

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

**BRIEF OF *AMICUS CURIAE*
AMERICAN INTELLECTUAL PROPERTY LAW
ASSOCIATION IN SUPPORT OF RESPONDENT**

WILLIAM G. BARBER
President

AMERICAN INTELLECTUAL
PROPERTY LAW
ASSOCIATION
241 18th Street, S.
Suite 700
Arlington, VA 22202
(703) 415-0780

DENISE W. DEFRANCO
Counsel of Record

LESLIE A. MCDONNELL
DAVID S. FORMAN
FINNEGAN, HENDERSON,
FARABOW, GARRETT &
DUNNER, LLP
55 Cambridge Parkway
Cambridge, MA 02142
(617) 452-1600
denise.defranco@finnegan.com

*Counsel for Amicus Curiae
American Intellectual Property Law Association*

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STATEMENT OF INTEREST

The American Intellectual Property Law Association (“AIPLA”) submits this brief as amicus curiae in support of Respondent, Prometheus Laboratories, Inc. (“Prometheus”).¹ AIPLA is a national bar association whose approximately 16,000 members have interests and practice primarily in the areas of intellectual property. AIPLA’s members include attorneys in private practice, corporate practice, and government or academic positions involved directly or indirectly in the practice of patent, trademark, copyright, unfair competition, and other fields of law affecting intellectual property. AIPLA members include both owners and users of intellectual property, representing the interests of both plaintiffs and defendants. The issue of patent eligible subject matter is vital to most, if not all, of AIPLA’s members.

¹ In accordance with Supreme Court Rule 37.6, amicus curiae states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than the amicus curiae or its counsel. After reasonable investigation, AIPLA believes that (i) no member of its Board or Amicus Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

Many members of AIPLA practice in the biotechnology, pharmaceutical, and medical services industries. The Court's decision in this case will potentially impact thousands of issued patents and pending applications relevant to those industries. Although AIPLA has no interest in any party to this litigation or stake in the outcome of this case, it has an interest in seeking a correct and consistent interpretation of laws affecting intellectual property in general and in seeking a reaffirmance of the Court's precedent of giving a wide scope to the terms of 35 U.S.C. § 101.²

SUMMARY OF ARGUMENT

Section 101 of the patent statute identifies the classes of invention that are eligible for patent protection. That statute has been construed broadly by this Court to exclude only three categories of invention: laws of nature, physical phenomena, and abstract ideas. The diagnostic methods claimed by Prometheus do not fall into any of these excluded categories. Prometheus's methods, like many other patents directed to personalized medicine, therapeutic treatment of humans, and diagnostic methods, utilize the natural metabolic process of the human body, but those natural processes are not what is "claimed" and therefore should not serve as a

² In accordance with Supreme Court Rule 37.3(a), the parties to this litigation have consented to the filing of this brief. The written consent of all parties has been entered in the docket of this case.

basis to deny patent protection. Simply put, the mere involvement of a natural metabolic process in claims directed to personalized medicine, therapeutic treatment of humans, or diagnostic methods should not be used as a basis to deny patent protection to that whole class of inventions, especially where the U.S. Patent and Trademark Office (“PTO”) has been granting patents on these types of inventions for decades and where the patent statute explicitly recognizes them.

Most of Petitioners’ complaints about Prometheus’s patent claims are misdirected at patent eligibility under 35 U.S.C. § 101, and instead should be addressed to other provisions of the patent statute. For example, Petitioners’ concerns that diagnostic method claims might stifle the medical community are already addressed by 35 U.S.C. § 287(c)(1), which exempts medical practitioners and related health care entities performing certain medical activities from being sued for patent infringement. Similarly, Petitioners’ criticisms regarding the over breadth of Prometheus’s claims are addressed by 35 U.S.C. §§ 102 (concerning the requirement of novelty), 103 (concerning the requirement of non-obviousness), and 112 (concerning the written description requirement). Moreover, in the recently enacted America Invents Act, Congress directed the PTO to conduct a study of the impact of limited uses of certain diagnostic method patents, necessarily showing that Congress recognizes diagnostic method patents as patent eligible subject matter under current law.

Therefore, this Court should conclude that Prometheus's claims are patent eligible under section 101 of the patent statute.

