

# **COMMENT**

## **PHYSICIANS AND SURGEONS AS INVENTORS: RECONCILING MEDICAL PROCESS PATENTS AND MEDICAL ETHICS**

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## I. INTRODUCTION

Physicians should strive continually to improve medical knowledge and skill, and should make available to their patients and colleagues the benefits of their professional attainments.

—Principles of Medical Ethics,  
American Medical Association, Section 2 (1971)

The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

—U.S. Constitution, Article I, Section 8, Clause 8

In the context of medical patents,<sup>1</sup> the physicians' ethical canon often conflicts with the policy goals of the federal intellectual property system. Physicians' fiduciary obligations to their patients may conflict with the "instrumental" nature of the U.S. patent system because inventors are encouraged to invest in research in hopes of later extracting profits and recovering their investments through the enforcement and licensing of the patent right.<sup>2</sup> While physicians' principal concerns must be to provide the best possible care currently available for their patients,<sup>3</sup> the patent system encourages future

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1. As used in this Comment, the term "medical patent" means a patent claiming technologies with any application to the medical treatment of humans or animals. A medical patent may contain claims for (i.e., protecting) a pharmacological composition, a mechanical device (such as a splint), a method for doing surgery, a method for using a device, a series of diagnostic steps to identify disease, or any combination of such claims. A "medical process patent" contains claims for a process (such as a surgical technique), but not claims for any distinct product. For further details of the statutory definition of patentability, see *infra* part IV and accompanying notes. See also 35 U.S.C. §§ 101-112 (1988). For a relatively brief description of the requirements of patentability, see PETER D. ROSENBERG, PATENT LAW BASICS chs. 6-9 (1994). For a more thorough analysis, see ROBERT P. MERGES, PATENT LAW AND POLICY: CASES AND MATERIALS 35-587 (1992) [hereinafter MERGES, PATENT LAW].

2. See generally MARC A. RODWIN, MEDICINE, MONEY, AND MORALS: PHYSICIANS' CONFLICTS OF INTEREST (1993); MERGES, PATENT LAW, *supra* note 1, at 1-10. See also E. Haavi Morreim, *Blessed be the Tie That Binds? Antitrust Perils of Physician Investment and Self-Referral*, 14 J. LEGAL MED. 359 (1993); E. Haavi Morreim, *Physician Investment and Self-Referral: A Philosophical Analysis of A Contentious Debate*, 15 J. MED. & PHIL. 425 (1990).

3. The Physician's Oath, World Medical Association Declaration of Geneva, as cited in THOMAS L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 441 (4th ed. 1994). See also THE HIPPOCRATIC OATH, AMERICAN MEDICAL

innovation by granting inventors the right to exclude others from practicing their innovations for a limited time.<sup>4</sup> For patents containing claims<sup>5</sup> for medical products (e.g., pharmaceuticals and medical devices) or medical processes (e.g., new therapeutic or surgical techniques), the operation of the patent system often means that physicians will either be barred from taking advantage of recent technological advances or, at the very least, be forced to license these advances from inventors for a fee ultimately charged to the patient.

These conflicts—between enforcing ethical norms on one hand and the policies underlying patent law on the other—have been the subject of heated debate in both the medical and legal communities for over a century,<sup>6</sup> and they continue to spur controversy.<sup>7</sup> This

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ASSOCIATION PRINCIPLES OF MEDICAL ETHICS, and THE INTERNATIONAL CODE OF MEDICAL ETHICS, *reprinted in* ROBERT M. VEATCH, CASE STUDIES IN MEDICAL ETHICS 351 (1979).

4. U.S. Const. Art. I, § 8, cl. 8. Under 35 U.S.C. §§ 154, 271 (1988), a patent holder may exclude others from making, using or selling subject matter claimed in the patent for 17 years from the date of issue of a valid patent. Under recently enacted legislation to bring the U.S. into compliance with the World Trade Organization's (WTO) General Agreement on Tariffs and Trade (GATT), Pub. L. No. 103-465, patent holders may exclude others for the longer of (1) 17 years from the date of issue of a valid patent or (2) 20 years from the date of filing an application with the U.S. Patent and Trademark Office (PTO) for a patent in force or one that will issue on an application filed after on or before June 8, 1995. Patents issued on applications filed after June 8, 1995 will be enforceable for 20 years from the date of filing an application with the PTO. For further details, see Changes to Implement 20-Year Patent Term and Provisional Applications, 58 Fed. Reg. 63,951 (1994).

5. A patent is composed, in relevant part, of a specification and one or a series of claims. The specification "shall contain a written description of the invention, and of the manner and process of making and using it." 35 U.S.C. § 112 (1988). The claims point out with particularity the "subject matter which the applicant regards as [the] invention." *Id.* Patent claims define the "metes and bounds" of the right which the patent confers on the inventor to exclude others from making, using or selling the invention and have often been compared to the limits of a real property grant. ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 13-15 (3rd. ed. 1994).

6. In 1855, the State Medical Society of Ohio adopted the following resolution: "[I]t is not derogatory to medical dignity, or inconsistent with medical honor, for medical gentlemen to take out a patent right for surgical or medical instruments." A national association of physicians then requested that the Ohio society either rescind that resolution or sever its affiliation with the national association. William H. Edgerton, *Medical Associations and Physicians' Patent Policies*, in THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT 563 (Robert Calvert, ed. 1964); F.E. Stewart, *Is It Ethical For Medical Men to Patent Medical Inventions?*, 29 JAMA 583 (1897); AMERICAN MEDICAL ASSOCIATION, PRINCIPLES OF MEDICAL ETHICS (1905) 12, § 8 (declaring it "derogatory to the professional character for physicians to hold patents for any surgical instrument or medicines"); Morris Fishbein, *Medical Patents*, 29 INDUS. AND ENGINEERING CHEMISTRY 1315 (1937).

7. See, e.g., Sabra Chartrand, *A Detection Method for Breast Tumors May Add Fire to a Debate Over Patents for Medical Procedures*, N.Y. TIMES, Jan. 30, 1995, at D2 (Professor Michael DeGregorio, inventor of U.S. Patent No. 5,384,260 (1995), a method of detecting breast cancer tumors that develop a resistance to Tamoxifen, expressed concern over the patenting of therapeutic methods, but was obligated to pursue the

debate has recently found its way into the United States Congress. On March 3, 1995, Representatives Greg Ganske (R-Iowa) and Ron Wyden (D-Oregon) introduced new legislation which would severely limit the patentability of medical processes, and on October 18, 1995, Senator Bill Frist (R-Tenn.) introduced legislation which would allow physicians and hospitals to infringe a class of medical patents without a license.<sup>8</sup> The bills, H.R. 1127 and S. 1334 respectively, are

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patent and assign the patent rights to Yale University.); Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1; Lauran Neergaard, *Move To Patent Surgical Procedure Sparks Fight Royalties: Doctors Say Controlling the Way They Practice Medicine in Such a Way is Unethical and Rives Up Health Care Costs*, L.A. TIMES, Apr. 2, 1995, at A14. For more scholarly analyses, see William D. Noonan, *Patenting Medical Technology*, 11 J. LEGAL MED. 263 (1990) [hereinafter Noonan, *Patenting Technology*]; William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651 (1995) [hereinafter Noonan, *Patenting Procedures*]; and George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, HASTINGS CENTER REPORT, June 1984, at 25 (1984).

8. On Friday, March 3, 1995, Rep. Ganske and co-sponsor Rep. Wyden introduced the following bill and submitted it to the House Judiciary Committee:

Section 1. Short Title.

This Act may be cited as the "Medical Procedures Innovation and Affordability Act."

Section 2. Limitation On Issuance Of Patents.

On or after the date of the enactment of this Act, a patent may not be issued for 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, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process.

H.R. 1127, 104th Cong., 1st Sess. (1995).

More recently, on October 18, 1995, Sen. Frist introduced the following bill and submitted it to the Senate Judiciary Committee:

Section 1. Short Title.

This Act may be cited as the "Medical Procedures Innovation and Affordability Act."

Section 2. Noninfringing Use.

Section 271 of title 35, United States Code, is amended by adding at the end thereof the following new subsection:

"(j)(1) For any patent issued on or after the effective date of this subsection, it shall not be an act of infringement for a patient, physician, or other licensed health care practitioner, or a health care entity with which a physician or licensed health care practitioner is professionally affiliated, to use or induce others to use a patented technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis. This section does not apply to the use of, or inducement to use, such a patented technique, method, or process by any person engaged in the commercial manufacture, sale, or offer for sale of a drug, medical device, process, or

both entitled the "Medical Procedures Innovation and Affordability Act." The House bill would make a surgical, therapeutic, or diagnostic method unpatentable unless the method involved an independently-patentable pharmaceutical composition or medical device. The Senate bill, however, would simply exempt patients, physicians and other licensed health care professionals, and health care entities from patent infringement actions if the patent claims "a drug, medical device, process, or other product that is [not] subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act."<sup>9</sup> Because, as a practical matter, medical procedures are left unregulated by these Acts, the Senate bill would make medical process patents unenforceable against typical infringers. The American Medical Association (AMA),<sup>10</sup> along with several other

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other product that is subject to regulation under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

"(2) For the purposes of this subsection—

"(A) the term 'device' has the same meaning as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(h));

"(B) the term 'drug' has the same meaning as defined in section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(g));

"(C) the term 'health care entity' means a for-profit or nonprofit entity that provides health care services, including a hospital, medical school, health maintenance organization, group medical practice, or a medical clinic;

"(D) the term 'licensed health care practitioner' means an individual other than a physician who is licensed by a State to provide health care services;

"(E) the term 'patient' means an individual who uses a patented technique, method, or process to self-administer a medical procedure, therapy, or method of diagnosis prescribed or recommended by a physician or other licensed health care practitioner;

"(F) the term 'physician' means a doctor of medicine or osteopathy or a doctor of dental surgery or medical dentistry legally authorized to practice medicine and surgery or dentistry by a State;

"(G) the term 'product' means a machine, manufacture, or composition of matter or improvement thereof;

"(H) the term 'professionally affiliated with' includes privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which the physician or licensed health care practitioner provides health care services (including teaching or instructional services) on behalf of or in association with a health care entity; and

"(I) the term 'State' means any State or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico."

S. 1334, 104th Cong., 1st Sess. (1995).

9. *Id.*

10. At Supplemental Resolution 2, A-94 (§ 480.975) (1994), the AMA condemned "the patenting of medical and surgical procedures" and announced its intention to work

medical associations,<sup>11</sup> has explicitly supported the House bill and probably will support the Senate bill as well.

It should be noted that the standard of patentability proposed in the House bill resembles the standard in the European Patent Convention, in which distinct products having medical uses (e.g., pharmaceuticals or medical devices) are patentable, but surgical or therapeutic processes are not.<sup>12</sup> Even though the "Medical Procedures Innovation and Affordability Act" would bring domestic patent law more closely into line with the patent laws of Europe (and, indeed, the patent laws of most other countries),<sup>13</sup> neither the bills' sponsors

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with Congress to outlaw the patenting of such procedures. AMA Policy Compendium Supplement, June 1994, at 30. Then, in June of 1995, Dr. John Glasson, Chair of the AMA Council on Ethical and Judicial Affairs, presented the *Report of the AMA Council on Ethical and Judicial Affairs* (June 1995) (draft on file with author) [hereinafter *AMA Report*], articulating the AMA's support for H.R. 1127 (also discussed in *AMA Criticizes Patenting of Medical Procedures*, BNA HEALTH CARE DAILY, June 21, 1995, at D5 [hereinafter *AMA Criticizes*]). See also Teresa Riordan, *Patents: New Legislation Seeks to Exclude Surgical Procedures from Patent Protection*, N.Y. TIMES, Mar. 6, 1995, at D2; Brian McCormick, *Just Reward or Just Plain Wrong?: Specter of Royalties from Method Patents Stirs Debate*, 37 AMER. MED. NEWS 33 (1994) [hereinafter McCormick, *Just Reward*]; and *Bill Would Limit Issuance of Patents on Medical Procedures*, 49 PAT. TRADEMARK & COPYRIGHT J. 530 (1995) [hereinafter *Bill Would Limit*] (general discussion of legislation).

11. Riordan, *supra* note 10, at D2.

12. The European Patent Convention provides in relevant part:

Methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

European Patent Convention (EPC), Article 52 ("Patentable Inventions"), ¶ 4.

