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 Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF *AMICI CURIAE* THE AMERICAN COLLEGE OF MEDICAL GENETICS, THE AMERICAN MEDICAL ASSOCIATION, THE ASSOCIATION OF PROFESSORS OF HUMAN AND MEDICAL GENETICS, THE ASSOCIATION FOR MOLECULAR PATHOLOGY, THE COLLEGE OF AMERICAN PATHOLOGISTS, AND THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES IN SUPPORT OF PETITIONERS

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INTEREST OF THE *AMICI CURIAE*

Amici curiae The American College of Medical Genetics, The American Medical Association, The Association of Professors of Human and Medical Genetics, The Association for Molecular Pathology, The College of American Pathologists, and The Association of American Medical Colleges respectfully submit this brief in support of petitioners Mayo Collaborative Services (d/b/a Mayo Medical Laboratories) and Mayo Clinic Rochester (collectively "Mayo") encouraging the grant of a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit, because that judgment stems from an interpretation of patentable subject matter that is inconsistent with this Court's precedent and with public policy regarding both innovation and health care.[1]

Amici are associations of physicians, medical educators, and other providers of healthcare-related services. *Amici* are greatly concerned with the potential impact of the Federal Circuit's decision to allow patenting of claims to natural phenomena such as the

[1] The parties have consented to the filing of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of the *amici curiae*'s intention to file this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae* and their members or their counsel made a monetary contribution to its preparation or submission.

correlations covered by Prometheus's patents. Such patents have great potential to impede the practice of medicine and raise the costs of medical treatment.

The American College of Medical Genetics (ACMG) is a private, non-profit, voluntary organization 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 1,500 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 Medical Association (AMA) is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in the AMA's House of Delegates, substantially all U.S. physicians, residents and medical students are represented in the AMA's policy making process. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

The AMA opposes the patenting of medical procedures, as such patents limit the dissemination and utilization of human knowledge.

The Association of Professors of Human and Medical Genetics (APHMG) was incorporated in 1995 as a non-profit organization to promote 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 broadly 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 1,900 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 of its definitions, in a manner consistent with the highest standards established by the Clinical Laboratory Improvement Amendments, the College of American Pathologists,

the ACMG, and the Food and Drug Administration. 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) is the world's largest medical society composed exclusively of pathologists, with nearly 18,000 members. Pathologists are physicians who examine tissues, blood, and other body fluids for the purposes of medical diagnosis and patient care. Through its accreditation and proficiency testing programs, the CAP is also a leader in assuring the quality of laboratory testing. More than 7,000 laboratories are accredited by the CAP, and approximately 23,000 laboratories are enrolled in the College's proficiency testing programs.

The Association of American Medical Colleges (AAMC) is a non-profit organization representing all 134 accredited medical schools in the United States, about 400 major teaching hospitals and health systems, and nearly 90 academic and professional societies representing about 125,000 faculty members. AAMC's member institutions are at the forefront of medical education, research and research training, and health care innovation and delivery. AAMC member institutions perform more than half 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.

SUMMARY OF ARGUMENT

New drugs and new tools for diagnosing illness and monitoring treatment are critical to the advancement of medicine. *Amici* medical associations do not dispute that patents on healthcare-related technologies can enhance the provision of high-quality and cost-effective medical care. The patents at issue in this case, however, do not claim innovative drugs or new diagnostic tools. Instead, these patents grant exclusive rights over the mere recognition that there is a natural statistical correlation between certain metabolite levels in the body, as measured by well-known means, and the potential toxicity and effectiveness of a well-known drug. If these patents remain in force, any physician who measures those metabolite levels, knows of the natural correlation, and thus is "warned" that it might be advisable to adjust the dosage becomes an infringer. This will be the case even if a physician had measured and considered the levels of these metabolites when treating patients prior to the issuance of the patents.

If such claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights in the use of scientific data

that is critical to and must be widely available for providing sound medical care. Conscientious physicians will be unwilling and unable to avoid considering relevant scientific information when reviewing test results. Thus, patent licenses increasingly will be required for physicians to conduct even well-established diagnostic tests. Laboratories will risk indirect infringement merely by educating doctors about the scientific meaning of test results. It is hard to imagine how the clinical diagnostic community will continue to provide quality patient care and how physicians will continue to practice medicine in an ethical and effective manner under such a regime.

