No. 04-607

IN THE

Supreme Court of the United States

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

Petitioner,

v.

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

Respondents.

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

BRIEF FOR RESPONDENTS

MARK A. LEMLEY
KEKER & VAN NEST LLP
710 Sansome Street
San Francisco, CA 94111
(415) 391-5400

GLENN K. BEATON
Counsel of Record
GIBSON, DUNN & CRUTCHER LLP
1801 California Street
Denver, Colorado 80202
(303) 298-5700

MIGUEL A. ESTRADA
MARK A. PERRY
JEFFREY A. WADSWORTH
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036
(202) 955-8500

Counsel for Respondents

QUESTION PRESENTED

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

"Whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

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

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

TABLE OF CONTENTS

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

TABLE OF AUTHORITIES
(continued)

Page(s)

CONSTITUTIONAL PROVISIONS

STATUTES AND LEGISLATIVE MATERIALS

TABLE OF AUTHORITIES
(continued)

Page(s)

RULES AND ADMINISTRATIVE MATERIALS

TABLE OF AUTHORITIES
(continued)

Page(s)

OTHER AUTHORITIES

BRIEF FOR RESPONDENTS

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

STATUTORY PROVISIONS INVOLVED

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

STATEMENT OF THE CASE

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

A. The Invention

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

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

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

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

---

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

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

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

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

---

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

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

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

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

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

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

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

B. The Patent

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

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

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

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

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

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

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

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

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

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

---

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

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

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

C. The Litigation

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

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

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

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

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

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

---

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

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

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

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

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

INTRODUCTION AND SUMMARY OF ARGUMENT

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

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

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

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

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

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

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

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

ARGUMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2. The specification also easily meets the enablement requirement, which "is satisfied when one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *AK Steel Corp.* v. *Sollac & Ugine*, 344 F.3d 1234, 1244 (Fed. Cir. 2003).

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

In fact, the specification describes in great detail the manner in which to conduct assays and correlations. For example, the specification describes "several different known assays suitable for use in determining levels of homocysteine in urine or blood," S.A. 12, as well as a new assay method

claimed in the '658 patent, S.A. 12-14. As the Federal Circuit explained, "the record shows repeatedly that the correlating step is well within the knowledge of one of skill in this art." Pet. App. 18a; *see* U.S. Br. 9 ("Especially from the perspective of such a person, the patent specification easily satisfies the enablement . . . requirement[] by explaining precisely how to perform the claimed method"). Petitioner has not even challenged this factual conclusion.

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

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

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

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

A. Subject Matter Patentability Is Not Properly Before The Court

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

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

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. The '658 Patent Claims Patentable Subject Matter

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

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

---

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

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

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

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

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

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

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

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

---

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

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

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

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

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

---

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

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

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

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

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

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

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

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

---

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

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

i. Claim 13 Entails A Physical Transformation Of Matter

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

---

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

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

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

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

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

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

Thus, as the Solicitor General has correctly recognized, "the various methods of assaying for total homocysteine that are described in the record entail significant physical or chemical alteration of a sample of blood or other bodily fluid." U.S. Br. 21 n.4. Petitioner has identified no assay method that does *not* involve the transformation of matter, and given the biochemistry involved, no such assay could exist. Thus, petitioner has not carried its burden of proving, by clear and convincing evidence, that claim 13 is invalid because it could be practiced without transforming matter. Nothing more is required under *Diehr* to sustain the patent.[16]

---

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1. Vacatur Would Call Into Question Thousands Of Issued Patents

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

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

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

---

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

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

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

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

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

---

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CONCLUSION

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

Respectfully submitted.