In EPC Article 21(1), "inventions which are susceptible of industrial application, which are new and which involve an inventive step" are defined as patentable. The proposed U.S. legislation would differ from the EPC standard in that medical process claims would be allowable, provided a distinctly patentable composition or device was "necessary" to the method.

Under the EPC standard, no such claims are allowed. This admittedly subtle distinction is discussed in part V.C., *infra*.

13. Forty-four countries, including all members of the European Patent Convention, Japan, Canada and Mexico, exclude methods of treatment of humans and animals from patentability. GATT OR WIPO? NEW WAYS IN THE INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY, SYMPOSIUM AT RINGBERG CASTLE, JULY 13-16, 1988, IIC Studies, Annex II, p. 299. In the December 15, 1993 General Agreement on Tariffs and Trade, Including Trade-Related Aspects of Intellectual Property Rights (GATT-TRIPS), representatives of the WTO (excluding the United States) agreed to implement uniform international standards of patentability. This particular agreement generated little controversy, for the substantive standards of patentability in the developed nations are relatively uniform with the exception of medical process patents. Article 27(3)(a) of the GATT-TRIPS agreement provides that member nations "may" exclude from patentability "diagnostic, therapeutic and surgical methods for

nor the AMA cite international harmonization as a motivating factor.<sup>14</sup>

Rather, Rep. Ganske<sup>15</sup> believes that the new law would encourage the "sharing of medical knowledge" and would promote the traditional and more natural "evolution" of medical science. He asserts that patent protection is simply not necessary to encourage the development of innovative medical procedures because medicine develops through a process of "evolution" not "revolution."<sup>16</sup> He also asserts that medical process patents prevent innovative surgical techniques from becoming widespread.<sup>17</sup> For this reason, he concludes that medical process patents only serve to limit physicians' options and consequently to deny patients access to the best possible medical care.<sup>18</sup>

In part II, I review and analyze the current debate over the patenting of medical processes, paying special attention to a controversial medical process patent and its physician-inventor, Arizona ophthalmologist Dr. Samuel Pallin.

Over the last decade, several commentators have addressed the concerns raised in the current debate.<sup>19</sup> In part III, I briefly review these analyses, focusing on the commentaries by George Annas<sup>20</sup> and Gregory Burch.<sup>21</sup> I also address the more recently expressed views of Timothy McCoy<sup>22</sup> and William Noonan.<sup>23</sup>

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the treatment of humans or animals." *Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, 25 INT'L REV. INDUS. PROP. & COPYRIGHT L. (IIC) 209 (1994).

14. Riordan, *supra* note 10, at D2. However, Rep. Ganske did testify before the House Judiciary Committee that more than 80 countries, including most European countries, expressly prohibit medical process patents. 1995 BNA-DAILY REPORT FOR EXECUTIVES 203 (Oct. 20, 1995).

15. Rep. Ganske is also a plastic surgeon. Neergaard, *supra* note 7, at A14.

16. *Id.*; *Patient Access to Medical Procedures Strengthened in Ganske-Wyden Bill*, U.S. Congressional News Release, Mar. 3, 1995 (on file with author) [hereinafter News Release].

17. Riordan, *supra* note 10, at D2.

18. News Release, *supra* note 16.

19. See, e.g., Timothy J. McCoy, *Biomedical Process Patents: Should They Be Restricted By Ethical Limitations?*, 13 J. LEGAL MED. 501 (1992); Noonan, *Patenting Technology*, *supra* note 7; Gregory F. Burch, Note: *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139 (1987); Annas, *supra* note 7, at 25. For a more general, and thorough, analysis of the norms of science and whether they obviate the need for intellectual property protection, see Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L. J. 177 (1987) [hereinafter Eisenberg, *Proprietary Rights*].

20. See Annas, *supra* note 7.

21. See Burch, *supra* note 19.

22. See McCoy, *supra* note 19, at 508-18.

23. Noonan, *Patenting Procedures*, *supra* note 7.

In parts IV and V, I address the special role attributed to medical processes by these commentators and by the authors of the proposed legislation. Specifically, in part IV, I present an abbreviated historical overview of the changes in patent law, medical ethics, and federal regulation of medical technology over the past century. I then use these observations to reappraise the product/process distinction currently applied to medical patents by the proposed legislation. In part V, I advance a classification scheme to analyze the ethical issues raised by the types of claims typically seen in medical patents.<sup>24</sup> This scheme separates (a) medical product claims, (b) so-called "new use" claims, and (c) "pure" surgical, therapeutic, or diagnostic procedure claims. Although these categories do overlap,<sup>25</sup> each lends itself to subtly distinct ethical and legal analyses.

I conclude that no relevant distinction, whether based on medical ethics, privacy concerns, or physicians' fiduciary duties to their patients, may be drawn among the three classes of claims for medical technologies. Instead, in subpart D of part V, I assert that the only relevant distinctions among the classes lie in who has developed the innovation and in who enforces the related patent rights.

Ultimately, I assert that only when an independent physician-inventor<sup>26</sup> pursues patent protection and then owns and enforces patent rights against other physicians are the most serious ethical concerns raised. Where an institution (bound by sufficient internal and external safeguards) pursues patent rights and sees to the licensing and enforcement of those rights, the ethical concerns raised

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24. For a definition of patent claims, see *supra* note 5.

25. A single medical innovation may yield a patent containing claims from all of these classes. Moreover, if a patent discloses and claims a new medical device, the inventor is entitled to claim specific uses of and techniques for employing the device that are disclosed in the specification.

It should also be noted that patent rights for a product (e.g., a pharmacological composition or a device) necessarily include the right to exclude others from any use of that product, even if a "new" use is developed by a later innovation and is independently patentable. The holder of an earlier, broader patent may "block" the holder of a later, more narrow patent from practicing the later invention, even as the holder of the later patent may "block" the earlier inventor from practicing the more narrow invention. For a more complete discussion of "blocking" patents in the context of new uses and patentable processes, see MERGES, PATENT LAW, *supra* note 1, at 182-86.

26. I have defined "independent physician-inventors" as those who are not bound by mandatory patent assignment contracts and "institutional physician-inventors" as those bound by such agreements. While this dichotomy is by no means rigid, it provides a meaningful framework from which I will draw examples. The proposal presented in part VI provides further details regarding the independent/institutional distinctions that I find most relevant.

are far less stark. This is because institutions—unlike individuals—must constantly be willing to license technologies, and thus they are far better positioned to enforce patents without harming the rights of other physicians or patients.

In part VI, I propose a system under which individual physicians would still have powerful financial incentives to develop new and useful medical innovations, but would not themselves own or enforce the rights to the patents resulting from these innovations. The proposal, based on a suggestion made over eighty years ago, would leave intact physician-inventors' ability to patent medical processes and profit from their inventions.<sup>27</sup> Under the proposal, physicians would be bound to assign patent rights either to an approved institution or to one of several national, member-run organizations subject to the oversight of the medical community. These national organizations would act as clearinghouses for the patent rights of physician-inventors,<sup>28</sup> setting rates of compensation for inventors, issuing blanket licenses for the patent rights they own and effecting efficient yet ethical means of patent enforcement. Through this mechanism independent physician-inventors would be shielded from patent-related ethical conflicts while the competing national interests in advancing medical science and in preserving physicians' ethical conduct would be served simultaneously.

## II. THE CURRENT DEBATE: SHOULD MEDICAL PROCESSES BE PATENTABLE?

The two sides of the debate over the propriety of patenting medical processes represent starkly contrasting positions. The most basic factual assumption of the proponents of patentability, that the prospect of patent protection is a necessary spur for research into better and less costly medical procedures, is flatly contradicted by the opponents of patentability.<sup>29</sup> This latter group, represented by the

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27. Fishbein, *supra* note 6, at 1317 (discussing proposal of 1914). The proposal is also described in the Letter of A.T. Sperry, 28 J. PAT. OFF. SOC'Y 371, 372 (1946) and in ARCHIE M. PALMER, NATIONAL RESEARCH COUNCIL, SURVEY OF UNIVERSITY PATENT POLICIES: PRELIMINARY REPORT 71 (1948).

28. The similarities to copyright clearinghouses such as the American Society of Composers, Authors, and Publishers (ASCAP); Broadcast Music, Inc. (BMI); and the Harry Fox Agency may be apparent to the sophisticated reader. I discuss the similarities between the proposed medical patent rights clearinghouses and ASCAP *infra* part VI.A.

29. Brian McCormick, *Restricting Patents: Bipartisan Bill Would Bar Ownership Claims for Medical Methods*, 38 AM. MED. NEWS 3 (1995) [hereinafter McCormick, *Restricting Patents*]; PTO Assails Bills to Limit Patents on Medical Procedures, 50 PATENT, TRADEMARK & COPYRIGHT J. 737 (1995).

AMA and Rep. Ganske, believe that physicians should continue to rely on traditional means for appropriating the value of their inventions, such as receiving a salary or fees that reflect their accomplishments, the acclaim of their peers ("the real glory")<sup>30</sup> and the respect of their patients. These non-patent mechanisms, it is argued, provide adequate incentives to invent new processes while maintaining the incentives to disseminate new information through the medical literature.<sup>31</sup> More importantly, they argue, physicians free of the confines of the patent system would also be free to abide by their fiduciary and ethical obligations to their patients.<sup>32</sup> Furthermore, by removing the costs of enforcing and licensing patents, either version of the proposed legislation necessarily would make medical care more affordable.<sup>33</sup>

The position taken by the AMA and supporters of the legislation may be characterized as a narrow form of the often-expressed "Principle of Non-Removal from the Public Domain."<sup>34</sup> This underlying principle of patent law dictates that all "known" technologies should be dedicated to the public domain<sup>35</sup> and that patents should not be awarded for technologies that would have been developed without the incentives of the patent system.<sup>36</sup> Of course, it is nearly impossible to determine whether a given procedure would

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30. McCormick, *Just Reward*, *supra* note 10.

31. *Hearings on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong., 1st Sess. (1995) [hereinafter Hearings] (testimony of Dr. Charles Kelman, President, The American Society of Cataract and Refractive Surgery) ("[T]here is little evidence that physicians and corporate investors require [the promise of significant financial rewards] to invest in research on pure medical procedures.").

32. *Id.* (testimony of Dr. H. Dunbar Hoskins, Jr., Executive Vice President, The American Academy of Ophthalmology) (Physicians are under an ethical obligation to share "their knowledge and skills for the benefit of humanity.").

33. *Id.* (testimony of Dr. Jack A. Singer) ("A Legislative response is the only effective solution to the threat that medical method patents pose to the availability, quality, and cost of health care in our country. Failure to enact the pending legislation [H.R. 1127] will do an injustice to patients and the medical profession, while contributing to exploding health care costs.").

34. HARMON, *supra* note 5, at 11-12 ("[T]he real reason for denying patent rights is the basic principle that no patent should be granted that withdraws from the public domain technology already available to the public.").

35. See 35 U.S.C. § 102 (1988) ("Conditions for patentability; novelty and loss of right to patent").

36. See 35 U.S.C. § 103 (1988) ("Conditions for patentability; non-obvious subject matter"). See also NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (J. Witherspoon ed., 1980) [hereinafter NONOBVIOUSNESS] and Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1 (1992) [hereinafter Merges, *Uncertainty*] (concluding that one function of § 103 is to encourage research with an uncertain prospect of success at its outset).

have been developed without the patent system when a patent system is in fact in place. Supporters of the legislation simply assert that the advances in medical science prior to the availability of medical process patents indicate that patent incentives are unnecessary, while opponents of the legislation cite the large number of applications for medical process patents as evidence, however vague, of the current need for the patent incentive.<sup>37</sup>

These proponents of patentability also assert that peer acclaim is rarely based on the actual value of new inventions and, moreover, that the patent system is superior to the traditional medical literature in disseminating truly novel procedures.<sup>38</sup> Additionally, they contest any assertion that the patent system sets up perverse incentives for a physician-inventor. Instead, they claim the patent system merely creates an additional cost-benefit decision for physicians and patients who wish to license the patented process but creates no notable conflicts between the interests of physician-inventors and their own patients.<sup>39</sup> Furthermore, they note that it would be "unfair" and "counterproductive" to place physicians and surgeons, unlike all other technical professionals, outside the patent system, because the incentives of the patent system have been necessary to spur developments in the medical sciences.<sup>40</sup> Finally, proponents of the patent system also note that whatever conflicts of interest or additional costs are introduced by the patenting of medical

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37. McCormick, *Restricting Patents*, *supra* note 29, at 3; PTO Assails Bills to Limit Patents on Medical Procedures, 50 PAT. TRADEMARK & COPYRIGHT J. 737 (1995). See also Hearings, *supra* note 31 (testimony of Dr. William D. Noonan) (noting that even though U.S. patents have been issued on surgical procedures for well over a century, the economic impact of such patents is unimportant).

