

IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES
(D/B/A MAYO MEDICAL LABORATORIES)
AND MAYO CLINIC ROCHESTER,

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

**BRIEF OF NEW YORK INTELLECTUAL PROPERTY
LAW ASSOCIATION AS *AMICUS CURIAE*
IN SUPPORT OF NEITHER PARTY**

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INTEREST OF *AMICUS CURIAE*¹

The New York Intellectual Property Law Association (“NYIPLA”) respectfully submits this brief *amicus curiae* in support of neither party.² NYIPLA is professional association of more than 1,500 attorneys whose interests and practices lie in the area of patent, copyright, trademark, trade secret and other intellectual property law.

NYIPLA members include a diverse array of attorneys specializing in patent law, from in-house counsel for businesses that own, enforce and challenge patents, to attorneys in private practice who represent inventors in various proceedings before the United States Patent and Trademark Office. A substantial percentage of NYIPLA attorneys participate actively in patent litigation, representing both patent owners and accused infringers. NYIPLA members frequently engage in

¹ Pursuant to Rule 37.6, no counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than NYIPLA, its members, or its counsel made a monetary contribution to its preparation or submission.

² Petitioners and Respondent have consented to the filing of briefs in support of either party or neither party in docket entries dated August 8 and 4, 2011, respectively.

patent licensing matters, representing both patent licensors and licensees.

NYIPLA's interest in this case stems from the suggestion in the patent law community that the Court may use this case as a vehicle for creating one or more strict categories of patent-ineligible subject matter under 35 U.S.C. § 101. The activities of NYIPLA members and practitioners depend on the consistently-applied and longstanding broad scope of patentable subject matter under the Patent Act. As a result, members have a strong interest in ensuring that the Court does not disturb the current clearly-defined framework governing the patentability of inventions that Congress set forth in the Patent Act and this Court has construed in its decisions.

NYIPLA expressly declines to take a position on whether the patent claims at issue in this case meet all of the statutory conditions of patentability. With that caveat in mind, however, NYIPLA respectfully submits that the Court should reaffirm its long-held conclusion that the scope of patent-eligible subject matter under 35 U.S.C. § 101 is extremely broad, encompasses any invention claiming a statutory class of patentable subject matter, and excludes only claims directed to laws of nature, physical phenomena and abstract ideas.

Regardless of the Court's ultimate decision on the questions the parties presented, NYIPLA urges the Court to reaffirm the rules governing the threshold patentability inquiry, synthesized in *Diehr*

and reaffirmed in *Bilski*, as those rules are clear, readily-implemented, and should not be disturbed.

SUMMARY OF ARGUMENT

After more than two decades of silence on the issue of patent eligibility under 35 U.S.C. § 101, this Court considered important principles relating to patent eligibility last year in *Bilski v. Kappos*, 561 U.S. ___, 130 S.Ct. 3218 (2010).

Significantly, *Bilski* reaffirmed the general principles and inquiries that govern patent eligibility under Section 101, first synthesized in *Diamond v. Diehr*, 450 U.S. 175 (1981). Specifically, the Court has adhered to and consistently applied an inquiry based on two questions:

1. Does the claimed subject matter fall within one of the four statutory categories of patent-eligible subject matter: (i) process, (ii) machine, (iii) manufacture or (iv) composition of matter (or any improvement thereof)?
2. Is the claimed subject matter directed to one of three so-called “fundamental principles,” *i.e.*, laws of nature, natural phenomena, or abstract ideas?

See Bilski, 130 S. Ct. at 3225; *Diehr*, 450 U.S. at 185 (citing, *inter alia*, *Gottschalk v. Benson*, 409 U.S. 63,

67 (1972) and *Parker v. Flook*, 437 U.S. 584, 589 (1978)).

Though the second question assures that a patent cannot claim a fundamental principle, this Court has long recognized that, as discussed in *Diehr* and *Bilski* and tracing its roots to hoary precedent, a patent claim may nonetheless be directed to the practical application of a fundamental principle (such as a method of curing rubber that uses a known algorithm).

