

No. 08-964

In the
Supreme Court of the United States

BERNARD L. BILSKI AND RAND A. WARSAW,
Petitioners,

v.

DAVID J. KAPPOS, UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR, UNITED
STATES PATENT AND TRADEMARK OFFICE,
Respondent.

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

**BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL
ASSOCIATION, THE AMERICAN COLLEGE OF
MEDICAL GENETICS, THE AMERICAN SOCIETY OF
HUMAN GENETICS, THE ASSOCIATION OF
PROFESSORS OF HUMAN AND MEDICAL
GENETICS, AND MAYO CLINIC
IN SUPPORT OF RESPONDENTS**

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INTEREST OF THE *AMICI CURIAE*¹

A basic tenet of medical ethics is that discoveries and advances in medical care should be shared freely and disseminated openly. This ethical principle makes such discoveries readily available for use in the diagnosis and treatment of patients, and facilitates the study and improvement of such discoveries. It also allows physicians to fulfill their fundamental obligation to meet the needs of their patients.

For more than 200 years, the patent laws have, with few exceptions, existed in harmony with the professional ethical duty to disseminate and use medical advances. *Amici* join with the government in appealing from the non-medical decision below because the Federal Circuit has more recently used its “machine or transformation” test to approve patents that cover physicians’ mental impressions, in *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, 2009 WL 2950232 (Fed. Cir. Sept. 16, 2009). The ruling directly conflicts with that ethical duty and with this Court’s case law.

The claims of the patents in *Prometheus* are effectively identical to the claims that three Justices of this Court found to be clearly invalid in *Laboratory Corp. of America Holdings v. Metabolite Laborato-*

¹ Counsel for the parties have consented in writing to the filing of this brief, and their letters of consent have been filed with the Clerk. Pursuant to Rule 37.6, no counsel for either party had any role in authoring this brief in whole or in part, and no party other than the named *Amici* has made any monetary contribution toward the preparation and submission of this brief.

ries, Inc., 548 U.S. 124, 135 (2006) (“*Labcorp*”). (The other six Justices felt that certiorari had been improvidently granted.) Specifically, the claims recite processes that comprise testing a patient in a particular way (sometimes after giving the patient a drug), and then identifying, in a physician’s head, a correlation between the patient’s test data and the patient’s health. Under the *Prometheus* and *Labcorp* patents, it does not matter what the physician does after that—she is an infringer as soon as she makes the mental correlation between the test results and the patient’s health. Rather than invalidating the claims by relying on the rationale in *Labcorp* and the precedent it cited, the Federal Circuit in *Prometheus* used its own “machine or transformation” test to find the claims valid, and dismissed the opinion of the *Labcorp* Justices as nonbinding.

The scope of patentable subject matter is quite broad, and can give rights over a new drug, a new diagnostic test, or even a new method of diagnosing a particular disease. But it does not extend to a physician’s consideration of a scientific fact. A claim so broad would preempt the physician from doing anything with the knowledge. Once recognized, the scientific fact cannot, and should not, be ignored the physician. It should be used in the diagnosis and treatment of patients. What the physician learns from it should be publicized so as to advance medical science. Of course, if the basic fact that certain test results correlate with a given physical condition were to be incorporated into some useful application, then that application might be a patentable advance over prior art. But the fact of the correlation alone is not.

If construed too broadly, Section 101 blocks the spread of medical knowledge, creates unfair monopolies, harms patients, and drives up the cost of healthcare. Properly construed, it allows a physician to think about the relationship between a test result and a patient's physical condition.

On behalf of hundreds of thousands of members nationwide, the medical organizations that submit this brief urge the Court to enforce proper limitations on patentability under Section 101.

