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IN RE BERNARD L. BILSKI AND RAND A. WARSAW

JAN HOBRALY
CLERK

**Appeal from the United States Patent and Trademark Office
Board of Patent Appeals and Interferences**

BRIEF FOR *AMICI CURIAE*
ELI LILLY AND COMPANY AND
THE ASSOCIATION OF AMERICAN MEDICAL COLLEGES
IN SUPPORT OF AFFIRMANCE

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CERTIFICATES OF INTEREST

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1. The full name of every party or *amicus curiae* represented by us is:

Eli Lilly and Company.

2. The name of the real party in interest represented by us is:

Eli Lilly and Company.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by us are:

None.

4. The names of all law firms and the partners or associates that appeared for the party or *amicus curiae* now represented by us or are expected to appear in this Court are:

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1. The full name of every party or *amicus curiae* represented by me is:

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3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or *amicus curiae* represented by me are:

None.

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Eli Lilly and Company (“Lilly”) and the Association of American Medical Colleges (“AAMC”) submit this brief as *amici curiae* in compliance with Rule 29 of Federal Rules of Appellate Procedure and with this Court’s Rule 29 to address the five questions set forth by this Court in its February 15, 2008 Order in this matter. That Order provided that “[amicus] briefs may be filed without leave of court.” Therefore, *amici* have not sought consent from the parties nor have they moved the Court for leave to file.

I. STATEMENT OF INTEREST OF *AMICI CURIAE*

Amicus curiae Eli Lilly and Company (“Lilly”) depends on an effective patent system. The ability to obtain patents and successfully enforce them is essential to the company’s investment in creating and developing innovative medicines.

Amicus curiae Association of American Medical Colleges (“AAMC”) is a non-profit organization representing all 129 allopathic medical schools in the United States, about 400 major teaching hospitals and health systems, and 89 academic and professional societies that are at the forefront of medical education, research and research training, and health care innovation and delivery. This innovation depends on unfettered generation and dissemination of new scientific knowledge and the broadest possible sharing

of scientific and medical information in support of the advancement of science, patient care, and the health of the public.

Over the course of the last several years, the credibility of the patent system has come under an accelerating attack. Legislative proposals have emerged that, if enacted into law, would limit the range of acts that represent infringement of a patent for a combination invention, reduce the level of available compensatory damages, restrict the grounds for obtaining punitive damages, expand interlocutory appeal rights, curtail patent owner venue choices, lower the burden to prove invalidity, or expand the availability of judicial compulsory licenses. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). Patent Reform Act of 2007, S. 1145, 110th Cong. § 4 (2007). At the same time, the National Academies of Science's widely-supported recommendations to improve the operation of the U.S. patent system have yet to move through Congress. *A Patent System for the 21st Century* (Stephen A. Merrill, Richard C. Levin & Mark Myers, eds., The National Academies Press, Washington, D.C. 2004), *available at* <http://www.nap.edu/catalog/10976.html>.

Proponents of changes that would make patent enforcement more difficult argue that they are justified by the burdens of responding to infringement charges, especially infringement of a new breed of patent that

claims inventions too abstractly. They assert that such patents contain claims that: are too difficult to interpret and too uncertain in their scope; can be asserted in unpredictable ways; and prove too difficult to invalidate in court.

Lilly and AAMC believe that the root cause of the problems arising from many of these patents is that they should never have been permitted to issue. Inspection of many such patents suggests that the statutory requirements for patent-eligibility are not being consistently met. Many appear to exhibit the same patent-eligibility defect that Lilly and AAMC believe infect the *Bilski* claims. In brief, the requirements for patent-eligibility are being given short-shrift.

This appeal, therefore, has the potential to be of singular importance, with the *en banc* decision holding the possibility to refocus concerns over such patents away from the ongoing congressional debates over diminishing patent remedies and back toward the primal issue of patent-eligibility. Congressional debates over the future of the patent system could be freed from concerns about patents that should never have been issued. A decisive holding could turn the congressional debates and the broader national dialogue over patents back to their historic tenor: how best to implement the National Academies' recommendations and promote respect for valid

patents that meet the exacting and rigorous requirements for patentability established by Congress.

Amici have a second and equally important interest in this appeal—maintaining an open, unitary patent system in which “*anything* under the sun made by man” will remain eligible for patenting. The worst outcome from this appeal would be for this Court to yield to the temptation to unduly restrict or arbitrarily limit what inventors may patent. Nothing in the patent statute should permit the crafting of special rules or special tests for patent-eligibility that could arbitrarily deny any classification of inventors the right to patent an invention.

