

No. 08-964

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In the  
**Supreme Court of the United States**

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BERNARD L. BILSKI AND RAND A. WARSAW,  
*Petitioners,*

v.

JOHN J. DOLL, ACTING UNDER SECRETARY OF  
COMMERCE FOR INTELLECTUAL PROPERTY AND  
ACTING DIRECTOR OF THE UNITED STATES PATENT  
AND TRADEMARK OFFICE,  
*Respondent.*

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

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**BRIEF FOR PROMETHEUS LABORATORIES  
INC. AS *AMICUS CURIAE* IN SUPPORT OF  
NEITHER PARTY**

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## QUESTION PRESENTED

Whether the Federal Circuit erred by holding that a “process” must be tied to a particular machine or apparatus, or transform a particular article into a different state or thing (“machine-or-transformation” test), to be eligible for patenting under 35 U.S.C. § 101, despite this Court’s precedent declining to limit the broad statutory grant of patent eligibility for “any” new and useful process beyond excluding patents for “laws of nature, physical phenomena, and abstract ideas.”

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### **INTEREST OF *AMICUS CURIAE***

Prometheus Laboratories Inc. (“Prometheus”) is a specialty pharmaceutical and diagnostic company committed to developing and commercializing novel pharmaceutical and diagnostic products to help physicians individualize patient care. Prometheus is focused on the detection, diagnosis and treatment of gastrointestinal diseases and disorders in the United States.

Prometheus has a vital interest in the proper interpretation of 35 U.S.C. § 101, the statute at the center of this case. Medical treatment and diagnostic patents, like those held by Prometheus, have become the essential underpinnings of a vibrant and innovative industry that has enormous practical value to ill patients. A ruling in this case that establishes an overly restrictive test under § 101 would stifle innovation and seriously undermine this nascent industry. As a company committed to improving lives through diagnostic and therapeutic innovations that enable doctors to provide optimal care to patients, Prometheus has a unique understanding of the practical and legal considerations relevant to the interpretation of § 101.<sup>1</sup>

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<sup>1</sup> Pursuant to Supreme Court Rule 37.6, Prometheus states that no counsel for any party authored this brief in whole or in part, and no person or entity other than Prometheus made any monetary contribution to the preparation or submission of this brief. Both parties received timely notice of Prometheus’s intent to file this brief, and both parties have filed blanket letters of consent.

### SUMMARY OF ARGUMENT

The patent at issue in this case claims a business method for hedging risks in the purchase and sale of commodities. The Federal Circuit held that this patent is invalid for failure to satisfy the subject matter requirements of 35 U.S.C. § 101. *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc).

This Court has long recognized that patentable subject matter under § 101 embraces “anything under the sun made by man.” *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (citation omitted). The only exception is that “laws of nature, natural phenomena, and abstract ideas” are not patentable and fall outside the scope of § 101. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981). This case concerns the proper scope of that judicially-created exclusion from patentability, and whether the Federal Circuit’s “machine-or-transformation” approach to § 101 appropriately captures its contours.

Prometheus does not take a position on whether the patent-in-suit satisfies § 101, nor on whether business methods in general should be patentable. Business method patents have been the subject of withering criticism in recent years, and much of that criticism is fair. Some of the problems with business method patents are related to § 101, as many such patents are drafted in a highly abstract way untethered to specific, real-world applications. Some of the problems have nothing to do with § 101, but arise from the fact that many patents have been granted for business methods that are strikingly obvious and not at all novel.

Prometheus writes here to emphasize that the Court’s interpretation of § 101 in this case may have significant ramifications beyond business method

patents, including far-reaching effects on the emerging and hugely important field of medical diagnostic and treatment processes. Educational institutions, non-profit organizations, corporations, and scientists invest hundreds of millions of dollars to uncover correlations between molecular markers in the human body (including genes) and various disease conditions, opening the way to new and highly effective diagnostic and treatment protocols. The PTO has routinely granted patents on these valuable diagnostic and treatment processes and, until recently, they have been upheld without controversy by the Federal Circuit. These foundational patents would be at risk, however, if courts apply the “machine-or-transformation” test in an overly restrictive way. This fear is not hypothetical: the Federal Circuit has already applied its holding below in a restrictive manner to reject—without analysis—medical diagnostic and treatment patents. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. Appx. 866, 867 (Fed. Cir. 2008) (three-sentence unpublished opinion).

