validity challenges (*i.e.*, definiteness, written description, and enablement). Pet. i. This Court invited the Solicitor General to address a question *not* presented in the petition—*viz.*, whether the '658 patent is "invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas.'" 125 S. Ct. 1413 (2005) (quoting *Diamond* v. *Diehr*, 450 U.S. 175, 185 (1981)). The government responded that "the validity of [the '658 patent] under the natural phenomenon doctrine was neither pressed nor passed upon below." U.S. Cert. Br. 5; *see also* Resp. Br. in No. 04-1579, at 2-3 n.*. The Court then granted the petition limited to question three as framed by petitioner—*i.e.*, whether the '658 patent is invalid under Section 112 for indefiniteness, insufficient written description, or non-enablement. J.A. 402-403.

INTRODUCTION AND SUMMARY OF ARGUMENT

"This Court has long understood the vital interest served by federal procedural rules" (*Coleman* v. *Thompson*, 501 U.S. 722, 751 (1991) (emphasis deleted)), and "[n]o proce-

dural principle is more familiar to this Court" than the forfeiture of a right through "the failure to make timely assertion of the right before a tribunal having jurisdiction to determine it." *Yakus* v. *United States*, 321 U.S. 414, 444 (1944); *Peretz* v. *United States*, 501 U.S. 923, 936-37 (1991). "These rules reflect the principle that a trial on the merits, whether in a civil or criminal case, is the 'main event,' and not simply a 'tryout on the road.'" *Freytag* v. *Comm'r*, 501 U.S. 868, 895 (1991) (concurring opinion of Scalia, O'Connor, Kennedy and Souter, JJ). Indeed, "[t]he very word 'review' presupposes that a litigant's arguments have been raised and considered in the tribunal of first instance." *Ibid.*; *see also Hormel* v. *Helvering*, 312 U.S. 552, 556 (1941).

In light of these bedrock principles, it is surprising that petitioner and its *amici* devote the great bulk of their arguments to a question that was not pleaded in the answer, tried in or decided by the district court, raised in or addressed by the court of appeals, presented in the certiorari petition, and on which certiorari was not granted: Whether claim 13 of the '658 patent recites only a "natural phenomenon" and thus falls within a judicial exception to subject matter patentability under 35 U.S.C. § 101. Petitioner is flat wrong on the merits of that question, but because petitioner never even tried to put it in issue below, much less to carry its heavy burden of proving invalidity by clear and convincing evidence, the Section 101 question may not be considered by this Court at this late date. *See, e.g.*, *Taylor* v. *Freeland & Kronz*, 503 U.S. 638, 646 (1992).

Indeed, it is unlikely that there has ever been another case in the annals of this Court in which a party so clearly embraced *every* avenue for forfeiting a right, in *every* court along the way. This Court would not readily excuse *any* of these forfeitures even in the most compelling circumstances. *Coleman*, 501 U.S. at 752-57 (late filing by attorney for death row inmate); *see also Browder* v. *Dir., Dep't of Corrs.*, 434 U.S. 257, 264-65 (1978). There is no good reason for

this Court to take a more forgiving tack where, as here, an ably represented, sophisticated commercial party has knowingly amassed a veritable constellation of forfeitures, each independently sufficient to preclude review of the belatedly asserted claim. To the contrary, this Court just recently reaffirmed, in another patent case, the longstanding rule that appellate courts are "*without power*" to reverse *or* grant a new trial when the party who lost at trial failed to set forth the argument it seeks to raise on appeal in a timely postverdict motion before the trial court—which is merely *one* of the many defaults committed by petitioner in this case. *See Unitherm Food Systems, Inc.* v. *Swift-Eckrich, Inc.*, No. 04-597, slip op. 5-9 (Jan. 23, 2006) (emphasis added); *see also Johnson* v. *N.Y., New Haven & Hartford R.R. Co.*, 344 U.S. 48, 54 (1952).

In any event, if this Court does consider the Section 101 question, it will have no difficulty concluding that claim 13 is drawn to statutory subject matter. Claim 13 sets forth a two-step diagnostic method that allows one to detect vitamin deficiencies. The claimed invention is for a Section 101 "process," and does not fall within one of the judicial exceptions to patentable subject matter. Claim 13 sets forth a practical application of the Inventors' discovery that elevated total homocysteine levels correlate with cobalamin or folate deficiencies. The process necessarily involves the physical transformation of a body fluid, and that alone means that the claimed process is patentable subject matter. The two-step process also produces what is indisputably a useful, tangible, and concrete result—the detection of vitamin deficiencies. The patent does not claim all practical applications of the correlation between elevated total homocysteine and vitamin deficiencies; to the contrary, there a number of important uses of that correlation that do not infringe the patent.

With respect to the question on which this Court *has* granted review—whether the patent meets the drafting and disclosure requirements of 35 U.S.C. § 112—the jury found

that petitioner did not meet its burden of proving by clear and convincing evidence that claim 13 fails Section 112's requirements of definiteness, written description, and enablement. J.A. 396-397. The district court sustained those findings, and the Federal Circuit affirmed. Pet. App. 16a-18a. This Court "cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error." *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949). This is not such an exceptional case, and the Court should affirm the validity of claim 13 under Section 112. Since Section 112 is the sole basis for invalidity included in the question presented on which this Court has granted certiorari (U.S. Br. 16), the judgment below should be affirmed.

ARGUMENT

I. Claim 13 Satisfies The Drafting And Disclosure Requirements Of 35 U.S.C. § 112

The sole question presented—"[w]hether a method patent setting forth an indefinite, undescribed, and non-enabling step . . . can validly claim a monopoly"—is tautological: A patent that fails the requirements of 35 U.S.C. § 112 is by definition invalid. But that is not this case. The facts, as found by the jury, sustained by the district court, and affirmed by the court of appeals, are that the '658 patent *does* meet the Section 112 requirements. Once corrected, the question presented can only be answered in the affirmative—*i.e.*, a method patent setting forth a definite, sufficiently described, and enabled step *can* validly claim a monopoly. Accordingly, the judgment should be affirmed.

A. Claim 13 Identifies With Definiteness The Scope Of The Invention

The purpose of the definiteness requirement is to provide "clear warning to others as to what constitutes infringement

of the patent." *Manual of Patent Examining Procedure* § 2173.02. Petitioner's indefiniteness challenge is that "[t]he claim as construed says *nothing* at all about what it means to actively 'correlate' a test result." Pet. Br. 39. This argument cannot be reconciled with the record or petitioner's own litigating position in the lower courts.

In the district court, *petitioner* proposed that "correlating" means to "establish a mutual or reciprocal relationship." Pet. App. 7a-8a. The district court adopted that proposed construction and then petitioner stipulated to it in a jury instruction:

> A method for determining the existence of a shortage of cobalamin or folate necessary to health in warm-blooded animals comprising the steps of 1) assaying a body fluid for a level of total homocysteine raised above the normal range and 2) establish[ing] a mutual or reciprocal relationship between a level of total homocysteine raised above the normal range in said body fluid with a shortage of cobalamin or folate necessary to health[,] the latter step describ[ing] a discrete step in a sequential process.

J.A. 376-377 (internal quotations omitted). The Federal Circuit agreed that establishing a mutual or reciprocal relationship was a sufficiently definite description. Pet. App. 16a; *see also* U.S. Br. 14 ("[C]laim 13 satisfies the definiteness requirement because it marks the boundaries of the patent claim with precision. . . . Although [the claim] language is undeniably sweeping, it is not unclear.").

Petitioner presented no evidence at trial to support its current assertion that the correlating step is unclear. To the contrary, its own medical expert, its own Discipline Director, and its own Laboratory Director all testified that the step was quite clear to them. J.A. 154, 150-151, 162-164, 112-113. In its jury instruction contentions, petitioner failed to assert that

the correlating step was unclear. J.A. 365-366, 385-388. In its opening statement and closing argument, petitioner never asserted that the correlating step was unclear. Trial Tr. 131-141, 1772-1798.

Petitioner itself has published extensive materials explaining the mutual and reciprocal relationship between total homocysteine and cobalamin and folate deficiencies. *See* J.A. 189-195, 255-256, 257-258, 259-261. Petitioner's literature acknowledges that the Inventors discovered "the clinical correlations and analytical methodology," and in particular that they had patented "methods for detecting and distinguishing cobalamin and folic acid deficiency." J.A. 196. Until it stopped paying royalties, petitioner never questioned the validity of the '658 patent on any grounds.

Now, as if the burden were on respondents to disprove petitioner's bald contention that *its own* construction of "correlating" is unclear, petitioner protests that "nothing . . . tells a practitioner how to actively 'establish' a 'relationship' between a particular test result and a vitamin deficiency." Pet. Br. 39. This assertion cannot be reconciled with the specification itself, which teaches that "[h]omocysteine levels above [the normal] ranges are indicative of cobalamin and/or folate deficiency; the higher the level, the stronger the indication." S.A. 14; *see also* S.A. 11. The patent goes on to quantify the total homocysteine ranges in the sample populations and to describe in detail the procedures by which the Inventors established the mutual and reciprocal relationship between total homocysteine and vitamin deficiency.[7] As the Federal Cir-

[7] Example I, Example VI, and Example VII all describe the Inventors' extensive patient studies, in which they established that total homocysteine was "diagnostically useful" in evaluating vitamin deficiencies and "more sensitive" than previous tests. S.A. 14-15, 27-29. These examples parallel the papers authored by the Inventors and published—after peer review—in prestigious medical journals. C.A. App. 8885-8895, 8644-8652, 8862-8871.

cuit explained, "the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art." Pet. App. 18a. Petitioner has not demonstrated any error in that factual determination.

B. The Specification Contains A Sufficient Written Description And Enables One Skilled In The Art To Practice The Invention

The jury and lower courts correctly concluded that the specification also contains a sufficient written description of the invention and enables a person skilled in the art to make and use the invention. J.A. 396-397; Pet. App. 34a-35a, 17a-18a.

1. The purpose of the written description requirement is to "convey 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 Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed Cir. 2005); *see Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶1, "Written Description" Requirements*, 66 Fed. Reg. 1099, 1104 (Jan. 5, 2001). As with its definiteness challenge, petitioner's sole challenge to the written description of the invention is that "nothing in the specification says exactly what [the correlating step] includes or how to do it." Pet. Br. 41. To the contrary, the specification explains that "[i]t has been discovered that elevated levels of homocysteine in body tissue correlate with decreased levels of cobalamin and/or folic acid in said body tissue." S.A. 12. The patent recites several prior-art methods of assaying for total homocysteine, but notes that "[t]he procedure has never been used to monitor homocysteine to detect or measure cobalamin or folic acid deficiency." *Ibid.*

The patent clearly describes how the Inventors practiced the correlating step en route to inventing the diagnostic

method of claim 13. *See* note 7 and accompanying text, *supra*; U.S. Br. 9 ("the patent specification easily satisfies the . . . written description requirement[] by . . . demonstrating that the applicants had in fact performed [the claimed method]"). Moreover, the Federal Circuit explained that "the PTO read the specification to include [the correlating] feature," and "the record reflects that [petitioner's] own expert and employees understood the meaning of 'correlating.'" Pet. App. 17a. Petitioner has not challenged either of these factual determinations as clearly erroneous—indeed, petitioner does not take issue with any aspect of the lower courts' rejection of its written description defense. Because the written description issue is "primarily factual" (*Union Oil Co.* v. *Atlantic Richfield Co.*, 208 F.3d 989, 1005 (Fed. Cir. 2000); *see* U.S. Br. 11), and "[t]he record is replete with evidentiary support" that one skilled in the art would "underst[and] from the specification that the '658 patent inventors possessed the 'correlating' step" (Pet. App. 17a), petitioner's written description argument fails.

2. The specification also easily meets the enablement requirement, which "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).

Petitioner's sole enablement challenge is that "nothing in the specification informs a skilled artisan what [the correlating step] is." Pet. Br. 41. This is wrong for the reasons just discussed: Since the specification describes in detail how the Inventors practiced the correlating step, it would enable one skilled in the art to replicate (or build upon) their research.

In fact, the specification describes in great detail the manner in which to conduct assays and correlations. For example, 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. As the Federal Circuit explained, "the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art." Pet. App. 18a; *see* U.S. Br. 9 ("Especially from the perspective of such a person, the patent specification easily satisfies the enablement . . . requirement[] by explaining precisely how to perform the claimed method"). Petitioner has not even challenged this factual conclusion.

II. Petitioner's Contention That Claim 13 Does Not Recite Patentable Subject Matter Is Not Properly Presented, And In Any Event Is Meritless

Section 101 of the Patent Act provides that "*[w]hoever invents or discovers any new and useful process*, machine, manufacture, or composition of matter, *may obtain a patent therefor*, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (emphases added). As this Court has recognized (*Diamond* v. *Chakrabarty*, 447 U.S. 303, 315 (1980)), Section 101 is the congressional implementation of the constitutional authority to "promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const. art. I, § 8, cl. 8. Contrary to petitioner's unsupported assertion that "[t]here is a longstanding and key distinction between a potentially useful scientific *discovery* and a patentable *invention*" (Pet. Br. 31), the Patent Act unequivocally states that "[t]he term 'invention' means invention or discovery." 35 U.S.C. § 100(a); *see Corning* v. *Burden*, 56 U.S. (15 How.) 252, 268 (1854) ("A new process is usually the result of discovery; a machine, of invention").

The Inventors "invent[ed] or discover[ed]" a "new and useful process"—a novel method for detecting cobalamin and folate deficiencies that often went undiagnosed using traditional methods. *See* Pet. App. 2a-3a; S.A. 12, 29. Claim 13 of the '658 patent, which recites that method, is "presumed valid." 35 U.S.C. § 282; *see Cardinal Chem. Co.* v.

Morton Int'l, Inc., 508 U.S. 83, 93 n.15 (1993). Moreover, "[t]he burden of establishing invalidity . . . shall rest on the party asserting such invalidity." 35 U.S.C. § 282; *see also Budde* v. *Harley-Davidson, Inc.*, 250 F.3d 1369, 1381 (Fed. Cir. 2001) (invalidity must be established by "clear and convincing evidence"); Pet. App. 15a. Petitioner has not met that heavy burden. Indeed, in the courts below it did not even try.

A. Subject Matter Patentability Is Not Properly Before The Court

The thrust of petitioner's submission in this Court is that "Claim 13 runs afoul" of "the 'established rule'" that "a scientific fact 'cannot be the subject of a patent.'" Pet. Br. 21 (quoting *Parker* v. *Flook*, 437 U.S. 584, 589 (1978)). Accordingly, petitioner's challenge "turns entirely on the proper construction of § 101 of the Patent Act, which describes the subject matter that is eligible for patent protection." *Flook*, 437 at 588; *see also Diehr*, 450 U.S. at 181-82, 185, 188-89, 191-92.[8] Yet, with the exception of a single cryptic footnote in its merits brief filed in this Court (Pet. Br. 19-20 n.10), petitioner has *never* so much as cited, much less invoked or discussed, Section 101 in the long history of this litigation.

Almost in passing, petitioner maintains that subject matter patentability is so important that it can be raised at any time in the litigation, even if it was not pleaded in the answer. Pet. Br. 20 & n.11. For this proposition, petitioner cites two 19th Century cases that state that non-patentability need not be pleaded. *Hill* v. *Wooster*, 132 U.S. 693, 698 (1890); *Slawson* v. *Grand Street R.R. Co.*, 107 U.S. 649, 652 (1883); *see*

[8] Petitioner's *amici* uniformly understand its challenge to be based on Section 101. *See, e.g.*, AARP Br. 26 ("There is no patentable *invention* in Claim 13 under § 101"); ACLA Br. 16 ("[E]ven when claim 13 is viewed as a whole, it still fails to describe a 'process' within the meaning of 35 U.S.C. § 101").

also, e.g., *Hendy* v. *Golden State & Miners' Iron Works*, 127 U.S. 370, 375 (1888). Unfortunately for petitioner, the proposition reflected in those cases has been thrice abrogated in the last century: Not only did Congress expressly reject it in the Patent Act of 1952 as a matter of substantive patent law, but both this Court's 1937 promulgation of the Federal Rules of Civil Procedure and related rules for appellate courts also foreclose it as a matter of federal procedural law.

