

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
ASSOCIATION OF UNIVERSITY TECHNOLOGY
MANAGERS IN SUPPORT OF RESPONDENT**

DONALD R. WARE
Counsel of Record
BARBARA A. FIACCO
HATHAWAY P. RUSSELL
JAMES M. FLAHERTY, JR.
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000
dware@foleyhoag.com

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STATEMENT OF INTEREST

This brief is submitted by the Association of University Technology Managers (“AUTM”) as *amicus curiae* in support of Respondent to urge the Court to affirm the judgment of the court of appeals, thereby rejecting the efforts of Petitioners and certain *amici* improperly to narrow the scope of patent eligibility under 35 U.S.C. § 101.¹

The issues raised in this case are of great importance to AUTM’s members whose central mission is to ensure that basic, early-stage scientific research is translated into commercial products for the public benefit.

AUTM was founded in 1974 as a non-profit professional association with the objective of addressing the concern that inventions funded by the United States government were not being commercialized effectively. Today, AUTM is the largest association of university technology transfer professionals, with a membership of more than 3,600 intellectual property managers and business executives from forty-five countries. AUTM’s members represent more than 350 universities,

¹ In accordance with Supreme Court Rule 37.3(a), counsel for all parties have consented to the filing of *amicus* briefs, and copies of the letters of general consent have been filed with the Clerk. Pursuant to Supreme Court Rule 37.6, AUTM 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 AUTM or its counsel.

research institutions, teaching hospitals, and government agencies worldwide, as well as hundreds of companies involved with managing and licensing innovations derived from academic and non-profit research.

AUTM has no interest in any party to this litigation or stake in the outcome of this case, other than its interest in seeking a correct, clear, and consistent interpretation of the United States patent laws in furtherance of AUTM's mission of advancing the field of technology transfer and enhancing the ability to bring academic and non-profit research to people around the world.

SUMMARY OF ARGUMENT

Congress intended that the threshold patent-eligibility standard set forth in § 101 of the Patent Act be construed broadly. Section 101 operates as a “coarse filter” to block at the outset only unpatentable laws of nature, natural phenomena, and abstract ideas, while allowing all other inventions and discoveries to be considered for patentability under the conditions set forth in other sections of the Patent Act. If a patent application describes a category of invention that is patent eligible, its patentability is then judged by the stringent requirements of §§ 102, 103, and 112, which protect against the issuance of patents for inventions and discoveries that lack novelty, are obvious in light of what is already known, or otherwise attempt to claim discoveries beyond what an inventor has invented and disclosed to the public. This framework encourages innovation in emerging—and even as yet unforeseen—fields of science and technology. AUTM urges this Court to reject Petitioners’ short-sighted attempt to narrow the scope of patent-eligible subject matter under § 101.

Technology transfer (“tech transfer”) licensing activity fuels innovation, particularly for biomedical technologies, but this success is dependent upon the clear, consistent, and correct interpretation of the patent laws, including § 101’s patent-eligibility standard. The fundamental purpose of tech transfer is to translate academic research into practical application, and tech transfer relies on the patent system to operate effectively. Patent rights are the

currency of the tech transfer process, allowing early-stage research to be moved from universities and research institutions to the private sector for development and commercialization.

A broad, encompassing standard of patent eligibility, as intended by Congress and supported by this Court's precedent, is important to encourage innovative research and development, particularly in nascent biomedical fields like personalized medicine and established, but rapidly-evolving, fields like diagnostic testing. Eliminating entire categories of inventions and discoveries at § 101's eligibility threshold, as Petitioners urge, would reduce the number and diversity of inventions entering the product development pipeline and defeat Congress's intent to use the patent system to move discoveries from the research laboratory to the clinical setting.

Under this Court's controlling law, the Prometheus claims at issue in this appeal are clearly patent eligible under the broad standard of § 101. Any concerns about the patentability of the Prometheus claims, however legitimate they may be, are not properly addressed in this appeal. Whether the Prometheus claims meet the requirements for patentability is not before the Court and is irrelevant to the § 101 patent-eligibility determination. To ensure a vibrant system of technology transfer, extending from the research stage to practical application in the commercial market, the broad patent-eligibility standard of § 101 should not be conflated with the rigorous requirements for patentability set forth in §§ 102, 103, and 112.