The text and history of § 101, and this Court’s cases, suggest that the threshold test of § 101 is intended merely to exclude patents on *abstract* principles, as opposed to concrete applications of those principles. Although that line has at times been difficult to draw (in part because any invention can be described and understood at different levels of abstraction), this fundamental distinction runs through and reconciles this Court’s jurisprudence in the area. A thoughtful and nuanced application of this distinction will separate unpatentable business methods that rely on abstract or purely mental processes or constructs from patentable medical processes that use correlations or markers in

the course of concrete diagnostic and treatment methods that save lives. Nuance and judgment are critical, though, because an overly restrictive interpretation of § 101 driven by dissatisfaction with business method patents may otherwise destroy one of our country's most robust, innovative, and vital industries, and squelch the promise of personalized medicine in its infancy.

## ARGUMENT

### I. A PROPER UNDERSTANDING OF § 101 WILL ENABLE THIS COURT TO ADDRESS BUSINESS METHOD PATENTS WITHOUT UNDERMINING MEDICAL TREATMENT METHODS

The expansive language of 35 U.S.C. § 101 provides that “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” is patent-eligible. This Court has “more than once cautioned that ‘courts “should not read into the patent laws limitations and conditions which the legislature has not expressed.”’” *Diehr*, 450 U.S. at 182 (quoting *Chakrabarty*, 447 U.S. at 308). Accordingly, while the Act's other sections provide stringent requirements for obtaining a patent, such as novelty (§ 102) and non-obviousness (§ 103), courts have consistently interpreted the threshold patentability hurdle of § 101 generously. See *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 130 (2001) (“[T]he language of § 101 is extremely broad.”).

At the same time, courts have long recognized that “laws of nature, natural phenomena, and abstract ideas” are not patentable standing alone. *Diehr*, 450 U.S. at 185. But that principle must be approached carefully, because every step of every invention can be expressed as simply a reflection of fundamental principles of physics, chemistry, or other sciences. *See id.* at 189 n.12 (“[A]ll inventions can be reduced to underlying principles of nature[.]”). As Justice Frankfurter recognized, “[e]verything that happens may be deemed ‘the work of nature,’ and any patentable composite exemplifies in its properties ‘the laws of nature.’” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 134-35 (1948) (Frankfurter, J., concurring).

The exclusion of “natural phenomena” and “scientific principles” has always been limited to *abstract* principles, as distinguished from their concrete applications. As an influential early court explained, a patent cannot claim mere scientific “principles,” which are “the first ground[s] and rule[s] for arts and sciences, or in other words the elements and rudiments of them. A patent must be for some new production from those elements, and not for the elements themselves.” *Boulton v. Bull*, 2 H. Bl. 463, 485 (C.C.P. 1795); *see also Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853) (“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.”).

A patent therefore may not claim abstract principles like the law of gravity,  $E=mc^2$ , multiplication tables, the Pythagorean Theorem, the role of oxygen in making fire, electromagnetism, qualities of metals, and

qualities of naturally-occurring bacteria. See *Chakrabarty*, 447 U.S. at 309; *Parker v. Flook*, 437 U.S. 584, 590 (1978); *id.* at 598-99 (Stewart, J., dissenting); *Gottschalk v. Benson*, 409 U.S. 63, 67-70 (1972); *Funk Bros.*, 333 U.S. at 130; *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 116 (1854); *EMI Group N. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001).

On the other hand, concrete applications of fundamental principles have long been patentable. Examples include using time and temperature to cure rubber, genetically engineering bacteria to clean up oil spills, using heat to incubate eggs, using electrical current to transmit voice and sound at a distance, using temperature and pressure to separate molecules, using gravity and puffs of air to separate out flour impurities, using a blast of hot air to improve a smelting furnace, and measuring electrical signals to ascertain the health of a patient's heart. See *Diehr*, 450 U.S. at 188; *Chakrabarty*, 447 U.S. at 310; *Waxham v. Smith*, 294 U.S. 20, 21-22 (1935); *United States v. Am. Bell Tel. Co.*, 128 U.S. 315, 351-52 (1888); *Tilghman v. Proctor*, 102 U.S. 707, 721-22 (1880); *Cochrane v. Deener*, 94 U.S. 780, 784-85 (1877); *Neilson v. Harford*, 151 Eng. Rep. 1266, 1273 (Ex. 1841); *Arrhythmia Research Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1060-61 (Fed. Cir. 1992). All of those patents relied on natural phenomena and laws for the efficacy of the process, and claimed a statutory monopoly over the practical consequences of those laws in a particular practical setting. The patents were valid, however, because they claimed a concrete process to achieve a tangible result, rather than claiming the underlying scientific principles in the abstract.

