No. 10-1150

IN THE
Supreme Court of the United States

MAYO COLLABORATIVE SERVICES (D/B/A MAYO MEDICAL LABORATORIES) AND MAYO CLINIC ROCHESTER,

Petitioners,

v.

PROMETHEUS LABORATORIES, INC.,

Respondent.

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

BRIEF OF HEALTH LAW, POLICY, AND ETHICS SCHOLARS AS AMICI CURIAE IN SUPPORT OF RESPONDENTS

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QUESTION PRESENTED

Whether a process for determining safe and effective dosages of prescription medicines based on the unique chemistry of individual patients contains patentable subject matter under 35 U.S.C. § 101.

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INTERESTS OF *AMICI*[1]

Amici are scholars of health law, policy, and ethics.[2] They have devoted their careers to the study and promotion of public health. Their perspective reflects a broad utilitarianism that seeks the greatest good for the greatest number. Public health focuses on populations rather than individuals, and collective goods rather than personal rights or interests. The foundational public health principle affirms one simple objective: to prevent avoidable suffering and death. *See Public Health Law and Ethics* xxiii (Lawrence O. Gostin, Univ. of Cal. Press 2002.

Amici have concluded that patent eligibility for claims to medical diagnostic and treatment processes prevents avoidable suffering and death. Steady improvement in medical treatment methods, especially for complicated, risky, and painful therapies, is vital. Advancement at some short-term cost is better than no advancement. The removal of long-standing incentives to improve disease treatment could do enormous damage to medical progress. This Court should not limit the arsenal of incentives available to combat future health threats.

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[1] The parties have lodged blanket letters of consent to the filing of amicus briefs with the Clerk of the Court. No counsel for a party authored this brief in whole or in part, and no person other than *amici* or their counsel made a monetary contribution to its preparation or submission.

[2] A complete list of *amici curiae* is set forth in the Appendix to this brief. The views presented here do not reflect those of any institution or organization.

Amici respectfully disagree with the ethical position set out in the brief of the American College of Medical Genetics, *et al.* ("Medical Associations' Br."). That brief highlights an opinion by the American Medical Association ("AMA") that patents on medical procedures are "unethical." It advocates a more restrictive patent policy that would deny protection for all innovative diagnostic and treatment methods. But that position undervalues the long-term costs of excluding innovative medical procedures from the patent system. *Amici* are sympathetic to some of the practical concerns raised by the medical associations. But Congress and the Executive are better positioned than this Court to resolve those concerns.

SUMMARY OF ARGUMENT

The physician inventors in this case identified a serious medical problem affecting millions of people, dedicated themselves to solving it, and succeeded. Autoimmune diseases, like Lupus, Crohn's disease, Graves' disease, or Type I Diabetes, turn the human body against itself. Instead of protecting healthy cells, tissues, and organs from foreign pathogens, diseased immune systems attack and destroy them. The appropriate therapeutic response is to suppress the patient's confused immune system. But disabling a body's natural defenses just enough to quiet the mutiny and not cause further harm is complicated and extremely risky. For years, the standard treatment method was trial and error: prescribe conservatively, then "wait and see." The patents-in-suit make claims to a better treatment process—a way of quickly pinpointing the effective

dosage for a particular patient. The question for this Court is whether that improvement—and other diagnostic and treatment processes like it—falls within the scope of patentable subject matter under 35 U.S.C. § 101.

Amici write to advocate caution in the Court's resolution of this question and offer Hippocrates' own counsel: First, do no harm. Patent protection for medical process inventions has resulted in long–term benefits to public health, benefits that result from both private investment, and increased public knowledge. This Court should not limit the arsenal of incentives available to combat future health threats. The "ethical" objections raised by the medical associations reflect a misplaced emphasis on the short-term concerns of individual patients at the expense of long-term public welfare.

ARGUMENT

I. MEDICAL PROCESS PATENTS ADVANCE PUBLIC HEALTH

A long-term, population-based approach to patent policy offers compelling reasons to maintain the patentability of medical diagnostic and treatment processes: those inventions save lives over time. Their patentability encourages sensible private investment in medical advances and fosters widespread public dissemination of medical discoveries.

