No. 09-490

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

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QUESTION PRESENTED

Whether the Federal Circuit correctly held that concrete methods for individually calibrating the appropriate dosages of synthetic drugs for treatment of patients suffering from 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 need, nor any compelling reason, for this Court to review the Federal Circuit's straightforward holding that a specific method for improving the treatment of patients with certain diseases by better calibrating the appropriate dosage of particular synthetic drugs for individual patients, through a series of concrete and transformative steps, is a patentable "process" under 35 U.S.C. §101. Petitioners distort the facts and holding below in an effort to manufacture a controversial legal question or conflict warranting this Court's attention. But on any fair reading, the decision below is unremarkable and does not conflict with any other decision. This case is not about doctors' mental judgments; 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*"), does not alter that conclusion. Because the patents-in-suit here describe concrete and improved methods of treating seriously ill patients and involve the administration and biochemical transformation of synthetic drugs, this case does not raise the issue that troubled the dissenting Justices in *LabCorp*. Moreover, the Federal Circuit recently synthesized this Court's §101 jurisprudence in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), and this Court will inevitably add its own guidance in reviewing that decision. The lower courts should have an opportunity to explore the important ramifications of that guidance

to medical diagnostic and treatment methods before this Court intervenes.

Petitioners' back-up suggestion of a grant, vacate, and remand ("GVR") in light of *Bilski* will also likely prove unnecessary. Certainly, a GVR will be unnecessary if this Court endorses the machine-or-transformation test, concludes that the test is too restrictive, or limits its holding to the appropriate standard for analyzing business method patents. A GVR would only be warranted if this Court intends in *Bilski* to substantially constrict process patents generally—an outcome that none of the parties in *Bilski* have requested.

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 to import into the analysis considerations relating to those *other* conditions and requirements (such as novelty and non-obviousness), the *only* issue here is whether Prometheus's patents describe a "process." The 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 to include "'anything under the sun made by man.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citation omitted). The only exception is a judicially-created rule that "laws of nature, natural phenomena, and

abstract ideas" are not themselves patentable. *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, weight loss, and rectal bleeding. CA10007; 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), infections, 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.

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

C. Prometheus's Specific 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 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-4a; 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, DNA, 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

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

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

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 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. In particular, 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. CA10016-18; CA10034-35.

The patents' various dependent claims further limit the method to certain disorders (such as inflammatory bowel disease), certain thiopurine drugs (such as 6-MP and 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

For many years, Mayo Medical Laboratories and its affiliates[4] have purchased and used Prometheus's patented test—over 17,000 times from 1999 to 2007. CA13136. In 2004, Mayo announced that it intended to begin selling its own competing test. App. 4a; CA11566. Mayo's test measures the same metabolites as Prometheus's test, and specifies similar metabolite levels for ensuring efficacy and avoiding toxicity. App. 4a; App. 88a-89a; 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. 5a; 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, seeking injunctive and declaratory relief and damages. App. 4a; 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. 92a-93a; CA12543; *see* CA11024; CA12228. But the court granted Mayo's motion to invalidate Prometheus's

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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."

claims under 35 U.S.C. §101. App. 59a; CA00042. The court dissected the claims and held that the processes' first two steps—administration of the drug and *determining resulting metabolite levels—should be* disregarded as mere "conventional" or "data-gathering" steps, and it viewed the final "warning" step as "only a mental step" because "it is the metabolite levels themselves that 'warn' the doctor that an adjustment in dosage may be required." App. 39a; CA00029.

Thus shorn, the court found that the patents-in-suit recite only correlations, which the court viewed as *natural phenomena because they "result[] from innate* metabolic activity in the human body," App. 39a-48a; 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 processes in question "transform" matter or data, because it believed that consideration applies only to "industrial" processes. App. 49a-50a; CA00036.

