

No. 10-1150

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**In the Supreme Court of the United States**

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MAYO COLLABORATIVE SERVICES  
(D/B/A MAYO MEDICAL LABORATORIES)  
AND MAYO CLINIC ROCHESTER,  
*Petitioners,*

v.

PROMETHEUS LABORATORIES, INC.,  
*Respondent.*

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

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**BRIEF FOR ARUP LABORATORIES, INC. AND  
LABORATORY CORPORATION OF AMERICA  
HOLDINGS (D/B/A LABCORP)  
AS *AMICI CURIAE*  
IN SUPPORT OF PETITIONERS**

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### INTERESTS OF *AMICI CURIAE*<sup>1</sup>

*Amici* are leading clinical laboratory companies. Like Petitioners, *amici* are in the business of analyzing blood specimens to aid in diagnosis, treatment, and prevention of disease. And like Petitioners, *amici* have active research programs through which they develop cutting-edge and life-saving assays and diagnostic techniques.

*Amicus* ARUP Laboratories, Inc. (“ARUP”) is a nationally renowned medical reference laboratory. ARUP is an enterprise of the University of Utah and its Department of Pathology. Offering highly complex and unique lab tests, ARUP provides screening services, as well as molecular and genetic assays with accompanying consultative support. ARUP’s tests cover numerous medical fields including allergy and immunology, chemistry, cytogenetics, endocrinology, fetal risk assessment, genetics, hematology, hepatitis and HIV, infectious diseases, neurology, oncology, and pathology. ARUP processes nearly 35,000 tissue and fluid specimens every day. Medical directors and genetic counselors are on staff at ARUP and provide consultation and result interpretation. ARUP’s clients include more than half of the

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<sup>1</sup> All parties to this case have consented to the filing of this brief, and their consents have been filed with the Clerk of this Court. No counsel for any party had any role in authoring this brief, and no person other than the named *amici* and their counsel has made any monetary contribution to the preparation and submission of this brief.

nation's university teaching hospitals and children's hospitals, as well as regional hospital networks, multihospital groups, major commercial laboratories, group purchasing organizations, military and government facilities, and major clinics.

*Amicus* Laboratory Corporation of America Holdings ("LabCorp") is the country's second largest independent clinical laboratory company whose 31,000 employees perform more than 270 million tests annually for more than 220,000 clients. LabCorp is a pioneer in commercializing new diagnostic technologies and the first in the industry to embrace genomic testing. Additionally, LabCorp was the petitioner in *Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) ("*LabCorp*") (dismissing writ of certiorari as improvidently granted), which concerned a patented method of detecting certain vitamin deficiencies. The method consisted of just two steps: (1) measure the levels of a particular amino acid in the body, and (2) recognize that elevated levels of the amino acid are correlated with certain vitamin deficiencies. LabCorp was accused of inducing infringement every time a doctor ordered its amino acid assay. The issue presented in this current case before the Court is strikingly similar to that of the *LabCorp* case and provides this Court the opportunity to confirm that natural phenomena and laws of nature cannot be removed from the public domain through creative use of the patent laws as Respondent seeks to do here.

*Amici* have a compelling interest in this case. Just as in *LabCorp*, the Federal Circuit has once again allowed a patent-holder to claim ownership of

a basic scientific phenomenon: the correlation between levels of a particular drug in the blood and patient health. *Amici*'s research activities, as well as the diagnostic services they offer to hospitals, physicians, and managed-care organizations across the country, depend on this type of scientific knowledge. *Amici* agree with Petitioners' arguments and submit this brief to explain further that the Federal Circuit's decision allows patentees and litigants to inhibit advancements in medical science and clinical services by asserting a monopoly over basic scientific phenomena.

### INTRODUCTION AND SUMMARY

The question presented in this case concerns the scope of patentable subject matter under the Patent Act of 1952. The Act provides: "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." 35 U.S.C. § 101. Although the scope of patentable subject matter is thus broad, it is settled precedent that it does not extend to natural phenomena. "The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: 'laws of nature, physical phenomena, and abstract ideas.'" *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)); see also *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

The correlation described in the patents at issue in this case is a scientific fact — a law of nature — relating drug levels to health in the human body. The patents assert exclusive rights over the process

of administering a drug and observing the results. This is improper. Whatever biochemical reaction occurs in a patient's body is not the subject of the patent laws, but rather is a natural phenomenon. These patents are not directed to new and unique medicines, reagents or testing equipment. They are directed instead to the basic concept of measuring drug levels and deciding a patient's relative health. This not only blocks the mental work of doctors advising patients, but also impedes the progress of research by seeking to own a basic law of nature concerning the human body's reaction to drugs. The preemptive effects of such patents on research, medical services and the growing field of personalized medicine are profound.

