#### INTHE

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

## BRIEF OF AMICUS CURIAE BOSTON PATENT LAW ASSOCIATION IN SUPPORT OF PETITIONERS

Steven J. Henry Robert M. Abrahamsen Wolf, Greenfield and Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210 (617) 646-8000 Joel R. Leeman

Counsel of Record

John J. Stickevers

Jakub M. Michna

Bromberg and Sunstein LLP

125 Summer Street

Boston, MA 02110-1618

(617) 443-9292

Attorneys for Amicus Curiae Boston Patent Law Association

221344



## TABLE OF CONTENTS

			Page
INTE	RES	ST OF AMICUS CURIAE	1
SUMN	/IAR	Y OF THE ARGUMENT	2
ARGU	JME	NT	
I.	Circ	y and Precedent Forbid the Federal cuit's Exclusion of Certain Methods Processes from Patent Protection	3
	A.	This Court Has Historically Accommodated New Technologies by Broadly Interpreting Section 101 of the Patent Act	3
	В.	The Machine-or-Transformation Requirement Conflicts With This Court's Precedent	6
	С.	The Federal Circuit's New Test Undermines the Broad Purpose of Section 101	11
II.	Call	Machine-or-Transformation Test s the Patentability of Many Landmark entions Into Question	13
III.	Elig	Lower Court's Formula for Patent gibility Creates Uncertainty That Will se Lasting Harm to Innovation	20
CONC	LUS	SION	25

## TABLE OF CITED AUTHORITIES

Page
Cases
Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83 (1993)
Comm'r of Internal Revenue v. Asphalt Products Co., Inc., 482 U.S. 117 (1987) 13
Diamond v. Chakrabarty, 447 U.S. 303 (1980)
Diamond v. Diehr, 450 U.S. 175 (1981) 5, 8, 9, 10
Ex parte Bo Li, No. 2008-1213, 2008 WL 4828137 (B.P.A.I. November 6, 2008) 23
Ex parte Cornea-Hasegan, No. 2008-4742, 2009 WL 86725 (B.P.A.I. January 13, 2009) 23
Ex parte Gutta, No. 2008-3000, 2009 WL 112393 (B.P.A.I. Jan. 15, 2009)
Gottschalk v. Benson, 409 U.S. 63 (1972) passim
<i>In re Alappat</i> , 33 F.3d 1526 (Fed. Cir. 1994) 23-24
<i>In re Bilski</i> , 545 F.3d 943 (Fed. Cir. 2008) <i>passim</i>
In re Nuijten, 500 F.3d 1346 (Fed. Cir. 2007) 15, 17

## Cited Authorities

	Page
KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727 (2007)	11
Parker v. Flook, 437 U.S. 584 (1978)	7, 8
Picard v. United Aircraft Corp., 128 F.2d 632 (2d Cir. 1942)	21
U.S. v. Line Materials Co., 333 U.S. 287 (1948)	20
Statutes	
35 U.S.C. § 101	issim
35 U.S.C. § 102	11
35 U.S.C. § 103	11
35 U.S.C. § 112	11
35 U.S.C. § 273	5

## Cited Authorities

	Page
Legislative Materials	
American Inventors Protection Act of 1999, S. 1798, Cong. 106th (1999)	5
Other Authorities	
Invent.org, Hall of Fame, Maurice Ralph Hilleman, http://www.invent.org/hall_of_fame/339.html (last visited Feb, 24, 2009)	
Ronald J. Mann, <i>The Role Of Patents In Venture-Backed Software Start-Ups</i> , Acad. Advisory Council Bulletin 2.1 (The Progress & Freedom Foundation, Washington D.C.) Apr. 2007, available at http://www.pff.org/issues-pubs/ip/bulletins/bulletin2.1software venturepatents.pdf.	20, 21
Manual of Patent Examining Procedure \$\ 2106, 2106.01 (8th ed. 2008, rev. 7)	24

#### INTEREST OF AMICUS CURIAE<sup>1</sup>

The Boston Patent Law Association (BPLA) is an eighty-five year old association of over seven hundred intellectual property professionals (lawyers, patent agents, and paralegals) practicing within the First Circuit. The BPLA provides educational programs and a forum for the interchange of ideas and information concerning patent, trademark, copyright, and other intellectual property rights. The Association's members serve a broad range of parties who rely upon the patent system: independent inventors, businesses of all sizes, the investment banking and venture capital communities, universities, research hospitals and other non-profit institutions.

