No. 10-

In the Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (D/B/A MAYO MEDICAL LABORATORIES) AND MAYO CLINIC ROCHESTER,
Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,
Respondent.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

This case concerns whether a patentee can monopolize basic, natural biological relationships. The Court has twice granted certiorari on the question presented, without yet resolving the issue. Last year, it granted certiorari, vacated, and remanded in this case to allow the Federal Circuit to reconsider this question in light of *Bilski* v. *Kappos*, 130 S. Ct. 3218 (2010). And seven years ago it granted certiorari but dismissed the writ as improvidently granted in *Laboratory Corp. of America Holdings* v. *Metabolite Laboratories, Inc.,* 548 U.S. 124, 135 (2006), because petitioner there had not adequately preserved the question.

The question presented is:

Whether 35 U.S.C. § 101 is satisfied by a patent claim that covers observed correlations between blood test results and patient health, so that the claim effectively preempts all uses of the naturally occurring correlations, simply because well-known methods used to administer prescription drugs and test blood may involve "transformations" of body chemistry.

RULES 14.1(b) AND 29.6 STATEMENT

All parties are identified in the caption of this petition. Petitioner Mayo Collaborative Services, a subsidiary of Mayo Clinic, is a for-profit Minnesota corporation that provides reference laboratory services under the name Mayo Medical Laboratories. Petitioner Mayo Clinic Rochester, a subsidiary of Mayo Clinic, is a charitable, nonprofit corporation located in Rochester, Minnesota. No publicly held company owns 10% or more of the stock of either petitioner.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners, Mayo Collaborative Services (d/b/a Mayo Medical Laboratories) and Mayo Clinic Rochester (collectively, "Mayo"), respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The Federal Circuit's opinion following remand from this Court (App., *infra*, 1a-23a) is reported at 628 F.3d 1347 (Fed. Cir. 2010). This Court's order granting certiorari, vacating, and remanding in light of *Bilski* v. *Kappos* (App., *infra*, 24a) is reported at 130 S. Ct. 3543 (2010). The Federal Circuit's original opinion (App., *infra*, 25a-49a) is reported at 581 F.3d 1336 (Fed. Cir. 2009). The district court's opinion holding Prometheus's patents invalid (App., *infra*, 50a-83a) is reported at 2008 WL 878910 (S.D. Cal. Mar. 28, 2008).

JURISDICTION

The court of appeals entered its judgment on December 17, 2010. This petition is filed within 90 days of that judgment. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

"The term 'process' means process, art or method, and includes a new use of a known process, machine,

manufacture, composition of matter, or material." 35 U.S.C. § 100(b).

INTRODUCTION

The issue presented in this case is one of exceptional importance in the healthcare and life science fields that affects patients across the Nation. Simply put, Prometheus's patents monopolize every useful implementation of a correlation between particular types of drug treatment and the natural bodily metabolism resulting from that drug treatment. This correlation is unquestionably a natural phenomenon. From it, doctors may determine if a dose of a drug is too high, too low, or needs no adjustment at all. But if Prometheus's patents are allowed to stand, doctors will no longer be free to consider this biological phenomenon in treating patients or in attempting to develop new treatments for disease. And numerous similar, overly-broad patents that restrict doctors' ability to treat patients will stand as well. This will stifle innovation, as well as raise the cost and degrade the quality of medical care throughout the United States.

This Court previously recognized the importance of the issue when it granted certiorari in *Laboratory Corp. of America Holdings* v. *Metabolite Laboratories, Inc.,* 548 U.S. 124, 135 (2006) ("*LabCorp*"). The Court could not resolve the merits there because a majority did not believe that the *LabCorp* petitioner adequately preserved the issue. But three dissenting Justices would have decided the case. In their dissent, they pointed out the great public importance of the issue and explained that the *LabCorp* patent claims—which are not materially different from Prometheus's claims here—were not even "at the boundary" of patentability.

The district court here reached the same conclusion, finding in a detailed opinion that Prometheus's claims were invalid because they "wholly pre-empt" natural correlations. App., *infra,* 75a-78a. But the Federal Circuit reached the opposite conclusion—both before this Court's decision in *Bilski* v. *Kappos*, 130 S. Ct. 3218 (2010), and after vacatur and remand—while twice declining even to consider *LabCorp*.

Before *Bilski,* the Federal Circuit applied its own "machine or transformation" test as a "definitive" standard under Section 101—a position this Court rejected in *Bilski*. But even though *Bilski* affirmed the primacy of a "preemption" analysis, the Federal Circuit on remand again mechanically applied its "machine or transformation" test, and it again "decline[d] to discuss" the reasoning of Justices Breyer, Stevens, and Souter in *LabCorp*. Even though Prometheus's patent claims merely recite a physician's mental recognition of a correlation between a patient's health and blood levels of metabolites after administration of a drug, the Federal Circuit held that such a correlation may be patented because the steps needed to elicit the correlation involve "transformations" of the human body. But these steps are simply the administration of the drug and the measurement of metabolite levels, both of which had been known in the art for decades. This was enough for the Federal Circuit to find patent-eligibility for a process that—far from constituting any innovation—is nothing more than the body's natural reaction to the ingestion of drugs, and a mental recognition of that natural reaction.

The Federal Circuit's decision is inconsistent with this Court's earlier precedents, with the reason-

ing of three Justices in *LabCorp*, and with *Bilski*. The *Bilski* Court recognized that the "preemption" standard controls Section 101 decisions. 130 S. Ct. at 3229-3231. Prometheus's claims broadly monopolize all uses of physician-recognized natural correlations —failing the preemption standard even if natural "transformations" of body chemistry may lead up to those correlations.

As reflected in the grant of certiorari in *LabCorp* and the host of amicus filings in that case, the question presented is one of extraordinary public importance. Justices Breyer, Stevens, and Souter explained in *LabCorp* that "special public interest considerations" are implicated by the question presented because overbroad patents will "inhibit doctors from using their best medical judgment," "force doctors to spend unnecessary time and energy to enter into license agreements," "divert resources" from healthcare tasks to "the legal task of searching patent files," and "raise the cost of healthcare while inhibiting its effective delivery." 548 U.S. at 138. Even more so today—with rising national concerns over healthcare quality and cost—these considerations warrant this Court's review, which may now proceed without the preservation problems that prevented resolution in *LabCorp*.