ARGUMENT**I. THROUGH THE PATENT SYSTEM, UNIVERSITIES AND OTHER RESEARCH INSTITUTIONS ARE ABLE TO TRANSFER EARLY-STAGE RESEARCH TO THE PRIVATE SECTOR FOR FURTHER DEVELOPMENT AND COMMERCIALIZATION.**

At its core, the function of the United States patent system is to drive innovation. This purpose is grounded in the U.S. Constitution, which provides that “The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. art I, § 8, cl. 8. Congress used this power to create the U.S. patent system, codified at 35 U.S.C. §§ 1-376. Section 101 defines the inventions and discoveries eligible for patent protection:

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

This Court has consistently recognized that “the language of § 101 is extremely broad.” *J.E.M. Ag. Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 130 (2001) (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980)). Congress used “expansive

terms” in defining the four categories of inventions eligible for patent protection under § 101—processes, machines, manufactures, and compositions of matter. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Chakrabarty*, 447 U.S. at 308). In *Bilski*, this Court expressly noted that by using the comprehensive modifier “any,” Congress “plainly contemplated that the patent laws would be given wide scope” and explained that “Congress took this permissive approach to patent eligibility to ensure that ingenuity should receive a liberal encouragement.” *Id.* (internal quotation marks and citations omitted).

A. Technology Transfer Plays an Important Role in Translating the Results of Early-Stage Research Into Commercial Products.

Universities and research-based institutions² play a critical role in achieving the goals of the patent system and promoting innovation through the technology transfer process. Tech transfer is an important means by which scientific discoveries and inventions are transferred from universities to private-sector organizations for development, commercialization, and practical application. These are expensive, time-consuming, and risky investments that universities cannot make. The tech transfer process typically involves three stages: (1) discovery of a promising new technology; (2) obtaining of intellectual property protection of the

² For simplicity, all institutions of this type will be referred to as “universities” throughout this *amicus* brief.

new technology through the filing of one or more patent applications; and (3) licensing of the applications and issued patents to the private sector to encourage and achieve further development, investment, and commercialization. For medical discoveries such as the patented treatment methods at issue in this appeal, tech transfer can be a key step in translating basic scientific research from the university researcher's laboratory "bench" to the patient's "bedside."

In their brief, Petitioners assert that "[p]atent protection assuredly is unnecessary to encourage or fund basic research of the sort reflected in the Prometheus patents, which is now routinely undertaken by scientists and researchers without regard to filing patents[,]” citing as support alleged “observations about the limited role of patents in encouraging medical research.” *See* Brief for Petitioners (“Petitioners’ Br.”) at 21, 49-52. Petitioners’ argument is a straw man, ignoring the ultimate goal of translating as much early-stage research as possible into publicly accessible diagnostic tools and therapeutic products that can prevent and cure disease.

Indeed, Petitioners’ request for a sweeping new, narrow interpretation of § 101 would radically change the patent system and undermine efforts to encourage the development and commercialization of pioneering research conducted in our nation’s universities. The development and commercialization path is long, arduous, and expensive. Patents are assets through which a university can pass on intellectual property rights to

small and frequently young companies focused on practical application of the technology. These companies, in turn, can pass them along to larger companies when greater capital is required to complete product development. The availability of intellectual property protection provides incentives to each entity along the development pathway to continue investing their capital as needed to bring a new invention to market. This process can be analogized to a relay race, with each participant passing along its patent rights like a baton. Not everyone finishes the race, but the incentive to persist is maintained by the promise of a limited period of exclusivity to market the ultimate product, the exclusivity defined in scope by the patents that surround it.

Because patents give inventions a tangible, legally transferrable form, their availability to cover the full range of innovative technologies is a fundamental premise of tech transfer. After filing patent applications on a promising new technology, a university actively seeks to license out to the private sector the applications and patents covering the technology. Most typically, the patent rights are licensed out exclusively, to a single licensee.³ Unlike

³ In a federally-funded survey of licensing practices at nineteen of the thirty U.S. academic institutions that have received the largest number of DNA-related patents in the field of biotechnology, the data demonstrated that start-up companies obtained, in nearly all cases, exclusive licenses. *See* Lori Pressman, *et al.*, *The licensing of DNA patents by US academic institutions: an empirical survey*, 24(1) NATURE BIOTECHNOLOGY 31 (2006), at Figure 5. “Exclusive licensing is

universities, these companies have capital they can invest at risk in product development. With the promise of limited-term exclusionary rights afforded by the patent system, these companies have economic justification to undertake the time-consuming and expensive studies needed to test the observed results of a university's research, first in animals, then in human patients in clinical trials, as the FDA requires for regulatory approval. This framework has greatly benefited the public by allowing universities the means to achieve practical application of early-stage scientific research. It takes advantage of market efficiencies to leverage public and private resources, helps create jobs, improves public health outcomes, and stimulates the economy. At the same time, universities use the revenues realized through licensing to help advance scientific research and education, a further benefit to the public.

Petitioners' narrow theory—focused on the conduct of “basic” research by scientists in the laboratory—is short-sighted and far removed from the reality of medical innovation. Without the availability of patent protection to fuel the engine of tech transfer, medical research in academic laboratories would more often sit on the shelf, and the number and diversity of innovative discoveries entering the product development pipeline would decline.

consistent with the need to lower the perceived risk of investing in unproven technology to attract private risk capital.” *Id.* at 37.

