No. 08-964

IN THE

Supreme Court of the United States

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.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE* NOVARTIS CORPORATION SUPPORTING PETITIONERS

EVAN A. YOUNG
BAKER BOTTS L.L.P.
1500 San Jacinto Center
98 San Jacinto Boulevard
Austin, Texas 78701-4078
(512) 322-2500

JENNIFER GORDON
SCOTT B. FAMILANT
STEVEN P. LENDARIS
JENNIFER COZEOLINO
BAKER BOTTS L.L.P.
30 Rockefeller Center
New York, NY 10112
(212) 408-2500

JEFFREY A. LAMKEN
Counsel of Record
BAKER BOTTS L.L.P.
1299 Pennsylvania Ave., NW
Washington, D.C. 20004-2400
(202) 639-7700

Counsel for Amicus Curiae Novartis Corporation

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D.C. 20002

QUESTIONS PRESENTED

1. 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."

2. Whether the Federal Circuit's "machine-or-transformation" test for patent eligibility, which effectively forecloses meaningful patent protection to many business methods, contradicts the clear Congressional intent that patents protect "method[s] of doing or conducting business." 35 U.S.C. § 273.

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BRIEF OF *AMICUS CURIAE* NOVARTIS CORPORATION SUPPORTING PETITIONERS

INTEREST OF *AMICUS CURIAE*

Novartis Corporation, through its U.S. affiliates (hereinafter collectively "Novartis"), provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet patient and social needs: innovative medicines, cost-saving generic pharma-

ceuticals, preventive vaccines, diagnostic tools, and consumer health products. Novartis is the only company that provides innovative benefits to patients in all of these areas. Novartis relies on the patent system to protect its many innovations in patient care. Without the promise of exclusive rights in validly patented subject matter, the investment incentive for the research and development needed to discover innovative pharmaceutical and diagnostic products is greatly diminished.

Novartis has great interest in this case because the Federal Circuit's rigid and putatively exclusive machine-or-transformation test, as articulated in the decision below, potentially threatens to remove from patent-eligibility under 35 U.S.C. § 101 the types of inventive processes in which Novartis has heavily invested and continues to pursue at great cost, including innovations relating to personalized medicine. Personalized medicine not only provides for more effectively and economically marshaled healthcare resources but also—and more importantly—improves patients' well-being and, indeed, saves lives. Affirmance of the Federal Circuit's approach for determining process patent-eligibility could have an immediate, negative impact on personalized health care, an area of great importance to patients and to Novartis.[1]

SUMMARY OF ARGUMENT

This Court should reject the Federal Circuit's one-size-fits-all test for assessing the patent-eligibility of process claims. That court held that § 101 of the Patent

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[1] Pursuant to this Court's Rule 37.6, *amicus* affirm that no counsel for a party authored this brief in whole or in part, that no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief, and that no person or persons other than *amicus* and its counsel made such a monetary contribution. Both parties have consented to the filing of this brief. The parties' letters so consenting have been filed with the Clerk's office.

Act, 35 U.S.C. §101, permits a process to be patented 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." Pet. App. 12a. Although the decision below evaluated a business-method claim, its machine-or-transformation test appears intended to apply to *any* process claim. *Id.* at 15a-16a. In that respect, the test overreaches and unduly restricts §101's textually broad scope.

The difficulty of reconciling the Federal Circuit's test with process claims arising in the context of the biological sciences—a field that differs greatly from the transaction hedging the Federal Circuit had before it—is strong evidence that the Federal Circuit went too far. This Court recently had an opportunity to consider the scope of patent-eligibility under §101 in a biological context in *Lab. Corp. of Am. Holdings* v. *Metabolite Labs., Inc.*, 548 U.S. 124 (2006). But the Court was unable to reach the merits because the issue was not properly preserved for its review. In his dissent, Justice Breyer (joined by Justices Stevens and Souter) stated that he would have reached the question presented and would have held that the patent claim at issue (a process claim for detecting a vitamin deficiency) amounted to "an unpatentable 'natural phenomenon.'" *Id.* at 132-34, 138 (Breyer, J., dissenting from dismissal of certiorari).

Although the decision below and the dissenting views expressed in *Lab. Corp.* spring from legitimate concerns, their proposed solutions, which are based on faulty premises, would unduly constrict the scope of §101. Both opinions unnecessarily raise uncertainties about the patent-eligibility of diagnostic methods that are based on the detection or measuring of "biomarkers," such as DNA sequences or other biological substances that are indicative of a host having or being predisposed to a certain disease

or condition. This case provides an opportunity to ensure that the scope of § 101 is properly calibrated.