The court further found 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. 48a; CA00035 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)) (second alteration in original). The court rejected Prometheus's argument that the patents foreclose use of the correlations only in the context of specific methods of patient treatment and did not prevent anyone from using those correlations in basic research or in the development of other treatment methods. App. 51a-54a; CA00037-38.

F. Federal Circuit Proceedings

The Federal Circuit reversed. Applying its recently-articulated synthesis of this Court's doctrine (the *Bilski* "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. 16a (quoting *Bilski*, 545 F.3d at 962).[5] The court stressed 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. 15a.

The Federal Circuit 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" given the metabolic processes involved. App. 17a. Second, "[d]etermining the levels of 6-TG or 6-MMP in a subject necessarily involves a transformation, for those levels cannot be determined by mere inspection." App. 18a. The court explained 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

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[5] The Federal Circuit declined to consider Prometheus's alternative argument that the methods are independently patentable by virtue of their integral ties to machines and compositions of matter. App. 11a, 16a.

sample." App. 18a. Indeed, "'at the end of the process, the human blood sample is no longer human blood; human tissue is no longer human tissue.'" App. 18a-19a (citation omitted).

The Federal Circuit determined further that these transformations are not "merely data-gathering" or "'insignificant extra-solution activity'" but are instead "central to the claims." App. 19a-20a (citing *Parker v. Flook*, 437 U.S. 584, 590 (1978); *Bilski*, 545 F.3d at 962). It explained 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). These transformations, moreover, are "'sufficiently definite to confine the patent monopoly within rather definite bounds.'" App. 18a (quoting *Benson*, 409 U.S. at 70).

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-22a. Thus, in this case, "[a]lthough a physician is not required to make any upward or downward adjustment in dosage during the 'warning' step," taken as a whole, the process "provide[s] useful information for possible dosage adjustments to the method of treatment using thiopurine drugs for a particular subject." App. 23a.

Finally, the Federal Circuit rejected the district court's "finding that the claims wholly preempt use of correlations between metabolite levels and efficacy or toxicity." App. 23a. The court explained that "the claims do not preempt natural processes" because they "utilize them in a series of specific steps." App. 24a

(citing *Diehr*, 450 U.S. at 187). As in *Diehr*, Prometheus's method patents do not "'preempt the use of [a fundamental principle]'" because they "'seek only to foreclose from others the use of that [principle] in conjunction with all of the other steps in their claimed process.'" App. 24a (quoting *Diehr*, 450 U.S. at 187).

The court also observed that the preemption inquiry is effectively subsumed into the "machine-or-transformation" test. *See* App. 24a ("[B]ecause the claims meet the machine-or-transformation test, they do not preempt a fundamental principle." (citing *Bilski*, 545 F.3d at 954)); *Bilski*, 545 F.3d at 953 (noting that *Diehr* "drew a distinction between those claims that 'seek to pre-empt the use of' a fundamental principle, on the one hand, and claims that seek only to foreclose others from using a particular *'application'* of that fundamental principle, on the other"). That is, "[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. 24a.

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 to the particular facts of this case.

While the claims of Prometheus's patents differ in certain particulars, each involves a common series of

steps to calibrate the proper use of synthetic thiopurine drugs in the treatment of certain auto-immune disorders, in order to ensure efficacy while avoiding potentially fatal side-effects. First, man-made drugs are administered to the patient and, within the body, are transformed into active metabolites—substances that would not occur in the body but for the administration of the drugs. Second, a bodily sample such as blood is collected and the patient's drug metabolite concentrations are measured—a process that requires physical transformation of the sample. Finally, the metabolite concentration measurements are compared to certain pre-determined levels to warn the doctor if the dosage might need to be adjusted.

Prometheus's technique of combining knowledge derived from scientific discovery with useful physical activities to achieve a functional end plainly satisfies §101. The patents-in-suit do not claim any purely natural phenomenon, and they do not consist of purely mental action. They inherently involve physical steps such as administering drugs, drawing blood samples, and testing blood for metabolites. Mayo does not, and could not, contend that these steps can be performed without transformations and machines. Indeed, 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 in that sense. Put simply, claiming a concrete process that improves the treatment of ill patients is not the same thing as claiming a natural correlation or mental exercise.