In this case, the Prometheus method of treatment claims are directed to determining optimal dosages of thiopurine drugs for use in treating autoimmune disorders through measurement of certain metabolites or “biomarkers.” All but one of the independent claims recite the steps of (1) “administering” a drug providing 6-thioguanine (“6-TG”) (or a similar compound) to a subject, and (2) “determining” the level of 6-TG and/or 6-methylmercaptapurine (“6-MMP”) in the subject’s blood following administration of the drug.⁴ The sole exception is one independent claim that omits the “administering” step. All independent claims conclude with one or more “wherein” clauses that specify certain circumstances when the levels of 6-TG or 6-MMP “indicate[] a need” to adjust the amount of drug administered to the subject. Such treatment methods, based upon analysis of the effects of specific drugs on individual patients, should clearly satisfy the broad patent-eligibility standard of § 101.

Research and development of this type, with the goal of optimizing medical treatments of individual patients, has spawned the new fields of personalized medicine and companion diagnostic testing.⁵ The

⁴ 6-TG and 6-MMP are metabolites of 6-mercaptopurine (“6-MP”), which is a synthetic compound that can be used to treat autoimmune disorders.

⁵ *See generally* Brief of *Amici Curiae* Roche Molecular Systems, Inc., Ventana Medical Systems, Inc., Hoffmann-La Roche Inc., and Abbott Laboratories, Inc. in Support of Neither Party, dated September 9, 2011.

societal value and cost-saving potential of advances in these fields was highlighted in a recent McKinsey publication, which reported that “[d]iagnostic tests are estimated to influence 60 to 70 percent of all treatment decisions, yet account for only 5 percent of hospital costs and 2 percent of Medicare expenditures.” See February 2010 McKinsey Quarterly, *The microeconomics of personalized medicine*.⁶ The availability of patent protection for inventions in these fields fosters innovation in biomedicine. Without it, many fewer inventions and discoveries would be transferred from “bench to bedside,” and our nation’s efforts to develop more effective and affordable healthcare would be hampered.

B. In Enacting the Bayh-Dole Act, Congress Recognized that the Patent System, with its Promise of Limited Exclusionary Rights, Is Critical to Spurring Commercialization of University Research for the Public Good.

In 1980, Congress responded to widespread concerns that the United States was losing its technological advantage and economic competitiveness in the global marketplace due to a perceived lack of innovation. It recognized that federal agencies that funded university research had imposed significant obstacles to commercialization of medical innovations and other new technologies

⁶ McKinsey’s *The microeconomics of personalized medicine* is available at http://www.mckinseyquarterly.com/The_microeconomics_of_personalized_medicine_2527.

growing out of government-sponsored research. Importantly, the means Congress chose to overcome these obstacles was to amend the Patent Act, through enactment of the University and Small Business Patent Procedures Act of 1980, commonly known as the Bayh-Dole Act, 35 U.S.C. §§ 200-212.

The Bayh-Dole Act added an entirely new section to the patent statute, with the intent of “[using] the patent system to promote the utilization of inventions arising from federally supported research or development.” Through Bayh-Dole, Congress expressly recognized that the promise of patent exclusivity was critical to incentivizing private sector investment in university technology. The importance and success of the Act has been borne out in the three decades since its passage.

One of the principal goals of the new tech transfer framework implemented by the Act was to solve the problem that universities were failing to interest private-sector companies in commercializing the universities’ inventions because they could not offer licensees exclusive rights in the technology. This inability to obtain exclusive patent rights discouraged licensees from investing resources in university discoveries, as they could not expect to earn a reasonable return on such a long-term and risky investment or even recoup the development costs.

The Act’s legislative history stresses the importance of using the patent system to allow exclusive licensing as a means to overcome the substantial costs and risks associated with

commercializing a new invention, particularly in the field of medicine. The Senate Report noted the estimate of many experts at the time “that the cost of taking a new invention from basic research through development and commercialization costs 10 times as much as did the basic research itself,” and “a medical discovery faces lengthy, expensive regulatory procedures before any new medicine can be marketed.” S. Rep. No. 96-480, at 19 (1979). Given these factors, the Report explains that “[w]hen [federal] agencies insist on retaining patent rights to medical discoveries and try to have them developed through nonexclusive licensing there are rarely any takers.” *Id.* at 20.

To fix this problem, Congress provided a procedure by which universities and other non-profit research institutions are allowed to retain legal title to inventions made using federal research funds. The provisions of the Act encourage universities to file patents on the full range of their inventions and then collaborate with small businesses and other commercial enterprises to promote the development and utilization of the federally-funded discoveries, principally through licensing.⁷ A paramount goal was to ensure that the universities’ research would achieve practical application. *See* 35 U.S.C. § 203 (providing that funding agency retains “march-in” rights that can be exercised if contractor or licensee fails to take “effective steps to achieve practical

⁷ *See* 35 U.S.C. § 202, which sets forth the Act’s provisions regarding disposition of patent rights.

application of the subject invention” within a reasonable time). The ability of universities to grant exclusive patent licenses is critical to this goal, because the chance of a limited period of exclusivity in the marketplace is what creates the economic incentive for companies to invest the enormous capital needed to obtain regulatory approval of new medical innovations. Disqualifying entire categories of innovative medical research from patent protection, as would be the result of Petitioners’ proposed narrowing of patent eligibility, would defeat Congress’s purpose in enacting Bayh-Dole.

