No. 10-1150

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.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE RESPONDENT IN OPPOSITION

RICHARD P. BRESS
Counsel of Record
J. SCOTT BALLENGER
GABRIEL K. BELL
LATHAM & WATKINS LLP
555 11TH STREET, NW
SUITE 1000
WASHINGTON, DC 20004
rick.bress@lw.com
(202) 637-2200

Counsel for Respondent

QUESTION PRESENTED

Whether the Federal Circuit correctly held that concrete methods for individually calibrating the appropriate dosages of specific synthetic drugs for treatment of patients suffering from particular serious autoimmune diseases are patentable processes under 35 U.S.C. §101.

RULE 29.6 STATEMENT

The following companies own 10% or more of Prometheus Laboratories Inc.'s stock: Apax Partners, Patricof & Co. Ventures, Inc., DLJ Banking Partners, Wachovia Capital Partners, the Sprout Group, and St. Paul Venture Capital.

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INTRODUCTION

There is no compelling reason for this Court to review the Federal Circuit's holding, which is straightforward and fact-bound. The court of appeals held merely that a specific method for improving the treatment of patients with certain diseases by better calibrating the dosage of particular synthetic drugs is a "process" under 35 U.S.C. §101, and therefore potentially patentable if it satisfies the Patent Act's other substantive requirements, such as novelty, non-obviousness, and enablement. Petitioners distort the facts and holding in an effort to manufacture a controversial legal question warranting this Court's attention. But on any fair reading, the decision below is unremarkable and perfectly consistent with this Court's precedent. This case is not about control over doctors' thoughts; it is about petitioners' for-profit laboratory attempting to produce and sell a multimillion dollar competing test, the economic value of which would derive entirely from respondent's invention.

This Court's prior grant (and dismissal) of certiorari in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) ("*LabCorp*"), provides no reason to grant certiorari here. Because the claims here describe concrete and improved methods of treating seriously ill patients and involve the administration and biochemical transformation of specified synthetic drugs, this case does not raise the issue that troubled the dissenting Justices in *LabCorp*. Moreover, this Court recently synthesized its §101 jurisprudence in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010). The lower courts should have an opportunity to explore the important ramifications of that guidance

for medical diagnostic and treatment methods before this Court again intervenes.

STATEMENT OF THE CASE

A. Statutory Background

The Patent Act provides that "[w]hoever 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. Despite petitioners' efforts throughout the litigation to import considerations relating to those *other* conditions and requirements (such as novelty and non-obviousness), the *only* issue here is whether Prometheus's claimed treatment methods describe "process[es]."

The Patent Act defines a "process" as a "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *Id.* §100(b). These categories are construed broadly, as §101 is meant be given "'wide scope.'" *Bilski*, 130 S. Ct. at 3225 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). "Congress took this permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Id.* (quoting 5 *Writings of Thomas Jefferson* 75-76 (H. Washington ed. 1871)). The only exception is a judicially-created rule that "'laws of nature, natural phenomena, and abstract ideas'" are not themselves patentable. *Id.* at 3238 (quoting *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)).

B. The Medical Problem

Immune-mediated gastrointestinal disorders, such as Crohn's disease, and other autoimmune diseases

afflict millions of individuals. CA10007.[1] Patients with these disorders often suffer from debilitating symptoms, including diarrhea, abdominal pain, arthritis, anemia, and rectal bleeding. *Id.*; CA10009-10. Physicians can treat the disorders with synthetic thiopurine drugs, such as azathiopurine (AZA) and 6-mercaptopurine (6-MP), which transform inside the body into therapeutic metabolites that suppress the patient's immune system and mitigate the symptoms. CA10007; CA10010-11; CA13073-75; CA13201.

Physicians often find it difficult, however, to determine the proper dosage for a particular patient, because individuals metabolize the drugs differently, CA10007, and it can take 3 to 6 months for the drug to demonstrate clinical benefits, CA13074. If a dosage turns out to be too high for a patient, it can result in severe, and potentially fatal, side-effects, including allergic reactions, neoplasia (cancer), hepatitis, bone marrow suppression, and pancreatitis. CA10007; CA10012. Even "minimal doses" can have toxic effects. CA13074. Historically, many physicians were thus reluctant to treat patients with these drugs, despite the potential benefits, absent a method for preventing toxic side-effects while still ensuring efficacy. CA10007.

C. Prometheus's Claimed Treatment Methods

Prometheus is a pharmaceutical and diagnostic company that develops products that help physicians treat gastrointestinal, autoimmune and inflammatory disorders. It is the sole licensee of the two patents at

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[1] Citations in the form "CA_____" refer to the Joint Appendix in the Court of Appeals.

issue. App.2a. The patents differ in certain respects, but each describes a method of improving the treatment of autoimmune diseases by permitting physicians to individually calibrate a patient's dosage without having to take a wait-and-see approach. *See* App.2a-5a; CA00028-29. These patented methods necessarily involve transformative processes, machines, and non-naturally occurring phenomena.

First, the physician administers the man-made thiopurine drugs to a patient, and the drugs are converted within the body to particular active metabolites, such as 6-thioguanine (6-TG)[2] and 6-methyl-mercaptopurine (6-MMP). CA13073-75. These metabolites do not otherwise naturally occur in the human body. CA13073.[3]

Second, the patient's metabolite levels are determined. This requires extracting a bodily sample, such as blood or oral mucosa. CA10011-12. Because "metabolite levels are not detectable in raw human tissue," all methods for measuring their concentration require "significant chemical and physical alteration of blood or human tissue" and sophisticated laboratory equipment and machines. CA13186-87; CA13503; CA10011. Some of the patents-in-suit specify the use of high pressure liquid chromatography (HPLC), which entails an intricate series of operations on the blood (including heating, centrifuging, separating, and adding various reagents), running the resulting solution

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[2] For purposes of this brief, 6-TG also refers to 6-thioguanine nucleotides (6-TGN). *See* App.3a n.1.

[3] One of the independent claims (and its associated dependent claims) assumes that the drugs have already been administered. *See* App.18a.

through a computer-controlled chromatography instrument, calculating the peak height or peak area, and feeding those figures into an equation, which finally outputs the metabolite levels. CA13186.

