

No. 10-1150

IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES, DBA 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 PHARMACEUTICAL RESEARCH
AND MANUFACTURERS OF AMERICA AS *AMICUS*
CURIAE IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association that represents the country’s leading research-based pharmaceutical and biotechnology companies.¹ In the past decade, PhRMA’s members have invested more than \$406 billion to discover and develop new medicines and new uses for existing medicines. *See* PhRMA, PHARMACEUTICAL INDUSTRY PROFILE 2011 at 42 (2011). In 2010 alone, the pharmaceutical industry invested a record \$67.4 billion in such research and development.

The results of this research save lives. *See generally* Frank R. Lichtenberg, *The Impact of New Drug Launches on Longevity: Evidence from Longitudinal, Disease-Level Data from 52 Countries, 1982-2001*, 5 Int’l J. of Health Care Fin. & Econ. 47, 71 (2005). Today, “the most important advances in treatment” often come from new uses for existing pharmaceuticals – products “whose properties were not completely understood until intensive research after the drug was introduced.” John Calfee, *The Golden Age of Medical Innovation*, *The American* (Mar./Apr. 2007), *available at* <http://www.american.com/archive/2007/march-april-magazine-contents/the-golden-age-of-medical-innovation>

¹ Pursuant to Supreme Court Rule 37.6, *amicus* states that no counsel for any party authored this brief in whole or in part, nor did any party, counsel for a party, or person other than *amicus*, its non-party members, or their counsel make a monetary contribution intending to fund this brief’s preparation or submission. All parties have consented to this filing.

[hereinafter “*Golden Age*”]. Researchers are also making significant advances in “personalized” medicine, which tailors treatment to a particular patient’s genetic or other biological characteristics. Life-saving treatments in these two areas include, for example, the use of AZT to treat HIV and the use of Herceptin to treat a particular group of breast cancer patients.

The Court’s decision in this case will potentially have a significant impact on PhRMA’s members.² A ruling limiting the availability of patents for medical processes under 35 U.S.C. § 101 could dramatically diminish the incentives for investment in innovation. The average cost of bringing a pharmaceutical to market is over a billion dollars. Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *Managerial & Decision Econ.* 469, 477 (2007). The costs of developing processes for new uses for existing drugs and processes for personalized medicine are similarly substantial. *See, e.g.*, Maya Said et al., *Continued Development of Approved Biological Drugs: A Quantitative Study of Additional Indications Approved Postlaunch in the United States 6* (Boston Consulting Group, White Paper, Dec. 2007), available at <http://www.bcgsea.com/documents/file15138.pdf>. In the absence of the incentives provided by patent protection for novel processes, promising research for new methods of diagnosis and treatment likely will not occur.

² A list of PhRMA members can be found at <http://www.phrma.org/about/member-companies>.

SUMMARY OF ARGUMENT

This Court's decisions make clear that a broad range of subject matter is eligible for patent protection under 35 U.S.C. § 101. They also make clear that the "law of nature" exception to § 101 should be interpreted narrowly. Under these decisions, medical-process patents involving pharmaceuticals – which are the products of human ingenuity, and cannot be found in nature – necessarily fall within the scope of § 101.

Congress has also clearly expressed its intent to protect medical-process patents involving pharmaceuticals. It has, for example, provided for term extensions for patents covering a "method of using" a drug product, 35 U.S.C. § 156(a), and has decided not to enact legislation that would have restricted the patentability of medical processes. Moreover, Congress has balanced the interests of physicians and inventors by immunizing physicians when they infringe certain method patents, but not when they infringe patents for new uses of pharmaceuticals.

Under this regime, medical innovation has thrived. Patents for medical processes, including those involving pharmaceuticals, have been issued and upheld for more than a hundred years. At present, tremendous and life-saving advances are being made with respect to various kinds of medical processes, including new uses for existing pharmaceuticals and processes for "personalized" medicine. These advances, which entail extraordinary risk and expense on the part of the

pharmaceutical and biotechnology industries, likely would not take place without the certainty and stability provided by the promise of patent protection.

Petitioners seek to change the law so as to destabilize this regime, and undercut the incentives for innovation, in at least three ways – all of which should be rejected. First, this Court should rebuff Petitioners’ suggestion to import an obviousness inquiry into the test for patentability under § 101. Second, the Court should decline to break apart a medical-process claim into its discrete steps for purposes of ascertaining whether a natural law is at play. Finally, the Court should make clear that assessment of whether a patent has an undesirably broad preemptive effect is a policy judgment best left to Congress, and does not control the determination of whether the patent’s subject matter is eligible for protection under § 101.

ARGUMENT

I. Under This Court’s Precedents, Medical-Process Patents Involving Pharmaceuticals Are Patentable Under Section 101

Section 101 provides that any “new and useful process” or “any new and useful improvement thereof” is entitled to patent protection, making no exception for any particular type of process. 35 U.S.C. § 101. Congress wrote § 101 with intentional breadth. The wide scope of patentable subject matter, beginning with the 1793 Patent Act and extending through each subsequent re-codification, reflects Jefferson’s view that “ingenuity should

receive a liberal encouragement.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980) (quoting 5 Writings of Thomas Jefferson 75-76 (H. Washington ed. 1871)); *see also Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010); *Diamond v. Diehr*, 450 U.S. 175, 182 (1981); 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) (describing § 101 as “coarse filter”).³ It also gives the law sufficient flexibility to meet “the revelations of . . . onrushing technology.” *Gottschalk v. Benson*, 409 U.S. 63, 71 (1972).

This Court has long identified “three specific exceptions to § 101’s broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas.” *Bilski*, 130 S. Ct. at 3225. These exceptions “are not the kind of ‘discoveries’ that the statute was enacted to protect,” *Parker v. Flook*, 437 U.S. 584, 593 (1978), because “they are the basic tools of scientific and technological work,” *Gottschalk*, 409 U.S. at 67; *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948), which must be available for building future inventions, *Bilski*, 130 S. Ct. at 3231.