In crossing over the line between patents on human invention and patents on nature itself, the patent claims in this case upset the "careful balance" struck by the patent laws that is "the very lifeblood of a competitive economy." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989). A United States patent confers upon its owner the powerful right to exclude others from practicing whatever invention is claimed in the patent for a defined period of time. See 35 U.S.C. § 271 (defining infringement); *id.* § 154 (20-year term). Such a right to exclude can also extend to the substantial equivalent of the patented invention. See, e.g., *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997). Such powerful rights should not be conferred upon claims on laws of nature.

The Prometheus patents and others like them allow no room to design around, imitate, or improve upon the so-called "invention" of a law of nature.

Doctors and laboratories test patients' blood and routinely evaluate the laws of nature in providing health care. But if claims like the ones at issue are sustained, such tests may be blocked by patents on the law of nature on which they are based. This is especially harmful given the nature of modern medicine, which allows doctors and reference laboratories to efficiently measure a battery of markers and conditions to diagnose and treat patients.

By contrast, invalidating the claims and reaffirming the principle set forth in *Diehr* and confirmed in *Bilski* will not disrupt or impede scientific research. Inventors and companies can and will file for patents for novel medicines, reagents, equipment and the like, including processes for using these inventions. Patent lawyers, however, should not be permitted a "land grab" to block use of underlying laws of nature. Reversing the Federal Circuit will simply restore the balance between natural phenomena and human-made inventions that Congress originally sought to strike in the patent laws — a balance that reflects the Constitution and has served the patent system and the progress of science very well. The decision below should be reversed.

## ARGUMENT

### I. THE PATENTS IMPROPERLY REMOVE A NATURAL PHENOMENON FROM THE PUBLIC DOMAIN

#### A. Patentable Subject Matter Does Not Include Laws Of Nature, Natural Phenomena, Or Abstract Ideas

Congress intended the scope of patentable subject matter to be broad and inclusive, even for tech-

nologies that had yet to be imagined. The Committee Reports accompanying the 1952 Patent Act provide that Congress intended statutory subject matter to “include anything under the sun that is made by man.” S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952), quoted in *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

But Congress likewise established just and appropriate limits to the reach of the patent statutes. The patent laws protect only *inventive* products and processes. Thus not every discovery is necessarily patentable. A bedrock principle of United States patent law is that: “Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas.” *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citations omitted). Accordingly:

[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that  $E=mc^2$ ; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”

*Chakrabarty*, 447 U.S. at 309 (quoting *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)); see also *Parker v. Flook*, 437 U.S. 584, 593 n.15 (1978) (“[R]ecognition of a theretofore existing phenomenon or relationship carries with it no rights to exclude others from its enjoyment.” (quoting P. Rosenberg, *Patent Law Fundamentals*, § 4, p. 13 (1975)); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972) (“Phenomena 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.”).

“[T]hese exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years.” *Bilski*, 130 S. Ct. at 3225 (citing *Le Roy v. Tatham*, 55 (14 How.) 156, 174-75 (1853)). This Court thus has properly hesitated to alter the fundamental concepts of patent law that have guided generations of inventors and succeeded in furthering the progress of science and useful arts. See *Bd. of Trs. of Stanford Univ. v. Roche Molecular Sys., Inc.*, 131 S. Ct. 2188, 2198-99 (2011).

As pointed out by Justice Breyer in *Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (“*LabCorp*”), a case presenting a question similar to that presented here, the justification for this longstanding principle is that too much patent protection can impede scientific progress, and that fundamental scientific principles are “part of the storehouse of knowledge” available to all. *Id.* at 127 (Breyer, J., dissenting from dismissal of writ as improvidently granted) (quoting *Funk Bros.*, 333 U.S. at 130).