MARK A. LEMLEY
KEKER & VAN NEST LLP
710 Sansome Street
San Francisco, CA 94111
(415) 391-5400

GLENN K. BEATON
Counsel of Record
GIBSON, DUNN & CRUTCHER LLP
1801 California Street
Denver, Colorado 80202
(303) 298-5700

MIGUEL A. ESTRADA
MARK A. PERRY
JEFFREY A. WADSWORTH
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, D.C. 20036-5306
(202) 955-8500

Counsel for Respondents

February 6, 2006

APPENDIX

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

§ 100. Definitions

When used in this title unless the context otherwise indicates—

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

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

* * * *

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

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

A person shall be entitled to a patent unless—

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

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

* * * *

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

* * * *

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

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

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

* * * *

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

§ 282. Presumption of validity; defenses

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

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

* * * *

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

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

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

* * * *

Federal Rule of Civil Procedure 8 provides in pertinent part:

Rule 8. General Rules of Pleading

* * * *

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

* * * *

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

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

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

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

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

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

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

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

* * * *

* * * *

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

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

* * * *

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

I. INTRODUCTION

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

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

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

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

* * * *

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

* * * *

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

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

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

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

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

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

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

This perspective has been embraced by the Federal Circuit:

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

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

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

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

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

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

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

The courts have also held that a claim may not preempt ideas, laws of nature or natural phenomena. The concern over preemption was expressed as early as 1852. *See Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852) ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 132, 76 USPQ 280, 282 (1948) (combination of six species of bacteria held to be non-statutory subject matter). Accordingly, one may not patent every "substantial practical application" of an idea, law of nature or natural phenomena because such a patent "in practical effect be a patent on the [idea, law of nature or natural phenomena] itself." *Gottschalk v. Benson*, 409 U.S. 63, 71-72, 175 USPQ 673, 676 (1972).

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

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

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

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

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

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

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

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

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

Determining whether the claim falls within one of the four enumerated categories of patentable subject matter recited in 35 U.S.C. § 101 (process, machine, manufacture or composition of matter) does not end the analysis because claims directed to nothing more than abstract ideas (such as mathematical algorithms), natural phenomena, and laws of nature are not eligible and therefore are excluded from patent protection. [*Diamond v.*] *Diehr*, 450 U.S. [175,] 185, 209 USPQ [1,] 7 [(1981)]; accord, e.g., *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197; *Parker v. Flook*, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); *Benson*, 409 U.S. at 67-68 , 175 USPQ at 675; *Funk*, 333 U.S. at 130, 76 USPQ at 281. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy*, 55 U.S. (14 How.) at 175. Instead, such "manifestations of laws of nature" are "part of the storehouse of knowledge," "free to all men and reserved exclusively to none." *Funk*, 333 U.S. at 130, 76 USPQ at 281.

Thus, "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter" under Section 101. *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197. "Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Ibid*. Nor can one patent "a novel and useful mathematical formula," *Flook*, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam power, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113-114 (1853); or "[t]he qualities of * * * bacteria, * * * the heat of the sun, electricity, or the qualities of metals," *Funk*, 333 U.S. at 130, 76 USPQ at 281; see *Le Roy*, 55 U.S. (14 How.) at 175.

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

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

An examiner must ascertain the scope of the claim to determine whether it covers either a § 101 judicial exception or a practical application of a § 101 judicial exception. The conclusion that a particular claim *includes* a § 101 judicial exception does not end the inquiry because "[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187, 209 USPQ at 8 (emphasis in original); accord *Flook*, 437 U.S. at 590, 198 USPQ at 197; *Benson*, 409 U.S. at 67, 175 USPQ at 675. Thus, "[w]hile a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be." *Diehr*, 450 U.S. at 188, 209 USPQ at 8-9 (quoting *Mackay*, 306 U.S. at 94); see also *Corning v. Burden*, 56 U.S. (15 How.) 252, 268, 14 L.Ed. 683 (1854) ("It is for the discovery or invention of some practical method or means of producing a beneficial result or effect, that a patent is granted . . .").

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

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

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

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

a. Practical Application by Physical Transformation

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

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

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

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

(1) "USEFUL RESULT"

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

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

(2) "TANGIBLE RESULT"

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

(3) "CONCRETE RESULT"

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

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

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

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

D. Establish on the Record a Prima Facie Case

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

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

* * * *

Date: 10/26/05

/s/
JOHN J. DOLL
Commissioner for Patents

ANNEX I

Flowchart for Subject Matter Eligibility

* * * *

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

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

* * * *

ANNEX III

Improper Tests For Subject Matter Eligibility

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

(A) "not in the technological arts" test

(B) *Freeman-Walter-Abele* test

(C) mental step or human step tests

(D) the machine implemented test

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

* * * *

c. (i) The Mental Step Test

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

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

c. (ii) The Human Step Test

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

* * * *