A. Section 101 Authorizes Medical Process Patents

The Founders enshrined in the Constitution their empirical judgment that patents promote societal progress. Article I, Section 8, of the U.S. Constitution provides Congress with the power "To promote the Progress of Science" "by securing for limited Times to" "Inventors the exclusive Right to their" "Discoveries." Accordingly, Congress enacted Section 101, which describes what is patentable: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title." 35 U.S.C. § 101. By providing a "limited Time[]" in which an inventor can exclude others from an invention, the patent laws promote "Progress."

In drafting Section 101 of the Patent Act, Congress "plainly contemplated that the patent laws would be given wide scope," *Diamond v. Chakrabarty,* 447 U.S. 303, 308 (1980), and chose "extremely broad" language in describing patent eligibility, *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.*, 534 U.S. 124, 130 (2001). It enacted "a dynamic provision designed to encompass new and unforeseen inventions," *id.* at 135; *see also Chakrabarty* at 316. And, at each opportunity, Congress has maintained its expansive view of patentable subject matter, to the benefit of American progress. *Classen Immunotherapies, Inc. v. Biogen, IDEC,* 2011 WL 3835409 at *17 (Fed. Cir. Aug. 31, 2011) (additional views of Rader, C.J., and Newman,

J.) (affirming patent eligibility for medical methods and comparing the stifling effects of eligibility restrictions in Europe with the benefits of strong American patent protection).

Accordingly, this Court has explained that "ingenuity should receive a liberal encouragement," *Chakrabarty* at 308 (quoting 5 *Writings of Thomas Jefferson* 75-76 (H. Washington ed. 1871)), to "fulfill the constitutional and statutory goal of promoting 'the Progress of Science and the useful Arts' with all that means for the social and economic benefits envisioned by Jefferson," *id.* 315. It "has more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (citations and internal quotation marks omitted).[3]

Consistent with the contemplated breadth of patentable subject matter, Section 101 does not exclude medical process patents. As the Solicitor General notes, "patent laws have long been understood to encompass improved methods of

[3] Congress's forward-looking commitment to the benefits of the patent system undermines this Court's now-outdated caution in *Flook* to avoid the extension of patent rights into areas "wholly unforeseen by Congress," *Parker v. Flook*, 437 U.S. 584, 596 (1978). *Flook* relied on a narrow statutory reading in *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972), which Congress subsequently overturned. *See* 35 U.S.C. § 271(f); *Microsoft Corp. v. AT&T Corp.*, 550 U.S. 437, 443-44 (2007); Pub. L. No. 98-622, Title I, § 101(a), 98 Stat. 3383 (Nov. 8, 1984). That Congressional "correction" demonstrates that the scope of patentable subject matter is broad to encourage and reward "wholly unforeseen" innovation.

treating patients to alleviate medical disorders." U.S. Br. 9. Indeed, for over 100 years, Congress has declined invitations to exclude medical treatment methods from Section 101. *See* H.R. 12451, 57th Cong. (1902); H.R. 1127, 104th Cong. (1995); *see also* Joel J. Garris, *The Case for Patenting Medical Procedures*, 22 AM. J.L. & MED. 85, 107-08. And for more than 50 years, the U.S. Patent and Trademark Office Board of Appeals has held that medical methods are patentable. *Ex parte Scherer*, 103 USPQ 107 (1954).

So too, the American Medical Association has explained that Section 101 covers medical processes. In describing this Court's opinion in *Chakrabarty*, the AMA's Council on Ethical and Judicial Affairs acknowledges that the "decision to broadly interpret the statutory scope of patentable inventions [under 32 U.S.C. § 101] makes it highly unlikely that medical procedures can be legally excluded from the legal definition of process without additional legislative action." AMA, *Report of the Council on Ethical and Judicial Affairs, Ethical Issues in the Patenting of Medical Procedures* 1 (1995) ("AMA 1995 Report").[4] A 2007 follow-up report likewise concedes that "U.S. patent law allows for the patenting of medical procedures." AMA, *Report of the Council on Ethical and Judicial Affairs, Amendment to Opinion E-9.095, Trademarks,*

[4] Available at http://www.ama-assn.org/resources/doc/ethics/ceja_1a95.pdf.