A number of formulations for doing so have arisen that would be destructive to maintaining a unitary patent system. An invention should not be declared patent-ineligible *merely* because, for example, it relates to a “business method” or an “algorithm,” or involves the use of “software code.” Similarly, the failure to lie within the “technological arts” or be “industrially applicable” should not become *categorical* patent disqualifiers.

To maintain a unitary patent system, it is essential for this Court to limit its decision in this appeal to patent-eligibility standards that arise directly and inherently from the words of the patent statute. In brief, it is in the interest of all who depend upon the patent system that the Court’s patent-

eligibility decision should impact no area of the useful arts to the benefit or detriment of any other.

Lilly and AAMC submit this brief, therefore, to persuade this Court that the patent statute and relevant judicial precedents interpreting it provide patent-eligibility for an invention claimed as a *process* only when each of the discrete steps of the process is limited to *acts*, as this term has long been understood under the patent law. Under rigorous statutory construction, *acts* must be *physically transformative*. They operate on, transform, make, or use *things*. *Things*, at least as Congress and the Supreme Court have referred to them for the purposes of patenting, are tangible or otherwise physical. To use the exact words of the patent statute itself, *things* can be *structures or materials*, without limitation as to the type or sort; such structures or materials may take on any form, be they *machines, manufactures or compositions of matter*.

In brief, therefore, this Court should rigorously interpret the words of the 1952 Patent Act¹ by holding that inventions claimed as processes are patent-eligible only if they contain one or more discrete steps, *each* step of

¹ Act of July 19, 1952, ch. 950, § 1, 66 Stat. 792 (codified as amended at 35 U.S.C. §§ 1-376 (2000)), referred to herein as the “1952 Patent Act.”

which must be limited to an *act* that is physically transformative, *i.e.*, operates on *something*.

Neither Lilly nor AAMC has a stake in the result of this appeal. The parties have not contributed to the preparation of this brief.

II. ARGUMENT

A. Patent-Eligibility Should Be Determined Using the Same Rigorous Methodology Applied to Other Patentability Determinations (Answering Questions 2, 3, and 4).

1. The Reach of a Claim Must Be Limited to Patentable Subject Matter, Given the Claim's Broadest Reasonable Construction.

The first step in determining patentability should involve testing the claim for patent-eligibility under 35 U.S.C. § 101. *In re Bergy*, 596 F.2d 952, 960 (CCPA 1979) (“The first door which must be opened on the difficult path to patentability is § 101”). This section of the patent statute states

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.

Like all issues of patentability, the assessment of patent-eligibility under section 101 necessarily begins with claim construction. *State St. Bank & Trust Co. v. Signature Fin. Group*, 149 F.3d 1368, 1370 (Fed. Cir. 1998)

(stating that “whether the . . . patent is invalid for failure to claim statutory subject matter under § 101 [] is a matter of both claim construction and statutory construction.”).

Construction of a claim in an application for patent, such as *Bilski*’s, means looking at the full reach of the claim. A claim must be given “the broadest reasonable interpretation consistent with the specification” during examination in the Patent Office. *In re Prater*, 415 F.2d 1393, 1396 (CCPA 1969). *See also In re Morris*, 127 F.3d 1048, 1054-55 (Fed. Cir. 1997). The reason for the rule is that claims can be amended during prosecution to make them “precise, clear, correct, and unambiguous. Only in this way can uncertainties of claim scope be removed” *In re Zletz*, 893 F.2d 319, 321-22 (Fed. Cir. 1989).

Once the full reach of the subject matter of the claim has been assessed, all subject matter falling within those “metes and bounds” must not only *contain* patentable subject matter, but the totality of the construed claim must be *limited to* patentable subject matter. *In re Slayter*, 276 F.2d 408, 411 (CCPA 1960) (“[A] generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus”); *See also In re Gosteli*, 872 F.2d 1008 (Fed. Cir. 1989); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997) (Written description for

species within genus does not establish that the genus is described.); *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1339 (Fed. Cir. 2003) (“To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without ‘undue experimentation.’”). The test for patent-eligibility, therefore, should be whether the claim, as reasonably broadly construed, has been clearly limited to patent-eligible subject matter.

2. Claims to “Combinations” Must Further Be Assessed to Determine if Each Individual Element of the Combination Has Been Limited to “Structure, Material or Acts.”