38. See Hearings, *supra* note 31 (testimony of Michael Kirk, Executive Director, The American Intellectual Property Law Association (AIPLA)) (stating that the proposed legislation would remove inventors' incentive to develop new medical processes and to disclose newly developed techniques to the public).

39. *Id.* (testimony of Michael Kirk) (noting that conflicts only arise where a physician is "unwilling to take a license under the patent" or a patentee refuses to license his rights and further noting that "[t]he proponents of [H.R. 1127] have never been able to point to any concrete examples of patients who were at risk of not having the benefits of [Dr. Samuel Pallin's] patented surgery technique").

40. *Id.* (testimony of Donald R. Dunner, Chair, Section of Intellectual Property Law, American Bar Association):

[The Section of Intellectual Property of the American Bar Association believes] that it would be unfair to single out one area of creativity—the creation of new and improved medical procedures—and deny rewards to those creators while providing them to all others. To do so would not only be unfair, but even more importantly, would be counterproductive. Our patent system and the premises upon which it is based have been tested. That testing has gone on for more than 200 years, and has produced results which are the envy of the world.

processes, these drawbacks are dwarfed by the conflicts and escalating costs inherent in the current medical environment, which includes the uncontested presence of patents covering pharmaceuticals and medical devices.<sup>41</sup>

A single independent physician-inventor appears as a focal point for both sides in the debate: Dr. Samuel Pallin, a Sun City, Arizona, ophthalmologist. In 1990, Dr. Pallin made an upside-down V-shaped incision in a patient's eye while removing a cataract but failed to stitch the incision after surgery because the patient was experiencing heart problems. To his surprise, Dr. Pallin discovered two weeks later that the scar had healed without a suture and had far less scar tissue than a normal, sutured incision.<sup>42</sup> He claims to have rushed to submit an article describing this procedure to a leading journal in the field, the *Journal of Cataract and Refractive Surgery*.<sup>43</sup> The *Journal* replied that Pallin's article offered no true innovation and summarily rejected his submission.<sup>44</sup>

Fearing that he would never be welcome in the "good old boy network"<sup>45</sup> of his profession, Pallin applied for and, on January 4, 1992, received U.S. Patent No. 5,080,111: "Method of Making Self-Sealing Episcleral Incision." He then offered to donate the patent to a national cataract surgeons group, but that offer was also rejected. Finally, he offered licenses to perform the patented

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41. *Id.* (testimony of Dr. William D. Noonan) (although opposed to the patenting of medical processes, Dr. Noonan testified that in spite of ethical concerns raised by pharmaceuticals and medical device patents, they were justified as incentives to invest. "The need for [patent] protection is clear with biopharmaceuticals and medical devices (or methods of using them) that may require millions of dollars for research, development, FDA approval and final marketing."). Cf. *id.* (testimony of Donald R. Dunner):

Virtually the only distinction between medical methods and medical devices is that, through the ordinary course of business, medical practitioners are insulated from direct involvement with patent-liability matters in regard to medical devices. That is, the makers of medical devices typically warrant, either expressly or by legal implication, that use of the device will not infringe another's patent right. The physician is therefore indemnified. With medical method patents, in contrast, the physician is typically the direct infringer with no indemnification. However, the mere fact that physicians are exposed to the effect of the patent laws does not suggest that those laws should be limited.

42. Jodie Snyder, *A Patent for Eye Surgery? Court Case Arises Over the Technique*, THE PHOENIX GAZETTE, Apr. 4, 1995, at A1.

43. *Id.*

44. See Hearings, *supra* note 31 (testimony of Dr. Samuel L. Pallin) ("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 . . .").

45. Neergaard, *supra* note 7, at A14; see also Hearings, *supra* note 31 (testimony of Dr. Samuel L. Pallin).

procedure at \$3 to \$4 per surgery, asserting that the figure was quite reasonable in light of the \$17 saved by avoiding a single suture.<sup>46</sup> The technique is now widely performed, although few surgeons have been willing to obtain a license from Pallin.

More insulting to Pallin, however, is the fact that Dr. Jack Singer, a Vermont ophthalmologist, claims to have invented "no-stitch" cataract surgery.<sup>47</sup> Singer maintains that he used a related incision a month before Pallin's discovery and that he did not seek a patent because he could not ethically seek a patent covering a medical procedure.<sup>48</sup> Pallin counters that his procedure is different than Singer's earlier surgery and that it yields superior results.<sup>49</sup> He has brought a patent infringement suit against Singer and the Dartmouth-Hitchcock Medical Center in the Federal District Court for the District of Vermont,<sup>50</sup> vowing that if he wins, he will charge any future licensee \$5 to use his technique.<sup>51</sup>

The debate stirred by the Pallin case has generated intense rhetoric on both sides. Pallin and his supporters note that "traditional" means of sharing medical information and technical advances failed in this case and that physicians should be encouraged to explore other means of disseminating their techniques, including filing for patents.<sup>52</sup> Pallin also argues that his professional skills, which lie in inventing and developing surgical techniques, should be no less rewarded by the patent law than the professional skills of chemists and engineers, whose labors routinely yield medical patents and associated licensing fees.<sup>53</sup> In broader language, members of the legal academy have joined Pallin, noting that "[t]he whole point of the monopoly of a patent is to act as an encouragement for innovation"<sup>54</sup> and failing to see why physicians would respond to the

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46. Neergaard, *supra* note 7, at A14.

47. Snyder, *supra* note 42, at A1; Neergaard, *supra* note 7, at A14.

48. Hearings, *supra* note 31 (testimony of Dr. Jack A. Singer) ("I have acted in complete compliance with the AMA code of medical ethics and the report of the AMA Council on Ethical and Judicial Affairs, which concluded: '[T]he Council believes that it is unethical for physicians to seek, secure, or enforce patents on medical procedures.'"). See also *AMA Report*, *supra* note 10 (also discussed in *AMA Criticizes*, *supra* note 10, at D5).

49. Snyder, *supra* note 42, at A1.

50. Pallin v. Singer, No. 593CV202 (D. Vt. filed July 6, 1993), cited in *Agency Opposes Bills to Create Patent Exception for Medical Procedures*, 1995 BNA-DAILY REPORT FOR EXECUTIVES 203 (Oct. 20, 1995).

51. Neergaard, *supra* note 7, at A14.

52. Hearings, *supra* note 31 (testimony of Dr. Samuel L. Pallin).

53. Neergaard, *supra* note 7, at A14.

54. Riordan, *supra* note 10, at D2 (statement of Roger E. Schechter, Professor of Law, George Washington University).

incentives of the patent system any differently than other technical professionals.

Supporters of the proposed legislation, however, see Pallin as an opportunist who seeks an endless financial reward even as he admits to expending little or no effort in developing his procedure.<sup>55</sup> Employing even more intense rhetoric, physicians have spoken of medical process patents as leading to the Balkanization of medicine,<sup>56</sup> and have compared Pallin's patent to a patent for "breaking an egg into a skillet for frying,"<sup>57</sup> misconstruing or simply ignoring the novelty and nonobviousness standards of patent law.<sup>58</sup> The AMA (perhaps playing on the public's fear of escalating medical costs) has even asserted that the cost of licensing medical process patents will add significantly to our nation's medical expenses.<sup>59</sup>

Three central issues emerge from the current debate: (1) whether the sharing of new medical techniques is currently valued in medicine, (2) whether physicians owe duties to patients other than their own (e.g., a duty to disclose innovative techniques without seeking an economic reward) and (3) whether physician-inventors, by patenting medical processes, create conflicts between their own financial interests and the interests of their patients. Though none of these issues, strictly speaking, raises questions of patent law, understanding the manner in which each is reflected in the patent law and in medical ethics may lead to a better appreciation of the conflict and, perhaps, to a suitable resolution.

### A. The Sharing of Medical Innovations

The supporters of H.R. 1127 maintain that physicians are compelled by a code of ethics to share their discoveries and knowledge with other physicians.<sup>60</sup> This so-called "sharing norm" may be seen in the AMA's 1971 Principles of Medical Ethics: "Physicians should strive continually to improve medical knowledge and skill, and should make available to their patients and colleagues

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55. See Hearings, *supra* note 31 (testimony of Dr. Charles Kelman, President, The American Society of Cataract and Refractive Surgery).

56. Neergaard, *supra* note 7, at A14.

57. Editorial, *Medical Greed Patently Absurd*, DAYTON DAILY NEWS, Apr. 7, 1995, at A18.

58. 35 U.S.C. §§ 102-103 (1988) (patentable invention must be both novel and nonobvious).

59. See McCormick, *Restricting Patents*, *supra* note 29, at 3; *Bill Would Limit*, *supra* note 10, at 530.

60. "[The AMA Council on Ethical and Judicial Affairs] believes that it is unethical for physicians to patent medical procedures." *AMA Report*, *supra* note 10 (also discussed in *AMA Criticizes*, *supra* note 10, at D5).

the benefits of their professional attainments."<sup>61</sup> Similarly, the 1991 AMA Code of Medical Ethics notes that "[t]he intentional withholding of new medical knowledge, skills, and techniques from colleagues for reason of personal gain is detrimental to the medical profession and to society and is to be condemned."<sup>62</sup> Of course, the meanings of "make available" and "withhold" in these contexts are subject to a variety of interpretations, but the phrase "make available to their patients" must not mean that physician-inventors are compelled to provide their services free of charge. Likewise, is offering a license to perform a patented procedure, while simultaneously publishing results in a medical journal, a way of making that skill "available"? Although an answer to this question cannot be found in the broad language of the ethical codes, perhaps the norms of the medical community provide some guidance.

The sharing norm, in the context of "basic" (not profit-yielding) research, has been addressed in great detail by Professor Rebecca Eisenberg.<sup>63</sup> She has concluded that the perspectives of the patent system and of basic research science are often irreconcilable, and that compromises should be and have been sought to accommodate the sharing of basic research information.<sup>64</sup> To the extent medical research may be characterized as "basic" research, her conclusions certainly apply, but they do not to the extent that research into medical processes is "applied" (profit-yielding) research. Because medical research often defies definition as either "basic" or "applied," Professor Eisenberg's observations may not provide a great deal of guidance.

Nevertheless, her concluding observation that "the patent system will influence the behavior of research scientists more effectively if it takes into account the norms and incentives that guide behavior in the scientific community"<sup>65</sup> may be applied to the current debate. Only by addressing the norms of the medical community may the patent system influence the behavior of physicians and surgeons to create better incentives for innovation. For this reason, a

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61. AMA PRINCIPLES OF MEDICAL ETHICS § 2 (1971), reprinted in VEATCH, *supra* note 3, at 354.

62. *New Medical Procedures*, AMA CODE OF MEDICAL ETHICS: CURRENT OPINIONS AND ANNOTATIONS 139 § 9.08 (1994).

63. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) [hereinafter Eisenberg, *Patents*]; Eisenberg, *Proprietary Rights*, *supra* note 19.

64. Eisenberg, *Patents*, *supra* note 63. (To accommodate both value systems, the author suggests that a broadened "experimental use" defense to infringement be fashioned to protect basic research.).

65. Eisenberg, *Proprietary Rights*, *supra* note 19, at 230.

compromise must be struck between the concerns expressed by physicians and by the proponents of patentability if a productive change is to be made in the patent law.

### B. Physicians' Duties to Patients Other Than Their Own

The question of what duty physicians might owe to patients in general, as opposed to their own patients, is also troublesome. Under the patent law, a physician-inventor who patents a medical process is certainly free to use that technique while treating any patient,<sup>66</sup> but other physicians must obtain (and likely pay for) a license from the patent owner if they wish to use the patented process for their own patients. For this reason, the act of patenting a new procedure can be seen as forcing a legal relationship between the physician-inventor and other physicians' patients. A question then presents itself: What legal duties, if any, arise out of this indirect relationship?

Once again, the AMA's Principles of Medical Ethics purport to provide guidance to the individual physician:

The honored ideals of the medical profession imply that the responsibilities of the physician extend not only to the individual [patient], but also to society where these responsibilities deserve [the physician's] interest and participation in activities which have the purpose of improving both the health and the well-being of the individual and the community.<sup>67</sup>

It appears, then, that a physician owes some duty to society at large or to the local community, but it is unclear whether that duty extends to individual members of the community. Thus, assuming a physician-inventor's duty to provide for other physicians' patients, that duty squarely contradicts the perspective of the patent system. In many ways this irreconcilable conflict parallels the conflict between the sharing norm and the patent system: physician-inventors who freely share their innovations with other physicians discharge any "responsibility" to society, but forcing such sharing might undermine the instrumental goals of the patent system, by eliminating the economic incentives for innovation that system seeks to create.