* * *

The American Medical Association (AMA) is a private, voluntary non-profit organization of 240,000 physicians and medical students, who practice in all states and all fields of medical specialization. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health. From its inception, the AMA has maintained a Code of Medical Ethics, including a set of core Principles and Opinions applying those Principles. The Code of Medical Ethics has been cited by ethicists, legal scholars and courts of law, including, on numerous occasions, this Court. Several of the Ethical Opinions, as well as reports of the AMA's Council on Ethical and Judicial Affairs, address ethical issues raised by the issuance of patents on medically useful information. The AMA has issued numerous statements regarding the need to avoid having patents interfere with appropriate medical care and the development of better medical treatments and technologies.

The American College of Medical Genetics (ACMG) is a private, nonprofit, voluntary organiza-

tion of clinical and laboratory geneticists. The Fellows of the ACMG are doctoral level medical geneticists and other physicians involved in the practice of medical genetics. With more than 1300 members, the ACMG's mission is to improve health through the practice of Medical Genetics. In order to fulfill this mission, the ACMG strives to 1) define and promote excellence in medical genetics practice and the integration of translational research into practice; 2) promote and provide medical genetics education; 3) increase access to medical genetics services and integrate genetics into patient care; and 4) advocate for and represent providers of medical genetics services and their patients. The position of the ACMG is that observations of naturally occurring correlations should not, in and of themselves, be patentable.

The American Society of Human Genetics (ASHG), founded in 1948, is the primary professional membership organization for human genetics specialists worldwide. It is a private, non-profit organization. The Society's nearly 8000 members include researchers, academicians, clinicians, laboratory practice professionals, genetic counselors, nurses, and others who have a special interest in the field of human genetics. ASHG serves research scientists, health professionals, and the public by providing forums to: (1) share research results at annual meetings and in *The American Journal of Human Genetics*; (2) advance genetic research by advocating for research support; (3) enhance genetics education by preparing future professionals and informing the public; and (4) promote genetic services and support responsible social and scientific policies.

The Association of American Medical Colleges (AAMC) is a non-profit organization representing all 129 allopathic medical schools in the United States, about 400 major teaching hospitals and health systems, and about 90 academic and professional societies representing nearly 110,000 faculty members. AAMC's member institutions are at the forefront of medical education, research and research training, and health care innovation and delivery. AAMC members perform nearly 55% of the extramural research sponsored by the National Institutes of Health, and they partner with industry in discovering new and better approaches to the diagnosis, treatment, and prevention of human diseases. The AAMC is committed to the continuing improvement of health care and the Continuing Medical Education of physician practitioners based on sound scientific evidence.

The Association of Professors of Human and Medical Genetics (APHMG) is a non-profit organization that promotes human and medical genetics educational programs in North American medical and graduate schools. Currently more than 90 medical and graduate schools are members. The APHMG represents the faculty that teach human and medical genetics to virtually all medical students in North America. As educators, they teach medical students to think about, diagnose and treat genetic diseases. It is the APHMG's position that all physicians must be free to think broadly, creatively, analytically and without fear that they risk infringing a patent merely by thinking about the relationship between certain treatments and their potential metabolic and clinical sequelae.

The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 1,600 physicians, doctoral scientists, and medical technologists who perform laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. The AMP is dedicated to the development and implementation of molecular diagnostic testing, which includes genetic testing in all its definitions, in a manner consistent with the highest standards established by CLIA, CAP, the ACMG, and the FDA. AMP members practice their specialty in widely diverse settings, including academic medical centers, independent medical laboratories, community hospitals, federal and state health laboratories, and the in vitro diagnostic industry, and are involved in every aspect of molecular diagnostic testing. AMP provides national leadership for the advancement of safe and effective practice and education for molecular diagnostic testing.

The College of American Pathologists (CAP) has nearly 17,000 physician members, including most of the eligible board-certified pathologists. It is the world's largest medical society composed exclusively of pathologists, who are physicians who obtain and interpret data as the result of examination of tissues, blood, and other body fluids for diagnosis and patient care. The CAP also serves the laboratory community throughout the world. More than 6,000 laboratories are accredited by the CAP, and approximately 23,000 laboratories are enrolled in the College's proficiency testing programs.

