

Appeal No. 2007-1130
(Serial No. 08/833,892)

UNITED STATES COURT OF APPEAL
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.

AMICUS CURIAE BRIEF OF
BIOTECHNOLOGY INDUSTRY ORGANIZATION

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TABLE OF CONTENTS

I.	INTEREST OF AMICUS	1
II.	ISSUES PRESENTED	3
III.	INTRODUCTION.....	3
IV.	ARGUMENT	5
1.	Claim 1 of the 08/833,892 Patent Application Must Be Analyzed Under the Relevant Statute and Supreme Court Precedent.....	5
2.	The Governing Standard Regarding the Patent-Eligibility of Process Claims Is Found in § 101, Supreme Court Precedent and Federal Circuit Law	6
3.	A Mental Step Must Be Presumed Incapable of Imparting Patentability on an Otherwise Unpatentable Process Claim	14
4.	A Process Need Not Result in a Physical Transformation of an Article or Be Tied to a Machine to Be Patent-Eligible Under § 101.....	17
5.	<i>State Street</i> and <i>AT&T</i> are not Inconsistent with Supreme Court and Federal Circuit Precedent and Need Not Be Overruled	21
V.	CONCLUSION	25

TABLE OF AUTHORITIES

CASES

<i>AT&T Corp. v. Excel Communications, Inc.</i> , 172 F.3d 1352 (Fed. Cir. 1999)	passim
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980)	passim
<i>Diamond v. Diehr</i> , 450 U.S. 180 (1981)	passim
<i>Funk Bros. Seed Co. v. Kalo Co.</i> , 333 U.S. 127 (1948)	26
<i>Gottschalk v. Benson</i> , 409 U.S. 63(1972)	passim
<i>In re Bilski</i> , No. 2007-1130, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008)	3, 5
<i>In re Comiskey</i> , 499 F.3d 1365 (Fed. Cir. 2007)	16, 18
<i>In re Heritage</i> , 150 F.2d 554 (C.C.P.A. 1945)	9
<i>In re Lintner</i> , 458 F.2d 1013 (C.C.P.A. 1972)	17
<i>In re Muchmore</i> , 433 F.2d 824 (C.C.P.A. 1970)	17
<i>In re Schrader</i> , 22 F.3d 290 (Fed. Cir. 1994)	24
<i>In re Warmerdam</i> , 33 F.3d 1354 (Fed. Cir. 1994)	10, 16
<i>Laboratory Corp. v. Metabolite Labs., Inc.</i> , 126 S. Ct. 2921 (2006)	8, 13, 24, 27
<i>Mackay Radio & Telegraph Co. v. Radio Corp. of Am.</i> , 306 U.S. 86 (1939)	9, 19, 25
<i>O'Reilly v. Morse</i> , 56 U.S. 62 (1853)	11, 12, 13, 25
<i>Parker v. Flook</i> , 437 U.S. 584 (1978)	passim
<i>Perricone v. Medicis Pharmaceutical Corp.</i> , 432 F.3d 1368 (2005)	21
<i>Perrin v. United States</i> , 444 U.S. 37 (1979)	7
<i>Risdon Iron & Locomotive Works v. Medart</i> , 158 U.S. 68 (1895)	13
<i>Smithkline Beecham Corp. v. Apotex</i> , 365 F.3d 1306 (2004)	17

<i>State St. Bank & Trust Co. v Signature Fin. Group</i> , 927 F. Supp. 502 (D. Mass. 1996).....	13
<i>State Street Bank & Trust v. Signature Financial Group</i> , 149 F.3d 1368 (Fed. Cir. 1998).....	passim
<i>Stern v. Trustees of Columbia University</i> , 434 F.3d 1375 (2006).....	21
<i>Tilghman v. Proctor</i> , 102 U.S. 707 (1880).....	9, 19
<i>United States v. Dubilier Condenser Corp.</i> , 289 U.S. 178 (1933).....	7

STATUTES

35 U.S.C. § 101.....	passim
35 U.S.C. § 282.....	23
35 U.S.C. §§ 102, 103 and 112.....	passim

OTHER AUTHORITIES

H.R. 3760.....	4
----------------	---

RULES

PTO’s Examination Guidelines, 61 Fed. Reg. 7478, 7479 (1996)).....	9
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I. INTEREST OF AMICUS

The Biotechnology Industry Organization (BIO) is a trade association representing of over 1100 companies, academic institutions, and biotechnology centers. BIO members are involved in the research and development of biotechnological healthcare, agricultural, environmental and industrial products. In the healthcare sector alone, the biotechnology industry has more than 370 therapeutic products currently in clinical trials being studied to treat more than 200 diseases. The vast majority of BIO members are small companies that have yet to bring a product to market and attain profitability.