### C. Physicians' Conflicts of Interest

An undercurrent from the much larger debate over physicians' conflicts of interest is detectable in the debate over medical process

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66. Subject, of course, to Food and Drug Administration (FDA) approval of the medical devices and pharmaceuticals used in the process. See *infra* part IV.

67. AMA PRINCIPLES OF MEDICAL ETHICS § 10 (1971), reprinted in VEATCH, *supra* note 3, at 354.

patents. Conflicts of interest arise most dramatically where a physician, who owes fiduciary duties to his patients, has an economic interest that creates an incentive to act against the best interests of his patient.<sup>68</sup> While patent rights represent but a single means by which physicians may profit at the expense of their patients' best interests, a patient's and a physician's interests may starkly contrast in the context of patent rights.<sup>69</sup> For example, a surgeon may use her own patented procedure and resist using a better-suited procedure if she can avoid paying a licensing fee on the "better" alternative. A related conflict, between a physician's research directed toward a patent and a patient's right to know the physician's motives, was at issue in *Moore v. Regents of University of California*.<sup>70</sup>

In *Moore*, plaintiff John Moore was successfully treated for hairy-cell leukemia by Dr. David Golde of the University of California at Los Angeles (UCLA) Medical Center. Golde, collaborating with other UCLA researchers, developed a valuable cell line from Moore's T-lymphocytes and obtained, for the University, a patent for the purified cell line. Neither Golde nor any of Moore's physicians disclosed the extent of the ongoing research or their developing economic interest in the outcome of that research, even as they continued to withdraw samples of Moore's "blood, blood serum, skin, bone marrow . . . and sperm" for reasons related *only* to the development of the purified cell line. The court, determining that Golde had entered into a "fiduciary"<sup>71</sup> relationship with Moore by agreeing to treat his disease, held "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose

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68. RODWIN, *supra* note 2. The author notes: "There are two main types of conflict of interest: (1) conflicts between the physician's personal interests (often financial) and the interests of the patient and (2) conflicts that divide a physician's loyalty between two or more patients or between a patient and a third party." *Id.* at 9. The conflicts of interest that arise from physicians applying for and receiving patents are almost exclusively financial conflicts of interest. The present analysis is, accordingly, limited to financial conflicts of interest.

69. *Id.*

70. 793 P.2d 479 (1990).

71. *Id.* at 485 n.10. The court cautioned:

In some respects the term "fiduciary" is too broad. In [the context of this case] "fiduciary" signifies only that a physician must disclose all facts material to the patient's decision. A physician is not the patient's financial adviser . . . [T]he reason why a physician must disclose possible conflicts is not because he has a duty to protect his patient's financial interests, but because certain personal interests may affect professional judgment.

*Id.* The same limitations on the use of the term "fiduciary" should be applied to this Comment.

personal interests unrelated to the patient's health, whether research or economic, that may affect [the physician's] medical judgment."<sup>72</sup>

Thus, under the *Moore* standard, potential conflicts of interest arising from physician-inventors' patents or patent applications may be largely resolved by mandating that physicians fully disclose to their patients any interests in medical patents while obtaining informed consent. Nevertheless, it is still unclear whether full disclosure would require an accounting of patent applications filed, patents held, or both. Furthermore, the developing jurisprudence of physician conflict of interest does not squarely address whether medical process patents should be granted.<sup>73</sup> Instead, it only indicates that physician-held patents create an opportunity for the interests of the physician and those of the patient to diverge. Thus, physician-held patents may be seen as creating yet another economic incentive, in a growing list, for physicians to act against the best interests of their patients.<sup>74</sup>

Neither the rhetoric surrounding the current debate nor the underlying questions that emerge provide easy answers to our central inquiry: whether medical processes should be patentable. This uncertainty arises primarily because it is impossible to know whether patent protection is necessary to spur medical invention or whether a physician's patent rights would, even with appropriate safeguards, necessarily interfere with her duties as the fiduciary of her patients. Because of this uncertainty, the analyses of the ethical (part III) and historic (part IV) perspectives on the patenting of medical processes become crucial to understanding and reconciling the seemingly irreconcilable positions in the current debate.

### III. PRIOR TREATMENT OF THE ETHICAL CONSIDERATIONS RAISED BY THE PATENTING OF MEDICAL PROCESSES

Before assessing the ethical concerns raised by the patenting of various medical technologies, it is essential to review the landscape of medical ethics and, more importantly, the recent analyses of the patent system's effect on this landscape. Several law reviews have presented articles that discuss the role of patents in medicine.

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72. *Id.* at 485.

73. See RODWIN, *supra* note 2, at 212-47 (asserting that disclosure is an effective remedy for conflicts of interest, but even stricter regulatory standards for avoiding conflicts should be applied to the medical community). See also E. Haavi Morreim, *Physician Investment and Self-Referral: A Philosophical Analysis of a Contentious Debate*, 15 J. MED. & PHIL. 425 (1990).

74. See Morreim, *supra* note 73.

However, no leading text in the field of medical ethics squarely addresses the issues raised by patents claiming medical advances.<sup>75</sup> Nonetheless, the literature of medical ethics provides an appropriate general vocabulary for discussing the ethical concerns raised by medical patents. The terminology used by Beauchamp and Childress in *Principles of Biomedical Ethics*<sup>76</sup> offers a useful frame of reference by dividing the ethical landscape into five broad, overlapping categories:<sup>77</sup> respecting patient autonomy,<sup>78</sup> avoiding maleficence,<sup>79</sup> allowing for beneficence,<sup>80</sup> serving justice,<sup>81</sup> and preserving these essential elements in the physician-patient relationship.<sup>82</sup> As further analysis will reveal, patient autonomy, avoiding maleficence (in the guise of physician conflict of interest), and the physician-patient relationship are most likely to be influenced by medical patents. In addition to these concerns, medical patents may create conflicts between physicians' financial incentives and the interests of the patient,<sup>83</sup> while the enforcement of medical patents may compromise a patient's rights to privacy.<sup>84</sup>

Recent commentaries on the patentability of medical processes have also used this framework, though each author values different ethical criteria. In *Biomedical Process Patents: Should They Be Limited By Ethical Limitations?*,<sup>85</sup> Timothy McCoy questions the role medical

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75. See, e.g., TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 441 (4th ed. 1994). The authors dedicate 12 pages in this 500-page treatise to "The Dual Role of Physician and Investigator," but do not discuss the patenting of an invention derived from such an investigation.

76. *Id.* See also STEPHEN G. POST, INQUIRIES IN BIOETHICS 1-7 (1993); VEATCH, *supra* note 3, at 59-136. Veatch, unlike Beauchamp and Childress, divides the field into four categories: duty to patient and society, health-care delivery, confidentiality, and truth-telling.

77. A recently published case book for the study of the legal issues of biomedicine has adopted this framework. See BARRY R. FURROW ET AL., HEALTH LAW: CASES MATERIALS AND PROBLEMS (1991). The authors dedicate entire chapters to "The Relationship of Provider and Patient" and "Access to Health Care." It should, however, be noted that this classification of ethical issues does not overlap with the classification scheme of the American College of Healthcare Executives' Code of Ethics. MARC D. HILLER, ETHICS AND HEALTH ADMINISTRATION 120 (1986). For further discussion of the ethical concerns that inform the decisions of health care administrators, as opposed to those of physicians, see *infra* part V.D.

78. BEAUCHAMP & CHILDRESS, *supra* note 75, at 120 (1986).

79. *Id.* at 189.

80. *Id.* at 259.

81. *Id.* at 326.

82. *Id.* at 395.

83. See generally RODWIN, *supra* note 2. See also *supra* part II.C.

84. See Jeffrey A. Taylor, Comment, *Medical Process Patents and Patient Privacy Rights*, 14 J. COMP. & INFO. L. 131 (1995).

85. McCoy, *supra* note 19.

patents play in limiting patients' access to health care<sup>86</sup> and information transfer,<sup>87</sup> while also discussing the impropriety of patenting living organisms.<sup>88</sup> Access to health care most directly triggers concerns for patient autonomy, justice and the physician-patient relationship. The "information-sharing ethic" cited by McCoy resembles the above-mentioned "sharing norm."<sup>89</sup> McCoy's third concern, whether living organisms should be patented, is generally not raised by medical process patents, and accordingly finds few parallels in the ethical scheme of Beauchamp and Childress.<sup>90</sup> Ultimately, McCoy concludes that the role patent protection plays in medical innovation simply outweighs any ethical concerns because patent protection creates an invaluable incentive to develop necessary medical technologies.<sup>91</sup> In light of the heightened tenor of the current debate, however, ignoring the ethical concerns raised by the medical community may not be considered a viable option.<sup>92</sup>

In *Ethical Considerations in the Patenting of Medical Processes*,<sup>93</sup> Gregory Burch discusses the controversial patent covering surrogate embryo transfer (SET)<sup>94</sup> (a reproductive technology that is controversial in its own right)<sup>95</sup> and ultimately focuses on the effect the patent might have on physician-patient relationships<sup>96</sup> and physician autonomy.<sup>97</sup> He concludes that the current patent law provides inadequate safeguards for physician autonomy and suggests that a mandatory licensing scheme for medical process patents would address this inadequacy.<sup>98</sup> While the approach does attempt to

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86. *Id.* at 510-12, 519.

87. *Id.* at 512-14, 519.

88. *Id.* at 515-17.

89. See *infra* part II.A.

90. Cf. Robert P. Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051 (1988) [hereinafter Merges, *Controversial Technologies*] (arguing that patent law is not the appropriate arena in which to regulate new lifeforms).

91. McCoy, *supra* note 19, at 518-19.

92. But see Noonan, *Patenting Procedures*, *supra* note 7, at 663 (noting that medical process patents have had little practical effect on domestic health care delivery and suggesting that such patents will never become more than "an occasional curiosity").

93. Burch, *supra* note 19.

94. See also Maria Bustillo et al., *Nonsurgical Ovum Transfer as a Treatment in Infertile Women: Preliminary Experience*, 251 JAMA 1171 (1984); Fern S. Chapman, *Going for Gold in the Baby Business*, FORTUNE, Sept. 17, 1984, at 41.

95. For a more thorough discussion of the ethical issues raised by SET and related technologies, see Annas, *supra* note 7, at 25.

96. Burch, *supra* note 19, at 1154-59.

97. *Id.* at 1152-54.

98. *Id.* at 1169-71.

strike a compromise, it merely forces the inevitable debate over each particular "reasonable royalty" into a court, while ignoring the United States patent law's traditional avoidance of mandatory licenses.<sup>99</sup>

In an earlier and briefer analysis of the patenting of SET techniques, George Annas (in contrast to Burch) places a special emphasis on the invasions of patient privacy *and* on the confidential physician-patient relationship, concerns which the mere enforcement of medical process patents could compromise.<sup>100</sup> Although he admits that the prospect of patent protection was essential in generating financing for the SET research,<sup>101</sup> he notes that the "subject matter" of such an advanced medical procedure "does not lend itself to patent infringement enforcement without potentially unbearable privacy violations."<sup>102</sup> Annas then concludes that patent applications claiming these procedures should be rejected unless the applicant provides a means of enforcement that will not compromise patients' privacy rights. Jeffrey Taylor, in his Comment *Medical Process Patents and Patient Privacy Rights*, proposes just such a enforcement mechanism.<sup>103</sup> He suggests that Congress may revise the Patent Act to allow better access to medical records (while preserving patient privacy) during enforcement of medical process patents. For example, he suggests that removing a patient's identity from medical records subject to civil discovery in a patent infringement action would protect the patient's privacy and obviate the need for informed consent.<sup>104</sup> While this proposal might address patients' rights to privacy, it

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99. In this country, only the Clean Air Act of 1970 provides for mandatory licensing of patented technology between private parties. 42 U.S.C. §§ 7401-7671 (1988). This mandatory licensing scheme, however, was only created to "curtail the tendency of patents to create a monopoly on a technology that facilitates compliance with the Act." Burch, *supra* note 19, at 1168. Furthermore, mechanisms already exist to prevent patentees from refusing to license technologies required by society. See, e.g., Vitamin Technologists v. Wisconsin Alumni Research Foundation, 146 F.2d 941, 944-45 (9th Cir. 1944) (*cited in* Kearns v. Chrysler, 32 F.3d 1541, 1551 (Fed. Cir. 1994)) (denying injunction where patentee refused to license its process for producing vitamin D to those who would fortify oleomargarine and infringer used process for that purpose).

