No. 08-964

IN THE

Supreme Court of the United States

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

v.

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

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

BRIEF OF *AMICUS CURIAE* MEDISTEM INC. IN SUPPORT OF THE PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE* [1]

Amici curiae, Medistem Inc., respectfully submits this brief in support of petitioners, Bernard L. Bilski

[1] Counsel for both parties have consented to the filing of this brief. Petitioner has filed a written consent for all amicus curiae briefs in support of either or neither party. Respondent's letter giving its written consent for Medistem Inc. to file this brief is on file with the Court. Counsel of record for all parties received notice at least 10 days prior to the due date of the amicus curiae's intention to file this brief. No counsel for any party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person or entity, other than *amicus curiae*, its members, or its counsel, made a monetary contribution to its preparation or submission.

and Rand A. Warsaw, urging the grant of the petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (*en banc*). Specifically, Medistem urges the Court to grant the petition and address the first question presented in the petition: Did the Federal Circuit err in holding that, to be eligible for a patent, a "process" *must* be tied to a particular machine or transform a particular article into a different state or thing?

An innovative biotechnology company, Medistem dedicates its business pursuits to research and development of regenerative medicine products in the area of adult stem cells. Through licensees/collaborators, the company has clinically implemented numerous stem cell therapies for treating debilitating conditions ranging from peripheral artery diseases, to autoimmune conditions, to neurodegenerative states. Medistem's platform technology, a novel stem cell type termed the "endometrial regenerative cell," falls under conventional patentable subject matter. The company also has many pending patent applications seeking to protect new methods it has developed to diagnose causes of diseases and methods to use stem cells in effectively treating those diseases and other medical maladies.

Entering into a new and previously unimaginable era of biotechnology, Medistem works on discoveries associated with predictive tests based on an individual's own genetic make-up, physical changes during development, and condition of disease. Previously, drug development focused on a "one size fits all" approach due, in large part, to technology's inability to rapidly screen patients for specific inter-human variability. With the tremendous knowledge

gained from the human genome project, and the geometrical rise in methods of detecting genes, gene expression, proteins, and small molecules, technology has given the field new ways of understanding a patient's unique medical "fingerprint." With this knowledge, biotech companies, such as Medistem, are developing new methods of diagnosing causes of illnesses and effecting treatment on an individualized patient basis.

Like many biotech companies, Medistem relies on the ability to obtain enforceable patent protection for the results of its research and development efforts. Having patent protection allows Medistem to obtain investment capital to fund its research and development efforts. The Federal Circuit's limiting the scope of patentable subject matter for "process" inventions in *Bilski* casts a cloud of uncertainty as to whether Medistem and other biotech companies can continue to protect with patents their inventions relating to methods of diagnosing causes of diseases and methods of selecting beneficial treatment protocols. Medistem fears that should biotech companies lose the ability to obtain enforceable patent protection on diagnostic and treatment methods, the ability to attract investment capital will sharply decline, and as a direct result the incentive to search for better ways to diagnose causes of diseases and find more effective treatments will decline. Medistem is not alone in its view. Addressing this issue in his dissent from the *en banc* court's opinion, Circuit Judge Rader cogently noted that excluding patent protection for methods of using discovered biological or physiological correlations will "undermine and discourage future research for diagnostic tools." *Bilski,* 545 F.3d at 1014. The advances in the diagnostic arts noted above and the industry's reliance on the patent

system's economic incentives to fund the efforts to make these advances show that Judge Rader's concerns should not be taken lightly.

The question of whether potentially life-saving diagnostic methods or treatments should be ineligible for patent protection if they are not tied to a particular machine or apparatus, or do not transform a particular article into a different state or thing, has great importance to our citizens. Medistem fears that due to its *en banc* status, the Federal Circuit's pronouncement in *Bilski* will be the *de facto* final word on the standard for determining the scope of patent eligible subject matter for all processes. This appears untenable in view of Circuit Judge Newman's detailed analysis of how the *Bilski* majority's new standard adopts a narrow view of patent eligibility for process inventions previously rejected by this Court. *See Bilski*, 545 F.3d at 978-85 (Newman, J., *dissenting*). Consequently, this Court's intervention is needed to correct the overly restrictive test the Federal Circuit adopted to solve the problem of identifying when a patent claims something that is a law of nature, and therefore unpatentable, compared to when it claims "a product of human ingenuity" that is eligible for patent protection. *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