Patents, Copyrights, and Other Legal Restrictions on Medical Procedures 2 (2007) ("AMA 2007 Report").[5]

The AMA's legislative efforts also confirm that Section 101 covers medical process patents. The AMA lobbied Congress to exclude medical procedure patents from the Patent Act's protection. *See* H. R. 587, 104th Cong., 1st Sess. (1995). Congress rejected medical lobbyists' initial attempts to restrict patentable subject matter, Weldon E. Havins, *Immunizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, or What?*, 77 U. DET. MERCY L. REV. 51, 63-64 (1999) (noting that the original proposal for § 287(c) attempted to prohibit patents on "any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis"). It then created Section 287(c)(1) to grant immunity from patent infringement suits to both "'medical practitioners' and 'related health care entities': when they engage in protected 'medical activity.'" 35 U.S.C. § 287(c)(1). Fears of the medical community were dominant factors shaping the content and scope of § 287(c). Jeff S. Rundle, *The Physician's Immunity Statute: A Botched Operation or a Model Procedure?*, 34 J. CORP. LAW 944, 948 (2009). The very premise of the AMA's efforts that resulted in Section 287(c)(1) is that Section 101 permits medical process.

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[5] Available at http://www.ama-assn.org/resources/doc/code-medical-ethics/9095b.pdf.

B. Medical Process Patents Encourage Private Investment

Patent law protects medical diagnostic and treatment innovations for the same reason it protects all types of inventions: patents spur progress.

Innovation in disease treatment is complicated and expensive. At the frontiers of medical science, the balance between risk and reward weighs heavily against making any effort. Research and development merely initiate the costly process of bringing an effective therapeutic intervention to market. Production, clinical trials, regulatory compliance, distribution, monitoring and insurance for adverse outcomes, and physician education all draw on limited investment resources.

Moreover, the growing imperative to contain health care costs makes "competitiveness and economic advantage…increasingly important." Todd Martin, *Patentability of Methods of Medical Treatment: A Comparative Study*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 381, 384 (2000). Almost any flavor of health care reform will rely on managed care. As available capital decreases, both public and private investors will be less likely to risk considerable spending on research that may not produce any value.

In this economically constrained environment, patents preserve the financial feasibility of investments in medical research. Private investors allocate resources based on whether the end result

can be commercialized and patented, not whether medical technology will be advanced. Innovative medical methods are cheaply reproduced by others, and without some promise of exclusivity, investment fades. Su-hua Lee, *Patent Protection for Essential Biomedical Inventions and Its Impacts on the Implementation of Public Health*, 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 115, 117 (2010) ("Without patents…better medical products needed to overcome…diseases would not be developed."). Patents motivate innovators with the promise of financial reward. Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH L.J. 1, 2 (1992) (concluding that one function of the Patent Act is to encourage research with an uncertain prospect of success at its outset); *see also, Eldred v. Ashcroft*, 537 U.S. 186, 247-48 (2003).

Additional factors align medical process patents with the public interest. Patents on diagnostic tests provide incentives for scientist-inventors to innovate beyond the basic, government-funded research for which no patent can be sought, and *apply* that theoretical research to a useful product.[6] That

[6] A basic research discovery cannot be patented unless the inventor can credibly describe the discovery's "specific and substantial" utility. U.S. Patent and Trademark Office, "2107 Guidelines for Examination of Applications for Compliance with the Utility Requirement." Available at www.uspto.gov/web/offices/pac/mpep/documents/100_2107.htm. *See also Brenner v. Manson*, 383 U.S. 519, 534 (1966) (A process claim must be reduced to a specific product, lest it "engross a vast, unknown, and perhaps unknowable area…[and] block off whole areas of scientific development without compensating benefit to the public.")

useful product is the benefit upon which the patent *quid pro quo* is based. *Brenner v. Manson*, 383 U.S. 519, 534 (1966). Basic research underpins, for example, the pharmaceutical industry's search for new drugs, but does not replace or duplicate it. *See, e.g.,* Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, 3 (2006) ("CBO Report") ("[P]rivate firms focus much more on applied research and development.").[7]

Additionally, medical process patents appropriately align investment incentives to expected consumer value: The patentee's profits as a monopolist are tied to demand. If an innovation is of no use to people, the innovation will not lead to private investment. But a patentable innovation that is of considerable use to sick people, for example, will likely produce a return and justify appropriate capital investment in research.