But these exceptions must be applied “narrowly.” *Bilski*, 130 S. Ct. at 3229. The “relevant distinction” is “between products of nature . . . and human-made invention.” *Chakrabarty*, 447 U.S. at 313. Thus, it is not possible to patent “the heat of the sun,

³ The Patent Act of 1793 used the term “art,” which Congress replaced with “process” when it enacted the current version of § 101 in 1952. *In re Bilski*, 545 F.3d 943, 951 n.4 (Fed. Cir. 2008), *aff’d*, 130 S. Ct. 3218 (2010).

electricity, or the qualities of metals,” *Funk Bros.*, 333 U.S. at 130, or the “law that $E=mc^2$ ” or the “law of gravity,” or “a new mineral discovered in the earth or a new plant found in the wild,” *Chakrabarty*, 447 U.S. at 309. But when human ingenuity is applied to create a process that involves these natural laws or objects, § 101 is satisfied. *See, e.g., Mackay Radio & Tel. Co. v. Radio Corp. of America*, 306 U.S. 86, 94 (1939).

This Court’s recent decision in *Bilski v. Kappos*, 130 S. Ct. 3218 (2010), reaffirmed this longstanding approach. The Court emphasized that any limits on the scope of patentability under § 101 must “further the purposes of the Patent Act” and be consistent “with its text.” *Id.* at 3231. And the Court rejected two “atextual” rules – that “business processes” are categorically unpatentable and that the “machine or transformation” test should be the “exclusive” means for determining whether a process satisfies § 101. *Id.* at 3229. At the same time, however, the Court described the machine-or-transformation test as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” *Id.* at 3227; *see also id.* at 3232 (Stevens, J., concurring) (“the entire Court agrees” that “the machine-or-transformation test is reliable in most cases”); *Cochrane v. Deener*, 94 U.S. 780, 788 (1877).

Patents involving pharmaceuticals – whether they cover a chemical substance or a process in which that substance is measured or employed – necessarily involve such a transformation, and fall within the scope of § 101. Pharmaceuticals are not

found materials like minerals or plants; they exist only as the result of human ingenuity. And the mixing of chemical substances, or a process for chemical transformation of a substance or object, is in the heartland of patent-eligible subject matter. *See, e.g., Tilghman v. Proctor*, 102 U.S. 707, 728 (1881) (“The mixing of certain substances together, or the heating of a substance to a certain temperature, is a process.”). That is true not only when the chemicals are mixed in a laboratory beaker but also when they are put into or measured in the human body. In this case, for example, the patent covers the administration of a man-made drug, which creates metabolites in the body that would not exist in the absence of that drug, as well as the determination of the resulting effects on the patient.⁴ Pet.App.17a-18a (description of “effect on the body after metabolizing the artificially administered drugs” and transformation entailed in “extract[ing] the metabolites . . . and determin[ing] their concentration”); *see also* Gov’t Br. 13-14. Although there are natural laws at work that help explain why the drug creates a particular metabolite at particular levels, none of this is purely the “handiwork of nature.” *Chakrabarty*, 447 U.S. at 310.

⁴ The patents here claim “methods for optimizing efficacy and reducing toxicity of treatment regimes for . . . autoimmune diseases that utilize drugs” that create metabolites called 6-TG and 6-MMP. Pet.App.16a-18a. Some of the claims contain three steps: (1) “administering” a drug that creates the metabolites, (2) “determining” the resulting metabolite levels, and (3) warning of “a need’ to increase or decrease the level of drug.” *Id.* at 3a. Others contain only steps 2 and 3. *Id.* at 18a.

II. Congress Has Balanced Competing Policy Considerations And Clearly Expressed Its Intent To Provide Patent Protection For Medical Processes Involving Pharmaceuticals

Congress has also made clear that medical processes are patentable, especially if they involve the administration of a pharmaceutical or a new use for a pharmaceutical. Any interpretation of § 101 that excludes medical processes involving pharmaceuticals would effectively write a number of provisions out of the U.S. Code, and would contravene other strong evidence of congressional intent.

As an initial matter, the statutory definition of “process” demonstrates that the mere fact that a process uses an existing compound does not remove it from the scope of patent protection. The statute defines the term “process” to mean “process, art or method” and states that it “includes a new use of a known process, machine, manufacture, composition of matter, or material.” 35 U.S.C. § 100(b). Accordingly, the fact that the patent at issue in this case makes use of a pharmaceutical that was invented by others, *see* Pet.Br.37 n.7, or a process for adjusting dosage that was already known in the art, does not remove Respondents’ claims from the scope of patentable subject matter under § 101. *See infra* pp. 28-30 (discussing separate role of obviousness in determining validity).

Congress has also more specifically addressed patents involving a method of using a pharmaceutical, in several different enactments.

First, the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585, assumes that such methods are patentable. In that statute, Congress required parties applying for approval of a new drug to list certain related patents, including any patent “which claims a method of using such drug.” 21 U.S.C. § 355(b)(1). Congress also required applicants to provide supplemental information when any new patents issue, including new patents on methods of use. *Id.* § 355(c)(2). And Congress provided (under some conditions) for term extensions for patents claiming not only a “method of manufacturing a [pharmaceutical] product” but also “a method of using a [pharmaceutical] product.” 35 U.S.C. § 156(a); *see also id.* § 156(f). Plainly, Congress would not have enacted these provisions if it did not intend for these processes to be patentable or if it believed that a significant subset of pharmaceutical-related medical-process patents fell outside the scope of § 101. *Edelman v. Lynchburg Coll.*, 535 U.S. 106 (2002).

