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, PATENT AND TRADEMARK OFFICE,
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 NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*[1]

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. In the past decade, PhRMA's members have invested more than $350 billion to discover and develop new medicines and new uses for existing medicines, leading to huge benefits to patients. *See* PhRMA, PHARMACEUTICAL INDUSTRY PROFILE 2009 50 (2009).

New medicines accounted for 40 percent of the increase in life expectancy between 1986 and 2000. *See* 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). The benefits from new uses for existing medicines are also vast. Today, "the most important advances in treatment often come from products which have been on the market for a while but 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-

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[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae or its counsel made a monetary contribution to its preparation or submission.

innovation/. These include, for example, the use of AZT to treat HIV and multiple uses of Herceptin and Avastin to treat different types of cancer.

The issue in this case will potentially have significant impact on PhRMA's members.[2] A ruling limiting the scope of patentability under § 101, 35 U.S.C. § 101, potentially could limit the patentability of medical processes, dramatically diminishing incentives for innovation. A 2004 Department of Commerce study estimated that the average cost of bringing a new drug to market is approximately $1.3 billion, including the costs for unsuccessful drugs. *See* U.S. Dep't of Commerce, Int'l Trade Admin., *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* 30-31 (Dec. 2004), *available at* http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf. The costs of developing new uses for existing drugs are also substantial. As the Boston Consulting Group explains, "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." 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.bcg.com/impact_expertise/publications/files/Biologics_Dec07_final.pdf. In the absence of the incentives provided by patent

[2] A list of PhRMA members can be found at http://www.phrma.org/member_company_list.

protection for novel processes, much of the promising research for new methods of diagnosis and treatment will not occur. The ability to patent products alone is insufficient to provide the necessary incentives, because many of the new methods make use of products that are already known and that therefore are not patentable (or have already been patented).

SUMMARY OF THE ARGUMENT

This Court should ensure that however the scope of patentability is assessed under § 101, inventors retain the ability to patent medical processes, especially methods of diagnosis and treatment that make use of pharmaceuticals. PhRMA expresses no view on the Bilski patent itself. As for the machine or transformation test the Federal Circuit adopted, PhRMA believes there is no need for a new test because the existing prohibition on patenting of laws of nature and abstract ideas is sufficient. If this Court nonetheless adopts the Federal Circuit's test or some other test, it should make clear that medical-process patents that make use of pharmaceuticals fall within it.

To do otherwise would be a radical departure from a long history of patent protection. Patents for medical processes have been issued since the 1800s, and, while there was some question about their patentability for a period of time, a number of decisions in the 1930s, culminating in a Board of Patent Appeals decision in 1954, made clear that medical processes are patentable. Since then thousands of patents have issued for medical processes.

Eliminating patent protection for medical processes would not only deviate from a long history of administrative and judicial decisions on the patentability of such processes, it would also be inconsistent with Congress's clear intent. Under the Hatch-Waxman Act, Congress has expressed its clear intent that these processes be patentable. It has, for example, provided for patent term extensions for patents covering a "method of using" a drug product, 35 U.S.C. § 156(a). Furthermore, both at the beginning and the end of the twentieth century, Congress decided not to enact legislation that would have restricted the patentability of medical processes. On the second occasion, Congress instead enacted a statute that balanced the interests of physicians and of inventors by immunizing physicians from the remedy provisions of the patent laws when they infringe certain method patents but not when they infringe patents for new uses of pharmaceuticals. Congress did not change the scope of patentability at all. Congress thus made clear that medical processes remain patentable.

That makes sense in light of the goal of the patent laws to promote the useful arts. Given the high cost, length and uncertainty of pharmaceutical development, there is a consensus that, in the absence of patent protection, there would be a significant reduction in development of new uses for existing pharmaceuticals, as well as other innovations in medical processes. Thus, it is critical that this Court interpret § 101 in a manner that protects patents for medical processes, particularly new uses for existing pharmaceuticals.

ARGUMENT

I. This Court Should Not Adopt a New Test for the Boundaries of § 101.

This Court has repeatedly made clear the breadth of the patent law and the bounds of patentability, excluding from the scope of patent protection only "laws of nature, natural phenomena, and abstract ideas." *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); *see also Diamond v. Chakrabarty*, 447 U.S. 303, 308-09 (1980). Under these principles, medical-process patents will be generally protected. Any medical process that makes use of pharmaceuticals, for example, will come within the scope of § 101, because the pharmaceutical is not a law of nature, natural phenomenon or abstract idea.[3] There is no need for further limits. The existing limits can be applied flexibly, consistent with the statutory language, to carry out the goals of the patent law.