This Court has developed more than two centuries of jurisprudence relating to what the Federal Circuit calls the “machine-or-transformation” test, a “useful tool” to determine whether a particular claim is directed to a fundamental principle or simply claims a practical application of a fundamental principle. In *Bilski*, the Court rejected the notion that the machine-or-transformation test was the sole or exclusive test to answer this question. Nonetheless, the Court recognized that the test remains a “useful tool” in the patentable subject matter eligibility analysis.

The Court should continue to apply these broad guidelines in determining patent eligibility. But NYIPLA respectfully submits that in order for the machine-or-transformation test to remain a useful tool, the Section 101 inquiry must end when the test is *met*. Other sections of the Patent Act establishing conditions of patentability—novelty, non-obviousness and sufficient disclosure—should

instead dictate whether a valid claim may issue. Unless a claim that meets the machine-or-transformation test is *de facto* patent-eligible, the test cannot be a useful tool. Put another way, satisfying the machine-or-transformation test should create a safe harbor of patent-eligible subject matter. But, of course, as a non-exclusive test, if a patent claim does *not* meet the machine-or-transformation test, continued analysis may be necessary to see if the patent claims a fundamental principle or simply a practical application of a fundamental principle.

Finally, NYIPLA emphasizes the vital role patents play in the United States economy. Patents—when appropriately awarded—encourage innovation and transparency, and advance the Constitutional goal of “promot[ing] the Progress of Science and useful Arts.” U.S. Const., art. I, § 8, cl.8. This Court should resist the temptation to bow to an outspoken minority who would undermine a patent system that our founding fathers thought was so important that they included it in Article I of the Constitution and enacted it into one of its earliest public laws. NYIPLA respectfully submits that this Court should reaffirm the broad scope of patent-eligible subject matter under Section 101.

ARGUMENT

The statutory language of 35 U.S.C. § 101 clearly defines patent-eligible subject matter:

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

35 U.S.C. § 101. Almost forty years of the Court's detailed interpretation confirms the breadth of the statute. In *Bilski v. Kappos*, the Court once again "decline[d] to impose limitations on the Patent Act that are inconsistent with the Act's text," 130 S.Ct. at 3231, and reconfirmed the wide scope for patentability of inventions under Section 101. *Id.* at 3225; see *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001); *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980); ("As this Court recognized over 20 years ago in *Chakrabarty*, the language of § 101 is extremely broad.") (citation omitted).

NYIPLA submits that nothing about the case at bar compels any reevaluation of the straightforward rules for assessing patent eligibility, that, when applied consistently, enable inventors,

practitioners and the public alike to determine with reasonable certainty whether an invention is patentable under Section 101.

**I. THE COURT SHOULD REAFFIRM
THE WELL-SETTLED GENERAL
PRINCIPLES GOVERNING PATENT-
ELIGIBLE INVENTIONS UNDER 35
U.S.C. § 101**

The Court has repeatedly referred to patentability under Section 101 as a “threshold” analysis, *e.g.*, *Diehr*. 450 U.S. at 188, that is assessed before other conditions and requirements of patentability are considered. *Bilski*, 130 S.Ct. at 3225. This threshold analysis raises two questions, each discussed below, that are necessary to determine whether an invention is directed to patent-eligible subject matter. *See id.*

**A. Claimed Inventions Must Be
Directed to One of the Four
Statutory Categories of Patent-
Eligible Subject Matter: Process,
Machine, Manufacture, or
Composition of Matter**

Section 101 broadly states that “any” subject matter in the four independent categories of invention—process, machine, manufacture or composition of matter—qualify for protection. 35 U.S.C. § 101. The Court reemphasized the comprehensive scope of those categories in *Bilski*,

stating that “Congress took this permissive approach to patentability to ensure that ingenuity should receive a liberal encouragement.” *Bilski*, 130 S.Ct. at 3225 (quoting *Chakrabarty*, 447 U.S. at 308-09 (quoting 5 Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)) internal quotation marks omitted)).

Since its amendment in 1952, the Patent Act has expressly provided that an inventor may obtain a patent covering a process, “subject to the conditions and requirements of this title.” 35 U.S.C. § 101. Congress defined “process” in an expansive manner: “process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter or material.” 35 U.S.C. § 100(b); *see Flook*, 437 U.S. at 588 n.9 (observing that the “statutory definition of ‘process’ is broad”).

