No. 10-1150

IN THE

Supreme Court of the United States

MAYO COLLABORATIVE SERVICES, DBA MAYO MEDICAL LABORATORIES, et al.,

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* INTELLECTUAL PROPERTY OWNERS ASSOCIATION IN SUPPORT OF RESPONDENT

DOUGLAS K. NORMAN
President
KEVIN H. RHODES, *Chair*
Amicus Brief Committee
INTELLECTUAL PROPERTY OWNERS ASSOCIATION
1501 M Street, NW
Suite 1150
Washington, DC 20005
(202) 507-4500

GARY M. HOFFMAN
Counsel of Record
MEGAN S. WOODWORTH
KENNETH W. BROTHERS
DICKSTEIN SHAPIRO LLC
1825 Eye Street, NW
Washington, DC 20006
(202) 420-4128
hoffmang@dicksteinshapiro.com

237520

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Constitutional Provisions

Statutes

Other Authorities

INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae Intellectual Property Owners Association (IPO) is a trade association representing companies and individuals in all industries and fields of technology who own or are interested in intellectual property rights. IPO's membership includes more than 200 companies and a total of over 12,000 individuals who are involved in the association either through their companies or as inventor, author, executive, law firm, or attorney members. Founded in 1972, IPO represents the interests of all owners of intellectual property. IPO regularly represents the interests of its members before Congress and the USPTO and has filed *amicus curiae* briefs in this Court and other courts

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae* or its counsel made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief by blanket consent letters filed with the Court on August 4 and 8, 2011.

on significant issues of intellectual property law. The members of IPO's Board of Directors, which approved the filing of this brief, are listed in the appendix.[2]

INTRODUCTION

Consistent with the goal of "promot[ing] the Progress of Science and useful Arts," set forth in Article I, Section 8, Clause 8 of the U.S. Constitution, Congress and Courts alike have broadly defined the types of inventions that may be eligible for patent protection. This goal of promoting innovation, which is served by a broad interpretation of "process, machine, manufacture, or composition of matter," within the meaning of 35 U.S.C. § 101, must be considered in light of concerns that the patenting of mere ideas, or natural laws or phenomena, will preempt all uses of those ideas, natural laws or phenomena, thus stifling innovation. To balance these important concerns, courts uniformly exclude certain fundamental building blocks of invention

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[2] IPO procedures require approval of positions in briefs by a three-fourths majority of directors present and voting.

(*i.e.,* natural phenomena, laws of nature, and abstract ideas) from the scope of patentable subject matter. The present case requires consideration of the boundary, in the field of medicine, between a non-patent-eligible natural phenomenon, and a specific, practical, and patent-eligible application of that natural phenomenon.

SUMMARY OF ARGUMENT

This Court has long recognized the need for patent law to incentivize innovation and the public disclosure of such innovation. This need is particularly crucial in the field of medicine, given the potential life-changing importance of its breakthroughs and the rapid pace of discoveries in the industry. This Court's precedent appropriately acknowledges that in 35 U.S.C. §101 a broad scope of patent-eligible subject matter well serves this goal. Although there is some concern that such a broad scope may in rare instances result in allowance of exclusive rights that may prove undesirable, the prevention of undesirable instances is more appropriately addressed with other substantive requirements for patentability.

In this case, the U.S. Court of Appeals for the Federal Circuit construed the asserted claims as methods of treatment, requiring a specific application of a correlation of metabolites in the body that requires a transformation of matter to a different state. The Federal Circuit held that the asserted claims represent patent-eligible subject matter under 35 U.S.C. § 101. Under this Court's precedent, such methods of treatment are patent eligible subject matter. Respondent's arguments to the contrary should be rejected, for they seek to draft new, extra-statutory exceptions onto Section 101 of the Patent Act or confuse patent-eligibility under Section 101 with the conditions for patentability under Sections 102, 103 and 112. IPO therefore urges this Court to affirm the judgment of the Federal Circuit.

ARGUMENT

I. Section 101 is a Low Threshold for Patent-Eligible Subject Matter, And Should Not Be Merged With the More Stringent Patentability Requirements of Novelty, Non-Obviousness,

Enablement and Sufficient Written Description.