100. Annas, *supra* note 7, at 25.

101. *Id.* at 25-26.

102. *Id.* at 26. For example, Annas envisions private investigators or paid informants being used to monitor the SET process.

103. Taylor, *supra* note 84, at 147.

104. *Id.* Montana and Washington have recently enacted modified versions of the 1985 UNIFORM HEALTH-CARE INFORMATION ACT to protect the confidentiality of medical records. MONT. CODE ANN. §§ 50-16-501 to 553 (1987) (Uniform Health Care Information); WASH. REV. CODE ANN., §§ 70.02.005-904 (West 1991) (Medical Records-Health Care Information Access and Disclosure).

does not address the medical community's "sharing norm," patients' autonomy, and the potential conflicts of interest raised by physician-owned patents.

Annas' and Taylor's observations do provide an effective counterpoint to McCoy's. They assert that privacy rights simply outweigh any valid patent policy in the context of medical process patents, while McCoy asserts that the underlying policies of the patent system simply outweigh any ethical concerns. Burch, perhaps seeking a compromise, proposes a mandatory licensing scheme. But such a licensing scheme does not address Annas' assertion that enforcement of patent rights will necessarily violate patients' rights to privacy. Even if licenses were granted to all interested physicians and patients, the patent holder would be obliged to monitor operating rooms to prevent others from avoiding the (mandatory) licensing fee. It appears, then, that an alternative compromise is required to strike a meaningful balance between the principles of medical ethics and the underlying policies of the patent system.

Although each author presents compelling arguments and sound reasons to examine the ethics underlying medical process patents, each assumes that medical processes raise ethical issues distinct from those raised by medical products. Quite surprising, then, is the observation that the commentators often sweep analyses of several controversial *product* patents into their analyses of the underlying ethical questions raised by medical *process* patents. It is precisely the ease with which a discussion of medical process patents can become a discussion of medical product patents that necessitates the reassessment of ethical considerations raised by medical *process* patents, *per se*. In the following part, I review the major historical developments in medical ethics and patent law that have led to the controversy that today surrounds medical process patents. By tracing these developments before discussing the various ethical issues raised by each class of medical patent claims, I hope to clarify the distinctions (valid or otherwise) that have led to the current controversy.

#### IV. HISTORICAL CONTEXT OF THE CURRENT DEBATE

Since its inception, the U.S. patent system has served one Constitutionally mandated goal: to promote science and the useful arts.<sup>105</sup> The Patent and Trademark Office (PTO), begun as the Patent

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105. U.S. CONST. art. I, § 8, cl. 8. This clause also empowers the Congress to establish a system of copyrights.

Administration under the direction of Thomas Jefferson in 1790,<sup>106</sup> has served this goal by issuing patents on worthy applications, while the federal courts have played their role by selectively enforcing or invalidating issued patents and reviewing PTO decisions.

Both the PTO and the courts, under statutes ranging from the Patent Act of 1793 (written by Jefferson) to the Revised Statutes of 1874 and the Patent Act of 1952,<sup>107</sup> have applied a "three-level" filter to distinguish inventions and discoveries worthy of patent protection from those not worthy.<sup>108</sup> To pass through the first level, the applicant must show that the claimed invention belongs among those advances that, if rewarded with a monopoly, would "promote science and the useful arts." This inquiry determines whether the application claims so-called "patentable subject matter" under 35 U.S.C. § 101 and its precursor statutes.<sup>109</sup> For example, fundamental principles, laws of nature and mathematical formulae have consistently been held not patentable subject matter because issuing monopolies for such advances might stifle scientific progress. However, mechanical devices, compositions of matter, and useful processes have, more or less consistently, been held to be patentable.<sup>110</sup>

Second, the applicant must demonstrate that the claimed invention is novel, that no one else has previously made the invention,<sup>111</sup> because rewarding a second "inventor" would not serve to promote science. Third, the applicant must show that the claimed invention is technically worthy of a patent, rather than the routine exercise of one having ordinary skill in the art. This rather ambiguous, court-made standard was long termed "the standard of invention" and was finally codified in 1952 as 35 U.S.C. § 103. It is now known as the standard of "nonobviousness."<sup>112</sup>

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106. P.J. Federico, *Operation of the Patent Act of 1790*, 18 J. PAT. OFF. SOC'Y 237 (1936).

107. The current Title 35 of the U.S. Code largely resembles the Patent Act of 1952. PTO regulations may be found at 37 C.F.R. For information regarding current organization and policies of the PTO (all provided by the PTO), see "<http://www.uspto.gov>" on the World Wide Web.

108. For a more thorough description of these three "basic" standards of patentability, see MERGES, PATENT LAW, *supra* note 1, at 36-42.

109. Prior to the Patent Act of 1952, all the requirements of patentability were codified as § 4886 of the Revised Statutes.

110. 35 U.S.C. § 101 (1988).

111. 35 U.S.C. § 102 (1988).

112. 35 U.S.C. § 103 (1988) ("Conditions for Patentability; Non-Obvious Subject Matter"). See also NONOBVIOUSNESS, *supra* note 36; Merges, *Uncertainty*, *supra* note 36 (concluding that one function of § 103 is to encourage research, the success of which was uncertain at its outset).

Atop this three-level filter, both the PTO and the courts have imposed barriers meant to serve more flexible ethical and public policy concerns. These concerns, though rarely raised today,<sup>113</sup> were often manifest as a "beneficial utility" requirement.<sup>114</sup> In several notable opinions ranging into the early twentieth century, the PTO and the courts denied applications for otherwise patentable devices because these devices (e.g., a coin-return device for a slot machine<sup>115</sup> and a random-selecting machine for distributing toys<sup>116</sup>) were potentially "injurious to the morals, health, or good order of society."<sup>117</sup> However, as the Food and Drug Administration (FDA)<sup>118</sup> and various other administrative agencies designed to safeguard the public became more influential, the roles of the PTO and of the patent law in protecting public morals and health have diminished.<sup>119</sup>

An understanding of the evolving standards of patentability is essential to resolving the current debate over medical process patents. The principal argument advanced by the AMA and other proponents of the legislation is that medical processes should not pass the first filter, because granting patents for such processes—in light of physicians' ethical duties to share their innovations—is simply not necessary to spur the progress of medical science.<sup>120</sup> So, by granting patents for such processes, the Patent and Trademark Office (PTO) is not fulfilling its Constitutional mandate to promote science and the useful arts. The other arguments against patentability, which focus

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113. In their role as courts of equity, the federal courts grant preliminary injunctions against alleged patent infringers only after considering four factors: (1) the relative rights and hardships of the parties, (2) the likelihood of ultimate success, (3) the possibility of irreparable harm, and (4) the public interest. *See, e.g.*, *Roche Prods. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984); *Datascope Corp. v. Kontron Inc.*, 786 F.2d 398 (Fed. Cir. 1986).

114. *Bedford v. Hunt*, 3 F. Cas. 37 (C.C.D. Mass. 1817). For a more general discussion, see MERGES, PATENT LAW, *supra* note 1, at 154-59.

115. *Schultz v. Holtz*, 82 F. 488 (N.D. Cal. 1897).

116. *Meyer v. Buckley Mfg. Co.*, 15 F. Supp. 640, 641 (N.D. Ill. 1936).

117. *Reliance Novelty Corp. v. Dworzek*, 80 F. 902, 904 (N.D. Cal. 1897).

118. As the proponents of S. 1334 have noted, neither the FDA nor any other government agency regulates medical procedures. *See supra* note 8 and accompanying discussion. A vast array of information regarding the FDA's history and current policies is available on the World Wide Web at "<http://www.fda.gov>".

119. *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995) (citing the PTO's "Guidelines for Examination of Applications for Compliance with the Utility Requirement," 60 Fed. Reg. 97 (1995) and holding that the PTO may not make a *prima facie* finding of lack of utility for a claimed antitumor agent under the implicit utility requirement of 35 U.S.C. § 112, ¶ 1, where the applicant provides only *in vivo* murine clinical data and disapproving PTO's actions requiring explicit evidence of efficacy in human clinical trials as an encroachment on the regulatory expertise of the FDA and an unfair burden on applicants for pharmacological inventions).

120. *Hearings, supra* note 31 (testimony of Dr. Jack A. Singer).

on ethical and conflict-of-interest norms,<sup>121</sup> though persuasive in their own right, are reminiscent of the now disfavored "beneficial utility" standard. For this reason, and because agencies other than the PTO now fulfill the role once served by the "beneficial utility" standard, these arguments against patentability should be carefully scrutinized.

The following analysis discusses the evolving standard of patentability for medical processes, the corresponding changes to the AMA's ethical code and the development of the FDA. In it, I attempt to place the current debate in context, aiding an evaluation of the various rhetorical and ethical objections to medical process patents.

While patents have been occasionally issued on medical processes since as early as 1846,<sup>122</sup> the current law of medical process patents may be traced to developments in the late nineteenth century. In an 1883 decision, *Ex parte Brinkerhoff*,<sup>123</sup> the Commissioner of the Patent Office denied an application for a patent claiming a method of treating hemorrhoids.<sup>124</sup> The Commissioner noted that although new pharmaceutical compositions had long been considered patentable, "the methods or modes of treatment of physicians of certain diseases are not patentable."<sup>125</sup> The Commissioner based this conclusion on the observation that patentable discoveries, in a majority of cases, must:

accomplish certain results, but no particular method or mode of treatment under all circumstances, and in all cases will produce upon all persons the same result, and, hence to grant a patent for a particular mode of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired and claimed result in all cases.<sup>126</sup>

In essence, the Commissioner found that medicine was neither advanced nor precise enough as a science to grant a patent in the field. The imprimatur of the PTO would unnecessarily confuse the public by suggesting that medical science was, in fact, predictable. He then held that medical processes, *per se*, were not patentable subject matter because of their inherent unpredictability.<sup>127</sup> Patents

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121. See *supra* parts II.B and II.C.

122. U.S. Patent No. 4,848 (1846) (method of using inhaled ether as anesthetic).

123. 24 Comm'r Manuscript Dec. 349 (Case No. 182, July 5, 1883), reprinted in 27 J. PAT. OFF. SOC'Y 797 (1945).

124. See I.J. Fellner, *Patentability of Therapeutic Methods*, 28 J. PAT. OFF. SOC'Y 90 (1946) [hereinafter Fellner, *Therapeutic Methods*].

125. 27 J. PAT. OFF. SOC'Y at 798.

126. *Id.*

127. *Id.*

must be reserved for only the "well-understood" arts, such as mechanics or chemistry.

At the time, such a ruling generated little controversy in the medical community. The specter of the so-called "patent medicines," typified by magical elixirs and merchants making wholly unsupported claims regarding their products,<sup>128</sup> loomed over the developing medical profession. This specter threatened to undermine the profession's status.<sup>129</sup> The medical community, in an effort to consolidate power and project a positive public image,<sup>130</sup> condemned any physician who "employ[ed] . . . the methods of charlatans," dealt in secret "nostrums," or merely offered "certificates attesting to the efficacy of secret medicines, or other substances used therapeutically."<sup>131</sup> The 1905 AMA Principles of Medical Ethics also condemned the patenting of any surgical instrument or medicine by a physician as "derogatory to the professional character."<sup>132</sup>

At the beginning of the twentieth century, the U.S. Congress twice (in 1902 and 1903) failed to enact legislation that would have made medical processes unpatentable.<sup>133</sup> However, by enacting the Federal Food & Drugs Act of 1906,<sup>134</sup> Congress did create the Food and Drug Administration (FDA).<sup>135</sup> Although the early FDA had little actual regulatory authority,<sup>136</sup> its creation signaled the eventual demise of the "beneficial utility" standard for medical patents. With the FDA's special expertise in ensuring the safety and efficacy

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128. PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 79-144, (1982) (chapter entitled "The Consolidation of Professional Authority, 1850-1930"). For specific examples of advertisements promoting "patent medicines," see A LBERT S. LYONS & R. JOSEPH PETRUCELLI, MEDICINE: AN ILLUSTRATED HISTORY 506-07, 527, (1987) (displaying at 506-07 advertisements for, among others: "Dr. C.V. Girard's Ginger Brandy"; "No-To-Bac," a cure for nicotine addition; and "Hood's Sarsaparilla"; and describing at 527 the success of "Dr. James's Fever Powder," a powder composed primarily of elemental antimony).