In *Bilski*, the Court refused to adopt a new rule categorically excluding patent-eligible subject matter from the term “process.” *Bilski*, 130 S.Ct. at 3227 (“Section 101 is a ‘dynamic provision designed to encompass new and unforeseen inventions.’”) (quoting *J.E.M. Ag Supply*, 534 U.S. at 135; *Charkrabarty*, 447 U.S. at 308 (cautioning that “courts should not read into the patent laws limitations and conditions which the legislature has not expressed”) (internal quotation and citation omitted)).

Though NYIPLA takes no position on whether the invention at issue claims patent-eligible subject

matter, there is no reason for the Court to turn away from its prior rulings by imposing potentially unworkable limitations on the word “process” to restrict subject matter eligibility.

B. Claimed Inventions Directed to Fundamental Principles—“Laws of Nature, Physical Phenomena, or Abstract Ideas”—Are Not Eligible for Patent Protection But Practical Applications of Fundamental Principles Are Patent-Eligible

Congress specifically intended that patentable subject matter “include anything under the sun that is made by man.” *Chakrabarty*, 447 U.S. at 309 (quotation and citation omitted). In *Chakrabarty*, however, the Court specifically excluded “laws of nature, physical phenomena, and abstract ideas” from patent-eligible subject matter under § 101. *Id.* at 313; *see also Bilski*, 130 S.Ct. at 3226; *Diehr*, 450 U.S. at 185; *Flook*, 437 U.S. at 588-89; *Benson*, 409 U.S. at 67 (“He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes.”); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

Abstract natural principles are excluded from patentable subject matter primarily because knowledge discovered by mere observation of the natural world has not been “applied to some practical purpose” in a manner that would make those observations useful and deserving of patent

protection. *Le Roy v. Tatham*, 63 U.S. (22 How.) 132, 137 (1859). As a result, “manifestations of laws of nature” are “free to all men and reserved exclusively to none.” *Funk Bros.*, 333 U.S. at 130. Natural phenomena and abstract ideas represent “the basic tools of scientific and technological work,” *Benson*, 409 U.S. at 67, that should remain “part of the storehouse of knowledge,” *Funk Bros.*, 333 U.S. at 130, ineligible for patenting.

On this basis, the Court has reasoned that “a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter” under Section 101, *Chakrabarty*, 447 U.S. at 309, nor can a patent issue claiming the qualities of natural products like metals or bacteria. *Funk Bros.*, 333 U.S. at 130. “Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” *Chakrabarty*, 447 U.S. at 309.

But the Court and the Federal Circuit have also recognized that categories of unpatentable abstract natural principles at times may be difficult to define, particularly so for processes. Indeed, no clear definition of “abstract” has emerged. *Flook*, 437 U.S. at 589 (“The line between a patentable ‘process’ and an unpatentable ‘principle’ is not always clear.”); *Bilski*, 130 S.Ct. at 3236 (noting the absence of a “satisfying account of what constitutes an unpatentable abstract idea”) (Stevens, J., concurring); *see also Research Corp. Tech., Inc. v. Microsoft Corp.*, 627 F.3d 859, 868 (Fed. Cir. 2010)

("[T]his court also will not presume to define 'abstract' beyond the recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act.").

1. Is the Claimed Process Directed to an Application of an Abstract Natural Principle?

Although a patent claim directed to an abstract natural principle is not patent-eligible, the Court has long recognized that "[i]t is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187-88 (emphasis in original) (citation omitted); see *Mackay Radio & Tel. Co. v. Radio of America*, 306 U.S. 86, 94 (1939) ("While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the knowledge of scientific truth may be."); *Le Roy*, 63 U.S. at 137 ("There can be no patent for a principle; but for a principle so far embodied and connected with corporeal substances as to be in a condition to act and to produce effects in any trade, mystery, or manual occupation, *there may be a patent*"). (emphasis added). A "claim drawn to subject matter otherwise statutory does not become non-statutory simply because it uses a mathematical

formula” or other principle of the natural world. *Diehr*, 450 U.S. at 187.