Whether a claimed invention is a valid subject matter for a patent under these principles has been the subject of various decisions of this Court since the 1952 Patent Act became law. In several of these decisions, the Court upheld the patentability of the subject matter. In *Chakrabarty*, for example, the Court held that human-made bacteria exhibiting characteristics different from any bacteria occurring in nature are patentable subject matter. 447 U.S. at 310. In *Diehr*, the Court held that a computerized industrial process for control of a rubber curing mold

is patentable, even though the process “admittedly employs a well-known mathematical equation.” 450 U.S. at 187. And in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124 (2001), the Court held that newly developed plant breeds are patentable subject matter. *Id.* at 145.

In several other decisions, however, the Court held the subject matter of a patent to constitute a law of nature beyond the scope of the Act. In *Parker v. Flook*, for example, the Court held that a process for monitoring chemical reactions by using a mathematical formula is not patentable. *See* 437 U.S. at 594. And in *Gottschalk v. Benson*, the Court held that a process related to converting decimals to binary numerals using a formula is not patentable. *See* 409 U.S. at 71-72.

The distinction between the two lines of cases turns on whether the patent holder seeks to preempt the underlying law of nature, precluding others from testing or observing it. As the Court noted in *Diehr*, “an *application* of a law of nature . . . to a known structure or process may well be deserving of patent protection.” *Diehr*, 450 U.S. at 187 (emphasis in original). The Court found such an application in *Diehr* because, in that case, the patent holders “do not seek to pre-empt the use of that equation” but “seek only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process.” *Id.* In contrast, the Court in *Gottschalk* found no patentable subject matter where “the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.” 409 U.S. at 72.

The distinction between the two lines of cases also turns, in the case of method claims like the ones at issue in this case, on whether the patented process is transformative. In analyzing the patentability of a claimed process, both *Diehr* (which upheld a claimed process) and *Gottschalk* (which struck down a claimed process) focused on the *end result* of the process. *See Diehr*, 450 U.S. at 184. Although transformation “is a useful and important clue, an investigative tool” for determining whether a patent on a claimed process is valid, it is not the sole test. *Bilski*, 130 S. Ct. at 3227.

For the reasons that follow, the Prometheus patent claims are on the non-patentable side of this well-established line because they involve no such transformation and seek to preempt all use by others of a basic natural phenomenon.

**B. The Prometheus Claims Improperly Assert Exclusive Rights To Measure And Observe A Natural Phenomenon — Namely, That Certain Levels Of 6-Thioguanine Correlate To Patient Health**

The Prometheus claims are directed to a natural phenomenon. As exemplified by claim 1 of U.S. Patent No. 6,355,623, the “process” for which Prometheus asserts exclusive rights is simply two steps: *administering* a drug and *measuring* the drug level in the patient:

1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Once the measurement is done, the results can assist a doctor in determining a course of treatment. The patent fully admits that the drugs for treatment of gastrointestinal diseases were known in the art. The “discovery” that the patent owner seeks to keep for itself is the correlation between drug levels and medical decisions. This correlation, however, should not be patentable.

It is critical to note that the patient’s health remains the same whether or not the measurement is done. The drug will have its effect with or without the measurement. It is also critical to note that Prometheus did not invent the drug in question. Nor did Prometheus invent any novel testing equipment or process. Any method of testing meets the claim. Any test infringes. Thus, testing labs such as ARUP and LabCorp could be accused of infringement by

providing results to doctors, and doctors would be accused of infringement by advising their patients and obtaining measurements of their patient's blood specimens. As Justice Breyer observed with respect to similar patents on a law of nature, "[a]t most, respondents have simply described the natural law at issue in the abstract patent language of a 'process.' But they cannot avoid the fact that the process is no more than an instruction to read some numbers in light of medical knowledge." *LabCorp*, 548 U.S. at 137.

The Prometheus claims are not applications of a scientific principle that might properly enjoy patent protection, such as the industrial process for molding rubber products in *Diehr*. See *Bilski*, 130 S. Ct. at 3230. Instead, these claims simply take a medical concept (administer a drug and measure for the drug in a patient) and apply it to a natural phenomenon occurring in the human body. This is not an industrial process that transforms one chemical into another; it is the discovery of a correlation between a particular drug and health state, and allowing such a discovery to be patented would improperly remove that natural correlation from the "storehouse of knowledge."