Second, in 1996, Congress *rejected* a proposal to preclude the issuance of a patent for any medical procedure that did not use a patentable product, and instead decided to exempt medical professionals from patent remedies *except* when they are violating patents for new uses of pharmaceuticals. This legislation arose in reaction to a controversy over a lawsuit by one physician against another for purportedly infringing a patent on a method of surgery – the first case of its type to go to trial. *See* Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. Pat. &

Trademark Off. Soc’y 381, 405 (2000); 142 Cong. Rec. 26,825-26 (1996) (statement of Sen. Frist). The bills initially introduced in the House and Senate would have either precluded the issuance of patents for medical procedures altogether unless the underlying product was itself patentable, H.R. 1127, 104th Cong. (1995), or redefined what would constitute infringement of patents for medical processes, including protecting medical professionals from any liability in that arena, S. 1334, 104th Cong. (1995). Neither bill attracted much support. See Richard P. Burgoon, Jr., *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c)*, 4 U. Balt. Intell. Prop. L.J. 69, 79-80 (1996).⁵

Instead, Congress took a nuanced approach that expressly recognized the importance of medical-process patents covering processes that employ pharmaceuticals. Congress decided to protect the interests of medical professionals to only a limited degree, shielding them when they are performing a medical activity unless they infringe certain specific kinds of biotechnology patents. Thus, the statute provides that “[w]ith respect to a medical practitioner’s performance of a medical activity that constitutes an infringement . . . the [remedial] provisions . . . of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.” 35

⁵ Congress had also previously considered and rejected similar legislation. H.R. 12,451, 57th Cong. (1902); H.R. 13,679, 58th Cong. (1904); William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. Pat. & Trademark Off. Soc’y 651, 654 (1995).

U.S.C. § 287(c)(1). But it then *excludes* from the definition of “medical activity” – and thus from the scope of the immunity provision – the “practice of a patented use of a composition of matter” and “the practice of a process in violation of a biotechnology patent.” *Id.* § 287(c)(2)(A); *see also id.* § 287(c)(2)(F).⁶

Thus, it is plain that Congress – having thoroughly considered the issue – wanted to protect *all* medical-process patents involving pharmaceuticals, including those that cover the relationship between the levels of a pharmaceutical in the body and a patient’s health. The legislative history underscores that conclusion. According to the Conference Report, “[u]ses of compositions of matter’ include, without limitation, novel uses of drugs . . . and novel methods for providing genetic or other biological materials to a patient.” H.R. Rep. No. 104-863, at 853 (1996). The report gives two examples of situations in which doctors would not be immunized: infringement of (1) “a claim that recites only the novel use of a drug for the treatment of diabetes that involves the administration of a drug at a particular time of day and/or at a specified dose and/or with a specified concomitant medicinal therapy,” and (2) a claim for a method of transplant surgery that uses a novel anesthetic or a novel dosing schedule for that anesthetic. *Id.* at 853-54. Accordingly, even if a dosing schedule essentially embodies what Petitioners describe as a natural

⁶ Congress has similarly exempted researchers from liability for infringement under certain limited circumstances. 35 U.S.C. § 271(e)(1); *see also Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005); Roche Amicus Br. 25-27.

correlation, it remains patentable, and doctors remain subject to patent remedies if they infringe the patent.

In explaining this legislation, Senator Frist focused heavily on the need to preserve the incentives for innovation that have produced the kinds of medical advances described in Part III below. He discussed the need for innovators to recoup their investments and noted that prior versions of the legislation “could have impacted many worthwhile patents in biotechnology and pharmacology.” 142 Cong. Rec. 26,825 (1996). In contrast, the legislation as it was ultimately enacted was not intended to “change patent law with respect to biotechnology, . . . drugs, or their methods of use,” so as not to “discourage the important research being done in these areas of medicine.” *Id.*

All of this makes clear that Congress has weighed the various policy considerations that Petitioners identify, *see, e.g.*, Pet.Br.48-58, and has decided that medical-process patents involving methods of using pharmaceuticals are entitled to protection even if they could conceivably affect the practice of medicine in some narrow circumstances. Because Congress has already determined that the benefits of pharmaceutical-related medical-process patents in spurring life-saving innovation outweigh any burdens that may be associated with those patents during their limited terms, Petitioners’ concerns are wholly misplaced. *See Chakrabarty*, 447 U.S. at 317; *cf. Bilski*, 130 S. Ct. at 3228-29 (construing § 101 in light of statutory defense to infringement of business-method patents).

Congress's enactments also show that any interpretation of § 101 that disqualifies medical-process patents involving correlations between administration of a pharmaceutical and reactions in the human body – a category into which a number of such patents fall – would significantly alter the scope of § 101 in a way that is inconsistent with the legislature's own policy choices. *See Bilski*, 130 S. Ct. at 3226 (noting that “courts ‘should not read into the patent laws limitations and conditions which the legislature has not expressed’” (quoting *Diehr*, 450 U.S. at 182)). When Congress wishes to remove a particular subject matter from the broad scope of patent protection, it knows how to do so. *See* 35 U.S.C. § 287; *cf., e.g.*, Pub. L. No. 112-29 § 14(a), 125 Stat. 284, 327 (2011) (stating that “any strategy for reducing, avoiding, or deferring tax liability” is not patentable because it “shall be deemed insufficient to differentiate a claimed invention from the prior art”). Here, far from excluding medical-process patents involving methods of using pharmaceuticals, Congress has repeatedly and expressly included them.

III. Patent Protection For Medical Processes Has Spurred Innovation That Improves Patient Health

Under the regime reflected in this Court's decisions and Congress's enactments, medical innovation has thrived. The resulting inventions comprise medicines, devices, and diagnostic and therapeutic methods that have enabled physicians throughout the world to diagnose and treat many diseases. Patent protection has been – and will

continue to be – critical in spurring the progress of science in this vital area.

1. Relying on § 101, innovators have developed and patented medical processes, such as the process of using a particular drug in a particular fashion, for more than a hundred years. *See Diehr*, 450 U.S. at 183-84; *see also* Gov't Br. 15-16. Early patents for medical processes included (1) patent 4,848, issued in 1846 for surgical anesthesia with ether, (2) patent 58,034, issued in 1866 for an improved method of curing rheumatism, (3) patent 65,044, issued in 1867 for an improved method of treating “affection” of the skin, (4) patent 2,008,526, issued in 1935 for treating hepatomegaly with electrical current, and (5) patent 2,322,245, issued in 1943 for a method of transcutaneous injection.

During these early years, courts and the Board of Patent Appeals frequently upheld these types of patents. For instance, in *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628 (S.D.N.Y. 1930), the court concluded that a method of performing operations by injecting toxin into the patient was patentable. *See id.* at 630. In *Ex parte Wappler*, 26 U.S.P.Q. (BNA) 191 (Pat. Off. Bd. App. 1935), the Board of Patent Appeals found patentable a method for shrinking living tissue. *See id.* at 192. And in *Ex parte Kettering*, 35 U.S.P.Q. (BNA) 342 (Pat. Off. Bd. App. 1936), the Board of Patent Appeals ruled that a method for producing fever in the human body was entitled to patent protection. *See id.* at 343.