STATEMENT

A. Prometheus's Sweeping Patent Claims.

Prometheus's broad patent claims attempt to turn a physician's thought processes into infringement.[1] Specifically, these claims encompass a physi-

[1] U.S. Patents 6,355,623 ("the '623 patent") and 6,680,302 ("the '302 patent"), reproduced at C.A. App. A10001 and A10019, are

cian's mental determinations when evaluating a patient who has been given a thiopurine drug, a kind of drug that was discovered over 30 years ago. Enzymes in the human body convert such drugs naturally into metabolites. App., *infra*, 65a. Low levels of such metabolites indicate an insufficient dose of the drug, and high levels indicate too much. Physicians understood these facts well before Prometheus filed its patent claims, as conceded in those claims.[2]

What the Prometheus patents purport to add is a recognition that *particular metabolite levels* are relevant to proper drug dosages for a variety of autoimmune disorders. App., *infra*, 2a-4a; '623 Patent at 8:40-46, C.A. App. A10010. Those correlations already existed in the studied patient population. Prometheus simply analyzed patient data assembled by other parties to "discover" the levels it claimed were relevant. App., *infra*, 65a-66a; C.A. App. A12833-12836, A13330-13331. For many years previously, doctors considered metabolite levels and made their own independent judgments about them—whether they were too high, too low, or just right. See n.2, *supra*.

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also available at http://tiny.cc/y867p and http://tiny.cc/TR2FY, respectively.

[2] See, *e.g.*, '623 Patent at 8:37-39, C.A. App. A10010 (citing "[p]revious studies" that concluded "measurement of 6-MP metabolic levels can be used to predict clinical efficacy and tolerance" to thiopurine drugs); '623 Patent at 9:13-14, C.A. App. A10011 (relevant metabolite levels "can be determined by methods well known in the art"); C.A. App. A12698-12701, A12705-12712, A12714-12718 (scientific papers from 1982-1990 describing tests for relevant metabolite of thiopurine); *id.* at A12722-12727 (1989 article discussing "acute thiopurine toxicity"); *id*. at A12842-12844 (conceding prior testing for thiopurine metabolites).

Claim 1 of the '623 patent, for example, has just two basic steps: (a) administering some indefinite amount of the drug to the patient, and then (b) considering whether that test dosage was too little, just right, or too much to treat the patient based on observed metabolite levels (known as 6-thioguanine (6-TG)):

> 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

C.A. App. A10016; see App., *infra*, 3a-5a (describing patent claims at issue). Other claims, such as claim 46 of the '623 patent, do not even require the "administering" step—and thus recite only the step of "determining." See App., *infra*, 4a-5a.

Importantly, Prometheus's claims do *not* recite what is to be done once the physician mentally re-

cognizes the correlation. App., *infra*, 60a-62a. The claims therefore cover and preempt *all* uses of the natural correlation. What the physician might do with her observation is irrelevant because simply thinking about the subject completes the act of infringement. As Prometheus's expert testified, if a physician reads an email with the test results, it would not matter if she "crumples it up, throws it away, reads it, acts on it, doesn't act on it, any assumptions you want to come up with." C.A. App. A13557-613558; see also C.A. Supp. App. A13805-13806. The physician infringes the moment she thinks or thinks again about the correlation, regardless of what she intends to do with the information or whether she acts upon it.

Notably, infringement occurs even when the dose of drug administered to a patient is a test dose and not a dose intended to treat the patient, because the claims do not specify the proper size of the dose but merely recite the mental recognition of metabolite levels that are too low or too high. The Federal Circuit's analysis, however, relies centrally on a supposition that the claims—even the claims that do not recite administration of any drug to the patient—are patent-eligible because they describe patient *treatment*. App., *infra*, 15a-18a. The falsity of that supposition goes to the core of this case. Prometheus's failure to claim any particular real-world use of the natural laws on which its claims rely—its failure to recite a particular treatment or anything else—causes the claims to preempt all such uses of the physician-recognized natural correlations.

Mayo argued in the district court in favor of a narrow interpretation of these patent claims that would require some real-world action, such as requir-

ing the doctor to adjust the amount of drug given to the patient. C.A. App. A12245-12249. But Prometheus opposed that position. It successfully argued that a physician only had to identify a potential need to adjust dosage—and nothing else—to infringe. The district court agreed with Prometheus that its patents were this broad. See App., *infra*, 107a-110a.

Prometheus's infringement accusations against Mayo researcher Dr. Rokea el-Azhary highlight the extraordinary breadth of these patents. Dr. el-Azhary is a dermatologist. She gave her dermatological patients a thiopurine drug to try to establish a therapeutic range for skin disorders. See C.A. App. A12846. But because the lab report she received referred to the correlation ranges in Prometheus's claims, Prometheus accused her of infringement:

> The Biochemical Genetics Laboratory at Mayo Clinic Rochester sent a report of test results to Dr. El-Azhary, or someone working for Dr. el-Azhary. The test results described the "therapeutic range" as "235-400." The Biochemical Genetics Laboratory at Mayo Clinic Rochester did not subsequently advise Dr. el-Azhary that the "therapeutic range" was not "235-400."
>
> Such information informed Dr. el-Azhary, or someone working for Dr. el-Azhary (and thus "indicated a need"), that the next dose of azathioprene given to the patient should be increased in order to be within the "therapeutic range."

C.A. App. A12788; A12821-12822. Prometheus even asserted infringement when Dr. el-Azhary subsequently received reports that did not list the "thera-

peutic range"—on the ground that the ranges were still in her memory. *Id.* at A12853-12854 ¶ 5.