The concept of an “application of a law of nature” is similar to the transformation of an abstract idea. It is the application of a law of nature that converts an observation made in the natural world into a process having a “new and useful end,” which is required for patent-eligible subject matter. *See Benson*, 409 U.S. at 67 (quoting *Funk Bros.*, 333 U.S. at 130). For claims reciting “a mathematical formula (or scientific principle or phenomenon of nature),” the primary inquiry is to determine “whether the claim is seeking patent protection for that formula in the abstract.” *Diehr*, 450 U.S. at 191. The relevant distinction for this threshold analysis is between “products of nature . . . and human-made inventions.” *J.E.M. Ag Supply*, 534 U.S. at 130 (quoting *Chakrabarty*, 447 U.S. at 313).

Diehr set forth three cardinal rules that must be followed when assessing whether a claimed process crosses the threshold from a patent-ineligible, abstract natural principle to the concrete human-made realm of patent-eligible subject matter.

1. The claim “must be considered as a whole.” *Diehr*, 450 U.S. at 188; *see Bilski*, 130 S.Ct. at 3230; *Flook*, 437 U.S. at 590 (“a process is not unpatentable because it contains a law of nature or a mathematical algorithm”).

2. “It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.” *Diehr*, 450 U.S. at 188; *Bilski*, 130 S.Ct. at 3230.
3. “The ‘novelty’ of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.” *Diehr*, 450 U.S. at 188-89; *see id.* at 193 n.15 (“The fact that one or more of the steps in respondents’ process may not, in isolation, be novel or independently eligible for patent protection is irrelevant to the question of whether the claims as a whole recite subject matter *eligible* for patent protection under § 101.”) (emphasis in original).

Considering the claim as a whole respects the overall patentability framework, as claims “particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention.” 35 U.S.C. 112, ¶ 2. For processes, an inventor’s characterization of the invention is critical because “a new combination of steps in a process may be patentable even though all the constituents in the combination were well known and in common use before the combination was made.” *Diehr*, 450 U.S. at 188.

But determining whether a claimed process is directed to a law of nature or a natural phenomenon or an application of a natural law or natural phenomenon can be as difficult as determining whether an invention claims an abstract principle.

NYIPLA respectfully submits that the machine-or-transformation test is a useful tool for this analysis and, if satisfied, creates a safe harbor of patent-eligible subject matter, namely patentable applications of laws of nature and patentable applications of natural phenomena.

2. Claimed Processes that Satisfy the Machine-or-Transformation Test Are Patent-Eligible

For processes that appear to cover a fundamental principle, *Diehr* noted that “[t]ransformation 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) (internal quotations omitted); *see also Flook*, 437 U.S. at 588 n.9 (“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.’”) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). The Court has confirmed that the machine-or-transformation test remains “a useful and important clue, an

investigative tool, for determining whether some claimed inventions are processes under § 101.” *Bilski*, 130 S.Ct. at 3227.

This appeal presents the Court with the perfect opportunity to confirm the vitality of the machine-or-transformation test in the context of the general principles governing patent eligibility. But NYIPLA respectfully submits that the machine-or-transformation test is a useful tool only if an explicit safe harbor exists for claimed processes that meet its requirements.

A transformation, if present, provides a compelling indication that the claimed inventive process is neither abstract nor directed to a natural phenomenon. *Chakrabarty*, 447 U.S. at 310 (“Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”); *Flook*, 437 U.S. at 594 (“Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.”).

The mere fact that a patentee is able to articulate a transformative step in a claim “connected with corporeal substances as to be in a

condition to act and to produce effects in any trade, mystery, or manual occupation” demonstrates that the claim is not to a principle, but is directed to an application of a law of nature rather than the natural phenomenon itself for which “there may be a patent”. *Le Roy*, 63 U.S. at 138.

Consistent with the broad scope of Section 101, the *type* of the transformation present in a process is immaterial to determining patent eligibility, because *any* transformation will carry a claimed invention across the § 101 threshold. *Tilghman v. Proctor*, 102 U.S. 707, 728 (1881) (discussing that a process may provide the “means” to achieve a “useful result,” even though “[a] process is an act, or a mode of acting . . . [that is] a conception of the mind, seen only by its effects when being executed or performed.”). While other analyses may similarly define the presence of an application of a fundamental principle, NYIPLA respectfully submits that once the machine-or-transformation test is met, the subject-matter eligibility requirement of Section 101 is likewise met. This is not to say that the machine-or-transformation test is the exclusive framework for determining what is patentable subject matter under Section 101—it is not. *Cf. Bilski*, 130 S.Ct. at 3227.