Moreover, the claims at issue are not directed to patentable subject matter. These claims run afoul of this Court's longstanding and recently reaffirmed prohibition on the patenting of "laws of nature, physical phenomena, and abstract ideas," under Section 101 of the Patent Act. *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 477 U.S. 303, 309 (1980)). As the district court recognized, the claims at issue here "wholly preempt" the natural relationship between the levels of the metabolites 6-TG and 6-MMP in the human body and the likelihood of therapeutic efficacy and toxicity of thiopurine drugs. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-CV-1200, 2008 WL 878910 at *10 (S.D. Cal. Mar. 28, 2008) (quoting *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972)).

The Federal Circuit has erred twice in finding that Prometheus's claims encompass patentable subject matter. *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 581 F.3d 1336 (Fed. Cir. 2009); *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, 628 F.3d 1347 (Fed. Cir. 2010). Even after this Court's remand for reconsideration in light of *Bilski,* the Federal Circuit's analysis was unchanged, continuing to rely heavily on a machine or transformation of matter test. While that test provides a "useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101," *Bilski*, 130 S. Ct. at 3227, it is inapposite to determining whether a patent claim preempts a natural phenomenon or scientific principle. Whether a natural phenomenon involves a "transformation of matter" cannot determine its eligibility for patenting, or virtually every natural phenomenon could be patentable.

The patentability of claims like those at issue here is of great consequence for the future of health care in the United States. The issue was left open by this Court's opinion in *Bilski* and remains unresolved in light of this Court's dismissal of certiorari in *Lab. Corp. of America Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006). The present case provides an appropriate and timely opportunity to resolve this important question.

ARGUMENT

I. Health Care Policy is Best Served by This Court's Well-Established Limits on Patentable Subject Matter, Which Preclude Claims to Observations of Natural Phenomena

The scope of patentable subject matter established by Congress in the Patent Act, 35 U.S.C. § 101, although quite broad, does not extend to scientific facts or observations of natural phenomena. *See Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citing *Parker v. Flook*, 437 U.S. 584, 593 (1978) and *Benson*, 409 U.S. at 67). The patents at issue here give Prometheus exclusive private ownership not of a new drug, a new diagnostic test, or even a new method of diagnosing a particular disease. Rather, the patents at issue effectively award Prometheus exclusive ownership of a pre-existing diagnostic test based on the mere *observation* of a naturally-occurring phenomenon: the correlation between the levels of certain metabolites produced naturally in the human body in response to administration of certain doses of thiopurine drugs, and the efficacy and toxicity of those drugs.

Amici medical associations recognize that healthcare-related patents can enhance the provision of high-quality and cost-effective medical care. The financial incentive that patents offer supports the expensive and uncertain research required to identify, test, and gain approval for new pharmaceuticals, medical devices, diagnostic testing kits, and other

products. In this respect, the patent system has served patients and the medical profession well.

Patents on scientific observations underlying medical care, however, do not have these salutary effects. Such patents raise ethical concerns for physicians, erode the quality of patient care by limiting use of the very knowledge physicians must rely on to diagnose and treat their patients, and threaten to stifle innovation and raise the costs of medical treatment.

A. Patents on Scientific Observations Raise Ethical Concerns for Physicians

Physicians have longstanding ethical obligations to advance and share useful medical knowledge with patients and other physicians. Principle V of the AMA's Principles of Medical Ethics states, "[a] physician shall continue to study, apply, and advance scientific knowledge," and "make relevant information available to patients, colleagues, and the public. . . ."[2] 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. . . .

[2] Available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.shtml (last visited April 13, 2011).

> 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.[3]

Basic scientific observations that could be useful to physicians in reaching diagnoses and treating patients or to others in devising medical innovations are quintessential examples of the kind of knowledge that physicians are obliged to share freely. To interpret the patent laws so as to make scientific observations eligible for patent protection threatens to undermine, rather than promote, the ethical practice of medicine.

Physicians also have an ethical obligation to consider the most up-to-date scientific information available when treating their patients. Measurements and observations such as those at issue here are part of the broader clinical evaluation that physicians must undertake when treating patients. It is a routine part of the practice of medicine—indeed, it is essential to meet appropriate medical standards of care—for physicians to monitor metabolite levels and to use those levels along with other laboratory and clinical parameters to guide dosage adjustments, thereby providing necessary and appropriate medical care for their patients.