Precisely where to draw the line between abstract principles and concrete applications may be challenging in hard cases, but any test must focus on excluding only *abstract* principles. Attempts to wield § 101 beyond that division will risk decimating broad fields of innovation. Essentially any mechanical or chemical process relies for its efficacy on the “correlation” between a human action and its “natural” consequences under scientific laws. This Court’s precedents recognize a narrow judicially-created exception to the otherwise sweeping scope of § 101, which prevents anyone from claiming a patent on such scientific laws *in the abstract*. See *Bilski*, 545 F.3d at 1013 (Rader, J., dissenting) (“The Supreme Court stated that all of the transformation and machine linkage explanations simply restated the abstractness rule.”). But that exception must be handled cautiously, and construed narrowly, or it will render broad fields of practical innovation unpatentable.

Unquestionably, many business method processes are troubling as a matter of patentability. See *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 397 (2006) (Kennedy, J., concurring) (noting the “vagueness and suspect validity” of business method patents). Many consist merely of simple methods of organizing basic human affairs, while others strike dangerously close to being purely mental concepts. See *Bilski*, 545 F.3d at 1010 (Mayer, J., dissenting) (noting the patent system has “run amok” with a “wide variety of non-technological ‘inventions’ such as arbitration methods, dating methods, tax-planning methods, legal methods, and novel-writing methods”) (citation omitted). However, the crucial lesson from this Court’s and the Federal Circuit’s interpretations of § 101 is that § 101

presents a poor tool to filter out *all* such inventions that are undeserving of patent protection. First, attempts to apply § 101 as a sweeping filter risk eliminating many broad swaths of genuinely innovative processes for which patent incentives are crucial. Second, a broad role for § 101 is not necessary because many troubling business methods are likely to fail other substantive requirements of patentability, such as novelty and non-obviousness. The bottom line is that applying § 101 to exclude only abstract concepts will preserve patentability for important fields of innovation such as personalized medicine, while filtering out some but not all business methods that are too abstract. Other business methods may be unpatentable for their failure to satisfy the more demanding, substantive requirements of the Patent Act. And those business methods that satisfy all of the Patent Act's filters are likely to be concrete and innovative enough to deserve patent protection.

Prometheus takes no position on whether the Bilski patent is so abstract as to fall outside of § 101. *Compare Bilski*, 545 F.3d at 997 (Newman, J., dissenting) (answering in the negative), *with id.* at 1013 (Rader, J., dissenting) (answering in the affirmative). But the Court should use this opportunity to clarify that § 101 only excludes patents on abstract principles, and does not compel any more searching or restrictive inquiry.

## II. AN UNDULY RESTRICTIVE INTERPRETATION OF § 101 COULD STIFLE THE DEVELOPMENT OF MEDICAL DIAGNOSTIC AND TREATMENT TECHNOLOGY

This Court has repeatedly emphasized that “[t]he subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts,’” and that if restrictions are appropriate they should come from Congress. *Chakrabarty*, 447 U.S. at 315-18 (quoting U.S. Const. art. I, § 8, cl. 8). The Court has also stressed that it has no intention of “freez[ing] process patents to old technologies, leaving no room for the revelations of the new, onrushing technology.” *Benson*, 409 U.S. at 71. In deciding whether a patent may cross § 101’s broad threshold, the Court has avoided rigid formulaic approaches, in favor of a flexible inquiry that considers whether the process “as a whole, is performing a function which the patent laws were designed to protect.” *Diehr*, 450 U.S. at 192.

The principal medical advances of the next century will likely include treatments optimized for individual patients on the basis of genetic or other testing, such as tests that identify correlations between protein levels in the human body and the efficacy of potentially-toxic drugs, or processes that identify genetic markers that make a patient likely to benefit (or not) from a uniquely targeted cancer treatment. Educational institutions, non-profit organizations, corporations and scientists have made significant investments in recent years uncovering the correlations between naturally-

occurring genes in the human body and the efficacy of various man-made treatment strategies, opening the way to new and highly effective treatment and diagnostic protocols. These innovations have consistently been held patentable by the U.S. Patent and Trademark Office, and recognized by the Federal Circuit. *See, e.g., Fiers v. Revel*, 984 F.2d 1164, 1166-67, 1172 (Fed. Cir. 1993); *In re Bell*, 991 F.2d 781, 782 (Fed. Cir. 1993). The patentability of such discoveries is vital to enabling innovators to recover the research investment and to continue to invest in future research.