ARGUMENT

I. The Patent Statute Accounts for the Policy Concerns Raised by Mayo.

Petitioners raises a host of policy concerns in an attempt to convince this Court that the diagnostic claims in this case should not be eligible for patent protection under 35 U.S.C. § 101. The flaw in Petitioners' arguments, however, is that Congress has already balanced the competing policy concerns associated with diagnostic method claims and enacted specific provisions to address those concerns. And rather than amend section 101 of the patent statute, Congress enacted other provisions to take those concerns into account.

A. The Patent Statute Expressly Precludes Patent Infringement Lawsuits Against "Medical Practitioners."

In its brief, Mayo complains that diagnostic method patent claims

prevent "doctors from using their best medical judgment," "force doctors to spend unnecessary time and energy to enter into license agreements," "divert resources from the medical task of health care to the legal

task of searching patent files for similar simple correlations,” and “raise the cost of health care while inhibiting its effective delivery.”

Mayo Br. at 2 (quoting *Lab. Corp. of Am. Holdings v. Metabolite Labs.*, 548 U.S. 124, 138 (2006) (Breyer, J., dissenting from dismissal of petition for writ of certiorari) (hereinafter “*LabCorp*”). The patent statute, however, expressly precludes patent infringement lawsuits against medical doctors and the health care institutions with which they affiliate for performing certain medical activities, thereby negating these concerns.

The patent statute gives a patent holder the right to sue for patent infringement: “A patentee shall have remedy by civil action for infringement of his patent.” 35 U.S.C. § 281 (2006). Section 287(c)(1), in turn, negates that right insofar as the suit would be with respect to “a medical practitioner’s performance of a medical activity.” 35 U.S.C. § 287(c)(1) (2006). More specifically, that section states that the “provisions of section[] 281 . . . shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.” *Id.* Thus, a patentee is not free to assert its patent against a medical practitioner for performing certain medical

activities.³ The statute further explains that “‘medical practitioner’ means any natural person who is licensed by the State to provide the medical activity,” that “‘medical activity’ means the performance of a medical or surgical procedure on a body,” and that “‘related health care entity’ shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.” *Id.* at § 287(c)(2).⁴

Therefore, Mayo’s concerns regarding doctors being required to search patent files or obtain patent licenses are illusory. Furthermore, these provisions of section 287(c), providing relief from infringement for certain activities by medical practitioners, would not be necessary (and in fact would be meaningless)

³ Medical activity that is not covered by 35 U.S.C. § 287(c) includes, for example “the practice of a process in violation of a biotechnology patent.” 35 U.S.C. § 287(c)(2)(A)(iii).

⁴ Prometheus’s patent claims are a “medical activity” within in the meaning of section 287(c)(2) because the claims require “administering a drug” to a patient and “determining the level” of a certain hormone in the patient. U.S. Patent No. 6,355,623, col. 20, ll. 13-16. *See generally Emtel, Inc. v. LipidLabs, Inc.*, 583 F. Supp. 2d 811, 819-24 (S.D. Tex. 2008) (holding that a claim directed to “diagnosing a medical condition,” falls within the scope of 35 U.S.C. § 287(c)(2)).

if these types of activities were not otherwise considered eligible for patenting under section 101.

B. The Recently-Enacted America Invents Act Reflects the Careful Balance Struck by Congress in Connection with Patent Eligibility and Diagnostic-Method Claims.

On September 16, 2011, the President signed the Leahy-Smith America Invents Act (hereinafter referred to as the “America Invents Act” or “AIA”). Pub. L. No. 112-29, 125 Stat. 284 (2011). As stated in House Report No. 112-98, the AIA was “a 6-year work in progress,” after numerous hearings before multiple committees of the Senate and House of Representatives. H.R. Rep. No. 112-98, at 57 (2011). In the AIA, Congress amended many provisions of the patent statute, but notably Congress declined to amend section 101, even though the process included numerous occasions for it to consider policy issues concerning patentable subject matter.