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[3] In some cases, under this approach, there may be debate about whether a particular medical process that does not use pharmaceuticals is patentable. Justice Breyer applied such an approach in his dissent in *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124 (2006) (Breyer, J., dissenting). PhRMA does not here take a position on whether Justice Breyer's dissent was correct on the facts of that case. But it is clear that under this approach, processes that use pharmaceuticals should be protected. However, at least one court has interpreted Justice Breyer's interpretation of this Court's case law to suggest otherwise. *See infra* n.5. The risk of a lower court misinterpretation that overly restricts the scope of § 101 will only be magnified if a new and more uncertain test is grafted onto existing limits to the scope of processes that are patentable.

In contrast, any additional test designed to narrow the scope of § 101 risks changing the focus in future cases from the purpose of the patent law to formalistic debates on the meaning of a specific court-created test. For example, while the Federal Circuit's *Bilski* test, properly understood, will protect critical medical processes that make use of pharmaceuticals, there is a significant risk that courts will not interpret it to do so. Under the Federal Circuit's test, process patents are protected if they operate on a machine or transform matter. *See*, *e.g.*, *In re Bilski*, 545 F.3d 943, 962 (Fed. Cir. 2008).[4] Because patents for the use of pharmaceuticals involve transformation of the pharmaceuticals themselves, as well as the patient, PhRMA believes that such patents come within the scope of § 101 under the Federal Circuit's test.

Nonetheless, there is some debate about this. In a case currently pending in the Federal Circuit, *Prometheus Laboratories, Inc. v. Mayo Collaborative Services*, No. 2008-1403, Mayo Collaborative Services argues that even in a case involving administration of a drug for diagnostic purposes that results in production of metabolites within the body, there is no requisite transformation within the meaning of *Bilski*.[5] Brief of Appellees at 32-36 (Mar.

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[4] The Federal Circuit purports to derive its test from this Court's case law, but, what this Court had made clear is that processes that use a machine or transform matter are patentable. *See, e.g.*, *Diehr*, 450 U.S. at 184. This Court has never held that processes that do not use a machine or transform matter are excluded from patentability.

[5] The patents at issue in *Prometheus* concern techniques to relieve pain for those suffering from Crohn's disease and other

30, 2009). Moreover, there is some question as to whether medical processes that do not use pharmaceuticals are "transformative" in the requisite sense even though, as shown below, Congress clearly intends them to be patentable.

Thus, if the Federal Circuit's test is upheld by this Court, there is cause for concern that later cases will devolve into technical debates on the meaning of "transformation," divorced from the goals of the patent law and from Congress's clear intent to ensure the protection of medical-process patents. In

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debilitating diseases of the digestive system. As the district court construed the claims, each claim involved the step of administering the drug and determining metabolite levels, which were not naturally occurring compounds, for diagnostic purposes to evaluate an adjustment in dosage. Prior to the Federal Circuit's decision in *Bilski,* the district court held these claims unpatentable, without applying the transformation test, based on its interpretation of Justice Breyer's dissenting opinion in *Metabolite*, 548 U.S. at 125 (Breyer, J., dissenting).

The district court's opinion evidences the risks of misapplication even of the current limits of § 101, as interpreted by Justice Breyer. In *Metabolite*, the homocysteines that were measured were naturally occurring. In contrast, in *Prometheus*, the metabolites measured were the result of administration of a non-naturally occurring pharmaceutical, which is neither an abstract idea nor a natural law and the use of which inherently limits the scope of the patent. Moreover, the district court ignored that the pharmaceutical administered was transformative, which under this Court's case law, should have made clear the process was protected. The district court's opinion thus shows how even the current limits on § 101 can be misapplied to limit unduly the scope of patent protection. Grafting additional limits on top of those will simply multiply those risks.

other words, the test adopted, whether the Federal Circuit's test or some variant, may become talismanic, with arguments focused on the terms of the test rather than on the terms used by, and purposes of, Congress. This Court should retain the focus on Congress's words and purpose.

If this Court nonetheless adopts the Federal Circuit's *Bilski* test, it should make clear either that (1) under that test, medical processes, particularly processes involving the administration of pharmaceuticals, are patentable, or (2) the test is limited to business method patents and other tests may be appropriate for medical-process or other patents. Alternatively, if this Court adopts a different approach to the scope of § 101 than the Federal Circuit adopted in *Bilski*, it should ensure that that test protects the patentability of medical-process patents.

II. Patents for Medical Processes Have Long Been Protected

The patent laws have long protected the patenting of medical processes, such as the process of using a particular drug for treatment. The Patent Act itself always protected the patenting of processes and made no exception for medical processes.[6] 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

[6] The Patent Act of 1793 used the term "art," which Congress replaced with the term process when it enacted the current version of § 101 in 1952. *See Bilski*, 545 F.3d at 951 n.4.