The Mayo Clinic ("Mayo") is a charitable, non-profit corporation based in Rochester, Minne-

sota. Mayo is the first and largest integrated, not-for-profit group practice in the world. Doctors from every medical specialty work together to care for patients, joined by common systems and a philosophy of “the needs of the patient come first.” More than 3,300 physicians, scientists and researchers and 46,000 allied health staff work at Mayo, which has sites in Rochester, Minn., Jacksonville, Fla., and Scottsdale/Phoenix, Ariz. Collectively, the three locations treat more than half a million people each year. In addition to an integrated clinical practice, Mayo meets the needs of patients through extensive education and research activities. The Mayo Clinic Rochester and Mayo Collaborative Services (d/b/a Mayo Medical Laboratories), of which the Mayo Clinic is a parent, are the named defendants in the *Prometheus* lawsuit.

SUMMARY OF THE ARGUMENT

Under this Court’s precedent, a patent claim cannot be valid if it would preempt use of a fundamental scientific principle or natural phenomenon. Just as the Federal Circuit’s “machine or transformation” test might help indicate whether an invention is a “technology” that can be the subject of a patent, it can also be helpful in determining whether the preemption standard is met. But the “machine or transformation” test must remain secondary and cannot supplant this Court’s requirement that a claim address a technology, or the Court’s preemption standard. *Bilski*’s claims should be held unpatentable, not because they fail to use a machine or make a physical transformation, but because their lack of machine or transformation indicates that they

do not involve what has traditionally been considered to be patentable subject matter. Likewise, when applied to patents that relate to medical treatment, the preemption standard prevents patentees from attempting to cover every possible application of a scientific observation, and requires them to limit their claims to a particular new and useful application or use of the observation.

It is important that this Court speak so that the Patent Office does not issue overreaching claims in the life sciences, and lower courts understand that they may not uphold patents whose claims impede the practice of medicine by prohibiting physicians from making their own observations of biological processes. Such patent claims undermine the ability of physicians to make informed treatment decisions based on the latest scientific knowledge, stifle innovation, and increase the cost and decrease the quality of treatment for serious diseases. Such patents chill research, and patents such as those in *Labcorp* and *Prometheus* chill talking and thinking of ideas by making talking and thinking into a tort.

ARGUMENT

I. The Federal Circuit’s “Machine or Transformation” Test Must Be Applied Properly

The claims in this appeal are unpatentable, as the government points out in its brief, because they fall well outside the limits that Congress and the Court have placed on patentability. In particular, the *Bilski* claims are not directed to “technology,” which can be seen in part by their failure to use a particular machine or apparatus, or effect a trans-

formation of subject matter. The absence of a machine or transformation is instructive in this case, but should not be determinative, and its relevance must be allowed to vary with each particular case. The outcome must be driven instead by more fundamental, historical standards of patentability.

Just as “machine or transformation” is merely one test to help determine whether an invention is directed to “technology,” it also cannot trump long-applied limits against patent claims that try to preempt the use of fundamental principles—like those at play in *Labcorp* and *Prometheus*. For example, the recognition that the earth revolves around the sun cannot itself be patented, whether the recognition was made through mental deduction or with the use of a specific model of computer. Nor could the recognition of DNA’s double helix structure be patented, even if the discoverers had to perform numerous chemical transformations of a DNA sample to recognize it.

