No. 08-964

In The Supreme Court of The United States

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

v.

JOHN J. DOLL, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING DIRECTOR, PATENT AND TRADEMARK OFFICE,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF OF *AMICI CURIAE* BIOTECHNOLOGY INDUSTRY ORGANIZATION, ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, WISCONSIN ALUMNI RESEARCH FOUNDATION & THE REGENTS OF THE UNIVERSITY OF CALIFORNIA IN SUPPORT OF NEITHER PARTY

THOMAS DILENGE
GENERAL COUNSEL
HANSJORG SAUER, PH.D.
DEPUTY GENERAL COUNSEL
BIOTECHNOLOGY INDUSTRY ORGANIZATION
1201 MARYLAND AVE., S.W.
SUITE 900
WASHINGTON, DC 20024
(202) 962-6695

E. ANTHONY FIGG
Counsel of Record
NANCY J. LINCK, PH.D.
MINAKSI BHATT
MARTHA CASSIDY, PH.D.
1425 K St., N.W.
SUITE 800
WASHINGTON, DC 20005
(202) 783-6040

(Additional Counsel listed on inside cover)

CHRISTOPHER L. WHITE
GENERAL COUNSEL
ADVANCED MEDICAL TECHNOLOGY
ASSOCIATION
701 PENNSYLVANIA AVE., N.W.
SUITE 800
WASHINGTON, DC 20004
(202) 783-8700

HOWARD W. BREMER
EMERITUS PATENT COUNSEL
WISCONSIN ALUMNI RESEARCH
FOUNDATION
614 WALNUT ST.
13TH FLOOR
MADISON, WI 53726
(608) 263-2500

P. MARTIN SIMPSON, JR.
MANAGING COUNSEL
BUSINESS TRANSACTIONS & LAND USE
OFFICE OF GENERAL COUNSEL
THE REGENTS OF THE
UNIVERSITY OF CALIFORNIA
1111 FRANKLIN ST.
12TH FLOOR
OAKLAND, CA 94607
(510) 987-9800

Counsel for Amici Curiae
Biotechnology Industry Organization,
Advanced Medical Technology Association,
Wisconsin Alumni Research Foundation &
The Regents of the University of California

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INTERESTS OF *AMICI CURIAE*

The Biotechnology Industry Organization ("BIO"), the Advanced Medical Technology Association ("AdvaMed"), the Wisconsin Alumni Research Foundation ("WARF"), and The Regents of the University of California ("University of California") (collectively "*Amici*") respectfully submit this brief.[1]

BIO is the country's largest biotechnology trade association, representing over 1200 companies, academic institutions, and biotechnology centers in all 50 States. BIO members are involved in the research and development of biotechnological healthcare, agricultural, environmental and industrial products. BIO member companies range from startup businesses and university spin-offs to large Fortune 500 corporations. The vast majority are small companies that have yet to bring products to market and attain profitability.

Previously unknown biological correlations -- "natural laws or principles" discovered through molecular biology techniques -- are increasingly used to guide biotechnological product development. BIO members invest heavily in the discovery and application of such correlations and depend on the

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[1] Pursuant to Supreme Court Rule 37.3(a), all parties have filed with the Court general written consents to the filing of *amicus* briefs. Pursuant to Rule 37.6, *amici curiae* state that no person or entity, other than BIO, AdvaMed, WARF, or University of California or members of these entities, has made any monetary contribution to the preparation or submission of this brief. Further, no counsel for Petitioner or Respondent authored this brief in whole or in part.

patent system to recoup vast development expenses incurred during the decade-long product development based on these correlations.

AdvaMed is the largest medical technology association in the world, representing more than 1,600 medical device, diagnostic, and health information system manufacturers and subsidiaries. AdvaMed's members manufacture 90 percent of the $75 billion of health care technology purchased annually in the United States and more than 50 percent of the $175 billion purchased around the world annually. AdvaMed member companies rely upon patent protection to support the development of new technologies, including orthopedic implants, heart valves, cardiovascular stents, and devices for diagnosing life threatening diseases. Medical devices often have short product life cycles, sometimes measured in months, due to rapid innovation derived from clinician input to improve functionality, efficacy and safety. This requires recouping investments quickly, heightening the necessity for a predictable patent system.

The University of California and WARF, the designee of the University of Wisconsin-Madison for its technology management, engage in and support scientific research, obtain patents on inventions arising from such research, license technologies to the private sector for commercialization and utilize licensing income to underwrite further academic research or for educational purposes.

The University of California and WARF are representatives of a larger academic sector that

drives innovation and research in the United States and provides clinical services utilizing the results of research. Moreover, the academic sector is credited as being the birthplace of the biotechnology industry. In 2006 U.S. academic institutions spent $48 billion on research and development (R&D). The federal government provided 63% for academic R&D expenditures in that year, with the institutions themselves contributing 19%. The life sciences field received the largest share of investment in academic R&D, accounting for about 60% of all expenditures and also of federal expenditures. NSF National Science Board, *Science and Engineering Indicators 2008*, vols. 1 & 2 (2008), http://www.nsf.gov/statistics/seind08.

In general, the non-profit research community carries out much of its R&D under the Bayh-Dole Act and its implementing regulations. As a stated policy and objective, the regulations have the use of the patent system to promote utilization of inventions arising from federally-supported research or development. 35 U.S.C. §§ 200-212; 37 C.F.R. § 401. Hence, the patent system is vital to transferring research results to the public. Technology transfer by universities and non-profit research institutions depends almost entirely on the underlying patent position for further investment and commercialization that it provides to partners and licensees. Given that most university-generated inventions are embryonic in nature and require significant effort and investment to develop a product, any uncertainty that accompanies a patent and its scope and validity increases the likelihood

that the technology will not be developed and decreases the chances that the public will benefit from the taxpayer's investment in the research that led to the patented technology.

In re Bilski, 545 F.3d 943 (Fed. Cir. 2008) raises that uncertainty, because it bears upon and casts doubt on the protection of certain inventions and particularly inventions defined by method claims in the biotechnology arts because of its "machine-or-transformation" recitations and requirements. That uncertainty puts in jeopardy the potential benefit that the public can derive from technology transfer, through the vehicle of the patent system, of inventions that have been generated through both privately-funded and taxpayer-supported research and development.

