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 *AMICUS CURIAE* MEDTRONIC, INC. IN SUPPORT OF NEITHER PARTY

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QUESTIONS PRESENTED

1. Whether the Court of Appeals for the 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, despite this Court's precedent declining to limit the broad statutory grant of patent eligibility for "any" new and useful process beyond excluding patents for "laws of nature, physical phenomena, and abstract ideas."

2. Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.

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INTEREST OF THE *AMICUS CURIAE*[1]

With the consent of the parties, this brief is filed by *Amicus Curiae*, Medtronic, Inc., which is a global leader in medical technology innovation. *Amicus Curiae* engages in the research and development, design, and manufacturing of medical products for use in the diagnosis, monitoring, and treatment of various diseases. *Amicus Curiae*'s business operations include the medical technologies of Cardiac Rhythm Disease Management, Spinal and Biologics, CardioVascular, Neuromodulation, Diabetes, Surgical Technologies, and Emergency Response Systems. Medtronic has no financial interest in the outcome of this case. Medtronic seeks an application of the patent laws in a manner that most effectively promotes innovation and most accurately reflects the intent of Congress.

SUMMARY OF THE ARGUMENT

The requirement that a process must be tied to a particular machine or apparatus, or must transform a particular article into a different state or thing to be eligible for patenting under 35 U.S.C. § 101 would

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[1] Pursuant to Supreme Court Rule 37, no counsel for any party authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* made a monetary contribution to the preparation or submission of the brief. Counsel of record for all parties were notified prior to filing and have consented to this filing. Letters of consent have been filed with the Clerk of the Court.

adversely affect medical technology innovation. The machine-or-transformation requirement would preclude the patenting of significant advances in medical research and development, diagnosis, prevention, and treatment. Without the full range of incentives of patent exclusivity, medical innovation will suffer the loss of investment and a retreat into secrecy, the very harms the patent laws were enacted to guard against. Moreover, impeding the patenting of medical breakthroughs jeopardizes public health goals, including affordable universal access, by deterring the invention and public disclosure of competitive medical technology. The machine-or-transformation requirement is therefore inappropriate and should be discarded.

ARGUMENT

I. The Experience of *Amicus Curiae* Medtronic, Inc., as a Global Leader in Medical Technology Innovation Suggests that the Court of Appeals' Revision of Section 101 of the Patent Act to Require a Machine or Transformation Will Jeopardize Progress Across Diverse Industries.

Ingenuity has many faces, and innovation takes many shapes. These simple truths, however, were ignored by the Court of Appeals when it decided the case now before this Court by fashioning a broad, limiting test with questionable application across different technologies. Indeed, this Court's review of

the Court of Appeals' judgment in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc), involves the significant revision of a patent law standard that has far reaching implications beyond the parties or any one particular industry. While much public attention has focused on the implications for financial services and computer software companies, the consequences, unintended or otherwise, for medical technology and health care have been understated. In this regard, *Amicus Curiae* seeks to better inform the impact of a change in patent eligible subject matter that *Bilski* represents.

The benefits of a robust patent system where Section 101 of Title 35 of the U.S. Code has earned the healthy reputation for inclusion, rather than exclusion, are reflected in the story of *Amicus Curiae*. Founded over a half century ago, *Amicus Curiae* began as a medical equipment repair shop. The company's first product, inspired by a musical metronome, was nothing short of a life changing therapy – a wearable, battery-powered cardiac pacemaker. This innovation was the foundation for dozens more therapies of *Amicus Curiae*, which used its electrical stimulation expertise to improve the lives of millions of people.

Over the years, *Amicus Curiae* adapted additional technologies for the human body, including radio frequency therapies, mechanical devices, drug and biologic delivery devices, and diagnostic tools. Today,

the technologies of *Amicus Curiae* are used to treat more than 30 types of chronic diseases affecting many areas of the body. Since its humble beginnings in Minnesota, *Amicus Curiae* has grown into a multinational company that uses technology to transform the way debilitating, chronic diseases are treated.

Amicus Curiae thus implements a diverse group of technologies with a focus on the need to provide precise clinical interventions as well as progressively decentralized health care delivery systems tailored to specific patient needs. Specifically, *Amicus Curiae*'s current and future product platforms integrate a hybrid of technologies, such as electromechanical, electrical, communication systems, biotechnology, drugs, and information systems, with the objective to identify patient risk and deliver appropriate therapy by continuously monitoring physiological parameters of a patient or indices of a disease state.