Claim construction for patent-eligibility purposes is not complete, however, in the case of an invention claimed as a combination of elements until analysis under 35 U.S.C. § 112, sixth paragraph (“Paragraph 6”) is undertaken. Because most inventions are claimed as combinations of discrete elements (discrete steps, in the case of an invention claimed as a process), most claims are subject to such analysis. Paragraph 6 states:

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

35 U.S.C. § 112, sixth para. (2008).

Paragraph 6 is premised on the recognition that an element in a combination claim can be set forth only in one of two ways. First, if an element omits recital of *structure, material, or acts*, it is permitted to set out nothing more than the function that the element is to perform or the result that is to be obtained using “means-for” or “step-for” construction. When an element of a claim is expressed as a means or step without elucidating what those means or step are, Paragraph 6 limits the reach of the claim. The price the inventor pays for electing to omit from an element any structure, material or act is that the element is construed to cover only those *corresponding* structures, materials, or acts described in the specification and equivalents thereof. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1583 (Fed. Cir. 1997). Alternatively, an element may expressly describe *what it is* rather than reciting the function or result. In such a case, the element must itself set out *structure, material or acts*.

Whether the inventor elects to include or to omit structure, material, or acts, Paragraph 6 requires that each element of a combination claim be limited to particular structure, material, or acts. Such must be found in the element or else the element must be so limited by operation of Paragraph 6. What this means, therefore, is that the subject matter of each discrete

element in a combination claim is subject to a limitation on eligibility for patenting imposed under Paragraph 6.

The judicial interpretation of Paragraph 6 underscores how the patent-eligibility requirement under Paragraph 6 operates. When the “without recital” clause under Paragraph 6 applies, Paragraph 6 assures that, even under the “broadest reasonable construction,” the claim element is nonetheless limited to corresponding structures, materials, or acts appearing in the specification. *In re Donaldson*, 16 F.3d 1189, 1194-95 (Fed. Cir. 1994). Where such corresponding structures, materials, or acts are found in the specification, the eligibility requirement under Paragraph 6 is satisfied. When they are not found in the specification, however, the element fails to satisfy the Paragraph 6 requirement and the claim is unpatentable. *Biomedino, LLC v. Waters Techs. Corp.*, 490 F.3d 946, 950 (Fed. Cir. 2007) (If no structure, material or act corresponding to the means- or step-plus-function limitation is found in the specification, then the claim is indefinite and invalid under 35 U.S.C. § 112, second paragraph).

Paragraph 6, therefore, inescapably imposes limits on patent eligibility. The patentability of a combination claim depends on limiting each discrete element to structures, materials or acts. They can be explicitly set out in the claim element. If not, they will be read into the claim as

limitations from the specification. If neither the claim element itself nor the specification set out a limiting structure, material or acts, the claim element does not pass muster under Paragraph 6.

The Paragraph 6 patent-eligibility requirement is distinct from that under section 101. Even if an invention is claimed as a process, machine, manufacture, or composition of matter and satisfies section 101, any invention claimed as a combination of elements must meet this subject matter eligibility test *as to each discrete element*. Paragraph 6 leaves the inventor no route of escape. This absence of any escape route for an inventor seeking to avoid the element-by-element inclusion of structure, material or acts reflects an unmistakable intent of Congress that combination inventions not receive less rigorous patent-eligibility scrutiny than other types of inventions. For example, product-type inventions that are not claimed as combinations must meet the test under section 101 of being machines, manufactures, or compositions of matter, *i.e.*, specific structures or materials. Just as a patent-eligible claim under section 101 must be directed to such subject matter, each discrete element of a patent-eligible combination must set out—expressly or by implication—such subject matter.

In summary, testing for patent eligibility requires a claim to be construed. The required construction is the *broadest reasonable one*. The various embodiments encompassed under such a construction of the claim must meet the test for patent eligibility. The claim must not merely be broad enough to *encompass* patent-eligible embodiments; it must be *limited to* patent-eligible embodiments.

In applying the requirement for patent-eligibility to an invention claimed as a combination, the claim must be parsed into its discrete elements or steps. Each such element must both encompass and be limited to embodiments that represent *structures, material or acts*. If structures, materials or acts are not set out in the claim explicitly, Paragraph 6 so limits the claim to such subject matter, thereby satisfying the requirement for patent eligibility but only so long as corresponding structures, materials or acts are identified in the specification.

3. Rigorous Statutory Construction and Precedent Require that Patent-Eligible Processes Consist of “Acts” that Are Each Limited to Transformation of Physical *Things*.