For example, in the AIA Congress affirmatively considered certain diagnostic method claims. *See id.* at § 27, 125 Stat. at 338-39. Rather than determine that such claims are not patent eligible, Congress simply required that the Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, referred to as “Director” in the patent statute, 35 U.S.C. § 3(a)(1) (2006), “conduct a study on effective ways to provide independent, *confirming* genetic

diagnostic test activity where gene patents *and exclusive licensing* for primary genetic diagnostic tests exist.” AIA § 27(a), 125 Stat. at 338 (emphasis added). Thus, Congress explicitly recognized the existence of gene patents, and by referencing “exclusive licensing” for genetic diagnostic tests, Congress implicitly recognized the eligibility for patent protection of diagnostic method claims generally. . In the AIA, Congress merely requested a study only of a particular use of such tests to provide “second opinion[s]” to the results first obtained using a patented test. *Id.* at § 27(b)(2).

Elsewhere in the AIA, Congress did more than simply direct a study on certain patentable subject matter. For example, the new law directs that “no patent may issue on a claim directed to or encompassing a human organism.” AIA § 33(a), 125 Stat. at 340. Likewise, Congress directed that claims directed to “any strategy for reducing, avoiding, or deferring tax liability” shall be “deemed insufficient to differentiate a claimed invention from the prior art.” AIA § 14(a), 125 Stat. at 327. Although not couched in terms of patent eligibility, the effect of that provision is to preclude patent eligibility for tax strategies because the patent statute otherwise excludes patent protection for inventions in the prior art. 35 U.S.C. § 102 (2006), *amended by* AIA § 3, 125 Stat. at 285-87.

Thus, in considering the AIA, Congress demonstrated its purview over the patentable subject matter issues that Petitioners raise.

Congress in that legislation affirmatively excluded certain types of inventions from patent eligibility, but it did not exclude patent protection for diagnostic method inventions. In connection with diagnostic method inventions, the balance struck by Congress at this time is only that a study of a limited subset of such inventions be conducted by the Director. In light of that balance, it would be inappropriate for this Court to conclude otherwise in this case. *See generally Bilski v. Kappos*, 130 S. Ct. 3218, 3228 (2010) (“A conclusion that business methods are not patentable in any circumstances would render § 273 [of title 35] meaningless. This would violate the canon against interpreting any statutory provision in a manner that would render another provision superfluous.”).

II. Prometheus’s Method Claims Are Patent Eligible under Section 101 and This Court’s Precedent.

A. The Methods Claimed By Prometheus Are Not Laws of Nature or Physical Phenomena.

Claim 1 of Prometheus’s U.S. Patent No. 6,355,623 recites two physical steps: (1) administering a certain type of drug to a patient, and (2) determining the extent to which that patient metabolized the drug into a specific metabolite. U.S. Patent No. 6,355,623, col. 20, ll. 13-17. Neither of these steps is a “law of nature.” Neither of these steps is a natural “physical phenomenon.” Ignoring these steps might allow one to focus exclusively on

that portion of the claim directed to a “need to increase” or a “need to decrease” the amount of drug later administered to that patient. However, such analysis would be inappropriate and conflict with this Court’s statement in *Diamond v. Diehr*:

In determining the eligibility of respondents’ claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The “novelty” of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

450 U.S. 175, 188-89 (1981).

Viewing the claim as a whole, as this Court directs we must, the claim recites a patent eligible “process,” 35 U.S.C. § 101 (2006), and that process is not a law of nature, a physical phenomenon, or an abstract idea. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Prometheus’s claims require administering a drug to a patient and measuring

that patient's ability to transform the drug into its metabolite. Both of these steps are the result of human intervention and do not occur in nature. The "wherein" clauses of the claims which follow these steps *apply* the results of these man-made steps to allow a determination whether an adjustment in the treatment is necessary. The distinction between a claim to a mere principle and a claim to a process which applies the principle to effect a useful result, has long been recognized by the Court. *See, e.g., Tilghman v. Proctor*, 102 U.S. 707, 724 (1880).

To be sure, Prometheus's patent claims, like many other patent claims related to the therapeutic treatment of humans, rely on the natural metabolic processes of the human body (much like many mechanical devices rely on the natural process of gravity). The mere fact that an invention exploits natural metabolic processes, however, cannot be used as a basis to render this whole class of inventions ineligible for patent protection. Over a long line of cases, this Court has explained that abstract ideas, laws of nature, and natural phenomena are not eligible for patent protection under § 101, but a practical application of one of these principles may be patented. *See, e.g., Bilski*, 130 S. Ct. at 3230 ("[W]hile an abstract idea, law of nature, or mathematical formula could not be patented, 'an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" (quoting *Diehr*, 450 U.S. at 187)); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)

(“If there is to be invention from such a discovery, it must come from the *application* of a law of nature to a new and useful end.”) (emphasis added).