REASONS FOR GRANTING THE PETITION

I. BECAUSE *BILSKI*'S "MACHINE OR TRANSFORMATION" TEST AFFECTS THE SCOPE OF PATENT ELIGIBILITY FOR *ALL* PROCESS-RELATED INVENTIONS, IT RAISES A QUESTION OF FUNDAMENTAL IMPORTANCE TO THE PATENT SYSTEM.

As Petitioners correctly state, the scope of subject matter eligible for patent protection presents the most "fundamental question" of patent law. Accordingly, any judicial rule impacting what an inventor can patent has significant importance to the patent system at the system's most rudimentary level.

Although the patent at issue in *Bilski* claimed a business method, the Federal Circuit did not confine its adoption of the "machine-or-transformation" test to business methods. Instead, the court more broadly considered "what test or set of criteria governs the determination by the Patent and Trademark Office ('PTO') or courts as to whether *a claim to a process* is patentable under § 101 or, conversely, is drawn to unpatentable subject matter because it claims only a fundamental principle." 545 F.3d at 952 (emphasis added). It answered that question by holding that "the machine-or-transformation test is the *only* applicable test and *must* be applied . . . when evaluating the patent-eligibility of process claims." *Id*. at 964 (emphasis added). Thus, its ruling appears to apply to all process claims of all issued patents and all pending patent applications.

The policy decision made by the Federal Circuit narrows the scope of subject matter eligible for patent protection for the entire category of "process"

patents including patents relating to biotechnology. Narrowing the scope of patentable subject matter forces innovators to use other means of protecting their inventions, such as maintaining the invention as a trade secret. While trade secret protection provides some measure of value to society, *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 493 (1974), it does not achieve the full, prompt and wide-spread public disclosure of the invention that the patent system provides. *See* 35 U.S.C. §§ 112 (invention disclosure requirements); 122(b) (patent applications published 18 months after filing), and 153 (issued patents recorded in the PTO). By definition a trade secret keeps the invention secret. It retards innovation since knowledge of the invention, how to make it, and how to use it, remains suppressed and concealed. In contrast, the disclosure of an invention as part of obtaining a patent gives the public full knowledge of the invention, and thereby allows other innovators to improve upon the invention. *See Bonito Boats*, *Inc. v. Thunder Craft Boats*, *Inc.*, 489 U.S. 141, 146 (1989) ("[T]he 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."). Further, patent law provides a more powerful enforcement right than trade secret law. *Kewanee Oil*, 416 U.S. at 489-90 (noting that trade secret law provides "far weaker protection" than patent law, and where "patent law acts as a barrier, trade secret law functions relatively as a sieve."). This allows companies and investors in companies to justify significant financial investment to develop new patentable technology since they can expect they will have the ability to protect the developed technology

and later reap rewards in the market.[2] A judicial narrowing of the scope of patent eligible subject matter will likely have significant adverse impact in the amount of economic investment made to support developing new technologies, and correspondingly a reduction in the amount of innovation, as investors will choose to invest elsewhere. Echoing this conclusion, Circuit Judge Rader stated his view that the majority's ruling in *Bilski* "inadvertently advises investors that they should divert their unprotectable investments away from the discovery of 'scientific relationships' within the body that diagnose breast cancer or Lou Gehrig's disease or Parkinson's or whatever." *Bilski,* 545 F.3d at 1014 (Rader, J., *dissenting*).

II. AS THE EXCLUSIVE TEST FOR DETERMINING PATENT ELIGIBILITY, BILSKI'S "MACHINE-OR-TRANSFORMATION" TEST CONFLICTS WITH THIS COURT'S PRECEDENTS AND FAILS TO REALIZE CONGRESS'S INTENT

Rejecting an argument that only processes involving "chemical action" were patent eligible, and therefore methods effected by "mere mechanical combinations" were ineligible for patent protection, this Court explained that "it is not the province of the courts to so limit the statute as to deprive meritorious inventors of its benefits." *Expanded*

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[2] A recent report on venture capital investment, shows that in the fourth quarter of 2008 the biotech industry obtained approximately 19% of all venture capital invested during that time among seventeen different industries. *See* PriceWaterHouseCoopers, *MoneyTree Report*, available at https://www.pwcmoneytree.com.