In this highly integrated medical product environment, physiological data or health information, which generally relate to "natural laws or principles" based on correlations, comparisons, and deductions, are being used to inform and manage therapy delivery and treatment. *Amicus Curiae* invests heavily in the innovative use, integration, and implementation of these physiological data and relies on the patent system to

advance innovation and deliver on *Amicus Curiae*'s long-standing mission to alleviate pain, restore health and extend life.

Most importantly, the public has been a direct beneficiary of the medical advances made possible by *Amicus Curiae* and others because a robust patent system has provided the incentive to innovate and invest in medical technology. The lives of countless patients, as well as those of their families and communities, have been touched by medical inventions such as rapid diagnostic tests and minimally invasive surgical procedures.

II. Examples of Significant Medical Advances that a Machine-Or-Transformation Requirement Would Render Patent Ineligible.

In an attempt to better inform this Court's understanding of the various medical technologies that may be affected by upholding the *Bilski* revision to patent eligibility, *Amicus Curiae* respectfully submits a series of examples drawn from composite experiences of *Amicus Curiae* as a global leader in medical technology innovation research and development on human conditions, disease states, and therapies relating to the heart, brain, spine, bladder, stomach, blood vessels, and more. These illustrations, which include Patient Diagnosis, Monitoring and Medical Data Management, and Personalized Medicine, reflect the extraordinary

breadth of technology in this industry sector and foreshadow the importance of recognizing the grave potential consequences, unintended or otherwise, of *Bilski* for medical technology and health care.

In particular, the examples highlight the problem of setting a limiting standard for patent eligibility that applies across diverse fields of technology to encourage inventors to elect the rights and obligations of the patent system. The machine-or-transformation requirement presents a poor fit for those fields that depend on the generation of predictive models from a comparison of individual sample information against a database of previously gathered information. Some have disparaged certain methodologies in this regard as the mere correlation of natural phenomena. However, while the bare observation and act of correlation *per se* may not be patent eligible, precisely how a specific correlation is achieved should be.

In the context of medical technology, the proper evaluation and effective treatment of patients depend upon complex correlations assessed over prescribed times. This, in turn, relies upon the generation of predictive models from a comparison of an individual patient's signs and symptoms against a database of studied human wellness parameters, which contain patterns of diagnosis, chosen treatment, and outcome. These efforts are far from trivial.

A. Patient Diagnosis

As applied to medical technology, the *Bilski* machine-or-transformation revision to Section 101 essentially precludes the patenting of patient diagnosis. Under the *Bilski* test, a method of diagnosis unaccompanied by a medical device or treatment step would be patent ineligible. However, the development of a diagnostic test almost always precedes the ability to treat the disease and is often a distinct research enterprise separated by years, if not decades.

Indeed, the Patent Office has begun to require patent applicants for medical diagnostics inventions, who seek to overcome rejections under Section 101 in the wake of *Bilski*, to recite treatment steps. And moreover, the Patent Office has been inconsistent in administering whether the additional recitation of treatment steps will suffice. In any event, this misapprehends the nature of medical diagnostics development, with the effect being an increasing use of Section 101 ineligibility as a dispositive ground for denial of patent grant.

The criticality to the health care system of achieving diagnostic correlation for predictive patient modeling notwithstanding, this type of correlation is what serves as the foundation for further research and development. Without the incentive to find such correlations due to the absence of patent exclusivity,

many avenues of medical treatment may remain underdeveloped or altogether unexplored.

The patent claims to diagnostic methodologies, which have been patentable under Section 101 because they yield a useful, concrete, and tangible result, would fail under the *Bilski* machine-or-transformation test. There is no preemption of a fundamental principle when a correlation is of defined scope, typically associated with a particular condition or disease state. For example, imagine a method of determining the risk of Sudden Cardiac Death (SCD) involving the identification of one or more single nucleotide polymorphisms in a patient. This insight could enable a health care provider to take active measures to successfully prevent or treat a life threatening condition before the occurrence of any adverse event.

Consider also the ability to treat children born with a pulmonary artery malfunction using a method of intelligent scheduling of required multiple surgeries as the children grow. This protocol would ensure that the necessary sizes and types of implantable medical devices are provided at the exact times needed to minimize the number of dangerous, painful, and sometimes disfiguring procedures.