BIO has a great interest in this case because its members rely heavily on the patent system to protect their platform technologies and to grow their businesses in the decades to come. By building quality patent portfolios, today members are able to secure the financial support needed to advance biotechnology products through regulatory approval to the marketplace, and to engage in the partnering and technology transfer that is necessary to translate basic life science discoveries into real-world solutions for disease, pollution, and hunger. Perhaps more than any other sector of this Nation's economy, biotechnology businesses understand the impact that carelessly conceived judicial exclusions from patent-eligibility can have on nascent technologies. For biotechnology, the debate about patent-eligibility under 35 U.S.C. § 101 did not end with *Diamond v. Chakrabarty*, 447

U.S. 303 (1980). As the outer boundaries of biotechnology continue to be expanded, BIO's members fully expect that new technologies and achievements that today seem inconceivable will continue to test the limits of patentable subject matter – both in the courts and in a broader societal discourse. BIO optimistically looks forward to that process, and submits this brief to assist this Court's long-standing efforts to guide the evolution of patent law in a tempered, predictable way that will accommodate new emerging technologies to the benefit of all and guard against unforeseen consequences in the life sciences.

BIO has no stake in the parties to this litigation or the specific disposition of this case, nor have the parties contributed to preparing this brief.

II. ISSUES PRESENTED

The Court's February 15, 2008 Order poses five questions:

- (1) Whether claim 1 of the 08/833,892 patent application claims patent-eligible subject matter under § 101?
- (2) What standard should govern in determining whether a process is patent-eligible subject matter under § 101?
- (3) Whether the claimed subject matter is not patent-eligible because it constitutes an abstract idea or mental process; when does a claim that contains both mental and physical steps create patent-eligible subject matter?
- (4) Whether a method or process must result in a physical transformation of an article or be tied to a machine to be patent-eligible subject matter under § 101?
- (5) Whether it is appropriate to reconsider *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998), and *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352 (Fed. Cir. 1999), in this case and, if so, whether those cases should be overruled in any respect?

In re Bilski, No. 2007-1130, 2008 WL 417680 (Fed. Cir. Feb. 15, 2008) (Order).

III. INTRODUCTION

Section 101 defines patent-eligible subject matter as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” Although the Supreme Court has identified categories of subject matter that do not fit into a statutory class, i.e., laws of nature, natural phenomena, and abstract ideas, the Court has construed § 101 broadly, noting that Congress intended statutory subject matter to “include anything under the sun that is made by man.” *Chakrabarty*, 447 U.S. at 309 n.6 (quoting Hearings on H.R.

3760 before Subcommittee No. 3 of the House Committee on the Judiciary, 82nd Cong., 1st Sess., 37 (1951)).

This Court should not create a new test for a method or process invention to be patent eligible. Such a test would likely be inconsistent with § 101 and the Supreme Court's broad interpretation of patentable subject matter and would add to already-existing confusion over the scope of patent-eligible subject matter. It also may have the unintended consequence of frustrating progress in the biotechnological arts. Therefore, BIO believes the current standard for patentable subject matter is appropriate -- a process or method is eligible for patenting under § 101, when viewed as a whole, unless it is limited to a law of nature, natural phenomenon, or an abstract idea.

BIO also notes that the scope of questions 2, 3 and 4 appear to reach beyond the specific issue in this case: Whether a business method that does not result in a physical transformation and is not necessarily computer-implemented is patentable subject matter under § 101. The potential breadth of the answers to questions 2, 3, and 4 raises serious concerns for BIO members. Certain answers could have unintended and unforeseen consequences for the biotechnology industry and frustrate members' ability to obtain full protection of biotechnological inventions.

Although different technologies are treated under the same patent statute, different technologies typically create very different factual patterns and different factual inquiries. Different technologies also frequently require different claim drafting techniques to obtain full protection of the types of inventions arising in each. Thus, cases concerning computer arts and business method arts are difficult to apply to the biotechnological arts. Further, application of broad language in cases concerning the computer and business method arts to the biotechnical arts may frustrate rather than promote progress in the biotechnological arts.