Prometheus’s patent claims are directed to practical applications of metabolic processes to achieve a useful result, namely determining the optimum treatment range for a particular individual based on his or her personal metabolic rate. Such a diagnostic process can minimize the hazardous side effects of available medicines while at the same time optimizing their healing effect on a personalized basis. Furthermore, applying the “important and useful clue” of the machine-or-transformation test to determine patent eligibility, *Bilski*, 130 S. Ct. at 3226, Prometheus’s process claims pass the physical transformation threshold for patent eligibility. As the Federal Circuit concluded, the “transformation is of the human body and of its components following the administration of a specific class of drugs and the various chemical and physical changes of the drugs’ metabolites that enable their concentrations to be determined.” *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355-56 (Fed. Cir. 2010).

B. Any “Correlation” Recited in Prometheus’s Claims Is Not a Law of Nature or a Physical Phenomenon.

Mayo repeatedly refers to that portion of Prometheus’s claims directed to a “need to increase” or a “need to decrease” the amount of a drug later

administered to the patient as a “natural correlation between metabolite levels and patient health.” *See, e.g.*, Mayo Br. at 6; *see also id.* at 5, 7, 13. Indeed, the theme of Mayo’s brief is that Prometheus’s invention is ineligible for patent protection because it claims a “natural correlation.” *Id.* at 18. Mayo’s own brief demonstrates that this is a misguided characterization. Specifically, Mayo makes much of the fact that it purportedly improved upon Prometheus’s blood test. *Id.* at 8-10. Indeed, Mayo goes so far as to argue that Prometheus’s patent claims reflect “disputable numbers.” *Id.* at 40. If Prometheus’s numbers can be so readily “improved upon” and “disputed,” one must ask how they could possibly reflect a law of nature. They cannot.

Even assuming, however, that the numbers recited in the claim (i.e., “less than 230 pmol per 8×10^8 red blood cells” and “greater than about 400 pmol per 8×10^8 red blood cells”) were “correct” and somehow “accurately” indicated any particular patient’s need for an increase or decrease in the amount of drug delivered, such “correlation” is still not a law of nature or physical phenomenon of the type that is ineligible for patent protection under this Court’s precedent. Simply put, this Court has never stated that a “correlation,” as distinct from a law of nature or physical phenomenon, is ineligible for patent protection. *But see LabCorp*, 548 U.S. at 137 (Breyer, J., dissenting from dismissal of petition for writ of certiorari) (equating a “simple natural correlation” with a “natural phenomenon”).

As a policy matter, “correlations,” even those related to nature or the diagnosis of a disease, should be treated differently than physical phenomena or laws of nature. In explaining that laws of nature are excluded from patent protection, this Court in *Diehr* used as examples Einstein’s fundamental law that $E = mc^2$ and Newton’s law of gravity, observing that “[s]uch discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’” *Diehr*, 450 U.S. at 185 (quoting *Chakrabarty*, 447 U.S. at 309). These examples demonstrate that the “law of nature” category that this Court has excluded from patent protection is directed at the most fundamental of physical principles. When such laws of nature are harnessed by human ingenuity into correlations that can be applied in practical and useful methods, such as methods of diagnosing or treating disease, patent protection should be available, and neither this Court nor Congress has ever said otherwise.

Indeed all of science is predicated on the observation of physical phenomena in order to discover “correlations” that are presumed to be consequences of the “laws of nature,” even if the connection is not immediately apparent. Here, the inventors determined that metabolite levels below a certain amount (one variable) indicated a need to increase drug dosing (the other variable), and that metabolite levels above a certain amount (one variable) indicated a need to decrease dosing (the other variable). Those correlations are subject to interpretation and revision, as evidenced by Mayo’s

arguments. Laws of nature and physical phenomenon, on the other hand, are not subject to the interpretation of the observer; they are truisms. They explain all observations of the known universe, e.g., the law of gravity or the theory of relativity.