The human fertilization technology developed in the 1980s illustrates how process patents promote medical progress. *See, e.g.*, Martin at 384; Steven L. Nichols, *Hippocrates, the Patent-Holder: The Unenforceability of Medical Procedure Patents*, 5 GEO. MASON L. REV. 227, 258 (1997). Surrogate embryo transfer technology transfers an embryo from one woman to another. The technology was financed by private investment funds after the National Institutes of Health declined to fund the project. William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF.

[7] Available at http://www.cbo.gov/ftpdocs/76xx/doc7615/10-02-DrugR-D.pdf.

SOC'Y 651, 656-57 (1995). Without the promise of patent protection, the technology would not have been developed.

Today's wealth of new medical diagnostics and treatments confirms that the patent system currently promotes the public interest. According to the Congressional Budget Office, "[t]he range of illnesses for which drug therapies exist has never been broader, and technological advances have yielded new drug treatments of increasing sophistication, convenience, and effectiveness." CBO Report at 4. The existing broad protection for medical process patents contributes substantially to these successes. *See* Garris at 93.

C. Medical Process Patents Increase Public Knowledge

Medical patents encourage widespread and immediate dissemination of medical knowledge. That is their entire purpose—patents offer the potential for limited financial rewards ex ante, but in exchange, they require full disclosure ex post. They are contracts "made by the acceptance…of the offer…to *disclose* [an] invention, in consideration that the United States will secure…the exclusive use and sale of it for [20] years." *Century Elec. Co. v. Westinghouse Elec. & Mfg.*, 191 F. 350, 354 (8th Cir. 1911).

To be sure, the medical community exchanges important information through publication in professional journals. Garris at 93. Publication offers professional recognition, which further

incentivizes research. And because patents limit the free use of inventive research, some fear that "[p]atenting medical processes…may adversely affect the development of new medical knowledge by limiting the willingness of researchers to share their work or to report its results in an objective manner." Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1139 (1987).

But patents do not disrupt professional norms of disclosure. Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 625 (2000). To the contrary, an inventor can publish her innovation immediately in any accommodating publication and subsequently apply for a patent within a year of the invention's initial disclosure. 35 U.S.C. § 102(b) (setting forth the "public use" or "on-sale bar," which states that a patent may not issue if "the invention was…described in a printed publication…or in public use or on sale in this country, more than one year prior to the date of the application…."). Furthermore, the international academic culture of patenting does not differ significantly from the established culture of publishing scholarship. *See Chou v. Univ. of Chi.*, 254 F.3d 1347, 1359 (Fed. Cir. 2001) ("[B]eing considered an inventor of important subject matter is a mark of success in one's field, comparable to being an author of an important scientific paper."). Both accomplishments are regularly taken into account in recognizing academic achievement.

In fact, the patent system may *better* facilitate dissemination of medical knowledge than publication in professional journals. Under U.S. patent law, the inventor must not only disclose the invention, but explain it in such full, clear, and succinct terms as to enable any person skilled in the art to replicate it. 35 U.S.C. § 112. Medical journals have no such requirement. Nor do they publish all data submitted to them—the peer review process necessarily narrows the spectrum of publishable research. Martin at 385. *See also* Brian McCormick, *Just Reward or Just Plain Wrong? Specter of Royalties From Method Patents Stirs Debate*, 37 AM. MED. NEWS, Sept. 5, 1994 at 3 (describing Dr. John Stephens' unsuccessful efforts to publish the use of ultrasound to determine gender in utero before securing a patent for that use); Allan Bloomberg, *et al.*, *Patenting Medical Technology: "To Promote the Progress of Science and Useful Arts*," 317 NEW ENG. J. MED. 565, 567 (1987) (describing the failure of publication to make an improved catheter used to diagnose heart disease widely available until it was patented).[8]