Three of the four categories for patent-eligible subject matter set out in section 101 consist exclusively of physical *things*, namely, machines, manufactures, and compositions of matter. As noted above, Congress made its intent express when it came to the patenting of *things*—patent-eligibility

is to be entirely unrestricted by field of technology. *State St. Bank*, 149 F.3d at 1373 (“The repetitive use of the expansive term ‘any’ in § 101 shows Congress’s intent not to place any restrictions on the subject matter for which a patent may be obtained beyond those specifically recited in § 101.”). The most clear-cut evidence of this intent comes from the Congressional Reports that accompanied the 1952 Patent Act, which stated:

A person may have “invented” a *machine* or a *manufacture*, which may include *anything* under the sun that is *made* by man, but it is not necessarily patentable under Section 101 unless the conditions of the title are fulfilled.

S. Rep. No. 82-1979, at 5 (1952) (emphases added). *See also Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to ‘include anything under the sun that is made by man.’”).

Congress’s intent was expansive, yet when Congress explained the *things* that might be conceived of as “made by man,” it selected only physical *things* for patent eligibility. By the words it used in section 101, namely, machine, manufacture, and composition of matter, Congress limited eligibility to physical *things*. It has always been recognized that Congress was not seeking to secure patent protection for non-physical things, such as the mere exercise of human intellect, whether in the form of ideas,

relationships, information, and any and all other abstract, ethereal, or disembodied subject matter.

When Congress substituted “process” for “art” in the list of patentable subject matter in 1952, it was acting in the face of the then-existing, established meaning of “process,” which meaning was incorporated into the statute. *In re Schrader*, 22 F.3d 290, 295-96 (Fed. Cir. 1994) (mentioning *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 106-08 (1991) (presumption that well-established common law principles are left unchanged by statutory enactment) and *McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 342 (1991) (presumption that when a statute uses a term of art, such as “process,” Congress intended it to have its established meaning)).

Indeed, the definition of “process” had long been settled by 1952. The historic and consistent definition of a “process” included the requirement that a process involve a transformation or reduction of physical matter, *i.e.*, *things*:

A process is a mode of treatment of certain *materials* to produce a given *result*. It is an act, or a series of acts, performed upon the *subject matter to be transformed and reduced to a different state or thing*. . . . The process requires that certain things should be done with certain *substances*, and in a certain order. . . .

Cochrane v. Deener, 94 U.S. 780, 788 (1877) (emphases added).

Confirmation of the settled meaning of the term “process” as referencing one or more physically transformative “acts” comes from Professor Robinson’s classic treatise on patent law, which stated:

An art or operation is an act or a series of acts *performed by some physical agent upon some physical object*, and producing in such object *some change either of character or of condition*. It is also called a “process”

William C. Robinson, *The Law of Patents for Useful Inventions* § 159 (1890) (emphases added). As evidenced by *Cochrane* and Robinson, it was well-established by 1952 that the term “process” referenced one or more “acts” and that the term “acts” referenced something physically transformative. These meanings were, thus, incorporated into the patent statute with the adoption of the 1952 Patent Act and remain there today unchanged.

Additional tenets of statutory construction further support the conclusion that the terms “process” and “acts” must be limited to those involving transformation of physical *things*. The meaning of statutory language, plain or not, depends on context:

Words are not pebbles in alien juxtaposition; they have only a communal existence; and not only does the meaning of each interpenetrate the other,

but all in their aggregate take their purport from
the setting in which they are used

NLRB v. Federbush Co., 121 F.2d 954, 957 (2d Cir. 1941) (L. Hand, J.)

(quoted in *Shell Oil Co. v. Iowa Dept. of Revenue*, 488 U.S. 19, 25, n.6
(1988)).

When considered together, section 101 and Paragraph 6 make clear that patent-eligibility turns on the meaning courts give to the terms “machine,” “manufacture,” “composition of matter,” and “process” as well as “material,” “structure,” and “acts.” While Congress on the one hand intended that patents should extend to “anything under the sun made by man,” it clearly defined what “things” could qualify by the words of section 101 and Paragraph 6, *i.e.*, machines, manufactures, compositions of matter or, in the case of combinations, things comprised of materials and structures. The presence of the words “machine,” “manufacture,” “matter,” “material,” and “structure,” which are all clearly limited to physical *things*, in immediate juxtaposition with the words “process” and “acts” is a clear signal that Congress was not setting up a system for protecting processes or acts involving the mere exercise of human intellect and the like. Interpreting the terms “process” and “acts” as either transforming or manipulating physical things places these terms *in pari materia* with the other three categories of eligible inventions in section 101 and with the other physical *things*

mentioned in Paragraph 6, *structures* and *materials*, and is essential for maintaining proportionality among the statutory categories.