1. Petitioner Failed To Plead Or Prove A Non-Patentability Defense As Required By The Patent Act

During the late 19th Century when petitioner's authorities were decided, the Patent Act set forth five specific defenses that defendants in infringement actions were required to plead and prove at trial. Patent Act of 1870, ch. 230, § 61, 16 Stat. 198, 208 (July 8, 1870) (R.S. 4920). If one of the five enumerated defenses was not included in an answer, courts would not allow a party to raise the defense at a later time. *E.g.*, *Guidet* v. *Barber*, 11 F. Cas. 103, 104 (C.C.D.N.J. 1873) (No. 5,857) (holding that a defense based on lack of novelty falls within enumerated defenses and cannot be raised if not "specified" in the answer). Significantly, the five enumerated defenses set forth in the 1870 version of the Patent Act did *not* call on defendants to plead lack of patentable subject matter as a defense. Accordingly, even courts that refused to consider one of the five enumerated defenses would excuse a defendant's failure to raise subject matter patentability in his answer. *Ibid.*

In 1952, Congress revised the Patent Act and broadened the range of defenses to be pleaded in infringement cases. New Section 282 replaced what had been Section 61 of the 1870 version of the Patent Act (R.S. 4920) with a broader, more inclusive list of defenses required to be pleaded. *See* Reviser's Notes, 1952 U.S.C.C.A.N. 2394, 2422 ("The five defenses named in R.S. 4920 are omitted and replaced by a

broader paragraph specifying defenses in general terms"). For the first time, Congress included among the defenses that "shall be pleaded" the defense of non-patentable subject matter under Section 101. 66 Stat. 792, 812 (codified at 35 U.S.C. § 282). The principle of *Slawson* and similar cases—that federal courts could consider subject matter patentability even when the defense was not raised in an answer—did not survive this substantive revision to the Patent Act.

Thus, the Patent Act now provides, in no uncertain terms, that "[t]he following shall be defenses in any action involving the validity or infringement of a patent *and shall be pleaded*: . . . Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability." 35 U.S.C. § 282 (emphasis added). "Part II" of title 35 includes the Section 101 requirements of subject matter patentability. *Standard Oil Co.* v. *Am. Cyanamid Co.*, 774 F.2d 448, 453 (Fed. Cir. 1985).

Petitioner failed to plead a lack of subject matter patentability under Section 101 in its answer. *See* J.A. 65-70.[9] Petitioner's answer includes assertions that claim 13 is invalid for failure to satisfy Sections 102 (novelty), 103 (nonobviousness), and 112 (definiteness), but the answer does not contain any assertion that claim 13 recites unpatentable subject matter or otherwise is invalid under Section 101. J.A. 66, 64-82. Moreover, petitioner introduced no evidence on this issue at trial; the jury was not charged on subject matter patentability, and it did not return a verdict on any Section 101 defense. *See* J.A. 362-393 (complete set of jury instructions); 394-397 (special verdict form).

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[9] Although petitioner maintains without elaboration that "the issue was raised below" (Pet. Br. 17 n.9), petitioner never even mentioned Section 101 or non-patentable subject matter in the lower courts. U.S. Cert. Br. 15 ("Indeed, petitioner did not mount any challenge, under any theory, to the patentability of the claimed subject matter under Section 101").

As this Court has recognized in numerous contexts, courts must strictly enforce statutory prerequisites to litigation. *See, e.g.*, *Hallstrom* v. *Tillamook County*, 493 U.S. 20, 33 (1989); *McNeil* v. *United States*, 508 U.S. 106, 113 (1993). This is especially important where, as is the case with patents, such requirements manifestly are designed to ensure that complex questions of law, fact, science and policy are fully vetted *at trial*. As Justice Breyer has observed, it is essential that courts "mak[e] difficult science-related choices only when there has been extensive, informed development of the relevant legal and policy issues *prior* to decision." Breyer, *Genetic Advances and Legal Institutions*, 28 J. L. Med. & Ethics 23, 23 (2000). Here, because petitioner failed to include a Section 101 defense in its answer, petitioner cannot now assert that the '658 patent fails the requirements of subject matter patentability. *See, e.g.*, *Elec. Storage Battery Co.* v. *Shimadzu*, 307 U.S. 5, 16-17 (1939) (refusing to consider a validity defense that an infringer failed to plead or prove in the lower courts); *Johnson & Johnson* v. *C.B. Stenvall, Inc.*, 193 F. Supp. 128, 132 (S.D.N.Y. 1961) ("[E]ven if the defense of abandonment had merit, it was neither pleaded in the answer nor noticed in writing at least 30 days before the trial as required by 35 U.S.C. § 282, and therefore is not entitled to consideration").

2. Petitioner's Failure To Plead A Non-Patentability Defense Runs Afoul Of General Pleading Rules

Petitioner's belated attempt to raise the Section 101 patentability defense also violates the Federal Rules of Civil Procedure, which expressly require defendants to plead "any . . . matter constituting an avoidance or affirmative defense." Fed. R. Civ. P. 8(c). As Professors Wright and Miller have observed, this rule has led the lower courts "virtually universal[ly]" to conclude that "a failure to plead an affirmative defense . . . results in the waiver of that defense and its exclu-

sion from the case." 5 *Federal Practice & Procedure* § 1278 (3d ed. 2004). Barely two years ago, in *Kontrick* v. *Ryan*, 540 U.S. 443 (2004), this Court agreed.

This Court held in *Kontrick* that a debtor forfeited his right to rely on a defense by failing to raise the issue in his answer or, indeed, at any time before the trial court reached the merits of the case. *See* 540 U.S. at 458-60. The Court made clear that "under the Bankruptcy Rules *as under the Civil Rules*, a defense is lost if it is not included in the answer or amended answer" or, "at the latest, 'at the trial on the merits.'" *Id.* at 459-60 (quoting Fed. R. Civ. P. 12(h)(2)) (emphasis added); see also *Hormel*, 312 U.S. at 556 ("our procedural scheme contemplates that parties shall come to issue in the trial forum vested with authority to determine questions of fact"). Here, as in *Kontrick*, petitioner is barred from raising the Section 101 patentability affirmative defense after it lost its case on the merits in the district court.

Petitioner further cemented the forfeiture of the Section 101 defense by failing to raise the issue at all until the case reached the merits stage at this Court. *See Helvering* v. *Tex-Penn Oil Co.*, 300 U.S. 481, 497-98 (1937) (petitioner "sought no ruling upon the question from the board or the lower court and is therefore not entitled to have it decided here"). Petitioner, represented by sophisticated counsel throughout this litigation, had multiple opportunities to attempt to inject the Section 101 invalidity argument into the case, and with each pleading, brief, or other submission petitioner knowingly bypassed that argument. At trial, petitioner put forth evidence and argument to support the invalidity arguments it had pleaded, but never mentioned Section 101 or subject matter patentability. No witness testified on the issue. No jury instruction was given regarding patentable subject matter or Section 101. Petitioner's pre-submission and post-trial motions for judgment as a matter of law similarly failed to raise a Section 101 defense. Dkt. 249, 250. As this Court recently reaffirmed in *Unitherm Food Systems, Inc.* v.

Swift-Eckrich, Inc., No. 04-597, slip op. 5-9, this last failure *by itself* was sufficient to deprive the Federal Circuit and this Court of any "power" to grant petitioner *any* relief (*i.e.*, reversal or a new trial), even if the Section 101 argument had been properly raised on appeal thereafter. *See also Cone* v. *W. Va. Pulp & Paper Co.*, 330 U.S. 212, 217-18 (1947); *Hopp v. City of Pittsburgh*, 194 F.3d 434, 440 (3d Cir. 1999) (Alito, J.).

Petitioner, of course, did *not* thereafter appeal any issue related to Section 101 or subject matter patentability to the Federal Circuit. Instead, petitioner reiterated its invalidity arguments under Sections 102, 103, and 112; it made no mention of Section 101 in its opening brief, its reply brief, or its petition for rehearing. In the court below, as in every other court of appeals, petitioner's failure to brief the claim it now seeks to present to this Court is, in and of itself, an independent basis for deeming that claim forfeited. *E.g.*, *Pandrol USA, LP* v. *Airboss Ry. Prods., Inc.*, 320 F.3d 1354, 1366 n.3 (Fed. Cir. 2003); *Becton Dickinson & Co.* v. *C.R. Bard, Inc.*, 922 F.2d 792, 800 (Fed. Cir. 1990).[10]

[10] Petitioner clings to a passage in its opening Federal Circuit brief to suggest that it raised the issue below. Pet. Br. 14 (quoting Pet. C.A. Br. 41). The desperate implausibility of this contention can scarcely be overstated. Although petitioner cited *Diehr* for the proposition that natural phenomena are excluded from patent protection, it did *not* challenge the validity of the patent under Section 101. *See* Pet. C.A. Br. 38. Indeed, after *respondents* pointed out in their answering Federal Circuit brief that petitioner had waived any conceivable Section 101 argument (Resp. C.A. Br. 71), petitioner said nothing further on the point. Thus, not only did petitioner fail to make an affirmative Section 101 argument, it also tellingly declined to engage on the question when respondents noted the waiver of any such issue.

3. This Court's Own Rules Preclude Consideration Of A Defense Of Non-Patentability

Petitioner nonetheless contends that this Court should review the Section 101 issue because that issue is "fairly included in Question 3." Pet. Br. 17 n.9. Even if that were true, it would not excuse the fact that the patentability issue was never raised in, or decided by, the courts below. *See, e.g.*, *Bankers Life & Cas. Co.* v. *Crenshaw*, 486 U.S. 71, 76-77 (1988) (treating issue "as if contained in a petition for a writ of certiorari," but "declin[ing] to decide the merits of the issue"). This Court is not a tribunal of "first view." *Adarand Constructors, Inc.* v. *Mineta*, 534 U.S. 103, 110 (2001) (quoting *Matsushita Elec. Indus. Co.* v. *Epstein*, 516 U.S. 367, 399 (1996) (opinion of Ginsburg, J.)).

In any event, the Section 101 issue is not "fairly included" in Question 3, which seeks review of the lower courts' determinations that claim 13 meets the requirements of Section 112. As this Court made clear in *Diehr*, Section 101's subject matter eligibility requirements are wholly *separate* from those set forth elsewhere, such as the novelty requirement of Section 102, the nonobviousness requirement of Section 103, or, by logical extension, the descriptive requirements of Section 112. 450 U.S. at 189-91; *see* U.S. Br. 14 (The "limitation under Section 101" on monopolizing natural phenomena "is entirely separate and distinct from the requirements of Section 112"). In light of *Diehr*, any Section 101 issue is sufficiently tangential to the Section 112 question presented as to make subject matter patentability *not* "fairly included therein." *Yee* v. *City of Escondido*, 503 U.S. 519, 537 (1992). Section 112's requirements and Section 101's requirements may "exist side by side," but "neither encompass[es] the other." *Ibid.*

Nor do any passing arguments in the *text* of the petition concerning the potential *consequences* of upholding the Fed-

eral Circuit's Section 112 rulings somehow serve to bring the Section 101 issue within Question 3. *See* U.S. Br. 15-16. To begin with, petitioner mentioned *Diehr* only to argue that it should not be held liable for *induced* infringement because the patent allegedly incorporates a "scientific fact"—a question on which this Court denied certiorari. Pet. 18-19. Moreover, even if a separate Section 101 invalidity argument *had* been included in the text of the petition—which it was not—that would not be sufficient to bring the issue before the Court under Rule 14.1(a), which "requires that a subsidiary question be fairly included in the *question presented* for [the Court's] review." *Izumi Seimitsu Kogyo Kabushiki Kaisha* v. *U.S. Philips Corp.*, 510 U.S. 27, 31 n.5 (1993).

In fact, it is abundantly clear that a Section 101 argument did not even occur to petitioner until the Court *sua sponte* sought the Solicitor General's views on such an argument, well after the petition and the opposition were filed. *See* Resp. Br. in No. 04-1579, at 2-3 n.*. For that reason, petitioner is wrong to contend that respondents should have opposed certiorari in this case on the ground that no Section 101 issue is properly before the Court. As the Solicitor General recognizes, nothing in this Court's rules required that respondents object, preemptively, to an issue that is not encompassed within any question presented. U.S. Br. 17; s*ee City of Springfield* v. *Kibbe*, 480 U.S. 257, 260 (1987). Because petitioner's Section 101 argument is not fairly encompassed within the question presented, and was neither pressed nor passed upon below, this Court should decline to consider it at this late date. And because that issue is the principal focus of the briefs filed by petitioner and its *amici*, this Court may wish to consider dismissing the writ of certiorari. *See, e.g.*, *Adarand*, 534 U.S. at 111; *City of Springfield*, 480 U.S. at 259-60.[11]

[11] Dismissal would be particularly appropriate because the '658 patent will expire in July 2007. The Section 101 issue that

B. The '658 Patent Claims Patentable Subject Matter

Assuming *arguendo* that the issue of subject matter patentability is properly before the Court, claim 13 of the '658 patent easily satisfies the requirements of Section 101. The Inventors discovered what could be considered, standing alone, a natural phenomenon, and then put that discovery to practical use by inventing a method for diagnosing cobalamin or folate deficiencies. In a line of cases culminating with *Diehr*, this Court has held that such "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." 450 U.S. at 187 (emphasis in original); *see also, e.g.*, *Chakrabarty*, 447 U.S. at 309-10; *Mackay Radio & Tel. Co.* v. *Radio Corp. of Am.*, 306 U.S. 86, 94 (1939); *Le Roy* v. *Tatham*, 55 U.S. (14 How.) 156 (1853).

Since *Diehr* was decided in 1981, the Federal Circuit has been the final arbiter on questions of subject matter patentability. During that time, the Federal Circuit has applied *Diehr* in many cases to determine whether claimed processes employing natural phenomena fall within the statutory subject matter set forth in Section 101. *See, e.g.*, *AT&T Corp.* v. *Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999); *State Street Bank & Trust Co.* v. *Signature Fin. Group, Inc.*,

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petitioner failed to raise during five years of litigation would have little practical significance just a year after this Term ends. At that time, the injunction entered by the district court (which has been stayed pending resolution of appellate proceedings) will also terminate. Although petitioner and some *amici* express concern with the scope of that injunction (*see* U.S. Br. 23-24, 29; Pet. Br. 36-37; AARP Br. 16), that concern—like petitioner's contention (Br. 48 n.28) that "the injunction should be vacated in light of whatever standard the Court announces in *eBay, Inc.* v. *MercExchange, L.L.C.*, No. 05-130"—is misplaced: Petitioner did not challenge the injunction in its petition, and the Court did not grant review of the scope of the injunction.

149 F.3d 1368 (Fed. Cir. 1998); *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (en banc). Today, it is clear that Section 101's subject matter requirements are met if a natural phenomenon incorporated in the claimed invention "has been reduced to some practical application rendering it 'useful.'" *Excel*, 172 F.3d at 1356-57; *accord Alappat*, 33 F.3d at 1543-44; *State Street*, 149 F.3d 1373.

The PTO has followed this Court's and the Federal Circuit's precedent regarding Section 101, and its *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, 1300 Off. Gaz. 142 (Nov. 22, 2005)—which "are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts" (App., *infra*, 5a)—are highly instructive.[12] Those *Guidelines* set forth the methodology that patent examiners are to use in determining whether patent applications claim statutory subject matter. *See* App., *infra*, 20a (flowchart summarizing steps in the analysis). As they are entitled at the very least to deference under *Skidmore* v. *Swift & Co.*, 323 U.S. 134, 140 (1944), the *Guidelines* (which petitioner fails even to mention) also provide a useful framework for judicial analysis of subject matter patentability.

1. The Claimed Invention Falls Within A Category Enumerated In 35 U.S.C. § 101

The expansive language of Section 101 allows a patent on "anything under the sun that is made by man." *Chakrabarty*, 447 U.S. at 308-09 (quoting S. Rep. No. 1979, at 5

[12] Because this volume of the *Official Gazette* is not yet available in print, we have reproduced pertinent portions of the PTO's *Subject Matter Eligibility Guidelines* in the appendix to this brief. *See also* 70 Fed. Reg. 75,451, 75,452 (Dec. 20, 2005) (requesting public comment on the *Guidelines*).

(1952), H.R. Rep. No. 1923, at 6 (1952)). In addition to machines, manufactures, and compositions of matter, Section 101 makes "processes" patentable. "A process is a mode of treatment of certain materials to produce a given result." *Cochrane* v. *Deener*, 94 U.S. 780, 788 (1877); *accord Diehr*, 450 U.S. at 183. Claim 13 fits this description precisely: It claims a process for treating certain materials (*i.e.*, assaying body fluids and correlating the assay results with vitamin status) to achieve a desired result (*i.e.*, detecting cobalamin or folate deficiencies).