Since the Court’s pronouncements in *Bilski*, the Federal Circuit has recognized that Section 101 is a “coarse eligibility filter, not the final arbiter of patentability.” *Classen Immunotherapies, Inc. v. Biogen IDEC*, ___ F.3d ___, No. 2006-1634, -1649,

2011 U.S. App. LEXIS 18126 at *22 (Fed. Cir. Aug. 31, 2011) (internal quotation omitted); *see also Research Corp.*, 627 F.3d at 868 (noting that Section 101 “directs primary attention to ‘the conditions and requirements of [Title 35]’”) (quoting 35 U.S.C. § 101).

Though not exclusive, if a court finds sufficient facts to satisfy the requirements of the machine-or-transformation test, and those findings are correct, then further attack on the subject matter eligibility of the claimed invention should end. All remaining questions of patentability can and should be resolved as separate analyses under 35 U.S.C. §§ 102, 103 and 112. *See Bilski*, 130 S.Ct. at 3225; *id.* at 3238 (Stevens, J. concurring) (noting the “risk of merely confirming our preconceived notions of what should be patentable or of seeing common attributes that track the familiar issues of novelty and obviousness that arise under other sections of the statute but are not relevant to § 101”) (internal quotation and citation omitted).

Over a century ago, the Court considered whether a method directed to expanding sheet metal by simultaneously cutting and stretching it was eligible for patent protection, given that, at the time, process patents only related to chemical reactions and elemental changes. *Expanded Metal Co. v. Bradford*, 214 U.S. 366, 374-75, 382 (1909) (noting the parties’ disagreement over whether *Corning v. Burden*, 56 U.S. (15 How.) 252 (1854) and *Risdon Locomotive Works v. Medart*, 158 U.S. 68 (1895) held

that patentable processes did not “include methods or means which are affected by mere mechanical combinations”). Noting that *Cochrane v. Deener*, 94 U.S. 780, had previously “sustained a process patent involving mechanical operations,” the Court concluded that patent-eligible processes were not limited to chemical action or elemental changes:

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. If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art. The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. *The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.*

Bradford, 214 U.S. at 384 (quoting *Cochrane*, 94 U.S. at 787) (emphasis added). Today, the Court should continue resisting calls to limit the scope of those transformative steps that can render a claimed process patent-eligible.

Taken as a whole, the useful clue provided by the transformation prong of the machine-or-transformation test illuminates those ways in which an invention provides something more than mere observations, concepts and ideas that exist in nature—subject matter that is not itself directly patentable.

C. Practical Applications of Laws of Nature Are Patent-Eligible

Here, the parties to this appeal ask the Court to decide whether the claimed correlations are patent ineligible like the relationship between variables defined by a mathematical algorithm or formula. In that regard, the parties dispute whether the claimed processes “wholly preempt” all uses of natural correlations between certain metabolite levels in the body and patient health, which the parties presume to be a law of nature. Pet.21 (quoting *Benson*, 409 U.S. at 71-72); Br.Opp. 26-27; *see also* Pet.15.

The Court should clarify that its precedents do not provide for a “preemption” analysis as a stand-alone patent-eligibility test, however. The key question established in the *Diehr* framework is whether a claimed invention is directed to one of the

three fundamental principles or only an application of those fundamental principles. Because all patent claims preempt the practice of an invention, to perform any useful work concerning patent eligibility under Section 101, a consideration of preemption *must* incorporate a critical assessment of whether the claim at issue actually claims a fundamental principle as a fundamental principle in contrast to an application of that principle. Otherwise, concluding that a claim “preempts” others from practicing a particular process does nothing but identify a broad claim that may, in fact, be unpatentable for failing to meet other conditions of patentability, but nevertheless is patent-eligible under Section 101.

Instead, courts must begin with and look to the long-established two-part framework governing patent eligibility under Section 101: (1) Does the claimed subject matter fall within one of the four statutory classes of patent-eligible subject matter? (2) Is the claimed subject matter directed to a law of nature, a physical phenomenon or an abstract idea?