In 1954, the Board of Patent Appeals expressly rejected an argument that medical processes are not

patentable subject matter. In *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954), the Board upheld a patent claim for a method of injecting fluid into the human body using a fluid jet rather than a hypodermic needle. The Board acknowledged that the usefulness of the claim depended on the reaction of the human body, but explained that “[t]here is nothing in the patent statute which categorically excludes such methods, nor has any general rule of exclusion been developed by decisions.” *Id.* at 110. Indeed, the Board noted that in cases like *Wappler* and *Kettering* “[c]laims involving treatment of the human body have been allowed on appeal.” *Id.* at 109-10.⁷

Since *Scherer*, patents for medical processes – including many patents involving the administration of a pharmaceutical or the assessment of its efficacy – have been routinely granted and upheld. *See, e.g.*, William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. Pat. & Trademark Off. Soc’y 651, 658-60 tbl. 1 (1995) (listing representative medical-method patents); *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1225-26, 1230 (Fed. Cir. 1994) (upholding against an inventorship challenge patents for use of AZT to treat HIV). Any ruling by this Court that threatened the patentability of

⁷ *Scherer* also addressed a nineteenth-century decision that had left open “how far patents can ‘invade the right of protecting health,’” Noonan, 77 J. Pat. & Trademark Off. Soc’y at 654, and – to the extent that the decision had held or implied that “medical or surgical methods are unpatentable” – expressly overruled it, *Scherer*, 103 U.S.P.Q. (BNA) at 110.

medical processes would be a radical departure from this long history of protection.

2. The availability of patents covering such medical processes has provided incentives for inventors to undertake highly expensive and risky research and development, and has therefore been critical to the advancement of medicine. At present, there are at least two areas in which medical processes involving pharmaceuticals are being used to make extraordinary advances in life-saving care: (a) processes involving new uses (also known as “indications”) for existing pharmaceuticals, and (b) processes involving “personalized” medicine, in which treatment is tailored to an individual patient’s physical makeup. Both of these kinds of processes are likely to involve, at some step along the way, the kind of “correlation” that Petitioners claim should not be entitled to any patent protection – for example, a correlation between the administration of an existing pharmaceutical and a reaction in the body that improves pain or cures disease, or a correlation between certain genetic or other patient characteristics and the efficacy of an existing pharmaceutical. But progress as to these kinds of processes would likely grind to a halt without stable and predictable patent protection, which offers the promise of recouping the extraordinary investments that are poured into inventing the processes and obtaining the government approval necessary to use them.

a. Today, much of the innovation in medical care comes from intensive study of possible new uses for existing medicines. Calfee, *Golden Age, supra*.

Where the underlying compound is already known, the compound itself is not eligible for patent protection. The “practice has therefore been to patent as a ‘useful process’ the use of a known drug for a recently discovered purpose.” Andres Rueda, *Cataract Surgery, Male Impotence, Rubber Dentures and a Murder Case – What’s so Special About Medical Process Patents?*, 9 U. Balt. Intell. Prop. L.J. 109, 146 (2001).

One example of a groundbreaking medical-process patent of this kind is the patent covering the use of AZT as a treatment for AIDS. AZT was originally developed as a cancer treatment – a role in which it “failed miserably.” Philip J. Hilts, *Experimental Drug AZT Was Designed for Tumors; Skill, Luck Led to Promising Tests on AIDS*, Wash. Post, Sept. 19, 1986, at A11. It was not until two decades after AZT was first synthesized that scientists began to pursue the drug as a potential HIV treatment under patent protection for the *process* of administering the drug to HIV-positive patients. *See Burroughs*, 40 F.3d at 1225-26, 1230. This discovery was one of the first and most significant victories in the battle against AIDS.

Other examples of such innovations abound. One recent empirical study found that in some classes of medicines, 70-80% of total patient use is attributable to indications developed and approved after the drug first came to market. Ernst R. Berndt et al., *The Impact of Incremental Innovation in Biopharmaceuticals*, 24 *Pharmacoeconomics* (Supp. 2d) 69, 81 (2006); *see also* Said, *supra* (noting that 47% of biologics approved between 1986 and 2006

had at least one additional indication). Medical-process patents covering new uses of existing compounds include, for example, “the application of minoxidil to treat baldness, the administration of a known sugar solution (mannitol) to get drugs into the brain, and the use of a cough medicine (dextromethorphan) to help stroke victims.” *Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary*, 104th Cong. 67 (1995) (prepared testimony of William D. Noonan, M.D.). They also include many new indications used to treat cancer. *See* Catherine Arnst, *Same Cancer Drugs, New Applications*, *Bus. Week Online*, June 3, 2007, available at http://www.businessweek.com/technology/content/jun2007/tc20070603_510760.htm.

And further advances of this kind are on the horizon. Indeed, a “substantial amount of laboratory research conducted by pharmaceutical companies” at present involves “the expensive and painstaking evaluation of known drugs and compounds for unknown curative properties.” Rueda, 9 *U. Balt. Intell. Prop. L.J.* at 146; *see also* Berndt et al., 24 *Pharmacoeconomics* at 71.

b. Personalized medicine is also an area in which extraordinary innovation is taking place. Until recently, “[d]rug selection” was “based on the average response of the patient population.” Matthew Avery, *Personalized Medicine and Rescuing ‘Unsafe’ Drugs with Pharmacogenomics: A Regulatory Perspective*, 65 *Food Drug L.J.* 37, 41 (2010). Personalized medicine identifies

“biomarkers” – genetic or other biological characteristics – that permit doctors to tailor a course of treatment to a particular individual. That allows doctors to guide “medication selection and dosage regimens” to “ensure maximal drug efficiency and minimal adverse drug reaction.” Teresa Kelton, *Pharmacogenomics: The Re-Discovery of the Concept of Tailored Drug Therapy and Personalized Medicine*, 19 No. 3 Health Law. 1, 1 (2007).