This Court's long-standing interpretation of patent eligibility under 35 U.S.C. § 101 has enabled great progress in biotechnology and medical technology, benefitting society through improved medicines and crops and life-saving medical devices and diagnostics. Biotechnology and medical technology innovators and investors have relied on that interpretation for decades. Today, however, at the dawn of an era of personalized medicine, made possible through understanding and applying natural principles, *Amici*'s members are concerned that unforeseen breakthroughs in the life sciences could be excluded from patenting under the Federal Circuit's rigid and constricted patent-eligibility test.

Amici submit this brief to assist this Court's long-standing efforts to guide the evolution of patent law

in a tempered, predictable way that will accommodate emerging technologies to the benefit of all, maintain the incentive for the biotechnology and medical technology industries to continue their massive investments, and guard against negative, unforeseen consequences.

SUMMARY OF THE ARGUMENT

Biotechnology and medical technology innovation and investment are predicated on inclusive standards of patent eligibility—standards that have enabled great progress in the two fields. Because these technologies require investment in unusually high-risk, expensive research and development, only broad, well-established eligibility standards can promote its progress.

Application of *Bilski's* rigid "machine-or-transformation" test to biotechnology and medical technology process inventions is contrary to this Court's precedent and creates uncertainty regarding their patent eligibility, even for those inventions that have already been patented. The uncertainty surrounding the application of *Bilski* to these inventions will deter critical investment in the biotechnology and medical technology industries. These process inventions are not abstract ideas, laws of nature, or natural phenomena. Rather each provides a useful and tangible end, potentially bringing the industry closer to addressing serious societal issues, including those due to unsolved medical needs. Yet, undoubtedly, many of these process claims would be in jeopardy if *Bilski* is permitted to stand and the consequent uncertainty

would discourage further investment and commercialization. Examples of such claims are those to processes for diagnosing or prognosing diseases and those to "biomarkers." Biomarkers play a critical role in predicting disease and facilitating drug development.

The Federal Circuit erred in holding that a process must be tied to a machine or transformation under 35 U.S.C. § 101. The governing standard regarding patent eligibility is found in § 101's unambiguous language—language that permits the patenting of "any new and useful process," if the other sections of title 35 are met. This Court has established the limits of § 101, consistently holding that those limits are broad, excluding only abstract ideas, laws of nature and natural phenomena. It has also disfavored rigid, bright-line tests, such as that imposed in *Bilski*.

Amici respectfully request this Court to (1) set aside the Federal Circuit's "machine-or-transformation" test and other restrictive tests that have confused the § 101 analysis, such as those labeled "preemption" and "post-solution activity;" and (2) reaffirm that the appropriate § 101 analysis requires reading the language of the statute broadly, only excluding claims to abstract ideas, laws of nature, and natural phenomena *per se*. In so doing, this Court will continue to foster the growth of the biotechnology and medical technology industries and encourage and enhance the transfer of technology from the university and non-profit sector in consort with the private sector and particularly small business.

ARGUMENT

Amici answer Petitioner's first question as follows:

> [T]he Federal Circuit erred by holding that a "process" must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing ("machine-or-transformation" test), to be eligible for patenting under 35 U.S.C. § 101.

I. BIOTECHNOLOGY AND MEDICAL TECHNOLOGY INNOVATION AND INVESTMENT ARE PREDICATED ON INCLUSIVE PATENT-ELIGIBILITY STANDARDS

A. Inclusive Interpretation of 35 U.S.C. § 101 has Enabled Great Progress in Biotechnology and Medical Technology

The U.S. patent system has deep historic roots in the mechanical, electrical, and chemical arts. However, prior to 1980, patent-eligibility rules that had developed in the context of these technologies provided an uncertain fit for many life sciences inventions that today are considered biotechnology.

By 1980, the structure of DNA had been discovered; the first biochemical replication of a viral gene achieved; and recombinant DNA technology (gene splicing) was beginning to be applied. The nascent biotechnology industry was on the verge of achieving amazing scientific and medical

breakthroughs, but significant investment was needed to fund research and development efforts and to bring biotechnology discoveries to market. That investment required the assurance of patent protection. Fortunately, this Court eliminated much uncertainty with respect to whether biotechnology inventions would be patent-eligible subject matter with its landmark decision, *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

In ruling that non-naturally occurring, genetically-engineered bacteria constitute patent-eligible subject matter under 35 U.S.C. § 101, this Court observed: In "choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Id.* at 308. The Court found this inclusive reading to be fully supported by the legislative history of the Patent Act. *Id.* at 309 (Congress intended statutory subject matter to include "anything under the sun that is made by man") (citations omitted).

Clarifying that human intervention is the touchstone of patent eligibility, this Court gave effect to an unambiguously broad reading of § 101, intended to include technologies that Congress could not have foreseen when it passed the 1952 Patent Act. *Id.* at 315. *Chakrabarty* provided a profound contribution to the growth of biotechnology in the United States and enabled our country to become an international leader in biotechnology.

Chakrabarty paved the way for biotechnology discoveries, such as recombinant human insulin, human growth hormone, tissue plasminogen activator, and alpha interferon, to begin to address previously unmet medical needs. In the healthcare sector alone, the biotechnology industry has since brought to market more than 200 new drugs and vaccines, products that have improved the lives of hundreds of millions of people worldwide. More than 400 therapeutic products are currently in clinical trials, being studied to combat more than 200 diseases, including heart disease, cancer, AIDS, Alzheimer's, Parkinson's, stroke, septic shock, diabetes, anemia, cystic fibrosis, multiple sclerosis, lupus, kidney disease and liver disease. These new therapies offer hope for patients who have no or only very limited treatment options.

Biotechnological innovation also has begun to make possible the identification of an individual's susceptibility to certain diseases, such as cancer or diabetes, through the discovery of certain genetic mutations in that individual's DNA. Other diagnostic applications include the ability to determine the type of infectious agent a particular patient is presenting by amplifying and identifying small amounts of such agent's DNA. Both of these applications will greatly enhance the treatment of individuals.