Rather than confronting these truths, Mayo misrepresents the scope of the patents-in-suit and distorts the Federal Circuit's holding in two fundamental ways. First, Mayo wrongly asserts that the "sole step" in the patented methods is a "physician's mental determination[]" or "thought process[]," Pet. 3-4, and that the methods consist of nothing more than natural phenomena and medical knowledge, Pet. 17-19. The Federal Circuit squarely rejected Mayo's characterization as a matter of law and fact. 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 or because Mayo views them as "mere data-gathering"—are contrary to the record and the law. 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."

Second, Mayo attempts to generate a conflict with this Court's precedents by misrepresenting the

Federal Circuit's actual holding. Mayo argues that the Federal Circuit failed to apply the "governing preemption standard." Pet. 16. But the Federal Circuit squarely analyzed and addressed the preemption issue, and properly applied this Court's established case law. The court of appeals explicitly held that "the claims do not preempt natural processes" but instead "utilize them in a series of specific steps." App. 24a (applying *Diehr*, 450 U.S. at 187). Mayo does not agree 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, §101 jurisprudence is currently in the midst of a significant re-evaluation. The Federal Circuit's opinion in *Bilski* substantially reframed the §101 inquiry based on its synthesis of this Court's precedents. This Court is presently reviewing *Bilski* and will surely add its own guidance and gloss on the appropriate standard. The proper application of §101 in the context of medical diagnostic and treatment

methods presents difficult questions 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 new standards articulated 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—particularly when this Court is already poised to issue one foundational §101 opinion this Term.

The real question here is whether this Court should GVR this decision in light of its forthcoming opinion in *Bilski*. Of course the answer depends on what this Court intends to say in *Bilski*, but respondent respectfully doubts that even a GVR is warranted. As the Federal Circuit recognized, these patents fully satisfy the restrictive "machine-or-transformation" test that the business method patent in *Bilski* failed. If this Court endorses *Bilski*'s machine-or-transformation test, or if it concludes that the test is too restrictive, then there is no need to revisit this case. A GVR also would not be warranted if this Court takes a modest approach in *Bilski* and limits its analysis to the business method context. The only scenario in which a GVR here would be appropriate is if this Court intends to use *Bilski* to articulate a substantially *more restrictive* analysis under §101 generally than the machine-or-transformation test that the Federal Circuit applied in *Bilski* and in this case. None of the parties in *Bilski*, including the government, have requested such an outcome. Indeed, Mayo itself asserts that *Bilski* "will not decide the independent

question raised here." Pet. 23. 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 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. 3, 4, 18, 19, 22. But this Court squarely rejected that approach to §101 in *Diehr*. Mayo also asserts, inexplicably, that the transformation resulting from administering the drugs was "[t]he *only* transformation cited by the Federal Circuit," Pet. 20 (emphasis added), utterly ignoring the second essential transformation—determining metabolite levels—on which the Federal Circuit also rested. App. 17a-18a. On any fair reading of the actual patent language and the Federal Circuit's opinion, Mayo's concerns completely disappear.

Second, Mayo attempts to generate a conflict with this Court's precedents by asserting that the Federal Circuit did not conduct a preemption inquiry—which is flatly incorrect. The Federal Circuit appropriately considered, and rejected, Mayo's preemption argument because, contrary to Mayo's preferred reading, the court of appeals 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. That ruling was 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. There is no need 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 construction of the patents-in-suit, 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 the treatment. The patents-in-suit cannot be infringed by mere thought.

Mayo offers a variety of arguments for why this Court should disregard the physical, transformative aspects of the patents-in-suit. Mayo argues, for example, that the administration and determination steps are old in the art, Pet. 3, 4, 18, 19, 22; that the transformation resulting from administering the drugs is "merely a preparatory data-gathering," Pet. 21, or a "natural" phenomenon, Pet. 20; and that the patents as a whole are not really about patient treatment, *e.g.*, Pet. 15, 24, 28. None of these contentions has merit.