A. The *Lab. Corp.* dissent and the machine-or-transformation test as applied by the court below focus on § 101 without giving full effect to its text or how it fits into the overall scheme of the Patent Act. Although § 101's scope is not boundless, this Court has recognized that it is a "dynamic provision designed to encompass new and unforeseen inventions." See *J.E.M. Ag. Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 135 (2001).

There is no reason why process claims based on detecting or measuring biomarkers should fall outside § 101's scope. Section 101 guarantees that "[w]hoever 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." The only explicit limitation on that expansive statutory language is the exclusion of processes that preempt laws of nature, natural phenomena, or abstract ideas.[2] Processes *applying* the foregoing, however, do not preempt them, and hence are eligible for patent protection under § 101.

Giving § 101 its ordinary and expansive meaning does not minimize the legitimate and important concerns underlying the *Lab. Corp.* dissent—that abusive or otherwise meritless patent claims not be allowed to impede the proper functioning of the patent system as a whole or to deprive society of free access to knowledge that is not attributable to an inventor. But this important policing

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[2] Although the "laws of nature" and "natural phenomena" exceptions are technically separate, they are analytically indistinct for purposes of this brief. When referring to the conceptual space occupied by both the "laws of nature" and "natural phenomena" exceptions, this brief will refer for convenience to "the laws of nature."

function is ordinarily not the job of § 101; it is instead, as § 101 itself indicates, the work of other "conditions and requirements" of the Patent Act. Sections 102, 103, and 112 are particularly potent statutory safeguards against claims unworthy of protection, *even if* those claims fall within the capacious scope of § 101.

B. Diagnostic-process claims properly fall within § 101's protection. They are integral and inseparable ingredients in the larger process of managing and treating disease. Such claims are at the front-end of the healing process. An extraordinary investment of intellectual and financial resources allows scientists to identify biomarkers, which in turn have created a new era of "personalized medicine," *i.e.,* individualized patient care tailored to a patient's unique biological profile, including his or her genetic makeup. Innovations in personalized medicine are thus largely based on the discovery of natural laws, specifically that biomarkers are, for example, predictive of disease or of responsiveness to specific drugs.

The dissent in *Lab. Corp.* expressed doubts about the patent-eligibility of diagnostic-process claims that, without reciting an underlying transformative event, appear to cover data gathering and a natural correlation.[3] The dissent's view that such claims are essentially and impermissibly directed to a law of nature *itself* is incorrect. That error arose because the assaying step of the claim at issue in *Lab. Corp.* was never fully analyzed below, if at all, in the § 101 context. Claims such as those at issue in *Lab. Corp.* are directed to a practical *application* of a

[3] For instance, a diagnostic claim might be phrased "a method for diagnosing disease X in a human patient comprising (a) detecting in a sample taken from such patient the presence of sequence Y in gene Z, wherein the presence of sequence Y in gene Z indicates the likelihood of developing disease X; and (b) diagnosing whether the patient will develop disease X based on the result of step (a)."

law of nature. They require the testing of a patient sample (an act of human intervention) for a particular biomarker, which, if present, signifies a corresponding disease or a predisposition to develop it in the future. Such test results, in turn, open the door for that patient to be treated in an individualized fashion. Consequently, diagnostic-process claims are directed to perhaps the most "useful" endeavor of all—directly enhancing the quality of, or even sustaining the very existence of, human life.

Importantly, such claims do not "preempt" the laws of biology, physics, or chemistry as they manifest themselves in nature, as the *Lab. Corp.* dissent suggests. The two steps of the claim (*i.e.*, "assaying" and "correlating") must be practiced for there to be an act of infringement. Hence, an individual who possesses a biomarker indicative of a particular condition does not infringe such claims by living and breathing. Neither do such claims stop anyone, including a patient's own physician, from simply thinking about possible medical predispositions in light of the presence or absence of a biomarker.

Similarly, the Federal Circuit's approach in the decision below has the potential to deny protection to diagnostic-process claims to the extent they neither tie the method of detecting a given biomarker to a particular machine nor recite a series of transformative steps that enable that detection. But the development of such diagnostic methods is the fruit of tremendous intellectual and financial exertion, and the resulting methods provide both increasing and extraordinary benefits to patients. The factual and policy considerations surrounding the patent-worthiness of claims to life-saving diagnostics are simply too distinct and complex to foreclose their ability to qualify for patent-eligibility on considerations other than whether they implicate machines or transformations. If the machine-or-transformation test were to deny such diagnostic methods the opportunity for patent

protection, the incentive for conducting such costly and useful research would be dramatically diminished.