Contrary to petitioner's assertion (Br. 23), it is of no moment that the patented process can be practiced using an assay procedure that may have been known previously.[13]

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[13] The government briefly questions whether claim 13 might be invalid under 35 U.S.C. § 102 (anticipation) "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." U.S. Br. 28. There are indeed other purposes for assaying for total homocysteine, such as detecting certain inherited enzyme defects (which are relatively rare). S.A. 14 ("When homocysteine levels are elevated in individuals *without inherited defects*, at least one of folate or cobalamin is deficient") (emphasis added); *see also* S.A. 11; J.A. 137; C.A. App. 9648, 9697, 5552. The injunction in this case does not prevent "doctors" from making use of such assays. Rather, it precludes *petitioner*—which is not a doctor—from assaying for total homocysteine because *petitioner* failed to offer any evidence that any of *its* assays were for any of these other purposes. In any event, as the government concedes, the anticipation issue is "not before this Court." U.S. Br. 28. At trial, petitioner raised an anticipation defense, which was rejected by the jury. J.A. 396-397. Petitioner reiterated its anticipation defense on appeal, where it was rejected by the Federal Circuit. Pet. App. 18a-19a. Petitioner did not seek certiorari on the anticipation issue, so it has been abandoned. *Posters 'N' Things, Ltd.* v. *United States*, 511 U.S. 513, 527 (1994). There is no reason, or basis, to consider or decide an issue raised only in passing by the United States as *amicus curiae*. *See, e.g.*, *United Parcel Service, Inc.* v. *Mitchell*,

"The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence." *Cochrane*, 94 U.S. at 788. Claim 13 teaches that doing "certain things" (assaying and correlating) with "certain substances" (body fluids) in a "certain order" (sequentially) will achieve a desired result—the diagnosis of vitamin deficiency. That is the essence of a patentable method. *Corning*, 56 U.S. (15 How.) at 268 ("It is when the term process is used to represent the means or method of producing a result that it is patentable").

It is therefore clear that claim 13 recites a process, and thus that it is drawn to statutory subject matter. The remaining question is whether the invention falls within one of the exceptions that this Court has recognized to Section 101's intentionally broad scope.

2. The Claimed Invention Does Not Fall Within A Judicial Exception To Section 101

"This Court has . . . recognized limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. These categories constitute "judicially created exception[s] to § 101." *Alappat*, 33 F.3d at 1542.

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451 U.S. 56, 60 n.2 (1981). In any event, the government's conjecture is mistaken. The PTO in fact rejected a previous iteration of claim 13 "as being anticipated" by prior art assays "[i]n the absence of a correlation step." J.A. 285. In response, the Inventors amended claim 13 "to recite a second step of correlating an elevated level of total homocysteine with a deficiency of cobalamin or folate." J.A. 290. The PTO then *withdrew* its Section 102 objection and allowed the patent as amended to issue. *See* Pet. App. 9a (summarizing prosecution history).

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. Of course, in the physical world "[e]verything that happens may be deemed 'the work of nature.'" *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 135 (1948) (Frankfurter, J., concurring). The Court has held that "[h]e who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes." *Id.* at 130 (majority opinion). But respondents do not claim a monopoly to the correlation discovered by the Inventors. Rather, claim 13 recites a *method* for using the correlation as a sequential step toward achieving the desirable end of diagnosing vitamin deficiencies. It is clearly patentable under existing law.

a. The Claimed Invention Covers A Practical Application Of A Natural Phenomenon

In *Flook*, the Court took a restrictive view of patentable subject matter and concluded that a claimed invention must include a novel or inventive aspect separate and apart from the discovery of a natural phenomenon itself. *See* 437 U.S. at 593-95. While petitioner repeatedly invokes this aspect of *Flook* (*e.g.*, Pet. Br. 28, 31), petitioner fails to acknowledge that the *Flook* approach was short-lived.

In *Diehr*, this Court retreated from language in *Flook* and made clear that "[t]he 'novelty' of any element or steps in a process, or even of the process itself, *is of no relevance* in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diehr*, 450 U.S. at 188-89 (emphasis added). Instead, the question "of whether a particular invention is novel is 'wholly apart from whether the invention falls into a category of statutory subject matter.'" *Id.* at 190 (quoting *In re*

Bergy, 596 F.2d 952, 961 (C.C.P.A. 1979), *vacated as moot*, 444 U.S. 1028 (1980)).[14] Thus, while a mathematical equation or law of nature "is not patentable in isolation," when incorporated as part of a process that yields a more efficient or useful end, "that process is at the very least not barred at the threshold by § 101." *Id.* at 188; *see also id.* at 187.

Although petitioner would have this Court apply the narrow view of subject matter patentability suggested by language in *Flook*, the Federal Circuit has since recognized—correctly—that *Flook* was "in part superseded" (*Arrhythmia Research Tech., Inc.* v. *Corazonix Corp.*, 958 F.2d 1053, 1057 n.4 (Fed. Cir. 1992)) and "expressly limited" (*Excel*, 172 F.3d at 1356) by *Diehr*. *See* U.S. Cert. Br. 11-15. Thus, a natural phenomenon "in the abstract" does not constitute patentable subject matter, but a claimed invention does meet Section 101's subject matter requirements when the phenomenon "has been reduced to some practical application rendering it 'useful.'" *Excel*, 172 F.3d at 1356-57; *accord Alappat*, 33 F.3d at 1543-44; *State Street*, 149 F.3d 1373.

Like the Federal Circuit, the PTO has adhered to *Diehr*. *See* U.S. Br. 21-22 n.4. Its *Guidelines* instruct patent examiners that a "practical application" of an abstract idea, law of nature, or natural phenomenon is patentable subject matter within the meaning of Section 101 "if the claimed invention

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[14] Although petitioner half-heartedly suggests that the Inventors did not in fact invent the process claimed in the patent (Pet. Br. 4 & n.2), failure to meet the requirements of Sections 102 or 103 "does not affect the determination" whether the patent "recite[s] subject matter which [is] eligible for patent protection under § 101." *Diehr*, 450 U.S. at 190-91 (internal quotation omitted). In any event, respondents established the novelty of the inventive method in the courts below (*see* Resp. C.A. Br. 55-60), and the Federal Circuit affirmed the jury's findings that petitioner had failed to prove anticipation or obviousness. Pet. App. 18a-21a. Petitioner's failure to challenge those factual findings in this Court renders its skewed recitation of history completely immaterial.

physically transforms an article or physical object to a different state or thing, *or* if the claimed invention otherwise produces a useful, concrete, and tangible result." App., *infra*, 5a (emphasis added). Under either of the independently sufficient parts of that test, claim 13 plainly passes the Section 101 threshold.[15]

i. Claim 13 Entails A Physical Transformation Of Matter

"Transformation and reduction of an article 'to a different state or thing' is the clue to patentability of a process claim that does not include particular machines." *Gottschalk* v. *Benson*, 409 U.S. 63, 70 (1972); *see Cochrane*, 94 U.S. at 788 ("A process is . . . an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing"). In *Diehr*, the Court held that "when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101." 450 U.S. at 192.

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[15] Although petitioner maintains (Br. 17, 23-24) that claim 13 involves no "post-solution activity," petitioner's arguments in this regard are misdirected. This Court noted in *Diehr* that "insignificant postsolution activity will not transform an unpatentable principle into a patentable process" (*Diehr*, 450 U.S. at 191-92), but the Court has never held that "post-solution activity" is a prerequisite to patentability. Nor has such a requirement been imposed by the Federal Circuit or the PTO. Indeed, it is not clear that the concept of "post-*solution* activity" has any applicability outside the area of mathematical algorithms (which, by definition, involve a "solution"). *See Flook*, 437 U.S. at 590. Here, because claim 13 undoubtedly meets the subject matter eligibility requirements that this Court *has* imposed, the issue of "post-solution activity" (or, for that matter, "pre-solution activity") simply has no bearing on this case.

The PTO's *Guidelines* recognize that the transformation of matter, in itself, is dispositive of the Section 101 question:

> The examiner first shall review the claim and determine if it provides a transformation or reduction of an article to a different state or thing. If the examiner finds such a transformation or reduction, *the examiner shall end the inquiry and find that the claim meets the statutory requirement of 35 U.S.C. § 101*.

App., *infra*, 14a (emphasis added). Because the invention of claim 13 *requires* the transformation of matter (*i.e.*, blood or other body fluid) in order to diagnose vitamin deficiencies, it is patentable under Section 101.

Petitioner states, without citation, that "Claim 13 recites no such transformative method" because "the assaying step does not direct a practitioner to transform anything." Pet. Br. 27; *see also, e.g.*, CCIA Br. 4 n.4 (asserting that claim 13 "produce[s] no transformation"). That is simply wrong as a matter of both biochemistry and the undisputed evidence.

The assaying step requires "assaying a body fluid for an elevated level of total homocysteine." S.A. 30. It is undisputed that total homocysteine includes at least four species of homocysteine, three of which do not exist in free form. Pet. Br. 2-3 n.1. As the patent itself explains, "[i]n the presence of proteins, . . . homocysteine . . . form[s] complexes with free sulfhydryl groups on the protein molecule; in samples derived from tissues, such protein complexes may tie up most of the . . . homocysteine present." S.A. 13. As a result, "*[r]eduction is required* for release and subsequent assay of protein bound sulfhydryl compounds." *Ibid.* (emphasis added). Or, as an article co-authored by the Inventors explains, "[d]etermination of total Hcy [homocysteine] in plasma/serum *requires the reduction* of the disulfide bond between Hcy and other thiols or albumin." J.A. 262 (emphasis added); *see also* J.A. 247.

Thus, as the Solicitor General has correctly recognized, "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." U.S. Br. 21 n.4. Petitioner has identified no assay method that does *not* involve the transformation of matter, and given the biochemistry involved, no such assay could exist. Thus, petitioner has not carried its burden of proving, by clear and convincing evidence, that claim 13 is invalid because it could be practiced without transforming matter. Nothing more is required under *Diehr* to sustain the patent.[16]

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[16] *Amicus* ACLA wrongly contends (Br. 18) that the transformation that is an integral part of the inventive diagnostic method is insufficient because it is a "means to the end" and "does precisely the reverse" of the patent at issue in *Diehr*. ACLA's novel distinction, however, has no support in the law. Claim 13 sets forth a two-step process, which indisputably cannot be completed without the physical transformation of matter. Contrary to ACLA's theory, *Diehr* says nothing about whether the physical transformation has to be the *final* step in a claimed process; rather, as the PTO *Guidelines* reflect, it holds that if a process performs a physical transformation "function" it passes muster under Section 101. *Diehr*, 450 U.S. at 192. Claim 13 does so. And because claim 13 requires the transformation of matter, petitioner's attempt to liken this case to *Funk Brothers* (Br. 21) is mistaken. In *Funk Brothers*, the Court held that "aggregation of species [of bacteria] fell short of invention within the meaning of the patent statutes" because no transformation had been effected: "The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement in the range of their utility." 333 U.S. at 131. The Court has since held that a "nonnaturally occurring" bacterium could be patented because it had "markedly different characteristics from any found in nature." *Chakrabarty*, 447 U.S. at 310. The Inventors' diagnostic method likewise is not to be found in nature, but rather is "a product of human ingenuity" (*id.* at 309) that meets every extant test for subject matter patentability.

ii. The Method Of Claim 13 Produces A Useful, Tangible, And Concrete Result

Claim 13 also passes the Section 101 threshold for the separately sufficient reason that it produces a useful, tangible, and concrete result. *See* App., *infra*, 15a. Although natural phenomena are not patentable subject matter when they are presented as "merely abstract ideas constituting disembodied concepts or truths that are not 'useful,'" when natural phenomena are incorporated in a claimed invention as part of a process that produces a "useful, concrete, and tangible result," the invention satisfies Section 101. *State Street*, 149 F.3d at 1373, 1375; *Alappat*, 33 F.3d at 1544; *Excel*, 172 F.3d at 1360. The "result" produced under the two-step process set forth in claim 13 is a diagnosis of a condition of the human body, namely the detection of cobalamin or folate deficiencies; this diagnostic result plainly meets the *State Street* factors.

The result produced by the inventive method is clearly "useful" in that it detects a potentially dangerous medical condition and improves the patient's chances of receiving proper treatment. *See, e.g.*, *Arrhythmia Research*, 958 F.2d at 1059-60 (holding that process claims setting forth "a method of analyzing electrocardiograph signals in order to determine a specified heart activity" are directed to statutory subject matter); *id.* at 1066 (Rader, J., concurring) (a method "for detecting the risk of a heart attack" qualifies as statutory subject matter under Section 101). In fact, petitioner concedes, as it must, that claim 13 sets forth a "practical use" by enabling the "detect[ion of] vitamin deficiencies." Pet. Br. 27.

The result produced under claim 13 is also "tangible," which the PTO defines as the opposite of "abstract." App., *infra*, 16a. Unless properly diagnosed, a patient suffering from cobalamin or folate deficiencies may not receive proper supplements to treat his or her condition. Proper medical di-

agnoses have tangible, real-life consequences and are far from "abstract." As with the method patent at issue in *Arrhythmia Research*, claim 13 does not "disclose mere abstract ideas, but a practical and potentially life-saving process." 958 F.2d at 1065-66 (Rader, J., concurring); *see also State Street* 149 F.3d at 1373 (explaining that *Arrhythmia Research* was decided consistently with the "useful, tangible, and concrete result" test); *accord Excel*, 172 F.3d at 1359.

Finally, claim 13 produces a "concrete" result. The PTO defines "concrete" as the opposite of "unrepeatable or unpredictable." App., *infra*, 17a. One of the great benefits of the process set forth in claim 13 is that it yields predictable, repeatable results. S.A. 27-28; J.A. 85, 177. By inventing a method that accurately and repetitively detects the presence or absence of cobalamin or folate deficiencies, the Inventors have added an important diagnostic technique to the arsenal of medical practitioners.

Petitioner has never disputed that claim 13 produces a useful, tangible, and concrete result. Instead, petitioner chooses to ignore the existence of that standard altogether, and clings to language in *Flook* to contend that because the usefulness of the patents at issue in that case "did not save them," it must be true that "specifying one practical use for a scientific correlation does not render a patent claim valid." Pet. Br. 28. That view was rejected in *Diehr*, however, which provided that when a process employing a natural phenomenon results in a practical use, it *does* fall within Section 101. *See Diehr*, 450 U.S. at 188, 192; *State Street*, 149 F.3d at 1375. Petitioner offers no basis for this Court to resurrect the superseded aspects of *Flook* and does not even attempt to square its theory of unpatentability with the rule developed in *Diehr*, applied in the Federal Circuit, and reflected in the PTO's *Guidelines*.[17]

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[17] Petitioner's invocation (Br. 24-25 & n.13) of *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989), does not improve its position.

Nor does petitioner's repeated contention that the patent is invalid because it allegedly precludes doctors from "thinking about" test results (*e.g.*, Pet. Br. 22), provide reason to question the patentability of claim 13. Aside from the fact that a computer could presumably be programmed to perform the correlating step on the results of an assay, the so-called "mental steps test" that petitioner and its amici seek to invoke (Pet. Br. 27 n.14; CCIA Br. 5; AARP Br. 21) was long ago repudiated as an appropriate measure of patentability. *See, e.g.*, App., *infra*, 21a-22a (citing *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970)). Thus, even "[i]f all the steps of a claimed process can be carried out in the human mind," the proper inquiry remains "whether the claimed process produces a useful, tangible, and concrete result," as "set forth in *State Street*." *Id.*

In any event, claim 13 is only infringed when the assaying and correlating steps are *both* performed, sequentially, for the purpose of diagnosing vitamin deficiencies. The act of assaying body fluids for total homocysteine for reasons other than diagnosing vitamin deficiencies would not infringe. Nor would the act of correlating alone, or what petitioner calls "thinking about" the relationship between total homocysteine and vitamin deficiencies.[18]

Grams has been expressly disapproved by the Federal Circuit (*Excel*, 172 F.3d at 1360), and no court has cited it since.