1. As a preliminary matter, Mayo fails to acknowledge that the Federal Circuit found *two* relevant transformations—both in the conversion of

man-made drugs to metabolites in the body, and in the measurement of metabolite concentrations. *Compare* Pet. 20 (transformation resulting from administering the drugs was "[t]he *only* transformation cited by the Federal Circuit" (emphasis added)) *with* App. 17a-18a (holding that there are two independent necessary transformations). Mayo argues (incorrectly) that the first transformation should be disregarded, but does not even acknowledge the second.

2. Mayo and its *amici* also repeatedly try to import novelty analysis into §101 by arguing that the physical, transformative steps of the patents-in-suit 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, 4 & n.2, 5, 6, 12, 15, 18, 19, 22, 24, 28. For example, Mayo protests that Prometheus did not invent thiopurine drugs or develop a new way of measuring metabolite levels. Pet. 4, 18, 22. 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* correlate to proper drug dosages." Pet. 4; *see also* Quest Br. 4, 6, 7, 8, 13; ACMG Br. 2, 3, 5, 7, 9, 10, 14, 17; AARP Br. 2, 4.

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. The fact that what is "novel" in the patents-in-suit is improved accuracy in dosage adjustments does not make the underlying process any less of a process.

One way to understand this point is that the patents-in-suit contain multiple steps that, standing alone, are clearly processes within the meaning of §101.

See App. 21a-22a. The steps of administering thiopurine drugs to patients, taking blood samples, and measuring metabolites are, individually or together, unquestionably "processes" and each would be patentable by their inventor so long as the Act's other requirements are met. 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 *amici* effectively concede that the patents-in-suit would satisfy §101 if Prometheus had invented either thiopurine drugs or HPLC. *See, e.g.*, Pet. 18 ("Prometheus cannot take advantage of a drug that was invented by someone else"); *see also* Pet. 3, 4 & n.2, 22; ACMG Br. 7 (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 attempt to dissect these patents into steps that Prometheus invented and those it did not, 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 and the Federal Circuit. 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."). The Federal Circuit has followed these settled principles for decades. *See, e.g.*, *Bilski*, 545 F.3d at 958; *In re Grams*, 888 F.2d 835, 839 n.5 (Fed. Cir. 1989); *In re Walter*, 618 F.2d 758, 766 (CCPA 1980).

3. Mayo also argues that the initial transformative steps of the patents-in-suit have no purpose beyond "data gathering." Pet. 21-22. But the Federal Circuit correctly recognized 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 the ongoing treatment of 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. 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 methods cannot be patentable because the final step does not require an adjustment of dosage. Pet. 6, 16-17. The Federal Circuit correctly understood that, because the purpose of the method is to provide useful information to a doctor, actual adjustment is not required. The court of appeals explained 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. 22a. In short, "[w]hen viewing the treatment methods as a whole, Prometheus has claimed therapeutic methods that determine the optimal dosage level for a course of treatment." App. 23a.

Mayo has pointed to 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. 15, 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, and there is no good reason they should not be. *See, e.g., Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1054 (Fed. Cir. 1992) (upholding diagnostic patent resulting in information about patient's heart risk); *In re Abele*, 684 F.2d 902, 904, 908 & n.9 (CCPA 1982) (upholding patent on use of algorithm to improve the 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).

4. Although they concede that the drugs and metabolites at issue here are not "naturally occurring," Mayo and its *amici* argue that Prometheus's treatment methods nonetheless are not patentable because the metabolites are created by the body's "natural"

reaction to foreign substances. *See, e.g.*, Pet. 20; Quest Br. 15. But 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. 18a. 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. 17a-19a.

