

No. 10-1150

IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES,
d/b/a MAYO MEDICAL LABORATORIES, ET AL.

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.

Respondent.

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

**BRIEF OF THE INTELLECTUAL PROPERTY
LAW ASSOCIATION OF CHICAGO AS *AMICUS
CURIAE* SUPPORTING RESPONDENT**

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TABLE OF CONTENTS

	Page
INTEREST OF THE AMICUS	1
SUMMARY OF ARGUMENT	2
DISCUSSION	4
I. The Claimed Method Satisfies Congress’ Broad Mandate Under 35 U.S.C. Section 101	4
A. The Court Has Fulfilled Congress’ Intent to Construe Section 101 Broadly	4
B. The Asserted Process Claims Recite Patent-Eligible Subject Matter and Do Not “Wholly Preempt” Any Natural Phenomenon	7
C. Congress Did Not Intend To Create Different Section 101 Tests For Different Claim Types	11
II. Section 101 Eligibility Is Different Than The Required Analysis Under Sections 102, 103, and 112	12
A. Satisfying Section 101 Does Not Mean A Patent Will Issue	12
B. The Court Previously Has Recognized that Section 101 Is A Gateway To Further Inquiry	17
CONCLUSION	19

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Bilski v. Kappos</i> , 130 S. Ct. 3218 (2010).....	6, 11, 15
<i>Bros. Inc. v. Browning Mfg. Co.</i> , 317 F.2d 413 (8th Cir. 1963).....	15
<i>Diamond v. Chakrabarty</i> , 447 U.S. 303 (1980).....	5, 14
<i>Diamond v. Diehr</i> , 450 U.S. 175 (1981).....	passim
<i>Eimco Corp. v. Peterson Filters & Eng'g Co.</i> , 406 F.2d 431 (10th Cir. 1968).....	15
<i>Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.</i> , 535 U.S. 722 (2002).....	7, 12
<i>Funk Bros. Seed Co. v. Kalo Inoculant Co.</i> , 333 U.S. 127 (1948).....	8
<i>Gottschalk v. Benson</i> , 409 U.S. 63 (1972).....	8, 9, 10, 12
<i>In re Bergy</i> , 596 F.2d 952 (CCPA 1979)	13, 14, 16
<i>KSR Int'l Co. v. Teleflex Inc.</i> , 550 U.S. 398 (2007).....	6
<i>Laboratory Corp. of Am. Holdings v. Metabolite Labs, Inc.</i> , 548 U.S. 124 (2006).....	17

TABLE OF AUTHORITIES—Continued

<i>Mackay Radio & Tel. Co. v. Radio Corp.</i> , 306 U.S. 86 (1939).....	11
<i>Nat'l Dairy Prods. Corp. v. Borden Co.</i> , 261 F. Supp. 771 (E.D. Wis. 1966).....	15
<i>O'Reilly v. Morse</i> , 56 U.S. 62 (1856).....	8, 17, 18
<i>Parker v. Flook</i> , 437 U.S. 584 (1978).....	9
<i>Quanta Computer, Inc. v. LG Elecs., Inc.</i> , 128 S. Ct. 2109 (2008).....	12
<i>SmithKline Beecham Corp. v. Apotex Corp.</i> , 403 F.3d 1331 (Fed. Cir. 2005).....	16
<i>State Street Bank & Trust Co. v. Signature Fin. Group</i> , 149 F.3d 1368 (Fed. Cir. 1998).....	15
<i>Vincent v. Suni-Citrus Prods. Co.</i> , 215 F.2d 305 (5th Cir. 1954).....	15
STATUTES	
35 U.S.C. § 101	passim
35 U.S.C. § 102	9, 14, 17
35 U.S.C. § 103	6, 7, 9, 15
35 U.S.C. § 112	passim
LEGISLATIVE MATERIALS	
S. Rep. No. 82-1979, 82d Cong., 2d Sess., at 5 (1952), <i>reprinted in</i> 1952 U.S.C.C.A.N. 2399	14

TABLE OF AUTHORITIES—Continued

BOOKS AND ARTICLES

Robert M. Kunststadt, <i>Sneak Attack on U.S. Inventiveness</i>	15
<i>The Supreme Court Engages in Judicial Activism in Interpreting the Patent Law in eBay, Inc. v. MercExchange, L.L.C.</i>	16
William J. Simmons, <i>Bilski Blundering Biotech</i>	15