The success of the Bayh-Dole Act in meeting its objectives is tangible and overwhelming. Since the Act took effect, more than 6,000 U.S. companies have been formed based on university discoveries; 4,350 university-licensed products are on the U.S. market; and 5,000 licenses between universities and industry are currently in effect. *See* AUTM’s *2010 Better World Report: The Positive Impact of Academic Innovations on Quality of Life* (“*2010 Better World Report*”), at viii;⁸ *see also* *The Bayh-Dole Act at 25*, at 22-25 (2006) (“*Bayh-Dole Act at 25*”).⁹ And of particular significance to the present appeal, more than 153 new medical products have been commercialized based on research funded by the

⁸ AUTM’s *2010 Better World Report* is available at <http://www.betterworldproject.net/AUTM2010BWR.pdf>.

⁹ The *Bayh-Dole Act at 25* white paper is available at http://www.bayhdolecentral.com/BayhDole25_WhitePaper.pdf.

U.S. government since enactment of the Act. *See 2010 Better World Report*, at viii.

Adopting Petitioners' narrow view of patent eligibility under § 101 on the theory that patents play an unnecessary role in fostering medical research would undermine Congress's reliance on the patent system through Bayh-Dole as the means to promote and assure the practical application of university-based research and innovation. Consistent with Congress's goals, this Court should reaffirm a standard of patent eligibility that broadly encompasses all fields of technology, including those not yet conceived or even imagined.

C. The Importance and Success of Technology Transfer in Driving Innovation is Shown By Licensing Activity Data and Real World Examples of Benefits Provided to the Public.

Recent data reported in the *AUTM U.S. Licensing Activity Survey Highlights: FY2010* ("2010 Highlights")¹⁰ confirm the Bayh-Dole Act's positive impact on innovation and the continuing importance of tech transfer to universities, industry, and the U.S. public. The *2010 Highlights* includes tech

¹⁰ The *2010 Highlights* are available at http://www.autm.net/AM/Template.cfm?Section=FY_2010_Licensing_Survey&Template=/CM/ContentDisplay.cfm&ContentID=6874. These survey highlights were released in advance of the more comprehensive *AUTM U.S. Licensing Activity Survey: FY2010*, published in November 2011.

transfer data from 183 U.S. institutions, including 155 universities, 27 hospital and research institutes, and one third-party technology investment firm. According to the report, “[d]espite continuing difficult economic conditions, university and research institute licensing and startup activity remained very strong.” *2010 Highlights* at 1. As support for this conclusion, the *2010 Highlights* cites the following data from 2010:

- 651 startup companies were formed, 5,362 licenses and options were executed, and 657 new commercial products were created.
- Total sponsored research expenditures were \$59.1 billion, with \$39.1 billion from the U.S. government and \$4.3 billion from industry.
- 20,642 invention disclosures were received, 18,712 U.S. patent applications were submitted, and 4,469 U.S. patent were issued.
- Total licensing income was \$2.4 billion.

The *AUTM U.S. Licensing Activity Survey Summary: FY2009* (“*2009 Summary*”) includes similar data, and also highlights the significance of medical research in the tech transfer process. For example, the *2009 Summary* reports that nearly 50% of all invention disclosures that were able to be

categorized fell within the biomedical or life sciences areas. *See 2009 Summary* at 22. These included invention disclosures in the following fields: (1) Medical (e.g., therapeutic, pharmaceutical)—24.5%; (2) Biomedical Engineering—14.2%; and (3) Biological/Life Sciences (e.g., research tools)—10.4%. *Id.* at 23.

The successful operation of the tech transfer process can be further appreciated and understood through an actual example of the system at work.

At Beth Israel Deaconess Medical Center (BIDMC) in Boston, researchers discovered a new diagnostic test that warns mothers before preeclampsia strikes. Preeclampsia is a potentially dangerous complication of pregnancy that can afflict women as early as the twentieth week of gestation with little notice. According to the Preeclampsia Foundation, this disease affects 5 to 8 percent of all pregnant women—some 200,000 annually in the U.S. alone—and is responsible for more than 70,000 maternal and 500,000 infant deaths globally per year. The only cure for preeclampsia is forced labor or cesarean section to deliver the infant prematurely. According to Ananth Karumanchi, M.D., of BIDMC, “even though doctors know they will see many women with the disease, there has not previously been a way to tell which of them has preeclampsia until the onset of signs and symptoms.” *See 2010 Better World Report* at 4.