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[8] For example, after a leading professional journal summarily rejected Dr. Samuel Pallin's description of his "stitchless" method for cataract surgery, he sought a patent. Joseph Reisman, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH L. J. 355, 366 (1995) (citing Congressional testimony of Dr. Samuel L. Pallin that "I was denied the opportunity to publish my writings and discovery in a traditional medical journal. I turned to the U.S. Patent Office to document what I had accomplished.…"). The Office granted Pallin's patent, and the procedure became—and remains—standard medical practice.

Moreover, while a subscription to one medical journal alone is expensive and access to all medical journals prohibitive for most, every patent document issued in the United States is in the public domain. The contents of the entire USPTO database—roughly 8 million patents and 3 million applications—are readily available online via the Office's Web site (or the slightly more user-friendly www.google.com/patents). Even bulk patent downloads are available to the public free of charge.[9] And patent documents can be made available immediately, whereas medical journals often suffer from delays associated with the submission, review, and publication process.

The alternative to patent protection for those seeking a reasonable return on their investment is often a far worse option for the spread of medical knowledge: total secrecy. Inventors who are denied the benefits of the Patent Act may choose to keep their inventions to themselves to prevent others from copying their work. Particularly as managed health care and the nationalization of insurance norms impose greater financial pressures on the health care system, those denied patent eligibility may seek trade secret protection to enable their continued research. *See* Garris at 92 & n.83.

The primary difference between a patent and a trade secret is that the public disclosure of a trade secret is legally *prohibited*—it destroys protection; whereas the public disclosure of a patent is legally

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[9] *See* http://www.google.com/googlebooks/uspto-patents.html.

required—it enables protection. Additionally, the force of a patent is limited to a certain period of time; the innovation ultimately returns to the public domain once the patent expires. But a trade secret lasts as long as there is a protected secret. *See* Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 367 (2011) ("Patents are often understood as a complementary choice to trade secrets, offering a strong limited-term monopoly in exchange for public disclosure.").

Trade secrecy not only arrests dissemination of medical knowledge, it also puts patients' safety at risk. When novel technologies are kept secret, the medical profession has no opportunity to review whether those potentially innovative techniques are safe and effective.[10]

As a logical middle ground between unprotected public disclosure and secrecy, medical patents are often the best way to expand public knowledge.

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[10] The favorite historical example of this effect is the obstetrical forceps, which the Chamberlen family kept a secret through four generations of physicians. 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, 132 (2001).

II. THE ETHICAL CONCERNS RAISED BY THE MEDICAL ASSOCIATIONS ARE SHORTSIGHTED OR MISDIRECTED

The Medical Associations' Brief raises ethical arguments to justify the legal exclusion of diagnostic and treatment methods from patentable subject matter. The brief (at 16-17) highlights Opinion 9.095 of the AMA's Code of Medical Ethics, which states that the "use of patents…to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical."

The AMA's position overemphasizes the immediate concerns of individual patients to the detriment of long-term public health. Although the medical associations raise legitimate practical concerns about the consequences of patent protection for medical processes, these concerns are for Congress or the Executive rather than this Court to address.

A. The Medical Associations' Objection To Medical Process Patents Reflects A Shortsighted Focus On Individual Patients

Medical ethics focuses on the individual patient even at the expense of long-term public welfare. The AMA's objection to medical process patents illustrates this tendency to prioritize the immediate needs of individual patients over what is best for society in the longer term.

i. Contemporary medical ethics advances the interests of individual patients

Modern medical ethics is focused on the individual. It was born in the wake of forced experimentation by Nazi scientists during the Second World War and found its first expression in the post-war Code of Nuremberg. Ian Kennedy and Andrew Grubb, *Medical Law*: Text with Materials 1011-26 (Butterworths 2d ed. 1994). In an effort to prevent the future dehumanization of patient-subjects, the Nuremberg Code outlined a set of clinical norms built around individual patient autonomy. Onora O'Neill, *Autonomy and Trust in Bioethics* 19-20 (Cambridge University Press 2002).