In agriculture, spurred by the expectation of U.S. patent protection, biotechnological innovation has had significant global impact, providing increased harvests, reduced pesticide and fuel use and significant economic benefit to farmers. In 2006 in

the United States over 8 billion pounds of additional crops were grown with over 100 million pounds fewer pesticides providing farmers with net returns of over $2 billion. Sujatha Sankula, Quantification of the Impacts on U.S. Agriculture of Biotechnology, Nov. 2006, Nat'l Center for Food & Agric. Pol'y, http://www.ncfap.org/documents/2005biotechExecSummary.pdf. In 2008 over 12 million small and resource poor farmers in countries like China, India, the Philippines and South Africa adopted U.S.-innovated biotech crops as means to grow out of poverty. *See* Clive James, Global Status of Commercializes Biotech/GM Crops, Int'l Service for Acquisition Agri-Biotech Applications Brief 39-2008, http://www.isaaa.org/resources/publications/briefs/39/executivesummary/pdf/Brief%2039%20-%20Executive%20Summary%20-%20English.pdf.

These tremendous benefits and opportunities would not have been possible without the inclusive reading this Court gave to § 101 in 1980.

B. Biotechnology and Medical Technology Research and Development Require Unusually High-Risk Investment that, in Turn, Requires Broad, Well-Established Patent-Eligibility Standards

Achievements in biotechnology result from extensive and expensive research and development efforts. See NIH: Moving Research from the Bench to the Bedside: Hearings Before the Subcomm. on Health of the House Comm. on Energy and Commerce, 108th Cong., 1st Sess. 47 (2003)

(testimony of Phylliss Gardner, M.D.) ("The biotechnology industry is the most research and development-intensive and capital-focused industry in the world."). U.S. biotechnology companies currently invest more than $30 billion annually in research and development. Virtually all of this investment is through private funding. Id. at 49 (noting that 98% of R&D investment comes from the private sector). The average capitalized cost of bringing a biologic from the laboratory to human clinical trials exceeds $600 million. Subsequent FDA-mandated human testing consumes another $624 million. Clinical development time alone consumes more than eight years. Joseph A. Di Masi and Henry G. Grabowski, The Cost of Biopharmaceutical R & D: Is Biotech Different? 28 Manage. Decis. Econ. 469-79 (2007).

AdvaMed's members spend roughly $9 billion annually on the research and development. Publicly traded diagnostics companies with marketed products invest about 35% of their revenue into R&D, and those with annual sales under $5 million may invest 200% or more of their revenue into R&D. The Lewin Group, Inc., *The Value of Diagnostics* 3 (2005). From 1989 to 2004 alone, the number of laboratory tests available to more accurately and promptly diagnose disease increased by approximately 60%. Frank R. Lichtenberg, *Better Information, Better Health, 1990-2003* (2006), http://www.inhealth.org/doc/Page.asp?PageID=DOC 000069. Innovations in diagnostic testing just between 1990 and 1998 may have increased life expectancy as a much as one-half year. Frank R.

Lichtenberg, *The Impact of New Laboratory Procedures and Other Medical Innovations on the Health of Americans, 1990-2003* (Nat'l Bureau Econ. Res. Working Paper No. W12120), http://www.nber.org/papers/w12120.

Investing in biotechnology is also very risky: For every successful pharmaceutical product, thousands of candidates are studied and rejected after large investments have been made. Only a small minority of drugs that advance to human clinical trials obtain FDA approval. *See* Tommy G. Thompson, 19th U.S. Secretary of Health and Human Services, *Remarks at the Milken Institute's Global Conference* (Apr. 26, 2004), http://www.hhs.gov/news/speech/2004/040426.html (noting that only approximately one in 5,000 biopharmaceutical products will achieve FDA approval). The FDA estimates that just a 10% improvement in the ability to predict drug failures before clinical trials could save $100 million in development costs per drug. Biomarkers: An Indispensable Addition to the Drug Development Toolkit, White Paper – A PHARMA Matters Report (Mar.2009),http://thomsonreuters.com/content/PDF/scientific/pharma/biomarkers2.pdf (hereafter "PHARMA Matters"). Thus, raising funds to support product research and development requires the expectation of reasonable financial returns from commercial products and services that are successful. That expectation rests on the understanding that novel, useful, and unobvious biotechnological innovations will be patent eligible under the principles established in *Chakrabarty*.

A dramatic example of how even perceived changes to patentability standards can impact biotechnology investment occurred on March 14, 2000, when President Clinton and British Prime Minister Blair issued a joint statement that was interpreted to foreshadow impending limitations on human gene patents. Biotechnology stocks fell sharply. At close of trading, the NASDAQ biotech index had fallen 13%, significantly lowering biotech market capitalization and dropping the NASDAQ over 200 points. Tom Reynolds, *Genome Data Announcement Fuels Stock Plunge, Misunderstanding*, 92 J. Nat. Cancer Inst. 594 (2000). Like the growth of biotechnology after *Chakrabarty*, this example illustrates that patent-eligibility standards directly impact biotechnology investment incentives. If those standards were constricted, uncertainty about the availability of patent rights would deter the high-risk investments that are essential to biotechnology.

II. APPLICATION OF *BILSKI* TO BIOTECHNOLOGY AND MEDICAL TECHNOLOGY INVENTIONS IS CONTRARY TO PRECEDENT AND CREATES UNCERTAINTY REGARDING ISSUED PROCESS PATENT CLAIMS

A. The *Bilski* Test Is Not Appropriate for Determining Patent Eligibility of Biotech-nology and Medical Technology Inventions Under § 101

In *Bilski,* the Federal Circuit did not confine its rigid "machine-or-transformation" test to business method patents, or even to patents in the computer arts. It appears to apply to all patents and, in fact, has been applied to patents in the biotechnological and pharmaceutical arts. *See Classen Immunotherapies, Inc. v. Biogen Idec*, Nos. 06-1634, 06-1649, 2008 WL 5273107, at *1 (Fed. Cir. Dec. 19, 2008) (summarily affirming a district court summary judgment that a biotechnology process claim was not patent eligible because it did not meet the *Bilski* test); *King Pharms. v. Eon Labs.*, 593 F. Supp. 2d 501, 512-13 (E.D.N.Y. 2009) (holding one pharmaceutical process claim did not meet the *Bilski* test).