65,044, issued in 1867 for an improved method of treating affection of the skin, (4) patent 506,449, issued in 1893 for a method of treating diseases electrically, (5) patent 2,008,526, issued in 1935 for treating hepatomegaly with electrical current, and (6) patent 2,322,245, issued in 1943 for a method of transcutaneous injection.

While the Patent Act on its face always encompassed medical processes, there was a period of time when judicial decisions cast some doubt on the patentability of such processes. In 1862, in *Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (C.C.S.D.N.Y. 1862) (No. 9,865), the New York Circuit Court rejected a patent for the use of ether, a known agent, as an anesthetic, because the patent was for a new effect for a well-known process of inhaling ether. However, some interpreted *Morton* as broadly holding that medical treatments were not patentable processes. In *Ex parte Brinkerhoff*, the Commissioner of Patents adopted such reasoning as one basis for rejecting the patent at issue, explaining that "[t]he methods or modes of treatment of physicians of certain diseases are not patentable." 24 Dec. Comm'r 349 (1883), *republished in New Decisions*, 27 J. Pat. & Trademark Off. Soc'y 797, 798 (1945). His rationale was that the result of any method of treatment was uncertain. *Brinkerhoff* was affirmed on a technicality, but the appeals court left open "the question of how far patents can 'invade the right of protecting health.'" William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. Pat. & Trademark Off. Soc'y 651, 654 (1995).

Whatever the implications of *Brinkerhoff*, patents for medical processes continued to be granted. *See supra*, at 9. Moreover, in the 1930s, both courts and the Board of Patent Appeals upheld patents for medical processes. In *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 630 (S.D.N.Y. 1930), the court rejected arguments that a method of operating by injecting toxin into a person was not patentable. Similarly, the Board of Patent Appeals found patentable methods for shrinking living tissue, *Ex parte Wappler*, 26 U.S.P.Q. (BNA) 191 (Pat. Off. Bd. App. 1935), and for producing fever in the human body, *Ex parte Kettering*, 35 U.S.P.Q. (BNA) 342 (Pat. Off. Bd. App. 1936).

Subsequently, the Board of Patent Appeals cleared up any lingering confusion and made explicit that medical processes are patentable. 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 using a fluid jet, instead of a hypodermic needle, to inject fluid into the human body. The Board held that it was irrelevant that the usefulness of the claim depended on the reaction of the human body, explaining 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. The Board noted that "[c]laims involving treatment of the human body have been allowed on appeal." *Id.* at 109-10 (citing *Wappler* and *Kettering*). The Board distinguished both *Morton* and *Brinkerhoff*, suggesting that the *Brinkerhoff* case was based on double patenting and that the additional reasoning of *Brinkerhoff* did not

justify categorical rejection of patents for medical methods:

> The only specific reason given is uncertainty of results, which does not appear to be a valid reason for categorically refusing all methods, and which reason is more properly considered under the question of utility which is a separate and distinct requirement for patentability. To the extent that *Ex parte Brinkerhoff* holds or implies that all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body, that decision is expressly overruled.

Id. at 110. Since *Scherer*, patents for medical procedures have been routinely granted. *See* Noonan, 77 J. Pat. & Trademark Off. Soc'y, at 658-70, tbl. 1 (listing representative medical method patents). Courts, including the Federal Circuit, have routinely upheld such patents. *See, e.g.*, *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). It would be a radical departure, indeed, if this Court were to adopt a test that called into question the patentability of such inventions.

III. Congress Balanced Competing Policy Concerns and Concluded that Patents for Medical Processes Should Be Protected.

Congress has effectively ratified the longstanding administrative and judicial interpretation that medical processes are patentable under § 101. Indeed, not only is Congress aware of this longstanding policy, Congress has made clear that it believes such processes are and should be patentable. For example, under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), Congress specifically required all applicants to the Food and Drug Administration for approval of a new drug to list any patents related to the drug, including any patent "which claims a method of using such drug."[7] 21 U.S.C. § 355(b)(1). Subsequently, applicants must provide supplemental information when any new patents issue, including new patents on methods of use. *Id.* § 355(c)(2). Lest there be any doubt that Congress intended new methods of use to be patentable, the Hatch-Waxman Act provides, under certain conditions, for patent term extensions both for a "method of using a [drug] product" and for a "method of manufacturing a [drug] product." 35 U.S.C. § 156(a); *see also id.* § 156(f) (defining "product" to include drug products). Obviously, Congress would not have passed these

[7] Information about these patents is then published as part of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book."

provisions if it did not intend for these processes to be patentable.