Although the court below acknowledged the need to encourage cutting-edge innovations, *Bilski*, 545 F.3d at 956, it crafted an exclusive “machine-or-transformation test” that, if applied restrictively, would do exactly the opposite. Indeed, the lower court explicitly acknowledged that “future developments in technology and the sciences may present difficult challenges to the machine-or-transformation test” and invited this Court to “alter or perhaps even set aside this test to accommodate emerging technologies.” *Id.* Under the Federal Circuit’s test, a method is patentable only if “(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing,” *id.* at 954, and only provided the machines and transformations are not merely part of “insignificant extra-solution activity,” *id.* at 957 & n.14. The court held that this test is the exclusive means for determining whether a method qualifies as a “process” under 35 U.S.C. § 101, or instead preempts an unpatentable natural law or abstract principle. *Bilski*, 545 F.3d at 957.

As the Federal Circuit essentially acknowledged, its machine-or-transformation test derives from cases

involving industrial-era processes rather than modern innovation, particularly in the fields of medicine and biotechnology. In theory there is no reason that that test cannot embrace the full scope of modern innovation, so long as its elements are not understood in an inappropriately restrictive way. But if courts read the decision to impose an unduly restrictive interpretation of § 101—as is already happening<sup>2</sup>—it puts the entire field of individualized medicine and treatment methods at risk, for at least three reasons.

First, courts applying the machine-or-transformation test might refuse to treat reactions in the human body as “transformations,” and instead view such reactions as unpatentable “naturally occurring” phenomena. Yet, nearly all medical diagnostic and method of treatment patents rely on correlations between markers occurring (naturally or unnaturally) in the human body and disease states or rely on the body’s “natural” reaction to the administration of artificial compounds. Indeed, the ultimate purpose of medical treatment is to “transform” a sick patient into a healthy one and such methods have long been thought patentable. *See, e.g., Impax Labs., Inc. v. Aventis Pharms. Inc.*, 545 F.3d 1312, 1314 (Fed. Cir. 2008) (upholding method patent treating Lou Gehrig’s disease with riluzole); *Merck & Co. v. Teva Pharms. USA, Inc.*, 347 F.3d 1367, 1369 (Fed. Cir. 2003) (upholding method patent for treating urolithiasis); *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d

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<sup>2</sup> *See Classen Immunotherapies, Inc. v. Biogen IDEC*, 304 Fed. Appx. 866 (Fed. Cir. 2008) (unpublished) (rejecting medical treatment patent in light of *Bilski*’s machine-or-transformation test, without analysis).

1223, 1224, 1230-32 (Fed. Cir. 1994) (upholding method patent for treating AIDS with AZT), *cert. denied*, 516 U.S. 1070 (1996).<sup>3</sup>

Second, if the Federal Circuit's focus on "machines" were applied to exclude other categories of patentable subject matter, it would implement a bias in favor of industrial age processes that would undermine medical treatment patents. *See Bilski*, 545 F.3d at 1011-14 (Rader, J., dissenting). The statute expressly states that patentable subject matter includes any useful "process, machine, manufacture, or composition of matter" and that a "process" includes "a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. §§ 101, 100; *see also id.* § 155 (providing term extension during FDA regulatory review for a "patent which encompasses within its scope a composition of matter or a *process for using such composition*") (emphasis added). Medical diagnostic patents and method of treatment patents frequently consist of "processes" involving compositions of matter that unquestionably fall within the text of § 101 but would fail a cramped application of the Federal Circuit's machine-or-transformation test. There is no evidence that Congress intended to single out machines, alone among the enumerated statutory subject matters, for special status under the patent

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<sup>3</sup> *See also In re Zierden*, 411 F.2d 1325, 1326, 1329 (C.C.P.A. 1969) (rejecting challenge to patented method for using compound to purify water and noting that "there is express statutory authority for a patent on a process which is a new use of a known process, composition of matter, or material") (citing 35 U.S.C. §§ 100(b), 101); *cf. Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 185 (1980) (assuming, without deciding, validity of patent drawn to method of using propanil as an herbicide).

laws. Indeed, two judges suggested that processes “involving manufactures, machines, or compositions of matter” are patentable under § 101. *Bilski*, 545 F.3d at 966 (Dyk, J., concurring, with Linn, J.). Nothing suggests that Congress wanted to bias the development of science toward solutions relying on mechanical rather than chemical or bio-chemical engineering. And processes involving synthetic, patentable compositions of matter, such as pharmaceuticals, no more preempt “natural laws” or “fundamental principles” than processes involving man-made machines do. This Court should clarify that a proper understanding of § 101 does not include any such arbitrary, non-statutory distinction.