C. Because diagnostic-process claims are proper under § 101, this Court should make clear that it is not endorsing the machine-or-transformation test as the definitive test for assessing the patent-eligibility of all process claims. But even if the Court were to adopt the machine-or-transformation test in some fashion, it should recognize that diagnostic-process claims are entirely unlike the business-method claims at issue in this case. A bare, descriptive mathematical formula addressing commodity-price hedging may be susceptible to the § 101 limitation on patenting "abstractions." But diagnostic-process claims such as those involving biomarkers implicate the very different limitation on claiming "laws of nature." Hence whatever merit there may be to using the machine-or-transformation test as one means to assess a process claim's patent-eligibility, this Court should make clear that it is not requiring satisfaction of that test as the only test for a diagnostic-process claim to be patent-eligible; that narrow question should at the very least be reserved for a case that squarely involves such patent claims and raises such issues.

ARGUMENT

THE FEDERAL CIRCUIT'S MACHINE-OR-TRANSFORMATION TEST UNDULY NARROWS THE SCOPE OF PATENT-ELIGIBILITY FOR PROCESS CLAIMS UNDER § 101

This case asks one of the most fundamental questions in patent law: When is a "process" eligible for patent protection under 35 U.S.C. § 101? In the opinion below, the Federal Circuit ruled that any process claim is patent-eligible 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." Pet. App. 12a. Three years ago, this Court considered a similar question in *Lab. Corp. of*

Am. Holdings v. *Metabolite Labs., Inc.*, 548 U.S. 124 (2006). Because the Court ultimately concluded that the question had not been properly preserved, it declined to address it. In dissent, Justice Breyer (joined by Justices Stevens and Souter) urged that the Court should have answered the question, and opined that the patent claim at issue—a process for detecting a vitamin deficiency—was "an unpatentable 'natural phenomenon.'" *Id.* at 138 (Breyer, J., dissenting from dismissal of certiorari).

The two opinions in those two cases chart different courses and involve different types of process claims (a business-method claim and a diagnostic-process claim). But both endanger the ability of the pharmaceutical and biotechnology industries, which are revolutionizing the nature of health care, to patent diagnostic processes emerging from intensive and costly research and development. Denying patents for such claims would contravene the text and purposes of the Patent Act. This case provides the Court an opportunity to rectify the erroneous approaches suggested by the decision below and the dissenting opinion in *Lab. Corp.*

A. The Text and Structure of the Patent Act Reflect §101's Broad Scope as Well as the Counter-Balance Provided by Other Sections of the Act

Any consideration of the scope of §101 must "begin[] with the plain language of the statute." *Jimenez* v. *Quarterman*, 129 S. Ct. 681, 685 (2009). Section 101 provides that "[w]hoever *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 (emphasis added). "Process" is defined as "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *Id.*

§ 100(b). The Federal Circuit, by pronouncing that the machine-or-transformation test is the sole prism through which a process claim's compliance with § 101 should be judged, failed to respect the capacious statutory standard established by § 101's text.

Section 101 identifies four independent classes of patent claims that are eligible for protection. So long as it is "new and useful," any "process," "machine," "manufacture," or "composition of matter" can be the subject a patent claim. The court below, by adopting the machine-or-transformation test, adds a requirement that makes qualifying a process claim under § 101, in comparison to the other three recognized classes of patent claims, more onerous. Nothing in the text of § 101, however, requires that a process claim's patent-eligibility should turn on its having a nexus to a machine or transformation. To the contrary, § 101 by its terms makes a new and useful "process" *or* "machine" *or* "manufacture" *or* "composition of matter" potentially patentable subject matter; nowhere does it limit patent-eligibility for processes to those that are "tied" to a machine or transformation of matter.

Moreover, imposing such a requirement is antithetical to § 101's intended reach. The machine-or-transformation test could, for instance, be *one* way of establishing that a process *is* patent-eligible. The Federal Circuit was therefore correct to observe that any "claimed process is surely patent-eligible under § 101" if it satisfies that test. Pet. App. 12a. But the court erred by making it the *exclusive* test applicable to *all types* of process claims—a *sine qua non* for process claims to be patentable subject matter. See *id.* at 15a-16a. In doing so, that court failed to give proper effect to, and unduly constricted, § 101.

This Court, by contrast, has repeatedly acknowledged § 101's breadth. For example, the Court has held that it was Congress's intent that the Patent Act authorize the

patenting of "anything under the sun that is made by man." *Diamond* v. *Diehr*, 450 U.S. 175, 182 (1981) (citation omitted). This broad perspective on § 101 has been the underlying basis for this Court's findings of patent-eligibility for a diverse array of subject matter, ranging from a directional antenna system in which the wire arrangement was determined by the logical application of a mathematical formula, see *Mackay Radio & Telegraph Co.* v. *Radio Corp. of Am.*, 306 U.S. 86 (1939), to organisms genetically engineered to break down crude oil, see *Diamond* v. *Chakrabarty*, 447 U.S. 303 (1980). Such a perspective recognizes that the text of § 101 is broadly inclusive. The only restrictions on that broad understanding of § 101 are the prohibitions against claiming "laws of nature, natural phenomena, and abstract ideas." *Diehr*, 450 U.S. at 185.