Dr. el-Azhary testified that she knew the numbers, but because Prometheus's range was developed from patients with gastrointestinal disorders, it was "irrelevant to [her] study" of metabolite levels in patients with dermatological disorders. C.A. App. A12848-12850. Under Prometheus's patents, Dr. el-Azhary must stop her dermatological research until she rids her memory of the gastrointestinal correlations—regardless of how she ultimately may use any test results—because Prometheus's patents preempt all possible uses of the correlations. If these claims are allowed to stand, Prometheus can sue anyone who thinks about the claimed correlations when conducting research or treating patients, no matter how they obtain such information—including by reading this petition.

B. The District Court's Decision Invalidating The Patents.

Prometheus sued Mayo in 2004 over a test that Mayo developed to measure metabolites in patients treated with thiopurine drugs. Mayo's proposed test did not use the ranges from Prometheus's patent claims. App., *infra*, 85a. After construing the claims broadly, the district court granted Prometheus summary judgment and held that the claims were infringed. *Id.* at 110a-116a. Mayo then moved for summary judgment that Prometheus's claims were invalid under 35 U.S.C. § 101, and the court granted Mayo's motion. See App., *infra*, 52a-54a (describing procedural history).

The district court relied on this Court's case law deeming patent claims invalid if they wholly preempt

all uses of a natural phenomenon or abstract idea. App., *infra*, 60a-63a, 66a, 72a-78a. The court first noted that the Prometheus claims recite correlations between thiopurine drug metabolite levels and therapeutic efficacy or toxicity. *Id.* at 62a-63a. The court rejected, as form over substance, Prometheus's argument that the claims recite "methods" rather than natural phenomena. Looking at the steps of the claims, the court explained that the steps reciting "administering" a drug and "determining" metabolite levels were mere data-gathering steps that were necessary precursors for reviewing the claimed correlations. *Id.* at 63a. In summarizing the claims, the court noted: "what the inventors claim to have discovered is that particular concentrations of [thiopurine metabolites] correlate with therapeutic efficacy and toxicity in patients taking AZA drugs." *Ibid.*

The court then held that the correlations are natural phenomena. Rejecting Prometheus's argument that the correlations could not be natural because thiopurine is a synthetic drug, the court observed that Prometheus's claims are directed to the correlations and not to the making of the drug. Prometheus's expert admitted that "the key therapeutic aspect of such thiopurine drugs is that they are converted naturally by enzymes within the patient's body to form an agent that is therapeutically active." App., *infra*, 65a. Prometheus also admitted that the testing and correlations already existed in a "database of patient's information," and that the correlations likely still exist in the current patient population. *Ibid*. As a result, the court (*id.* at 66a) concluded that Prometheus

> did not "create" the correlation between thiopurine drug metabolite levels and therapeutic efficacy and toxicity. Instead, the correlation results from a natural body process, which as the inventors concede, was preexisting in the patient population, and it exists in the patient population today.

In analyzing Prometheus's claim, the district court found instructive the *LabCorp* opinion of Justices Breyer, Stevens, and Souter, which, citing this Court's precedents, explained that the similar claim there failed "the requirement that it not amount to a simple natural correlation, *i.e.*, a 'natural phenomenon'":

> At most, respondents have simply described the natural law at issue in the abstract patent language of a "process." But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge. One might, of course, reduce the "process" to a series of steps, *e.g.*, Step 1: gather data; Step 2: read a number; Step 3: compare the number with the norm; Step 4: act accordingly. But one can reduce *any* process to a series of steps. The question is what those steps embody. And here, aside from the unpatented test, they embody only the correlation between homocysteine and vitamin deficiency that the researchers uncovered. In my view, that correlation is an unpatentable "natural phenomenon," and I can find nothing in [the claim] that adds anything more of significance.

LabCorp, 548 U.S. at 137-138 (citation omitted), quoted at App., *infra*, 67a-68a.

The district court then concluded that the Prometheus claims preempt a natural phenomenon under this Court's precedents. It noted that this Court's preemption standard in *Gottshalk* v. *Benson*, 409 U.S. 63 (1972), and *Parker* v. *Flook*, 437 U.S. 584 (1978), governs, and not a "transformation" test. App., *infra*, 72a-74a. And it explained that Prometheus's sweeping claims improperly preempt all uses of these correlations, because every activity recited in the claims other than recognition of the correlations was simply data gathering necessary to observe the natural correlations (*id.* at 75a-78a):

> what the inventors claim to have discovered is that particular concentrations of 6-TG and 6-MMP correlate with therapeutic efficacy and/or toxicity in patients taking AZA drugs. Because the claims cover the correlations themselves, it follows that the claims "wholly pre-empt" the correlations.

C. The Federal Circuit's First Decision Upholding The Patents, And This Court's Post-*Bilski* Vacation Order.

The Federal Circuit reversed. It applied its own "machine or transformation" test as a "definitive" standard, and glossed over Justice Breyer's *LabCorp* opinion in a footnote. See App., *infra*, 33a-34a, 40a n.3. Prometheus invited that ruling by insisting in its briefing that "a freestanding preemption inquiry is inappropriate" because "*Bilski's* 'machine or transformation test is the singular test for a process claim under § 101.'" Prometheus Reply Br. 21 n.3 (Fed. Cir. Apr. 24, 2009).

In a petition for certiorari that was supported by numerous amici,[3] Mayo argued that the Federal Circuit erred by elevating the "machine or transformation" test over this Court's holdings that require analysis of a patent claim's preemption of the use of natural phenomena. Mayo Pet., No. 09-490, at 13. Mayo showed (at 14-19) that because the Prometheus claims do not say what is to be done with a doctor's recognition of the natural correlations they recite, they cover all uses and thus improperly preempt them. Amici emphasized that attempted patenting of medical correlations "has led to severe restraint on the provision of medical care and a greatly increased cost and reduced availability of vital medical services" (Am. Br. of AARP, *et al.*, No. 09-490, at 4); that interference with physicians' mental processes raises ethical concerns and erodes physicians' ability to provide quality care (Am. Br. of American College of Medical Genetics, *et al.*, at 9-11); and the Federal Circuit's holding lets companies claim ownership of matter that is already in the public's "storehouse of knowledge." Am. Br. of Quest Diagnostics, *et al.*, at 5. For its part, Prometheus asserted in its brief in opposition (at 24-26) that "machine or transformation" was the definitive standard.