[18] Petitioner was found to infringe the patent because petitioner marketed its total homocysteine assays for use in diagnosing vitamin deficiencies via the method of claim 13. J.A. 173, 189-195, 255-256, 257-258, 259-261; *see MGM Studios Inc.* v. *Grokster, Ltd.*, 125 S. Ct. 2764, 2779 (2005) ("The classic case of direct evidence of unlawful purpose occurs when one induces commission of infringement by another, or entices or persuades another to infringe, as by advertising") (internal quotation and citation omitted). Whether other persons or entities infringe the '658 patent is a separate question on which no evidence was presented below. Petitioner attempts to dispute this by noting (Br. 15) that one of the

b. The Claimed Invention Does Not "Preempt" Public Use Of Any Natural Phenomenon

As just demonstrated, claim 13 recites a practical application of the correlation between elevated total homocysteine and cobalamin and folate deficiencies discovered by the Inventors. The only remaining question on patentability is whether claim 13, as construed by the lower courts, is so sweeping as to "preempt" public use of that correlation. *Diehr*, 450 U.S. at 191; *see* App., *infra*, 15a. A patent sweeps too broadly if it comprises every "substantial practical application" of a natural phenomenon, because it "in practical effect would be a patent on the [phenomenon] itself." *Benson*, 409 U.S. at 71-72.

Respondents do not seek, and the '658 patent does not claim, a monopoly on the correlation between total homocysteine and vitamin deficiencies. Rather, the Inventors have patented a particular *application* of that correlation, when used as a sequential step in a diagnostic method. In this regard, the Inventors here are analogous to the patentees in *Diehr*: "Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt use of that equation. Rather, they seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." 450 U.S. at 187.[19]

Inventors "testified that it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency." Pet. App. 14a. What the Inventor actually said was that it would be malpractice to "fail to treat in response to [a] high homocysteine level." J.A. 106. She was not asked whether the purpose of the hypothetical assay was to detect cobalamin and folate deficiencies or, for example, to instead diagnose an inherited enzyme defect. *See* note 13, *supra*.

[19] For this reason, petitioner errs in attempting to equate the '658 patent with Samuel Morse's effort to monopolize "electro-

The government asserts, incorrectly, that "claim 13 appears to cover all substantial practical applications of the natural phenomenon." U.S. Br. 24. That assertion rests entirely on the jury's finding in connection with the contributory infringement claim (which was not considered by the court of appeals) "that no *substantial* non-infringing uses *of the total homocysteine assays* had been proven on the trial record." *Id.* at 23 (emphases added).[20] But the "natural phenomenon" at issue in this case is *not* the assay performed by petitioner, but rather the *correlation* between total homocysteine and vitamin deficiencies—as the government elsewhere acknowledges. *Id.* at 19. The jury made *no* finding that claim 13 covers substantially all practical applications of that correlation.

Contrary to the government's suggestion, there is no reason to "vacate and remand for further proceedings to determine whether all substantial practical applications of the correlation are claimed by the patent." U.S. Br. 26-27. As the government acknowledges, *petitioner* bears the burden of proving that no such applications exist. *Id.* at 24. Yet petitioner offers only the bare assertion that "[t]he scientific

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magnetism." Pet. Br. 35 (quoting *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 112 (1853)). Whereas Morse claimed all uses of a natural phenomenon, the '658 patent claims just one. The more apt analogy is Alexander Graham Bell's telephone patent. *Dolbear* v. *Am. Bell Tel. Co.*, 126 U.S. 1, 535 (1888) ("It may be that electricity cannot be used at all for the transmission of speech except in the way Bell has discovered, and that therefore, practically, his patent gives him its exclusive use for that purpose, but that does not make his claim one for the use of electricity distinct from the particular process with which it is connected in his patent").

[20] Although the jury found that there were no substantial non-infringing uses for the assays performed *by petitioner* (a for-profit provider of test results), it made no such finding as to total homocysteine assays performed by others for a different purpose (such as detecting an inherited enzyme defect).

principle that elevated homocysteine is associated with vitamin deficiencies is substantially covered by Claim 13" (Pet. Br. 28), citing *nothing* in the record—let alone the clear and convincing evidence that would be required to prevail. If the record were entirely silent, then the statutory presumption of validity would require affirmance of the judgment. This Court does not sit to order remands for consideration of issues that the petitioner failed to raise at any previous stage of the litigation. *E.g.*, *Pasquantino* v. *United States*, 125 S. Ct. 1766, 1781 n.14 (2005); *Yee*, 503 U.S. at 533.[21]

In any event, the record in fact discloses several noninfringing uses of the correlation. One such use is suggested by a study where the authors recommend cobalamin and folate supplements for all men over 45, and all women over 55, in order to reduce and prevent elevated total homocysteine levels (which are associated with heart disease and other illnesses), *without* first assaying total homocysteine in any patient. J.A. 107-108, 204-205; C.A. App. 4687-4688, 8711-8717. The authors estimated that this treatment strategy would save hundreds of thousands of lives, and billions

[21] Although petitioner now asks this Court to hold the patent invalid and "reverse the judgment against [petitioner] in its entirety" (Pet. Br. 19), an order directing entry of judgment against respondents is obviously precluded by the Seventh Amendment because no jury has found the *factual* predicates to a Section 101 defense. *Dimick* v. *Schiedt*, 293 U.S. 474, 486-87 (1935). Moreover, on the record in this case it would be inconceivable for the Court to remand for further proceedings. *Unitherm*, slip op. 7 ("This Court's observations about the necessity of a postverdict motion under Rule 50(b), and the benefits of the district court's input at that stage, apply with equal force whether a party is seeking judgment as a matter of law or simply a new trial"). Indeed, petitioner's request to be placed in a better position than it would have occupied had it complied with all applicable substantive and procedural rules speaks volumes not only of the weakness of its position but also of its misunderstanding of the role of this Court in our judicial system.

of dollars, over a ten-year period. J.A. 205. In another study, the authors determined that the toxicity of a chemotherapy treatment appeared related to patients' levels of total homocysteine. Aware of the correlation discovered by these Inventors, the authors recommended administering supplemental cobalamin and folate, thereby lowering the toxicity of an important drug that "has demonstrated promising clinical activity in a wide variety of solid tumors, including non-small cell lung, breast, mesothelioma, colorectal, pancreatic, gastric, bladder, cervix, and head and neck." C.A. App. 9763. Cancer patients who receive this drug today receive it in conjunction with supplemental cobalamin and folate as recommended by these authors. C.A. App. 4713-4714, 9763-9778.[22] Treating patients with vitamin supplements to reduce the risk of heart attack or the toxicity of a cancer drug, without first assaying for total homocysteine, constitute uses of the correlation at issue that do not infringe the patent.

Moreover, a number of other non-infringing uses of the correlation discovered by the Inventors appear in the medical literature, which is readily available to persons skilled in the art. As just one example, a recent study posited that elevated total homocysteine could play a role in the incidence of bone fractures sustained by stroke victims. To test this hypothesis, half of a control group were given placebos while the other half received cobalamin and folate supplements; the patients who received vitamin supplements suffered far fewer fractures than the ones who did not. *See* Sato, *et al.*, *Effect of Folate and Mecobalamin on Hip Fractures in Patients with Stroke*, 293 J. Am. Med. Assoc. 1082 (2005). As a practitioner's resource recently summarized this study, "it is reason-

[22] Since the record in this case was closed, the FDA has approved this drug for the treatment of mesothelioma, an asbestos-related cancer, as well as to treat the most common form of lung cancer. *See* Rollins & Lindley, *Pemetrexed: A Multitargeted Antifolate*, 27 Clinical Therapeutics 1343 (2005).

able to give these inexpensive and safe vitamins [B_{12} and folate] to patients with stroke." American College of Physicians Journal Club, *Folate plus vitamin B_{12} reduced hip fractures in patients with poststroke hemiplegia*, Vol. 143 No. 2 (Sept./Oct. 2005). Treating stroke victims with vitamin supplements to reduce fractures, without first assaying for total homocysteine, is yet another use of the correlation discovered by the Inventors that does not infringe the '658 patent.

Many more substantial practical applications of the correlation that do not infringe claim 13 are undoubtedly being practiced currently, or could be developed in the future, but these examples will suffice to show that petitioner has not carried *its* burden of proving, by clear and convincing evidence, that such uses are absent and the patent is therefore invalid. Rather, the examples confirm claim 13's validity under the government's own analysis. U.S. Br. 24 n.5, 26. The patent is not "preemptive" within the meaning of *Diehr* and *Benson*.

C. The Sea Change Sought By Petitioner Would Be Unnecessarily Disruptive To The Patent System

As demonstrated above, claim 13 of the '658 patent meets the subject matter eligibility requirements of current law, as enunciated by this Court (in *Diehr*), the Federal Circuit (in *State Street*, *Excel*, and *Alappat*), and the PTO (in its interim *Guidelines*). Thus, in order to grant petitioner any relief on the subject matter patentability argument that it has raised for the first time in this Court, the Court would have to revisit *Diehr*, overturn settled Federal Circuit precedent, and disapprove the standards by which the PTO has reviewed and issued tens of thousands of patents.

Petitioner seems intent on obscuring from the Court just how radical its position is. By clinging to *Flook* as if it had been left untouched by *Diehr*, failing even to cite the principal Federal Circuit decisions, and ignoring the PTO's *Guide-*

lines, petitioner has chosen to mount a sneak attack on the governing law. But if petitioner were to obtain a decision from this Court questioning the validity of the '658 patent on the ground that it claims non-patentable subject matter, 25 years of consistently applied patent law would come undone.

1. Vacatur Would Call Into Question Thousands Of Issued Patents

"Since this Court decided *Diehr* almost 25 years ago, PTO has generally followed the Federal Circuit's understanding that *Diehr* substantially limited *Flook*, and has issued numerous patents based on that understanding—including patents on medical diagnostic methods, other types of diagnostic and testing procedures, and computer-related processes." U.S. Cert. Br. 14. If this Court were to accept petitioner's invitation and change the law of subject matter patentability, the validity of some or all of those patents would be thrown into doubt. "A decision overturning PTO's approach could call into question a substantial number of patent claims and undermine the settled expectations of numerous participants in technology-based industries." *Ibid.*; *cf. Warner-Jenkinson Co.* v. *Hilton Davis Chem. Co.*, 520 U.S. 17, 32 n.6 (1997) ("To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by our decision").[23]

[23] While petitioner seeks to minimize the impact of a decision in its favor, its *amici* are more straightforward. They recognize that such a decision would further their agenda of abolishing all past, present, and future patents on business methods, software, gene sequences, or medical procedures. *E.g.*, CCIA Br. 2, 6; Financial Services Industry Br. 7-8, 14-17; Affymetrix, Inc. Br. 3-4, 15-16; AARP Br. 2, 9. The wholesale challenge to *State Street* and its progeny mounted by these *amici* should await resolution in

1. A decision questioning the validity of claim 13 of the '658 patent would especially call into question hundreds or thousands of patents on medical diagnostic methods, which frequently recite the sequential steps of assaying (or determining) the amount of a particular substance of the body and correlating the determined amount with a disease. Claim 1 of U.S. Patent No. 6,811,993, for example, claims a three-step diagnostic method of "determining the level of [Protein Kinase C] activity in monocytes of the subject; optionally comparing the level of PKC activity in monocytes of the subject with a standard; and correlating the level of PKC activity with the extent, stage, or severity of the cardiovascular complication of diabetes." Because many diseases are indicated by "markers"—proteins, enzymes, amino acids, or other substances that change (in quantity or behavior) in the presence of the disease—patents on useful diagnostic processes that employ such markers are in fact common. *See* U.S. Patent Nos. 6,461,831 (Background and Written Description) (discussion of this issue in the context of Alzheimer's disease); 6,929,918 (Background and Written Description) (same in the context of prostate cancer).[24]

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a case in which the issue is actually presented by a party. *See Bell* v. *Wolfish*, 441 U.S. 520, 531-32 n.13 (1979).

[24] Although petitioner maintains (Br. 19) that "[c]orrelations are elemental tools of all science, and as such are free to all and patentable by none," a search of the PTO's database indicates that approximately 20,000 patents have issued since 1976 with "correlate" (or a variant thereof) as a claim limitation. The government clearly does not share petitioner's view that correlations are *per se* unpatentable. *See also, e.g.*, U.S. Patent Nos. 6,004,528 (Claim 10) ("method for aiding in the diagnosis of cancer"); 6,962,793 (Claim 1) ("method for diagnosing Alzheimer's disease"); U.S. Patent No. 6,979,533 (Claim 1) ("method for detecting receptivity of the endometrium of a mammal to embryo implantation"); U.S. Patent No. 4,836,218 (Claim 1) (method for detecting temporomandibular joint disorders). *Amicus* ACLA expresses concern (Br.

The havoc caused by a decision questioning the validity of the '658 patent would extend far beyond the realm of medical diagnoses to every patented invention that incorporates a natural relationship (including most drugs, many medical devices, and a host of computer software and hardware applications). For example, on petitioner's theory Bell's process for communicating information over the telephone would have been unpatentable, because it was merely a practical application of the natural phenomenon that electricity can be used to propagate sound waves over a wire. *But see* note 19, *supra*. And pharmaceutical companies could not patent methods of treating conditions such as depression, Alzheimer's, or heart disease with drugs, since they have merely discovered that certain chemicals interact with the human body in ways directed by chemistry and patented practical applications of such discovered interactions. *Cf. Diehr*, 450 U.S. at 189 n.12 ("To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious").

2. The PTO, and the Federal Circuit, have implemented *Diehr* with a workable set of principles of subject matter eligibility that have guided the issuance and review of patents for the past quarter-century. If those standards are flawed such that they ought to be changed, petitioner and its *amici* have at least three avenues of redress.

First, the PTO itself has invited public comment on the standards of subject matter patentability. 70 Fed. Reg. at 75,452; *see Warner-Jenkinson*, 520 U.S. at 33-34 (noting the

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11-13) that a method of diagnosing prostate cancer using antibody assays could be patented. In fact, numerous patents have issued on such diagnostic methods. In addition to Claim 7 of the '918 patent cited in the text above, *see, e.g.*, U.S. Patent No. 6,482,599 (Claim 35).

"primacy of the PTO in ensuring that the claims allowed cover only subject matter that is properly patentable"). Its final guidance, which presumably will be entitled to deference under *Chevron U.S.A. Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984), could materially assist in this Court's ultimate review of the issue.

Second, Congress can always step in to change the Patent Act. Indeed, a comprehensive patent reform bill is pending at this moment. *See* "Patent Reform Act of 2005," H.R. 2795, 109th Cong., 1st Sess. (introduced June 8, 2005); *cf. Warner-Jenkinson*, 520 U.S. at 28 ("Congress can legislate the doctrine of equivalents out of existence any time it chooses"). Its decision for the past quarter-century not to override *Diehr* suggests an acceptance of it. *See J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145-46 (2001) ("As in *Chakrabarty*, we decline to narrow the reach of § 101 where Congress has given us no indication that it intends this result"). This is especially so here, where Congress in the interim has responded to complaints about the patentability of other types of inventions not by restricting patentable subject matter, but by limiting remedies or adding defenses for those inventions. *See* 35 U.S.C. § 287(c) (restricting remedies for surgical procedure patents); 35 U.S.C. § 273(a)(3) (adding prior user defense against business method patents).

And third, the Federal Circuit, established by Congress as the expert court in the patent area, should at least be given the first opportunity to consider these issues. *See Warner-Jenkinson*, 520 U.S. at 40 (noting the Federal Circuit's "sound judgment" in the patent area of its "special expertise").

Petitioner wants to bypass all of these avenues and asks this Court to rule, in the first instance and without the benefit of a full record, that an issued patent, imbued with the statutory presumption of validity, is invalid for failing to claim

patentable subject matter notwithstanding the fact that claim 13 passes all extant requirements for subject matter eligibility. As the Solicitor General has explained, "if this Court were to consider reevaluating almost a quarter-century of administrative practice and lower court jurisprudence, it should do so based on a full record in a case where the issue was properly raised, litigated, and decided below." U.S. Cert. Br. 19. This is not that case.

2. Affirmance (Or Dismissal) Would Have No Adverse Consequences In The Context Of This Case

Petitioner and its *amici* predict dire consequences for public health if the '658 patent stands, going so far as to assert that a decision for respondents would "depriv[e] patients of needed medical services." Pet. Br. 30. At best, these are policy arguments better addressed to the political branches; at worst, they are nothing but scare tactics.