Even those exclusions have their limitations, as process claims involving such laws, phenomena, or ideas are patent-eligible if the process is a new and useful *application* of those laws, phenomena, or ideas. *Id.* at 187. Other decisions by this Court make the same point: "'He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly *of it* which the law recognizes. If there is to be invention from such a discovery, it must come from the *application* of the law of nature to a new and useful end.'" *Gottschalk* v. *Benson*, 409 U.S. 63, 67 (1972) (quoting *Funk Bros. Seed Co.* v. *Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (emphasis added)). This Court's precedents thus establish a bright-line test under which one may not preempt a law of nature *itself*, but may patent an *application* of it for "new and useful" ends. This should not be viewed as an unusual balance to strike; virtually any useful patent claim must ultimately rely on laws of nature to generate worthwhile results. As articulated in more detail in Section B, *infra*, diagnostic-process claims like the one at

issue in *Lab. Corp.* are not directed to a law of nature itself, but to a practical application of a law, namely the use of a natural correlation to make a diagnosis. Hence they do not offend § 101.

This does not minimize or trivialize the legitimate and important concerns expressed, in particular, in the *Lab. Corp.* dissent. Those concerns underscore the necessity of having proper safeguards to weed out abusive or otherwise meritless patents. If "anything under the sun" can be patented, that overabundance can create genuine inefficiencies and unfairness. "[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts,' the constitutional objective of patent and copyright protection." *Lab. Corp.*, 548 U.S. at 126-27 (Breyer, J., dissenting) (emphasis in original). One can agree with this concern while disputing how best to deal with it. Section 101 may appear to be unduly embracive, but it bears emphasis that it is, by its own terms, not the final hurdle a claim must clear before it can be patented. Rather, patentability ultimately turns on meeting "the conditions and requirements of" the rest of the Patent Act. 35 U.S.C. § 101.

Those "conditions and requirements" appear principally in §§ 102, 103, and 112 of the Patent Act. For example, §§ 102 and 103 preclude claims from covering subject matter that is anticipated by or obvious in view of the art. See, *e.g.*, *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1345, 1352 (Fed. Cir. 2002) (claims to growing sprouts to reduce the level of carcinogens and, in turn, the risk of developing cancer in animals that consume them were anticipated; the carcinogen-lowering potential of sprouts are "inherent properties * * * put there by nature" such that the patentee had "not claimed anything that is new"); *Schering Corp.* v. *Geneva Pharms., Inc.*, 339 F.3d 1373, 1382 (Fed. Cir. 2003) (method of treating hay-fever

with a metabolite of loratadine was inherently anticipated because loratadine, a prior art therapy, inherently converts to the metabolite upon ingestion); *In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988) (producing the claimed genus of proteins would have been obvious in view of the prior art). Indeed, § 102 provides an added level of protection against claims directed to a law of nature itself because such a law would inherently be within the art and hence anticipate such claims. See *EMI Group N. Am., Inc.* v. *Cypress Semiconductor Corp.*, 268 F.3d 1342, 1351 (Fed. Cir. 2001) (citing *Funk Bros. Seed*, 333 U.S. at 130).

Section 112 provides further protection. It ensures that claims are properly supported by a specification that describes their subject matter in a sufficiently clear and detailed fashion that they can be made and used. See, *e.g., Regents of the Univ. of California* v. *Eli Lilly & Co.*, 119 F.3d 1559, 1567 (Fed. Cir. 1997) (disclosure of the genetic sequence for rat insulin gene did not entitle the patentee to generically claim mammalian or vertebrate insulin genes or the human insulin gene); *In re Fisher*, 421 F.3d 1365, 1367 (Fed. Cir. 2005) (claims to purified nucleic acid sequences that encode proteins and protein fragments in maize plants were not enabled; "the claimed invention lacks a specific and substantial utility and * * * the * * * application does not enable one of ordinary skill in the art to use the invention").[4]

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[4] See also *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398 (2007) (expanding the circumstances under which claims can be deemed obvious); *Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) ("Both the novelty and the nonobviousness requirements of federal patent law are grounded in the notion that concepts within the public grasp, or those so obvious they readily could be, are the tools of creation available to all."); *O'Reilly* v. *Morse*, 56 U.S. (15 How.) 62, 119-20 (1853) (patent specification's description did not adequately support claims generically directed to using electro-