Both processes—which undoubtedly have particular machines and/or transformations that are core to their execution—are unpatentable if they are not limited to some particular application of the principle, because they would cover, and thus “preempt,” every possible implementation that could come from recognizing the fundamental principle. See *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

The Federal Circuit, however, has elevated its *Bilski* “machine or transformation” test into the fundamental standard for patentability. Specifically, in *Prometheus*, the court decided that the “transformation,” for certain of the patent claims, was the natural change that occurs to human blood when it is te-

sted. 2009 WL 2950232, at *8-9. That minimal transformation should not have carried the day, because the claims were all fully preemptive—i.e., they covered a physician’s observation of a correlation in test data, and thus prevented the physician from doing *anything* with that observation. The Federal Circuit, however, validated the claims, noting that “machine or transformation” drove the result:

The proper inquiry under § 101 is whether these methods meet the Supreme Court’s machine or transformation test articulated in *Benson* and *Diehr*, and applied in *Bilski*, and, if so, whether the machine or transformation is central to the purpose of the claims.

Id. at *8. The court then made clear that it believed its “machine or transformation” test was the determinant of preemption, and not simply a helpful indicator:

[B]ecause the [Prometheus] claims meet the machine-or-transformation test, they do not preempt a fundamental principle.

Id.

Such a stretched reading “transformation” fails to take into account this Court’s historical holdings that “[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.” *Bilski*, 545 F.3d at 952, *citing Benson*, 409 U.S. at 67. Rather, “[i]f there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.” *Funk Brothers v. Kalo*, 333

U.S. 127, 130 (1948). Even if a natural process, such as photosynthesis or digestion, involves the transformation of matter, it remains “the handiwork of nature” and is not patentable. *Id.* at 131. And even if an observation of a fundamental principle requires some sort of preparatory transformation, a party cannot claim such an observation.

Under this Court’s own case law, the presence of a machine or transformation in a patent claim has not necessarily indicated whether the patentee is attempting to cover a real-world application of a general principle or instead trying to preempt all uses of the principle. For example, the patentee in *Diamond v. Diehr* limited its claims to using the Arrhenius equation in order to open or close an injection mold, and the Court found the claims valid, 447 U.S. 175, 187 (1981). But a machine’s presence, even in the middle of an invention, does not always prevent preemption. In *Parker v. Flook*, for example, the invention involved computing alarm limits with a machine, but was not limited with respect to how the limits were ultimately applied, and the claims were held invalid, 437 U.S. 584, 594-95 (1978).

The Prometheus claims are like those in *Flook*, and unlike those in *Diehr*. They recite recognizing a particular natural result (the metabolization level of certain chemicals in a human body), and are open to any use of that recognition. They thus preempt all uses. In fact, although the Prometheus patents are directed to gastrointestinal disorders, Prometheus accused a Mayo physician even though she was conducting dermatology research. In Prometheus’ view, it did not matter what she intended to do with her knowledge because the Prometheus patents cover *all*

uses of the knowledge.² Despite this, the Federal Circuit assumed that the presence of certain chemical reactions *ipso facto* meant that the Prometheus claims could not be preemptive, when in fact it should have used those tests only as an aid to determine whether the claims were preemptive.

The Federal Circuit's application of its *Bilski* test in *Prometheus* also puts its cross-wise with the reasoning of Justices Breyer, Stevens, and Souter in their dissent from dismissal of the writ as improvidently granted in *Labcorp*. There, the claims again ended with a physician recognizing a correlation between an elevated level of a certain chemical in the blood and a patient's health. 548 U.S. at 134-35. In writing at length on the issue, Justice Breyer noted that the case was "not at the boundary," because it was nothing more than "an instruction to read some numbers in light of medical technology." *Id.* at 135. The Prometheus claims have the same problems, even though they deal with other chemicals and sicknesses, so the *Labcorp* analysis was properly central to the district court's opinion in *Prometheus*. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 2008 WL 878910 (S.D. Cal. Mar. 28, 2008). But the Federal Circuit dismissed the Justices' reasoning in a footnote and without analysis:

² Such an interpretation also would unnecessarily bring the patent laws into conflict with the First Amendment, as the ACLU pointed out in its brief *amicus curiae* in the Federal Circuit in this case. See http://www.aclu.org/pdfs/freespeech/in_re_bilski_aclu_amicus.pdf.

That dissent is not controlling law and also involved different claims from the ones at issue here.