Third, those calculated metabolite levels are transformed into a warning to the physician about the efficacy or toxicity of the patient's dosage. A 6-TG level "greater than about 400" and a 6-MMP level "greater than about 7000" indicate that a downward adjustment in drug dosage may be required in order to avoid toxic side-effects. CA10016-18. Conversely, a 6-TG level of "less than about 230" indicates a need to increase the dosage to ensure therapeutic efficacy. *Id.* The various independent claims each recite some combination of these three pre-determined levels. *Id.*; CA10034-35.

The patents' various dependent claims further limit the method to certain disorders (such as inflammatory bowel disease), certain thiopurine drugs (such as AZA), certain methods for determining metabolite levels (such as HPLC), certain measurement units (such as red blood cells), and certain toxic side-effects (such as hepatic toxicity). *See, e.g.*, CA10016-17 ('623 Patent, dependent claims 2, 4, 5, 6, 12, 31, 32).

D. Mayo's Competing Commercial Test

Mayo Medical Laboratories and its affiliates[4] purchased and used Prometheus's patented test over 17,000 times from 1999 to 2007. App.5a-6a; CA13136. In 2004, Mayo announced that it intended to begin selling its own competing test. App.6a; CA11566.

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[4] Hereafter, Mayo Collaborative Services dba Mayo Medical Laboratories, a for-profit entity, and Mayo Clinic Rochester are referred to collectively, or individually, as "Mayo."

Mayo's test measures the same metabolites as Prometheus's test, and specifies similar metabolite levels for ensuring efficacy and avoiding toxicity. App.6a; App.111a-12a; CA11566. Mayo was poised to earn a 60% profit margin on this competing product. CA13136.

When Prometheus brought the present suit, Mayo stayed its hand. App.6a; CA10905. Mayo has noted, however, that it is anxious to "begin selling its competitive product." Appellees' Opp. to Mot. to Stay 4 (Fed. Cir. filed Aug. 11, 2008).

E. District Court Proceedings

Prompted by Mayo's announcement, Prometheus filed this patent infringement action. App.6a; CA10036-41. Mayo counterclaimed for declaratory relief of non-infringement and of patent invalidity under 35 U.S.C. §§101, 102, 103, and 112. CA10045. On cross-motions for summary judgment, the district court held that Mayo's test "literally infringes all elements of the patents-in-suit," App.115a; CA12543; *see* CA11024; CA12228, a holding that Mayo has not challenged. But the court then granted Mayo's motion to invalidate Prometheus's claims under 35 U.S.C. §101. App.83a; CA00042.

The district court only concluded that Prometheus's claims do not describe a patentable "process" by disregarding important steps. The court held that the processes' first two steps—administration of the drug and determining resulting metabolite levels—could be ignored because they are mere "conventional" or "data-gathering" steps that are not independently novel. App.62a; CA00029. Limiting its analysis to the third—"warning"—step, the court held that that step embodies only natural phenomena because it relies on

correlations that "result[] from innate metabolic activity in the human body," App.63a-71a; CA00030-35—even though the metabolites are not naturally-occurring in the human body and result from a physical transformation of the synthetic thiopurine drugs. The court thought it irrelevant whether the claimed processes "transform" matter or data, because it believed that transformation is relevant only to the patentability of "industrial" processes. App.73a; CA00036.

The court concluded that the patents "'wholly pre-empt' use of the natural phenomenon such that the 'practical effect is [an improper] patent on the [phenomenon] itself.'" App.72a; CA00035 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)) (second alteration in original). It rejected Prometheus's argument that the patents foreclose use of the correlations only in the context of specific methods of patient treatment and do not prevent anyone from using those correlations in basic research or in the development of other treatment methods. App.75a-78a; CA00037-39.

F. Federal Circuit's First Decision And Mayo's First Cert Petition

The Federal Circuit reversed. Applying its "machine-or-transformation test," the court held that Prometheus's methods "squarely fall within the realm of patentable subject matter because they 'transform an article into a different state or thing,' and this transformation is 'central to the purpose of the claimed process.'" App.40a (citation omitted). The Federal Circuit also rejected the district court's "finding that the claims wholly preempt use of correlations between metabolite levels and efficacy or toxicity." App.47a-

48a. The court explained that the patents do not preempt all use of the correlations in the abstract, but merely describe a specific process to "utilize [the correlations] in a series of specific [treatment] steps." App.48a (citing *Diehr*, 450 U.S. at 187). The court emphasized that "the only issue" it was addressing was "whether the claims meet the requirements of §101" and that "[t]his appeal does not raise any questions about lack of novelty, obviousness, or overbreadth, since those are separate statutory requirements for patentability under §§102, 103, and 112, respectively." App.39a.

Mayo filed a petition for certiorari. While that petition was pending, this Court decided *Bilski*. The *Bilski* decision rejected two proposed "categorical" limitations on §101 patentability. First, the Court held that the machine-or-transformation test is an important tool for determining patent eligibility, but that an invention may be patent-eligible even if it does not satisfy that test. 130 S. Ct. at 3227. Second, the Court held that business method patents are not *per se* unpatentable. *Id.* at 3229. Ultimately, however, the particular business method claims at issue in *Bilski* fell short because, evaluated as a whole, they merely described the abstract idea of risk hedging and would "preempt" use of that broad concept "in all fields." *Id.* at 3229-31 (applying *Gottschalk v. Benson*, 409 U.S. 63 (1972), and *Parker v. Flook*, 437 U.S. 584 (1978), as "limited" by *Diamond v. Diehr*, 450 U.S. 175 (1981)).

In *Bilski*'s wake, this Court rejected Mayo's request for plenary review in this case, but vacated the decision below (as well as another Federal Circuit decision finding certain medical methods

*un*patentable[5]) and remanded for further consideration in light of *Bilski*. App.24a.

G. Federal Circuit's Second Decision

After supplemental briefing, the Federal Circuit again held Prometheus's methods patentable under §101. The court explained that, under *Bilski*, patent eligibility turns on whether Prometheus's claims "are drawn to a natural phenomenon, the patenting of which would entirely preempt its use as in *Benson* or *Flook*, or whether the claims are drawn only to a particular application of that phenomenon as in *Diehr*." App.12a (citing *Bilski*, 130 S. Ct. at 3230). It concluded that the claims "do not wholly preempt all uses of the recited correlations" between metabolite levels and efficacy or toxicity, but instead "involve a particular application of the natural correlations." App.15a. The court explained that "the claims do not preempt all uses of the natural processes" because they "utilize them in a series of specific steps … comprising particular methods of treatment." *Id.* (citing *Diehr*, 450 U.S. at 187). As in *Diehr*, Prometheus's method patents "'seek only to foreclose from others the use of that [principle] in conjunction with all of the other steps in their claimed process.'" *Id.* (quoting *Diehr*, 450 U.S. at 187).