While the petition was pending, this Court decided *Bilski* v. *Kappos*. Though *Bilski* included three opinions, all agreed on a number of key points. First,

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[3] AARP, the Public Patent Foundation, the American College of Medical Genetics, the American Society of Human Genetics, the Association of Professors of Human and Medical Genetics, the Association for Molecular Pathology, the College of American Pathologists, Quest Diagnostics Inc., Laboratory Corporation of America Holdings, Arup Laboratories, Inc., and Tricore Reference Laboratories.

they disapproved of the Federal Circuit's rote reliance on "machine or transformation" as the standard for patent eligibility, and demanded a more nuanced inquiry. Each opinion also affirmed that natural phenomena and abstract ideas lie outside the bounds of Section 101, so that claims that have the practical effect of preempting natural phenomena are invalid. The Court also reaffirmed its decisions in *Benson*, *Flook*, and *Diamond* v. *Diehr*, 450 U.S. 175 (1981), and stated pointedly that it was not endorsing any prior Federal Circuit precedent. Moreover, the opinions by Justice Stevens (joined by Justices Ginsburg, Breyer, and Sotomayor) and Justice Breyer (joined in relevant part by Justice Scalia) each referenced *LabCorp* approvingly, and the majority opinion emphasized the need to set the Section 101 bar high enough to avoid flooding courts "with claims that would put a chill on creative endeavor and dynamic change." 130 S. Ct. at 3229. It was no surprise that, after *Bilski*, this Court granted certiorari in this case, vacated, and remanded.

D. The Federal Circuit's Second Decision Upholding The Patents.

On remand, the Federal Circuit refused to alter its decision, stating that this Court in *Bilski* "did not undermine" the Federal Circuit's prior analysis—an analysis that equated this Court's ultimate preemption standard with the Federal Circuit's "machine or transformation" test. App., *infra*, 14a. The Federal Circuit repeated its conclusion that alteration of a patient's body through metabolizing a drug, and the testing of the patient's blood for metabolite levels, were "transformations" that made the claims patentable. *Id.* at 15a-16a.

As for preemption, the Federal Circuit reasoned that "the claims do not preempt all uses of the natural correlations; they utilize them in a series of specific steps." *Id.* at 15a. But because the steps that lead up to the correlations are *not* uses of the correlations, they do nothing to narrow the scope of the patent and do not leave others free to use the correlations in different ways, including to develop new ways of treating patients. Instead, those data-gathering steps are simply the commonplace and well-understood steps of administering a drug and measuring its metabolites—the only way to assess the correlations. The result of the Federal Circuit's analysis is to uphold claims that in fact preempt anything that a physician might do with these naturally-existing correlations.

When confronted with *LabCorp*, the Federal Circuit again dismissed it, summarily stating that it "decline[d] to discuss a dissent"—even though the dissent analyzed and applied this Court's precedents, and Justice Breyer's opinion on the merits is the only word from any Justice on this critical issue. *Id.* at 16a n.2. No Justice disagreed with Justice Breyer's substantive analysis. The majority dismissed the petition in *LabCorp* solely because the issue had not been preserved or decided below.

REASONS FOR GRANTING THE PETITION

The Federal Circuit's decision conflicts with this Court's precedents because it broadly extends the "machine or transformation" test and fails to give effect to the "preemption" standard for patent-eligibility. Where a claim, like the Prometheus claims here, recites a natural phenomenon—and even the Federal Circuit agreed that the correlations in the Prometheus claims are natural phenomena—

but does not recite a real-world application of the phenomenon, and thus covers all such real-world applications, it is repugnant to the statute and invalid. Like the claims in *LabCorp*, the Prometheus claims do not come close to escaping the preemption prohibition.

I. THE FEDERAL CIRCUIT'S RULING RAISES THE SAME ISSUE THAT WARRANTED A GRANT OF CERTIORARI IN *LABCORP*.

A. This Court Previously Recognized The Exceptional Public Importance Of The Issue Presented.

Seven years ago, when the Court granted certiorari in *LabCorp,* it recognized the critical importance of the issue presented here to the United States economy and to the quality and cost of healthcare delivery. That a majority of Justices voted to dismiss the petition on procedural grounds does not undercut the issue's importance. The importance of the issue has only grown over the last seven years as a result of the Nation's efforts to constrain healthcare costs.

While the entire Court recognized the importance of the issue, the three Justices who would have decided the case on the merits highlighted the error in the Federal Circuit's approach. As set forth by Justice Breyer (joined by Justices Stevens and Souter), the claims there were directed to a method of "correlating" a blood homocysteine level with a deficiency in folate, just like the correlation between metabolites and patient condition in the Prometheus claims. Hence, "[t]here can be little doubt that the correlation [is] a 'natural phenomenon.'" 548 U.S. at 135. And the drafting of the claims to make the cor-

relation a "process" was plainly insufficient in *LabCorp*. The claim described a "natural law"—and dressing that law up "in the abstract patent language of a 'process'" was not enough to "avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge." *Id.* at 137. The blood testing steps of the claim were "nothing * * * that adds anything more of significance," leaving the "correlation [a]s an unpatentable 'natural phenomenon.'" *Id.* at 138. Accordingly, a simple patient blood test that leads to an unpatentable mental recognition is not a patentable process.

The Court's decision in *Bilski* provides strong support for this analysis. Although *Bilski* addressed a "business method" invention, all the Justices explicitly noted that scientific and biological laws must be available for anyone to copy and use in various ways.[4] The Court also warned the Federal Circuit that it was not free to return to its old legal standards. 130 S. Ct. at 3231 ("Nothing in today's opinion should be read as endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past"). And five of the Justices quoted *LabCorp* with approval, and not just in passing. One opinion specifically endorsed *LabCorp*'s balancing analysis and catalogue of evils of over-broad patents, and another endorsed *LabCorp*'s discussion of the limits on patent-eligibility. *Bilski*, 130 S. Ct. at 3255,

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[4] *E.g.,* 130 S. Ct. at 3225 (Section 101 does not cover "laws of nature, physical phenomena, and abstract ideas") (majority); *id.* at 3235 (*Benson* and *Flook* stand for proposition that a patent may not claim a "phenomenon of nature or abstract idea") (Stevens, J., concurring); *id.* at 3258 ("phenomena of nature," "mental processes," and "abstract intellectual concepts are not patentable") (Breyer, J. concurring).