Determining whether the general subject matter of an invention is a law of nature or a physical phenomenon should be a relatively straightforward threshold inquiry. Some members of the Court, however, have noted that the actual scope of non-patent-eligible laws of nature remains elusive. *See Lab. Corp. of America Holdings v. Metabolite Labs., Inc.*, 548 U.S. 124, 134 (2006) (Breyer, J., dissenting) (stating that “the category of nonpatentable ‘[p]henomena of nature,’ like the

categories of ‘mental processes’ and ‘abstract intellectual concepts,’ is not easy to define”).

In *Benson*, the Court considered the patentability of a mathematical algorithm, defined as a “procedure for solving a given type of problem.” 409 U.S. at 65. The *Benson* court went on to equate mathematical algorithms to “phenomena of nature,” 409 U.S. at 67, a classification later confirmed in *Flook*, which held that mathematical algorithms are unpatentable subject matter regardless of their novelty or utility. *Flook*, 437 U.S. at 585. One member of the Court later recognized, however, that “the inclusion of the ambiguous concept of an ‘algorithm’ within the ‘law of nature’ category of unpatentable subject matter has given rise to the concern that almost any process might be so described and therefore held unpatentable.” *Diehr*, 450 U.S. at 219 (Stevens, J., dissenting).

Like mathematical algorithms and formulas, correlations between variables may establish useful relationships between measurable features of the natural world. Assuming *arguendo* that the claimed correlations in this case are directed to laws of nature, if the claimed processes cover only practical applications of those laws of nature, they are “at the very least not barred at the threshold by § 101.” *Diehr*, 450 U.S. at 188. Under the general principles reaffirmed in *Bilksi, supra*, § I, the Court may also rely on the machine-or-transformation test as a useful clue: if the claimed processes include one or more transformative steps, the claimed invention is

sufficiently non-abstract and non-natural to be patent-eligible.

Regardless of the conclusion reached by this analysis, the Court should resist invitations to exclude certain methods from the broad scope of patentable subject matter. Because technology may evolve faster than descriptive categories may be defined, Section 101 must remain a “dynamic provision designed to encompass new and unforeseen inventions.” *J.E.M. Ag Supply*, 534 U.S. at 135. Given the several competing public policy interests at play, the Court has observed that only Congress may endeavor to create such a limitation. *See Bilski*, 130 S.Ct. at 3227 (“A categorical rule denying patent protection for ‘inventions in areas not contemplated by Congress . . . would frustrate the purposes of the patent law.’”) (quoting *Chakrabarty*, 447 U.S. at 315).

Writing separately to express additional views about the “rising number of challenges” to patent eligibility, in which “litigants continue to urge this court to impose limitations not present in the statute,” Chief Judge Rader recently stated that

[s]ubject matter eligibility under section 101 has become the ‘substantive due process’ of patent law—except that reading non-procedural requirements into the constitutional word ‘process’ has more historical and

contextual support than reading abstractness into the statutory word ‘process’ because Title 35 already contains ample protections against vague claims. *See* 35 U.S.C. § 112. Indeed it is difficult to ‘invent’ any category of subject matter that does not fit within the four classes acknowledged by Title 35: process, machine, [article of] manufacture, or composition of matter. This court should decline to accept invitations to restrict subject matter eligibility.

Classen, supra, 2011 U.S. App. LEXIS 18126, at *45 (Rader, C.J., concurring). Chief Judge Rader went on to explain that

patentability, as opposed to subject matter eligibility, depends on the *substantive* conditions in the rest of the title. *See* 35 U.S.C. §§ 102, 103, 112. Many litigation-spawned applications of section 101 do not focus on categories of subject matter that deserve no patent protection but on the particularities of claim language, a question of

patentability depending on prior art and adequate disclosure.

Id. at *51 (Rader, C.J., concurring).

NYIPLA concurs wholeheartedly with Chief Judge Rader's views, and urges the Court, by reaffirming the clear rules it has already established for patent eligibility under Section 101, to put an end to the extra-statutory efforts of the lower courts to improperly restrict the broad scope of patentable subject matter.