2009 WL 2950232, at *8 n.3.

The Federal Circuit's radical expansion of Section 101 in *Prometheus*, with nary a nod to this Court's precedent or the *Labcorp* Justices' reasoning, highlights that the "machine or transformation" test, whatever its value, needs to be better defined as a helpful tool, but not a determinant of more general standards for patentability.

II. Public Policy is Well Served by Current Limits on Patentable Subject Matter, Which Preclude Patenting Scientific Data

The *amici* recognize that healthcare-related patents can enhance the provision of high-quality and cost-effective medical care. The financial incentive offered by patents supports the expensive and uncertain research required to identify, test, and gain approval for products such as new pharmaceuticals, medical devices, and diagnostic testing kits. In this respect, the patent system has served patients and the medical profession well.

Patents on basic scientific principles underlying medical care, however, undermine these salutary effects. Such patents raise ethical concerns for physicians, threaten to stifle innovation and raise the costs of medical treatment, and erode the quality of patient care by limiting the knowledge physicians may use to diagnose and treat their patients.

1. Patents on Scientific Principles Raise Ethical Concerns for Physicians

Physicians have longstanding ethical obligations to advance and share useful medical knowledge with patients and physicians. Principle V of the AMA's Principles of Medical Ethics states that a "physician shall continue to study, apply and advance scientific knowledge," and "make relevant information available to patients, colleagues, and the public."³ Opinion 9.08 of the Code of Medical Ethics of the AMA elaborates upon this basic principle:

Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. . . . The intentional withholding of new medical knowledge, skills and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.⁴

Discovery of a basic scientific principle that could be useful to others in devising medical applications or to physicians in diagnosing and treating patients is a quintessential example of the kind of medical knowledge that physicians are obliged to share freely. To interpret the patent laws to make scientific principles eligible for patent protection threatens to undermine, rather than promote, the ethical practice of medicine.

³ Available at www.ama-assn.org/ama/pub/category/2512.html (last visited April 5, 2009).

⁴ Available at http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_3i07.pdf (last visited April 5, 2009)

2. Patents Solely on Scientific Facts Threaten to Stifle Innovation, Including the Development of Personalized Medicine, and to Increase Health Care Costs

Basic scientific facts “are part of the storehouse of knowledge of all men.” *Funk Bros.*, 333 U.S. at 130. Ensuring wide dissemination and free access to such facts is essential to scientific progress. The patentees in *Labcorp* and *Prometheus* are neither the first nor the last to consider the implications of particular blood chemical levels in relation to human health. Ready access to basic facts, such as a relationship between levels of drug metabolite and the drug’s efficacy and toxicity, are essential to important, ongoing research efforts. Exclusive rights to scientific facts hinder efforts to develop or employ new and superior medical advances that would build on them.

Disclosure of such correlations creates incentives for laboratories, such as Mayo’s, to compete to develop fast and inexpensive ways of testing and for researchers to study similar correlations. But a patent that covers mere physician recognition of a test result may “shut[] the door” to the development or use of such new tests, and discourage further research and development. *O’Reilly v. Morse*, 56 U.S. 62, 113 (1853).⁵

⁵ The great weight of academic research confirms that allowing patents to preempt important fields like medical diagnosis by monopolizing biological laws would inflate health care costs while simultaneously retarding (rather than promoting) innovation. See M. Boldrin & D. Levine, *Against Intellectual Monopoly* 73-77, 89-92, 184-187, 214-218, 238, 246

3. Patents on Scientific Principles Erode Physicians' Ability to Provide Quality Patient Care

Patent claims like those in *Labcorp* and *Prometheus* conflict with physicians' ability to provide effective patient care. A physician cannot design around a scientific principle to avoid infringement. A physician who learns—from the medical literature, colleagues, continuing medical education, or elsewhere—of some patented correlation cannot put that