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[3] Available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion908.shtml (last visited April 13, 2011).

B. Patents on Scientific Observations Erode Physicians' Ability to Provide Quality Patient Care and Burden their Use of Pre-Existing Laboratory Tests

Quality patient care demands that a physician consider test results in light of, among other things, current medical knowledge. Prometheus argued below that a doctor infringes simply by thinking about the correlation between dosage efficacy and toxicity after receiving results of a metabolite test *even if the test was ordered for a reason other than a desire to adjust dosage in light of the limits set out in the patent claims*. Pet. 22. A doctor who had a pre-existing practice of testing levels of the same metabolites would become an infringer if he or she *merely considered what to do about the results in light of relevant scientific information.* There can be no design around a scientific fact. A physician who learns—from the medical literature, colleagues, continuing medical education, or some other source—of the statistical correlation between metabolite levels and drug efficacy and toxicity cannot—and should not—put that knowledge out of mind.

Moreover, if the claims at issue here were properly patentable, a laboratory might induce infringement simply by informing a doctor of the correlation in conjunction with delivery of test results or perhaps even by publishing articles or brochures discussing the correlation. Indeed, confronting very similar facts in *Metabolite Labs., Inc. v. Lab. Corp. of America Holdings*, 370 F.3d 1354 (Fed. Cir. 2004), the Federal

Circuit found that the defendant laboratory had induced infringement through the publication of medical articles.[4] *Id.* at 1365.

The potential ramifications of the Federal Circuit's ruling that such claims are patentable are profound and sobering. By uncovering a correlation between obesity and a particular illness, for example, a researcher could obtain a patent on the process of having a patient step on a scale and then considering that natural correlation in deciding whether to recommend that the patient diet to lose weight. Any entity that made or sold scales and that dared to mention the correlation in a brochure might then be liable for intentionally inducing infringement. An observation that some patients tend to run a particularly high fever if given too much of a particular drug could lead to a patent on taking a patient's temperature and considering whether to raise or lower the dosage with that natural response in mind. Patients, physicians, and thermometer manufacturers might

[4] This Court is currently considering the state of mind standard for inducement of infringement, *Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 458 (2010) (mem.). Though very important in many contexts, the standard is unlikely to be determinative in cases such as this one. Laboratories performing diagnostic tests are highly likely to be aware of broad diagnostic patents, because the patent holders will notify them. Laboratories also generally inform doctors of the scientific significance of test results, and the public health depends on their doing so. Thus, whatever the outcome of *Global-Tech*, diagnostic test laboratories will find it difficult to avoid indirectly infringing the type of claims at issue here.

directly or indirectly infringe because a thermometer reading "warns" that it might be advisable to adjust dosage of the drug.

Such results are unthinkable, yet they are eminently plausible applications of the Federal Circuit's ruling that the claims in this case constitute patentable subject matter. If patent licenses are required for physicians merely to *consider* newly discovered implications of well-established diagnostic tests, and if laboratories become indirect infringers merely by educating doctors about those implications, it is hard to imagine how medical diagnostics will continue to provide quality patient care.

C. Patents on Scientific Observations Threaten to Stifle Innovation, Including the Development of Personalized Medicine

Basic scientific facts are "part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none." *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros.*, 333 U.S. at 130). Ensuring wide dissemination of and free access to such facts is essential to scientific progress. Ready access to basic facts, such as a relationship between levels of drug metabolites and the drug's efficacy and toxicity, is essential to medical research. Physicians' understanding of correlations, such as those claimed here, evolves as knowledge of the body's natural responses

to treatment accumulates through medical practice and is shared throughout the medical community.

These patentees are neither the first nor the last to study the implications of these particular metabolite levels for human health. Pet. 5. To improve existing treatment regimens, laboratories such as Mayo continually strive to develop better and less expensive tests of metabolite levels, along with more accurate standards for the clinical interpretation of those levels. Researchers, such as Dr. El-Azhary, seek to study similar correlations so as to understand the body's responses to drugs in different disease contexts and to develop appropriate clinical responses. Pet. 9. Patents such as those at issue here impermissibly burden such medical research, effectively "shut[ting] the door" to scientific progress. *O'Reilly v. Morse*, 56 U.S. 62, 113 (1853).