The BPLA desires a reliable patent system that fulfills its Constitutional role of promoting the progress of the useful arts. It views the decision below as a threat to that role, because it injects instability into the system and quashes critical incentives for innovation, to the detriment of the American economy.

The BPLA takes no position on the eligibility of Petitioners' claimed invention for a patent. Rather, the petition should be granted so this Court can address

<sup>1.</sup> No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission. Petitioners and respondent have indicated their consent to the filing of this brief by, respectively, filing a letter with the Clerk of the Court and serving a letter on amicus's counsel. The respondent's letter is submitted herewith. All counsel of record received notice of amicus's intention to file this brief at least ten days before it was due.

the important question of law it raises and, in doing so, restore a proper rule of patent-eligibility against which Petitioners' invention, and other method inventions, can be fairly measured.

#### SUMMARY OF THE ARGUMENT

The machine-or-transformation requirement that the Federal Circuit has newly imposed on method claims sharply disrupts the well-founded expectations of inventors, practitioners, investors, and—not least of all—of this Court, as to the broad statutory eligibility for patent protection of "any new and useful process." Even as the Federal Circuit professes to discern the origin of its restrictive test in a too-close reading of this Court's precedent, that same precedent explicitly forswears such a test.

Congress enacted an inclusive test for patent eligibility, recognizing that paradigm-changing inventions come in unpredictable forms and often push existing frontiers. This Court has made similar observations. The Federal Circuit, however, subverts the broad legislative purpose with a restrictive test that will inevitably block valuable inventions.

Indeed, it is plain that many celebrated innovations of the past that truly reshaped our world would have been denied full patent protection under the machine-or-transformation test. Where the invention is embodied as a method or a process, an apparatus or system claim does not provide adequate protection. The danger of the lower court's pronouncement is that method inventions of equal scientific and creative eminence, that

may be claimed in pending and future applications, will be rejected for form, rather than substance. As patents are essential to attract investments in great ideas, an improperly narrow test will impair the commercialization of inventions, causing harm to the economy and constraining the introduction of useful products and services to the public.

The Court should grant certiorari and restore the broad eligibility for patent protection that Congress intended for innovative methods and processes.

#### **ARGUMENT**

- I. Law and Precedent Forbid the Federal Circuit's Exclusion of Certain Methods and Processes from Patent Protection
  - A. This Court Has Historically Accommodated New Technologies by Broadly Interpreting Section 101 of the Patent Act

In the eighteenth century, the cutting edge of technology included plows, sextants, and smelting processes, that is, the machines and arts needed for what was largely an agricultural and seafaring nation still on the verge of the Industrial Revolution. In that era, it would have been harmless to confine eligible subject matter to machinery or industrial processes, because innovation was limited to physical building blocks such as iron and steel, springs and gears, and steam and water power. Electricity was not yet harnessed, and the microscope had as yet yielded relatively little.

But in the nineteenth century, new inventions progressed from the seen to the unseen – from the transmission of electrical signals over a distance (Morse's telegraph, Patent No. 1,647 and Bell's telephone, Patent No. 174,465), to incandescence (Edison's light bulb, Patent No. 223,898).

A narrow definition of eligible subject matter, limited to physical machines or industrial processes, would have blocked these landmark inventions from a full measure of patentability. Without the incentives created by our patent system, these world-altering innovations may never have come to be, let alone entered the public domain when the limited term of their patents expired. Crucially, this Court accommodated this new wave of technology by endorsing a broad rule for subject matter eligibility.