129. I leave it to the reader to decide whether confusion between "patent medicines" and "medical patents" still influences the debate over the patentability of innovations in the medical sciences.

130. STARR, *supra* note 128, at 88-92.

131. AMA PRINCIPLES OF MEDICAL ETHICS 12, §§ 7-8 (1905) ("Patents and Secret Nostrums").

132. *Id.* § 8.

133. Noonan, *Patenting Procedures*, *supra* note 7, at 654 (1995).

134. Federal Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768 (amended 1934). See generally "<http://www.fda.gov>" on the World Wide Web.

135. For a general discussion of the role of the FDA, see Barry S. Roberts, *Regulatory Update: The FDA Speeds Up Hope for the Desperately Ill and Dying*, 27 AM. Bus. L.J. 403 (1989).

136. For example, under the Federal Food & Drugs Act of 1906, the FDA could not test medications for safety or efficacy until they had entered interstate commerce. Such delayed testing was often too late to allow the FDA to protect consumers.

of medicines, the PTO's role as guarantor of the efficacy of patented devices and processes could be, and eventually was, limited.

Into the early twentieth century, physicians continued to pursue patent protection for their innovations, despite the pronouncement of *Ex parte Brinkerhoff*, the stated policy of the AMA, and a still-ineffectual FDA. Such patents were occasionally granted, even for medical processes. In a 1930 decision, *Dick v. Lederle Antitoxin Laboratories*,<sup>137</sup> a district court upheld patent claims for a method of diagnosing susceptibility to scarlet fever.<sup>138</sup> The Dick court noted the diagnostic method's reproducible results and its acknowledged value in the medical community as reasons to disregard, in this case, the general prohibition of medical process patents.<sup>139</sup>

The late 1930s marked the emergence of the FDA as a viable and effective regulatory agency. In response to the "Elixir of Sulfanilamide" tragedy of 1937,<sup>140</sup> Congress enacted the Food, Drug & Cosmetic Act of 1938.<sup>141</sup> This legislation empowered the FDA to require proof of safety before approving any medication for the market, and it gave the FDA authority to enforce its decisions by inspecting and regulating interstate commerce.<sup>142</sup> The growing power of the FDA was seen at the time as an effective complement to the PTO's regulatory efforts.<sup>143</sup>

Soon thereafter, in the mid-1940s, a debate over the patentability of medical processes re-emerged among patent lawyers.<sup>144</sup> While a part of this debate concerned the larger issue of

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137. 43 F.2d 628 (S.D.N.Y. 1930).

138. The patent in *Dick* is an excellent example of a medical patent claiming both a product and a process for using the product (the diagnostic method). Under the proposed legislation, H.R. 1127, all the claims in such a patent would be allowable, provided they met the requirements of patentability. *See supra* note 8.

139. *Dick*, 43 F.2d at 631.

140. Arthur H. Hayes, Jr., *Food and Drug Regulations After 75 Years*, 246 JAMA 1223, 1224 (1981) (discussing how, in 1937, a Tennessee manufacturer introduced a sulfa drug in liquid form which contained highly toxic diethylene glycol. The FDA conducted no safety tests prior to marketing, and at least 107 persons died after ingesting the drug).

141. 52 Stat. 1040 (1938) (currently codified at 21 U.S.C. §§ 301-392 (1994)).

142. 52 Stat. 1040, 1052, 1057. In 1976, the FDA was also empowered to regulate the sale of medical devices. However, the FDA still does not regulate the use of medical or surgical processes. CHIEF EXECUTIVE'S NATIONAL PERFORMANCE REVIEW OF THE FDA, Apr. 6, 1995, available at "<http://www.fda.gov/po/reinvent.html>" on the World Wide Web.

143. Sperry, *supra* note 27, at 371-72 (noting that the evils of "patent medicines" had been ably mitigated by the Pure Food & Drug Act and the PTO, as well as the medical profession's efforts to stigmatize medical patents).

144. Fellner, *Therapeutic Methods*, *supra* note 124. Four letters responding to the Fellner article were also published in the Journal of the Patent Office Society during 1946: Letter of George Benjamin, 28 J. PAT. OFF. SOC'Y 369; Letter of A.T. Sperry, 28 J.

whether processes, *per se*, should be patentable, the unique issues raised by medical processes attracted special attention. One patent attorney contended that the underlying holding of *Brinkerhoff* (that medicine was not a precise science) was untenable in the light of "modern" medical advances, and suggested that a *per se* rule against medical process patents delayed progress.<sup>145</sup> His arguments elicited responses not unlike those seen today. These responses ranged from the uncompromising—"the sphere of medical patents does *not* include medical applications . . . This is all. This principle has to be maintained."<sup>146</sup>—to the now familiar concerns for physician autonomy—"the physician should be equally free to perform any therapeutic methods which his skill and education indicate."<sup>147</sup>

Meanwhile, in *Martin v. Wyeth, Inc.*,<sup>148</sup> a district court withdrew from the holding in *Dick* by invalidating a claim for a method of treating mastitis in cows. The court proclaimed that medical process patents were contrary to the physicians' ethical code and thus contrary to the public interest, even as it invalidated the patent on other grounds. At about the same time, however, the AMA was reformulating its code of ethics to allow physicians more flexibility in applying for and receiving patents. The rather severe language of the 1905 Code was replaced, in 1940, by more ambiguous language: "It is unprofessional to receive remuneration from patents or copyrights on surgical instruments, appliances, medicines, foods, methods, or procedures. It is equally unprofessional by ownership or control of patents or copyrights either to retard or to inhibit research or to restrict the benefit of patients or the public . . ."<sup>149</sup> This revised language suggests that it was acceptable for physician-inventors to patent their inventions, but not to enforce them or receive licensing fees.

In 1952, the patent law was recodified as Title 35 of the U.S. Code and the first level of the filter of patentability was codified as 35 U.S.C. § 101 ("Patentable Subject Matter"): "Whoever invents or discovers any new and useful process, machine, manufacture, or

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PAT. OFF. SOC'Y 371; Letter of George Benjamin, at 28 J. PAT. OFF. SOC'Y 842; and Letter of L.A. Austrian, 28 J. PAT. OFF. SOC'Y 844. I.J. Fellner's response to the comments of George Benjamin was also published at 28 J. PAT. OFF. SOC'Y 678 (1946).

145. Fellner, *Therapeutic Methods*, *supra* note 124, at 106-08.

146. Austrian, *supra* note 144, at 844 (emphasis in original).

147. Sperry, *supra* note 27, at 371.

148. 96 F. Supp. 689, 695 (D. Md.) *aff'd*, 193 F.2d 58 (4th Cir. 1951).

149. AMA PRINCIPLES OF MEDICAL ETHICS 8, § 5 (1940) ("Patents and Perquisites"). For a revealing and extensive overview of university patent policies regarding medical patents during the 1930s and 1940s, see PALMER, *supra* note 27 (also providing synopsis of AMA ethical guidelines).

composition of matter, or any new and useful improvement thereof, may obtain a patent . . . ." For the first time the patent statute provided for the explicit protection of processes. In light of this new language, the PTO overruled *Brinkerhoff* only two years later in *Ex parte Scherer*,<sup>150</sup> which held that a method of jet-injecting fluids under a patient's skin was patentable. With *Scherer*, the Patent Office Board of Appeals thus formally opened the field of medical process patents. The Board effectively reversed *Brinkerhoff's* presumption that medical processes were unpredictable and hence unpatentable, noting that the new patent statute did not "categorically" define medical processes as unpatentable.<sup>151</sup>

In 1955, only one year after *Scherer*, the AMA again modified its view of the ethics of patenting medical devices. Now it would be ethical for a physician "to patent surgical instruments, appliances, and medicines, or copyright publications, methods, and procedures."<sup>152</sup> Only the uses of or profits from these patents and copyrights that would "retard or inhibit research or restrict the benefits derivable" were deemed unethical.<sup>153</sup> The AMA condoned physicians' profiting from the enforcement of patent rights, as long as these profits did not "inhibit research" or "restrict benefits."

Recent developments have led to even broader definitions of "patentable subject matter." Hailed by many as the spark that ignited the modern biomedical industry, the Supreme Court's ruling in *Diamond v. Chakrabarty*<sup>154</sup> significantly expanded the scope of patentable subject matter by dismissing a broad range of ethical arguments designed to narrow the range of patentable inventions. In *Chakrabarty*, a narrowly divided Court held a man-made bio-organism patentable and concluded that the relevant distinction under the patent law was "not between living and non-living, but between products of nature . . . and human-made inventions."<sup>155</sup> The Court dismissed the many hazards feared to accompany biomedical science, noting that whether "claims are patentable may determine whether research efforts are accelerated by hope of reward or slowed by want

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150. 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954).

151. *Id.* at 110.

152. AMA PRINCIPLES OF MEDICAL ETHICS 11-12, § 7 (1955) ("Patents and Copyrights"). For a review of the various AMA ethical standards during the 1950s, see Edgerton, *supra* note 6, at 564-67 (concluding that the medical profession generally endorses the use of the patent system as a tool for bringing inventions into general use, provided the invention is made widely available and is exploited with dignity).

153. AMA PRINCIPLES OF MEDICAL ETHICS 11-12, § 7 (1955) ("Patents and Copyrights").

154. 447 U.S. 303 (1980) (Burger, J.) (5-4 decision).

155. *Id.* at 313.

of incentive,"<sup>156</sup> but need not determine the ultimate value of the research to society. Other regulatory agencies, such as the FDA, could better determine the social and medical value of such inventions.<sup>157</sup> The Court intimated that if Congress felt a need to monitor an ethically troubling technology, it could empower an agency to oversee that technology.<sup>158</sup> The same reasoning may be at work in the current Senate bill.<sup>159</sup> That bill would apparently provide that if and when FDA authority expands to govern medical processes, medical process patents would be enforceable against physicians, patients, or other health care entities. However, as long as no federal agency is empowered to regulate the use of medical processes, medical process patents should be, by and large, unenforceable.

The creation of the Court of Appeals for the Federal Circuit (CAFC) in 1982<sup>160</sup> further signaled a strengthening of the patent grant, as it unified the appellate jurisdiction of patent disputes and judicial review of the PTO in a single federal appellate court. The CAFC recently sealed the fate of the "beneficial utility" standard for medical patents. In *In re Brana*, the court (with the PTO's blessing) yielded all authority to regulate the safety and efficacy of medical products to the FDA.<sup>161</sup> If and when the scope of federal regulatory authority expands to govern the use of medical processes, *Brana* suggests that the PTO would again yield to a sister agency.

In light of the broad construction of 35 U.S.C. § 101 now favored by the courts, the unified jurisprudence of the CAFC, and the ever-relaxing ethical standards of the AMA, it should come as no surprise that medical process patents have become quite

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156. *Id.* at 317.

157. *Id.*

158. *Id.*

159. See *supra* note 8 and accompanying text.

160. The Federal Courts Improvement Act of 1982, Pub. L. 97-164, 96 Stat. 25 (codified, in part, as 28 U.S.C. § 1295(a) (1988)) (including in the jurisdiction of the CAFC appeals from decisions of the PTO Board of Patent Appeals and Interferences and of federal district courts to which a case was directed pursuant to Title 35 of the U.S. Code (The Patent Act)).

161. 51 F.3d 1560, 1567 (Fed. Cir. 1995) (citing the PTO's "Guidelines for Examination of Applications for Compliance with the Utility Requirement," 60 Fed. Reg. 97 (1995)). See also "<http://www.fda.gov/opacom/hpcdrh.html>" (describing the FDA's Center for Devices and Radiological Health, which is responsible for ensuring the safety and effectiveness of medical devices), "<http://www.fda.gov/opacom/hpdrug.html>" (describing the FDA's Center for Drug Evaluation and Research, which regulates prescription and over-the-counter medicines for human use), and "<http://www.fda.gov/opacom/hpvet.html>" (describing the FDA's Center for Veterinary Medicine, which ensures that animal drugs and medicated feeds are safe and effective), all on the World Wide Web.

commonplace.<sup>162</sup> Nonetheless, in a June 1994 resolution, the AMA condemned physicians who would seek patents for "medical and surgical" procedures,<sup>163</sup> while it continued to tacitly approve physicians who would patent surgical or diagnostic instruments.<sup>164</sup>

In view of the medical community's continually changing views on the ethics of obtaining medical patents,<sup>165</sup> as well as the changing role of the PTO in adjudicating the social and ethical worth of patent applications, the AMA's support of the pending legislation<sup>166</sup> should raise some eyebrows at the very least. In the following part, I advance a scheme better suited to understanding the implications medical patents have for the ethical concerns of patient autonomy and privacy, as well as for physicians' potential conflicts of interest. Using this scheme as a framework, I then propose a mandatory assignment system for physician-inventors, which will address both the concerns of the medical community and the underlying policies of the patent law.