Moreover, on multiple occasions, Congress considered but did not pass legislation that would have excluded medical and surgical methods and devices from the field of patentable subject matter. The 57th and 58th Congresses considered such legislation in 1902 and again in 1904. H.R. 12451, 57th Cong. (1902); H.R. 13679, 58th Cong. (1904). At the time, the Report of the House Committee on Patents noted that it had been the practice of the Patent Office to grant such patents and further noted that the state of the law on patenting therapeutic methods was unsettled. *See* Noonan, 77 J. Pat. & Trademark Off. Soc'y at 654. Congress did not pass this legislation. *See id.*

In the 1990s, Congress again considered and rejected legislation to eliminate medical processes from the scope of patent protection. Instead, Congress immunized doctors from lawsuits for infringing a subset of these patents -- a subset that does not include patents for processes for the use of particular pharmaceuticals. By doing so, Congress made clear its understanding that medical-process patents are within the scope of § 101.

In particular, on March 3, 1995, Congressman Greg Ganske introduced H.R. 1127, which would have precluded the issuance of a patent for any medical procedure that did not use a patentable product. H.R. 1127, 104th Cong. (1995). A companion bill in the Senate, introduced on October 18, 1995, rather than precluding the patenting of

medical processes, sought to redefine what would constitute infringement of patents for medical processes. S. 1334, 104th Cong. (1995). This bill would have defined activities by medical professionals as non-infringing even if they made use of patented processes. *Id.*

These bills were drafted as a result of a controversy over a lawsuit by one physician against another for purportedly infringing a patent on a method of cataract surgery (the "Pallin case," *see Pallin v. Singer*, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995)). *See* 142 Cong. Rec. 26825-26 (1996) (statement of Sen. Frist). Doctors became concerned that they would be sued for using particular surgical procedures. Arguably, this concern was vastly overblown. Although medical-process patents had been extant for decades, the Pallin case has been cited as the first of its type to go to trial. Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. Pat. & Trademark Off. Soc'y 381, 405 (2000).

In any event, Congress ultimately did not respond to the Pallin case by reducing the scope of patentability or declaring physician actions to be non-infringing. Indeed, neither bill attracted broad support. *See* Richard P. Burgoon, Jr., *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c)*, 4 U. Balt. Intell. L.J. 69, 80 (1996). Instead, after the House held hearings on the proposed bills, *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. (1995)

[hereinafter *Hearing on H.R. 1127*], Congress took a more nuanced approach. Under the enacted legislation, medical processes remain patentable, infringers other than medical professionals are subject to suit and award of remedies, and medical professionals who use patented processes are still deemed to infringe.

Instead of changing the scope of patentability, Congress protected the interests of medical professionals by exempting them, with important exceptions, from the remedial provisions of the patent laws when they are performing a medical activity.[8] Even this exemption does not apply to new uses of pharmaceuticals. That is because the statute excludes from the definition of "medical activity," and thus from the immunity provision, the following: "(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice

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[8] *See* 35 U.S.C. § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, 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."). The statute does not immunize the activities of persons involved in the commercial development, manufacture, sale, importation, or distribution of drugs, devices, biotechnology products, or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office). *See* 35 U.S.C. § 287(c)(3).

of a process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2)(A).[9]

The exception for use of "a composition of matter" means that Congress concluded that medical practitioners remain subject to the remedial provisions of the patent law when they violate patents for new uses of pharmaceuticals. According to the Conference Report, "'Uses of compositions of matter' include, without limitation, novel uses of drugs, . . . novel methods of combining drug therapies, and novel methods for providing genetic or other biological materials to a patient (including gene therapies)." H.R. Rep. No. 104-863, at 853 (1996) (Conf. Rep.). The report gives two examples of situations where doctors would not be immunized: (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

[9] With respect to patented processes that use a composition of matter, the statute further states that "the term 'patented use of a composition of matter' does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method." 35 U.S.C. § 287(c)(2)(F). In other words, if a patented process merely adds a reference to a drug or other composition of matter for no reason other than, for example, to circumvent the immunity provisions, the immunity provisions are still applicable.

anesthetic. *Id.* at 853-54.[10] Thus, new regimens for administering a drug and new uses for a drug are both subject to full protection.