This Court has addressed the patent eligibility of biotechnology inventions under § 101 on several occasions. *See, e.g., J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124 (2001); *Chakrabarty*, 447 U.S. 303; *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948). In each of

these cases, this Court asked whether the claimed invention was merely the discovery of a law of nature (or natural phenomenon) or did it result "from the application of the law of nature to a new and useful end." *Funk Bros.*, 333 U.S. at 131-32. *Accord J.E.M. Ag Supply*, 534 U.S. at 145-46; *Chakrabarty*, 447 U.S. at 303, 310. While these cases involved claims to products rather than processes, "the same principle applies" when analyzing process claims for patent eligibility. *Diamond v. Diehr*, 450 U.S. 175, 188 n.11 (1981). This Court has never applied the Federal Circuit's machine-or-transformation test in a biotechnology case. The havoc such an application would cause is explained below.

B. The Federal Circuit's *Bilski* Test Would Create New Uncertainty and Stifle Biotechnology and Medical Technology Innovation

Requiring biotechnology and medical technology process claims to be coupled to a physical transformation of matter or tied to a specific machine will exclude from patent eligibility inventions directed to new and useful methods which are of great value to society – inventions that also are specific and concrete (are not abstract ideas), that result from human intervention (are not natural phenomena) and that are applications yielding a new and useful end (are not laws of nature).

1. Biotechnology and medical technology processes are not abstract ideas, laws of nature or natural phenomena

Consider the following claims to hypothetical inventions:

> 1. A method of diagnosing Disease X in a patient in need thereof, which comprises detecting elevated Protein Y levels in a body fluid sample from said patient.
>
> 2. A method of determining whether a malignant tumor in a patient in need thereof is susceptible to Anti-Cancer Drug X, which comprises measuring the level of expression of Gene Y in said malignant tumor compared to a control non-malignant tissue from said patient, wherein expression levels of Gene Y in said malignant tumor greater than twice that of said control non-malignant tissue correlate with susceptibility of said tumor to Anti-Cancer Drug X.

Neither claim is tied to a particular machine or results in transformation of an "article." Yet claim 1 is not directed to an abstract idea or law of nature; it is a method of diagnosing disease with specific and concrete steps, yielding a useful and tangible end (a method of diagnosing Disease X). Likewise, claim 2 is not directed to the "idea" that susceptibility of a tumor to Cancer Drug X is related to Gene Y expression; it is directed to a method for determining

whether Cancer Drug X therapy would be useful against a particular tumor.

Consider also the following hypothetical example concerning physiologic monitors: Hemodynamic monitors measure naturally-occurring parameters of a patient's blood stream. For example, changes in blood oxygenation can be monitored to detect a sepsis infection. Some of these parameters are themselves novel, or can be measured or communicated in novel ways, to facilitate a surgeon's treatment and diagnosis of disease. These are inventions that save lives on a daily basis. Such novel systems to determine hemodynamic parameters are usually best claimed as processes, for example:

> 1. A process for determining blood oxygenation including: determining a blood pressure pulse wave; deriving a blood oxygenation parameter from the pulse wave using equation X; and communicating the blood oxygenation parameter to medical personnel.

Despite the life-saving potential of such inventions, there could be difficulties with obtaining or enforcing such process claims under *Bilski*, even in kit format.

Determining where a "natural phenomenon" leaves off and becomes "touched by the hand of man" under *Chakrabarty* may be difficult in practice to determine. However, where such a "touch" can be recognized, the invention is not an abstract idea, law

of nature, or natural phenomenon *per se* and should not be excluded from patent eligibility.

For algorithm improvements, it may be impossible to find a linking "machine" that isn't conventional or easy to design around. For example, the hardware might be a conventional monitor, pressure sensor and catheter that are not a "particular machine" under *Bilski*. Instead, the novelty may be in the way the information is processed, such as by an improved, empirical (manmade) mathematical algorithm (e.g., equation X above) and application of that innovation to a useful end. Recitation of a generalized computer system executing equation X, however, might not satisfy *Bilski's* "particular machine" requirement. On the other hand, introducing sufficient limitations to make the monitor a "particular machine" runs a high risk of a design-around since distributed computing allows an infinite number of ways to shift data and process duties between physically disparate hardware and software.

Meeting the *Bilski* "transformation" test is also difficult because the monitor itself does not perform a treatment or diagnosis. The monitor is determining and communicating a natural parameter with a novel – but abstract – equation. The treatment or diagnosis step could be added to the claim, which would likely satisfy *Bilski*. In this instance, however, the infringer selling the monitor would not be directly infringing the patent. Instead, the medical personnel performing the treatment or diagnosis would have to be joined in the suit as a joint tortfeasor. This result would upend Congress'

intent under 35 U.S.C. § 287(c), which spares medical personnel liability from patent infringement suits on medical methods.

Numerous process (or "method") claims directed to biotechnological inventions that arguably do not yield a physical transformation or require machine implementation have been issued by the U.S. Patent and Trademark Office ("USPTO"). *See, e.g.,* U.S. Patent No. 6,410,516 (method of modifying effects of external influences on a eukaryotic cell to induce intracellular signaling); U.S. Patent No. 6,869,762 (method of predicting susceptibility to Crohn's disease). These issued claims are presumed valid and therefore directed to patent-eligible subject matter. 35 U.S.C. § 282. Some of these claims depend on the discovery of a biological phenomenon which allows the method to work, and some have a "calculation" or "mental" step. Nevertheless, none claims an abstract idea, law of nature or natural phenomenon *per se*. Instead each provides a valuable and concrete contribution to the useful arts and is exactly the kind of subject matter that the patent system was designed to protect. Limiting process claims to those which can pass the rigid *Bilski* test would unnecessarily limit protection for innovations in unexpected and highly deleterious ways.

2. Biomarkers are useful to predict disease and form the bases for their treatment

Over the past decade scientists increasingly have been able to use the growing knowledge of the

biology of disease to address conditions that once were impossible to diagnose, predict, or treat. *See generally* PHARMA Matters, *supra* at p. 13. Newly discovered natural phenomena, such as genetic or physiological abnormalities that correlate with the likelihood of developing a disease or being susceptible to a treatment, have become known as "biomarkers," which today form an important component of almost every major clinical trial. A biomarker is "a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes or pharmacological responses to a therapeutic intervention." *Biomarkers and Surrogate Endpoints,* 69 Clinical Pharmacology & Therapeutics 89, 91 (2001). A biomarker's usefulness is based on its correlation to the status of a disease or organism, performed through mental operations or otherwise. For example, in the late 1980s, scientists discovered that HIV viral load could be used to predict the impending onset and progression of AIDS, allowing physicians to monitor the status of their patients, and patients to make personal decisions based on how long they could expect to remain symptom-free. Researchers sought and obtained patents for methods in the growing diagnostic and therapeutic arsenal against HIV, including, for example, U.S. Patent No. 5,674,680, owned by the Rockefeller University:

> 1. A method for predicting the time of onset of the development of clinical signs of immunodeficiency associated with disease progression in an

individual infected with human immunodeficiency virus (HIV) comprising:

(a) determining a level of expression of HIV messenger RNA (mRNA) in peripheral blood cells obtained from the individual; and

(b) correlating the level of expression of HIV messenger RNA with the time of onset of the development of clinical signs of immunodeficiency; wherein

(i) a high level of HIV mRNA correlates with a high likelihood for the development of clinical signs of immunodeficiency within about two years; and

(ii) a low level of HIV mRNA or no detectable HIV mRNA correlates with a low likelihood of the development of clinical signs of immunodeficiency for at least five years.