The Federal Circuit also found that the claims satisfy the "transformation prong" of the machine-or-transformation test, which, as *Bilski* explained, remains a "'useful and important clue, an investigative tool'" to patentability. App.14a-15a (quoting *Bilski*, 130 S. Ct. at 3227). The court found that the methods

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[5] *See Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F. App'x 866 (Fed. Cir. 2008), *cert. granted, vacated and remanded*, 130 S. Ct. 3541 (2010).

transform an article into a "'different state or thing'" and that this transformation is central to the purpose of the claimed process. App.14a-16a (quoting *Bilski*, 130 S. Ct. at 3227). Specifically, it determined that the method claims entail at least two transformations. First, "[w]hen administering a drug such as AZA or 6-MP, the human body *necessarily* undergoes a transformation" in response to the administration of these synthetic drugs. App.17a. Second, "[d]etermining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation." App.18a. The court explained that the determining step "clearly" involves "a transformation" because "[s]ome form of manipulation, such as the high pressure liquid chromatography … is necessary to extract the metabolites from a bodily sample." *Id.* Indeed, "'at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue.'" *Id.* (citation omitted).

The Federal Circuit determined further that these transformations cannot be disregarded as "mere[] data-gathering" or "'insignificant extra-solution activity.'" App.18a-19a (citing *Flook*, 437 U.S. at 590). The court found that "[t]he invention's purpose to treat the human body is made clear in the specification and preambles of the asserted claims." App.17a. It explained, therefore, that "the administering step provides thiopurine drugs *for the purpose of treating disease*, and the determining step measures the drugs' metabolite levels *for the purpose of assessing the drugs' dosage during the course of treatment*." App.20a (emphasis added). Those transformations are not peripheral or tacked-on, but "central to the claimed methods" and "'sufficiently definite to confine the

patent monopoly within rather definite bounds.'" App.18a (quoting *Benson*, 409 U.S. at 70).

Finally, the Federal Circuit explained that the inclusion of a mental step—even as the final step—does not render an otherwise patentable process unpatentable. App.21a-23a. Thus, in this case, "[a]lthough a physician is not required to make any upward or downward adjustment in dosage during the 'warning' step," the process, taken as a whole, "provide[s] useful information for possible dosage adjustments to the method of treatment using thiopurine drugs for a particular subject." App.23a.

Mayo did not seek rehearing.

REASONS FOR DENYING THE WRIT

In an effort to manufacture a legal question meriting this Court's review, Mayo attacks a straw man that bears little resemblance to the method claims actually at issue in this case. On any fair reading of the record, the decision below is an unremarkable application of longstanding principles, as reiterated in *Bilski*, to the particular facts of this case.

Prometheus's technique of combining knowledge derived from scientific discovery with useful physical activities to achieve a functional end plainly satisfies §101. The patents do not claim or preempt any purely natural phenomenon. They describe physical steps such as administering man-made drugs, drawing blood samples, and testing blood for metabolites, within an improved method for treating seriously ill patients. Each of the first two steps *standing alone* would plainly constitute a "process" that satisfies §101. Combining them, along with new knowledge, could not possibly make them less of a "process."

These patents do not claim correlations between metabolite levels and toxicity/efficacy in the abstract, but instead apply those relationships in concrete physical processes to generate useful treatment information for physicians. In that regard they are indistinguishable from the method patent this Court approved in *Diamond v. Diehr*, 450 U.S. 175 (1981), which employed an observed "natural" correlation (the Arrhenius equation) in a process for optimizing the time that rubber is left curing in a mold. *All* processes that operate in the physical world employ natural laws at some point in the process.

Rather than confronting these truths, Mayo misrepresents the scope of the patents and distorts the Federal Circuit's holding in two fundamental ways. First, Mayo wrongly asserts that the patented methods merely claim a "physician's mental determination[]" or "thought process[]," Pet.4-5, and that the methods consist of nothing more than natural phenomena and medical knowledge, Pet.17-19. Mayo (like the district court) goes astray by focusing only on the one step in the process that relies on a natural correlation or "mental step," while ignoring all the other concrete steps that confine the patent's scope. The plain language of the claims, as the court of appeals found, establishes a concrete treatment method involving specific physical steps to administer synthetic drugs, measure metabolites, and produce valuable information for use in calibrating further treatment. Mayo's attempts to ignore those undeniable physical steps—either because they were not invented by Prometheus, Pet.5, 24, or because Mayo views them as mere "data-gathering," Pet.25, 27—are contrary to the record and the law. And the idea that the administration of a

potentially toxic drug is simply "for testing, not treating," Pet.25, disregards the Federal Circuit's claim construction (and defies common sense). The Federal Circuit properly determined that the asserted claims, viewed *as a whole*, are "claims to methods of treatment" whose "purpose [is] to treat the human body." App.16a-17a.

Second, Mayo attempts to generate a conflict with this Court's precedents by misrepresenting the Federal Circuit's holding. Mayo argues that the Federal Circuit "broadly extend[ed] the 'machine or transformation' test" and "fail[ed] to give effect to the 'preemption' standard for patent-eligibility." Pet.15; *see also* Pet.24. Neither is true. The Federal Circuit faithfully applied this Court's precedent, as recounted in *Bilski*. It explained that "the claims do not preempt all uses of the natural correlations" but instead "utilize them in a series of specific steps." App.15a (applying *Diehr*, 450 U.S. at 187). And it considered the integral involvement of physical transformations as a "'useful and important clue, an investigative tool'" that in this case "leads to a clear and compelling conclusion, *viz.*, that the present claims pass muster under §101." App.14a-15a (quoting and applying *Bilski v. Kappos*, 130 S. Ct. 3218, 3227 (2010)). Mayo disagrees with the lower court's application of established law to these facts, but that is not a basis for this Court's review.

The petition's only superficial appeal is that this Court previously granted certiorari in *LabCorp*, and the patent in *LabCorp* also involved medical "correlations." But this case does not genuinely present the issue that troubled the dissenting Justices in *LabCorp*. The patent there did not involve the administration of synthetic (or, indeed, any) drugs as

part of a course of treatment for a particular disease. The *LabCorp* patent involved merely the observation of certain biological markers that exist in nature without any human agency or intervention at all, and the drawing of conclusions from that data. This Court may wish to revisit the *LabCorp* issue at some point, but it is not well presented here.