In addition, patents on scientific observations, such as the statistical correlations involved here, would stifle rather than incentivize developments in medical practice, including the practice of personalized medicine. Such patents, which do not cover inventive diagnostic tests but instead seek to preempt the scientific observations underlying proper diagnosis and treatment, threaten to slow the development of diagnostic testing and undermine competition to provide inexpensive and high quality testing, leading inevitably to higher-priced medical treatment.

Moreover, patents are not needed to incentivize physicians and researchers to study the kinds of

clinical correlations at issue in this case. For example, the Secretary's Advisory Committee on Genetics, Health, and Society conducted an extensive investigation into the need for patents in the context of genetic diagnostic testing and found:

> [P]atents do not appear to be necessary to stimulate research and genetic test development. . . . [S]cientists are principally motivated to conduct research by their curiosity, career ambitions, and desire to advance understanding of health and disease. . . . Similarly, laboratories have sufficient non-patent incentives to develop genetic tests: clinical need and demand drive development, and development costs are minimal.[5]

Patents are equally unnecessary to stimulate research and development of the diagnostic methods claimed here. Academic researchers and clinicians do not need patents to motivate them to study the scientific correlations between metabolite levels and the body's responses to treatment. Development costs for these diagnostic tests are also low, in part because approval of such tests does not involve the high regulatory costs involved in the development of pharmaceuticals and medical devices. Exclusive

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[5] Secretary's Advisory Committee on Genetics, Health, and Society, *Gene Patents and Licensing Practices and Their Impact on Patient Access to Genetic Tests* (April 2010) at 90, *available at* http://oba.od.nih.gov/oba/sacghs/reports/SACGHS_patents_report_2010.pdf (last visited April 13, 2011).

rights do not promote innovation in this context. On the contrary, when scientific knowledge of the medical implications of clinical tests is freely available there is enormous incentive for physicians to *make use of that knowledge* to provide necessary and appropriate care for their patients.

II. Because the Claims Asserted in this Case Impermissibly Preempt Natural Phenomena, the Ruling Below is Inconsistent with This Court's Precedents

A. The Asserted Claims Are Directed to Natural Phenomena

The claims at issue here seek to patent the statistical observation that some doses of thiopurine drugs tend to be too high for some patients and some tend to be too low. These claims run afoul of time-honored prohibitions on patenting "laws of nature, physical phenomena, and abstract ideas," *Bilski*, 130 S. Ct. at 3225 (quoting *Chakrabarty*, 477 U.S. at 309), because they "wholly preempt" the natural relationship between the levels of the metabolites 6-TG and 6-MMP in the human body and the likelihood of therapeutic efficacy and toxicity of thiopurine drugs. *Prometheus*, 2008 WL 878910 at *10 (quoting *Benson*, 409 U.S. at 71-72).

Any argument that the observed correlations between metabolite levels and drug toxicity are patentable because the metabolites are by-products of a synthetic drug is inconsistent with precedent and

would lead to absurd results. In patent law, "natural" means "nature's handiwork" as generally juxtaposed with the products of human agency and ingenuity. *See Chakrabarty*, 447 U.S. at 310; *Flook*, 437 U.S. at 591-94. Thiopurine drugs are man-made compositions of matter, undeniably patentable under 35 U.S.C. § 101. A natural response to a man-made invention, however, has never been patentable. In *Funk Brothers*, for example, the patentee combined laboratory cultures of selected bacteria to form an "inoculant" that assisted nitrogen fixation in plants. *Funk Bros.*, 333 U.S. at 129. Despite the human effort required to select, culture, and combine the bacteria, this Court found the mixture unpatentable because the mutual non-inhibition of nitrogen fixing properties was a natural response to being combined. Though the combination was artificial, the bacteria "serve[d] the ends nature originally provided and act[ed] quite independently of any effort of the patentee." *Id.* at 131.

This distinction between a man-made product and its natural behavior has long been recognized. In *O'Reilly v. Morse*, for example, this Court discussed the English case, *Neilson v. Harford*, 151 E.R. 1266 (1841), and distinguished between the unpatentable "principle that hot air will promote the ignition of fuel better than cold" and the patentable invention of a mechanical apparatus for supplying hot air. *O'Reilly*, 56 U.S. at 114-16. Any invention involving igniting fuel in a furnace is in some sense synthetic, yet that fact would not have rendered patentable a claim to

the principle of using hot air to aid ignition. Nor did the fact that printing characters at a distance is a human endeavor save a claim to the basic scientific concept of using "the motive power of the electric or galvanic current" to make such characters. *Id.* at 119.