Third, courts applying the *Bilski* test might treat the analysis of correlations between markers in the human body and disease conditions necessary to improve patient treatment as “insignificant extra-solution activity” or “mere data gathering.” For example, a method involving extracting, transforming, and analyzing bodily fluids in order to diagnose a disease and provide vital information for calibrating patient treatment is a concrete process with real-world benefits (saving or enhancing lives). However, the decision below could be read to permit courts to exclude the transformations and machines necessarily involved in those steps as peripheral to the process, without providing the courts useful direction to distinguish the peripheral from the essential. *Bilski*, 545 F.3d at 957. A test for § 101 that establishes a needlessly restrictive conception of transformation or “machines,” or an overly expansive exclusion of what constitutes “mere data gathering” or “insignificant extra-solution activity” would threaten to render all

medical treatment and diagnostic methods unpatentable.

The dissent in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (“*Lab Corp*”), starts down this dangerous path. In *Lab Corp*, the Court was poised to consider the patentability of a medical diagnostic method for determining vitamin deficiencies based on a patient’s homocysteine levels, but instead determined the issue was not properly presented. This provoked a dissent, which argued that the method was an unpatentable natural phenomenon because it “embod[ies] only the correlation between homocysteine and vitamin deficiency.” *Id.* at 137 (Breyer, J., dissenting).

However, as one judge in *Bilski* argued, the *Lab Corp* dissent “is premised on a fundamental misapprehension of the distinction between a natural phenomenon and a patentable process.” *Bilski*, 545 F.3d at 1014 (Rader, J., dissenting). There is nothing “abstract” about a “new process that detects the life-threatening condition” by assaying a patient’s blood and measuring certain amino acid levels. *Id.* Only by ignoring the concrete thrust and steps of the diagnostic patent as a whole could the *Lab Corp* dissent conclude that the process consisted of nothing more than a natural law akin to such grand principles as gravity or  $E=mc^2$ . 548 U.S. at 134-37. For example, the dissent argued that the necessary physical transformation of a blood sample is not a qualifying “transformation” for purposes of § 101 because the method is “not a process for transforming blood or any other matter.” *Id.* at 136. Also, the dissent found irrelevant the method’s useful and tangible result of improving patient care. *Id.* at 136-37.

The *Lab Corp* dissent's restrictive application of § 101, to which the court below gave a passing nod, *Bilski*, 545 F.3d at 965 n.27, puts all such diagnostic and treatment patents at risk. Indeed, in another case, a district court leaned heavily on the *Lab Corp* dissent in rejecting even more clearly patentable methods for improving treatment of autoimmune diseases (such as Crohn's disease) involving administering thiopurine drugs, measuring the resulting metabolite levels in the patient's blood, and deriving useful data for calibrating future treatment. See *Prometheus Labs., Inc. v. Mayo Collaborative Servs.*, No. 04-cv-1200 JAH (RBB), 2008 WL 878910 (S.D. Cal. Mar. 28, 2008), *appeal pending* No. 2008-1403 (Fed. Cir.) (oral argument held Aug. 5, 2009). Even though these methods provide doctors with crucial individualized information that permits far more effective (often life-saving) treatment of seriously-ill patients, the district court rejected the process patents under § 101 as embodying nothing more than "natural phenomena" and "mere[] data-gathering" steps. *Id.* at \*6-12 (relying on reasoning in *Lab Corp* dissent). Applied restrictively, the *Bilski* machine-or-transformation test might similarly render all such treatment methods unpatentable. See *Classen*, 304 Fed. Appx. at 867 (unpublished) (rejecting immunization method patents in light of *Bilski*). This would not only upset the settled expectations of thousands of patent-holders, but more importantly would stifle future developments in a field that has produced improved methods for diagnosing and treating such debilitating or life-threatening conditions as lung cancer, breast cancer, ovarian cancer, prostate cancer, Alzheimer's disease, fibromyalgia, bone loss, and urolithiasis. See, e.g., U.S. Pat. Nos. 7,368,233

(2008), 4,968,603 (1990), 5,840,501 (1998), 5,599,677 (1997), 5,985,581 (1999), 7,056,686 (2006), 5,541,221 (1996), 4,621,077 (1986).