3259. It is not surprising that a majority of the Justices looked to Justice Breyer's *LabCorp* opinion: it provides a clear-cut summary of this Court's prior precedents in the life sciences context.

Despite this guidance, the Federal Circuit went in a completely different direction. It has twice in this case treated the *LabCorp* Justices' analysis in dismissive footnotes. And it has never explained how the facts of these two cases can be distinguished from one another. That would be impossible to do. The Federal Circuit's opinion shows that it would find the *LabCorp* claim to satisfy Section 101 because it involves taking a blood sample from a patient, assaying it, and then thinking about what the resulting natural correlation means for patient health.

This Court's guidance is now sorely needed. There is a broad consensus that appropriate application of Section 101 to biotechnology claims, and particularly the application of Section 101 to method claims involving natural, biological correlations, needs resolution. See, *e.g.*, Peter Lee, *Patent Law and the Two Cultures*, 120 YALE L.J. 2, 81 (2010) (observing after the GVR in this case that the Federal Circuit and this Court are "locked in dialogue" over the contours of process patentability, and questioning whether the Federal Circuit in this "important case" will "respond in kind" to this Court's approach in *Bilski* or continue with its "divergent cultur[e]"); Dan Vorhaus & John Conley, *Bilski and Biotech: Business as Usual, for Now*, GENOMICS L. REP. (June 28, 2010), available at www.genomicslawreport.com/index.php/2010/06/28/bilski-and-biotechnology ("Although the Court's narrow ruling left a direct treatment of the difficult issues surrounding biotechnology patents for another day, those issues continue to

loom large"); Margaret Kubick, *An Uncertain Future: The Impact of Medical Process and Diagnostic Method Patents on Healthcare in the United States*, 9 NW. J. OF TECH. & INTELLECTUAL PROP. 280, 292 (2010) ("To solve the current state of confusion surrounding process patent eligibility in the wake of *In re Bilski*, *Prometheus*, and *Bilski* v. *Kappos*," this Court "needs to provide a clear rule for patent applicants to follow").

Indeed, two related cases are now pending in the Federal Circuit, and there is no doubt they will be decided under erroneous law if this Court does not grant review.[5] There is nothing left to percolate, as the Federal Circuit is required by its own rules to follow the decision in this case. See *Hometown Fin., Inc.* v. *United States*, 409 F.3d 1360, 1365 (Fed. Cir. 2005); *South Corp.* v. *United States*, 690 F.2d 1368, 1370-1371 (Fed. Cir. 1982) (en banc). Beyond these known litigations are countless researchers and innovators who are paralyzed by patent monopolies like Prometheus's and by the Federal Circuit's ruling in this case. At the same time, countless patients are denied access to superior care at lower cost (to themselves, to insurers, and to state and federal governments).

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[5] *Ass'n for Molecular Pathology* v. *U.S. Patent & Trademark Office*, No. 2010-1406 ("*Myriad*"); *Classen Immunotherapies, Inc.* v. *Biogen Idec*, Nos. 2006-1634, 2006-1649. Notably, the Section 101 issue in this Petition stands alone and has been the subject of multiple rounds of briefing that have focused the arguments and produced definitive (and opposed) rulings from the courts below. The Federal Circuit has yet to decide either *Myriad* or—following a vacatur and remand by this Court in light of *Bilski*—*Classen*.

In short, this is not an issue that will benefit from the passage of more time. The Federal Circuit's lack of deference to *Bilski* on remand and adherence to rejected legal standards confirm the need for review by this Court.

B. This Court Has Long Invalidated Patent Claims That Attempt To Preempt All Uses Of Natural Phenomena.

The substantive analysis of Justices Breyer, Souter and Stevens in *LabCorp* is based on this Court's established precedent. Although Section 101 is expansive in its reach, *Diamond* v. *Chakrabarty*, 447 U.S. 303, 309 (1980), it also is subject to important limits. In particular, a patent claim cannot preempt, either directly or by practical effect, a law of nature, natural phenomenon, or abstract scientific idea. As *Chakrabarty* observed:

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

Id. at 309 (quoting *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)). As the Court has also noted, "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Benson*, 409 U.S. at 67.

This exception to patentability applies not only to a patent claim that is aimed directly at a natural

phenomenon, but also to one whose "practical effect would be a patent on the [phenomenon] itself," because such a claim "wholly pre-empt[s]" all uses of the natural phenomenon. *Benson*, 409 U.S. at 71-72; see *Bilski*, 130 S. Ct. at 3230; *id* at 3253 (Stevens, J., concurring in the judgment); *id* at 3258 (Breyer, J., concurring in the judgment).

Thus, where a claim recites a law of nature or biological process, a court must look to whether the claim seeks protection for the phenomenon "in the abstract" or instead implements the phenomenon "in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect." *Diehr*, 450 U.S. at 191. The presence in a patent claim of a machine or transformation that uses a natural phenomenon may, in some cases, indicate that a patent claim encompasses *only* a definite subset of the uses for that phenomenon. But the role of machines and transformations in the analysis is subservient to the more general inquiry into preemption.

C. Prometheus's Claims Are Invalid Because They Preempt All Uses Of Natural Correlations.

The Prometheus claims, like the *LabCorp* claims, center on a natural phenomenon—the correlation between certain metabolite levels and patient health. That correlation is dictated by natural enzymatic activity inside the human body. Prometheus's own expert admitted that the drugs are "converted *naturally* by enzymes within the patient's body" into metabolites, as the district court found. The Federal Circuit did not disturb that finding by the district court, and agreed that the correlations were "naturally occurring." App., *infra*, 15a.