Dr. Karumanchi and his team of researchers at BIDMC are developing the first diagnostic test for preeclampsia based on many years of careful

research. Dr. Karumanchi hypothesized that the placenta must be secreting toxic substances into the mother's blood, and indeed, one molecule in particular, sFlt-1, stood out as being very important. "We found that the sFlt-1 protein levels increased several weeks ahead of signs and symptoms. By finding that early warning marker, we now have a way to predict which women will suffer from the disease, and we can prepare early to address the problem," says Dr. Karumanchi. *Id.* at 5.

But the discovery did not arrive as a lightning strike: "There was no Eureka! moment. It took time for us to appreciate the discovery, and it took time for a number of colleagues across the field to confirm the findings," reports Dr. Karumanchi. *Id.* Based on this work, Dr. Karumanchi and his colleagues filed patent applications on their discoveries.

In 2005, BIDMC licensed the technology to Nephromics, and Nephromics in turn sublicensed the preeclampsia diagnostic test method to several leading diagnostic companies. In August 2011, Siemens Healthcare Diagnostics entered into a global licensing agreement with Nephromics to develop two assays to be used as an aid to the diagnosis of preeclampsia. "This story is a tremendous example of the marriage of great science, effective technology transfer and commercialization, leading to the development of a preeclampsia diagnostic. And we are lucky—it will

be accomplished in less than a decade,” says Patrick Jeffries, president of Nephromics. *Id.* at 6.¹¹

Recognizing the critical importance of innovation in medical technologies, the Food and Drug Administration recently issued a report entitled *Driving Biomedical Innovation: Initiatives to Improve Products for Patients* (“*Driving Biomedical Innovation*”).¹² Focusing on the critical role of tech transfer to biomedical innovation, the October 2011 report notes that “[t]ranslating a new idea from a discovery into a medical product is a complex process involving an entire ecosystem consisting of academia, industry, small businesses, payors, physicians, government agencies, and patient and consumer groups.” *Driving Biomedical Innovation* at 4. During a conference call discussing the report, FDA Commissioner Margaret Hamburg, M.D., explained that “it’s very, very important that we have this kind of cross-fertilization, with industry and academia and government all working together to help ensure that we have the understanding and systems in place and the tools that we need to be

¹¹ Numerous other examples of the tech transfer process at work can be found in AUTM’s *2010 Better World Report*. See *supra* note 8.

¹² FDA’s *Driving Biomedical Innovation* report is available at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm>.

able to translate from scientific discoveries into real-world product.”¹³

Tech transfer, in short, is a vital component of the innovation process. Imposing new limits on patent eligibility, as Petitioners propose, would set back the highly successful university-industry collaboration that has benefited the public over more than three decades since enactment of the Bayh-Dole Act.

D. Petitioners Ignore the Economic Realities That Play a Central Role in Bringing New Technologies to Market, as Their Own Actions Demonstrate.

Petitioners assert that Mayo Labs developed an improved product, and could have offered it at a lower price than the Prometheus product, but for the fact that Mayo Labs was blocked from launching it by Prometheus’s patent lawsuit. *See* Petitioners’ Br. at 8-11, 22. This assertion turns the patent bargain—early disclosure of inventions in exchange for a limited patent monopoly—on its head. As this Court has long recognized, the public benefits by having access to disclosures of inventions in order to build upon and improve them:

¹³ *See FDA Commish Hamburg Looks to Spur Med-Tech Innovation* (October 6, 2011), available at <http://www.aimbe.org/2011/10/fda-commish-hamburg-looks-to-spur-med-tech-innovation/>.

The federal patent system . . . embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. . . . In consideration of . . . disclosure and the consequent benefit to the community, the patent is granted.

Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-51 (1989) (internal quotation marks and citations omitted).

Mayo's "improvement" story is simply another example of the benefits of the patent bargain, not a reason to eliminate patent eligibility for innovations arising out of a vibrant and growing field of technology. The very reason Mayo Labs could develop a purportedly improved product and potentially offer it at a lower price point was that Mayo Labs was able to take advantage of the work disclosed by the inventors of Prometheus's patented methods, without incurring the initial investment Prometheus itself had made when it licensed the technology from the inventors. If patents are not available in fields like personalized medicine, inventors will be motivated to maintain critically significant data and discoveries as trade secrets in proprietary databases rather than disclose it to the public in patent applications, which are published eighteen months after they are filed in the U.S. Patent and Trademark Office ("USPTO").

In a similar vein, Petitioners complain that “no monopoly was necessary to incentivize the research that led to Prometheus’s patents,” and “Prometheus simply bought the right, after the fact, to patent [the inventors’] conclusions.” Petitioners’ Br. at 44. Once again, Petitioners fail to recognize how tech transfer operates to benefit the public. As discussed above, the tech transfer framework recognizes that research is a continuum, a partnership between research institutions and commercial enterprises, that serves the public. Tech transfer allows the private sector to acquire rights to research generated within universities and, through investment and marketing, turn it into commercial products that have practical application—the stated goal of the Bayh-Dole Act.