Petitioner is a for-profit company that is seeking to maximize its revenue by avoiding the royalties due respondents under the licensing agreement that petitioner previously entered into. There is not a shred of evidence in the record that petitioner's payment of royalties to respondents, or the ultimate cost of the homocysteine assays performed by petitioner, have ever affected a single doctor's treatment decision. There is absolutely no evidence that, if the judgment below were affirmed (or the writ dismissed), any patient's care, or the cost of that care, would change in any way.[25]

Patented inventions are common in the field of medicine. In addition to diagnostic methods, a physician may employ

[25] Nor is there any evidence that any doctor will be held liable for patent infringement. As respondents explained in their brief in opposition (at 9), and petitioner has not contested, "[n]ot a single physician has been enjoined, sued or even threatened with suit, and none will be."

diagnostic machinery (such as an MRI machine), medical devices (such as implants or prosthetics), and of course a wide range of pharmaceuticals, all of which may be covered by one or more patents. For this reason, AARP's assertion (Br. 9) that claim 13 "would prohibit physicians from practicing good medicine without a patent license" proves far too much. "Good medicine" may in fact require physicians to practice patented inventions on a daily basis—by engaging in patented diagnostic methods, by using patented devices, or by prescribing patented pharmaceuticals. Although the patent regime may increase (or decrease) the cost of patient care, Congress has made the policy judgment that the benefits of increased innovation provided by the patent system justify any distortions that patents might introduce into the healthcare delivery system.

Indeed, this case proves the soundness of Congress's policy judgment: The patent system helped motivate these Inventors and their universities and agents to conceive of, develop and commercialize an invention that has saved thousands of lives and millions of dollars in health care costs by allowing for prompt and accurate diagnoses of a serious but easily treated condition. *Cf. Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002) ("Fundamental alterations in these rules risk destroying the legitimate expectations of inventors in their property"). Indeed, over ten million homocysteine assays are now performed each year to detect cobalamin and folate deficiencies.

As Justice Breyer has recognized, this area of the law is a particularly thorny one. Breyer, *supra*, 28 J. L. Med. & Ethics at 27 ("Should it matter if the more apt description of the scientist's work is the 'discovery' of how a portion of the body functions, rather than the 'invention' of how to use a part of that body to perform a useful, say, diagnostic task? This latter question will sometimes seem unanswerable."). For now, the PTO and the Federal Circuit have found *Diehr* a workable guide, and Congress has not seen fit to provide oth-

erwise. If the law is to be changed, it should be in a case in which the issues are pleaded, litigated, and decided at all levels, with full input from all potentially affected constituencies—*not* in this case, where the question of subject matter patentability has been raised by petitioner only at the last stage of the proceedings, and on a spare if not empty record.

CONCLUSION

The judgment of the court of appeals should be affirmed. In the alternative, the writ of certiorari should be dismissed.

Respectfully submitted.

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APPENDIX

Title 35 U.S.C. § 100 provides in pertinent part:

§ 100. Definitions

When used in this title unless the context otherwise indicates—

(a) The term "invention" means invention or discovery.

(b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

* * * *

Title 35 U.S.C. § 102 provides in pertinent part:

§ 102. Conditions for patentability; novelty and loss of right to patent

A person shall be entitled to a patent unless—

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or

* * * *

(f) he did not himself invent the subject matter sought to be patented[.]

* * * *

Title 35 U.S.C. § 103 provides in pertinent part:

§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

* * * *

Title 35 U.S.C. § 282 provides in pertinent part:

§ 282. Presumption of validity; defenses

A patent shall be presumed valid. Each claim of a patent (whether in independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims * * *. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

* * * *

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title [§§ 100 *et seq.*] as a condition for patentability,

(3) Invalidity of the patent or any claim in suit for failure to comply with any requirement of sections 112 or 251 of this title, [or]

(4) Any other fact or act made a defense by this title.

* * * *

Federal Rule of Civil Procedure 8 provides in pertinent part:

Rule 8. General Rules of Pleading

* * * *

(c) Affirmative Defenses. In pleading to a preceding pleading, a party shall set forth affirmatively accord and satisfaction, arbitration and award, assumption of risk, contributory negligence, discharge in bankruptcy, duress, estoppel, failure of consideration, fraud, illegality, injury by fellow servant, laches, license, payment, release, res judicata, statute of frauds, statute of limitations, waiver, and any other matter constituting an avoidance or affirmative defense. When a party has mistakenly designated a defense as a counterclaim or a counterclaim as a defense, the court on terms, if justice so requires, shall treat the pleading as if there had been a proper designation.

* * * *

Patent Act of 1870, ch. 230, § 61, 16 Stat. 198, 208 provides in pertinent part:

Sec. 61. *And be it further enacted*, That in any action for infringement the defendant may plead the general issue, and having given notice in writing to the plaintiff or his attorney, thirty days before, may prove on trial any one or more of the following special matters: —

First. That for the purpose of deceiving the public the description and specification filed by the patentee in the patent office was made to contain less than the whole truth relative to his invention or discovery, or more than is necessary to produce the desired effect; or,

Second. That he had surreptitiously or unjustly obtained the patent for that which was in fact invented by another,

who was using reasonable diligence in adapting and perfecting the same; or,

Third. That it had been patented or described in some printed publication prior to his supposed invention or discovery thereof; or,

Fourth. That he was not the original and first inventor or discovered of any material and substantial part of the thing patented; or,

Fifth. That it had been in public use or on sale in this country, for more than two years before his application for a patent, or had been abandoned to the public.

* * * *

* * * *

The *Official Gazette of the United States Patent and Trademark Office*, Vol. 1300, No. 4, pp. 142 *ff.* (November 22, 2005), provides in pertinent part:

Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility

* * * *

The principal objective of these guidelines is to assist examiners in determining, on a case-by-case basis, whether a claimed invention falls within a judicial exception to statutory subject matter (i.e., is nothing more than an abstract idea, law of nature, or natural phenomenon), or whether it is a practical application of a judicial exception to statutory subject matter. The guidelines explain that a practical application of a 35 U.S.C. § 101 judicial exception is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a useful, concrete, and tangible result.

I. INTRODUCTION

These Examination Guidelines ("Guidelines") are based on the USPTO's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit and the Federal Circuit's predecessor courts.

These Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. These Guidelines have been designed to assist USPTO personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law and it is these rejections which are appealable. Conse-

quently, any failure by USPTO personnel to follow the Guidelines is neither appealable nor petitionable.

The Guidelines set forth the procedures USPTO personnel will follow when examining applications. USPTO personnel are to rely on these Guidelines in the event of any inconsistent treatment of issues between these Guidelines and any earlier provided guidance from the USPTO.

* * * *

Annex I which appears at the end of this section includes a flow chart of the process USPTO personnel should follow.

* * * *

IV. DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH THE SUBJECT MATTER ELIGIBILITY REQUIREMENT OF 35 U.S.C. § 101

A. Consider the Breadth of 35 U.S.C. § 101 Under Controlling Law

Section 101 of title 35, United States Code, provides:

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

As the Supreme Court held, Congress chose the expansive language of 35 U.S.C. § 101 so as to include "anything under the sun that is made by man." *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980). In *Chakrabarty*, 447 U.S. at 308-309, 206 USPQ at 197, the court stated:

> In choosing such expansive terms as "manufacture" and "composition of matter," modified by the

> comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope. The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, ch. 11, § 1, 1 Stat. 318. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." V Writings of Thomas Jefferson, at 75-76. See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10 (148 USPQ 459, 462-464) (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952). [Footnote omitted]

This perspective has been embraced by the Federal Circuit:

> The plain and unambiguous meaning of section 101 is that any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may be patented if it meets the requirements for patentability set forth in Title 35, such as those found in sections 102, 103, and 112. The use of the expansive term "any" in section 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically

> recited in section 101 and the other parts of Title 35 . . . Thus, it is improper to read into section 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations.

[*In re*] *Alappat*, 33 F.3d [1526,] 1542, 31 USPQ2d [1545,] 1556 [(Fed. Cir. 1994) (en banc)].

35 U.S.C. § 101 defines four categories of inventions that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter. The latter three categories define "things" or "products" while the first category defines "actions" (i.e., inventions that consist of a series of steps or acts to be performed). See 35 U.S.C. 100(b) ("The term 'process' means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.").

Federal courts have held that 35 U.S.C. § 101 does have certain limits. First, the phrase "anything under the sun that is made by man" is limited by the text of 35 U.S.C. § 101, meaning that one may only patent something that is a machine, manufacture, composition of matter or a process. *See, e.g.*, *Alappat*, 33 F.3d at 1542, 31 USPQ2d at 1556; *In re Warmerdam*, 33 F.3d 1354, 1358, 31 USPQ2d 1754, 1757 (Fed. Cir. 1994). Second, 35 U.S.C. § 101 requires that the subject matter sought to be patented be a "useful" invention. Accordingly, a complete definition of the scope of 35 U.S.C. § 101, reflecting Congressional intent, is that any new and useful process, machine, manufacture or composition of matter under the sun that is made by man is the proper subject matter of a patent.

The subject matter courts have found to be outside of, or exceptions to, the four statutory categories of invention is limited to abstract ideas, laws of nature and natural phenomena. While this is easily stated, determining whether an ap-

plicant is seeking to patent an abstract idea, a law of nature or a natural phenomenon has proven to be challenging. These three exclusions recognize that subject matter that is not a *practical application or use* of an idea, a law of nature or a natural phenomenon is not patentable. *See, e.g.*, *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874) ("idea of itself is not patentable, but a new device by which it may be made practically useful is"); *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94, 40 USPQ 199, 202 (1939) ("While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be."); *Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759 ("steps of 'locating' a medial axis, and 'creating' a bubble hierarchy . . . describe nothing more than the manipulation of basic mathematical constructs, the paradigmatic 'abstract idea'").

The courts have also held that a claim may not preempt ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. *See Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852) ("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."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be non-statutory subject matter). Accordingly, one may not patent every "substantial practical application" of an idea, law of nature or natural phenomena because such a patent "in practical effect be a patent on the [idea, law of nature or natural phenomena] itself." *Gottschalk v. Benson*, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

B. Determine Whether the Claimed Invention Falls Within An Enumerated Statutory Category

To properly determine whether a claimed invention complies with the statutory invention requirements of 35 U.S.C. § 101, USPTO personnel must first identify whether the claim falls within at least one of the four enumerated categories of patentable subject matter recited in section 101 (process, machine, manufacture or composition of matter).

In many instances it is clear within which of the enumerated categories a claimed invention falls. Even if the characterization of the claimed invention is not clear, this is usually not an issue that will preclude making an accurate and correct assessment with respect to the section 101 analysis. The scope of 35 U.S.C. § 101 is the same regardless of the form or category of invention in which a particular claim is drafted. *AT&T* [*Corp. v. Excel Communications, Inc.*], 172 F.3d [1352,] 1357, 50 USPQ2d [1447,] 1451 [(Fed. Cir. 1999)]. *See also State Street* [*Bank & Trust Co. v. Signature Financial Group, Inc.*], 149 F.3d [1368,] 1375, 47 USPQ2d [1596,] 1602 [(Fed. Cir. 1998),] wherein the Federal Circuit explained

> The question of whether a claim encompasses statutory subject matter should not focus on *which* of the four categories of subject matter a claim is directed to—process, machine, manufacture, or composition of matter—[provided the subject matter falls into at least one category of statutory subject matter] but rather on the essential characteristics of the subject matter, in particular, its practical utility.

For example, a claimed invention may be a combination of devices that appear to be directed to a machine and one or more steps of the functions performed by the machine. Such instances of mixed attributes, although potentially confusing as to which category of patentable subject matter it belongs in, does not affect the analysis to be performed by the exam-

iner. Note that an apparatus claim with process steps is not classified as a "hybrid" claim; instead, it is simply an apparatus claim including functional limitations. *See, e.g.*, *R.A.C.C. Indus. v. Stun-Tech, Inc.*, 178 F.3d 1309 (Fed. Cir. 1998) (unpublished).

The burden is on the USPTO to set forth a *prima facie* case of unpatentability. Therefore if the examiner determines that it is more likely than not that the claimed subject matter falls outside all of the statutory categories, the examiner must provide an explanation. For example, a claim reciting only a musical composition, literary work, compilation of data, or legal document (e.g., an insurance policy) *per se* does not appear to be a process, machine, manufacture, or composition of matter. If the examiner can establish a *prima facie* case that a claim does not fall into a statutory category, that does not preclude complete examination of the application for satisfaction of all other conditions of patentability. The examiner must further continue with the statutory subject matter analysis as set forth below. Also, the examiner must still examine the claims for compliance with 35 U.S.C. §§ 102, 103, and 112.

If the invention as set forth in the written description is statutory, but the claims define subject matter that is not, the deficiency can be corrected by an appropriate amendment of the claims. In such a case, USPTO personnel should reject the claims drawn to nonstatutory subject matter under 35 U.S.C. § 101, but identify the features of the invention that would render the claimed subject matter statutory if recited in the claim.

C. Determine Whether the Claimed Invention Falls Within § 101 Judicial Exceptions—Laws of Nature, Natural Phenomena and Abstract Ideas

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. § 101 (process, machine, manufacture or composition of matter) does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible and therefore are excluded from patent protection. [*Diamond v.*] *Diehr*, 450 U.S. [175,] 185, 209 USPQ [1,] 7 [(1981)]; accord, e.g., *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197; *Parker v. Flook*, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); *Benson*, 409 U.S. at 67-68 , 175 USPQ at 675; *Funk*, 333 U.S. at 130, 76 USPQ at 281. "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*, 55 U.S. (14 How.) at 175. 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, 76 USPQ at 281.

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, 206 USPQ at 197. "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, 198 USPQ at 195; electromagnetism or steam power, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113-114 (1853); or "[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals," *Funk*, 333 U.S. at 130, 76 USPQ at 281; see *Le Roy*, 55 U.S. (14 How.) at 175.

While abstract ideas, natural phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, natural phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of section 101, the claim must be considered as a whole to determine whether it is for a particular *application* of an abstract idea, natural phenomenon, or law of nature, rather than for the abstract idea, natural phenomenon, or law of nature itself.

1. Determine Whether the Claimed Invention Covers Either a § 101 Judicial Exception or a Practical Application of a § 101 Judicial Exception

An examiner must ascertain the scope of the claim to determine whether it covers either a § 101 judicial exception or a practical application of a § 101 judicial exception. The conclusion that a particular claim *includes* a § 101 judicial exception does not end the inquiry 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, 209 USPQ at 8 (emphasis in original); accord *Flook*, 437 U.S. at 590, 198 USPQ at 197; *Benson*, 409 U.S. at 67, 175 USPQ at 675. Thus, "[w]hile 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, 209 USPQ at 8-9 (quoting *Mackay*, 306 U.S. at 94); see also *Corning v. Burden*, 56 U.S. (15 How.) 252, 268, 14 L.Ed. 683 (1854) ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .").

2. Determine Whether the Claimed Invention is a Practical Application of an Abstract Idea, Law of Nature, or Natural Phenomenon (§ 101 Judicial Exceptions)

For claims including such excluded subject matter to be eligible, the claim must be for a *practical application* of the abstract idea, law of nature, or natural phenomenon. *Diehr*, 450 U.S. at 187, 209 USPQ at 8 ("*application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection."); *Benson*, 409 U.S. at 71, 175 USPQ at 676 (rejecting formula claim because it "has no substantial practical application").

To satisfy section 101 requirements, the claim must be for a practical application of the § 101 judicial exception, which can be identified in various ways:

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

a. Practical Application by Physical Transformation

The examiner first shall review the claim and determine if it provides a transformation or reduction of an article to a different state or thing. If the examiner finds such a transformation or reduction, the examiner shall end the inquiry and find that the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a transformation or reduction, the examiner has not determined as a final matter that the claim is non-statutory. The examiner must proceed in further inquiry.

b. Practical Application That Produces a Useful, Concrete, and Tangible Result

For eligibility analysis, physical transformation "is not an invariable requirement, but merely one example of how a mathematical algorithm [or law of nature] may bring about a useful application." *AT&T*, 172 F.3d at 1358-59, 50 USPQ2d at 1452. If the examiner determines that the claim does not entail the transformation of an article, then the examiner shall review the claim to determine if the claim provides a practical application that *produces* a useful, tangible and concrete *result*. In determining whether the claim is for a "practical application," the focus is not on whether the steps taken to achieve a particular result are useful, tangible and concrete, but rather that *the final result achieved* by the claimed invention is "useful, tangible and concrete." The claim must be examined to see if it includes anything more than a § 101 judicial exception. If the claim is directed to a practical application of the § 101 judicial exception producing a result tied to the physical world that does not preempt the judicial exception, then the claim meets the statutory requirement of 35 U.S.C. § 101. If the examiner does not find such a practical application, the examiner has determined that the claim is nonstatutory.