## V. A CLASSIFICATION SCHEME FOR ADDRESSING WHETHER MEDICAL PROCESSES SHOULD BE PATENTABLE

The foregoing analysis suggests that the proposed statutory distinctions between medical product claims and medical process claims may be no more than historical accident. However, the historical analysis alone does not address the possibility that serious ethical and practical differences may be reflected in the distinction between medical products and processes sought in the proposed legislation. In this part, I address the ethical and social concerns

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162. See Noonan, *Patenting Procedures*, *supra* note 7, at 658-60 (1995) (Table 1, listing 48 selected medical process patents but maintaining that such patents are not a "recent phenomenon"). See also Felsenthal, *supra* note 7, at B1; Neergaard, *supra* note 7, at A14.

163. At Supplemental Resolution 2, A-94 (§ 480.975) (1994) the AMA condemned "the patenting of medical and surgical procedures" and announced its intention to work with Congress to outlaw the patenting of such procedures.

164. AMA CODE OF MEDICAL ETHICS: CURRENT OPINIONS AND ANNOTATIONS 140, § 9.09 (1994) ("Patent for Surgical or Diagnostic Instrument"), which provides: "A physician may patent a surgical or diagnostic instrument he or she has discovered or developed. The laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery."

165. I am aware that the AMA does not represent the entire medical community. I have simply chosen the AMA as a convenient mechanism to trace the evolving views of the medical community.

166. In June of 1995, Dr. John Glasson, Chair of the AMA Council on Ethical and Judicial Affairs, presented the *AMA Report*, *supra* note 10, articulating the AMA's support for H.R. 1127 (also discussed in *AMA Criticizes*, *supra* note 10, at D5).

raised by the three broad classes of medical patents and focus on the three chief ethical concerns discussed in part III: autonomy of patients and physicians, patients' rights to privacy, and the maintenance of sound physician-patient relationships. I then conclude that while the two pending bills crudely distinguish among types of medical patents, neither resolves the ethical concerns common to the classes. Rather, a distinction based on whether or not a physician owns the patent would more effectively address the ethical concerns raised by medical patents.

### A. Medical Product Claims

The first class of patent claims, those protecting new medical products (and necessarily protecting their use in medical treatments), are typified by claims for synthetic drugs and medical devices.<sup>167</sup> Such innovations are patentable in the U.S.,<sup>168</sup> throughout Europe,<sup>169</sup> and, under the recent General Agreement on Tariffs and Trade, Agreement on Trade Related Aspects of Intellectual Property Rights (GATT-TRIPS) accord, in all World Trade Organization (WTO) countries.<sup>170</sup> It is thus accurate to say that international consensus supports the patentability of medical products.

This consensus seems odd, however, in view of the developing international controversy surrounding the patenting and marketing of pharmaceuticals.<sup>171</sup> For example, Glaxo PLC, the world's second largest pharmaceutical producer and owner of a patent for the best-selling prescription medicine Zantac, has recently seen its sales decline as entire countries,<sup>172</sup> as well as several domestic health

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167. Medical product claims are often classified by the PTO as belonging to either utility patent class 424 ("organic compounds/medical") or classes 602-604 ("Medical & Surgical Equipment").

168. 35 U.S.C. § 101 (1988) ("any new and useful process, machine, manufacture, or composition of matter" is patentable).

169. EPC Article 52(4). See *supra* note 12.

170. General Agreement on Tariffs and Trade, Agreement on Trade Related Aspects of Intellectual Property Rights (GATT-TRIPS) Article 27 ("Patentable Subject Matter") provides, in part: "[§ 1] [P]atents shall be available for any invention, whether products or processes, in all fields of technology, provided they are new, [are non-obvious] and are capable of an industrial application," subject to the provision that member states may exclude from patentability "[§ 3(a)] diagnostic, therapeutic and surgical methods for the treatment of humans or animals."

171. See, e.g., Stephen D. Moore & Elyse Tanouye, *Innovation Fails to Shield Glaxo in HMO World*, WALL ST. J., Jan. 25, 1995, at B1, B4.

172. *Id.* at B4 ("[T]he French government has refused to pay for patients' use of the [highly-touted migraine] drug, as it is still wrangling with Glaxo over a price, and health authorities in the Netherlands wrested sizable price cuts by threatening to deny coverage for its citizens.").

maintenance organizations (HMOs), have refused to purchase particular pharmaceuticals. These countries and HMOs believe the drug is overpriced and redundant of less expensive options.<sup>173</sup> While these developments may be seen as mere market corrections for overpriced goods, the fact remains that millions of patients are denied access to such new treatments by the elevated prices often attached to patented pharmaceuticals,<sup>174</sup> as well as by governmental and HMO austerity measures.

Even more severe ethical objections are raised where a patent holder exercises its right to exclude others from the market while not producing the patented medical product itself. Although every medical product claim potentially raises this concern, the courts do consider the potential public harm of enforcing an injunction in favor of such an unscrupulous patentee.<sup>175</sup> For example, in *Milwaukee v. Activated Sludge, Inc.*,<sup>176</sup> the appellate court denied an injunction against the use of a waste treatment system on the theory that enforcement would have created an irreparable harm to the local community.<sup>177</sup> The CAFC has suggested<sup>178</sup> that it will continue to deny injunctions where the patent-holder has simply failed to exploit its

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173. *Id.*, at B1, B4.

174. The patent grant gives its owner the right to prevent others from selling the patented product during the patent term. If the patentee can sell the product during that term and no noninfringing substitute is available to consumers, the patentee can elevate the price of the product without fear of direct competition in a narrowly defined market. The potential to capture such a market, in essence, creates the incentives underlying the patent system. For a more detailed analysis of these incentives, see Eisenberg, *Patents*, *supra* note 63, at 1024-30.

175. 35 U.S.C. § 283 (1988) provides that federal courts have jurisdiction to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." The CAFC has justified always considering public benefits and harms when reviewing injunctions by noting that the standards of public interest, not the requirements of private litigation, measure the need for injunctive relief, *Roche Prods. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 868 (Fed. Cir.), *cert. denied*, 469 U.S. 856, 865-66 (1984), and that "[i]f Congress wants the federal courts to issue injunctions without regard to historic equity principles, it is going to have to say so in explicit and even shameless language," *id.* at 867 (quoting *Hecht Co. v. Boules*, 321 U.S. 321, 331 (1944)). See also *Reebok Int'l v. J. Baker, Inc.*, 32 F.3d 1552, 1555 (Fed. Cir. 1994); *Chrysler Motors Corp. v. Auto Body Panels of Ohio*, 908 F.2d 951, 954 (Fed. Cir. 1990).

176. 69 F.2d 577 (7th Cir.), *cert. denied*, 293 U.S. 576 (1934).

177. *Id.* at 593.

178. In *Kearns v. Chrysler*, 32 F.3d 1541, 1551 (Fed. Cir. 1994), the court cited *Vitamin Technologists v. Wisconsin Alumni Research Foundation*, 146 F.2d 941, 944-45 (9th Cir. 1944) (denying injunction where patentee refused to license its process for producing vitamin D to those who would fortify oleomargarine and infringer used process for that purpose). The court used this citation to support the uncontroversial proposition that "the right to exclude... is not absolute even during the life of a patent, but is discretionary." *Kearns*, 32 F.3d at 1551.

patent rights,<sup>179</sup> or when an injunction would deny the public access to necessary medical products.<sup>180</sup> Nevertheless, the owner of a vital medical product patent may lawfully extract monopoly prices during the term of the patent and thus can create severe barriers to most patients' access to health care.

The enforcement of surgical device patents, covering either devices used during surgery or those left in the body of the patient, may also infringe upon patients' rights to privacy.<sup>181</sup> Where a claim protects a device, a patent owner need only "mark" the device with the U.S. patent number to assure the recovery of damages<sup>182</sup> from anyone who "uses or sells" the device without the permission of the patent owner.<sup>183</sup> In *American Medical Systems, Inc. v. Medical Engineering Corp.*, the CAFC justified this rule in the context of claims covering an implanted medical device and a method of implanting the device.<sup>184</sup> The court's ruling suggests that both physicians (by using or selling medical devices) and patients (by using medical devices) may be liable for damages, even where an implanted, hence unseen, device is used. To enforce such claims, a patentee (or, perhaps, a court) may be forced to inspect whether an appropriate "mark" was affixed to the implanted device, potentially encroaching upon patients' rights to privacy during and after surgery.

Agreements between physicians and pharmaceutical or medical device companies may also lead to severe conflicts between the financial interests of the physician and those of the patient. For example, if a physician were compensated by a patentee for

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179. E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co., 835 F.2d 277 (Fed. Cir. 1987) (denying injunction).

180. *Vitamin Technologists*, 146 F.2d at 945 (denying injunction where patentee refused to license its process for producing vitamin D to those who would fortify oleomargarine and infringer used process for that purpose).

181. Annas, *supra* note 7, at 25.

182. 35 U.S.C. § 287(a) (1988). See also *American Medical Sys. v. Medical Eng'g Corp.*, 6 F.3d 1523, 1538 (Fed. Cir. 1993), holding:

The purpose behind the marking statute is to encourage the patentee to give notice to the public of the patent. The reason that the marking statute does not apply to the method claims is that, ordinarily, where the patent claims are directed to only a method or process there is nothing to mark. Where the patent contains both apparatus and method claims, however, to the extent that there is a tangible item to mark [the patent holder must affix a mark to] avail itself of the constructive notice provisions of section 287(a).

183. 35 U.S.C. § 271(a) (1988).

184. *American Medical Sys.*, 6 F.3d at 1538-39 (holding claims for an inflatable, prosthetic penile implant and for a method for implanting the device were infringed willfully, but where no notice of a valid U.S. patent appeared on the device, district court correctly denied damages).

prescribing a patented medication, the physician would have strong financial interests potentially adverse to the interests of the patient. Only in extreme cases does medical malpractice liability provide incentives counter to the positive incentives for financial agreements between physicians and pharmaceutical companies. Where several courses of treatment are available, the potential for abuse and conflicts of interest should be self-evident. In fact, the regulation of agreements between pharmaceutical manufacturers and physicians is currently the subject of intense debate,<sup>185</sup> indicating that the more narrow concerns raised by medical product patents are real.

In light of these strong ethical and conflict-of-interest concerns, the consensus of support for medical product patents may seem odd. However, when the high costs of developing new and more effective pharmaceuticals and the strong regulatory role entrusted to the FDA are considered,<sup>186</sup> rationales for protecting medical product claims do emerge. The investments needed for research expenditures justify patent protection; and, because most product patent owners are not physicians and may be prevented from influencing physicians, situations that give rise to conflicts of interest may be avoided through appropriate regulation. These considerations soften the ethical and conflict-of-interest concerns of medical product patents, if only slightly.

## B. Medical "New Use" Claims

The second class of patent claims, those protecting new medical uses for known products, presents a distinct set of ethical dilemmas because the product is "available" but the use valued by physicians and their patents is protected by a distinct claim. This class of claims is typified by any newly discovered medical applications of a known technology,<sup>187</sup> such as the use of a laser in arterial surgery<sup>188</sup> or the use of a hair loss treatment to combat a reproductive disorder.<sup>189</sup>

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185. RODWIN, *supra* note 2, at 55-94.

186. The FDA is empowered to regulate pharmaceuticals for human or animal use, medicinal feeds for animals, and medical devices. For more information, see generally "<http://www.fda.gov>" on the World Wide Web.

187. Medical "new use" claims, like medical product claims, are often classified by the PTO as belonging to either class 424 ("organic compounds/medical") or classes 602-604 ("Medical & Surgical Equipment").

188. See U.S. Patent No. 4,862,886 (1989) ("Laser Angioplasty"). Assignee Summit Technologies owns eight patents related to the use of lasers in medical treatments. While some of these patents are, strictly speaking, medical process patents, many contain specific "new use" claims for the purposes of this analysis.