Section 101 of the Patent Act of 1952 defines the scope of eligible subject matter. *Any useful* process or thing may be eligible for patent protection:

Whoever invents or discovers *any* new and *useful* process, machine, manufacture, or composition of matter, or *any* new and *useful* improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101 (emphasis added). This Court has interpreted this provision broadly to fulfill the legislative mandate. *Diamond v. Chakrabarty*, 447 U.S. 303, 308-309 (1980) (noting that "Congress plainly contemplated that the patent laws would be given wide scope," and

that "Congress intended statutory subject matter to 'include anything under the sun that is made by man"").<sup>2</sup>

This Court has also recognized that the legislature intended a broad rule for patent eligibility because valuable inventions are often unforeseeable – and a broad rule provides protection for such unforeseeable inventions. *Chakrabarty*, 447 U.S. at 316 ("A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability.").

This broad statutory language is subject to only a few judicially created exclusions. Laws of nature, natural phenomena, and abstract ideas are not patent-eligible, as a matter of public policy. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981) ("Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none."). These are the only exclusions enunciated by this Court. Outside of these three exclusions, any useful process or thing is eligible for patent protection, provided it satisfies other statutory requirements (e.g., novelty, non-obviousness, definiteness).

<sup>2.</sup> As recently as the American Inventors Protection Act of 1999, Congress had an opportunity to limit the scope of eligible subject matter—in this instance, by excluding business method inventions from protection. Instead of doing so, Congress implicitly approved of broad subject matter eligibility by leaving Section 101 unchanged; Congress merely amended Section 273 to include an "earlier inventor" defense for parties alleged to infringe methods "of doing or conducting business." American Inventors Protection Act of 1999, S. 1798, Cong. 106th (1999) (as introduced to the Senate, Oct. 27, 1999) (codified at 35 U.S.C. § 273(b)(1)).

### B. The Machine-or-Transformation Requirement Conflicts With This Court's Precedent

Although this Court—in harmony Congressional legislation—has consistently endorsed a broad rule for patent eligibility, the Federal Circuit has now turned Section 101 on its head. In re Bilski enunciates a radically narrow standard for subject matter eligibility, 545 F.3d 943 (Fed. Cir. 2008) (en banc), based on a misreading of this Court's jurisprudence. As the Federal Circuit would have it, process claims must either be "tied to a particular machine or apparatus" or "transform a particular article into a different state or thing." Id. at 954. The court emphasizes that its new "machine-or-transformation test" is now the "governing test" for eligibility of process claims. Id. at 956. If a process claim does not meet one of these two prongs, it is not eligible for patent protection.

Yet, this Court has consistently stated that physical transformation and connection to a machine are not requirements for the patent eligibility of processes. In *Gottschalk v. Benson*, for example, this Court explicitly addressed these restrictions:

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. It is said that the decision precludes a patent for any program servicing a computer. We do not so hold.

It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. *Such is not our purpose*.

409 U.S. 63, 71 (1972) (emphasis added). This Court reinforced this viewpoint in  $Parker\ v.\ Flook$ , the second modern case on eligibility of process claims:

An argument can be made, however, that this Court has only recognized a process as within the statutory definition when it either was tied to a particular apparatus or operated to change materials to a "different state or thing." As in Benson, we assume that a valid process patent may issue even if it does not meet one of these qualifications of our earlier precedents.

437 U.S. 584, 589, n.9 (1978) (citations omitted and emphasis added). Thus, the Federal Circuit's new standard, which requires that a process either be tied to a machine or transform an article, contravenes the guidance of this Court.

The Federal Circuit concedes that its machine-ortransformation test is not prefigured by this Court's pronouncements in *Benson* and *Flook*: "We recognize, however, that the [Supreme] Court was initially equivocal in first putting forward this [machine-ortransformation] test." *Bilski*, 545 F.3d at 956. This gentle acknowledgment, however, does not go far enough, and it revises history. This Court did not "put forward" such a test, much less do so in an "equivocal" fashion.

*Id.* at 979 (Newman, J., dissenting) ("Although my colleagues now describe these statements [in *Benson* and *Flook*] as 'equivocal,' there is nothing equivocal about 'We do not so hold."").