OTHER AUTHORITIES

<i>Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos</i> , 75 Fed. Reg. 43,922, 43,926 (July 27, 2010)	3
Supreme Court Rule 37	2
Supreme Court Rule 37.6	1

INTEREST OF THE AMICUS¹

Founded in 1884, the Intellectual Property Law Association of Chicago (“IPLAC”) is the oldest intellectual property law association in the nation. Its approximately 1,000 members represent a full spectrum of the profession ranging from law firm attorneys to sole practitioners, corporate attorneys, law school professors, and law students. IPLAC is centered in Chicago, a principal forum for patent litigation in this country. Every year, IPLAC’s members prosecute thousands of patent applications and litigate many patent lawsuits.²

IPLAC is a not-for-profit organization dedicated to maintaining a high standard of professional ethics in the practice of patent, trademark, copyright, trade secret, and associated fields of law. A principal aim is to aid in the development and administration of these laws and the manner by which they are applied by the courts and by the United States Patent and Trademark Office. IPLAC is further dedicated to providing a medium for the exchange of views on intellectual property law among those

¹ In accordance with Supreme Court Rule 37.6, IPLAC states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than IPLAC or its counsel.

² While over 30 federal judges are honorary members of IPLAC, none of them was consulted or participated in any way on this brief.

practicing in the field and to educating the public at large.

IPLAC has no interest in any party to this litigation or stake in the outcome of this case, other than its joint desire for a correct interpretation and application of the United States Patent Laws. In accordance with Supreme Court Rule 37, counsel of record for the parties have filed letters with the Clerk of Court consenting to the filing of amicus briefs.

SUMMARY OF ARGUMENT

The framers of our Constitution understood the importance of rewarding inventors, for limited times, for their creative endeavors. Congress then implemented a plan for protecting the rights of the inventor and promoting the advance of the useful arts by broadly drafting the patent statute without technological exclusions, ready to embrace yet unknown innovations. Thus, the language of 35 U.S.C. § 101 (“section 101”) places few limits on the types of invention eligible for patent protection and reflects Congress’ judgment on how best to fulfill its Constitutional mandate.

For more than a century, the Court has applied section 101 using a flexible and broad subject matter analysis to accommodate incredible, sweeping, and unforeseen advances in technology. Without such subject matter flexibility, many of the inventions that have made the United States the technology leader of the world would never have been discovered or would have been hidden from the

public with no incentive for revelation or commercialization. Similarly, section 101's flexibility accommodates smaller yet still deserving inventions. It is this elasticity of section 101, with few exceptions and without technological limitation, that has helped to make the U.S. patent system the strongest in the world, supporting innovation like no other.

Yet, Petitioner seeks to have the Court rule on a specific type of claim, indeed a specific claim, and determine whether this category, "correlations between blood test results and patient health," can exist as patentable subject matter. This is precisely the type of specific exclusion the framers sought to avoid and that Congress through its implementation in statute carried forth. Rather than precluding all uses of a natural phenomenon, Prometheus' claims merely seek to preempt others from using a particular application of that phenomenon, precisely the type of subject matter envisioned to be encompassed by the patent statute.

Petitioners sound the alarm that should this case stand, it will become a beacon for issuance and maintenance of "bad patents." However, such broad hyperbole does not comport with the totality of the requirements for achieving patentability. Section 101 is, by design, a "coarse filter." PTO, *Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of Bilski v. Kappos*, 75 Fed. Reg. 43,922, 43,926 (July 27, 2010).

After section 101, the remaining provisions of the Patent Act require the nuanced, fact-intensive distinctions necessary to separate patentable from unpatentable inventions. A patentable invention

must be both new and nonobvious. In addition, the inventor must fully and clearly describe the invention to enable others to understand and practice it. The inventor also must claim the invention distinctly to inform the public of its reasonable metes and bounds. Enforcement of these requirements ensures that granted patents legitimately promote the useful arts and advance the frontiers of technology, as the nation's founders intended. The public domain, and Mayo's concerns, therefore, are adequately protected by these other, more stringent, criteria for patentability.

IPLAC urges the Court not to disturb the broad and accessible threshold of statutory subject matter that has fostered innovation and public disclosure over a wide variety of useful arts—and importantly, in new and emerging fields of technology. The judgment of the Federal Circuit should be affirmed.