Correlations are the basis for this kind of personalization. People with a certain set of genetic characteristics may respond to a particular pharmaceutical when others do not; or they may require a higher dosage for the pharmaceutical to be effective, or experience a drug as toxic to their systems at lower levels than others do. Development of personalized medicine requires clinical research that identifies these correlations and permits creation of diagnostic tests to identify the relevant biomarkers. *See* Michael J. Donovan, *Legal Issues Stemming from the Advancement of Pharmacogenomics*, 14 UCLA J.L. & Tech. 1, 43-45 (2010).

Advances in personalized medicine lower costs from adverse medical events and save lives. For example, Herceptin, a long-known compound, was discovered to effectively treat an aggressive form of breast cancer – but only in the subset of breast cancer patients with an overexpression of the HER-2 protein due to a genetic anomaly. *See* Calfee, *Golden Age, supra*; Michael J. Shuster & Pauline Farmer-Koppenol, *Protecting Patents for Personalized Medicine*, BioPharm Int’l (Sept. 1, 2008), *available at*

<http://biopharminternational.findpharma.com/biopharm/article/articleDetail.jsp?id=545358>; *see also* Roche Amicus Br. 10-11. When administered to HER-2-positive breast cancer patients after surgery, Herceptin cuts the chances of a recurrence *in half*. Calfee, *Golden Age*, *supra*. By discovering the correlation and investing in the development of commercially viable diagnostic tests to identify patients with the HER-2 genes, pharmaceutical companies made it possible to personalize breast-cancer treatment so that Herceptin can be administered only to those patients likely to benefit from it. Avery, 65 Food Drug L.J. at 42; Roche Amicus Br. 10-11. An editorial in the New England Journal of Medicine called this a “revolutionary” advance that “suggests a dramatic and perhaps permanent perturbation of the natural history of the disease, maybe even a cure.” Gabriel N. Hortobagyi, *Trastuzumab in the Treatment of Breast Cancer*, 353 New Engl. J. Med. 1734, 1735-36 (2005); *see also generally* Mara G. Aspinall & Richard G. Hamermesh, *Realizing the Promise of Personalized Medicine*, Harv. Bus. Rev., Oct. 2007, at 108, 111.

In light of success stories like this one, it is not surprising that pharmaceutical companies are investing significant resources in this area. A recent survey found that 12-50% of drugs in the development pipeline are personalized. Tufts Center for the Study of Drug Development, *Personalized Medicine is Playing a Growing Role in Development Pipelines*, 6 Impact Report 1, 12, Nov./Dec. 2010; *see also, e.g.*, Francis S. Collins, *Personalized Medicine: A New Approach to Staying Well*, Boston Globe, July

17, 2005, at E12 (statement by NIH director that “personalized medicine remains one of the most compelling opportunities we have to improve the odds of staying healthy”).

c. Petitioners suggest that patent protection is not necessary in order for advances in medicine like these to take place – and may even prevent such advances. Pet.Br.48-58. Petitioners are wrong. Without some assurance that breakthroughs in these areas will fall within the scope of patentable subject matter, the extraordinary progress described above will likely cease, and the public will suffer.

There is no question – indeed, Petitioners concede, *see id.* at 49-50 & n.9 – that patent protection drives the development of new *compounds* used to treat human beings. Such development is highly risky, involves multiple phases of pre-clinical and clinical testing often lasting for more than a decade, and is extraordinarily costly. *See* DiMasi & Grabowski, 28 *Managerial & Decision Econ.* at 475-76; U.S. Dep’t of Commerce, Int’l Trade Admin., *Pharmaceutical Price Controls in OECD Countries* 30-31 (Dec. 2004). Moreover, this cost must be recouped in a patent term that is often effectively much shorter than the statutory term because of the length of the regulatory review and approval process. Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 *J. Int’l Econ. L.* 849, 852 (2002). There is broad consensus that, under these expensive and difficult circumstances, innovation would not take place without the promise of patent protection – and that this is true not only with respect to start-ups, which are dependent on patents

to signal commercial viability, but also with respect to well-established companies. *See, e.g., Bilski*, 130 S. Ct. at 3253 (Stevens, J., concurring) (“scholars generally agree that when innovation is expensive, risky, and easily copied, inventors are less likely to undertake the guaranteed costs of innovation”); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1615-17 (2003); Ted Sichelman & Stuart J.H. Graham, *Patenting By Entrepreneurs: An Empirical Study*, 17 Mich. Telecomm. Tech. L. Rev. 111, 157, 164 (2010).

Development of processes involving new uses for existing compounds and processes for personalized medicine involves similar challenges, and patent protection is equally necessary to ensure continued progress in these highly significant areas of innovation. Just like an initial indication, a new indication must clear regulatory hurdles, including clinical trials and approval by the FDA – and this process is costly, time consuming, and risky. Indeed, the “size and the complexity of the clinical trials for each new indication are similar to the size and the complexity of those conducted prelaunch and . . . the failure rates remain high.” Said, *supra*, at 6.⁸ FDA approval of a new indication for an existing pharmaceutical typically takes three to six years. *See id.* at 5. Research and development in

⁸ In some cases, the government may require additional trials or impose other costly requirements *after* it has approved a new indication. *See* FDA, *Guidance for Industry: Postmarketing Studies and Clinical Trials* (Apr. 2011), available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM172001.pdf>.

personalized medicine – for which a dizzying amount of data must be gathered, tested, and analyzed – is arduous in these same ways. *See* Avery, 65 Food L.J. at 43-45; Peter Huber, *Who Pays for a Cancer Drug?*, Forbes, Jan. 12, 2009, at 72; Roche Amicus Br. 10-11; *see also, e.g.*, Shuster & Farmer-Kopenel, *Protecting Patents, supra*.