The Prometheus claims preempt all relevant uses of the correlations. In particular, the claims end with the step of recognizing the correlation and thus cover *anything* that a physician might do with her knowledge of the correlation. Prometheus's expert confirmed the sweeping preemptive effect of the claims by testifying that a physician who receives test results that identify the claimed ranges will infringe regardless of what she does with the information—it does not matter if she "crumples it up, throws it away, reads it, acts on it, doesn't act on it, any assumptions you want to come up with." C.A. App. A13557-613558; see also C.A. Supp. App. A13805-13806. A clearer demonstration of the claims' extraordinary preemptive scope could not be imagined.

The preemptive impact of Prometheus's claims is particularly severe because they govern human thought that involves, in any medical context, metabolite ranges that Prometheus observed in patients who took gastrointestinal drugs. Dermatologist Dr. el-Azhary cannot stop thinking about Prometheus's ranges once she learns of them, even if her goal in reviewing a patient's test results is to find entirely different numbers relating only to dermatology. As a result, Prometheus has obtained an unwarranted monopoly across a broad field of medical practice. The preemptive scope of the Prometheus claims is unprecedented. It constitutes an embargo on research and analysis essential to the development of medical knowledge and patient care.

The way in which Prometheus's claims resemble those found invalid in *Benson* and *Flook*, and differ from those found valid in *Diehr*, confirm the proper result here. The claims in *Benson* recited a computa-

tion for converting numbers from one form to another, but did not recite what was to be done with the numbers once they were converted. Hence, the patent covered all such uses of the idea and would wholly preempt the underlying mathematical formula. 409 U.S. at 71-72. In a like manner, the claims in *Flook* recited a method for updating an alarm limit for use in a chemical process, but never recited what was to be done with the computation even though the claims did recite some "post-solution activity." 437 U.S. at 590. Because the claims covered all uses, they, like the claims in *Benson*, were held invalid.

By contrast, the claims in *Diehr*, which recited use of the Arrhenius equation, *also* recited a particular application of the equation: using the output of the equation to determine when to open or close an injection mold. In distinguishing that situation from *Benson* and *Flook*, the Court explained (450 U.S. at 187) that

> respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber. Their process admittedly employs a well-known mathematical equation, but they do not seek to pre-empt the 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.

Prometheus's claims are like those in *Benson* and *Flook*, and unlike those in *Diehr*. In particular, claim 1 (quoted above) does not recite anything that should be done with a physician's recognition of a natural correlation, such as changing a patient dosage. The physician's thought process is analogous to the com-

puter processing in *Benson* and *Flook*—where the claims preempted all uses of the computer algorithms because those claims did not limit themselves to any real-world application of the algorithms. Thus, under this Court's well-established precedent, overreaching claims like those asserted by Prometheus are invalid.

D. The Federal Circuit's Broad Extension Of The "Machine Or Transformation" Test Has Produced A Square Conflict With This Court's Preemption Standard.

The Federal Circuit acknowledged that thinking about "possible dosage adjustments" is a "mental ste[p] and thus not patent-eligible *per se*." App., *infra*, 21a, 23a. Yet the court found the claims valid because they include two (and sometimes only one) "prior steps [that] provide useful information" (*id.* at 23a), even though those steps are well-known, are performed every day by countless medical personnel, and owe nothing at all to Prometheus. The court upheld the patents because those preparatory steps of administering the drug and determining a metabolite level involve "transformations" of matter (*id.* at 15a-20a)—transformations that, far from being any innovation, are simply the body's natural reaction to ingestion of drugs. Those bodily transformations in no way limit the uses that may be made of the admittedly natural correlations.

The Federal Circuit's elevation of these preparatory steps to case-dispositive importance rests on a two-fold misunderstanding. First, central to the court's preemption analysis was its observation that, rather than preempting all uses of the natural correlations, the claims "utilize them in a series of specific steps." App., *infra*, 15a. However, these steps are not

uses of the natural correlations, but just the opposite—natural actions that *lead up to* the natural correlations. Recitations in a claim involving machines or transformations are relevant when they show that the inventors have carved out a subset of real-world applications of a natural phenomenon, *e.g.*, by covering only particular uses of the phenomenon on a particular machine (and leaving open to the public other uses on other machines) or by applying the phenomenon in the real world by transforming something else (and leaving open to the public other transformations). That is precisely what happened in *Diehr*, where the patentee limited its claims to using the Arrhenius equation for a particular rubber molding process, and left open its use in other applications. 450 U.S. at 187-188. Prometheus, by contrast, has attempted to monopolize *all* uses of the natural, physician-recognized correlation.

Second, the Federal Circuit asserted that the preliminary steps were "specific treatment steps." In other words, the "inventive nature of the claimed methods stems * * * from the application of a natural phenomenon in a series of steps comprising particular methods of treatment." App., *infra*, 15a. But the preliminary steps are for testing, not treating. They are "nothing more than a data gathering step," which "cannot make an otherwise nonstatutory claim statutory." *In re Meyer*, 688 F.2d 789, 794 (CCPA 1982).

Prometheus's claims do not recite any amount of any drug to be given to any patient. They also say nothing about the ultimate use of the correlations, and thus cover all types of treatment, research, or any other kind of activity, as Prometheus's own expert confirmed. C.A. App. A13557-13558; see also C.A. Supp. App. A13805-13806. Patent drafters know

how to recite administration of "a therapeutically effective amount" of a drug for method of treatment claims. See, *e.g.*, *Geneva Pharms., Inc.* v. *GlaxoSmithKline PLC*, 349 F.3d 1373, 1383-1384 (Fed. Cir. 2003) ("effective amount" is "a common and generally acceptable term" in claims covering pharmaceutical treatment methods); *Rapoport* v. *Dement*, 254 F.3d 1053, 1056 (Fed. Cir. 2001) (claim to treatment method "comprising administration of a therapeutically effective amount" of a drug). Prometheus was careful not to do so here.