Based on such technology, viral load subsequently was used to show that HIV-positive

individuals receiving combination therapy had a higher reduction in viral load than those on monotherapy, and that combination therapy was therefore more effective in slowing the onset and progression of the disease. The viral load biomarker was used to develop and assess the Highly Active Antiretroviral Therapy treatment (drug cocktail) regimens used by many people living with HIV today. Charles Flexner, *HIV Drug Development*, 6 Nature Reviews Drug Discovery 959 (2007).

The drug irinotecan (Camptosar®) is an example of the use of a biomarker in "personalized medicine" to guide both clinical practice and subsequent clinical trials. Irinotecan is used to treat advanced colorectal cancer. Once administered, irinotecan is converted to an active metabolite, and then eventually inactivated by an enzyme, UGT1A1. About 10% of the population have reduced UGT1A1 enzyme activity because of a genetic variation in the enzyme. These patients inactivate the drug more slowly and therefore are exposed to overly high drug concentrations when administered a conventional dose and consequently may experience life-threatening side effects such as neutropenia (a decrease in white blood cells) and diarrhea. The toxicity of irinotecan had long been a concern. However, once researchers discovered the link between the UGT1A1 enzyme and irinotecan toxicity, clinicians were able to identify those patients who needed to be given a reduced amount of irinotecan. Based on this discovery, the U.S. Food and Drug Administration added a warning to irinotecan's labeling in 2005. This biomarker

technology is an important clinical and commercial invention for which patent protection has been obtained. U.S. Patent No. 6,395,481. Claim 21 reads:

> 21. A method for screening individuals for variation in glucuronidation activity comprising detecting polymorphisms in a uridine diphosphate glucuronosyltransferase I (UGT1A1) gene promoter, the method comprising determining the presence of five (TA) repeats in said promoter, wherein the presence of five TA repeats correlates with increased expression of the UGT gene.

This pharmacogenomic technology also has led to improvements in other drug development. Almost immediately, it prompted use of the UGT1A1 biomarker to guide other ongoing studies, including several new irinotecan and oxaliplatin-based chemotherapies.

A well-known story in the history of biomarker drug development involves the *her-2* gene and receptor, discovered in the early 1980s. Scientists found that 20–30% of breast cancer patients have an overabundance of the HER-2 receptor on their cancer cells ("HER-2 overexpressers"). This biomarker's presence correlates with an aggressive form of breast cancer, and therefore a poor prognosis. Discovery of this correlation allowed testing for this biomarker to become an important diagnostic tool that guided decisions for using then-

existing treatments such as aggressive surgery or chemotherapy. The University of California obtained several patents protecting this important technology, including now-expired U.S. Patent No. 4,968,603. Claim 1 reads:

> 1. A method for screening patients to determine disease status, said method comprising:
>
> measuring the level of amplification or expression of the HER-2/neu gene in a sample from a patient suffering from breast or ovarian adenocarcinoma; and
>
> classifying those patients having an increased level of amplification or expression of the HER-2/neu gene relative to a reference level characteristic of normal cells as being more likely to suffer disease relapse or having a decreased chance of survival.

The HER-2 biomarker also provided scientists with a new target for an entirely novel therapy. In 1997, many years after the HER-2/*neu* gene discovery, the FDA approved the antibody trastuzumab (Herceptin®), a new therapy that specifically targets HER-2 receptors in HER-2 overexpressers. This therapy successfully reduces the spread and progression of cancer in many patients who had very few treatment options prior to this important discovery. Currently, HER-2/*neu* testing is required to determine whether a breast cancer patient can receive Herceptin therapy.

3. Biomarkers play a critical role in drug research and require significant investment for their discovery

Today, biomarkers play a critical role in drug research, providing the potential for "safer drugs, in greater numbers, approved more quickly." Federico Goodsaid and Felix Frueh, *Biomarker Qualification Pilot Process at the FDA*, 9 A.A.P.S. Journal 1, art. 10, E105 (2007). Biomarkers are an important element in the FDA's efforts to speed development and approval of new drugs and biologics. *See* Dept. of Health and Human Services, U.S. Food and Drug Admin., The Critical Path Initiative: Projects Receiving Critical Path Support in Fiscal Year 2008 (Apr. 2009), http://www.fda.gov/ScienceResearch/SpecialTopics/CriticalPathInitiative. They also are the object of major research efforts by the National Institutes of Health (Biomarker Consortium), universities, and the private sector. *See* Gregory J. Downing, *Partnerships in Biomarker Research,* Biomarkers in Clinical Drug Development 247-270 (John C. Bloom & Robert A. Dean eds., Informa Health Care, 2003); s*ee also*, *e.g.*, Nat'l Inst. Health, Biomarker Consortium, http://www.biomarkersconsortium.org; Pharmaceutical Research and Manufacturers of America Biomarker Consortium, http://www.innovation.org. *Amici* invest heavily in the discovery of new natural correlations, believing that the fruits of this research can be applied in future clinical practice.