In addition, *LabCorp* preceded this Court's foundational §101 opinion in *Bilski*, which rejects "categorical limitations" on §101 in favor of case-by-case development of the law. 130 S. Ct. at 3225, 3228. The proper application of §101 in the context of medical diagnostic and treatment patents is of great importance to the public health and to multi-billion dollar industries. No doubt some of these patents will survive §101 scrutiny and others will fail. But the lower courts have barely begun to wrestle with the appropriate distinctions, particularly in light of the analysis synthesized in *Bilski*. This Court should not reach out to make wide-ranging new law on questions this important without the benefit of lower courts' development of the issues in various concrete settings.

Accordingly, the petition for a writ of certiorari should be denied.

I. MAYO'S PETITION DISTORTS THE FACTS AND RECORD BELOW

Mayo's petition is built on two fundamental distortions.

First, Mayo repeatedly asserts that the methods consist solely of a mental step. As the Federal Circuit recognized, that is not accurate. On their face and as construed by the Federal Circuit, these patents claim a concrete method of patient treatment that includes

physical steps which cannot possibly be practiced merely by thinking about scientific knowledge. Mayo believes that those physical steps should be disregarded because they are not the point of novelty of Prometheus's method claims (*i.e.*, not what Prometheus invented). *See, e.g.*, Pet.i, 3, 5 & n.2, 15, 24, 26, 30. But this Court squarely rejected that approach to §101 in *Diehr*. On any fair reading of the actual patent language, Mayo's concerns completely disappear.

Second, Mayo attempts to generate a conflict with this Court's precedents by asserting that the Federal Circuit "broadly extend[ed] the 'machine or transformation' test and fail[ed] to give effect to the 'preemption' standard for patent-eligibility." Pet.15. Both assertions are flatly incorrect. The court of appeals appropriately considered, and rejected, Mayo's preemption argument because it recognized that the patents here do not "preempt" any natural phenomena except in connection with the concrete steps specified on the face of the patents. *All* patents "preempt" specific applications of natural laws or phenomena in that sense, because nothing happens that is not governed by natural laws. And the court's consideration of the transformations that are integral to the claimed treatment method was perfectly consistent with *Bilski*'s reaffirmation of the importance of such analyses. The court's ruling was thus based on established principles, and does not conflict with any of this Court's opinions.

Once those erroneous characterizations are put aside, it is clear that the Federal Circuit's decision is well grounded in this Court's doctrine. Mayo's disagreement with the outcome provides no reason for

this Court's intervention.

A. Mayo Misrepresents the Purpose and Scope of the Patents-in-Suit

At root, Mayo simply disagrees with the Federal Circuit's claim construction, but that is no ground for this Court's review. In particular, Mayo refuses to acknowledge that these patent claims, as carefully examined by the Federal Circuit, describe concrete treatment methods involving specific steps to administer certain drugs to a patient, measure specific metabolites, and produce valuable information for use in calibrating that patient's treatment. The patents cannot be infringed by mere thought.

Mayo offers a variety of arguments for why this Court should disregard the concrete physical steps required to infringe these patents. Mayo argues, for example, that the administration and determination steps are old in the art, Pet.i, 3, 5 & n.2, 15, 24, 26, 30, and that the inventive portion of the patents targets pure mental processes, Pet.22-27; that the transformation resulting from administering the drugs is merely preparatory "data gathering," Pet.25, or a "natural" phenomenon, Pet.21, 24; and that the patents as a whole are not really about patient treatment, *e.g.*, Pet.25-26. None of these contentions has merit.

1. Mayo and its *amici* repeatedly try to import novelty analysis into §101 by arguing that the physical, transformative steps of the patents should be disregarded because those steps were previously well known in the art—and that without those steps all that remains is a mental step. *See, e.g.*, Pet.i, 3, 5 & n.2, 15, 24, 26, 30; Brief of *Amici Curiae* the American College of Medical Genetics et al. in Support of Petitioners 5, 13 ("ACMG Br."). For example, Mayo protests that

Prometheus "cobble[d] together two well-known preliminary steps" and then attached an "admittedly insufficient mental step." Pet.26. According to Mayo and its *amici*, Prometheus's claims are not patentable because what the patents "purport to add [to the art] is a recognition that *particular metabolite levels* are relevant to proper drug dosages." Pet.5; *see also* ACMG Br.5, 13.

The Federal Circuit properly recognized that "the claims are not simply to the mental steps," App.21a, and that viewed "as a whole" the processes at issue here do not consist simply of novel "correlations," App.23a. Mayo's contention that what is "novel" is improved accuracy in dosage adjustments does not make the process as a whole any less of a process.

One way to understand this point is that, as the Federal Circuit found, the initial physical steps of Prometheus's methods—administering thiopurine drugs, drawing blood, and determining metabolite levels—clearly describe "processes" that would be patent eligible under §101 and patentable by their inventor so long as the Patent Act's other requirements are met. App.21a-22a. Adding an additional step—warning the physician of a possible need to adjust dosage based on specific measurement levels—does not make the processes, individually or in the aggregate, suddenly not processes any more. App.22a ("In the instant case, the presence of the mental steps similarly does not detract from the patentability of the administering and determining steps."). Indeed, Mayo and its *amici* have effectively conceded that the patents-in-suit would satisfy §101 if Prometheus had invented either thiopurine drugs or HPLC. *See, e.g.*, Pet.5 & n.2; Pet. for Writ of

Certiorari, No. 09-490, at 18 (Oct. 22, 2009) ("Prometheus cannot take advantage of a drug that was invented by someone else …."); ACMG Br.8 (implicitly acknowledging that "a new diagnostic test, or even a new method of diagnosing a particular disease" is patentable under §101). But whether a patent properly describes a "process" or instead an unpatentable "natural law" does not turn on who invented what.

Mayo's continued attempt to dissect these patents into old and new steps, and to ignore the latter for purposes of determining whether they describe a "process" under §101, is flatly inconsistent with longstanding precedents of this Court. In *Diehr*, this Court squarely held that process claims "must be considered as a whole," and that "[i]t is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." 450 U.S. at 188; *see also id.* at 193 n.15 ("The fact that one or more of the steps in respondents' process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under §101."). This Court reiterated these settled principles in *Bilski*. 130 S. Ct. at 3230-31. Mayo is attempting to reintroduce a conceptual error that this Court decisively banished from the law thirty years ago.