The Federal Circuit infers Supreme Court approbation for the machine-or-transformation test from this Court's purported silence in its latest case on process eligibility. Specifically, the lower court reads much into the fact that the *Diamond v. Diehr* opinion did not reiterate *Benson* and *Flook*'s reservations about a restrictive test of patent eligibility: "[T]his caveat was not repeated in *Diehr* when the [Supreme] Court reaffirmed the machine-or-transformation test." *Id.* at 956 (emphasis in original).

The Federal Circuit's reasoning begs the question of whether this Court ever affirmed the machine-ortransformation test in the first place, let alone "reaffirmed" it. The answer to this question is an emphatic no. In Benson and Flook, this Court explicitly disapproved the machine-or-transformation test. This Court's act of not repeating itself in Diehr does not indicate a warming toward a test that was previously viewed as too rigid to accommodate inventions entitled to protection.

Instead of following the plain import of *Flook* and *Benson*, the Federal Circuit focuses on a 28-word clause from the *Benson* case, which it claims as support for its machine-or-transformation test:

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.

409 U.S. at 70 (emphasis added). The Federal Circuit explains that the usage of the definite article indicates that transformation is the *only* clue to — that is, an essential requirement for — patentability of process claims not tied to machines:

We do not consider the word "clue" to indicate that the machine-or-implementation test is optional or merely advisory. Rather, the [Supreme] Court described it as *the* clue, not merely "a" clue.

Bilski, 545 F.3d at 956, n. 11. (emphasis in original).

This statement is the sole basis for the Federal Circuit's machine-or-transformation test. The irony of the Federal Circuit's analysis is that it derives support for the machine-or-transformation test from a labored reading of an excerpt from an opinion that, as shown above, expressly distances the Court from such narrow criteria for patent eligibility.

Moreover, the Diehr case itself does not support the machine-or-transformation test. The Federal Circuit reasons that Diehr "reaffirmed" the principle that transformation is the clue to patentability of a process claim that does not include particular machines. Id. at 956. But this interpretation is not supported by the facts and holding of Diehr.

In *Diehr*, this Court held that a particular process (for curing synthetic rubber) was eligible for patent protection. 450 U.S. at 187, 191. Where the ruling is expressly inclusionary—that is, it holds a process to be encompassed by Section 101—it is anomalous to discern an announcement by this Court of an exclusionary rule, namely, one that places certain processes *beyond* the ambit of Section 101. Also, since the patent claim in *Diehr* was in fact tied to machines, the case provided no suitable occasion to hold that transformation is a clue to patentability of a process claim that does *not* include particular machines.

The claim at issue required both a computer and a rubber-molding press, id. at 180, and this Court's holding did not therefore depend on transformation at all. In fact, when referring to transformation, the *Diehr* court preceded the phrase "transforming or reducing an article to a different state or thing" with an "e.g.," denoting that transformation is just one example, not an exclusive requirement of eligibility.<sup>3</sup>

The Federal Circuit has transformed this Court's insights and open-ended examples of eligible subject matter into an inflexible machine-or-transformation test. Manifestly, the Federal Circuit has misconstrued this Court's broad vision and guidance concerning patent eligibility.

<sup>3. &</sup>quot;[W]hen a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, 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." Diehr, 450 U.S. at 192.

This Court granted certiorari in 2006 to strike down an inflexible rule devised by the Federal Circuit for determining the obviousness of an invention under Section 103 of the Patent Act: "Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1742-43 (2007).

The Federal Circuit's newly created test in *Bilski* calls out for equally urgent attention, as it goes to a concern even more foundational to the patent system: Will the broad Congressional protection for "any new and useful process" be circumscribed in a manner that is at odds with this Court's pronouncements? The Boston Patent Law Association respectfully asks the Court to grant certiorari to restore a capacious and flexible approach to the eligibility requirement of Section 101.<sup>4</sup>

# C. The Federal Circuit's New Test Undermines the Broad Purpose of Section 101

The machine-or transformation test clashes with Section 101, with legislative intent, and with over a century of precedent and settled expectations. Congress created an inclusive rule for eligibility, subject to only three judicially created exclusions, *Chakrabarty*, 447 U.S. at 308-309, but in *Bilski*, the Federal Circuit excludes all processes unless they meet one of only two requirements.