Investment in such studies has been rewarded. For example, retrospective analysis of several colorectal cancer drug trials showed that one reason why some patients did not respond to certain antibody therapy was because of a mutation of the *k-ras* gene. This finding now allows physicians to tailor such therapy to the genetic status of individual patients and to identify patients who are likely to respond to these biologic drugs. Patients who formerly would have undergone needless, ineffective treatment now can be redirected immediately to alternative therapies. The discovery of the importance of the *k-ras* gene has significantly impacted the clinical management of metastatic colorectal cancer, resulting in changes to clinical practice guidelines as well as labeling changes for the EGFr antibody biologic drugs cetuximab and panitumumab. Center for Drug Evaluation and Research, U.S. FDA, *Class Labeling Changes to anti-EGFR Monoclonal Antibodies, Cetuximab (Erbitux) and Panitumumab (Vectibix):* KRAS *Mutations*, http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm172905.htm; Carmen, J. Allegra et al., *American Society of Clinical Oncology Provisional Clinical Opinion*, 27 J. Clinical Oncology 2091 (2009).

Biomarkers also are used to guide clinical trials of leading-edge treatments. For example, in preliminary clinical studies of the MAGE-A3 antigen-specific cancer immunotherapeutic (MAGE-3 ASCI), a member of a new class of biologic cancer therapeutics, scientists found one can predict the likelihood of a positive treatment response or the risk of relapse in individual lung cancer patients by

identifying specific genetic signatures. This finding guided the design of the largest lung cancer clinical trial ever conducted, which currently is underway and forms the basis for major ongoing commercial drug and diagnostic development efforts by BIO members. *Abbott and GSK to Collaborate on Molecular Diagnostic Test to Select Candidate Patients for Future Cancer Immunotherapy*, N.Y. Times, July 13, 2009.

Innovations in the fields of biomarkers and medical devices show great promise of revolutionizing medicine in the coming decades, allowing for personalized medicine and a higher standard of patient care. The *Bilski* "machine-or-transformation" test would stifle investment and innovation in these fields, and is not an appropriate standard for determining patent eligibility under § 101.

III. *BILSKI* IS INCONSISTENT WITH THE BROAD STANDARD FOR PATENT ELIGIBILITY IN § 101 AND THIS COURT'S PRECEDENT

Section 101 defines patent-eligible subject matter as "*any* new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ." (emphasis added). By crafting this statute using clear, broad language to include "any" new and useful process, machine or material rather than naming discrete fields of invention, Congress sought to promote the progress of all areas of science and technology, recognizing that the most important inventions are

often unforeseeable. *See Chakrabarty*, 447 U.S. at 316. Especially in emerging fields such as biotechnology and medical technology, neither Congress nor this Court can predict those inventions "most benefiting mankind" and destined to "push back the frontiers." *Id.* For instance, when the 1952 Patent Act was passed, no one could have predicted advances such as individualized medicine using biomarkers, genetic testing for diseases or genetically-engineered organisms. Yet under the plain language of § 101, inventions in each of these fields can be protected. The Federal Circuit's rigid, bright-line *Bilski* test is inconsistent with the clear language of § 101, and this Court's precedent.

A. The Governing Standard Regarding Patent Eligibility of Process Claims is 35 U.S.C. § 101 and this Court's Precedent

"In cases of statutory construction, we begin with the language of the statute." *Diehr*, 450 U.S. at 181-82. Here, that language reflects the inclusive nature of § 101: "Whoever invents or discovers any new and useful process . . . may obtain a patent therefor, subject to the conditions and requirements of this title." The statute "does not mean 'some,' or even 'most,' but all." *Bilski*, 545 F.3d at 1012 (Rader, J., dissenting). As this Court has stated:

> Unless otherwise defined, "words will be interpreted as taking their ordinary, contemporary, common meaning," and, in dealing with the patent laws, we have more than once cautioned that

> "courts *should not read into the patent laws limitations and conditions which the legislature has not expressed.*"

Diehr, 450 U.S. at 182 (citations omitted). *See also* H.T. Markey, *"Why Not The Statute?,"* 65 J. Pat. Off. Soc'y 331, 331-40 (1983).

Of course, there are "limits to § 101 and every discovery is not embraced within the statutory terms. Excluded from such patent protection are laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185. Thus,

> 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, *quoted in Diehr*, 450 U.S. at 185.

> The abstractness and natural law preclusions not only make sense, they explain the purpose of the expansive language of section 101. Natural laws and phenomena can never qualify for patent protection because they cannot be invented at all. . . . . Furthermore, abstract ideas can never qualify for patent protection because the Act intends, as section 101 explains, to

> provide "useful" technology. An abstract idea must be applied to (transformed into) a practical use before it qualifies for protection.

Bilski, 545 F.3d at 1013 (Rader, J., dissenting).

Aside from the three narrow exclusions, subject matter within the statutory categories identified in § 101 is patent eligible. Thus, an application of a law of nature, natural phenomenon or abstract idea can be patented as part of a process. *See Diehr*, 450 U.S. at 187. In fact, "all inventions can be reduced to underlying principles of nature." *Id.* at 189 n.12; *see also Lab. Corp. of Am. Holdings v. Metabolite Labs.,* 548 U.S. 124, 134-36 (2006) (Breyer, J., dissenting from dismissal of writ of certiorari as improvidently granted) ("many a patentable invention rests upon its inventor's knowledge of natural phenomena; many 'process' patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process").

Admittedly, the "line between a patentable 'process' and an unpatentable 'principle' is not always clear. Both are conception[s] of the mind, seen only by [their] effects when being executed or performed." *Parker v. Flook*, 437 U.S. 584, 589 (1978) (quoting *Tilghman v. Proctor*, 102 U.S. 707, 728 (1881)) (alternations in original). Nevertheless, difficulty in applying the statute does not justify or require adoption of a bright line test:

> The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and

> statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.

Chakrabarty, 447 U.S. at 315.

B. The Federal Circuit Erred by Holding that a "Process" must be Tied to a Machine or Transformation" Under 35 U.S.C. § 101

A patent-eligible process has not in the past and should not now require physical transformation or machine implementation. The Federal Circuit's machine-or-transformation test requires ignoring this Court's rejection of such a rigid test in favor of a broader, more reasoned approach. *See, e.g., Gottschalk v. Benson*, 409 U.S. 63, 67 (1972); *Flook*, 437 U.S. at 590; *Diehr*, 450 U.S. at 185 (each identifying a patent-eligible process as "any new and useful process," except those to abstract ideas, natural phenomena and laws of nature).