2. Mayo also argues that the initial physical steps of these patents should be ignored on the ground that they supposedly have no purpose beyond "data gathering"—they are "for testing, not treating." Pet.25. Again, the Federal Circuit rejected Mayo's assertion on the facts—correctly recognizing that the

"administering" and "determining" steps of these patents *do not* merely describe the gathering of data for an abstract equation, but rather are concrete physical steps in an ongoing method for treating desperately ill patients. "While it is true that the administering and determining steps gather useful data," that is not their sole purpose, as those two steps are integrally "part of a treatment protocol." App.19a-20a. No patient is given thiopurine drugs solely for purposes of gathering data for an equation, nor would it be ethical to do so.

Mayo also argues that the patents cannot constitute patentable treatment methods because the final step does not *require* an adjustment of dosage. Pet.22-23, 25. That argument is also misguided. The patents describe methods that produce information useful to treatment decisions. But how a doctor incorporates that information into treatment decisions may be affected by other, unrelated variables. The Federal Circuit correctly understood that "[a]lthough a physician is not required to make any upward or downward adjustment in dosage during the 'warning' step, the prior steps provide useful information for possible dosage adjustments to the method of treatment." App.23a. Thus, "[t]he addition of the mental steps to the claimed methods … does not remove the prior two steps from that realm." App.21a.

Mayo has identified no precedent that conflicts with the Federal Circuit's conclusion that a process patent can end with a mental step. Far from being "unprecedented," Pet.22, there are literally thousands of patents on medical and other methods that "end" by providing the user with useful information. The lower courts have long recognized that such processes are

patentable. *See, e.g.*, *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1054 (Fed. Cir. 1992) (upholding diagnostic patent producing information about patient's heart risk); *In re Abele*, 684 F.2d 902, 904, 908 & n.9 (C.C.P.A. 1982) (upholding patent on use of algorithm to improve usefulness of information provided by CAT scans, and noting that "'the fact that [the] equation is the final step is not determinative of the section 101 issue'") (citation omitted) (alteration in original); *see also Griffin v. Bertina*, 285 F.3d 1029, 1031 (Fed. Cir. 2002) (addressing patent that correlates gene mutations to risk of thrombosis); CA12939-3013 (collecting numerous such patents).

There is, moreover, no good reason why physical processes that produce useful information should, as a class, be unpatentable. The gist of Mayo's position is that a valid patent must direct the doctor to take a final, physical step or steps in response to the information generated. But (as Mayo well knows) modern medicine is far too individualized for that kind of patent drafting to be practical or desirable. Specifying exactly what a treating physician must do with useful diagnostic or treatment information would require patents to contain infinitely complex decision trees that would likely become obsolete long before the patent term expires.

Such an arbitrary and unwieldy regime would strangle rewards for innovation in biotechnology, medical diagnosis, and personalized medical care—fields in which U.S. businesses have become global leaders. *See, e.g.*, Brief of *Amicus Curiae* American Intellectual Property Law Association in Support of Appellant, No. 2008-1403, at 18-21 (Fed. Cir. Jan. 22, 2009) ("AIPLA C.A.Br."). It would also fly directly in

the teeth of *Bilski*, which denounces judicially created categorical exclusions that usurp Congress's prerogative. 130 S. Ct. at 3225-26 (stressing that §101's terms are "expansive" and that judiciary does not have "*carte blanche*" to impose new limitations); *id.* at 3227 (Kennedy, J., plurality opinion) (disavowing intent to "create uncertainty as to the patentability of … advanced diagnostic medicine techniques"). Indeed, federal law has "explicitly contemplate[d] the existence" (*id.* at 3228) of medical method patents since at least 1996, when Congress responded to the medical community's concerns about infringement liability by immunizing certain uses of such patents rather than limiting patent eligibility. *See* 35 U.S.C. §287(c); John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 Wm. & Mary L. Rev. 609, 634-37 (2009).

3. Although they concede that the drugs and metabolites at issue are not "naturally occurring," Mayo and its *amici* argue that Prometheus's treatment methods are not patentable because the metabolites are created by the body's "natural reaction" to these foreign substances. *See, e.g.*, Pet.24; Brief of Quest Diagnostics et al. as *Amici Curiae* in Support of Petitioners, No. 09-490, at 15 (Nov. 25, 2009) ("Quest Br.").

From the beginning of this litigation, Mayo has pretended that the patents-in-suit claim only "natural phenomena" while steadfastly ignoring the process steps that require concrete human actions. Once a drug is introduced into the human body, its metabolic effects can be predicted (and correlated) according to natural laws. But diagnostic and treatment patents that employ similar effects and correlations—such as

patents on methods of administering new drugs—are routine and uncontroversial, and have never been thought to implicate the rule against patenting natural phenomena. Mayo's contrary argument harkens back to the discredited view that "all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body," which was rejected over fifty years ago in *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (B.P.A.I. 1954).

The correlations exploited by Prometheus's patented methods embody a truth about how the physical world responds to human intervention—in the same way that the Arrhenius equation, embedded in the patent upheld in *Diehr*, expressed a truth about the physical properties of rubber when heated under pressure. Mayo's argument that these patents are suspect because they employ "naturally-occurring correlations" thus could be deployed against essentially any process, including the one in *Diehr*.

As the Federal Circuit explained, "quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law." App.17a. The Federal Circuit properly recognized that any natural laws implicated in the patents-in-suit are incorporated in the context of physical processes that rely on multiple transformations. App.16a-19a.

That analysis is consistent with this Court's precedents—which have identified transformations as "a useful and important clue" to patentability of processes not involving a particular machine. *Bilski*, 130 S. Ct. at 3227; *see also Diehr*, 450 U.S. at 184; *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972). *Diehr*, for example, recognized that, while "all inventions can be

reduced to underlying principles of nature," 450 U.S. at 189 n.12, there is no concern about preempting natural phenomena where methods inherently involve transformations or necessarily require machines and thus "seek only to foreclose from others the use of that [principle] in conjunction with all of the other steps in their claimed process," *id.* at 187. As the Federal Circuit determined, Prometheus's methods are patentable because they require multiple transformations and cover a "particular application" of natural processes to treat "a specific disease by administering specific drugs and measuring specific metabolites." App.15a.