The district court in this case correctly concluded that "the relevant inquiry is whether the correlations are 'man-made,' not whether a man-made drug was used to produce the correlation." *Prometheus*, 2008 WL 878910 at *9. Here, the claimed correlations between drug metabolite levels and drug toxicity and efficacy are natural phenomena. Nothing in the claims purports to affect the way in which a patient's body responds to the administration of the medications: the phenomena are merely observed.

Because the claimed statistical correlations are natural phenomena, the claims are unpatentable, since they wholly preempt every substantial use of those correlations. The claims cover every instance in which any physician considers whether to adjust thiopurine drug dosage in light of metabolite level measurements. *Id*. at *10. These claims are unlike those in *Diehr*, 450 U.S. at 180, n.5, to which the Federal Circuit analogizes them. *Prometheus Labs.*, 628 F.3d at 1355. The claims in *Diehr* were directed to "a physical and chemical process for molding precision synthetic rubber products . . . beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure," *Diehr*, 450 U.S. at 184, which employed a mathematical formula to

determine when to open the press. The claims in this case are different. They do not *apply* a natural phenomenon as part of a patentable process. Rather, they merely instruct one to measure a natural phenomenon and then consider its implications.

B. The "Transformation of Matter" Inquiry is Unhelpful in Determining Whether a Claim is Directed to Unpatentable Natural Phenomena

Both before and after the remand for reconsideration in light of this Court's opinion in *Bilski*, the Federal Circuit focused the bulk of its attention on applying the machine or transformation of matter test. *Prometheus Labs.*, 628 F.3d at 1355-56; *Prometheus Labs.*, 581 F.3d at 1345-46. As this Court held in *Bilski*, that test is "a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101." *Bilski*, 130 S. Ct. at 3227. It is inapposite, however, to determining whether a claim preempts a natural phenomenon. Photosynthesis, the freezing of water into ice and its evaporation into steam, and the rusting of iron—all involve transformations of matter, but are unpatentable unless they are part of an invention that does not preempt the phenomenon. Moreover, virtually any measurement of a natural phenomenon involves some material transformation. Nonetheless, measuring a natural phenomenon and

then considering its scientific or medical significance does not turn it into patentable subject matter.

This Court should clarify that, whatever the usefulness of the machine or transformation of matter test in determining the patentability of some kinds of processes, such as the abstract hedging methods in *Bilski*, 130 S. Ct. at 3229, the fact that a natural phenomenon involves a material transformation does not render it patentable.

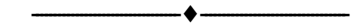
III. The Issue Raised in this Case is of Great Importance and is Left Open After This Court's Ruling in *Bilski*

As argued throughout this brief, the potential for patents that preempt natural phenomena to interfere with the ethical and effective practice of medicine and with the improvement of health care through advances in diagnostic testing is a very serious matter. Exclusive rights to fundamental information about scientific correlations are liable to raise the cost of medical care prohibitively without compensating benefits to medical research. As health care professionals, we believe that patients are served best by the free and broad dissemination of scientific information that is relevant to providing better and more personalized health care treatments. If this Court lets the Federal Circuit's ruling stand, patients, physicians, and laboratory service providers will become entangled in a growing thicket of patents on basic

diagnostic information to the detriment of the nation's health.

This Court granted certiorari to address this issue in *Lab. Corp. v. Metabolite*, though certiorari was later dismissed as improvidently granted because the patentable subject matter issue was not properly considered by the lower courts. *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 132-33 (2006) (Breyer, J., dissenting). Here this Court has the benefit of full exploration of the issue in a considered district court opinion and two Federal Circuit opinions which were informed by extensive briefing by both parties and numerous *amici*.

In *Bilski*, this Court reaffirmed the time-honored patentable subject matter exceptions for "laws of nature, physical phenomena, and abstract ideas," noting that these subject matters are "free to all men and reserved exclusively to none." *Bilski*, 130 S. Ct. at 3225 (quoting *Funk Bros.*, 333 U.S. at 130). The patent claims at issue in this case raise important questions concerning the patentability of natural phenomena and scientific correlations that were not aired in *Bilski* because of its focus on the appropriate standard of patentability for business methods and similar processes. We thus contend that this case warrants the attention of this Court.



CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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