But patent claims to such innovations may be susceptible to *Bilski* patent ineligibility although they do not preempt a fundamental principle or

equate with an insignificant extra-solution activity. To the contrary, these inventions improve the quality of health care delivered and patient outcomes through earlier diagnosis, less invasive treatment options, and reductions in hospital stays and rehabilitation times. These important medical innovations would be undermined if this Court were to uphold the *Bilski* machine-or-transformation test.

B. Monitoring and Medical Data Management

The dependable and accurate relay of patient data is an essential component of life saving treatment. There are numerous applications for patient data management that span the spectrum of chronic to acute care. In one instance, a methodology has been developed to communicate information of the physiological state of a patient who has experienced an emergency medical event to a patient treatment center to enable the receiving facility to prepare for the patient's arrival. One application of this methodology could be routing event data from a field device, such as an external defibrillator, to a computer server for information distribution throughout various hospital displays.

Another patient data management system transfers cardiac information to assist doctors in making a decision on whether to bring the patient to a clinic or otherwise monitor long term trends, therapy, and cardiac events. Specifically, the system is a patient

management tool that builds upon ideas relating to continuous monitoring of physiological variances or indicators, which are used to monitor a cardiac patient remotely and tailor therapy and health care as appropriate. Thus, the system is dependent upon correlations, extrapolations, and deductions based on the detection or monitoring of natural phenomena. In most of these types of patient management systems, the process of diagnosis, monitoring, or even therapy delivery may not be tied to a machine or apparatus or transform a particular article into a different state or matter. Generally, the major aspect of the operation may be comparative, correlative, iterative, and deductive, rather than transformative.

Although certain embodiments of this technology can be captured through patent claims that include specific device elements (and thus pass muster under the *Bilski* machine-or-transformation test), if patent protection to the methodology itself were unavailable, the initial concept may not have resulted in further development to achieve actual application. The business of innovation often depends on the initial formulation of a system that only later finds integration with real world devices. To deny patent eligibility for such methodologies would impede this innovation.

C. Personalized Medicine

The field of personalized medicine and pharmacogenomics is rapidly gaining traction in the medical technology space. The ability to correlate a patient's genomic profile and gene expression with drug adverse event data can enable health care providers to maximize the probability of a desired treatment outcome and minimize the risk of harmful side effects. The recognition and understanding of the relationships between certain genetic mutations and the occurrence of common diseases to develop treatments tailored to an individual patient is the exciting potential this medical technology presents. However, the labor and cost intensity of these correlations are discouraging without the incentive of patent exclusivity.

As an example, the identification of genetic markers arguably would suffer inactivity or delay due to concerns over collaboration, material transfer, and licensing, in the absence of the defined intellectual property rights that patents provide. The *Bilski* machine-or-transformation test, if upheld as the sole test for patent eligibility under Section 101 as espoused by the Court of Appeals, would not easily resolve questions about personalized medicine inventions where a machine element or transformation event seems inapposite. Like the jurisprudence relating to the patent law doctrine of equivalents, where this Court recognized that the

function-way-result test might be inapplicable to certain technologies, the *Bilski* standard is similarly unaccommodating to certain technologies that exist today as well as those yet to come.

III. Section 101 Should Be Inclusive, Rather Than Exclusive.

Section 101 is the principal invitation of the patent laws to would-be innovators everywhere to bring forward the products of their inventive efforts. Using Section 101 in a gate keeping role projects a disenfranchising image of a system established, in the words of President Abraham Lincoln, to add "the fuel of interest to the fire of genius." Without the continued openness of Section 101, this essential combustion that drives the engine of innovation may become a thing of the past. With public health priorities already taking center stage, we cannot afford to deny the promise of medical advances that have yet to be seen by restricting patent eligible subject matter under a machine-or-transformation test.

Unlike the other conditions for patentability set forth under the patent statutes, namely novelty and nonobviousness, Section 101 of Title 35 governs patent eligible subject matter and utility, both of which do not require a comparative assessment of the claimed invention against the prior art. Without such a measure, Section 101 is ill suited to execute a

gate keeper function because it is relatively insensitive to the pace of innovation in a specific art. Rather, Section 101 looks more holistically to progress in the useful arts and best fulfills a role as a static prescription, which embraces existing technology, and more importantly, encourages the ingenuity of technology yet to come. Accordingly, attempting to refine Section 101 to strike a normative balance today merely defers the debate until a new technology of concern arrives. But the true detriment of revising the patent eligibility standard now would be the incalculable lost opportunity from potential innovators discouraged from invention and public disclosure.