Consider a pot of boiling water. When a pot of pure water is heated under 1 atmosphere of pressure, the water will always boil (i.e. convert from a liquid to a gas) at 100°C, because the underlying physical chemistry of water molecules causes this result. That is, it would be inconsistent with the laws of nature for the pot of water to boil at any other temperature because such effect reflects a law of nature and/or a physical phenomenon. Correlation based on that natural phenomenon, on the other hand, might relate to the observation of two variables associated with the pot of boiling water. For example, if the pot of boiling water were infused with certain botanicals (one variable), one might notice that campers near the pot of boiling water tended to receive fewer mosquito bites (the other variable). One could recite this correlation in a patent claim directed to a method of reducing the number of mosquito bites one receives while camping. Certainly such method, which applies a correlation to practical and useful effect, should be eligible for patent protection, if novel and non-obvious under other provisions of the patent statute.

The PTO has long recognized the patentability of diagnostic claims, including those that apply a biological correlation. Indeed, *Petitioners' own*

patent portfolio includes many patents directed to biological correlations. *See, e.g.*, Mayo's U.S. Patent 5,928,883, col. 9, ll. 12-20 (claiming "A diagnostic method comprising: obtaining a physiological sample of material from the gastrointestinal tract of a human [with] an inflammatory bowel disorder; and determining the level of the eosinophil pro-inflammatory granule protein eosinophil peroxidase in said sample, wherein the level is *correlated* to the presence or absence of said inflammatory bowel disorder.") (emphasis added); Mayo's U.S. Patent 6,235,486, col. 31, ll. 2-12 (claiming "A method for detecting or determining breast cancer in a human, comprising: a) contacting an amount of an antibody . . . with the cells of a human tissue sample so as to form a binary complex comprising the antibody and the cells; and b) determining or detecting the presence or amount of complex formation in the sample and *correlating* the presence or amount of said complex to the presence or absence of breast cancer in said human.") (emphasis added); and Mayo's U.S. Patent 6,475,723, col. 18, ll. 26-37 (claiming "A method for determining a diagnosis, prognosis or risk of a Tau pathology in a patient, said method comprising detecting a tau gene mutation in genomic DNA of the patient, wherein [the mutation has specified characteristics], and wherein said mutation is associated [i.e., correlates] with said Tau pathology.")

Thus, adopting Petitioners' view that "correlations" are the same as "natural laws" and/or "physical phenomena," would substantially "disrupt

the settled expectations of the inventing community.” *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997)). As the Supreme Court warned in *Festo*, “[t]o change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous patents which have not yet expired and which would be affected by [the] decision.” 535 U.S. at 739 (quoting *Warner-Jenkinson*, 520 U.S. at 32 n.6).

Moreover, narrowing the interpretation of section 101 to exclude claims that include a biological correlation, like those in Prometheus’s patents or for that matter in Mayo’s patents, would have an unintended and chilling effect on the medical research industry. Medical research and diagnostic companies spend billions of dollars annually to develop new methods for diagnosing or predicting a susceptibility to disease, as well as new methods of making and testing drugs in order to ensure their safety and efficacy. Diagnostic tests to identify increased risk, to allow early detection, and to ensure safe and/or effective administration of drugs are vital to improving the health and quality of life throughout the world. Patent protection for diagnostic and therapeutic processes is necessary to ensure that the companies investing in medical research are adequately compensated for large development and regulatory costs. Patent protection provides a necessary incentive for others to invest in

similar research and development, leading to increased economic health as well as advancing the general well being of the public.

III. Petitioners' Many Complaints Are Appropriately Addressed by Other Provisions of the Patent Statute.

Understandably, one might be sympathetic at first to some of Petitioners' many complaints in this case. Mayo might be correct that Prometheus should not be allowed to assert its patents against Dr. el-Azhary's dermatological research. *See Mayo Br.* at 25. Mayo might be correct that claims in the Prometheus patent are "vague and open-ended." *See id.* at 44. Mayo might be correct that "the method of blood testing for metabolites are well known and have been used by physicians and researchers for decades." *See id.* at 24. These issues, however, are not presently before this Court. More importantly, they are not appropriately addressed under section 101 of the patent statute—the patent statute has other provisions that squarely address these concerns with requirements that the claimed invention is new, nonobvious and clearly disclosed.⁵

⁵ See 35 U.S.C. §§102, 103, 112. AIPLA takes no position on whether these defenses apply to the Prometheus claims in this case or that Mayo would prevail on any one of them. AIPLA intends simply to explain how the comprehensive patent statute has other provisions that more appropriately and more directly address the complaints Mayo has raised before this Court.