<sup>4.</sup> Sections 102, 103 and 112 of the Patent Act, when properly applied, provide safeguards against the granting or enforcement of unmeritorious patent claims. 35 U.S.C. §§ 102-103, 112. Section 101 was not intended to take their place.

The legislature intended a broad rule for patent eligibility because valuable innovations often "push back the frontiers" and arrive in unexpected forms. *Id.* at 316. The Federal Circuit rule inevitably withholds protection for certain unforeseeable processes. Indeed, under its new standard, only processes of a predetermined type are allowed, namely, those that are tied to a machine or transform an article.

The Federal Circuit has tacitly acknowledged the infirmity and obsolescence of its standard by recognizing that it may need to be altered to accommodate new technologies:

Nevertheless, we agree that future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade. Thus, we recognize that the Supreme Court may ultimately decide to alter or perhaps even set aside this test to accommodate emerging technologies. And we certainly do not rule out the possibility that this court may in the future refine or augment the test or how it is applied. At present, however, and certainly for the present case, we see no need for such a departure . . .

Bilski, 545 F.3d at 956 (emphasis added).

It is not for the Federal Circuit, however, to decide which categories of processes or other inventions are eligible for patent protection. *Benson*, 409 U.S. at 72-73 (explaining that the eligibility of software is a "policy matter" to which the legislature, not the Court, is competent to speak). In categorically limiting patent-eligible processes to machines and transformations, the Federal Circuit exceeds its judicial function.

Where a court oversteps its bounds and announces a rule contrary to statute ("... any new and useful process...") and legislative intent, grant of certiorari is appropriate to restore the law. Comm'r of Internal Revenue v. Asphalt Products Co., Inc., 482 U.S. 117, 120 (1987) (where lower court's holding conflicts with another circuit court's "and is in obvious conflict with the plain language of the statute, we grant certiorari ..."). This is particularly true where the rule provides a perilously narrow answer to one of the most fundamental questions within the patent universe: What is eligible for patent protection? Cardinal Chemical Co. v. Morton Int'l, Inc., 508 U.S. 83, 89 (1993) (granting certiorari because a rule defining patent rights "is a matter of special importance to the entire Nation.").

## II. The Machine-or-Transformation Test Calls the Patentability of Many Landmark Inventions Into Question

Innumerable inventions over the decades have been protected by method claims that are neither apparatustied nor transformation-reciting. Some were pivotal discoveries of far-reaching economic and social consequence. Had the Federal Circuit's "machine-ortransformation" requirement prevailed at the time,

these methods and processes would likely not have earned patent protection and their proven capacity to beneficially shape our world would likely not have been realized.

The Federal Circuit has imposed an aggressive test that conflicts with Congressional intent, this Court's precedent, and the settled expectations of the creative and investment communities. The test threatens innovation and associated commercial activity, and threatens scientific and economic incentives in this country.

Such effects may not have been intended by the Federal Circuit, but they are the foreseeable result of the machine-or-transformation test. The following are examples of issued, but expired, patents for momentous inventions that, experience and common sense dictate, should be eligible for patent protection.

Few would expect that foundational inventions in FM radio would fall outside the patent system. Yet, consider U.S. Patent No. 1,342,885, granted to Edwin Armstrong, the so-called father of FM radio, for devising a process which was rapidly adopted in nearly all radio communication, and remains the standard approach for converting the received radio signal to a lower frequency for intermediate processing. Claim 1 of the Armstrong patent reads:

1. The method of amplifying and receiving high frequency electrical oscillatory energy which comprises, combining the incoming energy with locally generated high frequency continuous oscillations of a frequency differing from said incoming energy by a third readily-amplifiable high frequency, converting the combined energy by suitable means to produce said readily-amplifiable high frequency oscillations, amplifying the third said high frequency oscillations, and detecting and indicating the resulting amplified oscillations.