1. The Federal Circuit has misinterpreted Supreme Court precedent

The Federal Circuit attributes its machine-or-transformation test to this Court. *Bilski*, 545 F.3d at 963 (referring to "the Court's machine-or-transformation test"); *id.* at 964 (stating that the "Supreme Court has enunciated a definitive test,"

i.e., the machine-or-transformation test). Yet this Court clearly has rejected such a test. *See, e.g., Flook*, 437 U.S. at 589 n.9 ("As in *Benson*, we assume that a valid process patent may issue *even if it does not meet* one of these qualifications [transformation or machine-implementation] of our earlier precedents.") (emphasis added) (internal citations omitted); *Benson,* 409 U.S. at 71 ("It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a 'different state or thing.' We *do not hold* . . . . ") (emphasis added). Thus, this Court has never held that the absence of a physical transformation or machine implementation is sufficient to declare a process *ineligible* for patent protection.

In invoking its *Bilski* test, the Federal Circuit has transformed what amounts to a "safe harbor" in certain circumstances into a rigid exclusionary test: According to this Court, a process that results in a physical transformation or is tied to a machine *is* patent eligible. *See, e.g., Diehr*, 450 U.S. at 192 ("when [a claimed invention] is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101); *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U. S. 86, 94 (1939); *Tilghman*, 102 U.S. at 721.

Amici recognize that this Court has stated: "Transformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include

particular machines." *Diehr*, 450 U.S. at 184 (quoting *Benson*, 409 U.S. at 70). However, that statement must be taken in context and in view of the facts in *Diehr*—facts establishing that a transformation was dictated by the claim in issue. While transformation may have been "the clue" in *Diehr*, neither transformation nor a machine limitation is required by this Court's precedent in all process cases. *See Benson*, 409 U.S. at 71.

2. The Federal Circuit has read limitations into "any new and useful process" not required by the language of § 101

The language of § 101 is "extremely broad." *J.E.M. Ag Supply*, 534 U.S. at 130; s*ee also Flook*, 437 U.S. at 588 n. 9. But the language is *not* ambiguous. *Chakrabarty*, 447 U.S. at 315. Yet, the Federal Circuit has construed the plain language § 101 in a way not contemplated by Congress, i.e., by "redefining the word 'process' in the patent statute." *Bilski*, 545 F.3d at 977 (Newman, J., dissenting). "In interpreting a statute, it is the language selected by Congress that occupies center stage . . . ." *Id.* at 987. As Congress intended by its broad language, it includes all practical applications of the statutory categories, including processes. *See, e.g., Diehr*, 450 U.S. at 187.

The breadth of the statute ensures it is a "dynamic provision designed to encompass new and unforeseen inventions." *J.E.M. Ag Supply*, 534 U.S. at 135. Denying patent protection for unforeseen

inventions, as *Bilski* surely would do, is "inconsistent with the forward-looking perspective of the patent statute." *Id.* This Court should "decline to narrow the reach of § 101 where Congress has given . . . no indication that it intends this result." *Id.* at 145-46.

3. This Court has disfavored rigid application of bright-line tests

In *Bilski*, the Federal Circuit has imposed a rigid test that precludes consideration of what is actually covered by the particular patent claim in question. The *Bilski* test brings to mind the Federal Circuit's "TSM" test in *Teleflex, Inc. v. KSR Int'l Co.*, No. 04-1152, 2005 WL 23377 (Fed. Cir. Jan. 6, 2005), *rev'd*, 550 U.S. 398 (2007). This Court repeatedly has rejected the application of such rigid, bright-line tests and has instead consistently applied flexible approaches.

In *KSR,* this Court rejected the "rigid approach of the Court of Appeals" because "[t]hroughout this Court's engagement with the question of obviousness, our cases have set forth an expansive and flexible approach inconsistent with the way the Court of Appeals applied its TSM test here." 550 U.S. at 415. This Court held that "rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *Id.* at 421.

Earlier, this Court criticized the Federal Circuit for its rigid application of the law in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002). In *Festo*, the Federal Circuit held that prosecution history estoppel prevented the inventor

from asserting any scope of equivalents. *See id.* at 737. It reviewed its precedent and found that it had "consistently applied the doctrine in a flexible way, not a rigid one." *Festo*, 535 U.S. at 738. This Court also found that the "Court of Appeals ignored the guidance of *Warner-Jenkinson*, which instructed that courts must be cautious before adopting changes that disrupt the settled expectations of the inventing community. See 520 U.S. at 28." *Festo*, 535 U.S. at 738. This Court was understandably concerned that

> Inventors who amended their claims under the previous regime had no reason to believe that they were conceding all equivalents. If they had known, they might have appealed the rejection instead. There is no justification for applying a new and more robust estoppel to those who relied on prior doctrine.

Id. at 739.

Likewise, in *Warner-Jenkinson,* this Court declined to retroactively narrow the scope of patent protection by adopting Petitioner's rigid, bright-line test to determine prosecution history estoppel, noting that "the PTO may have relied upon a flexible rule of estoppel when deciding whether to ask for a change in the first place." *Warner-Jenkinson Co. Hilton Davis Chem. Co.,* 520 U.S. 17, 32 n.6 (1997). ("To change so substantially the rules of the game now could very well subvert the various balances the PTO sought to strike when issuing the numerous

patents which have not yet expired and which would be affected by our decision.")

In this case, the Federal Circuit's rigid rule will cause similar uncertainty regarding patent protection for inventions previously believed to be patent eligible, including many in biotechnology and medical technology. Investment in these inventions were based on the expectation that patent eligibility would be determined by § 101's broad language and this Court's precedent—not the Federal Circuit's rigid *Bilski* test. "Indeed, the full reach of [*Bilski's*] change of law is not clear, and . . . many existing situations may require reassessment under the new criteria." *Bilski,* 545 F.3d at 977 (Newman, J., dissenting). "Uncertainty is the enemy of innovation. These new uncertainties not only diminish the incentives available to new enterprise, but disrupt the settled expectations of those who relied on the law as it existed" before *Bilski*..

C. Additional Tests Further Restrict the Scope of Patent-Eligible Process Claims and Should be Rejected in favor of This Court's Broad Interpretation of § 101

To determine whether the claimed invention is patent eligible under § 101, the appropriate question to ask is whether the claimed invention is a law of nature, natural phenomenon or abstract idea *per se*. However, several additional tests have been applied from time to time. The machine-or-transformation test, at issue here, is among them. Two others are those labeled "preemption" and "post-solution activity." *See, e.g., Benson*, 409 U.S. at 71-72

(preemption); *Flook*, 437 U.S. at 591 (post-solution activity). In *Bilski,* the Federal Circuit relied on these additional tests. 545 F.3d at 957, 562 (preemption and post-solution activity, respectively). While these additional tests may appear helpful in a given case, their application often has caused confusion and likely has led to the inappropriate loss of patent rights in many cases.