The Federal Circuit's decision is fully consistent with *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, where this Court rejected an attempt to patent a combination of natural bacteria exhibiting nothing more than their natural qualities. 333 U.S. 127 (1948). There is nothing purely natural about administering synthetic drugs and deriving diagnostic information from levels of the resulting metabolites found nowhere in nature. Neither the drugs nor the patient's reaction exhibit "natural" qualities (indeed, the body's natural immune system is *suppressed* by the drugs). The Federal Circuit's decision is also consistent with *Diamond v. Chakrabarty*, where this Court held that genetically-engineered bacteria *are* patentable because they did not exist in nature. 447 U.S. 303, 310 (1980).

In sum, contrary to the assertions of Mayo and its *amici*, the decision below is consistent with this Court's precedents, as Prometheus is not attempting to patent "'basic medical knowledge,'" Pet.26 (quoting Quest Br.8-10), but instead concrete processes employing several categories of patentable subject matter.

4. Mayo protests that the patents-in-suit might randomly ensnare doctors and researchers who do nothing more than inadvertently hear or think about the identified correlations between metabolite levels and drug efficacy or toxicity. *See, e.g.*, Pet.9, 22, 29-30. That is plainly incorrect. As the Federal Circuit found, no one infringes Prometheus's treatment patents merely by thinking about correlations. App.21a-23a. Infringement occurs only after potentially toxic drugs are administered to an ill patient, blood samples are extracted, metabolite levels are measured using sophisticated scientific instruments, and a warning is provided about a possible need to adjust dosage. App.21a-22a ("[A] physician who only evaluates the result of the claimed methods, without carrying out the administering and/or determining steps that are present in all the claims, cannot infringe ...."). Those steps are not taken inadvertently, and once they are completed the benefits of the patented process have been realized—even if the patient's doctor ultimately makes a medical decision not to adjust treatment.

Mayo's protestations about unwittingly ensnared doctors are also disingenuous because Mayo admits that it wants to sell a multimillion dollar competing test to those same doctors. This case is about the infringing business plans of Mayo's for-profit diagnostic laboratory. As Mayo concedes, Prometheus does not sue doctors and did not sue Dr. el-Azhary. *See* CA10036-41, CA12595-600; CA12758-59; CA12786-87; CA12820-21. Instead, Prometheus sued the Mayo entities for infringing the patents "directly, contributorily, and by inducement of others," such as Dr. el-Azhary. CA12596.

Mayo makes much of the fact that "Dr. el-Azhary is

a dermatologist" and therefore purportedly unconcerned with the treatment protocols and metabolite ranges addressed by these patents. Pet.8-9, 22. But that is untrue. Mayo neglects to mention that the patients in Dr. el-Azhary's study were being treated for *autoimmune* dermatological conditions expressly covered in the patents. *See* CA12853-54. In particular, the patients were being treated for a "non-IBD autoimmune disease"—specifically, "an autoimmune dermatological condition, such as bullous pemphigoid and pemphigus vulgaris." CA12787; CA12820-21; CA12853. Several claims in the patents-in-suit require "administering a drug providing [6-TG] to a subject having [a] non-IBD autoimmune disease," CA10017, such as "pemphigus vulgaris," CA10014. This again highlights Mayo's persistent pattern of distorting the patents and refusing to read them as written.

B. The Federal Circuit's Fact-Specific Analysis Does Not Conflict With This Court's Preemption Standard

Mayo argues that 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." Pet.15. Mayo is incorrect on both counts. The Federal Circuit's analysis is an unremarkable application of established principles to the facts of this case.

1. The Federal Circuit correctly recognized that the claims do not preempt natural processes because they only cover a "particular application" of natural processes to treat "a specific disease by administering specific drugs and measuring specific metabolites" and

"utilize [natural processes] in a series of specific steps." App.15a. Quoting *Diehr*, the Federal Circuit explained that the claims here "'do not seek to preempt the use of [a fundamental principle]'" but instead "'seek only to foreclose from others the use of that [fundamental principle] in conjunction with all of the other steps in their claimed process.'" *Id.*

The judicially-created prohibition on patents that "preempt" natural laws or phenomena is directed at patents that attempt to monopolize broad scientific principles in the abstract, like a patent on the Pythagorean Theorem, the Ideal Gas Law, or "the basic concept of hedging, or protecting against risk." *Bilski*, 130 S. Ct. at 3231. The patents here only "preempt" use of the indicated correlations in connection with the use of specific synthetic drugs and medical treatment steps—in the same way that all patented methods can be said permissibly to "preempt" specific applications of the natural principles they employ.[6] They do not preempt natural principles in any relevant (and prohibited) sense. They do not, for example, attempt to monopolize the general concept of diagnosing abnormalities, like patents the Federal Circuit has previously invalidated. *See In re Grams*, 888 F.2d 835, 836 (Fed. Cir. 1989) (process applies to "any complex system, whether it be electrical, mechanical, chemical [or] biological"); *In re Meyer*, 688

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[6] Examples include using time and temperature to cure rubber, using heat to incubate eggs, using gravity and puffs of air to separate out flour impurities, and using a blast of hot air to improve a smelting furnace. *See Diehr*, 450 U.S. at 188; *Waxham v. Smith*, 294 U.S. 20, 21 (1935); *Cochrane v. Deener*, 94 U.S. (4 Otto) 780, 784-88 (1876); *Neilson v. Harford*, 151 Eng. Rep. 1266, 1273-75 (Ex. Ct. 1841).

F.2d 789, 790 (C.C.P.A. 1982) (process applies to undefined "complex system" and indeterminate "factors" drawn from unspecified "testing"); App.20a-21a (distinguishing *Grams*). Nor do they claim a general protocol for calibrating *all* drug dosages for *all* diseases. They offer a particular means of calibrating "a method of treatment for *particular* diseases using *particular* drugs." App.23a (emphasis added).

On their face, Prometheus's patents do not even foreclose other means of treating *these particular* autoimmune diseases with *these particular* thiopurine drugs. Doctors and scientists are free to develop new ways to treat these diseases and to calibrate the drugs at issue. One can easily imagine, for example, development of a method for measuring metabolite levels that does not require analysis of a bodily sample or a *pre*-treatment diagnostic test to determine the proper dosage for each individual. Such innovations are in no way preempted by Prometheus's patents. Prometheus's claims make no attempt to cover all possible solutions to the particular problem of calibrating thiopurine drugs for treatment of specific auto-immune diseases.