DISCUSSION

I. The Claimed Method Satisfies Congress' Broad Mandate Under 35 U.S.C. Section 101

A. The Court Has Fulfilled Congress' Intent to Construe Section 101 Broadly

The Federal Circuit's decision is consistent with the Court's precedent over the past half century. Section 101 broadly defines the scope of patent eligible subject matter:

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

35 U.S.C. § 101. Thus, section 101 sets forth four separate categories of statutory subject matter: “*any* new and useful [1] process, [2] machine, [3]manufacture, or [4] composition of matter.” *Id.* (emphasis & numbering added). Prometheus’ claims at issue cover a specific process, i.e., category [1] above. That process specifies the discovery in patients with immune gastrointestinal disorder of a therapeutically effective, non-toxic dose of thioguanine. The claimed process recites specific yields and ranges; it is not vague.

This Court has interpreted the language of section 101 broadly: “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Devoid of limiting language, section 101 readily accommodates the rapid pace of innovation and the assimilation of new technologies, including technologies never anticipated at the time section 101 was enacted. As this Court has put it, patentable subject matter includes “anything under the sun that is made by man.” *Id.* at 309. Thus, this Court has not seen fit to exclude particular

technologies from section 101, no matter how unusual or bizarre. *See Diamond v. Diehr*, 450 U.S. 175, 182-83 (1981).

Recently the Court in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), confirmed the liberal application of section 101. Considering the Federal Circuit’s “machine or transformation” test for determining patentable subject matter, the Court “cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed” and ruled that “machine or transformation” could not be the *sole* test under Section 101. *Id.* at 3226 (quotations omitted). “Congress plainly contemplated that the patent laws would be given wide scope,” and “took [a] permissive approach to patent *eligibility* to ensure that ingenuity should receive a liberal encouragement.” *Id.* at 3225 (quotations omitted & emphasis added).

Although the Court in *Bilski* recognized that its precedents provide “three specific exceptions” to section 101’s patent-eligibility principles, these exceptions do not give “the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute’s purpose and design.” *Id.* at 3226. This is yet another opportunity for the Court to reaffirm the broad scope of section 101.³

³ The Court also has emphasized the importance of the flexible approach to patent law in other contexts outside section 101. *See, e.g., KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 407, 415, 427 (2007) (rejecting rigid interpretation of 35 U.S.C. § 103 imposing “teaching, (Continued ...)

B. The Asserted Process Claims Recite Patent-Eligible Subject Matter and Do Not “Wholly Preempt” Any Natural Phenomenon

Consistent with the broad language and interpretation of section 101, the Federal Circuit correctly applied this Court’s narrow exceptions for laws of nature, physical phenomena, and abstract ideas. This protection of the public commons does not place limits or exclusions on the *subject matter* of the four specified categories of section 101; instead, it provides guidance to the decision-maker to prevent wholesale removal from the public of natural or scientific principles.

The few exceptions that exist to section 101—laws of nature, physical phenomena, and abstract ideas—are a matter of common sense: An inventor is not entitled to claim one of these basic principles in isolation because to do so would remove it from the public. *See, e.g., Diehr*, 450 U.S. at 185.⁴ These are

suggestion, or motivation test (TSM) test” as sole test for obviousness; section 103 “must not be confined within a test or formulation too constrained to serve its purpose” (quotations omitted); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 738 (2002) (rejecting “complete bar” test, as an unbending approach to the doctrine of prosecution history estoppel; “we have consistently applied the doctrine in a flexible way, not a rigid one”).

⁴ *Diehr* described the true limits on patent eligibility:

(Continued ...)

the “basic tools of scientific and technological work,” *Gottschalk v. Benson*, 409 U.S. 63, 67-68 (1972), “free to all men and reserved exclusively to none,” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (*Funk Bros.*).

For example, the Court has refused to permit a patent claim only where it would “wholly pre-empt” the use of a mathematical formula. *Benson*, 409 U.S. at 71-72. A mathematical formula, which, “like a law of nature, ... cannot be the subject of a patent.” *Diehr*, 450 U.S. at 185-86. “It 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.” *Id.* at 187 (emphasis added); *see also O’Reilly v. Morse*, 56 U.S. 62, 119 (1856) (provided application contains sufficient detail, “[w]hoever discovers that a certain useful result will be produced in any art, machine, manufacture, or composition of matter by the use of certain means is entitled to a patent for

This Court has undoubtedly recognized 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. ‘An idea of itself is not patentable. A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.’

Id. at 185 (internal citations & quotations omitted).

it”). Thus, “it is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.” *Parker v. Flook*, 437 U.S. 584, 590 (1978).