These fundamental errors led the Federal Circuit to cobble together two well-known preliminary steps that were already part of the "storehouse of knowledge," and attach them to an admittedly insufficient mental step, to create a sprawling monopoly for Prometheus. The court's ruling, which rewards a mere drafter's trick, was erroneous, severely chills medical researchers like Dr. el-Azhary who are trying to make life-saving improvements in medical care, and should be reversed. See *Funk Bros.*, 333 U.S. at 130-132 ("packaging" "qualities [that] are the work of nature" with elements that make no difference in the way the natural principle operates is "not enough" for patentability); *LabCorp*, 548 U.S. at 137 ("one can reduce *any* process to a series of steps. The question is what those steps embody"); *Diehr*, 450 U.S. at 192 (refusing to "allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent protection").

The implications of the Federal Circuit's approach are truly astounding. Amici have pointed out, for example, that among the "huge swaths of basic medical knowledge" that "can be removed from

the public domain" by adopting drafting tricks like Prometheus's is "foundational knowledge" in the field of organ transplantation, where the dosage of anti-rejection drugs is critical and physicians make substantial effort to adjust treatment to ensure optimal therapeutic ranges for these drugs, using measurements of drug metabolites in patients' blood. Am. Br. of Quest Diagnostics, *et al.*, No. 09-490, at 8-10. A patent in that currently unpatented area, amici point out, would interfere with physicians' ability freely to adjust dosages to meet the needs of the particular patient. *Id.* at 10-11.

Non-medical uses of blood tests could likewise be constrained by over-expansive patents. Every state, for example, currently punishes driving with a blood alcohol level at or above 0.08 percent. See INSURANCE INSTITUTE FOR HIGHWAY SAFETY, DUI/DWI LAWS (March 2011), available at http://www.iihs.org/laws/dui.aspx. A patent claim that recites drawing blood, measuring blood alcohol content, and making a determination whether that level "indicates the need" to not drive a vehicle could under the Federal Circuit's analysis preclude states from considering changes to their DUI standards without paying the patent holder a license fee.

Of course, it makes no difference that Prometheus invested time and effort in researching this biological correlation, or that it believes its formula has practical value. $E=mc^2$ is not patentable (*Chakrabarty*, 447 U.S. at 309), even though the discovery has enormous value and was preceded by time-consuming data-gathering steps.

It was not the "intent of Congress" in Section 101 that "a process claim," still less one consisting solely of universally recognized data-gathering steps and a

natural phenomenon, should "confer power to block off whole areas of scientific development" by creating "a monopoly of knowledge." *Brenner* v. *Manson*, 383 U.S. 519, 534 (1966). Because such a patent "creates a monopoly of knowledge" that removes "incentive for others to undertake a search for uses," it "should be granted only if clearly commanded by the statute"—which here it is not. *Ibid.*

II. CERTIORARI SHOULD BE GRANTED TO AVOID OVER-BROAD PATENT MONOPOLIES THAT SUBVERT MEDICAL RESEARCH AND PATIENT TREATMENT.

This Court in *LabCorp* already found the issue presented here to be certworthy. This case is an appropriate vehicle to resolve the important issue left undecided there for lack of issue preservation. The Prometheus invention is easy to understand and centered on a plain natural phenomenon. The Section 101 issue was the only issue raised on appeal, and it was addressed directly and extensively by the Federal Circuit and the district court in opinions that reached opposite results. And because the Federal Circuit has exclusive jurisdiction over patent appeals from district courts (28 U.S.C. § 1295), erroneous decisions such as this one have immediate nationwide impact. Accordingly, this Court often grants review of Federal Circuit rulings based on the importance of the issue presented to the interpretation and application of the patent laws. *E.g., Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). Review is especially warranted here because the Federal Circuit's analytical error is fundamental and will be repeated if not corrected by this Court.

The critical need for this Court to resolve that issue now is evidenced by the extensive amicus partic-

ipation in *LabCorp* and in this case, both at the Federal Circuit and previously on certiorari. Many *amici* stressed that patents like Prometheus's frustrate improvements in healthcare, drive up costs, and freeze innovation, as the dissenting Justices in *LabCorp* also recognized (548 U.S. at 138):

> [S]pecial public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of health care while inhibiting its effective delivery.

AARP pointed out in its previous amicus brief in support of certiorari that "the increased rate at which the Patent Office has granted" patents on medical correlations "has led to severe restraint on the provision of medical care and a greatly increased cost and reduced availability of vital medical services, damaging the public health of the nation." Am. Br. of AARP, *et al.*, No. 09-490, at 4, 6, 13. These adverse consequences are profound given the sweep of the Federal Circuit's ruling, and extend far beyond gastrointestinal disorders. If Prometheus can obtain a patent on correlations between drug administration and resulting biological reactions in the human body, and prevent medical researchers and providers

from thinking about those correlations in different ways, a host of medical entrepreneurs will claim patent monopolies on blood tests with the same preclusive effects. A patent claimant could seek, for example, to monopolize the correlation between administration of anticoagulant drugs and chemical reactions in the blood, asserting that these reactions are "man-made" phenomena, and thereby preclude improvements in this commonplace and essential form of medical care. Unreasonably broad patent monopolies, which have no relationship to the contribution made to the art by the patent owners, will block all improvement in entire fields of medicine.

Therapeutic drug monitoring is fundamental to safely and effectively treating a variety of patient disorders. Mayo, and physicians throughout the world, routinely measure metabolite levels in patients being treated with an array of drugs, including those for the treatment of epilepsy, heart arrhythmias, and depression. See, *e.g.*, Buster Mannheimer, *et al.*, *Impact of Multiple Inhibitors or Substrates of Cytochrome P450 2D6 on Plasma Risperidone Levels in Patients on Polypharmacy,* 30 THERAPEUTIC DRUG MONITORING 565 (2008); Svein Johannessen, *et al., Therapeutic Drug Monitoring of the Newer Antiepileptic Drugs*, 25 THERAPEUTIC DRUG MONITORING 347 (2003). Therapeutic monitoring is also important for medicines used in the treatment of organ transplant and cancer patients. See, *e.g.*, Teun van Gelder, *et al.*, *Therapeutic Drug Monitoring of Mycophenolate Mofetil in Transplantation*, 28 THERAPEUTIC DRUG MONITORING 145 (2006). Improvements in the administration of all these lifesaving drugs would be curtailed if patent claimants could assert a monopoly over every use of metabolite or other therapeutic correlations.