Today's medical ethics flourishes within that historical context; it focuses heavily on the personal interests and rights of individual patients. Its central concerns remain the protection of individual patient autonomy against the self-interest of the physician. Deirdre Dwyare, *Beyond Autonomy: The Role of Dignity in "Biolaw,"* 23 OXFORD J. LEGAL STUD. 319, 328 (2003). The predominant bioethics text, Tom Beauchamp and James Childress' *Principles of Biomedical Ethics*, prioritizes the individual patient's rights and well-being as the post-Nazi era watch cry of medical practice. *See* Marc A. Rodwin, *Strains in the Fiduciary Metaphor: Divided Physician Loyalties and Obligation in a Changing Health Care System*, 21 AM. J.L. & MED. 241, 247 (1995). That individual patient-centered paradigm has richly informed the practice of modern medicine for the better. It raised physicians'

awareness of their duties to individual patients and to potential conflicts of interest.

Consistent with this focus on the individual patient, the American Medical Association's Code of Medical Ethics ("AMA Code") prioritizes responsibility to the patient over general public obligations. The Code first states that "[a] physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health," AMA Code, xiv, ¶ VII (2001). But it quickly clarifies that "a physician shall, while caring for a patient, regard *responsibility to the patient as paramount*," *id.* at xiv, ¶ VIII (emphasis added), and that the fundamental doctor-patient relationship obligates a physician to "place patients' welfare…above obligations to other groups." *Id.* § 10.015. *See also* Douglas Mossman, *Critique of Pure Risk Assessment or Kant Meets Tarasoff*, 75 U. CIN. L. REV. 523, 578 (2006) ("In traditional medical ethics, doctors serve individual patients and have fiduciary obligations to them, not those around them.").[11]

A physician's commendable sensitivity to an individual patient's immediate welfare can distort

[11] The AMA's focus on the individual patient also arose out of concern that physicians not sacrifice health for profit. *See, e.g.,* Stephanie P. Browner, *Profound Science and Elegant Literature: Imagining Doctors in Nineteenth-Century America*, 15-38 (Univ. of Penn. Press 2005) (discussing enduring conceptualizations of medical science as distinct from the selfish pursuit of pure profit); Kara W. Swanson, *Food and Drug Law as Intellectual Property Law: Historical Reflections*, 2011 WIS. L. REV. 331, 368-69 (2011).

her perspective on long-term policymaking. *See, e.g.*, William M. Sage, *Relational Duties, Regulatory Duties, and the Widening Gap Between Individual Health Law and Collective Health Policy*, 96 GEO. L.J. 497, 499-501 (2008). Physicians and their professional associations may value individual autonomy and patient-specific protections from potential conflicts of interest more than the general health and well-being of the community. Gostin at 67. They may also attend more closely to a given policy's effect on one particular patient than to its lasting effects on future patient groups. *See, e.g.*, Richard Saver, *In Tepid Defense of Population Health: Physicians and Antibiotic Resistance*, 34 AM. J.L. & MED. 431, 484 (2003) (linking the long-term problem of antibiotic resistance to the individual-patient paradigm in medical practice). The defining values of medical ethics are thus "sometimes…harmful to critical thinking about healthy communities." Gostin at xxiii.

ii. The medical associations' objection to medical process patents serves the interests of individual patients at the expense of long-term public welfare

Consistent with the AMA's principles of prioritizing the individual over the public, the AMA has long grounded its opposition to medical process patents in concern for the individual patient under the care of the health professional. The original version of its opinion opposing medical process patents complained that patents "pose substantial risk to the effective practice of medicine by limiting the availability of new procedures to patients and

should be condemned on this basis." AMA 1995 Report at 8.