In *Diehr*, this Court held that a claim that incorporated a mathematical equation constituted patentable subject matter because the claim, as a whole, defined a rubber molding process and not just an equation. 450 U.S. at 192–93. In doing so, the *Diehr* Court distinguished two earlier decision by the Court: *Parker v. Flook* and *Gottschalk v. Benson*. Distinguishing *Flook* as merely reciting a mathematical formula, the Court stated: “In contrast [to *Flook*], the respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber.” *Diehr*, 450 U.S. at 187.⁵ “Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented.” *Flook*, 437 U.S. at 594.

⁵ Although the Court concluded that the claims in *Flook* did not entirely pre-empt the mathematical formula at issue, it held that lack of preemption did not necessarily establish eligibility as a process claim. 437 U.S. at 589. There also must be “some other inventive concept in [the] application” of the formula. *Id.* at 594. The problem in *Flook* arose because the claim was not sufficiently definite and lacked specific utility, an issue more appropriately addressed under sections 102, 103 and 112. (See *infra* pp. 14-20.)

Similarly, the claims in *Benson* were directed to a method of programming a computer to convert signals from binary coded decimal form into pure binary form. The Court rejected the claims because they were not limited in scope; indeed, “the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm *itself*.” *Benson*, 409 U.S. at 71-72 (emphasis added).

The mathematical formula at issue in *Diehr* was well known, as were the process steps of installing rubber in a press, closing the mold, and determining the temperature of the mold. Additional steps included “constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time.” *Diehr*, 450 U.S. at 187. While the Court noted that “insignificant post-solution activity will not transform an unpatentable principle into a patentable process,” *id.* at 191-92, that was not the case in *Diehr*:

On the other hand, when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of §101.

Id. at 192. What separates abstract ideas, scientific truths, or phenomena of nature from patent-eligible

invention is the application of the idea, truth or phenomena to “a new and useful end.” *Diehr*, 450 U.S. at 188 n.11 (quotations omitted); *see also Mackay Radio & Tel. Co. v. Radio Corp.*, 306 U.S. 86, 94 (1939) (“[w]hile 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.” (quotations omitted)).

C. Congress Did Not Intend To Create Different Section 101 Tests For Different Claim Types

Accepting Mayo’s arguments in this case would lead to a rule carving out from section 101 certain types of claims—like the diagnostic methods claims at issue—and treating them differently. Indeed, Mayo all but concedes that it is seeking the development of special rules for such claims: its Petition (at 18) asserts that the “appropriate application of Section 101 to biotechnology claims, *and particularly the application of Section to method claims involving natural, biological correlations, needs resolution.*” (emphasis added).

This is precisely the approach to section 101 that the Court in *Bilski* rejected. In *Bilski*, two “categorical limitations” on “process” patents under section 101 were proposed: the “machine-or-transformation test” and the categorical exclusion of “business method” patents. 130 S. Ct. at 3225. Neither was adopted by the Court. *See id.* at 3228 (“Section 101 similarly precludes the broad contention that the term ‘process’ categorically excludes business methods.”).

Rigid rules excluding types of subject matter have been rejected. *See, e.g., Quanta Computer, Inc. v. LG Elecs., Inc.*, 128 S. Ct. 2109 (2008) (rejecting rule excluding method claims from the doctrine of patent exhaustion). The unanimous Court in *Quanta Computer* noted, “[o]ur precedents do not differentiate transactions involving embodiments of patented methods or processes from those involving patented apparatuses or materials.” *Id.* at 2117; *see also Benson*, 409 U.S. at 67-68 (“We dealt there with a ‘product’ claim, while the present case deals with a ‘process’ claim. But we think the same principle [of preemption] applies.”). This Court concluded that the patent exhaustion analysis for a process claim depends on the facts of the particular case, just as it does for an apparatus claim. *Quanta Computer*, 128 S. Ct. at 2118. The Court should do the same here—carving out Prometheus’ patent claims from section 101 would create a new set of preemption rules for diagnostic methods claims, while the low bar set by the “wholly preempt” rule in *Diehr* would apply to all other patent claims. “[C]ourts must be cautious before adopting changes that disrupt the settled expectations of the inventing community.” *Festo*, 535 U.S. at 739. Prometheus’ claims fall within the scope of patentable subject matter under section 101.