Advances in medical technology would not be immune from the effect of the machine-or-transformation requirement set forth in *Bilski*. Medical technology encompasses numerous products and processes, including medical devices and supporting software. Indeed, there are many aspects of medical technology that would pass muster nonetheless under the *Bilski* revision to patent eligibility, but significant other aspects remain that would be impeded. And even in those instances where a device component or transformation step may be incorporated into a patent claim, the patentee may still suffer a reduced scope of rights due to a greater likelihood of competitive design around.

Medical technology can also involve the evaluation, diagnosis, and treatment of patients. By way of example, a method of patient assessment can relate to predictive modeling by comparing the patient's signs and symptoms to a database of other patient information to obtain the likelihood of a particular condition and/or likely success of certain therapy if applied to that patient. This medical treatment, whether or not implemented through a general purpose computer, yields a "useful, concrete and tangible result." *See State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1373 (Fed. Cir. 1998) (citing *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994) (en banc)).

To be certain, such methodologies do not constitute "laws of nature, natural phenomena, [or] abstract ideas," *see Diamond v. Diehr*, 450 U.S. 175, 185 (1981) (citing *Parker v. Flook*, 437 U.S. 584, 589 (1978), and *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)), and thus, in the Court of Appeals' parlance in *Bilski*, are not fundamental principles. Nor are they prohibited mental steps. *See Benson*, 409 U.S. at 67; *In re Comiskey*, 499 F.3d 1365, 1377 (Fed. Cir. 2007) (holding that "mental processes," "processes of human thinking," and "systems that depend for their operation on human intelligence alone" are not patent-eligible subject matter under *Benson*). However, under the machine-or-transformation requirement of *Bilski*, it is unclear whether the

Patent Office and the federal courts would deny patent protection on the grounds of ineligibility under 35 U.S.C. § 101. The experiences of *Amicus Curiae* in patent application examinations since *Bilski* suggest the Patent Office has increasingly relied on this ground of rejection.

IV. Section 101 Should Invite the Patenting of All Inventions that Result from Human Ingenuity and Manipulation.

As related to medical technology, the confusion *Bilski* creates has resurrected the concern contemplated by this Court briefly in *Lab. Corp. v. Metabolite*, 548 U.S. 124 (2006) ("*LabCorp*"), and has manifested in cases such as *Classen Immunotherapies, Inc. v. Biogen Idec*, 304 Fed. Appx. 866, 2008 WL 5273107 (Fed. Cir. 2008) (non-precedential), and *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 2008-1403 (Fed. Cir. 2009) (reviewing Civil No. 04cv1200 JAH (RBB), 2008 WL 878910, 86 U.S.P.Q.2d 1705 (S.D. Cal. Mar. 28, 2008)). Some have criticized patent claims to certain medical diagnosis, for example, on the basis that they seek patent coverage for the mere correlation of natural phenomena. What constitutes mere correlation is then a question open to reasonable dispute.

In *LabCorp*, this Court dismissed the writ of certiorari as improvidently granted. Justice Breyer,

joined by Justices Stevens and Souter, dissented from the order. The dissent argued that the Court should have taken the case in order to lend necessary clarity to an important issue in patent law. The patent claims at issue in *LabCorp* recited "correlating an elevated level of total homocysteine in [a sample of] body fluid with a deficiency of cobalamin or folate." In the dissenters' view, a natural correlation between two substances in the body is a "natural phenomenon" that cannot be patented. *LabCorp*, 548 U.S. at 135.

At least one member of the Court of Appeals has recognized the potential havoc that the application of the *Bilski* machine-or-transformation test may create with medical technology innovation. In dissent from the en banc opinion of the Court of Appeals, Judge Rader states:

> Before the invention featured in Lab Corp., medical science lacked an affordable, reliable, and fast means to detect this debilitating condition. Denial of patent protection for this innovation – precisely because of its elegance and simplicity (the chief aims of all good science) – would undermine and discourage future research for diagnostic tools. Put another way, does not Patent Law wish to encourage researchers to find simple blood tests or

> urine tests that predict and diagnose breast cancers or immunodeficiency diseases? In that context, this court might profitably ask whether its decisions incentivize research for cures and other important technical advances. Without such attention, this court inadvertently advises investors that they should divert their unprotectable investments away from discovery of "scientific relationships" within the body that diagnose breast cancer or Lou Gehrig's disease or Parkinson's or whatever.