This Court has referred to the assessment of the patentability of an invention under Section 101 as a "threshold" inquiry. *Diamond v. Diehr*, 450 U.S. 175, 188 (1981); *Bilski v. Kappos*, 130 S.Ct. 3218, 3225 (2010). This inquiry is separate from assessing whether a patent claim meets the substantive conditions for patentability set forth elsewhere in the Patent Act. *Id.; Parker v. Flook*, 437 U.S. 584, n.18 (1978). This Court has appropriately held that permissive application of this "threshold" is consistent with Congressional intent, as evidenced by the statutory language and legislative history. *See Diamond v. Chakrabarty*, 447 U.S. 303, 307-08 (1980).

In this case, the Petitioners appear to be asking this Court to use Section 101 beyond its intended purpose as a permissive threshold for filtering patent-eligible subject matter. Repeatedly, Petitioners' Brief suggests that the claimed invention should not be patentable because it involves methods that are well-known to doctors, thereby implicating

issues of novelty or obviousness. *See* Brief For Petitioners ("Pet. Br.") at 22, 24-25, and 34-35.

As this Court recognized in *Diehr* and *Flook*, courts should not confuse the issue of patentability under Section 101 with the analysis of novelty or obviousness under Sections 102 and 103, respectively. *Diehr*, 450 U.S. at 189-90; *Flook*, 437 U.S. at n.18. "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 190 (quoting *In re Bergy*, 596 F.2d 952, 961 (C.C.P.A. 1979)). This Court has explicitly rejected Petitioners' approach "to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis," finding that approach particularly inappropriate for process claims, which may be patentable "even where all the constituents of the combination were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188.

The other requirements for patentability—novelty under Section 102, non-obviousness under

Section 103, and written description and enablement under Section 112—are more appropriate gatekeepers for determining the patentability of inventions. Section 101 merely defines the field of patent-eligible subject matter. The substantive requirements for patentability provide strong protection against overreaching claims that seek exclusive rights on pre-existing knowledge. Under Sections 102 and 103 of the Patent Act, an inventor is already prohibited from patenting an application of a phenomena of nature that is not novel or non-obvious. Similarly, under Section 112, an inventor is entitled to protection only to the extent that his inventions are fully described in and enabled by the disclosure that he provides.

Accordingly, even if there is some concern over whether the particular claims at issue in this case should be patentable in view of the "well-known" subject matter that they encompass (Pet. Br. at 24-25), the Court should not accept Petitioners' invitation to narrow the scope of patent-eligible subject matter under Section 101 in order to

invalidate the claims.[3] Rather, the Court should apply Section 101 in its proper purpose as a permissive threshold, and leave for another day the questions of whether the substantive conditions of patentability are met for the claimed invention.

II. A Broad Scope of Subject Matter Eligibility is Particularly Important for Medical Treatments.

This Court has repeatedly recognized that a permissive approach to subject matter eligibility serves an important role in promoting technological innovation in our country. *E.g., Bilski*, 130 S.Ct. at 3225; *Chakrabarty*, 447 U.S. at 308. This Court also has acknowledged that this approach is consistent with the intent of our country's founders and Congress: "Congress took [a] permissive approach to patent eligibility to ensure that 'ingenuity should receive a liberal encouragement.'" *Chakrabarty*, 447 U.S. at 308 (quoting 5 Writings of Thomas Jefferson 75-76 (Washington ed. 1871)). In accordance with

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[3] IPO takes no position on whether Respondent's claims meet these other requirements for patentability.

this intent, "anything under the sun that is made by man" falls within the scope of patent-eligible subject matter. *Chakrabarty*, 447 U.S. at 308-09.

With these goals in mind, this Court has "more than once cautioned that courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.'" *Bilski*, 130 S.Ct. at 3226 (quoting *Diehr*, 450 U.S. at 182). Likewise, the Court has emphasized the need for flexibility in the law to accommodate technological innovation: "Section 101 is a 'dynamic provision designed to encompass new and unforeseen inventions.'" *Bilski*, 130 S.Ct. at 3227 (quoting *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 135 (2001)).