Accordingly, medical-process patents are (like patents on the pharmaceuticals themselves) critical to spurring innovation that will save or improve countless lives. Without the promise of protection that will enable recoupment of the enormous investment that goes into development of these processes, the development will not be undertaken. *See, e.g.*, Said, *supra*, at 6 (concluding based on empirical research that patent protection drives the development of new indications); Deloitte Consulting LLP, *Avoiding No Man's Land: Potential Unintended Consequences of Follow-On Biologics* 17 (Mar. 2009) (“[i]n order for personalized medicine to become a reality, drug innovators will need a regulatory environment that allows a return on their investments”); President’s Council of Advisors, *Priorities for Personalized Medicine* 21 (Sept. 2008), *available at* http://www.whitehouse.gov/files/documents/ostp/PCAST/pcast_report_v2.pdf 21 (“The ability to obtain strong intellectual property protection through patents has been, and will continue to be, essential for pharmaceutical and biotechnology companies to make the large, high-risk R&D investments required to develop novel medical products, including genomics-based molecular diagnostics.”); Frances Toneguzzo, *Impact of Gene*

Patents on the Development of Molecular Diagnostics, 5 Expert Op. Med. Diag. 273, 275 (2011) (“[f]or validation of molecular diagnostics, patents are critical to incentivize the significant investment required”); *see also* Grabowski, 5 J. Int’l Econ. L. at 850-53; Rueda, 9 U. Balt. Intell. Prop. L.J. at 132 (“Without intellectual property protection, companies and individuals who otherwise may have poured time and resources towards medical process research may not do so.”). In an area so fraught with uncertainty, the stability and certainty of patent protection is absolutely critical.

Of course, a company that owns the patent on a pharmaceutical compound already has some incentive to research additional indications – but that incentive is unlikely to be sufficient. The approval process for a second indication frequently takes long enough that the patent period for the original compound has run or nearly run, leaving no possibility of obtaining a meaningful return on investment. *See* Said, *supra*, at 3-4; Martin, 82 J. Pat. & Trademark Off. Soc’y at 396. Moreover, innovations related to new uses for existing drugs frequently happen at the hands of companies that did not discover the compound in the first place. *See, e.g., Burroughs*, 40 F.3d at 1225. Such companies can protect their investment in innovation only by patenting the *process*.

Petitioners try to counter these weighty concerns by contending that academic research is inhibited by patent protection for medical processes. Pet.Br.52-56. Academic research does not generally put life-saving tests and treatments in the hands of patients;

the tremendous investments described above are necessary to do that. *See, e.g., Burroughs*, 40 F.3d at 1225-26 (explaining that while AZT's effects on HIV were first demonstrated in NIH research, the investment of a biotechnology firm turned the drug into a useful treatment for the disease). In any event, however, Petitioners' suggestion is without any basis – and, indeed, empirical research suggests that patent protection is no bar to academic advances. According to one study, only 1% of academic respondents reported a project delay of more than a month due to patents on inputs necessary for their research; none reported abandoning a research project due to the existence of patents. John P. Walsh et al., *Final Report to the National Academy of Sciences' Committee Intellectual Property Rights in Genomic and Protein-Related Inventions: Patents, Material Transfers and Access to Research Inputs in Biomedical Research* (Sept. 20, 2005), available at <http://www2.druid.dk/conferences/viewpaper.php?id+776&cf=8>; *see also, e.g.,* Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 *Hous. L. Rev.* 1059, 1061 (2008) (collecting empirical research), *cited in* Pet.Br.55; Richard Epstein, *Heller's Gridlock Economy in Perspective: Why There Is Too Little, Not Too Much Private Property*, 63 *Ariz. L. Rev.* 51, 77-78 (2011); Roche Amicus Br. 21-27.⁹

⁹ In addition, the mere fact that a medical process falls within the scope of patentable subject matter does not mean that a

In fact, just the opposite is true. Patent disclosures educate the research community on important advances and spark additional progress. Patents make the exchange or acquisition of knowledge more efficient and less costly, allowing the scientific community to learn from the successes and failures of others. *See Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945); Epstein, 63 Ariz. L. Rev. at 80; *see generally* Letter from Sir Isaac Newton to Robert Hooke (Feb. 5, 1675), *reprinted in* Robert K. Merton, *On The Shoulders of Giants: A Shandean Postscript*, at ii (1965) (“[i]f I have seen further [than you and Descartes] it is by standing on ye sho[ul]lders of Giants”). And many advances take place when researchers try to “invent around” an existing patent, finding new (and perhaps better and cheaper) ways to achieve results. *See, e.g., State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235-36 (Fed. Cir. 1985) (explaining that the “‘negative incentive’ to ‘design around’ a competitor’s products” brings “a steady flow of innovations to the marketplace”).

Accordingly, it is clear that disrupting expectations of patent protection in medical processes will severely restrict important medical gains. As one author succinctly explains, “[t]he surest way to hobble medical technology” – particularly with respect to new areas where great advances in medicine are currently being made – “is to damage intellectual property (IP) protections, mainly patents.” Calfee, *Golden Age, supra*.

patent will issue, or survive a challenge; the patent statute sets up a number of other hurdles. *See infra* pp. 28-30.

IV. Petitioners' Approach Destabilizes This Regime And Undercuts Incentives For Innovation

While purporting to rest on this Court's existing precedents, Petitioners call into question the long-established regime that has given rise to these important medical advances. While Petitioners do not clearly state any one test for determining whether something is patentable subject matter, their approach departs from precedent in at least three important respects: (1) it imports into the § 101 analysis an inquiry into the novelty of the invention that is mandated by different provisions in the statute and that should be carried out only after the "coarse filter" of § 101 is applied; (2) it breaks apart a process claim into its individual steps, and examines each step separately to assess whether a natural law is at play; and (3) in the guise of an inquiry about the scope of "preemption," it gives primacy to policy considerations that are properly within the province of the legislature.¹⁰ Were this Court to adopt any of these three aspects of Petitioners' approach, the resulting changes to an area in which "it is especially important that the law remain stable and clear," *Bilski*, 130 S. Ct. at 3231 (Stevens, J., concurring), would disrupt the "settled expectations of the inventing community," and therefore severely undercut the incentives for

¹⁰ In addition, as discussed above, Petitioners err in assuming that the metabolite correlations at issue in this case, which result from a man-made pharmaceutical, are a natural phenomenon. *See supra* p. 7.

medical innovation, *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 739 (2002).