In explaining the foregoing legislation, which he had introduced, Senator Frist contrasted "innovations in pure procedures -- such as discovery of a better way to suture a wound or set a broken bone" with "innovations in medical drugs and devices." 142 Cong. Rec. 26825 (1996) (statement of Sen. Frist). He explained that enforcement against doctors of patents claiming "pure procedures" would be disastrous, and innovations in these areas would happen without "the midwifery of patent law." *Id.* But because of the need to recoup investments, "[t]he appropriateness and importance of allowing patents for pharmaceuticals and medical devices is now well-established." *Id.* He noted that the Ganske amendment proposed in the House "could have impacted many worthwhile patents in biotechnology and pharmacology."[11] *Id.* In contrast, the legislation Senator Frist proposed, "would in no way, however, change patent law with respect to biotechnology, medical devices, drugs, *or their methods of use*. As a

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[10] Use of compositions of matter does not include uses of medical devices or other machines. *See id.*

[11] After the initial legislation he proposed in the House, Congressman Ganske proposed an amendment that was similar to his original proposal except that it exempted from the proposed changes patents "for a new use of a composition of matter or biotechnological process." H.R. 3814, 104th Cong. § 619 (1996) (as passed by House, July 24, 1996). So even the amendment Senator Frist criticized as inadequately protecting patents related to pharmaceuticals had already exempted compositions for new uses of pharmaceuticals.

result, this narrowly tailored legislation would in no way discourage the important research being done in these areas of medicine." *Id.* (emphasis added). The legislation Senator Frist proposed was adopted with slight alterations in the Conference Committee.[12]

In enacting this legislation, Congress thus balanced competing policy objectives. While it protected medical practitioners from lawsuits based on claimed advances in "pure procedures" such as surgical techniques that might not require substantial investments to develop, Congress did not permit medical practitioners to use patented processes that make use of pharmaceuticals, or similar inventions that require substantial investment. And it decided not to reduce the scope of patentability for any medical processes.

Under this Court's case law, when Congress amends a statute without "casting doubt" on administrative or judicial interpretation, that is evidence of its ratification of the interpretation. *See Edelman v. Lynchburg College*, 535 U.S. 106, 117-18 (2002). That principle applies even more clearly here where Congress amended the statute in a way that itself makes clear its adoption of the administrative

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[12] Even in this form the legislation drew strong objections. For example, Senator Orrin Hatch (R-Utah), Chairman of the Senate Judiciary Committee (which has jurisdiction over patent matters), wrote in a letter to the Senate Majority Leader that the section "constitutes a significant departure from principals of American patent law that have been on the books for over two hundred years. The amendment would preclude a certain class of patent-holders from enforcing their patent rights against infringement, a change that renders these patents virtually meaningless." *See* 142 Cong. Rec. 26640 (1996).

and judicial interpretation that medical processes are patentable and where Congress in a separate statute, the Hatch-Waxman Act, further demonstrated its agreement with this interpretation. This Court should respect Congress's clear intent.

IV. The Purpose of Patent Law Requires Protection of Medical-Process Patents.

There is an additional reason why this Court should take care to assure the continued patentability of medical processes. Such patentability serves the primary purpose of patent law: to advance the useful arts by providing an incentive for innovations. *Chakrabarty*, 447 U.S. at 307; U.S. Const. art. I, § 8, cl. 8. That is particularly true for processes that make use of pharmaceuticals. Patenting new uses for existing products has been an established part of patent law since the Patent Act of 1952, Act of July 19, 1952, Ch. 950, 66 Stat. 792. *See* 35 U.S.C. § 100(b); *Rohm & Haas Co. v. Roberts Chems., Inc.*, 245 F.2d 693, 699 (4th Cir. 1957). Such patents are critical to the advancement of medical care.

Today, much of the innovation in medical care comes from intensive study of possible new uses for existing drugs. Calfee, *The Golden Age of Medical Innovation*, *supra*. As one article points out in discussing the June 2007 annual meeting of the American Society of Clinical Oncology, "[w]hereas breakthrough advances in new, targeted therapies stole headlines at recent years' gatherings, the current highlights are studies showing improved uses for . . . established drugs." Catherine Arnst,

Same Cancer Drugs, New Applications, Bus. Week Online, June 3, 2007, *at* http://www.businessweek.com/technology/content/jun2007/tc20070603_510760.htm. For example, Herceptin, which was originally approved for one use, was subsequently found, when administered after surgery, to reduce the odds of a recurrence of a type of breast cancer *by half*, suggesting, according to the *New England Journal of Medicine*, "a dramatic and perhaps permanent perturbation of the natural history of the disease, maybe even a cure." Calfee, *The Golden Age of Medical Innovation*, *supra* (describing studies in the *New England Journal of Medicine* and the British medical journal, *The Lancet*).

Patents issued for processes that make use of already-known products include "the use of AZT to treat AIDS, 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." *Hearing on H.R. 1127*, *supra*, at 67 (prepared testimony of William D. Noonan, M.D., Klarquist, Sparkman, Campbell, Leigh and Whinston). In these cases, the product itself is not patentable (or has already been patented), because it is already known. "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). The patentability of

medical processes provides an incentive for researching the new use.