In determining whether a claim provides a practical application that produces a useful, tangible, and concrete result, the examiner should consider and weigh the following factors:

(1) "USEFUL RESULT"

For an invention to be "useful" it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the utility of an invention has to be (i) specific, (ii) substantial *and* (iii) credible. MPEP § 2107 and [*In re*] *Fisher*, 421 F.3d [1365,] ___, 76 USPQ2d [1225,] 1230 [(Fed. Cir. 2005)] (citing the Util-

ity Guidelines with approval for interpretation of "specific" and "substantial"). In addition, when the examiner has reason to believe that the claim is not for a practical application that produces a useful result, the claim should be rejected, thus requiring the applicant to distinguish the claim from the three § 101 judicial exceptions to patentable subject matter by specifically reciting in the claim the practical application. In such cases, statements in the specification describing a practical application may not be sufficient to satisfy the requirements for section 101 with respect to the claimed invention. Likewise, a claim that can be read so broadly as to include statutory and nonstatutory subject matter must be amended to limit the claim to a practical application. In other words, if the specification discloses a practical application of a § 101 judicial exception, but the claim is broader than the disclosure such that it does not require a practical application, then the claim must be rejected.

(2) "TANGIBLE RESULT"

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a § 101 judicial exception, in that the process claim must set forth a practical application of that § 101 judicial exception to produce a real-world result. *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because had "no substantial practical application."). "[A]n *application* of a law of nature or mathematical formula to a . . . process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (emphasis added); *see also Corning*, 56 U.S. (15 How.) at 268, 14 L.Ed. 683 ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . ."). In other words, the opposite meaning of "tangible" is "abstract."

(3) "CONCRETE RESULT"

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. *In re Swartz*, 232 F.3d 862, 864, 56 USPQ2d 1703, 1704 (Fed. Cir. 2000) (where asserted result produced by the claimed invention is "irreproducible" claim should be rejected under section 101). The opposite of "concrete" is unrepeatable or unpredictable. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether that process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary artisan in that field. An appropriate rejection under 35 U.S.C. § 101 should be accompanied by a lack of enablement rejection under 35 U.S.C. § 112, paragraph 1, where the invention cannot operate as intended without undue experimentation. *See infra*.

3. Determine Whether the Claimed Invention Preempts an Abstract Idea, Law of Nature, or Natural Phenomenon (§ 101 Judicial Exceptions)

Even when a claim applies a mathematical formula, for example, as part of a seemingly patentable process, the examiner must ensure that it does not in reality "seek[] patent protection for that formula in the abstract." *Diehr*, 450 U.S. at 191, 209 USPQ at 10. "Phenomena of nature, though just discovered, mental processes, abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67, 175 USPQ at 675. One may not patent a process that comprises every "substantial practical application" of an abstract idea, because such a patent "in practical effect would be a patent on the [abstract idea] itself." *Benson*, 409 U.S. at 71-72, 175

USPQ at 676; *cf. Diehr*, 450 U.S. at 187, 209 USPQ at 8 (stressing that the patent applicants in that case did "not seek to pre-empt the use of [an] equation," but instead sought only to "foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process"). "To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection." *Diehr*, 450 U.S. at 192, 209 USPQ at 10. Thus, a claim that recites a computer that solely calculates a mathematical formula (*see Benson*) or a computer disk that solely stores a mathematical formula is not directed to the type of subject matter eligible for patent protection. If an examiner determines that the claimed invention preempts a § 101 judicial exception, the examiner must identify the abstraction, law of nature, or natural phenomenon and explain why the claim covers every substantial practical application thereof.

D. Establish on the Record a Prima Facie Case

The examiner should review the totality of the evidence (e.g., the specification, claims, relevant prior art) before reaching a conclusion with regard to whether the claimed invention sets forth patent eligible subject matter. The examiner must weigh the determinations made above to reach a conclusion as to whether it is more likely than not that the claimed invention as a whole either falls outside of one of the enumerated statutory classes or within one of the exceptions to statutory subject matter. "The examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability." *In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). If the record as a whole suggests that it is more likely than not that the claimed invention would be considered a practical application of an abstract idea, natural phenomenon, or law of nature, the examiner should not reject the claim.

After the examiner identifies and explains in the record the basis for why a claim is for an abstract idea with no practical application, then the burden shifts to the applicant to either amend the claim or make a showing of why the claim is eligible for patent protection. *See, e.g., In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995); *see generally* MPEP § 2107 (Utility Guidelines).

* * * *

Date: 10/26/05

/s/
JOHN J. DOLL
Commissioner for Patents

ANNEX I

Flowchart for Subject Matter Eligibility

* * * *

DETERMINE WHETHER THE CLAIMED INVENTION COMPLIES WITH THE SUBJECT MATTER ELIGIBILITY REQUIREMENT OF 35 U.S.C. § 101

- Does the Claimed Invention Fall Within an Enumerated Statutory Category?
- Does the Claimed Invention Fall Within a § 101 Judicial Exception—Law of Nature, Natural Phenomena or Abstract Idea?
    - Does the Claimed Invention Cover a § 101 Judicial Exception, or a Practical Application of a § 101 Judicial Exception?
        - Practical Application by Physical Transformation?
        - Practical Application That Produces a Useful (35 U.S.C. § 101 utility), Tangible, and Concrete Result?
    - Does the Claimed Invention Preempt an Abstract Idea, Law of Nature, or Natural Phenomenon (§ 101 Judicial Exception)?
- Establish on the Record a Prima Facie Case

* * * *

ANNEX III

Improper Tests For Subject Matter Eligibility

As set forth in the patent eligible subject matter interim guidelines, a practical application of a 35 U.S.C. § 101 judicial exception is claimed if the claimed invention physically transforms an article or physical state to a different state or thing, or if the claimed invention otherwise produces a useful, concrete, and tangible result. Therefore the following tests are ***not*** to be applied by examiners in determining whether the claimed invention is patent eligible subject matter:

(A) "not in the technological arts" test

(B) *Freeman-Walter-Abele* test

(C) mental step or human step tests

(D) the machine implemented test

(E) the *per se* data transformation test.

* * * *

c. (i) The Mental Step Test

If a claimed process is performed by a machine, it is immaterial whether some or all the steps could be carried out by the human mind. As stated in [*In re*] *Musgrave*, 431 F.2d [882,] 893, 167 USPQ [280,] 289-90 [(C.C.P.A. 1970)]: "[W]e cannot agree with the board that these claims (all the steps of which can be carried out by the disclosed apparatus) are directed to non-statutory processes merely because **some or all** [emphasis added] the steps therein can also be carried out in or with the aid of the human mind or because it may be necessary for one performing the processes to think." Therefore, USPTO personnel should no longer rely on the mental step test to determine whether a claimed invention is directed to statutory subject matter. If all the steps of a claimed proc-

ess can be carried out in the human mind, examiners must determine whether the claimed process produces a useful, tangible, and concrete result, i.e., apply the practical application test set forth in *State Street*.

c. (ii) The Human Step Test

It is immaterial whether the process may be performed by some or all steps that are carried out by a human. Claims are not directed to non-statutory processes merely because **some or all** the steps therein can also be carried out in or with the aid of a human or because it may be necessary for one performing the processes to do some or all of the process steps. The inclusion in a patent of a process that may be performed by a person is not fatal to patentability. *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1496, 1 USPQ2d 1337, 1341 (Fed. Cir. 1987) (citing *Diehr*, 450 U.S. at 175); *see e.g. Smith & Nephew, Inc. v. Ethicon, Inc.*, 276 F.3d 1304, 61 USPQ2d 1065 (Fed. Cir. 2001) (method claim where all the steps are carried out by a human). Therefore, USPTO personnel should no longer rely on the human step test to determine whether a claimed invention is directed to statutory subject matter.

* * * *

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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No. 04-607

IN THE

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LABORATORY CORP. OF AMERICA HOLDINGS
Petitioner,

v.

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Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

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BRIEF OF *AMICUS CURIAE* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF NEITHER PARTY

INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae Intellectual Property Owners Association ("IPO") is a nonprofit, national organization of about 120 large and midsize companies and more than 250 small busi-

[1] The parties have consented to the filing of this brief *amicus curiae*. The letters of consent have been filed with the Clerk of the Court. In accordance with Supreme Court Rule 37.6, *amicus curiae* states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the *amicus curiae* or its counsel.

nesses, universities, inventors, authors, executives, and attorneys who are interested in patents, trademarks, copyrights, and other intellectual property rights. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO members receive about thirty percent of the patents issued by the Patent and Trademark Office to U.S. nationals. IPO regularly represents the interests of its members before Congress and the Patent and Trademark Office ("PTO"), and has filed *amicus curiae* briefs in this Court and other courts on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the Appendix.

IPO expressly declines to take any position on whether there is a factual or legal basis for finding Respondent's patent invalid or unenforceable.

IPO's interest in this case arises from the indication that this case may be used as a vehicle for limiting the type of innovations eligible for patent protection under 35 U.S.C. § 101. IPO believes that the bounds of patentable subject matter, as delineated by the Patent Act and by *Diamond v. Diehr*, 450 U.S. 175 (1981), are both correct and clear. Any narrowing of these bounds would likely disturb the existing property rights of patentees and disrupt incentives for current and future scientific and technological research.

DISCUSSION

There are a number of provisions in the current patent laws that serve to limit the scope of patent rights granted by the Government. First, an invention must fall within the scope of the subject matter established as patentable by the Patent Act, defined as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[2] Second, the invention must have

[2] 35 U.S.C. 101.

demonstrable specific utility,[3] be novel,[4] and constitute a non-obvious change from what was done before.[5] Third, the inventor must provide a written description of the invention sufficient to enable a person to make and use the invention, must disclose the best mode of practicing the invention, and must distinctly claim the subject matter of the invention.[6] Only in exchange for meeting all of those requirements does an inventor obtain patent rights, and then only for a limited time.[7]

Among these requirements, the scope of allowable subject matter is generally the easiest hurdle to surmount, as is warranted by the broad language of the Patent Act itself ("any new and useful process . . .") and by this Court's precedent. *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (noting that "Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"). There are limits on patentable subject matter, however; as the *Diehr* court recognized, "laws of nature, natural phenomena, and abstract ideas" are "[e]xcluded from such patent protection." *Id*. at 185.

The question presented for review in this case does not, on its face, challenge the current standards for patentable subject matter. However, in its invitation to the Acting Solicitor General to express the views of the United States in this case, the Court indicated an interest in considering whether the patent-in-suit claimed patentable subject matter. That inquiry required consideration of *Diehr* and the scope of patentable

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[3] *Brenner v. Manson*, 383 U.S. 519 (1966).

[4] 35 U.S.C. § 102.

[5] 35 U.S.C. § 103(a).

[6] 35 U.S.C. § 112.

[7] 35 U.S.C. § 154(a)(2) ("such grant shall be for a term . . . ending 20 years from the date on which the application for the patent was filed in the United States.").

subject matter. The Solicitor General counseled denial of the petition for writ of certiorari and endorsed the PTO's application of the *Diehr* standards to determine the scope of patentable subject matter.

IPO believes that the current standards for patentable subject matter, as set forth by the Court in *Diehr*, correctly delineate between those innovations that should be eligible for patent protection and those that should not. Accordingly, IPO believes that this case should not serve as a vehicle for overturning or altering those standards. Rather, this case should reinforce the standards of *Diehr* and thus, support the expectation that innovations in yet unknown areas of technology will be eligible for patent protection.

SUMMARY OF ARGUMENT

The standards for determining whether an innovation constitutes patentable subject matter have been correctly enumerated by this Court's precedent. The language of the Patent Act along with cases such as *Diehr* and *Chakrabarty* support patent rights in virtually every area of research or development. For several reasons, this broad scope of patentable subject matter best "promote[s] the progress" in the useful arts.

First, the broad scope of subject matter eligibility properly places research and development decision-making into the hands of individuals and private entities. The U.S. patent system is primarily an economic tool for providing incentives that promote innovation. However, by its very nature, the course of innovation is unpredictable. Through countless unexpected leaps, the state of the art in many fields of science and technology is vastly different from that of twenty-five years ago when *Diehr* was decided, and the next twenty-five years will likely continue or accelerate the rapid development of new technologies. Limiting the scope of patentable subject matter for certain areas would change this natural course of

development by attenuating the incentive to innovate. IPO believes that an open technological playing field with broad patent eligibility is the best approach in a free market system. Cases may arise where the government hopes to either encourage or discourage innovation in a particular subject matter. Those cases, however, are best left to Congress.[8]

Second, the pace and unpredictability of innovation in science and technology hinders any nuanced control over the scope of patentable subject matter. Piecemeal limitations on patent eligibility, such as a *pro forma* technologic requirement or an expansion of the "natural phenomena" exception, would simply raise further questions as the art advances. Only a broad scope of eligibility settles the law and leaves the landscape clear for maximum innovation.

Third, even without a subject matter requirement, a patent may not recapture art already in the public domain—including unrecognized natural phenomena, mathematical formulas, and laws of nature. The Patent Act provides that a patentable invention must be new, novel, and nonobvious and must be described sufficiently to enable one of ordinary skill in the art to practice the invention. Under the well-established doctrine of inherency, even a natural phenomenon, mathematical formula, or law of nature that was unknown at the time a patent application was filed may serve as prior art against the invention. The availability of these requirements as additional gatekeepers for patent rights over natural phenomena and

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[8] For over fifty years, Congress has chosen to maintain a broad scope of patentable subject matter, described as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 U.S.C. § 101. *See also*, Rebecca Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53 Vand. L. Rev. 2081, n. 13 (2000) (noting that, in the wake of a judicial recognition of "business method" patents, Congress enacted new legislation that addressed and "arguably endorsed" the subject matter eligibility).

laws of nature further warrants against narrowing the eligibility requirements of 35 U.S.C. § 101.

ARGUMENT

I. THE COURT'S PRECEDENT ALREADY PROPERLY IDENTIFIES THE LIMITS OF PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. § 101.

In several cases, the Court has discussed the scope of patentable subject matter; IPO asserts that those decisions correctly identify the limits of patentable inventions. The existing limits efficiently promote innovation in many different fields, avoid unnecessary judicial entanglement, and allow other provisions of the Patent Act to serve as clear gatekeepers for patentability. A narrowing of the current scope of patentable subject matter would threaten all of those benefits.

Section 101 of the Patent Act identifies "Inventions patentable" and serves as the initial patentability threshold. 35 U.S.C. § 101. The "broad language" of §101 provides for the patenting of processes, machines, articles of manufacture, and compositions of matter. *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); *Diamond v. Diehr*, 450 U.S. 175, 182-83 (1981). In *Chakrabarty*, the Court acknowledged that "Congress plainly contemplated that the patent laws be given wide scope." 447 U.S. at 308. Although the Patent Act does not have any express exclusions from statutory subject matter, the Court has recognized a list of exceptions to the scope of patentable subject matter, in particular, "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. In determining whether process claims that do not involve particular machines are patentable subject matter, transformation of an article "'to a different state or thing' is the clue to patentability." *Id*. at 184; *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972).

In its brief as *amicus curiae*, the United States provided a clear outline of the rules for eligibility as patentable subject matter. *Brief of the United States as Amicus Curiae* at 5-9. In addition, the United States outlined several reasons for not using this case to alter the scope of eligibility.[9] IPO provides three further reasons why the current scope of eligibility should not be altered.

A. The broad scope of subject matter eligibility promotes a free market approach that best allocates research and development resources without judicial entanglement.

The primary underlying premise of a market economy is that relying on the market forces or "invisible hand" of supply and demand leads to greater efficiency and wealth. *See* Adam Smith, *The Wealth of Nations*, Book I (R.H. Campbell et al. eds., Clarendon Press 1976). At its core, the patent system is an economic tool that creates a strong market force—an incentive to innovate. That is, in exchange for a limited grant of exclusivity to practice his or her invention, the patentee agrees to publicly disclose that invention.

The current broad scope of subject matter eligible for patent protection allows the patent system to serve as an incentive to pursue any of a great range of potentially patentable lines of research, with each line competing for scarce resources and funding. A narrowing of patentable subject matter would cut off some of those lines and cause a reallocation of resources to other fields. The resulting system "would reduce the diversity of patentable innovation and restrict the wealth-generating potential of the patent system with artifi-

[9] Specifically, the Government noted that (a) the record is not sufficiently developed to permit comprehensive consideration of subject matter eligibility requirements and (b) a decision narrowing eligibility requirements would undermine settled expectations and call into question a substantial number of patent claims. IPO agrees with both of these points.

cial limits on efficient market solutions." Erik Maurer, *An Economic Justification for a Broad Interpretation of Patentable Subject Matter*, 95 Nw. U. L. Rev. 1057, 1905 (2001). An open technological playing field with broad patent eligibility is the best approach in a free market system to maximizing wealth; further narrowing patent protection to certain subject matter areas would artificially limit the incentive to innovate in those areas and thus restrict market efficiency.