Based on rigorously-applied statutory construction principles, therefore, a logically-consistent, bright-line test for patent eligibility for process claims can be stated: A process is not patent-eligible unless each step constituting it is limited in its broadest reasonable construction to an act that transforms a physical *thing*. This “bright line” eligibility test is completely consistent with holdings on patent-eligibility in prior cases, such as *Gottschalk v. Benson*, 409 U.S. 63 (1972); *Parker v. Flook*, 437 U.S. 584 (1978); *Diamond v. Diehr*, 450 U.S. 175, (1981); *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989); *In re Warmerdam*, 33 F.3d 1354 (Fed. Cir. 1994); *In re Schrader*, 22 F.3d 290 (Fed. Cir. 1994); and *In re Comiskey*, 499 F.3d 1365 (Fed. Cir. 2007). Excluding claims that encompass abstract, ethereal, or otherwise disembodied concepts from eligibility occurs exactly when the claim is not clearly *limited* to acts that self-evidently transform physical things.

In summary, rigorous statutory construction and longstanding judicial precedent compel the conclusion that, to be eligible for patenting, a process must involve and be limited to transformation of physical *things*, and, for a

multi-step process, each of the discrete acts that constitute the process must similarly be limited to transforming physical *things*.

4. Patent Eligibility Is Forfeited if Any Discrete Act in a Process Is Not Limited to Transforming Physical Subject Matter.

The requirement that the discrete acts of an invention claimed as a multi-step process must each be limited to transforming physical *things* means, therefore, if even one step in a process claim, construed as broadly as reasonably possible, is not so limited, then the claim is ineligible for patenting. Patent eligibility, like all other conditions and requirements for patentability, requires that the invention meet the requirements for patentability based upon the full scope of the protection that is being sought. *See supra* Section A1.

The same concerns that compel excluding laws of nature and abstract ideas from the scope of patentable subject matter when considering the claim as a whole apply with equal force when examining the individual elements of a claim. The Supreme Court cautioned as much in *Flook*, when it expressed concern that post-solution acts may be insufficient to limit a claim to patent-eligible subject matter. 437 U.S. at 590. The Paragraph 6 analysis provided in this brief, which was missing from *Flook*, simply clarifies the manner in which the words of the patent statute can be applied to preclude

the outcome of concern to the Supreme Court. Indeed, applying the present “all elements” test for physicality is an objective, reliable, efficient, and complete answer to the Court’s concern in *Flook*, and it avoids the need to ponder how much pre- or post-solution activity suffices.

5. The Section 101 and Paragraph 6 Requirements Should Exhaustively Define Patent-Eligibility, Consistent with Extending Patenting to “Anything Under the Sun Made by Man.”

Given the listing of the four, exclusive statutory categories in section 101 coupled with the requirement for structure, material or acts in Paragraph 6, courts should not and need not otherwise constrain or limit the reach of patenting or impose new and restrictive limitations and conditions. The Supreme Court has thus far avoided add-on eligibility strictures based on field or category of technology, and this Court should do likewise.

Chakrabarty, 447 U.S. at 308, quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933). Thus, once a claim has been fully digested for patent eligibility by rigorously applied claim construction and the limitations explicated herein under section 101 and Paragraph 6, no basis should exist for imposing extra-statutory tests. These two sections of the statute, rigorously applied, should offer the necessary and sufficient tests for patent eligibility.

B. Claim 1 of Bilski's Patent Application Is Ineligible for Patenting (Answering Question 1).

Applying the construction principles discussed *supra* to Claim 1 of Bilski's 08/833,892 application (the '892 application) reveals no possible basis for patent-eligibility. The claim recites, in pertinent part, a "method for managing the consumption risk costs of a commodity," which method includes three discrete steps: 1) "*initiating* a series of transactions;" 2) "*identifying* market participants;" and 3) again "*initiating* a series of transactions."

The claim is a "combination" claim within the meaning of Paragraph 6. Nothing in the language of these elements suggests that they are limited to steps for achieving a particular result to be achieved or a particular function to be performed. They do not use the formulation "step for," that is indicative of the intent to be covered by the "safe harbor" limitation of Paragraph 6, *i.e.*, limiting the discrete steps of the claim to corresponding acts set out in the specification. Therefore, the acts required by Paragraph 6 must be laid out in each of the elements of the claim.