In this case, the inventors who worked at a Canadian teaching hospital entered into a licensing agreement with Prometheus. Prometheus then further developed and commercialized the inventors’ method of treatment, making the test available to countless more patients than would otherwise have had access to it. Indeed, there was no commercial test of this type accessible to patients at all before Prometheus’s product entered the market. This is exactly how tech transfer is meant to work.

Not surprisingly, it is Mayo Labs—a for-profit subsidiary of Mayo Clinic—that would have offered the “improved” test. This arrangement underscores that product development and commercialization is market driven, and that the economic profit motive is central to the ultimate goal of providing patients with access to innovative medical technologies.

Given this, Petitioners' complaints that the Prometheus patents operate as "bottlenecks on innovation competition" preventing others from "independently developing competing processes or products" ring hollow. *See* Petitioners' Br. at 45. Those complaints certainly do not support the restrictive standard for patent eligibility under § 101 that Mayo proposes.

The right to exclude others from practicing patented inventions for a limited term is the foundation of the patent system, as Petitioners well know.¹⁴ Indeed, Mayo itself has obtained patents on methods and kits for determining the level of thiopurine methyltransferase activity in a biological sample, which presumably would have provided its "improved" test with patent protection from other competing laboratories interested in developing their own improvements to the test, and even today it has more such patents pending at the USPTO. *See* U.S. Patent Nos. 7,452,689 and 7,727,737; U.S. Patent Publication Nos. 2006/0263840 and 2009/0029399.

E. Petitioners' Policy Arguments Are Properly Addressed to Congress, Not This Court.

Petitioners' many policy arguments regarding the proper balance between incentivizing innovation

¹⁴ According to USPTO databases, more than 500 issued patents have been assigned to the "Mayo Foundation for Medical Education and Research" or other Mayo entities, and more than 300 published patent applications assigned to Mayo are currently under review at the USPTO.

and limiting competition (*see, e.g.*, Petitioners’ Br. at 42-59) should be directed to Congress, not this Court. As the Court recently explained in *Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238 (2011), “Congress has amended the patent laws to account for concerns about ‘bad’ patents” in the past. *Id.* at 2252. And Congress will do so in the future, where warranted, as it did most recently in enacting the Leahy-Smith America Invents Act, signed into law in September 2011. Petitioners should address their request to narrow the scope of patent protection to Congress, as such issues “remain[] in its hands.” *See id.*; *see also Bilski*, 130 S. Ct. at 3226 (“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.”) (internal quotation marks and citations omitted).

II. THE PROMETHEUS CLAIMS FALL WITHIN § 101’S BROAD PATENT-ELIGIBILITY STANDARD.

The Prometheus claims at issue in this appeal involve the steps of (1) “administering” a synthetic drug of a certain type and (2) “determining” the level of resulting metabolites in the subject’s blood following administration of the synthetic drug. The claims conclude with one or more “wherein” clauses that specify circumstances when the metabolite

levels “indicate[] a need” to adjust the amount of synthetic drug administered to the subject.¹⁵

These claims fall squarely within the standard for patent eligibility adopted by this Court in *Diamond v. Diehr*, 450 U.S. 175 (1981), and reaffirmed in the Court’s recent *Bilski* decision. In *Diehr*, this Court articulated a flexible test for determining patent-eligible subject matter designed to encompass new and evolving technologies and held that the process claims at issue—including several with “comparing” steps—fell within the scope of patent-eligible subject matter. While acknowledging that laws of nature, natural phenomena, and abstract ideas are excluded from the scope of § 101, the *Diehr* Court held that “an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.” 450 U.S. at 187 (emphasis in original).

In an effort to provide guidance on the line between, for example, a natural phenomenon and a patent-eligible process that applies the natural phenomenon, this Court has repeated that an important clue to patentability is whether a process transforms or reduces an article to a different state or thing having concrete application. *See Bilski*, 130 S. Ct. at 3226-27. A “new and useful end” distinguishes an application of a law of nature, natural phenomenon, or abstract idea from those

¹⁵ As noted, one independent claim that omits the “administering” step.

concepts in isolation. *Diehr*, 450 U.S. at 188 n.11; *see also Bilski*, 130 S. Ct. at 3230 (summarizing *Diehr* holdings). The *Diehr* and *Bilski* Courts emphasized that this analysis must be applied to the claim *as a whole*, recognizing that inventions are, more often than not, new combinations of old elements and that it is therefore inappropriate to dissect a claim into separate elements to analyze its validity. *See Diehr*, 450 U.S. at 188; *Bilski*, 130 S. Ct. at 3230.

Petitioners ignore this Court's holdings in their attack on the Prometheus claims. First, they violate a fundamental tenet of the *Diehr* decision by characterizing the Prometheus invention as nothing more than a "correlation," arguing that the inventors of the Prometheus methods did not "invent" [the] correlations between patient condition and metabolite levels, but merely recognized them as existing in the patient population that they studied." Petitioners' Br. at 5. This assertion is fundamentally flawed.