Prometheus's specific, particularized treatment methods look nothing like the abstractions rejected in *Benson*, 409 U.S. at 68 (where the use could "vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents"), or *Flook*, 437 U.S. at 586 (where there were a "broad range of potential uses of the method" because "[a]ll that it provides is a formula"). As the Federal Circuit held, "[t]he inventive nature of the claimed methods stems not from preemption of all use of these natural processes, but from the application of a natural

phenomenon in a series of transformative steps comprising particular methods of treatment." App.15a. And they do not even arguably preempt researchers' use of the indicated correlations to perform statistical analysis on historical patient data. For all of its complaining about "countless researchers and innovators who are paralyzed by patent monopolies like Prometheus's," Pet.19, Mayo has yet to identify any use that is preempted aside from its desire to market a competing commercial test for the exact same specific application.

2. The Federal Circuit's application of the machine-or-transformation analysis was also unremarkable—not a "Broad Extension." Pet.24. Mayo's real quibble is that it does not agree with the Federal Circuit's application of that test to the facts of this case—fundamentally, because Mayo disagrees with the Federal Circuit's reading of the patents-in-suit. But this Court has never granted certiorari in a case merely to construe the plain language of a patent.

As applied below, the machine-or-transformation test requires courts to determine not just whether the physical process steps entail transformations or machines but also whether those steps are *integral* to the purpose of the patent—*i.e.*, not merely as field of use limitations, data gathering, or other "insignificant extra-solution activity." App.19a. That analytic approach is fully consistent with, and flows from, the approach this Court took in *Diehr* and in *Bilski*. In *Diehr*, this Court held that the rubber curing processes at issue did not "seek to pre-empt the use of [a well-known mathematical] equation" because they "seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed

process"—steps that are "transformation[al]" and not mere field of use limitations or "insignificant postsolution activity." 450 U.S. at 187, 184, 191. Conversely, in *Bilski*, this Court held that "[t]he concept of hedging … is an unpatentable abstract idea." 130 S. Ct. at 3231.

Although Mayo persists in its view that the patents-in-suit are more analogous to the abstractions rejected in *Benson* and *Flook*, *see* Pet.22-24, the Federal Circuit rightly found that Prometheus's claimed methods for optimizing the treatment of particular diseases through the improved calibration of dosages of specified drugs are most akin to the patented application of fundamental principles in *Diehr*, *see* App.15a. The Federal Circuit's opinion is in this respect a routine, fact-specific application of this Court's doctrine.

II. REVIEWING THE SCOPE OF §101 IN THE CONTEXT OF MEDICAL DIAGNOSTIC METHODS IS PREMATURE

Stripped of the mischaracterizations and manufactured conflicts, Mayo's principal argument is that certiorari is warranted here because the Court previously granted (then dismissed) certiorari in *LabCorp*. Pet.2-4, 16-21, 26, 28-29, 34; Brief of *Amici Curiae* AARP and Public Patent Foundation in Support of Petitioners 3-7 ("AARP Br."); ACMG Br.21; Quest Br.12. That argument is wrong for two reasons.

A. *LabCorp* Presented Different Issues and Provides No Basis for Granting Review

This case does not genuinely present the issues that made *LabCorp* difficult. Unlike the processes in *LabCorp*, Prometheus's processes are directed not merely at observing a naturally-occurring characteristic of the body, but at *treating* (transforming) the body by administering a safe and effective dose of a synthetic drug. The patent in *LabCorp* essentially consisted of measuring homocysteine levels and drawing conclusions from the "natural relationship between homocysteine and vitamin deficiency" that exists in any "warm-blooded animal," 548 U.S. at 129, 134 (Breyer, J., dissenting). The processes embodied in the patents-in-suit involve administering a specific synthetic drug, measuring metabolic byproducts that, absent that human intervention, would exist nowhere in nature, and considering whether the results warrant an adjustment in the patient's dosage.[7] As the American Intellectual Property Law Association explained below, there are "significant distinctions" between these patents and those in *LabCorp* because "the context of the invention in this case is the physical transformation of drugs into metabolites that can be measured to provide valuable diagnostic information" and "[t]his physical transformation is integral to the invention and establishes patent eligibility." AIPLA C.A. Br.10.

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[7] Prometheus does not argue that patentable processes must employ synthetic—as opposed to natural—drugs, only that doing so here removes any doubt as to patentability.

The Federal Circuit correctly recognized that *LabCorp* "involved different claims from the ones at issue here." App.16a n.2.[8] The Federal Circuit has previously suggested that the *LabCorp* methods might be unpatentable. *In re Bilski*, 545 F.3d 943, 965 & n.27 (Fed. Cir. 2008) (en banc). It is unnecessary for this Court to prejudge the Federal Circuit's consideration of those issues with a preemptive strike—particularly in a case that does not squarely present them.

B. The Federal Circuit Has Only Just Begun to Apply §101 To Medical Diagnostic and Treatment Methods In the Wake of *Bilski*

The application of §101 to medical diagnostic and treatment methods is in its infancy, and the district courts and the Federal Circuit should have an opportunity to explore the important distinctions in various concrete settings before this Court attempts to craft a comprehensive solution.

Just last year, in *Bilski*, this Court synthesized its precedents on §101. In addressing the business method patent in *Bilski*, however, this Court disapproved the imposition of judge-made "categorical limitations" on patentability, 130 S. Ct. at 3225, and left the further development of the law—including questions about "the patentability of software, advanced diagnostic

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[8] The Federal Circuit also rightly rejected Mayo's argument that a majority of this Court has approved of the *LabCorp* dissent's opinion of the diagnostic method claim at issue in that case. On Mayo's view, apparently, just citing (or joining an opinion that cites) an uncontroversial sentence in an opinion means that a Justice endorses every aspect of the cited opinion. *See* Pet.17-18.

medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals," *id.* at 3227-28 (plurality opinion)—to future case-by-case resolution. *See id.* at 3231 ("The Court … need not define further what constitutes a patentable 'process,' beyond pointing to the [statutory] definition … and looking to the guideposts in *Benson*, *Flook*, and *Diehr*.").

The scope of §101 is obviously of great importance in patent law, with widespread effects across many industries. This case is the Federal Circuit's first post-*Bilski* application of §101 to a medical method. The development of the law would benefit from the district courts' and Federal Circuit's consideration in the first instance of the various gradations of medical diagnostic and treatment methods on the spectrum between *Prometheus* and *LabCorp* and beyond.