Construed as discrete acts, and given their broadest reasonable construction, these steps would cover *any and all form of initiation* or *any and all form of identification*. Each of the acts could reasonably be construed to include the mere exercise of human intellect. *Initiating* can

encompass merely resolving to so. *Identifying* can encompass merely making a mental note. There is no reference to the use or involvement of any machine, manufacture or composition, let alone the transformation or manipulation of any structure or material. As such, not one of the three steps in Bilski's Claim 1 is clearly *limited* to an act of transforming or manipulating structures or materials, much less a machine, manufacture, or composition.

In short, neither the discrete steps individually nor the three steps collectively are limited to subject matter that constitutes transformative or manipulative acts upon *something* physical. Hence, Claim 1 of the '892 application does not claim patent-eligible subject matter. Any decision *en banc* should declare the same conclusion.

C. This Court Should Repudiate *State Street's Dicta* on Patent Eligibility (Answering Question 5).

The analysis above provides this Court sufficient rationale for its holding with respect to the Court's first four questions. In its opinion, the Court additionally should repudiate *State Street's dicta*, as well as its antecedent in *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) and its sequelae in *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999) and other cases.

1. *State Street's Dicta* Has Been Wrongly Taken to Mean that a “Useful, Concrete and Tangible Result” Suffices for Patent-Eligibility.

The *State Street* invention was claimed as a combination of seven discrete, means-plus-function elements that together formed a machine. *State St. Bank*, 149 F.3d at 1371. The claim was directed to a perfectly patent-eligible invention under section 101. The court did not have before it any issue under Paragraph 6. However, assuming that the patent's written description set out a corresponding structure or material for each of the seven elements, Paragraph 6's patent-eligibility test would likewise be satisfied. Thus, *State Street's* import should have been confined to an observation that a software-implemented invention, *i.e.*, a computing machine, can be facilely claimed as a patent-eligible machine.

As for *State Street* itself, the devil lies in the *dicta*, not in the holding. The claim at issue in *State Street* should have produced not a ripple, much less a wave, upon the law of patent eligibility. For the past decade, however, *dicta* in the opinion have had a tsunami-like effect on patent-eligibility. The *dicta* can be interpreted as sanctioning patent-eligibility for subject matter whenever it produced “useful, concrete and tangible results.”² These

² The expression “useful, concrete, tangible result” first appeared in *In re Alappat*, 33 F.3d at 1544. The same expression appeared in *State Street*

statements fostered a view that ineligibility for patenting would be rare to non-existent. *Hughes Aircraft Co. v. United States*, 148 F.3d 1384, 1385 (Fed. Cir. 1998) (noting that “[w]e have come a long way from the days when judges frowned on patents as pernicious monopolies deserving scant regard. Today, patents are the backbone of much of the national economy, and, as this court has recently held, *virtually anything is patentable. . . .*”) (citation omitted, emphasis added) (Clevenger, J., dissenting from order declining suggestion for rehearing *en banc*, in which Gajarsa, J. joined.).

This Court should declare that the “useful, concrete, and tangible results” language in *State Street* is not a free ticket to patent-eligibility. As argued *supra*, the plain language of the patent statute requires that patent-eligible subject matter be limited to things that are physical and processes that are physically transformative. For combinations, patent eligibility requires that discrete elements each satisfy such a test for physicality. To provide the greatest clarity in the law, this Court should overrule *Alappat*, *State Street*, and *AT&T* to the extent that they hold anything inconsistent with the analysis herein. *State Street*’s narrow section 101 holding should be

several times (See *State St. Bank*, 149 F.3d at 1373 and 1375). Finally, *AT&T* recited this mantra, or words of similar import, at least ten times. See *AT&T Corp.*, 172 F.3d at 1358-59.

reaffirmed, but its oft-quoted text referencing “useful concrete and tangible results” should be retired from the patent lexicon.

2. Rigorous Patent-Eligibility Rules May Quell Calls for Destructive Congressional Intervention.

Viewing all manner of inventions as patent-eligible solely on account of their “useful, concrete, and tangible results” has produced an unprecedented flood of patents. Critics of the patent system allege these patents are particularly difficult to understand, let alone properly examine. James Bessen & Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovation at Risk*, at 18-19, 152-55, 160-64, and 198-200 (Princeton Univ. Press 2008). In the same vein, Supreme Court Justice Anthony Kennedy recently commented, “[t]he potential vagueness and suspect validity of [business method] patents may affect the calculus under the four-factor test.” *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 397 (2006) (Kennedy, J., concurring).