Metal Co. v. Bradford, 214 U.S. 366, 382 (1909). Instead, "[a]n examination of the extent of the right to process patents requires consideration of the object and purpose of the Congress in exercising the constitutional power to protect, for a limited period, meritorious inventions or discoveries." *Id.*

The Federal Circuit majority's ruling that "the machine-or-transformation test is the only applicable test and must be applied . . . when evaluating the patent-eligibility of process claims," *Bilski*, 545 F.3d at 964, fails this directive. The narrow and rigid definition of patent-eligible processes alarmingly threatens to exclude potentially life-saving diagnostic and treatment inventions from patent-eligible subject matter. *See e.g.*, U.S. Patent No. 7,348,149 (methods of diagnosing Parkinson's disease); U.S. Patent Nos. 6,355,623 and 6,680,302 (methods of treating IBD/Crohn's disease).[3] The Federal Circuit has already summarily applied *Bilski* in a two sentence opinion to affirm a summary judgment holding claims to an immunization schedule invalid under 35 U.S.C. § 101. *E.g.*, *Classen Immunotherapies, Inc. v. Biogen IDEC*, No. 2006-1634, -1649, 2008 WL 5273107, *1 (Fed. Cir. Dec. 19, 2008) (*nonprecedential*), *en banc reh'g denied* (Fed. 9, 2009), *aff'g,* No. WDQ-04-2607, 2006 WL 6161856, *5 (D. Md. Aug. 16, 2006).

Like the rejected contention in *Expanded Metal*, *Bilski*'s exclusive "machine-or-transformation" test (with its gloss of discounting the presence of

[3] These two patents are the subject of *Prometheus Labs., Inc. v. Mayo Collaborative Serv.*, an appeal that the Federal Circuit stayed while deciding *Bilski*. No. 2008-1403 (Fed. Cir. July 29, 2008), *underlying decision*, 04cv1200 JAH (RBB), 2008 WL 878910 (S.D. Cal. Mar. 28, 2008).

"insignificant extra-solution activity" performed by machines, 545 F.3d at 957 n.14) has the capacity to exclude from patent protection a whole category of inventions without properly accounting for Congress's stated intent to permit patent eligibility for "anything under the sun that is made by man." *Chakrabarty*, 447 U.S.at 309. *See also J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.,* 534 U.S. 124, 135 (2001) (§ 101 is "a dynamic provision designed to encompass new and unforeseen inventions."). The test also appears directly contrary to the guidance this Court gave in *Gottschalk v. Benson*:

> 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 that no process patent could ever qualify if it did not meet the requirements of our prior precedents.

409 U.S. 63, 71 (1972). *Accord Bilski*, 545 F.3d at 978-85 (Newman, J., *dissenting*) (detailing why the *Bilski* "machine-or-transformation" test conflicts with Supreme Court precedent).

When this Court held product claims to an aggregation of several types of naturally occurring bacteria unpatentable as claiming something that lacked "invention," in *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* it left open "the question whether the *methods* of selecting and testing the non-inhibitive strains are patentable." *Id.* 333 U.S. 127, 130 (1948) (emphasis added). Methods of "selecting" biological materials to use in treatment protocols to effect a therapy are often products of human ingenuity. They *apply* principles of nature. Although such a method may not be tied to a particular machine or apparatus, and may not transform an article from one state to

another, it can be a "new and useful process" under 35 U.S.C. § 101. *See Bilski,* 545 F.3d at 1014 (Rader, J., *dissenting*) (noting that a method that applies a discovered biological relationship in a diagnostic test for potentially fatal conditions in patients is a human invention that produces a useful, tangible, and concrete result).