The opinion's accompanying report expanded on the AMA's focus on the individual: "One of the fundamental principles in medicine is that the health of the patient is a physician's most basic concern." *Id.* at 3. The first and primary reason that the report opposed medical process patents was "the unacceptable picture of a patent procedure becoming unavailable to patients who require it." *Id.*

The AMA's admirable fidelity to the individual patient's rights and needs has misled it in this instance to a counterproductive position on patent policy. In some cases a particular patient may not benefit immediately from a new innovation because the patent puts the new improvement out of his financial reach. Over time, however, the investment and knowledge made possible by patent protection leads to improved public health. By failing to balance this side of the patent equation, the medical associations' orientation towards medical process patents in this case demonstrates how medical ethics are "sometimes…harmful to critical thinking about healthy communities." Gostin at xxiii.

In 2007, the AMA revisited, and shifted, the rationale for its opposition to medical process patents. The AMA deleted reference to the effective practice of medicine. Instead, the AMA revised Opinion 9.095 "to further emphasize the policy's emphasis on sharing medical knowledge." AMA 2007 Report at 4. The AMA also addressed trade secret protection and confidentiality agreements.

The AMA's Code now emphasizes the "significant limitation on the dissemination of medical knowledge" patents may cause. AMA Code of Medical Ethics, Opinion 9.095.[12]

As with its focus on the individual patient, the AMA's attachment to traditional modes of sharing medical knowledge minimizes the long-term value to the public welfare that patent protection affords. The AMA's revised view also reflects its earlier assertion that medical process patents do not promote progress.[13] That view conflicts with the Founders' empirical judgment, embedded in the Constitution, that patents do promote societal progress.

Indeed, for other types of patents the medical associations recognize the contributions to patient health and welfare made possible by innovations protected under the Patent Act. The associations write that the "patent system has served patients and the medical profession well, drawing investment into the development of new treatments."). Medical Associations' Br. 10-11. The associations also agree that "health-care-related patents can enhance the

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[12] Available at http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.page.

[13] In its 1995 report, the AMA writes: "While the argument that the patenting of medical processes is necessary to enable and promote procedural advances seems strong initially, there is no evidence of the argument's empirical soundness." AMA Council on Ethical and Judicial Affairs, Report 1 – A-95, "Ethical Issues in the Patenting of Medical Procedures" at 6 (1995) ("1995 AMA Report"). http://www.ama-assn.org/resources/doc/ethics/ceja_1a95.pdf.

provision of high-quality…medical care." *Id.* at 10. And the AMA's Code of Medical Ethics, Opinion 9.09 explicitly permits physicians to patent a surgical or diagnostic instrument, conceding that "[t]he laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery."[14]

The medical associations provide no reason why the "sound doctrine that one is entitled to protect one's discovery" should not also apply to medical process patents. As explained above, medical process patents promote patient health and welfare. From a medical perspective, the relevant question should be whether the invention promotes public health. The medical associations provide no reason to distinguish among different *kinds* of medical innovations amenable to patent protection.

B. The Medical Associations' Practical Concerns Should Be Directed To The Executive Or Congress

The AMA report that informed Opinion 9.095 also raises practical objections to medical process patents based on how the Patent and Trademark Office ("PTO") interprets provisions of patent law other than Section 101. These and similar real-world concerns have considerable force. But just as

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[14] *Cf.* F. E. Stewart, *"Is It Ethical for Medical Men to Patent Medical Inventions?*" 29 JAMA 583-87 (1897) ("The only object in patenting a medical invention is to utilize it for money-making purposes.... The medical inventor...will unconsciously use his best endeavor to promote the sale of his goods, rather than make it his chief object to benefit his patients who may purchase his goods.").

in *Chakrabarty*, the "contentions now pressed on [the Court] should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts." *Id.* at 316–17. *See also* Anna E. Lumelsky, *Diamond v. Chakrabarty*: *Gauging Congress's Response to Dynamic Statutory Interpretation by the Supreme Court*, 39 U.S.F. L. REV. 641, 658 (2005).