For these reasons, BIO respectfully asks the Court to consider the impact its opinion in this case may have on the biotechnology industry and carefully craft its analyses and holdings based on the facts in this case.

IV. ARGUMENT

As a “friend of the Court,” BIO addresses the Court’s five questions.

1. Claim 1 of the 08/833,892 Patent Application Must Be Analyzed Under the Relevant Statute and Supreme Court Precedent

BIO’s expertise is in the biotechnological arts, not in business methods or commodity trading. Thus, BIO does not take a position regarding whether *Bilski’s* claim 1 falls within §101, except to note that, contrary to the USPTO’s position (USPTO’s Supplemental Br. at 5), a patent-eligible process does not require physical transformation or machine-implementation. To the extent the USPTO relies upon footnote 9 in *Parker v. Flook*, 437 U.S. 584 (1978), the USPTO has

misread that footnote. The Supreme Court clearly stated in *Flook*, that “a valid process patent may issue *even if it does not* meet one of these qualifications [transformation or machine-implementation] of our earlier precedent.” (emphasis added). *Id.* at 589 n.9. See also *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972) (“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.”). BIO discusses this issue further in response to Question 4, *infra* at pp. 17-21.

2. The Governing Standard Regarding the Patent-Eligibility of Process Claims Is Found in § 101, Supreme Court Precedent and Federal Circuit Law

“In cases of statutory construction, we begin with the language of the statute.” *Diamond v. Diehr*, 450 U.S. 180, 181-82 (1981). Section 101 reads in relevant part: “Whoever invents or discovers any new and useful process . . . may obtain a patent therefor, subject to the conditions and requirements of this title.” The statute does not qualify or limit patentable “processes” to those that physically transform subject matter or that otherwise involve one of the other categories of patent-eligible subject matter. Rather, as the Supreme Court has stated:

Unless otherwise defined, “words will be interpreted as taking their ordinary, contemporary, common meaning.” *Perrin v. United States*, 444 U.S. 37, 42 . . . (1979) and, in dealing with the patent laws, we have more than once cautioned that “courts ‘should not read into the

patent laws limitations and conditions which the legislature has not expressed.” *Diamond v. Chakrabarty*, [447 U.S. at] 308, quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 . . . (1933).

Diehr, 450 U.S. at 182; *see also* H.T. Markey, “Why Not The Statute?,” 65 J. Pat. Off. Soc’y 331-40 (1983).

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

a new mineral in the earth or a new plant found in the wild is not patentable subject matter. Likewise Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are “manifestations of . . . nature, free to all men and reserved exclusively to none.”

Chakrabarty, 447 U.S. at 309, *quoted in Diehr*, 450 U.S. at 185. The Supreme Court in *Diehr* stated that *Benson* and *Flook* “stand for no more than these long-established principles.” *Diehr*, 450 U.S. at 185 (emphasis added). The Supreme Court explained that the mathematical formulae in *Benson* and *Flook* could be equated to a law of nature. *Id.* at 185-87.

Nevertheless, an application of a law of nature, natural phenomenon or abstract idea can be patented as part of a process. *See Diehr*, 450 U.S. at 187. In fact, “all inventions can be reduced to underlying principles of nature.” *Id.* at 189 n.12; *see also Laboratory Corp. v. Metabolite Labs., Inc.*, 126 S. Ct. 2921, 2926

(2006) (“many a patentable invention rests upon its inventor’s knowledge of natural phenomena; many ‘process’ patents seek to make abstract intellectual concepts workably concrete; and all conscious human action involves a mental process”). Thus, many processes are unquestionably patent eligible, such as traditional industrial processes, processes that apply traditional life-science technology, processes for the treatment or cure of diseases, and the like.

Certain concepts have done more to confuse the § 101 analysis than to clarify it. These include the mathematical algorithm and business methods exceptions, mental steps, physical transformation, machine-implementation, post-solution activity, preemption and the like. *See, e.g., Diehr*, 450 U.S. at 188 (preemption); *Flook*, 437 U.S. at 591 (post-solution activity); *Benson*, 409 U.S. at 66 (mathematical algorithm); *In re Heritage*, 150 F.2d 554, 556 (C.C.P.A. 1945) (mental steps); *Mackay Radio & Telegraph Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939) (machine implementation); *Tilghman v. Proctor*, 102 U.S. 707, 721 (1880) (physical transformation).