This Court has consistently recognized that an "application of the law of nature to a new and useful end," falls within the scope of patentable subject matter. *Funk Bros.*, 33 U.S. at 130. *Accord Diamond v. Diehr*, 450 U.S. 175, 187 & n.11 (1981) (noting that "the same principle applies to a process claim"); *Parker v. Flook*, 437 U.S. 584, 594 (1978) ("Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application."). Based on a quasi-bright[4] line rule on whether a process is "tied" to a machine or "transforms" matter, *Bilski*'s exclusive "machine-or-transformation" test threatens to exclude process inventions from patent eligibility that apply, but do not claim, laws of nature without permitting the invention to be considered on its individual merits for whether it meets the statutory requirement of being a "new and useful process."

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[4] Circuit Judges Rader, Newman and Mayer each noted in their separate dissents, that aspects of the majority's "machine-or-transformation" test raise questions on how to apply the test in practice. 545 F.3d at 994-95 (Newman, J. *dissenting*); 545 F.3d at 1010 (Mayer, J. *dissenting*); 545 F.3d at 1015 (Rader, J. *dissenting*).

Our patent system exists "to encourage innovation and its fruits: new jobs and new industries, new consumer goods and trade benefits." *Paulik v. Rizkalla,* 760 F.2d 1270, 1276 (Fed. Cir. 1985) (*en banc*). If unchecked, *Bilski*'s test has the potential of creating a disincentive to innovate in the biotechnology industry, and particularly in the area of diagnostic and treatment methods, and the emerging field of "personalized medicine." This runs counter to the accepted view that: "A strong intellectual property system is necessary to stimulate investment in innovation. It is essential that government patent systems offer protection for innovations relating to personalized medicine, as well as high quality patent examination that allows patents of appropriate scope and quality."[5]

III. WITHOUT THIS COURT'S REVIEW, *BILSKI*'S "MACHINE-OR-TRANSFORMATION" TEST WILL BE THE LAW OF THE LAND

Since *Bilski* is an *en banc* opinion, all subsequent three-judge panels of the Federal Circuit must follow it.[6] *Kingsdown Med. Consultants*, *Ltd. v. Hollister*

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[5] Public policy statement on intellectual property of the Personalized Medicine Coalition (PMC), available at http://www.personalizedmedicinecoalition.org/sciencepolicy/public-policy_intellectual-property.php. The PMC describes itself as a non-profit group that works to advance the understanding and adoption of personalized medicine for the ultimate benefit of patients. Its members and partners include a wide range of federal government agencies, academic institutions, trade associations, large and small companies, venture capital firms, health insurance companies, and strategic partners. http://www.personalizedmedicinecoalition.org/about/pmc_memb-ers.php.

[6] The Federal Circuit has exclusive jurisdiction over practically all appeals from the district courts where the action arose

Inc., 863 F.2d 867, 876, n.16 (Fed. Cir. 1988) (*en banc*) ("precedent may not be changed by a panel"). Only this Court, an Act of Congress, or a subsequent *en banc* panel of the Federal Circuit can alter the ruling. *See South Corp. v. United States*, 690 F.2d 1368, 1370 n.2 (Fed. Cir. 1982) (*en banc*). Consequently, while future court opinions may have latitude to further refine the "machine-or-transformation" test, absent action by this Court, Congress, or a subsequent *en banc* panel of the Federal Circuit,[7] no district court, three-judge panel of the Federal Circuit, or the PTO can refuse to apply the "machine-or-transformation" test as the *exclusive* test for assessing patent eligibility for process inventions. Nothing is left to percolate up from within the Federal Circuit on whether new and useful processes created by human ingenuity should merit patent protection if they don't meet the "machine-or-transformation" test.

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under the Patent Act. 28 U.S.C. § 1295(a)(1). *But cf. Holmes Gp., Inc. v. Vorando Air Circulation Sys., Inc.*, 535 U.S. 826 (2002). It also has exclusive jurisdiction for all appeals from the PTO's Board of Patent Appeals and Interferences. 28 U.S.C. § 1295(a)(4)(A).

[7] The Federal Circuit's last *en banc* consideration of patent eligible subject matter came fifteen years ago in *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) (*en banc*).

CONCLUSION

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

Respectfully submitted,

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