As the foregoing examples make clear, the Patent Act strikes a balance that makes frequent recourse to § 101 unwarranted. Consequently, there was little reason for the decision below to impose a restrictive construction on that provision by requiring processes to have a relationship to a machine or to the transformation of matter. To the contrary, that requirement is incompatible with the broad scope of § 101 that this Court has long recognized and that its text commands. To the extent the *Lab. Corp.* dissent can be construed as endorsing that test as the only way to judge a diagnostic-process claim's compliance with § 101, see 548 U.S. at 136 (Breyer, J., dissenting), it too suffers from the same fundamental defect.

To be sure, § 101 does provide a gate-keeping function that would be triggered where the claim at issue attempts to patent nothing more than a "natural phenomenon." See *Lab. Corp.*, 548 U.S. at 137-38 (Breyer, J., dissenting). But as shown in Section B, *infra*, diagnostic-process claims like the one in *Lab. Corp.* properly fall within § 101's scope.

B. Diagnostic-Process Claims Merit Protection Under § 101 Because They Are Applications of "Laws of Nature"

Viewing a claim to a diagnostic process as nothing more than a claim to the discovery of a law of nature, as the dissent did in *Lab. Corp.*, is analytically flawed. That view ignores expressly-recited claim steps and wholly misunderstands the nature and import of such process claims. As explained below, the nature of the subject-matter covered by diagnostic-process claims makes clear

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magnetism to print characters at a distance). There is no doubt that the principles articulated in this Court's patent law precedent, while developed outside the biological context, are fully capable of application in that context, and that diagnostic-process claims—like any other claim—are subject to scrutiny under §§ 102, 103, and 112.

that such revolutionary, 21st century subject matter is properly protected under § 101 and is not, as the *Lab. Corp.* dissent asserted, excluded from protection as an improper preemption of "laws of nature."

1. *The Ability to Detect or Measure Biomarkers Makes Personalized Medicine Possible*

Advancements in human genetic research have exploded in the 28 years since this Court last considered the scope of patent-eligibility for processes under § 101 in *Diehr*. The Human Genome Project—the first complete sequencing of the entire human genome—is perhaps the most prominent example; it has captured the public's imagination in showing how far science has moved. By providing researchers with a detailed map of the genes on all 23 human chromosomes, the Human Genome Project has accelerated the identification of relationships between specific genes and diseases. Products encoded by genes sequenced under the Human Genome Project have complex interrelationships; teasing out those relationships, and identifying malfunctions in these gene products, particularly those that cause diseases, has only just begun to produce improved medical treatments. Finding those relationships provides doctors with unprecedented tools for the treatment and prevention of disease. Indeed, the identification of those relationships will allow our healthcare system to shift from reaction to prevention. Simple genetic tests have the potential to flag disease predisposition long before any symptoms occur, when steps can be taken to delay or even prevent what otherwise would be inevitable. That shift to prevention is widely recognized as having the potential to result in unprecedented gains in patient outcome and cost containment.

Recent advances in the biological sciences have also identified relationships between biomarkers and diseases that not only indicate an individual's predisposition for a

particular disease, but also how a patient may respond to particular treatments for that disease. The identification of biomarkers that help predict the efficacy of particular therapies permits physicians to tailor a treatment regimen for a particular patient. Such tailoring, in turn, lowers healthcare costs. That benefits not only individual patients and public and private insurance companies. It also benefits the federal government and state governments that now bear substantial healthcare funding obligations. Personalized medicine achieves significant efficiencies—and dramatic improvements in results and quality of life—by identifying which therapeutics will work for a particular patient, and which might be less effective, without physicians having to engage in the expensive, time-consuming, and often empirical process of determining whether a patient responds favorably to a therapy, which has been the hallmark of traditional medicine.

Novartis and many other healthcare companies are expending hundreds of millions of dollars to identify new biomarkers and apply their detection to new diagnostic and therapeutic methods. Although driven by the desire to improve healthcare, the prospect of patent protection also provides an important incentive to expend the time, effort, and dollars involved in making biomedical discoveries and translating them into new medical procedures that help patients. The days of administering a drug to all patients sharing a particular disease may soon be over as healthcare companies identify the patient subpopulations most likely to benefit from any one particular therapy. Thus, it is of paramount importance that appropriate consideration be given to the patentability of the process claims at the heart of personalized medicine.