That analysis is consistent with the Court's precedents—which have identified transformations as "the clue" to patentability of processes not involving a particular machine. *See Diehr*, 450 U.S. at 184; *Benson*, 409 U.S. at 70; *see also Bilski*, 545 F.3d at 956.[6] *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." 450 U.S. 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 various diseases." App. 24a.[7]

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[6] Regardless of whether *Bilski* properly found transformational steps and machine-ties to be the *exclusive* measure of patentability, they are at least *sufficient* criteria under *Diehr*.

[7] The patents here only "preempt" use of the correlations in connection with the use of specific synthetic drugs and medical treatment steps. They would not "preempt," for example, the use

Contrary to Mayo's assertion (Pet. 18-19), the Federal Circuit's decision here does not conflict with *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), where this Court rejected an attempt to patent a combination of natural bacteria exhibiting nothing more than their natural qualities. 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 fully consistent with *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), where this Court held that genetically-engineered bacteria *are* patentable because they did not exist in nature. *Id.* at 310.

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 "fundamental medical knowledge," Quest Br. 4, but instead concrete processes employing several categories of patentable subject matter.

5. 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. 6-8, 15. As the Federal Circuit found, however, no one infringes Prometheus's patents merely by thinking about correlations. Infringement occurs only after

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of the correlations in performing statistical analysis on historical patient data.

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. 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." CA12596.

Mayo makes much of the fact that "Dr. el-Azhary is a dermatologist" and therefore purportedly "unconcerned with metabolite ranges" addressed by these patents. Pet. 6. 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 at 15:46-:47. This again highlights Mayo's persistent pattern of distorting the patents and refusing to read them as written.

B. Mayo Ignores the Federal Circuit's Explicit Preemption Analysis and Holding

Mayo and its *amici* argue that the Federal Circuit's application of the machine-or-transformation test "conflicts with this Court's preemption standard." Pet. 13; *see also* Pet. 9, 11-22, 19; ACMG Br. 17 ("[T]he Federal Circuit erred in employing [the machine-or-transformation test] as the 'definitive test' for patentable subject matter where the issue is whether a claim preempts a natural phenomenon."). According to Mayo, the Federal Circuit erred in failing to conduct a freestanding "preemption" inquiry above and beyond the machine-or-transformation test.

These arguments betray Mayo's recognition that it cannot prevail unless this Court articulates a §101 standard that is substantially more restrictive than the (already quite restrictive) "machine-or-transformation" test that the Federal Circuit articulated in *Bilski* and applied here. In any event, there is no inconsistency between that test and the more general "preemption" analysis that appears in some of this Court's cases. 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 various diseases" and "utilize [natural processes] in a series of specific steps." App. 24a. 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 machine-or-transformation test—as articulated by the Federal Circuit based on this Court's precedents—is simply another way of assessing whether there is undue preemption of an abstract idea or natural phenomenon. *See id.* ("Regardless, because the claims meet the machine-or-transformation test, they do not preempt a fundamental principle."). As applied below, the 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.[8] As the Federal Circuit previously explained in *Bilski*, "a claim that is tied to a particular machine or brings about a particular transformation of a particular article does not pre-empt all uses of a fundamental principle in any field but rather is limited to a particular use, a specific application." 545 F.3d at 957. In short, the Federal Circuit determined through its rigorous machine-or-transformation test that the patents-in-suit do not preempt an abstract idea or natural phenomenon.

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[8] *See also* App. 24a ("The 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.").

Indeed, for all its bluster, Mayo itself implicitly acknowledges that the "governing preemption standard" is subsumed in (and fully satisfied by) determining whether the claims merely "recite some 'post-solution activity.'" Pet. 16 (citation omitted); *see also* Pet. 20, 21 ("[I]f [the transformation] is merely a preparatory data-gathering step—leaving the rest of the claim open to preempt all uses of the principle—it does not make an otherwise unpatentable claim patentable."). Mayo's real quibble is that it does not agree with the Federal Circuit's application of that principle 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.