See also Brief for the United States As Amicus Curiae Supporting Neither Party at 26-32.

For example, Petitioners' complaint that Prometheus is inappropriately asserting its claims in the field of dermatological research should be addressed as an issue of claim construction. Notably, the claim at issue recites a method "for treatment of an immune-mediated gastrointestinal disorder." U.S. Patent 6,355,623, col. 20, ll. 9-10. The claim further requires administering a drug to a subject "having said immune-mediated gastrointestinal disorder." *Id.* at col. 20, ll. 13-14. Certainly such claim language might appropriately be construed as a matter of law by a court as excluding methods for the treatment of dermatological disorders. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996).

Similarly, Petitioners complain that Prometheus asserts that its patents cover treatment for "all types of autoimmune diseases." Mayo Br. at 24. Petitioners might rely on Section 112, paragraph 1, in defense of such argument. Section 112, paragraph 1, requires the patentee to provide "a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same." 35 U.S.C. § 112, ¶ 1 (2006). This statutory provision provides two separate requirements for patentability: (1) the written description requirement, and (2) the enablement requirement.

See Ariad Pharm., Inc. v. Eli Lilly and Co., 598 F.3d 1336, 1344 (Fed. Cir. 2010) (en banc). As explained by the Federal Circuit, “[t]he purpose of the written description requirement is to ‘ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor’s contribution to the field of art as described in the patent specification.’” *Id.* at 1353-54 (citation omitted). Here, it could be argued that Prometheus has not described any invention beyond the treatment of immune-mediated gastrointestinal disorders. Therefore, the patent might be invalid for failing to satisfy the written description requirement, if the claims are construed any more broadly than that. *See id.* at 1358 (holding patent claims invalid for lack of written description).

Similarly, Mayo’s complaint that Prometheus’s claims are vague and open-ended might be appropriately be addressed under the second paragraph of section 112 of the patent statute, which requires that a patent “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, ¶ 2 (2006). This statutory provision has been applied to hold vague and open-ended claims invalid as indefinite. *See Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1356 (Fed. Cir. 2005) (invalidating patent claims for indefiniteness under 35 U.S.C. § 112, ¶ 2).

Finally, Mayo's contention that the claimed process is well known and has been used for decades might appropriately be addressed under sections 102 and 103 of the patent statute. Section 102 sets forth the requirement for novelty of the claimed invention. 35 U.S.C. § 102 (2006); *see, e.g., Brown v. 3M*, 265 F.3d 1349, 1353 (Fed. Cir. 2001) (invalidating patent claims under 35 U.S.C. § 102 for lack of novelty). Section 103 sets for the requirement of non-obviousness of the claimed invention. 35 U.S.C. § 103 (2006); *see, e.g., Graham v. John Deere Co.*, 383 U.S. 1, 13 (1966) (invalidating patent claims under 35 U.S.C. § 103 as obvious in view of the prior art). Thus, if Prometheus's claims are directed to well known methods or even obvious variations of well known methods as Petitioners allege, the claims might be invalid under sections 102 or 103 of the patent statute.

Petitioners urge that the cases upon which they rely do "not improperly import novelty and obviousness analysis into Section 101 from Sections 102 and 103" because "[s]ection 101 on its face limits patentable subject matter to a 'new and useful process.'" Mayo Br. at 36 (quoting *Parker v. Flook*, 437 U.S. 584, 591, 594 (1978)). But this Court has squarely rejected that argument:

It has been urged that novelty is an appropriate consideration under § 101. Presumably, this argument results from the language in § 101 referring to any "new and useful" process, machine, etc. Section 101,

however, is a general statement of the type of subject matter that is eligible for patent protection “subject to the conditions and requirements of this title.” Specific conditions for patentability follow and § 102 covers in detail the conditions relating to novelty. *The question therefore of whether a particular invention is novel is “wholly apart from whether the invention falls into a category of statutory subject matter.”*

Diehr, 450 U.S. at 189-90 (emphasis added) (footnote omitted) (quoting *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979). Thus, rather than rely on section 101 of the patent statute to defend this case, Petitioners should rely on the many other provisions of the patent statute available to them.