Claim 1 does not recite a machine or apparatus and therefore does not meet the machine prong of the test. The claim involves a series of combining and amplifying steps. But these steps are performed on "energy" (i.e., a signal), and therefore this claim would ill-qualify for protection under the transformation prong of the test because no "article" is transformed. See In re Nuijten, 500 F.3d 1346, 1353, 1356 (Fed. Cir. 2007) (holding that signals are transitory and intangible, and therefore do not qualify as "manufactures" or "articles"). Yet it is clear that the claim is directed to the operations of a radio receiver and, as such, would conventionally be understood to be eligible for patent protection.<sup>5</sup>

<sup>5.</sup> Cast similarly into doubt would be the eligibility of claim 2 of U.S. Patent No. 4,200,770 to Martin Hellman, et al., for "Cryptographic Apparatus and Method." The Hellman patent covers the so-called public key encryption system, an invention of immense significance to the world of data communication, effectively enabling secure communications for modern e-commerce, and other types of transactions. While a transformation of data arguably occurs, that data could as easily represent English language text as a voltage measured in a circuit. Hence, the transformation appears not to satisfy the *Bilski* criterion.

The vast field of information and signal processing extends, of course, beyond radio, to such diverse areas of endeavor as television, the Internet, computing, control systems, image processing and medical imaging. While the underlying "hardware" will embody some of the advances achieved in these areas, often it is the method where an invention resides: whether a way to send more information over a given bandwidth (e.g., more channels on a TV cable or fiber); or a more efficient means to store data; or a process for transmitting information securely.

The invention in these instances is not in the machine but in the process or method followed by the machine. Obtaining patent coverage only for the hardware embodiments in the patent application, but not on the process itself, often fails to protect the invention adequately. To establish that certain parties are direct infringers, method claims are required.

A more modern example than FM radio comes from the world of wireless communications. Qualcomm's U.S. Patent No. 4,901,307, issued in 1990, discloses the CDMA (carrier-division, multiple access) technology that lies at the heart of the dominant cellphone transmission standard in use in this country. While much of the claim set is devoted to apparatus claims, there is also a significant group of method claims, beginning at claim 33:

33. In a spread spectrum multiple access communication system . . . a method for providing high system user capacity . . . comprising the steps of:

providing a plurality of system user addressable narrow band information signals;

converting said plurality of system user addressable narrow band information signals into . . . wide band code-division-spread-spectrum communication signals;

transmitting said plurality of codedivision-spread-spectrum communication signals between system users;

receiving, at each respective system user, . . . code-division-spread-spectrum communication signals . . . ;

providing for each respective system user an increase in system user realized average  $signal\ power\ldots$ ; and

converting, at each respective system user, received address corresponding codedivision-spread-spectrum communication signals into corresponding user addressable information *signals*.

## (emphasis added.)

Manifestly, this claim does not recite steps that are tied to a specific machine or apparatus. As in the FM radio patent, this claim requires the manipulation of signals, but signals are not articles, see Nuijten, 500 F.3d at 1353, 1356, and the plain language of the machine-or-transformation test would place in doubt the

patent-eligibility of this claim. Over the past decade, CDMA technology has been the backbone of the cellular communications industry. The fact that such a method could be ineligible is a telling indictment of the *Bilski* test's incapacity to accommodate emerging innovations.

Certain inventions in the fields of medical diagnostics and treatments would also have been thwarted by the machine-or-transformation requirement. One such example is U.S. Patent No. 4,459,286, titled "Coupled Haemophilus Influenzae Type B Vaccine. The inventor, Maurice Ralph Hilleman, is hailed as the most prolific vaccine scientist of the twentieth century by the National Inventors Hall of Fame. He was singled out for "saving more lives than any other scientist" and was inducted into that prestigious body in 2007 with a citation to U.S. Patent No. 4,459,286.6

### Claim 6 of that patent reads:

6. A method of treating mammalian species which comprises administering to said species an immunologically effective amount of a composition comprising a polysaccharide/protein conjugate which comprises H. influenza type b polysaccharide and a T-cell-stimulating N. meningitidis serotype outer membrane protein, said polysaccharide and protein being coupled through 6-aminocaproic

<sup>6.</sup> Invent.org, Hall of Fame, Maurice Ralph Hilleman, http://www.invent.org/hall\_of\_fame/339.html (last visited Feb, 24, 2009).

acid, and a member of the group consisting of a pharmaceutically-acceptable carrier, an adjuvant, and a pharmaceutically-acceptable carrier and adjuvant.