Read as a whole, each of the Prometheus claims meets the "transformation" test. Both the "administering" and "determining" steps of the claims involve transformations, supporting patent eligibility under § 101. Administering a man-made drug necessarily has the effect of transforming the human body, and determining the levels of metabolites in blood samples requires transformation of the samples through manipulation and measurement. *See Bilski*, 130 S. Ct. at 3226-27.

More broadly, the Prometheus patents are not claiming a natural phenomenon. The inventors recognized the usefulness of measuring certain specific metabolite levels in order to optimize administration of a particular category of synthetic drugs on a patient-by-patient basis to treat certain diseases. This “correlation” embodies the inventors’ practical solution to the problem that individual patients metabolize these drugs differently, making effective dosing difficult and sometimes dangerous. Indeed, Mayo’s own purported improvement on the Prometheus method underscores that the claimed method simply represents one group of inventors’ practical solution to the problem based on their understanding of the drugs’ effect on the human body; the claimed method is not an absolute truth, law of nature, or natural phenomenon.

Next, Petitioners argue that Prometheus’s claims “preempt all practical uses of a natural phenomenon across a broad field” (Petitioners’ Br. at 26), relying on *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972). This argument does not withstand analysis. *See, e.g.*, Brief of the United States as *Amicus Curiae* Supporting Neither Party (“U.S. Br.”), dated September 9, 2011, 17-26.¹⁶

¹⁶ The United States points out that Petitioners’ preemption argument fails for two reasons: “First, the [claimed] correlation is not a ‘law of nature’ or ‘physical phenomenon’ in the relevant sense because it exists only as the result of human intervention. Second, the claimed methods do not preempt all practical uses of the relationship between metabolite levels and

Petitioners broadly assert that patents claiming correlations between the administration of medication and a resulting biological effect can never be patent eligible under § 101. *See* Petitioners' Br. at 6, 47-48. Patents of this type, however, have long been recognized as claiming patent-eligible subject matter. *See* U.S. Br. at 9, 13-17. If Petitioners' position were true, innumerable patents directed to drug dose ranges and "effective amounts" of drugs would be invalid as claiming non-patentable subject matter under § 101, because dosages and effective amounts are fundamentally "correlations" between the administered drug and the resulting biological effect.

Adopting Petitioners' reasoning would adversely affect the entire biomedical field. Studies designed to identify appropriate amounts of drugs to be administered to a particular subpopulation of patients having a specific "biomarker" profile are costly and time-consuming, and patent protection is often needed to justify the investment in such studies. To hold that inventions directed to effective dosing based upon biomarker studies or other personalized treatment methods are ineligible for patent protection would greatly hinder the delivery of more efficient, focused, and cost-effective healthcare alternatives to patients in need.

human health, at least if the correlation is described at an appropriately high level of generality." U.S. Br. at 18-19.

III. THE STRICT PATENTABILITY REQUIREMENTS OF §§ 102, 103, AND 112 SUFFICIENTLY PROTECT AGAINST THE ISSUANCE OF OVERBROAD PATENTS WITHOUT THE NEED FOR NARROWING THE STANDARD OF PATENT ELIGIBILITY.

As this Court recently reiterated, “[t]he § 101 patent-eligibility inquiry is only a threshold test.” *Bilski*, 130 S. Ct. at 3225. Quoting § 101, the Court reinforced the fundamental concept that in order to qualify for patent protection “the claimed invention must also satisfy ‘the conditions of patentability of this title.’” *Id.* These conditions of patentability are found in § 102 (novelty), § 103 (nonobviousness), and § 112 (disclosure requirements). The limitations found in §§ 102, 103, and 112 “serve a critical role in adjusting the tension, ever present in patent law, between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design.” *Id.* at 3229. As Justice Stevens wisely cautioned, concurring in *Bilski*:

Given the many moving parts at work in the Patent Act, there is a risk of merely confirming our preconceived notions of what should be patentable or of seeing common attributes that track the familiar issues of novelty and obviousness that arise under other sections of the statute but are not relevant to § 101.

Id. at 3238 (internal quotation and citation omitted).

In the Patent Act, Congress recognized that the combination of a broad definition of patent *eligibility* with stringent conditions for *patentability* strikes a balance by encouraging innovation without unduly inhibiting competition.¹⁷ *See id.* at 3225 (“Congress took this permissive approach to patentability to ensure that ingenuity should receive a liberal encouragement.”) (internal quotation and citation omitted). This Court’s precedents illustrate the stringent patentability requirements of §§ 102, 103, and 112 that serve as an effective gauntlet to evaluate claimed inventions that meet the broad patent-eligibility standard of § 101 but may not be deserving of patent protection.