In this very case, Mayo sought to adjust the metabolite reference range deemed relevant by Prometheus to achieve more accurate results and improved patient care. App., *infra*, at 85a; Mayo Mem. in Support of Summary Judgment (Mar. 17, 2005), at 5-6 (Dkt. No. 15). But Prometheus blocked that innovation by asserting that it infringed Prometheus's exclusive right to specify relevant biological correlations. Prometheus thus claims the power to prevent all doctors—who considered metabolite levels on their own years before these patent claims were filed (see p. 5 n.2, *supra*)—from exercising independent medical judgment based on ordinary blood evaluations.

The harmful impact of overly broad intellectual property protection on innovation is also of more general concern for the U.S. economy. Academic commentary confirms that allowing patents to preempt important fields like medical diagnosis, by monopolizing scientific laws, would greatly increase costs and retard innovation. LAWRENCE LESSIG, THE FUTURE OF IDEAS 205-217 (2001) (describing negative impact of broad patent protection on innovation; "we should be most concerned when existing interests use the legal system to protect themselves against innovation"); WILLIAM LANDES & RICHARD POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW 305-306 (2003) (patent monopolies on "scientific principles" threaten "enormous potential for rent seeking" and "enormous transaction costs that would be imposed on would-be users"); JAMES BESSEN & MICHAEL MEURER, PATENT FAILURE 8-9, 17, 27 (2008) (patents of "mental correlations" make it "very difficult to know [the patents'] boundaries," creating the "nee[d] to check a very large number of patents," inviting "disputes and litigation," and en-

couraging "patent trolls" to "opportunistically take advantage of poor patent notice to assert patents against unsuspecting firms"); DAN BURK & MARK LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 123-124 (2009) (innovators must be able to work out new uses of abstractions and natural phenomena "without fear of patent liability" because patents "cove[r] entire concepts"); Robert Merges & Richard Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 915 (1990) ("[T]he real threat of a patent like this stems from the industry's close ties to science. * * * The Patent Office and courts should not permit the overprivatization of the scientific knowledge that makes the industry possible"); Lee Branstetter, *Do Stronger Patents Induce More Local Innovation?*, 7 J. INT'L ECON. L. 359, 369 (2004) ("well-structured research projects conducted by competent scholars" have "failed to find" innovation benefits from broad patent monopolies); Andrew Torrance & Bill Tomlinson, *Patents and the Regress of Useful Arts*, 10 COLUM. SCI. & TECH. L. REV. 130, 138, 162-167 (2009) (collecting economic research showing lack of stimulus to innovation from broad patent grants); see *Bilski*, 130 S. Ct. at 3253-3255 & nn.45-52 (Stevens, J, concurring in judgment).

At this time of paramount national concern over healthcare costs and quality, "a heavy burden of persuasion should be placed upon those who would extend such protection." Stephen Breyer, *The Uneasy Case for Copyright*, 84 HARV. L. REV. 281, 322-323 (1970) (citing research in patent and copyright fields). Prometheus has offered no such justification for its sweeping monopoly on medical thought and research.

Beyond this, the decision below cannot be reconciled with the ethical duties of physicians. As explained in the amicus brief filed in support of Mayo's prior petition by the American College of Medical Genetics and other medical organizations (at 9-11), and in the amicus brief of the American Medical Ass'n filed in *Bilski*, No. 08-964 (at 14), patent protection of Prometheus's claims conflicts with ethical standards that require physicians to spread knowledge—and improve diagnostic criteria—for the benefit of mankind.

The Federal Circuit's decision also poses exceptional threats to First Amendment freedoms. Throughout our Nation's history, the freedom to think—to consider what one has seen, to reach mental conclusions based on those observations, and to change one's future plans in light of those conclusions—has been deemed sacrosanct. Reflecting that tradition, this court held in *Ashcroft* v. *Free Speech Coalition*, 535 U.S. 234, 253 (2002), that speech is generally protected from government restriction because "[t]he right to think is the beginning of freedom, and speech must be protected from the government because speech is the beginning of thought." Federal legislation, like the patent laws, must be construed to avoid conflict with First Amendment freedoms whenever possible. See *Edward J. DeBartolo Corp.* v. *Florida Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 574-575 (1988); *New York* v. *Ferber*, 458 U.S. 747, 769 n.24 (1982); ACLU Am. Br. in *Bilski*, No. 2007-1130 (Fed. Cir. Apr. 3, 2008), at 5-7, 14, available at http://www.aclu.org/pdfs/freespeech/in_re_bilski_aclu_amicus.pdf (a patent like that at issue in *LabCorp* amounts "to a patent on pure thought or pure speech"; courts "should

interpret patent law doctrines * * * so as to avoid the difficult application of First Amendment doctrines").

The decision below would make mere thought actionable under patent law and threaten sanctions that include actual and treble damages. 35 U.S.C. § 284. Simply drawing a mental conclusion becomes, under the Federal Circuit's view, patent infringement, even without any further act. The infringement is complete when a doctor (like Dr. el-Azhary) has recognized a correlation between the patient's metabolite levels and the patient's status, regardless of what the doctor may do based on such recognition. This cannot be the legal rule in a Nation committed to the First Amendment and to the tradition of freedom of thought.

At bottom, the Federal Circuit's ruling authorizes patents monopolizing mere observation of natural phenomena that result from carrying out steps that are part of the public's storehouse of knowledge. That ruling flouts this Court's precedents and the fundamental purpose of the patent laws. And it puts a stranglehold on innovation and progress in the vital field of medical diagnosis.

CONCLUSION

The petition for a writ of certiorari should be granted to resolve the question left undecided in *LabCorp*.

Respectfully submitted.

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