The incentives afforded by the patent system, which spur on these critical advancements, may be at risk if this Court adopts the approach of the dissent in *Lab. Corp.* or

the Federal Circuit's decision below. It is all too easy to dismiss the relationships being identified in this new era of personalized medicine as discoveries of the laws of nature. After all, they reflect a correlation between a biomarker and a patient's predisposition to have a disease or respond to a particular drug. But the discovery of those relationships and their utility in treating diseases can represent a critical advance in the important art of making the unhealthy healthy, or providing the individual who is prone to disease with immunity to its effects. Where a new and useful process for identifying those who are at risk for disease or most likely to benefit from a particular treatment is discovered, it represents a true advance in the art of medicine and technology. The fact that the claimed invention is not tied to a particular machine or transformation should not exclude it from being patentable subject matter nor make it less worthy of patent protection.

2. *The Claim at Issue in* Lab. Corp. *Is Patent-Eligible Under § 101*

The invention at the core of the controversy in *Lab. Corp.* was a method for detecting B vitamin (cobalamin or folate) deficiencies. See *Metabolite Labs., Inc.* v. *Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358-59 (Fed. Cir. 2004). Deficiencies in cobalamin and folate are medically significant. If left untreated, such deficiencies can lead to serious complications including cardiovascular, neurologic, and psychiatric pathologies, such as stroke, peripheral neuropathy, and depression. See, *e.g.*, Robert C. Oh & David L. Brown, *Vitamin B12 Deficiency,* 67 Am. Fam. Physician 979, 979 (2003). Claim 13 of U.S. Patent No. 4,940,648, the only claim at issue in *Lab. Corp.*, reads as follows:

> 13. A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:

> assaying a body fluid for an elevated level of total homocysteine; and
>
> correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

See 370 F.3d at 1358-59. The law of nature exploited in the claimed method is the fact that cobalamin and folate are used by the body as co-factors for enzymatic activity. Much as an automobile engine cannot convert gasoline into motive power in the absence of spark plugs, the enzyme that the body employs to convert homocysteine into cysteine cannot effectively accomplish that conversion in the absence of its co-factors cobalamin and folate. Thus, an increase in homocysteine and a decrease in cysteine, both of which would occur if the enzyme were not functioning properly, may be indicative of a deficiency in one or both of the co-factors. Claim 13 therefore represents a particular application of the discovery that homocysteine is converted to cysteine by an enzyme requiring cobalamin or folate as a co-factor for optimal activity. Specifically, the claim is directed to measuring increased levels of homocysteine (which occur because it is not being enzymatically converted to cysteine) as a marker for a cobalamin or folate deficiency.

The concerns raised by Justice Breyer in his dissent in *Lab. Corp.* are significant and deserve a full and robust debate. But the debate in *Lab. Corp.* was distorted by the way in which that case had been litigated, and the issues framed, in the lower courts. Under controlling jurisprudence, patent-infringement liability attaches to a method claim when a single party can be held accountable for practicing all steps of the claim. See *Muniauction, Inc.* v. *Thomson Corp.*, 532 F.3d 1318, 1328-30 (Fed. Cir. 2008) (a method claim is infringed only when a single party can be found to have performed every step of the claim, or where a party can be held

vicariously liable for others practicing those steps). In *Lab. Corp.*, the parties did not dispute before the Federal Circuit whether the doctors performed one of the critical steps, which was the assaying step. See *Metabolite Labs.*, 370 F.3d at 1364 n.1. Instead, the focus of the parties' arguments was the district court's interpretation of the correlating step of the claim and whether, as a result of that construction, the doctors could be said to have performed it. Because the assaying step was not in dispute, the correlating step became determinative of whether doctors infringed the claim.

The exclusive focus of the infringement inquiry on the correlating step all but ensured that the import of the assaying step would be conceptually disregarded as merely "gather[ing] data" in the context of the dissent's § 101 analysis. See *Lab. Corp.*, 548 U.S. at 137 (Breyer, J., dissenting). Without the benefit of a fully developed record regarding the meaning and import of the assaying step, the *Lab. Corp.* dissent appeared to construe claim 13 as embodying only the correlation between elevated homocysteine levels and a deficiency in cobalamin or folate, and, in turn, viewed the claim as impermissibly directed to a law of nature, in violation of § 101.

The assaying step is an integral limitation of the claim that cannot be disregarded when analyzing the claim's compliance with § 101. Indeed, were the correct analysis applied, it would have been clear that the claim does not attempt to monopolize a law of nature. It is a general principle of patent law that "claims must be considered as a whole." *Diehr*, 450 U.S. at 176, 188; see also *Aro Mfg. Co.* v. *Convertible Top Replacement Co.*, 365 U.S. 336, 345 (1961) (applying this principle to analyzing infringement); *Para-Ordnance Mfg., Inc.* v. *SGS Importers Int'l, Inc.*, 73 F.3d 1085, 1088 (Fed. Cir. 1995) (applying the principle to a determination of obviousness).