Broad eligibility for patentability is vital because innovation, by its very nature, is unpredictable and leads to nonobvious results. Fifty years ago, neither software stored in computer memory nor genetically modified organisms were considered patentable subject matter. But of course, these new areas of technology had barely been conceived fifty years ago. As technology advanced, attempts to secure patents for inventions of these types met resistance in the form of a high eligible subject matter barrier. That is, then existing law led to "crises in eligibility" that regularly appeared when new forms of technology became popular. Eileen Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 Tenn. L. Rev. 707 (2004). The crises arose because the new technologies did not fit well within the then-existing standards for eligibility. For instance, *Diehr* and *Chakrabarty* were both cases involving new technology whose patent eligibility was opposed by the PTO. *Diehr*, 450 U.S. at 181; *Chakrabarty*, 447 U.S. at 306-07. Prior inventors were likely directed to other technological fields because they anticipated that they could not reap the economic benefit of innovation. Today, businesses developing technologies from the fields involved in those cases, computer-controlled operations and biotechnology, are substantial engines driving the growth of the American economy. However, their success relies heavily on protection of their intellectual property rights—rights that would not have existed under a narrower interpretation of subject matter eligibility.

The next breakthrough technology area is unknown—perhaps it has not yet been conceived. One thing is certain, however. If no patent rights are available to protect innovation in that area, investment dollars and inventors will be directed elsewhere economically. Providing an open technological playing field with full access to patent rights, regardless of the subject matter, is the best approach to ensure success in a free market system and to avoid creating disincentives against the very type of innovation that leads to landmark breakthroughs.

In some cases, there may be good reason for the government to either encourage or discourage innovation in a particular subject matter. For instance, the government may want to encourage the development of childhood vaccines or the discovery of a better method of detecting explosives hidden within luggage. Various incentives such as government grants, patent extensions, and even patent prizes have been discussed as means for stimulating research. *See, e.g.*, Michael Abramowicz, *Perfecting Patent Prizes*, 56 Vand. L. Rev. 115 (2003). All of these situations, however, are best handled by Congress and the legislative process.

B. The rapid pace and unpredictability of innovation in science and technology hinders any nuanced judicial control over the scope of patentable subject matter.

Science and technology—"the useful arts" identified in the Constitution as potential subjects for a patent system—are progressing at a blistering pace. U.S. Const., art. I, § 8, Cl. 8. Every day, hundreds of innovations, both large and small, are conceived and the downstream processes of development and patenting are begun. As entirely new areas of technology develop at an ever increasing rate, the law must remain flexible to accommodate such pace and unpredictability—making

any nuanced control over the scope of patentable subject matter difficult at best.

Piecemeal limitations on patent eligibility, such as a specific technological arts requirement or an expansion of the "natural phenomena" exception, would simply raise further questions as the art advances. Exceptions to the notion of patentable broad subject matter would likely be challenged by patentees in the PTO and in court and would create an atmosphere of uncertainty that would necessarily chill innovation.

For example, after the decision in *State Street Bank & Trust Co. v. Signature Financial Group, Inc*., 149 F.3d 1368 (Fed. Cir. 1998), PTO examiners were instructed to reject method claims under § 101 if the claims did not include a clear link to the "technological arts." Over time, any functional aspect of the requirement was lost and all that remained was a formalistic test that could be passed by merely reciting that a step of the questioned claim operated "through a computer." *See Ex parte Lundgren*, 76 U.S.P.Q.2d 1385 (Bd. Pat. App.& Int. 2005). In *Lundgren*, the PTO's Board of Patent Appeals and Interferences finally eliminated the technological arts test, finding "no judicially recognized separate "technological arts" test to determine patent eligible subject matter under § 101." The PTO concluded, as IPO urges here, that limiting the scope of eligibility created an artificial barrier to claiming inventions.

Similarly, numerous inventions today use newly-discovered principles. Currently, inventors can direct their research to make sure they can take economic advantage of their work. An expansion of the "natural phenomena" exception might cause such inventors to avoid disclosing the fruits of their labors or protecting them through trade secret protection. Neither of those approaches adds to the storehouse of knowledge from which others can draw to conceive further inventions. IPO believes that only a broad range of eligibility

within the scope of § 101 will settle the law in a manner beneficial to the public.

C. Strong requirements of novelty, nonobviousness, and description protect against overreaching patents and warrant against further restricting patentability based on subject matter.

One of the concerns often expressed with regard to the scope of patentable subject matter is that patents will issue that allow a monopoly on knowledge that existed independent of any invention. No one wants such overreaching or overbroad patents, and the prevention of those inappropriate patents is certainly within the purview of the Court. However, there is no cause for alarm merely because subject matter is patentable. Even without the subject matter eligibility requirements, statutory language of the Patent Act provides strong protections against attempts to obtain overreaching claims or claims directed to natural phenomena, mathematical formulas or laws of nature. Specifically, such claims must be new, nonobvious, and described sufficiently to satisfy the requirements of 35 U.S.C. § 112. As such, fears of patents directed to these areas are not well-founded and do not require any expansion of the exceptions to patentable subject matter eligibility.

It is a fundamental premise of the patent system that inventions already in the public domain may not be recaptured in a later patent application.[10] If publicly known, natural phenomena, mathematical formulas, or laws of nature would certainly serve as prior art against any patent application claiming rights thereto. Further, under the doctrine of inherency, a

[10] Under 35 U.S.C. §102(b), a one-year grace period prevents an inventor from capitalizing on an invention for more than one year prior to filing his or her patent application.

natural phenomenon, mathematical formula, or law of nature that was unknown at the time a patent application was filed may nevertheless serve as prior art against the invention. *See In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002). That is, the Court established over fifty years ago that natural phenomena and laws of nature are part of the "storehouse of knowledge of all men," regardless of whether those phenomena or laws were previously discovered.

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.

Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

Furthermore, an inventor must provide a written description of his or her invention. That description must enable one of ordinary skill in the art to practice the full scope of the invention, a requirement that would be difficult (if not impossible) to meet if an inventor sought to cover all uses of natural phenomena or laws of nature. By strictly enforcing all of the requirements of 35 U.S.C. § 112, the PTO can avoid any need to constrict § 101.

These requirements for patentability under 35 U.S.C. §§ 102, 103(a), and 112 further warrant against narrowing the eligibility requirements of 35 U.S.C. § 101.

CONCLUSION

IPO believes that the standards of patentable subject matter eligibility are correctly delineated by the Patent Act and *Diehr*. IPO further believes that this case should not serve as a vehicle for creating further limitations that might disrupt those standards.

Respectfully submitted,

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No. 04-607

In The Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS (dba LabCorp),

Petitioner,

v.

METABOLITE LABORATORIES, INC. and COMPETITIVE TECHNOLOGIES, INC.,

Respondents.

On Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF THE PUBLIC PATENT FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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INTEREST OF THE *AMICUS CURIAE*[1]

The Public Patent Foundation ("PUBPAT") is a not-for-profit legal services organization founded in 2003 to represent the public interest in the patent system, and most particularly the public's interests against the harms caused by wrongly issued patents and unsound patent policy. PUBPAT provides the general public and specific persons or entities otherwise deprived of access to the patent system with representation, advocacy, and education. It is funded by grants from the Rockefeller Foundation, the Echoing Green Foundation, the Rudolph Steiner Foundation and the Open Society Institute as well as donations from private individuals.

PUBPAT believes that the patent system can be improved through use of the patent system's existing legal structures. For example, the USPTO has consistently granted PUBPAT's requests for agency reexamination of particular patents that PUBPAT believes were wrongly issued. PUBPAT has also advocated for sound patent policy before this Court, the United States Court of Appeals for the Federal Circuit, the United States Patent & Trademark Office, the European Parliament, and the United States House of Representatives Subcommittee on Courts, the Internet, and Intellectual Property.

PUBPAT has an interest in this matter because the decision of this Court will have a significant effect on the

[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for a party authored this brief in whole or in part, and that no person or entity, other than *amicus curiae* and its counsel made a monetary contribution to the preparation or submission of this brief. Written consent of the parties was obtained and will be filed with the Clerk of the Court in accordance with Supreme Court Rule 37.3.

public interest represented by PUBPAT. More specifically, PUBPAT has an interest in ensuring that this Court's established limits on patentable subject matter are maintained.

SUMMARY OF ARGUMENT

Almost twenty-five years have passed since this Court last addressed the core issues of patentable subject matter. In that time, the Court of Appeals for the Federal Circuit has replaced this Court's substantive standard with a more formalistic approach that has expanded the definition of patentable subject matter to include virtually anything. This expansion by the Federal Circuit conflicts with this Court's precedent and, as such, merits remediation.

In addition, there are two other issues that should be considered when addressing patentable subject matter. First, allowing claims that effectively cover all uses of a law of nature or abstract idea frustrates the patent system's goal of disclosure. Second, patent claims that restrict communication regarding abstract ideas or laws of nature are contrary to the First Amendment.

I. THE COURT OF APPEALS FOR THE FEDERAL CIRCUIT HAS IMPERMISSIBLY VEERED FROM THIS COURT'S PRECEDENT REGARDING PATENTABLE SUBJECT MATTER.

Almost twenty-five years have passed since this Court last addressed the core issues of patentable subject matter. *Cf. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001) (addressing whether utility patents

may be issued for plants). In that time, the Court of Appeals for the Federal Circuit has replaced this Court's substantive standard with a more formalistic approach that has expanded the definition of patentable subject matter to include virtually anything. This expansion by the Federal Circuit is judicially erroneous and merits remediation.

A. This Court's Precedent Sets Out Limits on Patentable Subject Matter.

Confronted with the rise of new technologies, this Court has addressed the issue of patentable subject matter several times. *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Diamond v. Diehr*, 450 U.S. 175 (1981). Since before the Civil War, this Court has consistently made it clear that subject matter which would have the practical effect of preempting a law of nature, mathematical formula, or abstract idea is ineligible for patent protection. *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113 (1854); *Benson*, 409 U.S. at 71. This age-old and time-tested precedent effectively establishes a penumbra of ineligibility for patent protection to safeguard the fundamental policy that laws of nature and abstract ideas be left unrestrained by patents.

To be eligible for patent protection, "[a] process itself, not merely the mathematical algorithm, must be new and useful." *Flook*, 437 U.S. at 591; *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948) ("He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the

application of the law of nature to a new and useful end."). This Court stated in *Flook* that it is "incorrect [to] assume[ ] that if a process application implements a principle in some specific fashion, it automatically falls within the patentable subject matter of § 101." *Id*. at 593. This Court explained that such an assumption is based on an impermissibly narrow interpretation of its precedent, including specifically *Benson,* and is "untenable" because "[i]t would make the determination of patentable subject matter depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for 'ideas' or phenomena of nature." *Id.*

In alignment with *Benson* and *Flook*, this Court's decision in *Diehr* held that structures or processes must, when considered as a whole, perform functions intended to be covered by patent law in order to be eligible for patent protection. 450 U.S. at 192. Although *Diehr* may have effectively overruled *Flook's* "point of novelty" test, it nonetheless followed and upheld the core holdings of both *Benson* and *Flook*. *Id.* at 190, 191-193 (*citing Benson* and *Flook* repeatedly and *stating* "[o]ur reasoning in *Flook* is in no way inconsistent with our reasoning here").

Benson, *Flook*, *Diehr* and the other decisions of this Court regarding patentable subject matter consistently established that the inquiry into whether subject matter is eligible for patenting is one of substance and function, not form. This Court requires that one look, not simply at the language of the patent claim to see if it recites a structure of multiple steps or components, but also at the practical effect of the claim to see if it in fact covers – or otherwise would restrict the public's use of – a principle, law of nature, abstract idea, mathematical formula, mental process or other abstract intellectual concept.

This substantive standard ensures that skilled patent draftsmanship is not capable of overcoming one of the most core principles of patent law recognized by this Court for more than 150 years that "[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 (1853); *Funk Bros.*, 333 U.S. at 130; *Benson*, 409 U.S. at 67 ("[p]henomena 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").

B. The Federal Circuit Has Strayed from This Court's Limits on Patentable Subject Matter.

Many scholars have noted that the creation of the Federal Circuit "did away as a practical matter with Supreme Court jurisdiction in patent cases." Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. Legal Stud. 247, 270 (1994). For example, through a series of decisions, the Federal Circuit has abandoned the substantive based standard established by this Court for determining patentable subject matter and replaced it with a more expansive formalistic approach that looks only to see whether a patent claim contains some structure or has some minimal practical utility. The Federal Circuit's form-over-substance approach has come to include virtually anything within patentable subject matter.

Initially, the Federal Circuit used the opinions of legal commentators to justify straying from *Benson* and *Flook*. *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958

F.2d 1053, 1057 n.4 (1992) ("Although commentators have differed in their interpretations of *Benson, Flook,* and *Diehr,* it appears to be *generally agreed* that these decisions represent *evolving views* of the Court, and that the reasoning in *Diehr* not only elaborated on, but in part superseded, that of *Benson* and *Flook*") (emphasis added) (*citing* R.L. Gable & J.B. Leaheey, *The Strength of Patent Protection for Computer Products,* 17 Rutgers Computer & Tech. L.J. 87 (1991); D. Chisum, *The Patentability of Algorithms*, 47 U. Pitt. L. Rev. 959 (1986)). Evidently, the Federal Circuit felt that "general agreement" amongst legal commentators justified abandoning this Court's precedent. In reaching this conclusion, the Federal Circuit also ignored the *Diehr* Court's statement that its decision there was in accord with *Benson* and *Flook*. *Diehr*, 450 U.S. at 185-193.

Also in *Arrhythmia*, the Federal Circuit stated that, "claims to a specific process or apparatus . . . will *generally satisfy* section 101." *Id.* at 1058 (emphasis added). This Court's precedent does not – in fact – support the proposition that any process or apparatus "generally satisfies" the requirements of patentable subject matter. *Diehr*, 450 U.S. at 193 ("[a] mathematical formula as such is not accorded the protection of our patent laws . . . and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment") (citing *Benson* and *Flook*). The new "general rule" promulgated in *Arrhythmia* was a major step in the Federal Circuit's departure from this Court's precedent regarding patentable subject matter.

Roughly two years later, the Federal Circuit said that this Court's precedent on patentable subject matter was too unclear to follow. *In re Alappat*, 33 F.3d 1526, 1543

n.19 and n.20 (Fed. Cir. 1994) ("The Supreme Court has not been clear", "The Supreme Court has not set forth, however, any consistent or clear explanation", "the understandable struggle that the [Supreme] Court was having in articulating a rule"). Contrary to the Federal Circuit's characterizations, however, this Court's precedent on patentable subject matter is plainly clear: the analysis is one of substance, not form, and asks whether a patent claim effectively preempts a law of nature, natural phenomenon or abstract idea.

After disregarding this Court's precedent as "unclear," the Federal Circuit substituted its own formalistic approach, which finds that virtually anything is eligible for patenting. *Id*. at 1542 ("[t]he use of the expansive term 'any' in § 101 represents Congress's intent not to place any restrictions on the subject matter for which a patent may be obtained"). The Federal Circuit's approach conflicts with this Court's precedent. For example, it ignores the firm statement in *Diehr* that "[a] mathematical formula does not suddenly become patentable subject matter simply by having the applicant acquiesce to limiting the reach of the patent for the formula to a particular technological use." 450 U.S. at 193.

In support of its holding, the Federal Circuit cited this Court's *Chakrabarty* decision for the proposition that, "Congress intended § 101 to extend to 'anything under the sun that is made by man.'" *Id.* (citing *Chakrabarty*, 447 U.S. 303, 309). However, the Federal Circuit then went much farther than *Chakrabarty's* holding by saying, "Thus, it is improper to read into § 101 limitations as to the subject matter that may be patented where the legislative history does not indicate that Congress clearly intended such limitations." *Id.* But such was precisely *not*

this Court's holding in *Chakrabarty*. Immediately following the language in *Chakrabarty* quoted by the Federal Circuit, this Court continued to say that, "[t]his is *not* to suggest that § 101 has *no* limits or that it embraces every discovery." 447 U.S. at 309 (emphasis added). In support of that statement, this Court referred to *Flook*, *Benson*, *Funk Bros.* and other cases, and not to any legislative history. Thus, this Court's precedent clearly shows that there are indeed limits on patentable subject matter beyond those expressly stated by Congress. The Federal Circuit's ruling to the contrary was error.