## **II. ALLOWING THE PROMETHEUS CLAIMS WOULD UPSET THE PATENT BALANCE CAREFULLY STRUCK BY CONGRESS AND THIS COURT AND WOULD HARM LIFE SCIENCES RESEARCH AND PATIENT CARE**

The Constitution requires that patents "promote the Progress of Science and useful Arts." Art. I, § 8, cl. 8. Fulfilling this constitutional purpose re-

quires a balance between rewarding existing research and ensuring that other research may go forward freely in the future. Allowing a patentee to remove a natural phenomenon from the public sphere would thwart this constitutional purpose by impeding rather than promoting the progress of biochemical research and medical treatments. Without access to testing and observing natural phenomena, medical researchers cannot build upon the discoveries of others and doctors cannot treat their patients.

Allowing claims such as the ones at issue here would block medical information based on natural, biochemical relationships from appropriate further scientific use. This impediment would be especially acute with respect to the information being tested in patients' blood. Disallowing claims such as those being asserted by Prometheus, by contrast, will cause little harm to scientific progress because a wide range of other appropriate claims would remain available to researchers like Respondent. Therefore, the balance struck in *Diehr* and related cases on the scope of patentable subject matter should be preserved.

**A. Existing Limitations On The Scope Of Patentable Subject Matter Reflect A Careful Balance Between Rewarding Existing Research And Ensuring Opportunity For Future Innovation**

Patents fundamentally balance free competition against government-granted exclusive rights. "The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any

concomitant advance in the ‘Progress of Science and useful Arts.’” *Eldred v. Ashcroft*, 537 U.S. 186, 215 (2003) (quoting *Bonito Boats*, 489 U.S. at 146); see also *Mazer v. Stein*, 347 U.S. 201, 219 (1954) (noting that the patent system is based upon the “conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors”).

Patent law persistently seeks to strike a balance between these competing interests. Some features of patent law ensure adequate returns to the large fixed costs of research and development. For example, Congress has decided upon a 20-year term for patents. See 35 U.S.C. § 154. And by denying an independent creation defense to patent infringement, this Court has permitted liability to attach even if a person has no knowledge of the patent. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 477 (1974). Other features of patent law seek to preserve opportunities for future innovation. For example, there is a statutory safe harbor for activities that would otherwise constitute patent infringement, so long as they are undertaken for purposes reasonably related to the development and submission of information under a federal law that regulates drugs. See 35 U.S.C. § 271(e); see also *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) (exemption applies to medical devices); *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 203-05 (2005) (exemption applies to preclinical research).

The definition of what constitutes patentable subject matter likewise reflects a balance that has been struck by Congress in section 101 of the Patent Act and by this Court in interpreting that section.

This balance — which distinguishes between natural phenomena and human-made inventions — has served the United States patent system and the progress of science in the nation very well.

The key to this balance is the recognition that there are interests in promoting innovation on both sides of any patent. As this Court stated in a different context in *Bonito Boats*, “[f]rom their inception, the federal patent laws have embodied a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” 489 U.S. at 146. As Justice Breyer has noted in the related context of copyright law, in ensuring a balance between preserving incentives to intellectual property holders and protecting the rights of others to develop new technologies, it is important to be sure that “the gains on the copyright swings would exceed the losses on the technology roundabouts.” *Metro-Goldwyn-Mayer Studios, Inc. v. Grokster, Ltd.*, 545 U.S. 913, 960 (2005) (Breyer, J., concurring).

Here, allowing claims like those of *Prometheus* would cause serious “losses on the technology roundabouts,” upsetting the balance that Congress and this Court have long struck with respect to patenting laws of nature. By precluding scientific inquiry (i.e., the ability to test, observe, and conclude) into naturally occurring phenomena, enforcing *Prometheus*’ patents and others like it would remove the common tools accessible to all scientists that allow scientific progress to be made. Invalidating *Prometheus*’ patents, by contrast, would still allow wide berth for patenting truly transformative human in-

ventions that add to rather than subtract from the public domain.