(Cambridge 2009) (describing dramatic increase in grants of patents over last decade resulting in a “patent thicket” harmful to innovation); Torrance & Tomlinson, *Patents and the Regress of Useful Arts*, 10 Colum. Sci. & Tech. L. Rev. 130, 138, 162-167 (2009) (collecting economic research showing lack of stimulus to innovation); Landes & Posner, *The Economic Structure of Intellectual Property Law* 305-306 (2003) (patent monopolies on “scientific principles” threaten “enormous potential for rent seeking” and “enormous transaction costs that would be imposed on would-be users”); L. Branstetter, *Do Stronger Patents Induce More Local Innovation?*, 7 J. Int'l Econ. L. 359 (2004) (finding absence of innovation benefits from expanded patent monopolies; despite “reasonably well structured research projects conducted by competent scholars,” studies “failed to find them in most contexts”); F. Knight, *Risk, Uncertainty and Profit* 372 (1921). At a minimum, at a time of heightened national concern over health care cost and quality, this research shows “that a heavy burden of persuasion should be placed upon those who would extend such protection.” S. Breyer, *The Uneasy Case for Copyright*, 84 Harv. L. Rev. 281, 322-323 (1970) (citing research in patent and copyright fields).

knowledge out of mind. Thomas Jefferson aptly described this characteristic of ideas:

If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea, which an individual may exclusively possess as long as he keeps it to himself; but the moment it is divulged, it forces itself into the possession of every one, and the receiver cannot dispossess himself of it.

L. Lessig, *The Future of Ideas: The Fate of the Commons in a Connected World* 94 (2001). Such is the nature of scientific fact; once known, it must be considered. Quality patient care demands that a physician consider test results in light of, among other things, current medical knowledge.

Granting exclusive rights to the mere consideration of scientific facts concerning medical diagnosis and treatment would distort patent law beyond recognition. By discovering a previously unknown correlation between obesity and illness, for example, a researcher could obtain a patent on the process of having a patient step on a scale, measuring a weight above a particular statistically significant value, and then thinking about whether to recommend that the patient diet to lose weight. Any entity that made or sold scales, and that dared to mention that correlation in a brochure, might then be liable for intentionally inducing infringement. Such a result is unthinkable. In the context of patient testing, a patentee could block a competitor from developing a test that is superior to, and wholly different from, the patentee's test because the patentee would have a monopoly on the fundamental concept at the center

any test. As a result, such patents not only drive up costs to patients, but also lower the quality of patient care.

Justice Breyer, in *Labcorp*, well expressed the potential dangers of giving such sweeping rights in heretofore unpatentable subject matter:

If I am correct in my conclusion in Part III that the patent is invalid, then special public interest considerations reinforce my view that we should decide this case. To fail to do so threatens to leave the medical profession subject to the restrictions imposed by this individual patent and others of its kind. Those restrictions may inhibit doctors from using their best medical judgment; they may force doctors to spend unnecessary time and energy to enter into license agreements; they may divert resources from the medical task of health care to the legal task of searching patent files for similar simple correlations; they may raise the cost of healthcare while inhibiting its effective delivery.

548 U.S. at 138. These negative effects are bound to ensue from the Federal Circuit's interpretation of the "machine or transformation" test in *Prometheus*.

CONCLUSION

For the foregoing reasons, *Amici* support the conclusion of the Federal Circuit, but caution that the "machine or transformation" test not be allowed to

override the Court's traditional standards for patentable subject matter.⁶

Respectfully submitted,

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⁶ Mayo intends to file its petition for certiorari in the *Prometheus* case in October 2009. The petition will raise the same Section 101 issues that this Court was unable to resolve for lack of proper issue preservation in *Labcorp*, 548 U.S. at 125 (Breyer, J. dissenting from dismissal of petition). Mayo properly preserved the issues in *Prometheus*, and the Federal Circuit actually decided them. That case thus presents an appropriate vehicle to resolve the important questions left unresolved in *Labcorp*.