This Court has recognized the mischief such concepts can cause. *See, e.g., State Street Bank & Trust v. Signature Financial Group*, 149 F.3d 1368, 1373 n.4 (Fed. Cir. 1998) (designation as a mathematical algorithm “has led to some confusion).

By keeping in mind that the mathematical algorithm is unpatentable only to the extent that it represents an abstract idea, this confusion may be ameliorated.”); *Id.* at 1377 (quoting with approval the PTO’s Examination Guidelines, 61 Fed. Reg. 7478, 7479 (1996)): “Claims should not be categorized as methods of doing business. Instead such claims should be treated like any other process claims.”); *In re Warmerdam*, 33 F.3d 1354, 1359 n.2 (Fed. Cir. 1994) (“Efforts to explain nonstatutory subject matter in other terms has bred such phrases as ‘method of doing business’, ‘transformation of subject matter,’ and ‘reactions of an individual’”) (internal citations omitted).

There is also confusion between what is “patent-eligible” under § 101 and what is patentable under 35 U.S.C. §§ 102, 103 and 112. *Compare Diehr*, 450 U.S. at 189-90 (“question therefore of whether a particular invention is novel is ‘wholly apart from whether the invention falls into a category of statutory subject matter.’”) *with Flook*, 437 U.S. at 594 (“process is unpatentable under § 101, not because it contains a mathematical algorithm . . . but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.”). This confusion is most apparent when courts rely on the “preemption” concept to deny § 101 status to a claim. “Preemption” is a claim breadth issue, appropriately considered under § 112, not § 101. *See, e.g., State*

Street, 149 F.3d at 1377 (“Whether the patent’s claims are too broad to be patentable is not to be judged under § 101, but rather under §§ 102, 103 and 112.”).

If a claim were granted to an abstract idea, law of nature, or natural phenomenon *per se*, then that claim would wholly preempt all uses of such an idea, law of nature or natural phenomenon. To the extent cases have so held, those holdings are consistent with § 101. *See, e.g., Benson*, 409 U.S. at 71-72 (“patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself”). However, when a claim limits such a use, the concept of preemption should not be applied. *See O’Reilly v. Morse*, 56 U.S. 62, 112-16 (1853).

A patent grants the inventor the right to exclude others from practicing his or her claimed invention, in other words, to *preempt* others from making, using, selling, offering for sale, or importing the claimed invention. The scope of this right depends upon what is in the prior art and the inventor’s ability to satisfy § 112. “Pioneering” inventions, such as Morse’s telegraph, often are difficult to fully protect. Typically there is little prior art to keep a pioneer inventor from obtaining patent protection commensurate in scope with the pioneer’s contribution. However, meeting § 112 for the full scope of the claim is more difficult, given the potentially broad scope of the claimed subject matter and lack of guidance from others in the field. *See, e.g., Morse*, 56 U.S. at 111, 112-13 (admitting Morse was

the “first and original inventor of the Telegraph” but voiding his broad claim to “the use of the motive power of the electric or galvanic current, which I call electromagnetism, however developed for marking or printing intelligible characters, signs, or letters, at any distances”).

The real issue in *Morse* was one of claim breadth, not of patent-eligibility:

And if he [Morse] can secure the exclusive use by his present patent he may vary it with every new discovery and development of the science, and need place no description of the new manner, process, or machinery, upon the records of the patent office. And when his patent expires, the public must apply to him to learn what it is. In fine he claims an exclusive right to use a manner and process which he has not described and indeed has not invented, and therefore could not describe when he obtained his patent. *The court is of the opinion that the claim is too broad, and not warranted by law.*

Id. at 113 (emphasis added). The Supreme Court’s holding thus sounds more in § 112 of the 1952 Patent Act than in § 101. The claim was held to be impermissibly broad because Morse neither sufficiently described it nor possessed it. Such findings can readily be considered under § 112 without resort to “preemption” under § 101. Confusion arose because the Supreme Court later equated Morse’s claim to one “for a mere principle,” *Risdon Iron & Locomotive Works v. Medart*, 158 U.S. 68, 76 (1895), even though the claim’s use was limited to one “for marking or printing intelligible characters, signs, or letters, at any distances.” *Morse*, 56 U.S. at 112-13. *See also LabCorp*, 126 S. Ct. at 2922; *Flook*, 437 U.S. at 2530 (both omitting the use limitation when discussing *Morse*).