1. This Court should reject Petitioners' attempt to import into § 101 the separate limits set forth in 35 U.S.C. §§ 102 and 103. Section 102 embodies the "anticipation" doctrine, barring a patent on an invention that was already known, used, described, or patented. 35 U.S.C. § 102. Section 103 bars a patent that is different from the prior art "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill." *Id.* § 103.

Petitioners repeatedly argue that Prometheus's patent does not satisfy the requirements of § 101 because the bulk of the claims at issue are insufficiently innovative. Petitioners assert, for example, that doctors "considered metabolite levels on their own years before these patent claims were filed," Pet.Br.25; that the "administration and testing steps are 'well known' and 'long prevalent' in medical practice," *id.* at 35; that respondents "did not invent the drug," *id.* at 37 n.7; and that the patent makes only a "minimal contribution to medicine," *id.* at 40.

These attacks on Prometheus's patent are not in any way addressed to separating invention from nature, as § 101 requires. *Chakrabarty*, 447 U.S. at 313. But Petitioners insist that because "Section 101 on its face limits patentable subject matter to a 'new

and useful process,” this reasoning is consistent with the statute. Pet.Br.36.

This Court has already squarely rejected that argument. As the Court explained in *Diamond v. Diehr*, 450 U.S. 175 (1981), the question “of whether a particular invention is novel is *wholly apart from whether the invention falls into a category of statutory subject matter.*” *Id.* at 190 (emphasis added) (internal quotation marks omitted). That is because the “new and useful” language in § 101 is by its own terms only “a general statement of the type of subject matter that is eligible for patent protection ‘subject to the conditions and requirements of this title.’” *Diehr*, 450 U.S. at 189 (quoting § 101). Highly “[s]pecific conditions for patentability follow” in the subsequent provisions, and Congress plainly intended those to control any determination of whether the invention is new or useful. *Id.*; *see also id.* at 191, 193 n.15.

These separate conditions are stringent, and the obviousness doctrine in particular is a substantial hurdle that not all would-be inventors will overcome. That is especially true with respect to patents in the biological arena, since “the requirement that an invention must be a ‘nonobvious’ advance to be patentable is particularly strictly applied in all the biological examining groups” at the Patent Office. Noonan, 77 J. Pat. & Trademark Off. Soc’y at 661. Indeed, “[t]he likelihood that a biological patent application will successfully issue as a patent is about one-half of the likelihood of success in conventional mechanical and electrical cases,” and the patents that do emerge from “this rigorous

patenting process” are generally “narrow in scope.” *Id.* Courts also often invalidate patents for obviousness when they are challenged in litigation. *See* Jennifer Nock & Sreekar Gadde, *Raising the Bar for Nonobviousness: An Empirical Study of Federal Circuit Case Law Following KSR*, 20 Fed. Cir. B.J. 369, 392 (2010). Accordingly, process patents that do no more than recite traditional medical tests or treatment courses will not survive obviousness review.

This analysis should be carried out under the specific requirements of the relevant statutory provision, however, and not transformed into some sort of free-floating assessment that is liable to depart from the rules that Congress has laid down in §§ 102 and 103. Lest the inquiry come unmoored from the “conditions and requirements” of the statute, 35 U.S.C. § 101, the patent eligibility analysis is – and should remain – “only a threshold test,” *Bilski*, 130 S. Ct. at 3225; *see also Flook*, 437 U.S. at 588 (explaining that the patent-eligibility inquiry “does not involve the familiar issues of novelty and obviousness that routinely arise under §§ 102 and 103 when the validity of a patent is challenged”); Gov’t Br. 16-17.

2. Together with their efforts to use the term “new” in § 101 to import an obviousness inquiry, Petitioners also seek to change the law in another way: by breaking apart a patent claim into small parts and then testing each part separately against § 101. Thus, Petitioners characterize most of the claim steps at issue here as obvious and the remaining step as embodying a natural law – and

insist that the entire claim should therefore be barred under § 101. Pet.Br.33-35 (characterizing part of the claim as a correlation that counts as a “natural phenomenon” and claiming that the “determining” and “administering” steps are invalid for “independent reasons”).

Certain *amici* also suggest that a patent claim need not be read as a whole for purposes of the § 101 inquiry. For instance, the ACLU argues that only a portion of a claim – whatever a court determines after the fact to be its “essence” – should be determinative of patentability under § 101, with the other portions “stripped away.” ACLU Br. 11. Although this argument is stated differently than Petitioners’, it amounts to the same thing: a request that this Court endorse a new and piecemeal approach to assessing a patent claim under § 101.

That approach is deeply flawed. As this Court has explained, there is a law of nature at work somewhere in every patent – perhaps most noticeably in ones that are permissible *applications* of such a law. *See, e.g., Funk Bros.*, 333 U.S. at 135 (Frankfurter, J., concurring) (“Everything that happens may be deemed ‘the work of nature,’ and any patentable composite exemplifies in its properties ‘the laws of nature.’”); *see also Diehr*, 450 U.S. at 189 n.12 (“all inventions can be reduced to underlying principles of nature”); Pet.App.17a (“quite literally every transformation of physical matter can be described as occurring according to natural processes and natural law”). For instance, the kinds of medical-process patents described above regarding new indications and personalized medicine, which

are adding immeasurably to the quality of patient care, involve such laws to the extent that they depend on chemical reactions and other basic scientific principles. Were it permissible to search for the law of nature hidden somewhere within a patent claim, then virtually every patent could conceivably be drawn into question under § 101.

For that reason, this Court has definitively stated that it is “inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.” *Bilski*, 130 S. Ct. at 3230 (quoting *Diehr*, 450 U.S. at 188); *see also id.* (emphasizing “need to consider the invention as a whole” in carrying out the § 101 inquiry). Indeed, analyzing a claim’s elements together is “particularly” important “in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made.” *Diehr*, 450 U.S. at 188.