The incentive that patent protection creates is particularly important with the rapid pace and unpredictability of medical treatments. The field of diagnostic medicine continues to develop, and scientists increasingly have been able to diagnose, predict, and treat medical conditions that were not long-ago unknown. For example, the promise of patent protection has led to the development of high-profile innovations like a prognosis for colon cancer

(U.S. Patent No. 7,163,801), a test for HIV/AIDS (U.S. Patent No. RE 38,352), and a test for breast and ovarian cancer (the HER-2/neu test, U.S. Patent No. 4,968,603). These medical advances depend heavily on the strong protection of intellectual property rights.

Patent protection for medical innovations has jump-started growth in the biotechnology industry, especially in small-to-mid size companies that rely heavily on patented technologies. *See NIH: Moving Research from the Bench to the Bedside: Hearing Before the Subcomm. On Health of the H. Comm. On Energy and Commerce*, 108th Cong. 47 (2003), *available at* http://energycommerce.house.gov/108/action/108-38.pdf (detailing the development of small biotechnology companies, and the research and development costs needed to sustain them). Developing a discovered correlation into a marketable diagnostic technology is extremely costly, and requires the efforts of venture capitalists, developers, managers, laborers, technologists, manufacturers, marketers, and distributors. *See* F. Scott Kieff, *On the Importance to Economic Success*

of Property Rights in Finance and Innovation, Searle Center Annual Review of Regulation, May 4, 2007, at 4-5, *available at* www.law.northwestern.edu/searlecenter/papers/Kieff_Annual_Rev_Final.pdf. Patent protection encourages this diverse group of people to cooperate. As in other fields, the eligibility for patent protection for medical treatment methods creates the incentive for inventors to disclose the innovation to the public in exchange for such protection. Correspondingly, the profit potential that may flow from the exclusive rights of an enforceable patent covering a medical invention provides the incentive for parties to work together to bring an innovation to market. *Id.* at 5. If the patent eligibility of medical diagnostic tools is questioned—or eliminated—funding for risky and expensive projects will be less forthcoming, and in turn, advances in medical diagnostic testing will be less forthcoming as well.

A change in the broad application of Section 101 not only would upset settled expectations in the medical field, but it could have a destructive impact on the continued advances in medicine that have led to society-improving breakthroughs. Only if

scientists, doctors, and investors can rely on broad access to patent protection will we continue to benefit from the incredible innovation in this field that our society has enjoyed in the last several decades.

III. Transformative Methods of Medical Treatment and Diagnostics Should be Patentable.

Although the line is not a bright one that makes the patent-eligibility of an invention a simple assessment, this Court has consistently recognized three categories that fail to meet the threshold for patent-eligibility subject matter under Section 101: laws of nature, natural phenomena, and abstract ideas. *E.g., Diehr*, 450 U.S. at 185. On the other hand, this Court's precedent recognizes that *applications* of laws of nature, natural phenomena, and abstract ideas, which are new productions from these elements, are patent-eligible. *See Parker v. Flook*, 437 U.S. 584, 591 (1978) ("While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.") (quoting *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939)).

Transformative methods of treatment should be patent-eligible. In the context of a specific category of disease, a novel method for the application of a naturally-occurring correlation with treatment steps that involve transformations of the body is eligible for patent protection. This Court indicated in *Gottschalk v. Benson* that "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." 409 U.S. 63, 70 (1971). Although the Court has since clarified that the machine-or-transformation test is not the sole criterion on which patent eligibility determinations should be based, the Court continues to recognize that transformation is an important investigative clue "for determining whether some claimed inventions are processes under § 101." *Bilski,* 130 S. Ct. at 3227. And while the Court was previously addressing transformations in the context of programming a binary computer (as in *Gottschalk*) and hedging investment losses (as in *Bilski*), methods of medical treatment that involve changes in the human body are no different. In fact, for the

reasons explained in Section II above, this type of process may be more deserving of broad patent eligibility than other fields of science and technology.