Indeed, *Alappat* was a highly divided *en banc* decision, wherein several members of the Federal Circuit recognized the judicial error being made. *Id.* at 1552, 1562 (Archer, C.J., *dissenting* "Losing sight of the forest for the structure of the trees, the majority today holds that any claim reciting a precise arrangement of structure satisfies 35 U.S.C. § 101. . . . [T]he rationale that leads to this conclusion and the majority's holding that Alappat's rasterizer represents the invention of a machine are illogical, inconsistent with precedent and with sound principles of patent law, and will have untold consequences", "the majority's test under § 101 that looks simply to whether specific structure is claimed is [ ] inconsistent with Supreme Court precedent").

Since *Alappat*, the Federal Circuit has continued its expansion of patentable subject matter through the implementation of its formalistic approach. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368 (Fed. Cir. 1998) (holding that anything with a "practical utility" is patentable subject matter); *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999). The effect of this expansion has been to eliminate the *Benson-Flook-Diehr*

limitation on patentable subject matter, because any semi-competent patent drafter can easily craft claims that have some structure or a "practical utility" that nonetheless preempt the use of a law of nature, abstract idea or natural phenomenon. The Federal Circuit believes such claims are patentable subject matter. This Court's precedent mandates that they are not.

In this case, the practical effect of claim 13 is to preclude the use of a law of nature, namely the natural correlation in mammalian physiology between elevated levels of total homocysteine and certain vitamin B deficiencies.[2] This is because, although the claim contains another element, an "assaying" step, that element is so general and broad that it has no practical limiting effect. Anyone performing the "correlating" step must, in some way, assay body fluid for an elevated total homocysteine level. Thus, under this Court's precedent, claim 13 is not patentable subject matter. In contrast, under the Federal Circuit's formalistic approach that anything with some structure or a "practical utility" is patent eligible, claim 13 would be patentable subject matter, as detecting vitamin B deficiencies is surely a "practical utility."

[2] Indeed, the application originally was more direct in its claim to the law of mammalian physiology concerning the homocysteine-cobalamin/folate relationship. During the application process the applicant expressly told the examiner that "[a]s applicants are the first to detect cobalamin or folate deficiency by assaying body fluids for total homocysteine, it is believed that they are entitled to a claim of equivalent scope, not limited to any particular steps or methods." Pet. App. 9a.

II. IN ORDER TO PROMOTE THE PATENT SYSTEM'S GOAL OF DISCLOSURE, A CLAIM THAT EFFECTIVELY COVERS ALL USES OF A LAW OF NATURE OR ABSTRACT IDEA SHOULD BE INELIGIBLE FOR PATENT PROTECTION.

Both patent and copyright laws are constitutionally bound "[t]o Promote Progress in Science and the Useful Arts." Patent law does this by providing (i) an incentive for the *achievement* of technological advances, (ii) an incentive for the commercialization of those advances, and (iii) an incentive for the *disclosure* of advances that are achieved. In the absence of the patent system, many inventions would be protected by trade secrecy, interfering with norms of science that favor prompt disclosure of new information, particularly new discoveries in basic science. As this Court said in *Sinclair & Carroll Co. v. Interchemical Corp.,* 325 U.S. 327 (1945):

> The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances in knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure.

Id. at 330-331 (citations removed). Similarly, in *Markman v. Westview Instruments, Inc.*, this Court emphasized that disclosure must occur not simply because "the limits of the patent must be known" to third parties, but also for "the encouragement of the inventive genius of others." 517 U.S. 370, 390 (1996). *See also Universal Oil Products Co. v. Globe Oil & Refining Co*., 322 U.S. 471, 484 (1944); Rebecca Eisenberg, *Patents and the Progress of Science*, 56 U. CHI L. REV. 1017, 1028 (1989) (concluding that the patent

system "facilitates disclosure by creating rights in inventions that survive disclosure"); Justin Hughes, *The Philosophy of Intellectual Property*, 77 Geo. L. J. 287, 316 (1988) (patent rights coupled with disclosure leads to expansion of the "commons" of ideas).

But such disclosure will do little or nothing to promote further progress – there will be no "encouragement of the inventive genius of others" – unless subsequent researchers are allowed to use the basic scientific teachings and discoveries disclosed in the patent. That those basic scientific teachings and discoveries remain unprotected is not just happenstance. There can be no "inventing around" a patent unless the patent discloses the basic scientific principles upon which the invention relies – those principles being broader than the invention claimed in the patent. This is the principal way by which "patent disclosure advances the 'Progress of . . . useful Arts' by permitting societal resources to be put to their best use in advancing more quickly beyond the patentee's contribution." Katherine Strandburg, *What Does the Public Get?: Experimental Use and the Patent Bargain*, 2004 Wisc. L. Rev. 81, 112 (2004).

To promote continuing progress in science and the useful arts, both patent and copyright delineate what may be protected ***and*** what may ***not*** be protected. In copyright, ideas and facts are unprotectable subject matter – things that may not be "propertized." *Feist Publications, Inc. v. Rural Telephone Service,* 499 U.S. 340 (1991) (facts are not copyrightable); *Harper & Row, Publishers, Inc. v. Nation Enterprises*, 471 U.S. 539, 547 (1985) ("no author may copyright facts or ideas"); *Baker v. Selden*, 101 U.S. 99 (1879) (methods cannot be copyrighted).

As discussed in Part I, this Court's patent precedent has made it clear that scientific truths, laws of nature, natural phenomena, and abstract ideas are unprotectable subject matter. *Rubber Tip Pencil Company v. Howard*, 87 U.S. 498, 507 (1874) ("an idea of itself is not patentable"); *Mackay Radio & Tel. Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939) ("a scientific truth, or the mathematical expression of it, is not patentable invention"); *Benson*, 409 U.S. at 67; *Flook*, 437 U.S. at 589; *Diehr*, 450 U.S. at 185 (stating that laws of nature, natural phenomena, and abstract ideas are excluded from patent protection). In both copyright and patent law, these realms of unprotectable subject matter have been established by courts, not Congress[3] – a point that, as discussed in Part I, the Federal Circuit overlooked in *In re Alappat*.

In copyright law, the merger doctrine is an important mechanism for drawing the line between what can and cannot be propertized. "[G]iven the dilemma either of protecting original expression . . . when that protection can be leveraged to grant an effective monopoly over the idea thus expressed, or of making the idea free to all with the concomitant result that the plaintiff loses effective copyright protection . . . copyright chooses the latter course." Melville B. Nimmer & David Nimmer, NIMMER ON COPYRIGHT § 13.03[B][3] at 13-79 (2005); *Veeck v. Southern*

[3] While the bar of copyright on "ideas" was codified in 1976 at 17 U.S.C. § 102(b), that section is silent on copyright not extending to "facts." Yet this Court in *Feist* was crystal clear that "facts are not copyrightable" remains a "well-established proposition," 499 U.S. at 344, just as this Court has consistently held that "[e]xcluded from such patent protection are laws of nature, natural phenomena, and abstract ideas," *Diamond v. Diehr*, 450 U.S. at 185, despite silence on this point in the Patent Act.

Bldg. Code Cong. Int'l Inc., 293 F.3d 791 (5th Cir. 2002) (*en banc*), *cert. denied,* 539 U.S. 969 (2003) (where privately created model building code became binding municipal code, expression and the "fact" of municipal law "merged" and code may be freely copied); *Kern River Gas Transmission Co. v. Coastal Corp*., 899 F.2d 1458 (5th Cir.), *cert. denied*, 498 U.S. 952 (1990) (expression of map showing location of pipeline and actual location of pipeline "merged" so that map was unprotected); *Morrissey v. Proctor & Gamble Co.*, 379 F.2d 675, 678 (1st Cir. 1967) (idea of particular kinds of sweepstakes and expression of sweepstakes rules merged where copyrighting expression "could exhaust all possibilities of future use of the substance").

This Court first enunciated the basic notion of the merger doctrine in *Baker v. Selden*, *supra,* concerning the scope of exclusive rights granted to the author of a copyrighted book "exhibit[ing] and explain[ing] a peculiar system of book-keeping." 101 U.S. at 100. This Court concluded that the exclusive rights of copyright extended only to expression itself and not to the teachings of the accounting method. In his opinion for this Court, Justice Bradley noted that protectable expression – the diagrams – would be, to some degree, dedicated to the public if those diagrams were necessary for practice of the uncopyrighted ideas:

> [a]nd where the art [the book] teaches cannot be used without employing the methods and diagrams used to illustrate the book, or such as are similar to them, such methods and diagrams are to be considered as necessary incidents to the art, and given therewith to the public.

Id. at 103. If the diagrams – a form of expression – and the unprotected accounting method "merge," then no copyright over the diagrams will prevent an individual from using the accounting method, even if that means they reproduce the diagrams in their own calculations.

In *Herbert Rosenthal Jewelry Corp. v. Kalpakian*, 448 F.2d 738 (9th Cir. 1971), the Ninth Circuit found that the defendant could not be liable for infringement of the plaintiff's copyright in a jewelry pin in the shape of a bee because the bee-shaped pin was quite life-like and, therefore, any other life-like bee pins would be "substantially similar" in expression to the plaintiff's jewelry. The court denied relief to the plaintiff succinctly stating the merger doctrine:

> When the "idea" and its "expression" are thus inseparable, copying the "expression" will not be barred, since protecting the "expression" in such circumstances would confer a monopoly of the "idea" upon the copyright owner free of the conditions and limitations imposed by the patent law.

Id. at 742. Of course, one of those fundamental "limitations imposed by the patent law" is that the exclusive rights of patent law do not extend to laws of nature – the issue in this case being that claim 13 would seal off a law of nature in that observing any instantiation of the general law of nature would violate the patent.

This Court has consistently recognized "the historic kinship between patent law and copyright law." *Sony v. Universal City Studios*, 464 U.S. 417, 439 (1984). *See also Fox Film Corp. v. Doyal*, 286 U.S. 123, 131 (1932) (concerning Court's determinations of tax treatment of royalties, "what we have said as to the purposes of the

Government in relation to copyrights applies as well, *mutatis mutandis*, to patents which are granted under the same constitutional authority to promote the progress of science and useful arts"). In both *Sony* and last Term's *Grokster* decision, this Court looked to patent law for development of rules of third party liability in copyright law. *MGM Studios Inc. v. Grokster, Ltd.,* 125 S. Ct. 2764, 2779 (2005) (drawing further parallel between third party liability in patent and copyright law).

While patent law draws a different line between what can be protected and what cannot be protected, it is nonetheless appropriate to look to copyright's merger doctrine as a model of how to resolve situations where a patent claim is arguably within patentable subject matter but would nonetheless *unquestionably* "exhaust all possibilities of future use of the substance" of the disclosure – in this case, a basic law of mammalian physiology. *Morrissey*, 379 F.2d at 678. To paraphrase *Herbert Rosenthal*, when the claimed patentable "process" and the underlying "law of nature" are inseparable, use of the "process" should not be barred, since protecting the "process" in such circumstances would confer a monopoly on the "law of nature" – violating a basic tenet of patent law. *See also* Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code,* 71 Tenn. L. Rev. 707, 753-754 (2004) (proposing that patent claims which preempt laws of nature be limited, when necessary, "with the use of the merger doctrine from copyright law").

In this particular case, upholding claim 13 would, in effect, prevent the patent from generating or communicating *any* information that could help other would-be inventors because *every* inference about homocysteine – cobalamin/folate correlation would infringe the claim. If

claim 13 is upheld – and has the scope set out by the Federal Circuit – the principal disclosure in the patent – use of a basic law of mammalian physiology – will be preempted. Indeed, this is just the sort of problem presaged by *Benson*, where this Court said that otherwise patentable subject matter is not eligible for a patent if the "practical effect" of the patent would cover a law of nature. 409 U.S. at 71-72. *Benson*'s "practical effect" test to bar patenting of what would otherwise appear to be patentable subject matter is, in effect, an inchoate patent law version of copyright law's merger doctrine.

Further, LabCorp's inducement liability was based on distributing informational materials that "state[d] that elevated total homocysteine correlates to cobalamin/folate deficiency." Pet. App. 15a and again at 16a. In other words, LabCorp's liability was based on *disclosing* the law of nature that is *disclosed* in the patent. LabCorp's publications stated a law of nature: "that elevated homocysteine correlates to cobalamin/folate deficiency," Pet. App. 15a, which is no different than information freely available from the National Institutes of Health ("NIH"). The NIH website describes the basic teaching of claim 13 in its own descriptions of the relationship of homocysteine and folate or cobalamin deficiency as follows:

> "An elevated level of homocysteine in the blood, a risk factor for cardiovascular disease, also can result from folate deficiency."
>
> "A deficiency of folate, vitamin B_{12} or vitamin B_6 may increase blood levels of homocysteine, and folate supplementation has been shown to decrease homocysteine levels and to improve endothelial function."

National Institutes of Health, Office of Dietary Supplements, http://ods.od.nih.gov/factsheets/folate.asp, last visited December 23, 2005. One can find similar information in all types of medical literature, which unquestionably should not be held in any way to violate private patent rights.[4] Although inducement liability can properly attach to the distribution of physical materials in addition to information, punishing the dissemination of information alone through inducement liability would negate patent law's own goal of disclosure. In fact, to do so would result in the USPTO itself being an indirect infringer of all the patents it issues.

III. PATENT CLAIM CONSTRUCTIONS THAT RESTRICT COMMUNICATION REGARDING ABSTRACT IDEAS OR LAWS OF NATURE ARE CONTRARY TO THE FIRST AMENDMENT.

This Court has long held that communication enjoys First Amendment protection unless it falls within certain narrow categories of expression that are of "such slight social value that any benefit that may be derived from them is clearly outweighed by the social interest in order and morality." *Chaplinsky v. New Hampshire*, 315 U.S. 568, 572 (1942). It is difficult to dispute that communication of scientific ideas and facts has significant social value. *Compare Miller v. California*, 413 U.S. 15, 24 (1973) (noting that the definition of obscenity will not apply to

[4] *See, e.g.* Folic Acid Deficiency, eMedicine, http://www.emedicine.com/med/topic802.htm, last visited December 23, 2005 ("the significance of folic acid deficiency is compounded further by the following attributes: • An association of folate deficiency with elevated homocysteine, leading to increased arteriosclerosis risks").

expressive material if it has serious "scientific value"). Accordingly, lower courts have identified as black letter law the principle that "the First Amendment protects scientific expression and debate just as it protects political and artistic expression." *Universal City Studios, Inc. v. Corley*, 273 F.2d 429, 446-47 (2nd Cir. 2001).

In this case, the Federal Circuit found direct infringement of claim 13 based "*solely* on whether the physicians perform the correlating step." Pet. App. 13a (emphasis added). The Federal Circuit's decision could thus be taken to construe as an infringer any person who discussed the relationship between elevated homocysteine and deficiencies in B vitamins. At a minimum, it would appear that a person who discussed the correlation after looking at an elevated homocysteine level in a particular assay (which they performed or was performed on their behalf) would infringe. This finding of infringement for a purely speech based activity seems contrary to First Amendment principles.

In the copyright context, this Court has mediated tension with the First Amendment through the idea/expression dichotomy, which "strike[s] a definitional balance between the First Amendment and the Copyright Act by permitting free communication of facts while still protecting the author's expression." *Eldred v. Ashcroft*, 537 U.S. 186, 220 (2003) (citing *Harper & Row*, 471 U.S. at 556). The *Eldred* Court further noted that "[d]ue to this distinction, every idea, theory, and fact in a copyrighted work becomes instantly available for public exploitation at the moment of publication." *Id.*

As discussed in Part II, patent law has no explicit counterpart to copyright law's idea/expression dichotomy

and its associated doctrine of merger. However, this Court's longstanding exclusion of laws of nature and abstract ideas from patentable subject matter has played a somewhat parallel function. Were laws of nature and abstract ideas to be patentable subject matter, scientific expression could be seriously restricted in violation of the First Amendment. Thus, when addressing the issue of patentable subject matter, which is but one area of increasing tension between patent law and the First Amendment, it is important to be mindful of the consequence such decisions will have on the Freedom of Speech.

CONCLUSION

For the foregoing reasons, this Court should uphold its limitations on patentable subject matter and remand this case for further examination of the patent in light of the bar on patenting laws of nature, scientific truths, and abstract ideas.

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