It is notable that Congress expressly considered whether medical methods should be patentable, and declined to amend the Patent Act to exclude such methods from its aegis. In 1995, Congress considered exempting certain medical methods from patent protection, but ultimately declined to do so. H.R. 1127, 104th Cong. (introduced Mar. 3, 1995). In 1996, Congress provided limited immunity from patent infringement liability for the performance of certain medical procedures, but it did not exempt such procedures from patent protection. 35 U.S.C. § 287(c); *see* Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 (1996). This Court has previously found such factors significant in construing § 101. *J.E.M. Ag Supply, Inc.*, 534 U.S. at 145 (reasoning that, in the face of numerous plant patents, Congress “not only failed to pass legislation indicating that it disagrees with the PTO’s interpretation of § 101, it has even recognized the availability of [§ 101] patents for plants”).

The incentives provided by the patent system are critical to promoting technological innovation in the field of personalized medicine, where development costs are high and costs of imitation are often low.<sup>4</sup>

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<sup>4</sup> *See* Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. Pa. L. Rev. 761, 823-24 (2002) (“Where the expense and time necessary to invent and commercialize a product is significant, the importance of patents increases. ... [T]he cost of searching for the next [biotechnology] breakthrough can be prohibitive.”); *id.* at 827 (“The easier it is for competitors to imitate a product, the greater is the need for patents.”); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L.

Denial of patent protection would “undermine and discourage future research” for such tools. *Bilski*, 545 F.3d at 1014 (Rader, J., dissenting). Indeed, some have credited this Court’s decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (recognizing the patentability of a genetically engineered bacteria), with spurring progress in genetic engineering. See FTC, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, ch. 1, at 21 & n.143 (2003), available at <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> (citing examples).

On the other hand, many business method patents, such as Amazon’s “one-click” patent, describe “simple ideas easily conceived” that could profitably have been developed without the incentives provided by the patent system. Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. Pa. L. Rev. 761, 826 (2002). Unlike such business methods that “by their very nature, provide a competitive advantage and thus generate their own incentives,” *Bilski*, 545 F.3d at 1005 (Mayer, J., dissenting), personalized medicine requires investment in innovation that may not be recouped absent patent protection. See also Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1616-18 (2003) (while innovation in business methods would continue in the absence of patent protection, “innovation would drop substantially

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Rev. 1575, 1616 (2003) (“The ratio of inventor cost to imitator cost [in pharmaceuticals], therefore, is quite large in the absence of effective patent protection.”); *id.* at 1589 n.37 (“[Two] studies found that patents play a major role in supporting innovation in only a few industries, most notably in chemistry and pharmaceuticals.”).

in the pharmaceutical industry in the absence of effective patent protection”). It is fair to question whether the availability of business method patents promotes innovation and research as opposed to rent-seeking, but those same concerns do not apply to diagnostic and therapeutic innovations.

In deciding this case about a business-method patent, the Court should take care not inadvertently to squelch the promise of genetic and personalized medicine by adopting a general approach to § 101 that would prove hostile to innovations in medicine and biotechnology. Concerns over expansive patents on abstract methods of arranging business dealings or legal affairs provide no warrant to artificially tie the scope of § 101 to a bygone industrial era. This Court should make clear that any § 101 test must avoid such pitfalls and remain flexible enough “to allow courts to adapt to the rapid technological and legal developments in the patent system.” *eBay Inc.*, 547 U.S. at 397 (Kennedy, J., concurring). At the very least, this Court should explicitly reserve the question of how best to analyze medical diagnostic and treatment patents so that the lower courts do not mistakenly apply any standards arising from this case to unsettle such patents. *Cf.* Gov. Opp. to Cert. at 17 n.4 (noting that the decision below did not resolve the “eligibility of biotechnological or chemical inventions”).

## CONCLUSION

This Court should hold that § 101 excludes only abstract principles, and at a minimum should interpret § 101 in a manner that does not threaten the

burgeoning field of medical diagnostic and treatment technology.

Respectfully submitted,

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