In this case, the Federal Circuit made it clear that it was interpreting the claims as active methods of treatment for a specific disease. *Prometheus Labs, Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347, 1355-56 (Fed. Cir. 2010). The Federal Circuit found that: "[t]he claims recite specific treatment steps, not just the correlations themselves. And the steps involve a particular application of the natural correlations: the treatment of a specific disease by administering specific drugs and measuring specific metabolites." *Id.* at 1355. The Federal Circuit also interpreted the step of "determining the level" (which is present in some form in every asserted claim) as the act of assessing the levels of certain metabolites, not as they are naturally occurring within the body of the subject, but rather, as affected by one or more drugs that have been administered to the subject. *Id.* at 1350-51. Although the Petitioners challenge whether the patent claims at issue contain patentable subject matter, they do not appear to

challenge the Federal Circuit's interpretation of these claims.[4]

Accordingly, the unchallenged construction of these claims requires a transformation of certain metabolites in the body in the treatment of a specific category of disease. As such, under this Court's precedent, the claims are directed to a patent-eligible specific application of a natural phenomenon.

This Court should also decline Petitioners' suggestion to separately analyze, as part of a Section 101 analysis, whether certain parts of Respondent's claims are merely data-gathering or insignificant post-solution activity. Such an inquiry impermissibly slices up the claim into various components, a tactic that this Court previously rejected in assessing the patentability of an invention. *Diehr,* 450 U.S. at n.12 (rejecting the

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[4] The IPO takes no position on whether or not Respondent's patent claims were properly interpreted. Rather, the opinions expressed in this *Amicus* Brief simply start with the presumption that the claims have been properly interpreted as transformative methods of treatment.

request to "dissect[] a claim into old and new elements" when assessing patentable subject matter "because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious"). As explained in *Diehr*, when a claim applies a formula "in a structure or process which, *when considered as a whole*, is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101." 450 U.S. at 192 (emphasis added).

Like the claims considered by the Court in *Diehr*, methods for treatment of a specific disease, that require transformation of bodily components based on administration of a drug, do not pre-empt all uses of any natural correlations or mathematical formulas. Thus, Respondent's claims are directed to a "process," which Congress in 35 U.S.C. §101 and this Court in the cases discussed above have defined as a type of invention that may be eligible for patent protection.

CONCLUSION

IPO believes that this Court's precedent appropriately interprets the broad standards for patent-eligible subject matter set forth in Section 101 of the Patent Act. The Court should decline to use this case to erect further, extra-statutory barriers to patent-eligible subject matter that would disrupt those standards, particularly in the field of medical diagnostic techniques, where innovation relies on broad patent protection. The construed claims in this case recite transformative methods of medical treatment that should fall within the broad scope of patent-eligible subject matter.

RESPECTFULLY SUBMITTED,

Douglas K. Norman
President
Kevin H. Rhodes, *Chair*
Amicus Brief
Committee
INTELLECTUAL PROPERTY
OWNERS ASSOCIATION
1501 M Street, NW
Suite 1150
Washington, DC 20005
(202) 507-4500

Gary M. Hoffman
Counsel of Record
Megan S. Woodworth
Kenneth W. Brothers
DICKSTEIN SHAPIRO LLC
1825 Eye Street, NW
Washington, DC 20006
(202) 420-4128
hoffmang@
dicksteinshapiro.com

APPENDIX

APPENDIX[1] — MEMBERS OF THE BOARD OF DIRECTORS INTELLECTUAL PROPERTY OWNERS ASSOCIATION

T.J. Angioletti
Oracle USA, Inc.

Russell W. Binns
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---

1. IPO procedures require approval of positions in briefs by a three-fourths majority of directors present and voting.

Appendix

Philip S. Johnson
Johnson & Johnson

George William Johnston
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Lisa K. Jorgenson
STMicroelectronics, Inc.

Dean Kamen
DEKA R&D Corp.

Charles M. Kinzig
GlaxoSmithKline

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Appendix

Russ Slifer
Micron Technology, Inc.

Daniel J. Staudt
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ConocoPhillips

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Bridgestone Americas
Holding, Inc.

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Abbott Laboratories