This patenting torrent has fueled a public debate focused on limiting or denying patents by subject matter classifications, such as business methods, tax strategy methods, estate planning methods, and like subject matter categories. Tax strategy patents have been singled out as a particularly aggravating type of business method patent. As of February 26,

2008, some sixty-four patents had been issued for tax-related advice, and over 107 such applications had been published. *See* American Bar Ass'n Listing of Patents Classified as Tax Strategy Patents by the PTO, *available at* <http://www.abanet.org/tax/patents/issuedtaxstrategy Patents.pdf>; American Bar Ass'n Listing of Patent Applications Classified as Tax Strategy Patents by the PTO, *available at* <http://www.abanet.org/tax/patents/publishedtaxstrategyapp.pdf>. In response, Congress is considering the piecemeal solution of barring such patents statutorily. Patent Reform Act of 2007, H.R. 1908, 110th Cong. § 10 (2007). A separate bill in the Senate deals selectively with tax planning strategies. S. 2369, 110th Cong. (2007).

Companies whose businesses and products are alleged to infringe “abstract” patents express an understandable concern that the reach of such patents cannot be anticipated and that invalidating such patents on other grounds is expensive, difficult and often futile. Bessen, *supra* p. 24, at 8-9, 70-71, and 160-63. Their response has been to advocate “remedial” legislation that would radically weaken the commercial impact of all patents. The prime target has been patent enforcement mechanisms. In the present Congress and the last, the litany of legislative proposals targeted at weakening enforcement include: limiting the acts that constitute

infringement, limiting the availability of injunctive relief, limiting the grounds for punitive damages, limiting the size of compensatory damages, limiting the patent owner's choice of venue, and limiting the prospect for prompt resolution of patent infringement of valid patents by permitting interlocutory appeals under more circumstances. Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). Patent Reform Act of 2007, S. 1145, 110th Cong. (2007) and H.R. 1908, 110th Cong. (2007).

This appeal affords an opportunity to moot such efforts by restoring rigor to the primal test of patentability: patent-eligibility. Retiring the *State Street dicta* on “results” would respond to the charges of critics that our patent system fails to operate in accord with common-sense notions of what should be and should not be eligible for patenting. The section 101 and Paragraph 6 analyses herein provides the Court a common-sense “bright line” consistent with constitutional authority, true to the statute, carefully built upon Supreme Court precedent, and aligned with a layman's understanding that patents are for *things* not ideas. It does so without a proscriptive rule on “business method patents” or detracting from Congress's intent that “anything under the sun made by man” be a core principle for interpreting the law of patent-eligibility.

Amici recognize that the patent-eligibility analysis herein might be criticized as anti-patent, as threatening settled expectations, or as unsuited for the emerging technologies of the 21st century. Such criticisms would be misplaced.

First and foremost, a clue that the current interpretations of section 101 and Paragraph 6 requirements lack needed rigor can be seen in the unprecedented level of patenting that has emerged in certain technologies and the complaints that the patents being issued are all but unintelligible to skilled patent professionals seeking to understand their reach and implications. Bessen, *supra* p. 24, at 8-11, 53-54, 68-71, and 212-13. Further, there is little evidence that rigorous application of other statutory requirements can substitute for a lax application of patent-eligibility requirements. *Id.* at 160-64.

Secondly, rigorous application of patent-eligibility standards is fundamentally pro-patent. It holds the clear promise for restoring confidence in the patent system. At the same time, the section 101 and Paragraph 6 analysis herein permits patent-eligibility assessments to proceed in an entirely non-discriminatory manner, the key to maintaining a unitary patent system. Software-implemented processes, for example, will be assessed for patent-eligibility no differently from biotechnology-related

processes. This reaffirmation of the patent system across the entire spectrum of the useful arts is the essence of a pro-patent posture.

Finally, as to any charge that the proffered analytical framework of this brief is grounded in the 19th century industrial economy rather than 21st century information economy, it is Congress, not the courts, that is authorized to recalibrate patent-eligibility standards. What Congress is *unlikely* to do is simply feed the current cynicism about modern patenting by amending “structure, material or acts” in Paragraph 6 to “*information, the exercise of human intellect, or structure, material or acts.*”

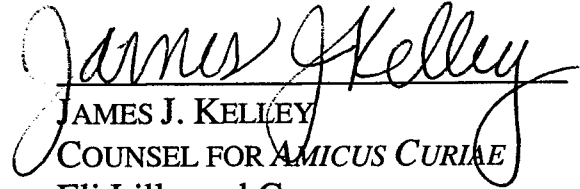
III. CONCLUSION

Patent eligibility rests on a few simple words of the patent statute that have meanings long settled by the courts. The requirements that they impose need only to be applied to the invention *as actually claimed*. Doing so would end the need for supplemental inquiries, many of which have confused and complicated patent eligibility questions. If section 101 is interpreted as containing an *exhaustive* listing of categories of inventions that are patent eligible and Paragraph 6 is interpreted as limiting the content of discrete elements for inventions claimed as combinations, then nothing more should be needed to assess patent-eligibility for claims.