This confusion was recognized in *State Street*. The district court held *Signature's* claim nonstatutory, finding that the subject invention was “claimed sufficiently broadly to foreclose virtually any computer-implemented accounting method necessary to manage” a particular type of financial structure. *State St. Bank & Trust Co. v Signature Fin. Group*, 927 F. Supp. 502, 516 (D. Mass. 1996). This Court pointed out: “Whether the patent’s claims are too broad to be patentable is not to be judged under § 101, but rather under §§ 102, 103 and 112. Assuming the above statement is correct, it has nothing to do with whether what is claimed is statutory subject matter.” *State Street Bank*, 149 F.3d at 1377.

Finally, the temptation to consider a claim other than as a whole, such as through a point-of-novelty approach, also invites confusion. *See, e.g., Diehr*, 450 U.S. at 188 (“In determining . . . eligibility . . . under § 101, . . . claims must be considered as a whole.”); *AT&T*, 172 F.3d at 1357 (§ 101 question is whether “the claimed subject matter as a whole is a disembodied mathematical concept representing nothing more than a “law of nature” or an “abstract idea,” or if the mathematical concept has been reduced to some practical application rendering it ‘useful.’”).

To add to the challenge of determining whether claimed subject matter is patent eligible, policy issues tend to drive § 101 analyses in emerging technologies. This was the case in the biotechnological arts prior to *Chakrabarty* and is the case

today in the business methods area. The burden on the USPTO, attempting to examine subject matter in which examiner expertise is not yet sufficiently developed and on which there may be little patent or printed publication prior art, cannot easily be ignored. Further, the burden on the public faced with invalid patents when the USPTO cannot reliably do its job cannot be discounted. Other policy-based objections might be raised against “business method” claims comprising mental steps, such as: (a) no patent incentive is needed for such methods that, essentially, drive human behavior, because humans inherently figure out new ways of behaving and interacting all the time; (b) because such methods may be capable of easy re-invention, society would lose little by denying patent protection and forcing trade secret protection; (c) the need for a patent incentive is reduced for such claims because the development of such methods may require little investment that must be recouped through a patent monopoly; and (d) such claims would be extremely difficult to enforce because infringement is hard, or impossible, to detect.

Such policy issues are for Congress to address, not the courts. *See, e.g., Chakrabarty*, 447 U.S. at 322 (“It is the role of Congress, not this Court, to broaden or narrow the reach of patent laws.”); *Flook*, 437 U.S. at 596 (“we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress”); *Benson*, 409 U.S. at 73 (“considered action by Congress

is needed”). The old adage “bad facts make bad law” applies here. If “bad law” results in order to avoid patenting subject matter the USPTO cannot examine effectively (in this case a commodity trading process), the consequences for valuable inventions could be devastating.

The Court should restate the basic principles underlying a § 101 analysis and apply them to the facts of this case without relying on confusing concepts and approaches, without weighing policy considerations, and without broadening the reach of the traditional exclusions from patent-eligibility. By doing so, the governing standard of § 101 will be consistent with past Supreme Court precedent and that of this circuit and will not further confuse the law on patent-eligible subject matter.

3. A Mental Step Must Be Presumed Incapable of Imparting Patentability on an Otherwise Unpatentable Process Claim

This Court need not create a new category of subject matter excluded from patentability under § 101. A purely mental process in which all steps can be performed in the human mind is inherently abstract. Such a process is not subject to examination, or even detection, by others until at least one step is acted upon in a tangible way. Thus, if a claim is composed of purely mental steps, it cannot be patent eligible and should be excluded from § 101. *Benson*, 409 U.S. at 67 (“mental processes, and abstract intellectual concepts are not patentable”), *quoted with approval in In re Comiskey*, 499 F.3d 1365, 1377 (Fed. Cir. 2007). *See also*

Comiskey, 499 F.3d at 1378 (“Following the lead of the Supreme Court, this court and our predecessor court have refused to find processes patentable when they merely claimed a mental process standing alone . . .”).

A claim held patent ineligible in *In re Warmerdam*, 33 F.3d 1354, 1357 (Fed. Cir. 1994) provides an example of a claim composed of purely mental steps:

1. A method for generating a data structure which represents the shape of [sic] physical object in a position and/or motion control machine as a hierarchy of bubbles, comprising the steps of:

first locating the medial axis of the object and

then creating a hierarchy of bubbles on the medial axis.