The assaying step of claim 13 serves a critical function. Beyond providing a measurement needed to make the correlation that the second step of the claim requires, the assaying step enables a doctor to make a diagnosis with respect to a particular patient and prescribe a therapy for treating that patient. That is no trivial matter. By according the assaying step its proper meaning, claim 13 is no longer directed to the law of nature *itself*, but to a practical *application* of that law. Indeed, as a matter of logic, the ability to make a diagnosis cannot be changed from an application of a law of nature into the law of nature itself, or vice versa, simply because the claim does or does not explicitly refer to a machine or transformative events.

As a result, the claim at issue in *Lab. Corp.* does not preempt "'basic tools of scientific and technological work,'" *Lab. Corp.*, 548 U.S. at 127 (Breyer, J., dissenting) (quoting *Gottschalk*, 409 U.S. at 67), that should be free for anyone's use. Significantly, the claim does not encroach on the practice of medicine as envisioned in the dissent. For example, the claim does not prevent doctors from drawing conclusions based on test results they are not accountable for generating. Similarly, the claim presents no bar to doctors mentally considering or applying the correlation when it is not tied to a test result. Nor does the claim cover the population of people whose bodies inherently manifest the correlation because they are deficient in cobalamin or folate. Rather, the claim is limited to only those situations where a single actor can be held accountable for both: (a) assaying the amount of homocysteine present in a body fluid; and (b) correlating an elevated amount with a cobalamin or folate deficiency.

In addition, the assaying step requires considerable human intervention; a doctor cannot detect a deficiency in cobalamin or folate through simple observation of a patient. Such a diagnosis can only be reached following

testing of a sample. Such deliberative action is tantamount to creating a machine that operates in accordance with the law of nature or using the law to induce a transformation. Hence, claim 13 falls comfortably within *Diehr*'s pronouncement that patent-eligibility should be extended to "anything under the sun that is made by man." *Diehr*, 450 U.S. at 182.

Furthermore, the patentee in *Lab. Corp.* was correct in arguing to this Court that the assaying techniques necessary to measure cobalamin and folate levels do invariably implicate transformations of one form or another. Hence, the claim at issue did not need to recite a particular assaying means, as the dissent suggests, see 548 U.S. at 136 (Breyer, J., dissenting), for the patentee to avail itself of such an argument; the claim language should have sufficed. Moreover, there is nothing otherwise inappropriate about using a term such as "assaying" (or "detecting" or "measuring") in the first step of a diagnostic-process claim so long as such a term: (a) is properly supported by the specification under § 112, see, *e.g.*, *In re Swinehart*, 439 F.2d 210, 213 (C.C.P.A. 1971); *In re Grimme*, 274 F.2d 949, 952 (C.C.PA. 1960); and (b) does not read on the prior art under §§ 102 and 103.

The points made above are equally applicable to virtually any diagnostic claim relating to personalized medicine. At a minimum, such claims involve an assay or detection step, such as a genetic test to determine the presence or absence of a particular DNA sequence, coupled to a subsequent correlation of the presence or absence of that sequence with a predisposition for either developing a disease or receptiveness to a particular therapy. In such contexts, the act of detecting the DNA sequence, or some other biomarker, is a significant corporeal intervention that invariably implicates transformative events. Moreover, the detection step enables the law of nature to be applied to facilitate a diagnosis or treatment. Such ap-

plications of the law of nature take the claim out of the realm of monopolizing the law of nature itself. Again, when not accountable for performing an assaying or detection step, doctors do not infringe when they use the results of such a step to counsel a patient. By embodying so much more than mere naturally-occurring correlations, diagnostic claims relating to personalized medicine fall well within the scope of § 101, as defined by this Court's precedent.

3. *The Rigidity of the Decision Below Improperly Threatens Diagnostic-Process Claims*

The Federal Circuit's unreasonably rigid application of the machine-or-transformation test also jeopardizes the patent-eligibility of diagnostic-process claims. In contrast to the test applied by the Federal Circuit, § 101 requires only that the "invent[ion] or discover[y]" for which protection is sought be "new and useful." As shown above, diagnostic-process claims are based on discoveries of previously-unknown relationships, without which the benefits they unlock would remain hidden. Additionally, they are indisputably "useful." Personalized medicine can be the difference between life and death. It directly enhances the quality of, or even sustains the very existence of, human life. It is hard to imagine a more "useful" invention than a process applying newly discovered natural relationships to that end.