The Federal Circuit's analytic approach is fully consistent with, and flows from, the approach this Court took in *Diehr*, 450 U.S. 175. There, 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." *Id.* at 187, 184, 191. The Federal Circuit's opinion here is in this respect a routine, fact-specific, and correct application of this Court's doctrine as set forth in *Diehr*. As the Federal Circuit explained, "even prior to *Bilski*, the asserted claims should have been found to be patentable subject matter." App. 16a n.2.

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. 2-3, 22-23, 28; AARP Br. 3-6; ACMG Br. 18; 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 itself 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) (emphasis added). The processes embodied in the patents-in-suit involve the administration of a synthetic drug and the measurement of metabolic byproducts that, absent that human intervention, would exist nowhere in nature.[9] As the American

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[9] Some *amici* claim that it "appear[s]" *LabCorp* also involved synthetic substances because "most forms of cobalamin ... do *not* occur in nature." Quest Br. 14 (citing Victor Herbert, *Vitamin B-12: Plant Sources, Requirements, and Assay*, 48 Am. J. Clinical

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." Br. of Amicus Curiae American Intellectual Property Law Ass'n 10 (Fed. Cir. Jan. 22, 2009) ("AIPLA C.A. Br.").[10]

The Federal Circuit recognized that *LabCorp* "involved different claims from the ones at issue here." App. 16a n.3. In *Bilski*, the Federal Circuit suggested that the *LabCorp* methods might be unpatentable. *Bilski*, 545 F.3d at 965 & n.27. 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 Flesh Out the Contours of the Machine-or-Transformation Test

More broadly, the application of §101 to medical

Nutrition 852, 852, 855, 858 (1988)). However, while cobalamin (also known as vitamin B12) is not native to "anything that grows out of the ground," it is "ubiquitous" in "animal products," such as milk. Herbert, *supra*, 48 Am. J. Clinical Nutrition at 852, 855. Of course, processes may well be patentable even if employing only natural products. 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.

[10] Contrary to the suggestions of some of Mayo's *amici*, Quest Br. 13, AIPLA does support §101 patentability in this case. *See generally* AIPLA C.A. Br.

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.

In *Bilski*, the Federal Circuit synthesized from this Court's precedents a new articulation of the §101 test, which will be shaped further by this Court's forthcoming decision in that case. In addressing the business method patent in *Bilski*, however, the Federal Circuit left open many difficult questions, including what kinds of steps might be ignored on the ground that they constitute mere data-gathering or insignificant extra-solution activity, and how closely a process must be tied to a particular machine or other statutory subject matter in order to confer patentability. (In *Bilski*, as here, the Federal Circuit did not need to explore the "machine" prong of the test at all.)

The scope of §101 is obviously of great importance in patent law, with widespread affects across many industries. This case is the first in which the Federal Circuit has applied the *Bilski* test to a medical method in a published opinion. The development of the law would benefit from the district courts' and Federal Circuit's consideration in the first instance the various gradations of medical diagnostic and treatment methods on the spectrum between *Prometheus* and *LabCorp* and beyond, under the machine-or-transformation test or whatever alternative standard this Court adopts in *Bilski*.

Amici present a parade of horribles as potential "*extensions* of the Federal Circuit's ruling" in this case. ACMG Br. 8 (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 already cases raising a variety of issues percolating up through the lower courts.[11] The Federal Circuit was created 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 lower courts' development of these issues in concrete settings. Intervention now would be premature.

III. GVR IN LIGHT OF *BILSKI* IS UNNECESSARY

This Court also should decline Mayo's invitation to GVR in light of *Bilski*. Pet. 28.