The need for the incentives provided by the patent system also extends to personalized medicine, which seeks to individualize treatment for patients. It does so by identifying genetic, genomic, and clinical information which is translated into precise diagnostic tests and targeted therapies that address a person's susceptibility of developing disease, the course of disease, and its response to treatment. Personalized medicine will allow physicians to make the most effective clinical decisions for individual patients and has the potential to improve drug efficiency, lower costs from adverse events through more targeted therapies, and save lives.[13] "[T]argeted drug therapies selected for individual patients based on genetic predisposition" will allow doctors to guide "medication selection and dosage regimens that ensure maximal drug efficiency and minimal adverse drug reaction." Teresa Kelton, *Pharmacogenomics: The Re-Discovery of the Concept of Tailored Drug Therapy and Personalized*

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[13] For example, one early success in personalized medicine involves the measuring of HER2/neu amplification in breast cancer patients. 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. For those patients whose tumors carry this amplification, the drug Herceptin reduces risk or recurrence by half. *Id.* For those patients whose tumors do not carry this amplification, the product does not have the same benefit.

Medicine, 19 Health Law. 1, 1 (2007). However, "[i]n order for personalized medicine to become a reality, drug innovators will need a regulatory environment that allows a return on their investments in research and development." Deloitte Consulting LLP, Avoiding No Man's Land: Potential Unintended Consequences of Follow-On Biologics 17 (Mar. 2009).

The development of a new medicine, or a new use for an existing medicine, is extremely expensive. Because of the difficulty of developing new medicines and the high safety and effectiveness standards that they must meet, relatively few research avenues are successful. Only 20 in 5,000 compounds that are screened enter preclinical testing in laboratories and on animals. FTC, To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, ch. 3, at 6 (Oct. 2003), *available at* http://www.ftc.gov/os/2003/10/innovationrpt.pdf. Even if a compound is determined to be safe enough to test on humans, there must be three phases of clinical testing to determine safety and efficacy before the FDA can give final approval for marketing. *Id.* As a result, the development and commercialization of a drug is a very lengthy and uncertain process, often taking more than a decade. *See* Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 Managerial & Decision Econ. 469, 475-76 (2007). Because of this lengthy and difficult process, the average cost of bringing a new drug to market is approximately $1.3 billion when the cost of unsuccessful efforts is taken into account. *See* U.S. Dep't of Commerce, Int'l Trade Admin.,

Pharmaceutical Price Controls in OECD Countries, *supra*, at 30-31. And 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 review and approval process. FTC, To Promote Innovation, *supra*, ch. 3, at 7 (explaining that "the effective patent life for a drug patent -- even with patent term restoration [under the Hatch-Waxman Act] -- is typically about 11 years, substantially shorter than the 20-year statutory patent term" (footnote omitted)). Even drugs that make it to market do not generally cover their development costs. *See id.*, ch. 3, at 5 (reporting on statements from PhRMA).

Because of the expense and difficulty of developing pharmaceuticals, patent protection is crucial. As a Federal Trade Commission report explained after gathering evidence on the costs and benefits of patent protection, "[p]articipants in the Hearings overwhelmingly expressed the view that patent rights for pharmaceuticals are essential for brand-name companies to prevent free riding and recoup their significant investments." FTC, To Promote Innovation, *supra*, ch. 3, at 9. Indeed, "pharmaceutical industry participants reported that 60% of inventions would not have been developed and 65% would not have been commercially introduced absent patent protection." *Id.*, ch. 2, at 11 (citing Edwin Mansfield, *Patents and Innovation:*

An Empirical Study, 32 Mgmt. Sci. 173, 175 (1986)).[14]

There are no significant countervailing considerations. Some have argued that particular patents have too broad a preemptive effect, a concern expressed by Justice Breyer in *Metabolite*. 548 U.S. at 126-28. These concerns do not apply to most pharmaceutical patents. First, patents on uses of *particular* pharmaceuticals are inherently limited in scope. Second, the complexity of biological systems means there are generally multiple pathways for understanding and treating most diseases.[15] Third,

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[14] In addition to providing incentives for invention, patent protection also helps ensure quick disclosure of inventions that do occur. *See Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249, 255 (1945). The PTO reports that as a result of the American Inventor Protection Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-552, "roughly 90 percent of all pending patent applications are published at eighteen months." FTC, To Promote Innovation, *supra*, ch. 1, at 26. In the absence of patent protection, however, inventors would have no incentive to disclose their invention until after completion of the lengthy FDA approval process. And even then they would only be required to disclose the use, not the underlying research. This is important in the pharmaceutical industry. The FTC cited testimony from pharmaceutical and biotech representatives, including those from generic pharmaceutical firms, explaining that patent disclosures guide efforts to design around patents and lead to other efforts at innovation. *Id.*, ch. 3, at 1-2, 4.