The Federal Circuit's test is, of course, one way to determine that a process is patent-eligible, but the adoption of a strict rule, which extols consistency at the expense of innovation, is in direct conflict with this Court's precedent. The diagnostic-process claims at the heart of personalized medicine are the result of the same kind of intellectual exertion and have the same utility as machine-age processes, even though they are couched in the language of molecular biology rather than that of mechanics and electronics. Factual and policy considera-

tions in the 21st century show the wisdom of this Court's description of § 101 as a "dynamic provision designed to encompass new and unforeseen inventions." *J.E.M. Ag. Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 135 (2001). The machine-or-transformation test takes the opposite approach, forcing all process claims into a mold that decidedly looks backward in time. These considerations cast considerable doubt on any approach that would allow life-saving diagnostics to be patented only if they can satisfy a rigid machine-or-transformation test.

* * *

The analysis suggested in the *Lab. Corp.* dissent and the machine-or-transformation test articulated by the decision below have the potential to deny patent protection to diagnostic-process claims that are no less deserving of that protection than any other new and useful discovery. They would do so, moreover, by writing new requirements into the text of § 101 and by refusing to acknowledge the full content of those claims. Nothing in the text or history of § 101 suggests that patent protection ought not extend to the valuable fruits of the exacting labor that must be invested to develop such important new medical advances. Nor is there any basis for this Court engrafting such an exclusion into the statute itself.

C. Regardless of How It Resolves the Instant Appeal, This Court Should Not Endorse the Machine-or-Transformation Test as the Definitive Means for Assessing the Patent-Eligibility of Process Claims

No doubt, petitioners and other *amici* will demonstrate that the Federal Circuit simply misread this Court's cases when it interpreted them as imposing the machine-or-transformation test as the definitive standard for judging the patent-eligibility of a process claim. The Court thus should reverse the decision below in light of

the Federal Circuit's fundamental misreading of this Court's cases and the text of § 101.

If the Court endorses the machine-or-transformation test in this context, nonetheless, it should make clear that its decision does not make that test the dispositive standard against which all process claims' compliance with § 101 must be judged. Novartis does not believe that diagnostic-process claims necessarily fail to satisfy the machine-or-transformation test as a general matter. But the Court ought not attempt to create a one-size-fits-all solution in the context of a case, like this one, which provides no reason to rule that expansively. As the *Lab. Corp.* dissent makes clear, a diagnostic-process claim may implicate the "laws of nature" exception to § 101, whereas business-method claims, like those at issue in the present case, implicate the distinct "abstractions" exception to § 101. The substantial differences between a claim to diagnosing a pathology (as illustrated in *Lab. Corp.*) and price hedging (as illustrated in this case), and the likely legal consequences stemming from those differences, only further underscore the fact that this case is not the proper vehicle for assessing whether a diagnostic-process claim must or can meet a machine-or-transformation test.

Accordingly, should this Court affirm the judgment below, it should reserve for another day whether the machine-or-transformation test should be the sole test for judging the patent-eligibility of diagnostic-process claims. Such a reservation will ensure that lower courts and litigants do not attribute to this Court a "holding" that extends inappropriately beyond the issues and matters before it. Reserving the issue will facilitate this Court's ability to resolve that issue after a full record is developed in an appropriate case squarely raising a diagnostic-process claim's compliance with § 101.

CONCLUSION

This Court's precedents regarding patent-eligibility under 35 U.S.C. § 101 have served the country well and, if reaffirmed, will continue to do so. By contrast, the Federal Circuit's rigid implementation of the machine-or-transformation test represents an unnecessary departure from this Court's precedents. And it has the potential to jeopardize the benefits of many modern innovations, including the innovations that will allow personalized medicine to become a reality. Similarly, the *Lab. Corp.* dissent too freely invokes the "law of nature" exception to deprive a diagnostic-process claim of patent-eligibility under § 101. This Court should therefore reaffirm its broad interpretation of § 101 and reverse the Federal Circuit's pronouncement that the so-called machine-or-transformation test is the sole test for judging the patent-eligibility of all process claims.

Respectfully submitted.

EVAN A. YOUNG
BAKER BOTTS L.L.P.
1500 San Jacinto Center
98 San Jacinto Boulevard
Austin, Texas 78701-4078
(512) 322-2500

JENNIFER GORDON
SCOTT B. FAMILANT
STEVEN P. LENDARIS
JENNIFER COZEOLINO
BAKER BOTTS L.L.P.
30 Rockefeller Center
New York, NY 10112
(212) 408-2500

JEFFREY A. LAMKEN
Counsel of Record
BAKER BOTTS L.L.P.
1299 Pennsylvania Ave., NW
Washington, D.C. 20004-2400
(202) 639-7700

Counsel for Amicus Curiae Novartis Corporation

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