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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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.

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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.