This claim does not perform any type of transformation. It simply requires administering a composition. Furthermore, there is no machine or apparatus in this claim. A polysaccharide/protein conjugate is a composition of matter or a manufacture, but it is not a machine or apparatus. Accordingly, this famed invention would also be susceptible to attack under the new test.

The impact of the machine-or-transformation test on drug development can only be detrimental. Patent protection for both new drugs and for new uses of known drugs (whether or not already approved for a primary use) is needed in many instances to justify the outsize expenses and risk in the process of conducting clinical trials and securing FDA approval. There is no indication the Federal Circuit contemplated this consequence.

These examples illustrate that numerous claims associated with epochal inventions would not have satisfied either prong of the machine-or-transformation test—thus demonstrating this Court's wisdom in not making such a test the measure of patent-eligibility and the Federal Circuit's clear error in doing so.

## III. The Lower Court's Formula for Patent Eligibility Creates Uncertainty That Will Cause Lasting Harm to Innovation

A patent is a contract between the patentee and society. The patentee discloses to the public a new and useful invention and, in exchange, is rewarded with a limited term of exclusivity.

In consideration of [an invention's] disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but, upon the expiration of that period, the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use.

*U.S. v. Line Materials Co.*, 333 U.S. 287 339-340 (1948) (Douglas, J., concurring). In this manner, the patent system fulfills the Constitution's mandate to "promote the progress of science and useful arts."

The patent system not only promotes innovation, but is a *sine qua non* for the commercialization of new inventions, and hence for competition. A patent represents the small entity's indispensable magnet to attract potential investors.<sup>7</sup> The patent is also the only

<sup>7.</sup> See, e.g., Ronald J. Mann, The Role Of Patents In Venture-Backed Software Start-Ups, Acad. Advisory Council Bulletin 2.1 (The Progress & Freedom Foundation, Washington D.C.) Apr. 2007, at 5, available at http://www.pff.org/issues-pubs/ip/bulletins/bulletin2.1softwareventurepatents.pdf (explaining that patents play a "role of considerable importance" for investments in software-based start-up companies).

shield that a small entity can use to ward off a big corporation who would copy its inventions.<sup>8</sup> This distinctive attribute of patents has long been extolled:

But if we never needed, or do not now need, patents as bait for inventors, we may still need them, in some instances, as a lure to investors. ... [I]ndustrial history discloses that [giant] corporations, at times and to some extent, have been prodded into undertaking such research and into developing improvements because of the threat of competition from occasional 'outsiders,' armed with patent monopolies, and supplied with funds by a few private enterprisers. Thus, paradoxically, monopoly may evoke competition: The threat from patent monopolies in the hands of such 'outsiders' may create a sort of competition a David versus Goliath competition—which reduces the inertia of some huge industrial aggregations that might otherwise be sluggish.

Picard v. United Aircraft Corp., 128 F.2d 632, 643-644 (2d Cir. 1942) (Frank, J., concurring). This constantly regenerating competitive activity provides society with innovations that may otherwise never come into being.

When patent rights become uncertain, these systemic benefits are eroded. If patentees and investors are unsure whether the patent laws will protect the fruit of their labors and investments, then why labor or invest

<sup>8.</sup> Id. at 9.

at all? If a giant corporation knows that patents offer uncertain protection, then why should it respect the ownership claim of a smaller competitor?

The flaw of the machine-or-transformation test is not that it sets out a new rule; the patent world has adapted repeatedly to reasoned rules from both this Court and the Federal Circuit that clearly guide inventors and practitioners. Nor is the test's excessive restrictiveness its chief cause for alarm. Rather, an equal peril inheres in the vagueness and ambiguity of the test. As a Bilski dissenter observes:

[T]his opinion propagates unanswerable questions: What form or amount of "transformation" suffices [to meet the transformation prong of the 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). Because of these unanswered questions, inventors, investors, patent holders and practitioners alike can no longer discern the eligible from the ineligible.