II. Section 101 Eligibility Is Different Than The Required Analysis Under Sections 102, 103, and 112

A. Satisfying Section 101 Does Not Mean A Patent Will Issue.

Applying the *Diehr* test for patentable subject matter to Prometheus’ claims, a first inquiry asks: do

the claims include a mathematical formula, scientific principle, or phenomenon of nature? If, as here, the answer appears to be yes, the second inquiry must be: does the claim, *as a whole*, apply or implement the mathematical formula, scientific principle, or phenomenon of nature in a specific, *useful* process or product? As to the claims at issue, the answer is yes.

More explicitly, claim 1 requires the specific steps of “administering a drug providing 6-thioguanine to a subject,” and “determining the level of 6-thioguanine in said subject.” See ’623 Patent, claim 1, col. 19, ll. 13-16. Those specific steps satisfy a patent-eligible process under Section 101 because the claim requires multiple steps that cause a useful result (treatment of a disorder) by transforming the patient’s body chemistry. The “determining” step also can be said to require the transformation of blood or tissue sample on which the metabolite test is performed. See Pet. App. 18a-19a; ’623 patent, col. 9, l. 12 to col. 10, l. 14.2.

Mayo’s argument that the Court should disregard the “administering” and “determining” steps because those steps are “[w]ell-known” and have been “familiar to physicians for decades,” Pet. Br. 36, misunderstands the rubric of Section 101 and its interplay with the other statutory sections. Section 101 itself ends with the foreshadowing caveat that even though a claim may be said to contain patent eligible subject matter, it still must satisfy the other requirements of sections 102, 103, and 112. “The understanding that these three requirements are *separate and distinct* is long standing and has been universally accepted.” *In re*

Bergy, 596 F.2d 952, 960 (CCPA 1979) (emphasis in original), *vacated & affirmed by Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

Judge Rich described them as doors that require separate keys. *Id.* at 960-62. In other words, simply because an invention contains patent eligible subject matter does not mean that a patent should issue. “The ‘novelty’ of any element or steps in a process, or even of the process itself” is a separate question to be considered under § 102 and “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. Section “101 was never intended to be a ‘standard of patentability’; the standards, or conditions as the statute calls them, are in § 102 and § 103.” *Bergy*, 596 F.2d at 963; *see also Diehr*, 450 US. at 189 (reinforcing that section 101 is a “general statement of the type of subject matter that is eligible for patent protection” and section 102 “covers in detail the conditions relating to novelty.”) (citations omitted).

The legislative history is consistent. “Section 101 sets forth the subject matter that can be patented, ‘subject to the conditions and requirements of this title.’ The conditions under which a patent may be obtained follow, and section 102 covers the conditions relating to novelty.” S. Rep. No. 82-1979, 82d Cong., 2d Sess., at 5 (1952), *reprinted in* 1952 U.S.C.C.A.N. 2399. Once section 101 is satisfied, the inventor still must satisfy sections 102, 103 and 112 before he will be entitled to a patent. *See Bergy*, 596 F.2d at 960-62 (discussing separate doors for sections

102 and 103). The object and purpose of section 103 is to promote “really novel advances in the art, rather than those attributable merely to a person having ordinary skill in the trade.” *Vincent v. Suni-Citrus Prods. Co.*, 215 F.2d 305, 315 (5th Cir. 1954). The test of nonobviousness is independent of the tests of novelty and utility, and patentability depends upon satisfaction of all three requirements. See, e.g., *Nat’l Dairy Prods. Corp. v. Borden Co.*, 261 F. Supp. 771 (E.D. Wis. 1966); see also *Eimco Corp. v. Peterson Filters & Eng’g Co.*, 406 F.2d 431 (10th Cir. 1968); *Bros. Inc. v. Browning Mfg. Co.*, 317 F.2d 413 (8th Cir. 1963).

Critics of a broad reading of section 101 express concern that if the scope of patentable subject matter is not cabined, innovation will be reduced.⁶ However, these arguments disregard the other sections of the patent statute—the other doors

⁶ See, e.g., Robert M. Kunststadt, *Sneak Attack on U.S. Inventiveness*, NAT’L L.J., Nov. 9, 1998 (complaining in the wake of the Federal Circuit’s decision in *State Street Bank & Trust Co. v. Signature Financial Group*, 149 F.3d 1368 (Fed. Cir. 1998), “It will be impossible to operate such businesses [advertising and marketing agencies] without advice from patent counsel.”); but see, William J. Simmons, *Bilski Blundering Biotech*, NATURE BIOTECHNOLOGY, March 2009, at 245 (complaining in the wake of the *Bilski* Federal Circuit decision that, “A recent change in the law, ... applies to pharma and biotech subject matter and may have a dramatic impact on the procurement and enforcement of patent rights in the U.S.”).

in Judge Rich's analysis that must be unlocked before a patent may issue. See *Bergy*, 596 F.2d at 960.