A particularly misleading test is that involving preemption. If a claim were granted to an abstract idea, law of nature, or natural phenomenon *per se*, then that claim would wholly preempt all its uses. To the extent cases have so held, those holdings are consistent with § 101. *See, e.g.*, *Benson*, 409 U.S. at 71-72 ("patent would wholly preempt the mathematical formula and in practical effect would be a patent on the algorithm itself"). However, when a claim limits such a use, it does not preempt an abstract idea, law of nature or natural phenomenon, and the concept of preemption should not be applied. *See, e.g., O'Reilly v. Morse*, 56 U.S. 62, 112-16 (1854) (claim 8 limited to using electromagnetism "for marking or printing intelligible characters, signs, or letters" and thus *not preempting* all uses of electromagnetism but rather is overly broad (a § 112 problem)); *Diehr*, 450 U.S. at 187 (claim to a process for molding synthetic rubber held patentable because while the "process admittedly employs a well-known mathematical equation," the inventors did "not seek to *preempt* the use of that equation").

By its very essence, a patent grants the inventor the right to exclude others from practicing the claimed invention, in other words, to *preempt* others

from making, using, selling, offering for sale, or importing the claimed invention. The scope of this exclusionary right depends upon what is in the prior art and the inventor's ability to satisfy § 112 requirements. Confusion with the preemption doctrine arises when, instead of considering whether the claim preempts the fundamental principle in question, courts ask whether the claim unduly *preempts the field of invention*, blocking others from entering the field. *See, e.g., Bilski*, 545 F.3d at 957 ("pre-emption of all uses of the principle *or in only one field* . . . indicate the claim is not limited to a particular application of the principle") (emphasis added). Such an inquiry is not appropriate and confuses concerns about patent eligibility with those relating to other provisions of title 35, such as § 112 (breadth) and §§ 102 and 103 (patentability in view of the prior art). Unless an inventor preempts a law of nature, natural phenomenon or abstract idea *per se*, his or her ability to exclude (preempt) others from making, using, selling offering for sale or importing the claimed invention is a function of §§ 112, 102 and 103, not of § 101.

The "post-solution," or "extra-solution," test further confuses the law. Since "all inventions can be reduced to underlying principles of nature," the subject matter of an invention must be viewed *in its entirety* to determine patent eligibility. *Diehr*, 450 U.S. at 188, 189 n.12. This principle is essential to biotechnological patents, since inventions within this discipline inherently relate to the natural phenomena and biological processes of living things. Yet the "post-solution" or "extra-solution" test invites

dissecting the claim and ignoring certain claim language. *Compare Diehr*, 450 U.S. at 175 n.5 (giving weight to all the claim limitations, including that requiring "opening the press automatically when a said comparison indicates equivalence") *with id.* at 215 (Stevens, J., dissenting) (suggesting that the mold-opening limitation should be treated as post-solution activity and given no "legal significance").

Similarly, the focus should be on the claim *as a whole* and not on what a court believes the "inventor claims to have discovered." *Diehr*, 450 U.S. at 205 (Stevens, J., dissenting) (suggesting this latter approach). This latter inquiry belongs with a patentability analysis under §§ 102 and 103. Making it part of the § 101 inquiry confuses the novelty and nonobviousness issues with the issue of whether the claim is to a law of nature, natural phenomenon or abstract idea. *See, e.g., Flook*, 437 U.S. at 591-95; and *Diehr*, 450 U.S. at 205-27 (Stevens, J., dissenting). "The 'novelty' of any element or step in a process . . . is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories . . . ." *Diehr*, 450 U.S. at 188-89.

Like the "preemption" and "extra-solution activity" tests, the Federal Circuit's machine-or-transformation test hinders appropriate application of § 101:

> [It] propagates unanswerable questions: What form or amount of "transformation" suffices? When is a

> "representative" of a physical object sufficiently linked to that object to satisfy the transformation test? . . . . What link to a machine is sufficient to invoke the "or machine" prong? Are the "specific" machines of *Benson* required or can a general purpose computer qualify?

Bilski, 545 F.3d at 1015 (Rader, J., dissenting).

Amid the above-described confusion, this Court now has the opportunity to clarify application of § 101. *Amici* respectfully request that it do so by reaffirming its long-standing principles underlying a § 101 analysis and applying them to the claim as a whole rather than relying on confusing concepts, rigid tests, or alternative approaches that have arisen in prior cases. By doing so, the governing standard of § 101 will conform to past precedent, promote science and the technological arts, and will not further confuse the law on patent-eligible subject matter.

CONCLUSION

For the foregoing reasons, *Amici* respectfully request this Court to set aside the Federal Circuit's *Bilski* test and reaffirm the breadth of 35 U.S.C. § 101 to include "any new and useful process," except one to a law of nature, natural phenomenon, or abstract idea *per se*.

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Respectfully submitted,

Thomas DiLenge
General Counsel
Hansjorg Sauer, Ph.D.
Deputy General Counsel
Biotechnology Industry Organization
1201 Maryland Ave., S.W.
Suite 900
Washington, DC 20024
(202) 962-6695

Christopher L. White
General Counsel
Advanced Medical Technology Association
701 Pennsylvania Ave., N.W.
Suite 800
Washington, DC 20004
(202) 783-8700

Howard W. Bremer
Emeritus Patent Counsel
Wisconsin Alumni Research Foundation
614 Walnut St.
13th Floor
Madison, WI 53726
(608) 263-2500

E. Anthony Figg
Counsel of Record
Nancy J. Linck, Ph.D.
Minaksi Bhatt
Martha Cassidy, Ph.D.
1425 K St., N.W.
Suite 800
Washington, DC 20005
(202) 783-6040

P. Martin Simpson, Jr.
Managing Counsel
Business Transactions & Land Use
Office of General Counsel
The Regents of the
University of California
1111 Franklin St.
12th Floor
Oakland, CA 94607
(510) 987-9800

Counsel for Amici Curiae
Biotechnology Industry Organization,
Advanced Medical Technology Association,
Wisconsin Alumni Research Foundation &
The Regents of the University of California