[15] *See, e.g.*, David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 Berkeley Tech. L.J. 985, 1010-17 (2005); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* Patents in the Knowledge-Based Economy 285, 292, 304-05 (Wesley M. Cohen & Stephen A. Merrill eds., 2003). Indeed, many of the recent drugs with multiple new uses have quickly spawned competitor

patent law itself imposes significant limits on the breadth of patents, and these requirements are applied far more rigorously in the biomedical area than elsewhere.[16] Finally, to the extent broad patents are issued and not licensed, there is a substantial economic literature suggesting that society nevertheless benefits because "innovation would drop substantially in the pharmaceutical industry in the absence of effective patent protection." *See* Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1615-17 (2003) (explaining that the prospect theory, that patents should be broad, stand alone, and confer almost total control "maps most closely onto invention in the pharmaceutical industry"); *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

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drugs with similar characteristics. Calfee, *The Golden Age of Medical Innovation*, *supra*.

[16] *See, e.g.*, Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575, 1590 (2003) (noting that biopharmaceutical and biotech patent prosecution takes a much longer time than does the prosecution of patents in other fields); Noonan, 77 J. Pat. & Trademark Off. Soc'y at 661 ("[T]he requirement that an invention must be a 'nonobvious' advance to be patentable is particularly strictly applied in all the biological examining groups. The 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. Many biological patents that emerge from this rigorous patenting process are narrow in scope, difficult to enforce, and unlikely to cover anything that will be widely or successfully used in practice.").

protection on pharmaceuticals would cost future consumers three dollars in lost innovation benefits for every dollar saved in reduced drug prices).

Even scholars who advocate narrow patent rights in some contexts, recognize the importance of patent rights for biopharmaceutical patents. One such scholar explains:

> In the specific context of the biopharmaceutical industry, the claim that broad, monopoly-conferring rights on nascent invention can provide a necessary spur to further innovation may well have merit. As matters currently stand, the research path from initial discovery of a potentially relevant DNA sequence or receptor to identification of a drug that is ready for clinical testing can be quite risky, lengthy, and expensive.

Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 Berkeley Tech. L.J. 813, 828-29 (2001).

Even among physicians, who historically have had concerns about patents that limit products used in, or processes of, treatment, "there seems to be general agreement that drugs and medical devices should be patentable, because they often require enormous expenditures." Noonan, 77 J. Pat. & Trademark Off. Soc'y at 656.[17] Thus, there is broad

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[17] Any continued criticism of patents for medical processes has generally been directed to patents for surgical techniques and

consensus on the importance of patent rights to pharmaceutical development. *See, e.g.*, Natasha N. Aljalian, *The Role of Patent Scope in Biopharmaceutical Patents*, 11 B.U.J. Sci. & Tech. L. 1, 47 (2005) ("The promise of full patent rights for successful discovery is important motivation for inventors entering the unpredictable, competitive biopharmaceutical area."); John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* Patents in the Knowledge-Based Economy 285, 286-87 (Wesley M. Cohen & Stephen A. Merrill eds., 2003) ("There is widespread consensus that patents have long benefited biomedical innovation. A forty-year empirical legacy suggests that patents are more effective, for example, in protecting the commercialization and licensing of innovation in the drug industry than in any other.").

The need for patent protection for new uses ("indications") for existing drugs is just as great as the need for patent protection of the initial product. Even in Europe, where the law is more restrictive and generally precludes patenting of methods of medical treatment, the law permits patenting of known products for new medical uses. Martin, 82 J.

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research tools. The American Medical Association, for example, which once took the view that patenting of surgical instruments was unethical, later reversed itself. *See* Martin, 82 J. Pat. & Trademark Off. Soc'y at 388-89. And while it continues to oppose process patents for surgical techniques, it signed on to the approach Congress took in its 35 U.S.C. § 287, as Senator Frist explained in his floor speech. *See* 142 Cong. Rec. 26825 (1996) (statement of Sen. Frist). That approach eliminated any problems with patenting of surgical techniques.