The profound truth underlying Congress' broad statement of eligibility is that it fosters *more* innovation. Indeed, the foundation of our patent system is the notion that the lure of a United States patent encourages creativity.⁷ Filing an application provides the applicant's *quid pro quo*—disclosure and ultimate publication—to the benefit of the public. Even if those applications do not issue as patents, the public benefits because of their dedication. A cramped reading of section 101 would discourage filings, and we would never know what the public lost without them.

Recognizing that section 101 opens only that first door to examination provides a lead toward resolving this Court's questions. The applicant still must open three more doors to sections 102, 103 and 112. See, e.g., *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1342, 1346 (Fed. Cir. 2005)

⁷ See, e.g., *The Supreme Court Engages in Judicial Activism in Interpreting the Patent Law in eBay, Inc. v. MercExchange, L.L.C.*, 10 Tul. J. Tech. & Intell. Prop. 165, 199-200 (2007) (a strong patent system provides incentives for enterprises and capital to smaller enterprises; however, a weaker patent system allows existing dominant enterprises to avoid additional competition and by reducing the economic value of patents increases incentives for the dominant enterprises to infringe).

(concluding that the claim at issue was directed to eligible subject matter under section 101, but holding the claim anticipated under section 102).

B. The Court Previously Has Recognized that Section 101 Is A Gateway To Further Inquiry.

The above approach also is compatible with the concerns Justice Breyer expressed in *Laboratory Corporation of American Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting from dismissal for improvidently granted review) about the dangers to innovation of too many patents. The issue is not the legitimacy of that danger but about which door to leave open to affect the necessary control. In this case and in others, the appropriate doors to substantively monitor are found in the “conditions for patentability,” i.e., where the claims are examined under sections 102, 103 and 112, not in the scope of subject matter eligible for patentability generally under section 101.

Indeed, this Court’s analysis of the issue in *O’Reilly v. Morse* more closely tracks the language of today’s section 112 rather than section 101. *Morse*, 56 U.S. 62, 112-13 (1856). In *Morse*, the court held that “[w]e perceive no well-founded objection to the description which is given of the whole invention and its separate parts, nor to his right to patent for the first seven inventions set forth in the specification of his claims. The difficulty arises on the eighth.” 56 U.S. at 112 (emphasis added). The Court held that the rejected patent claim (no. 8) was too broad:

[H]e claims an exclusive right to use a manner and process which he has not

described and indeed had not invented, and therefore could not *describe* when he obtained his patent. The court is of opinion that the claim is too broad, and not warranted by law.

Id. at 113 (emphasis added). This Court went on to explain that if the patentee “specifies the means he uses in a manner so full and exact that anyone skilled in the science to which it appertains can, by using the means he specifies, without any addition to or subtraction from them, produce precisely the result he describes, ... the patent confers on him the exclusive right to use the means he specifies to produce the result or effect he describes, and nothing more.” *Id.* at 119 (“And if this cannot be done by the means he describes, the patent is void.”).

Similarly, Mayo’s complaint here is not about statutory subject matter, but about the scope of the claims compared with the underlying description of the invention. For instance, Mayo’s Brief asserts that “Prometheus’ claims do not recite any amount of any drug to be given to any patient.” Mayo also asserts that the claims at issue “say nothing about the ultimate use of the correlations, and thus cover all types of treatment, research, or any other kind of activity. Pet. App. 25. In short, Mayo’s complaints are over the language of Prometheus’ claims, *not* whether it satisfies patentable subject matter.⁸

⁸ “Patent drafters know how to recite administration of a therapeutically effective amount of a
(Continued ...)

To the extent that Mayo's concerns may be legitimate, they should be properly addressed under one of the substantive statutory sections. In this case, the appropriate door under Judge Rich's analysis is found in the "conditions for patentability," i.e., sections 102, 103 and 112, not in the scope of subject matter under section 101, which would risk foreclosing valuable and unforeseeable future innovations.

drug for method of treatment claims. Prometheus was careful not to do so here. (Pet. 25-26 (internal citations and quotations omitted) (alleging that Prometheus' claims employed "drafting tricks" to remove "huge swaths of basic medical knowledge").)

CONCLUSION

For the foregoing reasons, IPLAC respectfully request that the Court affirm the judgment of the Federal Circuit.

Respectfully submitted,

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