In re Bilski, 545 F.3d 943, 1014 (Fed. Cir. 2008) (en banc) (Rader, J., dissenting). *Amicus Curiae* concurs with these policy sentiments.

Furthermore, while "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are . . . the basic tools of scientific and technological work," see *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)), that does not mean all methods, which originate from the invention or discovery of a natural correlation, are similarly patent ineligible. To hold otherwise would be a departure from the wisdom of *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980), that "anything under the sun that is made by man" is patent eligible under 35 U.S.C.§ 101, which

implicitly recognized that human intervention could take unpatentable subject matter into the realm of patentability. In particular, the mere correlation of natural phenomena mantra belies the reality that much more often than not, the diagnosis of a patient, and the subsequent treatment based on that diagnosis, are not the products of mere observation and simple correlation. In other words, although a correlation step may be at the heart of the claimed medical treatment, most procedures involve not only the sophisticated appreciation that a correlation may exist, but the studied determination to act based on a perceived significance of that correlation. But these complex methods may not necessarily involve a machine or transforming an article into a different state or thing.

In *Classen*, the Court of Appeals affirmed the district court's summary judgment that Dr. Classen's patent claims were invalid under 35 U.S.C. § 101 because the claims were neither tied to a particular machine or apparatus, nor did they transform a particular article into a different state or thing. The patent claim at issue involved a method of determining whether an immunization schedule affected the incidence or severity of a chronic immune-mediated disorder in a treatment group of mammals relative to a control group of mammals. The Court of Appeals offered no additional reasoning, its opinion being a

mere 69 words, twenty words shorter than the actual patent claim.

In *Prometheus*, the Court of Appeals is presently reviewing the district court's summary judgment that the claims of U.S. Patent No. 6,355,623 are invalid under 35 U.S.C. § 101. The patent claim at issue involved a method of optimizing therapeutic efficacy for treatment of an immune mediated gastrointestinal disorder by determining the level of 6-thioguanine. The district court analysis fell in lockstep with this Court's *LabCorp* dissent.

In any event, these cases reflect the tip of the iceberg of possible judicial controversy over the patentability of medical technology if the *Bilski* machine-or-transformation standard is upheld. Moreover, in a particularly crowded field of technology, such as medical technology, the uncertainty over entitlement to patent exclusivity can disqualify otherwise innovative methods and their associated products from access to commercial investment, market entry, and/or post-market entry sustainability.

V. A Machine-Or-Transformation Requirement Would Harm the Public by Deterring Prompt and Open Disclosure of Medical Breakthroughs and by Discouraging Investment in Medical Innovation.

The oft cited purpose of the patent laws is to promote the progress of the useful arts through the creation

of temporary exclusivity rights as an incentive for the prompt, public disclosure of inventions because the patent exclusivity facilitates innovative efforts and encourages investment in such endeavors. These principles apply with equal if not greater force in the medical technology industry sector, where commercial competition is intense. Beyond the known beneficial effects today of an enfranchising patent eligibility standard under Section 101, perhaps a more essential consideration is the maintenance of a Section 101 test that will continue the promise of patent protection for innovations to come.

The Court of Appeals decision in *Bilski* opens the door to the use of Section 101 as an instrument for determining precisely what innovation will be acceptable. In *Chakrabarty*, this Court took the wise approach of interpreting Section 101 as broadly inclusive in favor of allowing the other statutory conditions for patentability to more finely monitor what inventions may be patented vis-à-vis the prior art. A Section 101 that embraces inclusiveness ensures continuing innovation in new as well as old fields of technology. Tinkering with Section 101 in hopes of crafting a standard generally applicable to past, present, and future technologies, however well intentioned, may bring unforeseeable consequences, including the unfortunate chilling of future innovation.

CONCLUSION

For the foregoing reasons, *Amicus Curiae* respectfully submits that the *Bilski* machine-or-transformation test has far reaching consequences for enterprises outside the financial services and computer software industry sectors that are critical to this country's public health goals and economic well being. Indeed, for companies, like *Amicus Curiae*, focused on medical technology innovation, the prospect of a revised patent eligibility standard that is less inclusive presents the grave concern that the development of critical lifesaving medical technology will be impeded.

Respectfully submitted,

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