**B. Allowing The Prometheus Patents To Stand Would Impede Future Biomedical Research And Treatment That Depends Upon Common Access To Natural Phenomena**

Science has always proceeded in an incremental way in which one discovery builds upon another. Experts in the scientific method have accordingly noted that scientific progress requires that research results be open for all to “use, attempt to replicate, and evaluate.” U.S. Nat’l Research Council Committee on Intellectual Property Rights in the Knowledge-Based Economy, *A Patent System for the 21st Century* 26 (2004). This aspect of scientific progress would be impeded if patents could extend to natural phenomena. The Council of the [United Kingdom] Royal Society has drawn a parallel implication:

[P]ure knowledge about the physical world should not be patentable under any circumstances. That it should be freely available to all is one of the fundamental principles of the culture of science. Only by having knowledge unencumbered by property rights can the scientific community disseminate information and take science forward.

Royal Society Working Group on Intellectual Property, *Keeping Science Open: The Effects of Intellectual Property Policing on the Conduct of Science* 8 (April 2003).

Whatever the effect of the scope of patentability on scientific research in the past, however, these principles are even more important to the next generation of biomedical research. The nature of the information contained within the genetic code presents new and unique incentives to try to own natural phenomena. Any holding that one may effectively own a natural biochemical relationship by excluding others from any and all testing of that relationship thus would have especially fundamental implications for future research in the field of DNA and human genetic conditions.

Likewise, valuable blood-testing and treatment of patients would be discouraged by allowing patent claims covering the most basic of medical practices — administering medicine and observing the results — to be applied to newly discovered natural phenomena.

ARUP itself publishes natural phenomena that its scientists discover in the course of their research and clinical testing.<sup>2</sup> These publications provide to the public domain information about hereditary diseases and genetics — information that

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<sup>2</sup> See, e.g., C.P. Vaughn, J. Robles, J.J. Swensen, C.E. Miller, E. Lyon, R. Mao, P. Bayrak-Toydemir, W.S. Samowitz, *Clinical Analysis of PMS2: Mutation Detection and Avoidance of Pseudogenes*, 31 HUMAN MUTATION 588-93 (2010); F. Gedge, J. McDonald, A. Phansalkar, L.S. Chou, F. Calderon, R. Mao, E. Lyon, P. Bayrak-Toydemir, *Clinical and Analytical Sensitivities in Hereditary Hemorrhagic Telangiectasia Testing and a Report of de Novo Mutations*, 9 J. MOLECULAR DIAGNOSTICS 258-65 (2007); D.K. Crockett, G. Pont-Kingdon, F. Gedge, K. Sumner, R. Seamons, E. Lyon, *The Alport Syndrome COL4A5 Variant Database*, 31 HUMAN MUTATION E1652-57 (2010).

existed in nature but required the effort and creativity of ARUP scientists and others to find. These discoveries allow for inventions to be created and for doctors to treat patients more effectively. Similarly, the tests that laboratories like ARUP and LabCorp run on patient samples measure the amount of drugs or markers, or the presence of genetic conditions, in the body, all of which are natural phenomena. These results or conditions would exist in the patients whether or not the measurements took place.

In contrast, if patents like those asserted by Prometheus were allowed to stand, all such naturally occurring biochemical relationships would be subject to ownership rights on the part of the person who discovers them. For instance, if the effect of a drug in the body creates condition “X”, the person who discovers this relationship might seek a patent covering all measurement of condition “X” or all evaluation of condition “X” by a doctor treating a patient. This is not a human-made invention, but a scientific discovery — and a patent to such a discovery would remove from the “storehouse of knowledge” that which should be free for all to use. Patents that claim the underlying natural phenomena and biochemical relationships will greatly impede medical research that builds upon the discovery of scientific facts.

For these reasons, there are special dangers in allowing only one laboratory or entity exclusive rights to the results of a natural phenomenon in the human body. Science will advance more rapidly, with benefits to patients, if laboratories may both compete with and collaborate with one another through common access to laws of nature.

**C. Invalidating Prometheus' Patents  
Would Neither Eliminate Incentives  
To Invest In Research Nor Disrupt  
The Patent System**

The state of the law with respect to ownership of biochemical relationships is relatively unsettled. This has resulted in a well-documented “land-grab” mentality, in which patent attorneys seek patents at the outer boundaries of the line between human invention and natural phenomena. This is not surprising, for without guidance about the scope of valid versus invalid subject matter, patent attorneys are obliged to seek the broadest possible claims for their clients. *See Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1382 (Fed. Cir. 2000) (a patent attorney has a “professional responsibility . . . to assist his or her client in defining her invention to obtain, if possible, a valid patent with maximum coverage”).