A GVR in light of *Bilski* is clearly unnecessary if this Court approves of the Federal Circuit's distillation of the machine-or-transformation test in *Bilski*. The Federal Circuit has already applied that standard to the facts here, and the courts' (and parties') resources would be better spent addressing the remaining issues in this case.[12]

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[11] *See, e.g., Ass'n for Molecular Pathology v. U.S. PTO*, ---- F. Supp. 2d ----, No. 09 Civ. 4515, 2009 WL 3614434, at *1 (S.D.N.Y. Nov. 2, 2009) (noting, but not yet resolving, §101 issue for patents involving "correlations between certain genetic mutations and an increased risk of breast and/or ovarian cancer"); *King Pharms., Inc. v. Eon Labs, Inc.*, 593 F. Supp. 2d 501, 512-13 (E.D.N.Y. 2009) (holding method fails *Bilski* test because "the act of informing another person of the food effect of metaxalone does not transform the metaxalone into a different state or thing").

[12] Moreover, the Federal Circuit explained that "even prior to *Bilski*, the asserted claims should have been found to be

A GVR is likewise unwarranted if this Court concludes that the Federal Circuit's test is too *restrictive*—if, for example, this Court determines that a "machine-or-transformation" is sufficient for patentability but not always necessary, or that the test should be applied flexibly to accommodate cutting-edge technologies outside of the business methods context. As the government suggested in *Bilski*, this Court "could leave open the possibility that some new and as yet unforeseen technology could necessitate the creation of an exception" to the machine-or-transformation test. *Bilski* Oral Arg. Tr. at 38:5-7.

A GVR in light of *Bilski* would be appropriate only if this Court articulates a substantially *more demanding* standard under §101—not just for business method patents but for all patents—than the "machine-or-transformation" test that the Federal Circuit applied there, and here. No one, including the government, is asking for such a sweeping opinion in *Bilski*. Indeed, the brief filed by the United States in *Bilski* cites the Federal Circuit's decision in this case favorably, as an example of a medical treatment method that should be patentable. *See* U.S. *Bilski* Br. 40 ("Methods of diagnosing a condition by testing, or assaying, for a characteristic that correlates to the condition may be claimed in any number of ways, and therefore patentability cannot be determined as a categorical matter." (citing *Prometheus* as an example of a method meeting the machine-or-transformation test)); U.S. *Bilski* Cert. Opp. 17 n.4 (acknowledging

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patentable subject matter." App. 16a n.2. As a result, there is no reason to think that the Federal Circuit will reach a different decision on remand, unless this Court substantially restricts the scope of §101 in its *Bilski* opinion.

that machine-or-transformation test need not adversely affect patents on "biotechnological or chemical inventions").

Mayo does not explain why a GVR would be appropriate here, instead merely offering a perfunctory request at the end of its petition. Pet. 28. In fact, Mayo itself recognizes that *Bilski* "will not decide the independent question raised here." Pet. 23. Mayo's *amici* similarly recognize that *Bilski* "does not involve patents on medical therapies or diagnostic techniques and appears likely to be decided without resolving questions about such subject matter." Quest Br. 4.

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

Mayo's arguments (echoed by some of its *amici*) on the merits essentially 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; Quest Br. 15-18. Mayo and its *amici* would clearly 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 "health care costs" (Pet. 25-26) 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 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. (introduced Mar. 3, 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 [§101] 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. 27; ACMG Br. 5, 9-11. But that has nothing whatsoever to do with appropriate interpretation of the language of §101. And in any event, the fact that doctors and hospitals may have to pay patent royalties

more often than software engineers does not interfere with patient care. *Amici* state that "[i]t is hard to imagine how the medical diagnostic community will continue to serve the goal of quality patient care and how physicians will continue to practice medicine in an ethical and effective manner under such a regime." ACMG Br. 5. 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. 26, Mayo and its *amici* argue that patentability somehow will hinder the development of such personalized medicine and scientific research. *See* Pet. 24-27; AARP Br. 5; ACMG Br. 11-12; Quest Br. 15-21. But none explain 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 further contend 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 in other fields without attempting to invoke patent protection. Congress has chosen to provide patent protection for medical diagnostic and treatment processes as it has for technological processes in those other fields. 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,

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