IV. Patent Protection is Vital to the Personalized Medicine Industry.

The impact of patent protection varies from industry to industry, but it is particularly critical to medical research industries such as pharmaceuticals, biotechnology, and personalized medicine. Medical research companies spend billions of dollars annually to develop new methods for diagnosing or predicting susceptibility to disease as well as new methods of making and testing drugs in order to ensure their safety and efficacy. Dep’t of Health & Human Services, *Personalized Health Care: Pioneers, Partnerships, Progress* at 79 (2008). Diagnostic tests to identify increased risk of disease, to allow early detection of disease, and to ensure safe

and/or effective administration of drugs are vital to improving the health and quality of living throughout the world. Patent protection for diagnostic processes is necessary to ensure that the companies investing in medical research are adequately compensated for large development and regulatory costs and to provide incentives for others to invest in similar research and development. Committee on Intellectual Property Rights in Genomic and Protein Research; National Research Council, *Reaping the Benefits of Genomic and Proteomic Research: Intellectual Property Rights, Innovation, and Public Health* at 20 (Merrill & Mazza eds., 2006). Thus, patent protection leads to increased economic health as well as advancing the general well being of the public.

Personalized medicine, in particular, is a nascent but growing industry focused on the development of therapies specific to the needs of individual patients. Personalized medicine designs therapies around a given patient's unique physiology, such as a particular patient's ability to metabolize a particular drug. R. Mullin, *Personalized Medicine*, 86 *Chemical & Engineering News* at 17-27 (Feb. 11, 2008); M. Aspinall and R. Hammermesh, *Realizing the Promise of Personalized Medicine*, 85 *Harv. Bus. Rev.* 109 (Oct. 2007). This approach to treatment avoids the high costs (in terms of lives and dollars) of the traditional trial and error approach to diagnosis and treatment. A notable example of personalized medicine is the development of a diagnostic test for sensitivity to the

blood-thinning drug Warfarin. Prior to the development of that new test, the traditional trial and error approach resulted in under- and overdosing that was estimated to cost the healthcare system over a billion dollars annually due to serious bleeding and strokes. HHS *Personalized Health Care* at 13; A. McWilliam, et al., *Health Care Savings from Personalizing Medicine Using Genetic Testing: The Case of Warfarin*, AEI-Brookings Joint Center for Regulatory Studies at 2-3 (Nov. 2006). Another example of personalized medicine is the identification of biomarkers of certain cancers. Once identified, these biomarkers may be used to determine whether a patient's particular cancer is effectively treated by a certain drug that may have significant side effects. See PricewaterhouseCoopers LLP, *The New Science of Personalized Medicine: Translating the Promise into Practice* at 7 (Oct. 2009) (describing a companion diagnostic test for determining whether administering Herceptin® (trastuzumab) to treat breast cancer will be effective).

One of the greatest challenges facing the personalized medicine industry is obtaining funding for the necessary clinical research. See HHS, *Personalized Health Care* at 83. The availability of patent protection is essential to obtaining that funding. A ruling that novel and nonobvious diagnostic methods are ineligible for patent protection would cripple the nascent personalized medicine industry, to the detriment of the public.

CONCLUSION

For the foregoing reasons, AIPLA urges the Court to find Prometheus's patent claims eligible for patent protection under section 101 of the patent statute.

Respectfully submitted,

William G. Barber
President
AMERICAN
INTELLECTUAL
PROPERTY LAW
ASSOCIATION
241 18TH ST., S.
STE. 700
ARLINGTON, VA 22202
(703) 415-0780

Denise W. DeFranco
Counsel of Record
Leslie A. McDonell
David S. Forman
FINNEGAN,
HENDERSON,
FARABOW, GARRETT
& DUNNER, LLP
55 Cambridge Blvd.
Cambridge, MA 02478
(617) 452-1600
denise.defranco@finnegan.com
com

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*Counsel for Amicus Curiae
American Intellectual
Property Law Association*