In the absence of clear guidance from this Court, the controversies described herein will likely continue. The above discussion provides a principled and foundational approach to reattaching patent-eligibility to what an invention, as claimed, *is*. It provides an analytical framework for responding to critics that the reach of the “useful Arts” should be constrained by Congress. It comports with common-sense notions about patenting.

This Court should act, even if its actions mean unsettling the settled expectations of some over the past decade. It is precisely those newly-settled expectations that have unsettled respect for the patent system among broad swaths of the public and certain industry sectors. Unsettling is now essential to righting the patent system on the most basic issue of patenting. The exercise of human intellect cannot be patented, but it is now needed to define precisely what can be.

Respectfully submitted,

A handwritten signature in cursive script that reads "James J. Kelley". The signature is written in black ink and is positioned above the typed name and title.

JAMES J. KELLEY

COUNSEL FOR *AMICUS CURIAE*

Eli Lilly and Company

Lilly Corporate Center

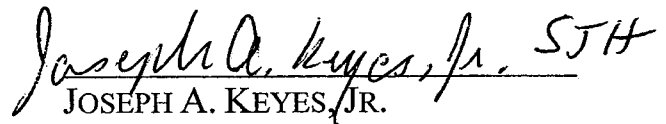
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Respectfully submitted,

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United States Court of Appeals for the Federal Circuit

IN RE BERNARD L. BILSKI AND RAND A. WARSAW

Appeal from the United States Patent and Trademark Office
Board of Patent Appeals and Interferences
Appeal No. 2007-1130
Application No. 08/883,892

Unsworn Declaration of Authority Pursuant to FCR 47.3 (d)

I, Stephen Heinig, Senior Research Fellow at the Association of American Medical Colleges, provide this Unsworn Declaration of Authority pursuant to Federal Circuit Rule 47.3 (d).

The Association of American Medical Colleges ("AAMC") decided very recently to join the *amicus* brief of Eli Lilly and Company in the matter of *In re Bilski* (07-1130), which brief is due to be filed in the United States Court of Appeals for the Federal Circuit on Monday, April 07, 2008.

Joseph A. Keyes, Jr. is the attorney who is representing AAMC in this matter.

Joseph A. Keyes, Jr. is not available to sign the *amicus* brief, entry of appearance, and certificate of interest on behalf of AAMC.

AAMC and Joseph A. Keyes, Jr. have authorized me, Stephen Heinig, to sign each of the mentioned documents, which I have done, placing my initials "SH" beside each of the signatures.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury, that the foregoing is true and correct.

Executed on April 7, 2008 By: Stephen J. Heinig

Printed Name STEPHEN J. HEINIG

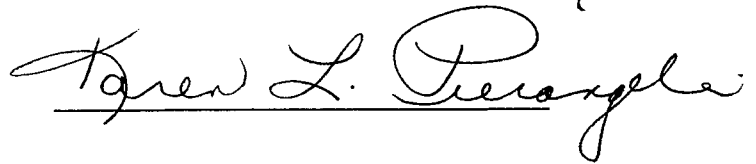
CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of April, 2008, two (2) bound copies of the foregoing BRIEF FOR *AMICI CURIAE* Eli Lilly and Company and the Association of American Medical Colleges were caused to be served, via Federal Express, to:

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(571) 273-0373 – Fax

I also hereby certify that on this 7th day of April, 2008, an original and thirty (30) bound copies of the foregoing BRIEF FOR *AMICI CURIAE* Eli Lilly and Company and the Association of American Medical Colleges were filed, via hand delivery, in the Office of the Clerk, United States Court of Appeals for the Federal Circuit.



Karen L. Perangle

**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME
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REQUIREMENTS**

I certify that this brief contains 5,999 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(a)(7)(B)(iii). In preparing this certificate, I have relied on the word count of the word processing system used to prepare this brief, including headings, footnotes, and quotations. This brief therefore complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B).

I certify that this brief has been prepared in a proportionally spaced typeface using Microsoft Word 97-2003 in fourteen (14) point, Times New Roman font. This brief therefore complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6).

By:

Dated: April 7, 2008

A handwritten signature in cursive script, reading "James Kelley", is written over a solid horizontal line.