Even the PTO's own appellate tribunal, the Board of Patent Appeals and Interferences, cannot agree on

<sup>9. &</sup>quot;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." *Bilski*, 545 F.3d at 977(Newman, J., dissenting).

how to construe the test. Contradictory and arbitrary decisions are issuing from that body already. In one case, the Board decided that a "computerized method performed by a data processor" was not eligible because the data processor was "nothing more than a general purpose computer," which does not qualify as "a particular machine or apparatus" under the machine-or-transformation test. See, e.g., Ex parte Gutta, No. 2008-3000, 2009 WL 112393 (B.P.A.I. Jan. 15, 2009) (emphasis added). This reasoning singles out computer-implemented methods for exclusionary treatment, giving the brush to computers' central role in modern technology.

Surprisingly, the implications of the machine-ortransformation test extend to statutory classes of inventions other than methods. For example, in another post-*Bilski* case, one panel of the Board upheld a computer-program product claim as patent-eligible because "[i]t has been the practice for a number of years that a [claim] of this nature be considered statutory at the USPTO as a product claim." *Ex parte Bo Li*, No. 2008-1213, 2008 WL 4828137 (B.P.A.I. November 6, 2008). By contrast, yet another panel rejected a computer-program product claim because the machine-or-transformation test purportedly necessitated the rejection. *Ex parte Cornea-Hasegan*, No. 2008-4742, 2009 WL 86725 (B.P.A.I. January 13, 2009).

These helter-skelter rulings overturn expectations built upon the Federal Circuit's opinion of fifteen years ago that a programmed general purpose computer is patent-eligible because it "in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software." *In re Alappat*, 33 F.3d 1526, 1545 (Fed. Cir.

1994) (en banc). The Federal Circuit's machine-ortransformation test now sheds doubt on years' worth of patents and applications for computer-implemented inventions.<sup>10</sup>

This Court should not wait for the Federal Circuit and the PTO to resolve these issues because too much is at stake. Moreover, under the Federal Circuit's rules, another *en banc* opinion is necessary to change the *Bilski* rule. Petitioners state that the machine-or-transformation test casts a cloud over tens of thousands of issued patents. Petition for Writ of Certiorari at 4, *Bilski et al. v. Doll*, No. 08-964 (Jan. 28, 2009). This is too conservative an estimate. Tens of thousands of patents are issued *each year*, and a very high percentage of patents contain method claims affected by that decision. <sup>11</sup> To wait for new

<sup>10.</sup> Before *Bilski*, the Patent and Trademark Office had given clear guidance to its examiners regarding the kind of computer-implemented inventions that it understood to pass muster under Section 101. Manual of Patent Examining Procedure §§ 2106, 2106.01 (8th ed. 2008, rev. 7) ("When functional descriptive material is recorded on some computer-readable medium, it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized."). Now, its Board is struggling to find a consistent reading of the Federal Circuit's decision. That struggle amply demonstrates how inherently problematic the decision is.

<sup>11.</sup> In USPTO Class 705, entitled "Data processing: financial, business practice, management, or cost/price determination," there are 18,000 issued patents and at least 48,000 pending applications. In PTO classes 700-704, 706-707, 726, and 902, which are also affected by the machine-or-transformation test, there are over 130,000 issued patents and at least 120,000 applications pending. This information can be accessed through the USPTO website at http://patft.uspto.gov/.

cases to work their way up through the PTO and the lower courts may mean that the Federal Circuit does not provide guidance for some years to come. Delay in restoring the system to its sensible and long-settled position causes upheaval in the technology and commercial spheres that society can ill afford.

#### CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

Respectfully submitted,

Joel R. Leeman

Counsel of Record

John J. Stickevers

Jakub M. Michna

Bromberg and Sunstein LLP

125 Summer Street

Boston, MA 02110-1618

(617) 443-9292

Steven J. Henry Robert M. Abrahamsen Wolf, Greenfield and Sacks, P.C. 600 Atlantic Avenue Boston, MA 02210 (617) 646-8000

Attorneys for Amicus Curiae Boston Patent Law Association