Pat. & Trademark Off. Soc'y at 396. As discussed above, news uses for existing drugs make up a critical part of medical research. As of 2007, 47 percent of biologics that were evaluated in one study have had at least one new FDA-approved indication after the initial approval. *See* Said et al., *Continued Development of Approved Biological Drugs*, *supra*, at 3.[18]

Like development of the initial product, development of new uses is costly and time consuming. As one author explains: "A substantial amount of laboratory research conducted by pharmaceutical companies 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 (*citing The*

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[18] Other types of medical-process patents are also important. For example, there are important patents on methods for diagnosis and optimization with respect to individual patients. Standard drug treatments have only a 25% rate of efficacy in cancer patients in part because each patient is biologically unique. *See* Mara G. Aspinall & Richard G. Hammermesh, *Realizing the Promise of Personalized Medicine*, Harv. Bus. Rev., Oct. 2007, at 108, 111 (citing Brian B. Spear et al., *Clinical Application of Pharmacogenetics*, 7 Trends in Molecular Med. 201 (2001)). Determining optimal treatments can be costly. *See* Peter Huber, *Who Pays for a Cancer Drug?*, Forbes, Jan. 12, 2009, at 72. Patent protection provides a key incentive for development of such methods of optimization. Patents in this area include U.S. Pat. No. 7,348,149 (Mar. 25, 2008) ("Methods of Diagnosing Parkinson's Disease"); U.S. Pat. No. 6,770,029 (Aug. 3, 2004) ("Disease Management System and Method Including Correlation Assessment"); U.S. Pat. No. 6,087,090 (July 11, 2000) ("Method for Predicting Drug Response").

FDA Approval Process: Hearing Before the Health and Environment Subcomm. of the H. Commerce Comm., 104th Cong. (1996)). One reason the work on new indications is expensive is that just like with the initial indication, in order to obtain FDA approval for a new indication, the innovator must submit data from clinical trials regarding the treatment's safety and efficacy in a particular patient population.

The FDA review and approval process is also lengthy. In 2007, the Boston Consulting Group conducted an analysis of 58 biologics consisting of biotechnology-derived protein products that were approved under the Public Health Service Act between 1986 and 2006. Said et al., *Continued Development of Approved Biological Drugs*, *supra*, at 2. It found that FDA review of a new indication for an existing biologic typically takes three to six years. *Id.* at 5. Companies whose products are approved typically accrue significant expenses even after FDA approval, including research on new indications and studies that are the subject of commitments made to FDA for post-approval research. As a result of factors such as these, development of new indications for existing drugs is very costly: while "[n]o comprehensive estimates currently exist that capture the full extent of investment occurring after the initial approval, . . . considering that 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 that the failure rates remain high, such costs are likely high and represent an important part of the overall R&D

investment in researching and developing new therapeutic biologics." *Id.* at 6. Because of the substantial expense of developing new indications, the Boston Consulting Group concluded that patent protection is important to promoting the development of new indications. *Id.*

Of course, a company that owns a patented product already has some incentive to research additional indications for that product. But that incentive often will not be sufficient because by the time the new indication is approved little or no time may be left in the patent protection for the product. The Boston Consulting Group found that one-third of the new indications were approved more than seven years after the approval of the initial indication. *Id.* at 3. And often it takes much longer. Biologics on the market for 11 years are still expected to have on average one additional indication approved over the remainder of their lifetime. *Id.* at 4.

Moreover, new uses for existing products may be developed by companies *other* than the original innovator; companies that have no patent protection over the product. They may also be developed using products never subject to patent protection or no longer subject to such protection. For example, the patents for the use of AZT to treat human immunodeficiency virus (HIV) constituted new use of a well-known composition.[19] *See Burroughs*

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[19] AZT was originally developed in 1964 as a potential cure for cancer. The inventor never sought a patent because tests showed that it "failed miserably" at its intended purpose. *See* Philip J. Hilts, *Experimental Drug AZT Was Designed for*

Wellcome, 40 F.3d at 1225-26, 1230 (describing these patents and fact that the compound AZT was already well known). For these companies, the only patent protection they can receive comes in the form of a patent on a medical process.

Eliminating patent protection would severely restrict medical research. *See* Rueda, 9 U. Balt. Intell. Prop. L.J. at 132 ("A serious concern weighing against stripping medical processes from patent protection is the impact such a move would have on incentives. Without intellectual property protection, companies and individuals who otherwise may have poured time and resources towards medical process research may not do so."). One author, who emphasizes that the greatest gains in medical research are coming from the invention of new indications, explains that "[t]he surest way to hobble medical technology is to damage intellectual property (IP) protections, mainly patents." Calfee, *The Golden Age of Medical Innovation*, *supra*.

CONCLUSION

Given the importance of patent protection to incentivize research, the history of protection of medical-process patents, and Congress's unambiguous intent, this Court should make clear, whatever result it reaches with respect to the Bilski patent, that methods of medical treatment and diagnosis, especially methods for new uses of existing pharmaceuticals, remain patentable. It should not adopt a new test for patentability that risks

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Tumors; Skill, Luck Led to Promising Tests on AIDS, Wash. Post, Sept. 19, 1986, at A11.

changing future cases into formalistic debates on the meaning of the court-created test. If it nonetheless adopts such a test, it should make clear that medical-process patents fall within it.

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