Discussing the statutory provisions requiring novelty and nonobviousness, the AMA's report *agrees* that patent protection for novel and nonobvious medical procedures would be "reasonable." 1995 AMA Report at 7.[15] The AMA, however, opposes patent eligibility on the grounds that "there is a significant gap between a strict interpretation of novel and non-obvious and the way that these terms are currently applied in assessing patent applications." *Id.* In the AMA's view, the PTO "has applied the statutory rules too broadly, resulting in unduly expansive patenting decisions." *Id.* The AMA's report concludes that "while the ethical problems with patenting might be solved in theory by drawing a distinction between inappropriate and appropriate medical process patents, such a solution is not useful in practice." 1995 AMA Report at 8.

To the extent the PTO is not advancing the evident purpose of the statutory nonobviousness and

[15] Section 102 of the Patent Act forecloses a patent if the "invention was known or used by others" 35 U.S.C. §§ 102(a) and (f). Section 103 withholds patent protection for inventions that would have been obvious to a person skilled in the art at the time the invention was made. 35 U.S.C. § 103(a).

novelty requirements, the AMA's complaint is with the Executive or, failing that, Congress. These administrative complaints are not a basis to misconstrue 35 U.S.C. § 101. Section 101 is "only a threshold test" that "defines the subject matter that may be patented" and leaves the fact-intensive analyses of novelty, nonobviousness, and written description to the Act's substantive "'conditions and requirements.'" *Bilski v. Kappos*, 130 S. Ct. 3218, 3225 (2010) (quoting §101). The "only role of Section 101" is to "identify the types of subject matter that may be *eligible* for patent protection if "'the conditions and requirements'" of Title 35 are satisfied. U.S. Br. at 31. It falls to the other provisions to make "more nuanced factual distinctions" between those inventions worthy of patent protection and those that are not. *Id.* at 32.

Physicians also have a duty to avoid costs where possible, particularly where lifesaving care is not widely available. Average prices of new drug products have been rising much faster than the rate of inflation. CBO Report at 1. Likewise, medical procedures are expensive. Burch at 1143. But concerns about cost and access, while serious, should be addressed to either the Executive or Congress.

The Executive can address the problem of access to expensive patented medical processes in a variety of ways. It can provide subsidies, tax breaks, or various other forms of financial assistance. Or it can appropriate a patent itself and compensate the patent holder after the fact. *See* Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro: A Reevaluation of Compensation Rules for Government*

Takings of Patent Rights, 40 AM. BUS. L.J. 125, 139-46 (2002). Some agencies have even made patent appropriations part of their official policies. *Id.* at 136, n. 47.

Alternatively, Congress is well-equipped to address the full range of patent-related ethical concerns, including "particular complaints about the perceived unfairness of applying a general legal standard to [medicine]." *See* Dan L. Burk and Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1631 (2003) (describing Congressional interventions lengthening patent terms for pharmaceuticals, protecting generic drug suppliers from liability for certain experimental uses, protecting physicians from infringement claims, and relaxing the obviousness standard for biotechnological processes). For example, in the America Invents Act Congress decided to prohibit patents on human organisms.[16] Other examples abound, and reflect the variety of practical problems policymakers are able to address. *See, e.g.*, Physician's Immunity Statute;[17] Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act);[18] Orphan Drug Act;[19] Best

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[16] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33 (a), 125 Stat. 284 (2011).

[17] Pub. L. No. 104-208, §616, 110 Stat. 3009, (codified at 35 U.S.C. § 287(c) (1996)).

[18] Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. §§ 355, 360(cc) (2006), 35 U.S.C. §§ 156, 271, 282 (2006)), as amended by Title IX of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended at 21 U.S.C. § 355(j)(5)(C)(i) (2006) and 35 U.S.C. § 355271(e)(5) (2006)).

Pharmaceuticals for Children Act.[20] To the extent medical process patents raise unique cost-related or other ethical concerns, Congress is free to act.

CONCLUSION

For the reasons set forth above, this Court should conclude that medical diagnostic and treatment methods are patentable subject matter.

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[19] Pub. L. No. 97-414, 96 Stat. 2049 (1983) (codified as amended at 21 U.S.C. § 360aa-ee (1998)).

[20] Pub. L. No. 107-109, 115 Stat. 1408 (codified as amended in sections of 21 U.S.C. and 42 U.S.C.).

APPENDIX

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