While this Court has never expressly decided the issue, the same result must follow when all the claim steps are drawn so as to read on a process that can be performed in the human mind, even if that process is also capable of being performed by other means, such as on a computer. *Smithkline Beecham Corp. v. Apotex*, 365 F.3d 1306, 1331 (2004) (Gajarsa, Circuit Judge, concurring) (“In short, patent claims drawn broadly enough to encompass products that spread, and appear, and 'reproduce' through natural processes cover subject matter unpatentable under § 101--and are therefore invalid.”); *In re Lintner*, 458 F.2d 1013, 1015 (C.C.P.A. 1972) (“Claims which are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter.”); *In re Muchmore*, 433 F.2d 824, 826, 167 (C.C.P.A. 1970) (“it is clear that claim 14 is too broad in the sense of section 103, since it reads on both

obvious and unobvious subject matter"). To hold otherwise would subject the public to allegations of infringement due to purely mental acts.

When a process combines a purely mental step with an otherwise patent-eligible physical step, the process is necessarily patent-eligible under § 101. Any other outcome would yield illogical results. *See, e.g., Diehr*, 450 U.S. at 181 (noting that the CCPA in *Diehr* had held that “a claim drawn to subject matter otherwise statutory does not become nonstatutory because a computer is involved”); *Comiskey*, 499 F.3d at 1379-80 (holding patent eligible claims to an “otherwise unpatentable mental process” in combination with a “general purpose computer or modern communications devices”).

However, when such a process claim would be unpatentable under 35 U.S.C. §§102, 103 or 112 but for the inclusion of an abstract mental step, patentability may be impacted under these sections. *See, e.g., Diehr*, 450 U.S. at 191; *Comiskey*, 499 F.3d at 1380. This is not because the Court must dissect the claim and ignore the abstract idea. Rather the Court must *presume* that the purely mental step cannot impart patentability on an otherwise unpatentable claim because it cannot be examined under the Patent Act. *See* § 101 (“Whoever invents or discovers any new and useful process . . . may obtain a patent therefor, *subject to the conditions and requirements of this title*”) (emphasis added). While this difference may appear to be one without substance, it is not. Section 101 requires that claimed

patent-eligible subject matter satisfy the “conditions and requirements of this title.” If a process claim would be unpatentable *but for the inclusion of a purely mental step*, then it must be presumed the claim as a whole does not satisfy the conditions and requirements of § 102, 103, or 112. However, the applicant or patentee would have the opportunity to rebut such a presumption with an affirmative showing.

4. A Process Need Not Result in a Physical Transformation of an Article or Be Tied to a Machine to Be Patent-Eligible Under § 101

A process that results in a physical transformation or is tied to a machine *is* patent eligible. *See, e.g., Diehr*, 450 U.S. at 192 (“when [a claimed invention] is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of § 101”); *Mackay Radio & Telegraph*, 306 U.S. at 94; *Tilghman*, 102 U.S. at 721.

However, the absence of such a relationship is not sufficient to declare the process ineligible for patent protection. *See, e.g., Benson*, 409 U.S. at 71 (“It is argued that a process patent must either be tied to a particular machine or apparatus or must operate to change articles or materials to a ‘different state or thing.’ We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents.”); *Flook*, 437 U.S. at 588 n.9 (“An argument can be made . . . 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.”) (internal citations omitted); *AT&T*, 172 at 1358 (“notion of ‘physical transformation’ can be misunderstood. . . . [I]t is not an invariable requirement, but merely one example of how a mathematical algorithm may bring about a useful application.”).

BIO recognizes that the Supreme Court has stated: “Transformation and reduction of an article ‘to a different state or thing’ is the clue to the patentability of a process claim that does not include particular machines.” *Diehr*, 450 U.S. at 184 (quoting *Benson*, 409 U.S. at 70). However, that statement must be taken in context and in view of the facts in *Diehr*—facts establishing a transformation was dictated by the claim in issue. While transformation may have been “the clue” in *Diehr*, given the facts before the Court, it is quite clear neither transformation nor a machine limitation is required in all process cases. *See Benson*, 409 U.S. at 71 (quoted *supra*).