Given the past pronouncements of this Court and the silence of Congress on this issue, there is no basis for excluding processes directed to analyzing the chemicals in a patient's body from patent eligibility given the broad scope of § 101. Even if those biologically-relevant chemicals themselves are naturally-existing products, their *application* in a useful and concrete process would be, and should be patent-eligible under *Diehr* and *Bilski*. And under the Court's general framework, this patent eligibility exists even though a claim may fail to meet other conditions of patentability, either justifying the claim's rejection during prosecution or rendering an issued claim invalid. *See Bilski*, 130 S.Ct. at 3225.

II. PATENTS ARE AN IMPORTANT AND VALUABLE PART OF OUR ECONOMY AND PROMOTE THE PROGRESS OF THE USEFUL ARTS

Patents play an important role in promoting the “progress” of the “useful Arts” and stimulating innovation. U.S. Const. art. 1, § 8, cl.8. The patent system promotes that progress in a variety of ways.

As this Court recognized, one way of promoting progress is by rewarding innovation with patent rights. *See, e.g., Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 730-31 (2002) (“The patent laws ‘promote the Progress of Science and useful Arts’ by rewarding innovation with a temporary monopoly.”) (quoting U.S. Const. art. I, § 8, cl. 8)); *Chakrabarty*, 447 U.S. at 307 (explaining that “[t]he Constitution grants Congress broad power to legislate to ‘promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.’ Art. I, § 8, cl. 8” and that “[t]he patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts”) (citations omitted).

President Lincoln, describing the development of a patent system as an important event “greatly favoring and facilitating useful discoveries and inventions,” explained:

Next came the patent laws. These began in England in 1624, and in this country with the adoption of our Constitution. Before then any man [*might*] instantly use what another man had invented, so that the inventor had no special advantage from his invention. The patent system changed this, secured to the inventor for a limited time exclusive use of his inventions, and thereby added the fuel of interest to the fire of genius in the discovery and production of new and useful things.

Abraham Lincoln, *Lecture on "Discoveries, Inventions and Improvements,"* delivered before the Library Association of Springfield, Illinois, Feb. 22, 1860, *reprinted in* THE WISDOM OF ABRAHAM LINCOLN 104 (Marion Mills Miller ed. 1908).³

But this is not the only way patent systems "promote progress." Public disclosure in patents is also important to innovative progress. Shortly after

³ Besides being the sixteenth president of the United States, Mr. Lincoln was the inventor on U.S. Patent No. 6,469, entitled "Buoying Vessels Over Shoals," (filed Mar. 10, 1849).

Congress passed the 1952 amendments to the Patent Act, Judge Rich—its principal architect—presented a series of lectures on the then-new Act, providing useful insight into the varying purposes of patent laws. Discussing how the patent laws serve “incremental inventions” and “become part of the technical literature,” Judge Rich stated:

In the remote corners of the most crowded arts, progress is made by the proliferation of ideas, different and unobvious ways of doing the same thing, so that the reservoir of inventions fills up. It should never be forgotten that patented inventions are published and become a part of the technical literature. This publication itself promotes progress in the useful arts and it is the prospect of patent rights which induces the disclosure and the issuance of the patent which makes it available.

Giles S. Rich, *The Principles of Patentability*, 42 J. Pat. Off. Soc’y 75, 83 (1960) (emphasis added).

Those wise words from almost half a century ago ring particularly true when it comes to new and unforeseen inventions in our modern age. Today’s inventions—aided by yesterday’s technological

advances—appear at a bewildering pace, casting doubt on the utility of any rigid categorization of patent-eligible subject matter, however carefully crafted or well-intentioned. Patent laws must remain flexible enough to welcome future developments, not squelch them. *See Bilski*, 130 S.Ct. at 3227; *Benson*, 409 U.S. at 71 (stating that the Court’s “purpose” is not to “freeze process patents to old technologies, leaving no room for the revelations of the new onrushing technology”).

Our patent system has permitted Judge Rich’s “reservoir of [disclosed] inventions” to foster ingenuity, create new technologies, and build entire industries for over two hundred years. That progress must continue and encourage the advances of tomorrow.

CONCLUSION

The Court should reaffirm the well-established governing principles for determining whether, as a threshold issue, a claimed process is patent-eligible under 35 U.S.C. § 101, and reject the use of any extra-statutory test or theory as a substitute for this settled law.

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