That rule is consistent with blackletter principles of patent law that are deeply embedded in the way that drafters and interpreters of patent claims approach their tasks. It is axiomatic that in interpreting a patent claim all of its elements must be considered, and none can be viewed in isolation. It is likewise axiomatic that an accused product or method does not infringe unless it satisfies each and every element of a claim. *See, e.g.*, 5A *Chisum on Patents* § 18.03(4)(a) (2007). Petitioners’ approach of breaking a claim into its building blocks, and then insisting that the claim is invalid if any one of those

blocks can be characterized as a law of nature (or as falling within one of the other exceptions associated with § 101), is irreconcilable with these well-established doctrines.

Petitioners try to fall back on statements in the caselaw that the § 101 exceptions “cannot be circumvented by . . . adding ‘insignificant postsolution activity,’” *Bilski*, 130 S. Ct. at 3230 (quoting *Diehr*, 450 U.S. at 191-92), or mere “data gathering” steps, *In re Meyer*, 688 F.2d 789, 794 (C.C.P.A. 1982); *see, e.g.*, Pet.Br.35. But those admonitions cannot justify any effort to carve up a claim in which the various steps are so bound up with each other. In Prometheus’s patent, it is the administration of the pharmaceutical that *creates* the metabolites in the first place, and the determining step that allows those new metabolites to be quantified – and both of these are necessary in order for a physician to be advised that metabolite levels are too low or too high to treat the family of diseases at which the patented method is directed.

The Federal Circuit’s opinion appropriately emphasized this connection between the different steps of the claim. The court of appeals explained that “transformation is central to the purpose of the claims” since “[m]easuring the levels of [the metabolites] is what *enables* possible adjustments to thiopurine drug dosage to be detected for optimizing efficacy or reducing toxicity during a course of treatment.” Pet.App.19a (emphasis added). The court correctly concluded that due to “the integral involvement of the administering and determining steps in Prometheus’s therapeutic methods, this case

is easily distinguishable from prior cases that found asserted method claims to be unpatentable for claiming data-gathering steps and a fundamental principle.” *Id.* at 20a; *see also* Gov’t Br. 15 (explaining that final portions of the claim at issue “are premised upon[] the transformation of the patient’s body chemistry that the administering step entails”).

Accordingly, this Court should rebuff Petitioners’ effort to change the law requiring unitary treatment of a claim. That change would create tremendous uncertainty about whether medical-process claims – and many other types of claims – are subject to protection under § 101, and thereby deprive the patent regime of the stability and flexibility necessary to promote innovation. *See Chakrabarty*, 447 U.S. at 316.

3. Finally, Petitioners assert that the patent eligibility of a process involving a natural phenomenon turns on whether the claim “confine[s]” its “field of preemption.” Pet.Br.34, 35, 38-39; *see also id.* at 48 (asserting that “the likely effect of a [particular] patent on innovation and competition has an important bearing on the patent’s validity”). Again, this approach would represent a significant and deleterious change in the law and introduce considerable uncertainty. “Preemption” is a concern that animates the application of the traditional test distinguishing between human ingenuity and the products of nature. But it is not an appropriate test in and of itself – because it is impossible to judge whether the scope of preemption associated with a particular claim is too broad without engaging in

unconstrained policy judgments of the kind that are best left to Congress.

As an initial matter, it is important to note that Petitioners' premise here is wrong: the Prometheus patent, like other processes involving pharmaceuticals, does not have an unlimited preemptive effect. Patents relating to *particular* pharmaceuticals – and the non-natural products that they create in the human body – are inherently limited in scope. *Compare Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting) (discussing naturally occurring metabolites). And the complexity of biological systems means there are generally multiple pathways for understanding and treating diseases.¹¹

In any event, however, it is clear that an invention is not ineligible for patent protection just because it has sweeping implications. To the contrary, highly valuable inventions historically have been granted patent protection, even if – for a limited time – they dominate a field of endeavor. *See, e.g.*, U.S. Patent No. 214,636 (Thomas Edison's light bulb); U.S. Patent No. 821,393 (Wright Brothers' flying machine).

The patent system provides the stimulus for such human ingenuity and recognizes its long-term benefit to society. Indeed, to the extent that broad

¹¹ *See, e.g.*, David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 Berkeley Tech. L.J. 985, 1010-17 (2005). Indeed, many recent drugs with multiple new uses have quickly spawned competitor drugs with similar characteristics. Calfee, *Golden Age, supra*.

medicine-related patents issue (despite the strictures of patent examining in this area, *see supra* pp. 29-30) and are not licensed, there is a substantial economic literature suggesting that society still benefits because “innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection.” Burk & Lemley, 89 Va. L. Rev. at 1617; *see also* James W. Hughes et al., “Napsterizing” Pharmaceuticals: Access, Innovation, and Consumer Welfare (Nat’l Bureau of Econ. Res., Working Paper No. 9229, 2002) (finding that eliminating patent protection on pharmaceuticals would cost future consumers three dollars in lost benefits for every dollar saved in reduced drug prices); *supra* pp. 21-23. Accordingly, patentability for a valuable biotechnology invention should not be vitiated because of its perceived “expense” during the short period of patent exclusivity.

Were this Court to adopt the approach that Petitioners urge, lower courts would be forced to engage in what is essentially a policy-based analysis in order to decide questions of patentability under § 101, asking in the most general terms whether the patent at hand sweeps too broadly and covers things that society would prefer to remain unencumbered. It is hard to imagine anything more likely to engender uncertainty and confusion among would-be inventors, and thus to discourage inventions that require significant up-front risk and investment of time and money – as do societally beneficial medical-process inventions.

In addition, beyond the basic inquiry about whether a patent claim (read as a whole) falls into

one of the three § 101 exceptions, making judgments about patent-eligible subject matter is a task that falls within Congress's area of expertise. As discussed above, Congress knows how to remove certain subject matter from the scope of patent protection, and has already addressed the policy considerations surrounding pharmaceutical-related medical-process patents. *See supra* pp. 12-13. Any further restrictions should be debated by the legislature, not imposed by courts making *ad hoc* judgments on a patent-by-patent basis about the costs and burdens of exclusivity. *See Chakrabarty*, 447 U.S. at 317 (“Whatever their validity, the contentions . . . pressed . . . should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.”).

CONCLUSION

For the foregoing reasons, *amicus* respectfully submits that the judgment of the Federal Circuit should be affirmed.

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