Many process claims that neither result in a physical transformation of an “article” nor are tied to a machine have issued and are clearly patent-eligible, such as the following:

1. A method for treating hypertension or glaucoma in a primate subject’s eye comprising periodically contacting the surface of the eye with an amount of an eicosanoid or an eicosanoid derivative effective to reduce intraocular pressure in the eye without any

substantial initial increase in said pressure and to maintain reduced intraocular pressure. [U.S. Patent No. 4,599,353 (patent in issue in *Stern v. Trustees of Columbia University*, 434 F.3d 1375 (2006))]

1. A method for treating skin sunburn comprising topically applying to the skin sunburn a fatty acid ester of ascorbic acid effective to solubilize in the lipid-rich layers of the skin an amount effective to scavenge therefrom free radicals present as a result of transfer of energy to the skin from the ultraviolet radiation which produced said sunburn. [U.S. Patent No. 5,409,693 (one of patents in issue in *Perricone v. Medicis Pharmaceutical Corp.*, 432 F.3d 1368 (2005))]

3. A method for classifying two or more genotypes of *Zea mays*, said method comprising the steps of:

- a) obtaining an energy value of said genotypes by aerial surveillance;
- b) performing operations on said energy value to develop a descriptor of a phenotypic trait in said genotypes;
- c) using said descriptor to compare values of said phenotypic trait in said *Zea mays* genotypes; and
- d) classifying said *Zea mays* plants based on said descriptor. [U.S. Patent No. 5,764,819]

1. A method for making a prognosis of disease course in a human cancer patient, the method comprising the steps of:
(a) obtaining a sample of a tumor from the human cancer patient;
(b) determining a level of nuclear localization of p53 protein in the tumor sample and comparing the level of nuclear localization of p53 in the tumor sample with the level of nuclear localization of p53 protein in a non-invasive, non-metastatic tumor sample;
(c) determining a level of thrombospondin 1 expression in the tumor sample and comparing the level of thrombospondin 1 expression in a non-invasive, non-metastatic tumor sample;
(d) determining by immunohistochemistry an extent of microvascularization in the tumor sample and comparing the extent of microvascularization in the tumor sample with the extent of microvascularization in a non-invasive, non-metastatic tumor sample;

wherein said prognosis is predicted from considering a likelihood of

further neoplastic disease which is made when the level of nuclear localization of in the tumor sample is greater than the level of nuclear localization of p53 protein in the non-invasive, non-metastatic tumor sample; the level of thrombospondin 1 expression in the tumor sample is less than the level of thrombospondin 1 expression in the non-invasive, non-metastatic tumor sample; and the extent of microvascularization in the tumor sample is greater than the extent of microvascularization in the non-invasive, non-metastatic tumor sample, and wherein the human cancer patient has breast cancer or prostate cancer. [U.S. patent 6,303,324]

1. A method for predicting the time of onset of the development of clinical signs of immunodeficiency associated with disease progression in an individual infected with human immunodeficiency virus (HIV) comprising:

- (a) determining a level of expression of HIV messenger RNA (mRNA) in peripheral blood cells obtained from the individual; and
- (b) correlating the level of expression of HIV messenger RNA with the time of onset of the development of clinical signs of immunodeficiency; wherein
 - (i) a high level of HIV mRNA correlates with a high likelihood for the development of clinical signs of immunodeficiency within about two years; and
 - (ii) a low level of HIV mRNA or no detectable HIV mRNA correlates with a low likelihood of the development of clinical signs of immunodeficiency for at least five years. [U.S. patent 5,674,680]

These issued process claims are presumed valid. 35 U.S.C. § 282. Yet, none is limited by a physical transformation of an article or machine implementation. Nevertheless, they are neither abstract ideas, laws of nature nor natural phenomena but instead each provides a valuable contribution to the pharmaceutical or biotechnological useful arts.

The “statutory definition of ‘process’ is broad,” *Flook*, 437 U.S. at 588 n.9, and only excludes from its scope laws of nature, natural phenomena, and abstract ideas *per se*. It does not exclude a practical application of any one of these categories. *See, e.g., Diehr*, 450 U.S. at 187. Determining whether patent claims involving emerging fields, such as business methods, fall within § 101 is not an easy task in view of the confusing concepts applied in prior caselaw, colored by political considerations. However, limiting processes to those involving a physical transformation of an article or ones tied to a machine is not the answer and would be contrary to the statute and to Supreme Court precedent. It would also frustrate advancements in the biotechnological arts.