Principles embodied in § 112, for example, bar sweeping, generalized claims attempting to reach beyond what an inventor has actually invented and disclosed to the public. In *O’Reilly v. Morse*, 56 U.S. (15 How.) 62 (1853), which is often cited as an early statutory subject matter case, the Court uses language that would, under current patent law, form the basis of a § 112 rejection for inadequate written description and/or enablement.

The Court allowed certain claims directed to Morse’s telegraph invention, but rejected a claim directed to an abstraction of that invention—the use

¹⁷ A simple example illustrating this concept is state driver’s licensing schemes, which have low eligibility criteria (often just minimum age and proof of residency) coupled with more stringent testing requirements that must be met prior to receiving a license.

of “electromagnetism, however developed for marking or printing intelligible characters, signs or letters, at any distances”—as attempting to claim any and all future methods of printing at a distance by means of the current, beyond what Morse had described or enabled. *Id.* at 119. In particular, the Court concluded that Morse invented the first seven of eight claims (those claims specifically pertaining to the telegraph and related applications of electromagnetism), but rejected the eighth because it claimed “an exclusive right to use a manner and process which [Morse] has not described and indeed had not invented, and therefore could not describe when he obtained his patent. The court is of the opinion that the claim is too broad, and not warranted by law.” *Id.* at 114. In short, Morse was not entitled to such a broad claim because “he claims what he has not described in the manner required by law.” *Id.* at 120.

As the Court of Appeals for the Federal Circuit recently explained in an unrelated case, “an invention which is not so manifestly abstract as to over-ride the statutory language of section 101 may nonetheless lack sufficient concrete disclosure to warrant a patent. In section 112, the Patent Act provides powerful tools to weed out claims that may present a vague or indefinite disclosure of the invention.” *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 869 (Fed. Cir. 2010).

Likewise, §§ 102 and 103 establish strict patentability requirements of novelty and non-obviousness. These are high hurdles. Where there is concern that an applicant improperly seeks to

capture inventions and knowledge already in the public domain, § 102 will block the issuance of patents because they lack the requisite novelty. Thus, for example, under § 102, an applicant is not entitled to obtain a patent for merely recognizing particular properties inherent in the prior art, even if such properties had not previously been recognized by persons skilled in the art. *See, e.g., In re Cruciferous Sprout Litig.*, 301 F. 3d 1343, 1349-51 (Fed. Cir. 2002).

Section 103 casts an even broader net, barring the issuance of patents claiming obvious variants of known inventions or combinations thereof, because “a patent for a combination which only unites old elements with no change in their respective functions . . . obviously withdraws what already is known into the field of its monopoly and diminishes the resources available to skillful men.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 415-16 (2007) (alteration in original; internal quotation marks and citations omitted); *see also id.* at 416 (“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.”).

This Court’s precedent has recognized the balance achieved by counter-balancing the broad eligibility standard of § 101 with the exacting patentability requirements imposed by §§ 102, 103, and 112. In *Diehr*, the Court explained that the question of whether patent claims fall within the § 101 categories of possibly patentable subject matter is very different from the question of whether the patentability conditions of §§ 102, 103, and 112

are met. 450 U.S. at 191. The *Diehr* Court concluded that, although a claimed process may not be “deserving of patent protection because it fails to satisfy the statutory conditions of novelty under § 102 or nonobviousness under § 103 [a] rejection on either of these grounds does not affect the determination that [the claimed process] recited subject matter which was eligible for patent protection under § 101.”¹⁸ *Id.*

In their brief, Petitioners repeatedly argue that Prometheus’s patented methods were well known and had been performed by doctors for many years. *See, e.g.*, Petitioners’ Br. at 21, 24, 25, 34-37. However, questions as to whether claimed inventions were “well known” and in the public domain are controlled by the novelty requirement of § 102, not by the eligibility requirement of § 101, the sole issue on appeal here. The Court’s consideration of § 101 eligibility here should disregard issues properly addressed under § 102 (and §§ 103 and 112).

For these reasons, and the reasons set forth in Section II above, the Prometheus claims are “at the very least not barred at the threshold by § 101.” *See Diehr*, 450 U.S. at 188. Whether the claims meet the

¹⁸ Although not expressly stated by the *Diehr* Court, this analysis would equally apply to the disclosure requirements of § 112, *i.e.*, failure to satisfy § 112 would not affect the determination that a claimed invention “recited subject matter which was eligible for patent protection under § 101.” *See id.*

strict conditions of patentability of §§ 102, 103, and 112 are separate questions reserved for another day.

CONCLUSION

For the foregoing reasons, AUTM urges this Court to affirm the judgment of the court of appeals and reject Petitioners' attempt improperly to narrow the scope of patent eligibility under § 101.

Respectfully submitted,

DONALD R. WARE
Counsel of Record
BARBARA A. FIACCO
HATHAWAY P. RUSSELL
JAMES M. FLAHERTY, JR.
FOLEY HOAG LLP
155 Seaport Boulevard
Boston, MA 02210
(617) 832-1000
dware@foleyhoag.com

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