Just because these pressures have led patent attorneys to seek and sometimes obtain patents that stretch the boundaries of patentability into the natural realm, however, does not mean that such increased scope is necessary to advances in science. This case presents a vital opportunity for the Court to curb this pressure on the outer boundaries of patentability, and to return the balance to the baseline set in *Diehr* and related decisions. There is little danger that so doing will harm genetic or other biomedical research by reducing incentives for making discoveries.

This is so for two reasons. *First*, nothing in the argument advanced by *amici* here would impede patents in the genetic area if those patents involved more than the mere observation and recitation of a

law of nature. Consistent with this Court's test in *Diehr*, patent claims may be appropriate as directed to applications of laws of nature such as new drugs, reagents, or equipment. Thus the scope of patentable subject matter still may legitimately extend to innovative tests, or inventive pharmaceutical compositions, or new and useful therapies, or any number of inventions in technology that researchers have yet to imagine, that add human invention to a natural phenomenon. The issue here, by contrast, is whether ownership rights should be permitted to result from the mere discovery of the phenomenon.

Second, invalidating claims like those of the Prometheus patent will not necessarily invalidate any patents per se. Claims define the metes and bounds of what the patent holders consider their exclusive rights. Each claim defines the scope of a different invention. 35 U.S.C. § 112. Patents contain multiple claims because patent applicants are allowed to claim several inventions based upon a single technical disclosure. Indeed, standard patent practice is to file a number of claims of varying scope precisely to protect against future uncertainty. Broad claims have the greatest coverage, but the highest likelihood of being invalidated (for example, by prior art). Narrow claims have the best chance of avoiding prior art, but offer the least coverage. Thus, one does not infringe a patent; one infringes a patent claim. Likewise, a court does not determine that a patent is invalid; it determines whether some or all of the claims are invalid.

**D. If There Is Any Ambiguity About The Patentability Of Natural Phenomena, It Should Be Resolved In Favor Of Petitioner In Order To Avoid Serious Constitutional Questions**

Just as this Court interpreted copyright law so as to ensure consistency with the Constitution, *see Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc.*, 499 U.S. 340 (1991), so too should it interpret patent law. There are two constitutional problems with the patent claim at issue in this case, and with all patents claiming exclusive rights to the results of a measurement of nature.

*First*, patents on measurements of nature, like the copyright struck down in *Feist*, deal with facts themselves. The corresponding lack of originality raises serious questions under Article I, which gives Congress authority to issue patents that “promote the Progress of Science and useful Arts.” U.S. Const. art. I, § 8, cl. 8. Patents on measurements of nature take information out of the public domain rather than putting ideas into the public domain provided for in the Constitution and of the patent disclosure provisions. *See* 35 U.S.C. § 112. In the present case, for example, a scientist or doctor was free before the patent issued to measure the level of 6-thioguanine in a blood sample and correlate that with the patient’s health. It was infringement to do so, however, after the patent issued. The subject matter provision of the Patent Act, 35 U.S.C. § 101, therefore should be interpreted to prohibit patents that preempt the use of principles or measurements of nature and that, in effect, bar future researchers from making

such measurements or from using information that is available from nature. Patents that have such effects do not “promote the Progress of Science.”

A second constitutional difficulty with patent claims on measurements of nature is that the patent may have a significant chilling effect on publication in violation of freedom of speech principles protected by the First Amendment. Under normal patent law principles, if the Prometheus claim is valid, a scientist, doctor, or medical firm publishing an article encouraging the use of a 6-thioguanine measurement as a way of optimizing drug therapy might be found to have induced infringement under 35 U.S.C. § 271(b) (“Whoever actively induces infringement of a patent shall be liable as an infringer.”).

No scientist, doctor, or laboratory should need to undertake an analysis of the intent requirements for inducing infringement before publishing a research article on the interactions of a known medicine and the human body. A spread of such patents would have an enormous chilling effect on scientific and commercial publication.

These constitutional considerations should provide an additional reason to reaffirm the *Diehr* principle by ruling for Petitioners in this case.

**CONCLUSION**

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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