5. *State Street* and *AT&T* are not Inconsistent with Supreme Court and Federal Circuit Precedent and Need Not Be Overruled

This Court in *State Street* addressed the patent eligibility of a claimed data processing system implemented on a computer. *State Street*, 149 F.3d at 1371-72. Appellant argued that the claim was not patent eligible, and was therefore invalid, under the mathematical algorithm and business methods exceptions. *Id.* at 1373-77. This Court properly rejected these arguments. *Id.* In so doing, the Court analyzed Supreme Court precedent, its own case law and that of the Court of Customs and Patent Appeals. It noted that “mathematical algorithms are not patentable subject matter to the extent that they are merely abstract ideas.” *Id.* at 1373. It further noted that “[The business method exception] is . . . an

unwarranted encumbrance to the definition of statutory subject matter in § 101, that [should] be discarded as error-prone, redundant, and obsolete.” *Id.* at 1375 (quoting with approval in *In re Schrader*, 22 F.3d 290, 298 (Fed. Cir. 1994) (Newman, J., dissenting)).

In *State Street*, this Court held that the “transformation of data . . . by a machine . . . into a final share price, constitutes a practical application of a mathematical algorithm, formula or calculation, because it produces ‘a useful, concrete and tangible result.’” *Id.* at 1373. Justice Breyer criticized this language in his dissent from the dismissal of a writ of certiorari in *LabCorp*, 126 S. Ct. at 2928 (joined by Justices Stevens and Souter). According to Justice Breyer, the Supreme Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary.” *Id.* (citing *Morse*, *Flook* and *Diehr*).

The difficulty with Justice Breyer’s criticism is that he extended the holding of *State Street* to all processes, and took it out of the specific factual context in which it was made -- machine-implemented data transformation. *See id.* (stating the case held “a process is patentable if it produces a ‘useful, concrete, and tangible result’”) (emphasis added). Further, he overlooked this Court’s unwavering application of the Supreme Court’s “judicially created exceptions, i.e., abstract ideas, laws of nature, etc.” *State Street*, 149 F.3d at 1372 n.1; *see also*

AT&T, 172 F.3d at 1355 (quoting *Diehr*, 450 U.S. at 185) (“the Court has specifically identified three categories of unpatentable subject matter: ‘laws of nature, natural phenomena, and abstract ideas’”). Finally, Justice Breyer does not acknowledge that the Supreme Court itself has used language similar to “useful, concrete and tangible result” in addressing § 101 issues. *See, e.g., Mackay Radio & Telegraph*, 306 U.S. at 94 (“While a scientific truth, or the mathematical expression of it, is not patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.”); *Funk Bros. Seed Co. v. Kalo Co.*, 333 U.S. 127, 130 (1948) (“He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.”).

In *AT&T*, this Court considered the patent-eligibility of method claims reciting the steps of “generating a message record for an interexchange call between an originating subscriber and a terminating subscriber; and including, in said message record, a primary interexchange carrier (PIC) indicator having a value which is a function of whether or not the interexchange carrier associated with said terminating subscriber is a predetermined one of said interexchange carriers.” 172 F.3d at 1354. In analyzing the patent-eligibility of *AT&T*’s claims, this Court employed language similar to that criticized by Justice Breyer. *Id.* at

1358 (“Because the claimed process applies the Boolean principle to produce a useful, concrete, tangible result without preempting other uses of the mathematical principle, on its face the claimed process comfortably falls with the scope of §101.”).

State Street and *AT&T* are consistent with the language of § 101 and controlling precedent and should not be revisited on the basis of Justice Breyer’s dissent in *LabCorp*. To the extent this Court believes that it must reemphasize the specific factual context in which it reached its holdings in *State Street* and *AT&T* (machine-implemented data transformation systems and methods), it can do so in this case without disturbing the earlier holdings -- holdings clearly reached after careful consideration of the facts of each case and the applicable law.

V. CONCLUSION

For the foregoing reasons, BIO respectfully requests this Court to maintain the time-tested standard for patent eligibility under § 101 and not accept the invitation to adopt tests that will only confuse the § 101 analysis and jeopardize full protection of otherwise patentable inventions.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Amicus Curiae Biotechnology Industry Organization ("BIO") submits its brief under Rules 32(a)(6)(A) and 32(a)(7)(B) of the Federal Rules of Appellate Procedure. Thus, I hereby certify that *Amicus Curiae* BIO's brief complies with the type-volume limitation therein provided, and I further certify that the foregoing Brief for *Amicus Curiae* BIO was prepared with Microsoft Word 2003 using a proportional spaced typeface using 14-point Times New Roman, and contains 6,055 words, excluding the Table of Contents and Table of Authorities, as determined by Microsoft Word 2003, including footnotes, excluding the table of contents, table of authorities and certificates of counsel.

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