Amici present a parade of "unthinkable" horribles as "*plausible* applications of the Federal Circuit's ruling" in this case. ACMG Br.13 (emphasis added). But, of course, the Federal Circuit, and ultimately this Court, will have plenty of opportunities to consider the difficult cases if and when they arise. There are cases raising a variety of issues percolating up through the lower courts.[9] The Federal Circuit was created

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[9] *See, e.g.*, *Ass'n for Molecular Pathology v. U.S. PTO*, No. 2010-1406 (Fed. Cir. argued Apr. 4, 2011) (addressing, inter alia, whether certain genetic testing methods satisfy §101); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 F. App'x 866 (Fed. Cir. 2008) (holding certain diagnostic methods unpatentable under §101), *cert. granted, vacated and remanded*, 130 S. Ct. 3541 (2010); *see also King Pharms., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501, 512-13 (E.D.N.Y. 2009) (holding certain medical methods fail

precisely for such situations—so that a specialist court could forge consistent nationwide patent law by grappling with challenging questions across a variety of factual circumstances. This Court should not reach out to make sweeping new law without the benefit of further development of these issues in concrete settings. Intervention now would be premature.

III. ADOPTION OF MAYO'S ARGUMENTS WOULD HAVE SERIOUS ADVERSE CONSEQUENCES FOR MEDICAL DIAGNOSTICS AND PERSONALIZED MEDICINE PATENTS

Mayo's policy arguments (echoed by some of its *amici*) reduce to a contention that the entire field of medical diagnosis and treatment would be better off without the patent system. *See* Pet.24-27; ACMG Br.3 ("The AMA opposes the patenting of medical procedures ...."). Mayo and its *amici* would prefer a regime in which doctors, hospitals, and for-profit medical laboratories (like Mayo's) could practice any medical method without paying patent royalties. Indeed, all of Mayo's stated concerns about "allowing patents to preempt important fields"; providing quality treatment "with an array of drugs, including those for the treatment of epilepsy, heart arrhythmias, and depression"; and "healthcare costs," Pet.30-32, would apply with equal force to the patentability of drugs or medical devices, so presumably Mayo wishes they were not patentable either. Such a regime would have certain advantages, although of course the flip-side of Mayo's vision is that pioneers and innovators in these

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under §101), *aff'd in part on other grounds*, 616 F.3d 1267 (Fed. Cir. 2010).

fields would not be incentivized by the rewards the patent system offers.

Suffice it to say that Congress has made a different judgment. In 1995, Congress considered exempting certain medical methods from patent protection, but declined to do so. H.R. 1127, 104th Cong. (1995). In 1996, Congress specifically addressed Mayo's concerns about patent liability for doctors by providing a limited immunity from patent infringement liability for the performance of certain medical procedures, but Congress pointedly *did not* exempt such procedures from patent protection generally. 35 U.S.C. §287(c); *see* Pub. L. No. 104-208, §616, 110 Stat. 3009, 3009-67 (1996). The upshot is that individual doctors generally are immune from suit, but the commercial entities that enable and induce the infringement (such as Mayo's for-profit laboratory) are not. This Court has previously found such factors significant in construing §101. *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 145 (2001) (Congress "not only failed to pass legislation indicating that it disagrees with the PTO's interpretation of §101, it has even recognized the availability of utility patents for plants.").

Mayo may be right that physicians in the course of patient care are less able to avoid patent infringement than professionals in other fields, because avoiding the patented method may be inconsistent with the physician's ethical obligations to his patient. *See* Pet.33; ACMG Br.5-6, 9-10. But that has nothing whatsoever to do with appropriate interpretation of the language of §101. *Amici* state that "[i]t is hard to imagine how the clinical diagnostic community will continue to provide quality patient care and how physicians will continue to practice medicine in an

ethical and effective manner under such a regime." ACMG Br.6. Nonsense. Mayo has no difficulty fulfilling its ethical obligations; it just has to pay inventors their appropriate reward as determined by the patent system.

Many crucial innovations in medical diagnostics and treatment involve a combination of previously-known physical steps along with mental steps or algorithms that improve the process. Rapid advances in personalized medicine will make innovations of that nature even more important than ever before, as inventors discover how existing treatments can be modified or calibrated to reflect an individual patient's particular biology. Citing "'the industry's close ties to science'" and the current "paramount national concern over health care costs and quality," Pet.32 (citation omitted), Mayo and its *amici* argue that patentability somehow will hinder the development of such personalized medicine and scientific research. *See* Pet.29-32; AARP Br.6; ACMG Br.13-16; Quest Br.15-21. But none explains why medical diagnostic and treatment methods employing innovative machines or artificial substances should be any less patentable than the machines or substances themselves. Crucial synthetic compositions and medical instruments, upon which modern medicine depends, are routinely patented with no detriment (indeed great benefit) to the provision of health care and the development of medical science.

Amici have further contended that many doctors are "trying to discern clinically relevant levels of known substances [even] without any purpose of seeking patent protection." Quest Br.20. Surely that is true, just as engineers often labor to solve difficult

problems without attempting to invoke patent protection. Congress has chosen to provide patent protection for medical diagnostic and treatment processes as it has for other technological processes. The fundamental premise of the patent system is that, in the long run, patent protection will make such beneficial inventions more available, by incentivizing inventors. As several other *amici* below recognized, "[p]atent protection is essential for continuing investment and innovation in the field of personalized medicine." AIPLA C.A. Br.21; *see also id.* at 18-21; Brief of Novartis Corp. as *Amicus Curiae* in Support of Plaintiff-Appellant and Reversal 15 (Fed. Cir. Jan. 22, 2009); Brief of *Amicus Curiae* Myriad Genetics, Inc. in Support of Appellant 10-13, 25-30 (Fed. Cir. Jan. 22, 2009); Brief of *Amici Curiae* Interested Patent Law Professors in Support of Neither Party 13-16 (Fed. Cir. Jan. 18, 2009); Corrected Brief of *Amicus Curiae* Biotechnology Industry Organization in Support of Neither Party 7-12 (Fed. Cir. Jan. 22, 2009). As these *amici* understand, advances in medical diagnostics and personalized medicine require substantial investments, and an unduly restrictive interpretation of §101 will choke these vital fields in their infancy.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

RICHARD P. BRESS
Counsel of Record
J. SCOTT BALLENGER
GABRIEL K. BELL
LATHAM & WATKINS LLP
555 11TH STREET, NW
SUITE 1000
WASHINGTON, DC 20004
rick.bress@lw.com
(202) 637-2200

Counsel for Respondent

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