189. See U.S. Patent No. 5,336,678 (1994) ("Use of Minoxidil for Treating Erectile Impotence").

Under the House bill these claims would not be allowable unless the underlying technology, be it a device or a pharmaceutical, is independently patentable.<sup>190</sup> However, under the Senate bill these claims would be allowable and could be enforced against physicians if the "known" technology were a drug or device subject to either the Food, Drug and Cosmetics Act or the Public Health Service Act.<sup>191</sup> The House bill would effectively eliminate medical "new use" claims, while allowing owners of product patents, alone, to license *all* uses of their product, even those uses developed by others.<sup>192</sup>

This proposed elimination of medical "new use" claims is startling, because the strong ethical objections raised against medical product patents are often tempered by the existence of other patents containing "new use" claims. In the context of a "new use" patent "blocked" by an earlier product patent, *neither* patent owner may lawfully practice the invention without a license from the other. In such a situation, both patentees must compromise to bring the product to market and, often, artificially elevated prices cannot be maintained because both patentees ultimately enter the market.<sup>193</sup> Where no "new use" claims may be granted, the original patentee may forbid any use of the product and may extract monopoly prices for whatever new medical uses it, or others, develops. This perverse situation creates strong *disincentives* for the development (and disclosure) of new medical uses of a patented product by anyone other than the original patentee, since all financial benefits derived from the new use would return to the original patentee instead of being shared by both inventors.<sup>194</sup>

Despite this odd consequence, the elimination of "new use" claims does alleviate certain ethical objections, especially the objection that "new use" claims potentially inhibit physicians' autonomy. Traditionally, physicians have had broad authority to prescribe any FDA-approved pharmaceutical for any ailment, even if

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190. See H.R. 1127, *supra* note 8.

191. See S. 1334, *supra* note 8.

192. Hearings, *supra* note 31 (testimony of Dr. Frank Baldino, Jr., President and Chief Executive Office of Cephalon, Inc.). Dr. Baldino testified that "despite the voiced intention of only focusing on pure medical procedure patents, H.R. 1127 would prevent the issuance of precisely the types of patents [new use patents] which Cephalon and members of our industry must secure in order to protect our discoveries."

193. MERGES, PATENT LAW, *supra* note 1, at 182-86.

194. Admittedly, the term of the original product patent and that of the "new use" patent may overlap for only a few years. In such a situation, the "new use" would enter the public domain more rapidly under H.R. 1127 than it does under the present system, but the strong disincentives for anyone but the patentee developing a medical "new use" during the term of the product patent would still remain.

the compound is not suggested for the prescribed use. "New use" claims, if enforced, would limit a physician's ability to prescribe useful drugs as freely as the traditional principles of physician autonomy suggest.

The elimination of "new use" claims might also allay some concerns regarding physicians' conflicts of interest. Physician-inventors with patent rights for new medical uses might encourage other physicians to use or license these uses, even though cheaper or more effective treatments are available. By eliminating "new use" claims, the House bill removes this potential conflict of interest in much the same way it eliminates the potential conflicts that arise from medical product claims. However, even if the elimination of "new use" claims would allay present concerns over physicians' autonomy and potential conflicts of interest, it would do so while creating a perverse incentive against developing new medical uses for already patented products and a concurrent incentive to conceal all such developments during the term of the dominant product patent. With regard to "new use" patents, then, the Senate bill may be a viable alternative since it would retain "new use" patents and leave the vast majority of such patents enforceable.

### C. "Pure" Medical Process Claims

The third and final class of medical claims, those protecting only manipulative steps such as surgical procedures, would be unpatentable under the House bill and unenforceable under the Senate bill.<sup>195</sup> The patenting of medical and surgical techniques triggers concerns over both the "sharing norm" in the medical community and the invasion of patients' rights to privacy. However, the specter of physician-inventors enforcing their patent rights by sending investigators into operating rooms to oversee potentially infringing procedures most directly triggers concern only over patients' rights to privacy.<sup>196</sup>

The mechanics of enforcing patent rights is also important in that it blurs the distinction between the scope of patent protection available under the European Patent Convention (EPC), Article 52, and that available under the proposed legislation. The EPC makes all medical processes unpatentable, but it allows for the patenting of medical devices.<sup>197</sup> The House bill is distinguishable in that it would allow for a patent covering a medical process, provided that an

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195. S. 1334, *supra* note 8.

196. Annas, *supra* note 7, at 25-26.

197. EPC Art. 52 ("Patentable Inventions"), ¶ 4. See *supra* note 12.

independently patentable device is "necessary" to the process."<sup>198</sup> In the context of enforcement (where the real-world value of the patent right is determined), this subtle distinction becomes irrelevant. Enforcement of patent rights will rely on detection of the underlying device under either regime. Under the House bill, the process patent could not exist, and would therefore have no value, without the claim covering the "necessary" device. Thus, the narrow exception of the House bill becomes all but meaningless.

The Senate bill takes a different approach. Under it, most "pure" medical or surgical processes would be patentable but would not be enforceable. To differentiate between patents protecting "pure" processes and the two other types of medical patents, the bill relies on the limited regulatory authority of the FDA.<sup>199</sup> As noted above, the FDA has the authority to regulate medical devices and pharmaceuticals but no direct authority to regulate medical or surgical procedures. Because procedure patents (unlike the two other types of medical patents) are not the subject of federal regulation, only patents for "pure" medical procedures would be unenforceable under the Senate bill.

Nevertheless, both bills address some of the potential conflicts of interests that may arise for physicians who own patent rights for new processes. Incentives presently exist, and would still exist under the narrow exception of the House bill, for a physician-inventor to recommend to other physicians, as well as to his patients, that they practice his patented surgeries. These conflicts are especially acute because of physicians' special roles as medical advisors. Relatively free of FDA regulation when prescribing "pure" surgical or diagnostic procedures, physicians (especially surgeons) are entrusted with critical surgical decisions by many patients, even though they are also the very individuals who patent, and profit from, these recommended surgical procedures.

The Senate bill addresses this conflict by tying enforceability to the scope of FDA regulatory authority. But concerns about patients' rights to privacy and physicians' conflicts of interest would not disappear if the FDA (or another federal agency) were given the authority to regulate medical or surgical procedures. Furthermore, the Senate bill fails to address the many ethical concerns raised by physician-owned patents other than the narrow class of "pure" process patents.<sup>200</sup> The bill may also create an artificial reason to limit the

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198. H.R. 1127, *supra* note 8.

199. S. 1334, *supra* note 8.

200. See generally Noonan, *Patenting Procedures*, *supra* note 7.

scope of FDA authority so that medical process patents would be enforced. Therefore, although the Senate bill may be a superior alternative since it addresses a concern the House bill does not, it fails to identify the only truly relevant distinction among the three types of medical patents.

#### D. The Relevant Distinction: The Inventor's Identity

The foregoing analysis of the three classes of medical patent claims indicates that, from the narrow perspective of medical ethics, the classes are not distinguishable in any meaningful way. While medical "new use" and process claims may lead to conflicts of interest more difficult to regulate than those of medical product claims, medical product claims present stark ethical dilemmas by restricting physician autonomy, patient autonomy, and access to health care. Also, medical product claims, if strictly enforced, threaten patients' rights to privacy far more severely than either "new use" or process claims.

The PTO and the courts might also find it difficult to distinguish "mere" medical process claims from otherwise patentable claims under the House bill and, likewise, to determine the precise scope of FDA authority under the Senate bill. The courts that interpret the EPC (where therapeutic methods are not patentable but industrial applications are)<sup>201</sup> have struggled with this distinction. These struggles should caution against the use of rules that draw facile distinctions between "medical" innovations, which are to be freely shared, and "industrial" innovations, which might be kept secret if not for the prospect of patent protection. The European Patent Organization's Technical Board of Appeal, in *In re Bayer AG*,<sup>202</sup> was forced to decide if the addition of a particularly effective immunostimulant to poultry feed for boosting market weight was an unpatentable "method of treatment of the animal body" or a patentable process "susceptible to industrial application." The Board based its holding of unpatentability on rather opaque reasoning: (1) the medical aspects of the process were "inextricably linked to" rather than "distinct from" the cosmetic aspects,<sup>203</sup> (2) the process was "curative" rather than "prophylactic,"<sup>204</sup> and (3) increased market

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201. EPC Art. 52 ("Patentable Inventions"), ¶ 4. See *supra* note 12.

202. Decision of the Technical Board of Appeal 3.3.2, T780/89 (Aug. 12, 1991), OJ EPO 7/1993, 440. It is unclear whether H.R. 1127 includes veterinary medicine in its definition of "medical." The EPC, however, clearly treats animal and human medical processes alike.

203. *Id.* § V, ¶¶ 3.1, 3.2, 3.3.

204. *Id.* § V, ¶ 3.5.

weight was not an "industrial application" but "merely a consequence of the therapeutic treatment."<sup>205</sup> Clearly, in this and a number of other situations,<sup>206</sup> the distinctions between industrial and medical (that is, between advances which require the incentive of patent protection and those that do not) may be difficult to justify or even explain.

The logical question, then, is by what other criteria may the patents that raise ethical objections be distinguished from the patents that do not? Or, more appropriately phrased: What else about medical process claims makes them the target of the medical community and the proposed legislation? The arguments that product and "new use" inventions are often more costly to develop or are more "tangible" in a way that merits protection<sup>207</sup> are often inaccurate and hence, as *In re Bayer AG* demonstrates, difficult to rationalize.

Perhaps the distinction lies not so much in the claimed subject matter, but in the professional role of the inventor. Physicians, logically enough, are most often the inventors of medical processes and "new uses," but rarely develop new pharmaceuticals or devices.<sup>208</sup> Thus, even though they are rarely expert synthetic chemists or mechanics, physicians are in a unique position to "experiment" with novel uses for known technologies and explore new surgical and therapeutic processes. In this regard, it is interesting to note that before what may be termed the "compartmentalization" of medicine (with synthetic chemists or mechanics working alone on their inventions, far from the hospital), physician-inventors were more closely involved in the development of all medical technologies.<sup>209</sup> Perhaps, then, it is not mere coincidence that the AMA's long-forgotten prohibitions against the patenting of any medical innovation were in force during the time when physicians typically invented all types of medical patents. I suggest that as the role of physician-inventors in developing medical products disappeared, the

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205. *Id.* § V, ¶ 7.

206. See *Hearings, supra* note 31 (testimony of Dr. William D. Noonan). Dr. Noonan testified that "European patent practice allows a new use of a known drug to be patented as a 'composition for use in the treatment' of a pathological condition" in spite of the ban against patents protecting methods of treating the human or animal body.

207. In fact, proponents of the House bill have made this argument. *Hearings, supra* note 31 (testimony of Dr. H. Dunbar Hoskins, Jr. and Dr. Jack A. Singer).

208. *Hearings, supra* note 31 (testimony of Dr. Charles D. Kelman). Dr. Kelman testified that "the advancements [in medical procedures] occur through gradual, on-the-job improvements and refinements of known methods in operating rooms and physicians' offices."

209. See PALMER, *supra* note 27 (providing a thorough analysis of medical patent policies for the first three decades of the twentieth century).

prohibitions against such patents became far less severe. Now that practicing physicians rarely develop medical products on their own, objections to the patenting of medical products are rarely voiced.<sup>210</sup>

This modern reality coupled with the lack of important differences between "objectionable" and "non-objectionable" medical patents leads to the conclusion that the only relevant distinction, with respect to ethical or conflict-of-interest concerns, lies in who owns (and is therefore empowered to enforce) the patent rights. The most serious ethical objections are raised only where physician-inventors own, license and attempt to enforce their own medical patents, or where physicians have interdependent relationships with other medical patent owners.

Very often, however, physician-inventors must assign all of their patent rights to the institutions for which they work and do not play an active role in the licensing or enforcement of the patent. At university medical centers this was an accepted, if rare, practice until passage of the Bayh-Dole Act in 1980.<sup>211</sup> After that legislation allowed patents to issue for the inventions developed with the aid of federal grants, nearly all major university medical centers created technology transfer administrations.<sup>212</sup> These administrations have served a valuable role by creating incentives to pursue both basic and applied research, reducing the costs of individual licensing transactions, and fostering cooperation between academia and industry.<sup>213</sup> Unlike individual inventors, technology transfer administrations have strong incentives, both internal and external, to share medical technology. Because relatively large organizations

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210. See *supra* part V.A.

211. Pub. L. No. 96-517, 94 Stat. 3019 (1980) (codified as 35 U.S.C. §§ 200-212 (1988)) ("Chapter 18. Patent Rights in the Inventions Made with Federal Assistance").

212. GARY W. MATKIN, AMERICAN COUNCIL ON EDUCATION, TECHNOLOGY TRANSFER AND THE UNIVERSITY (1990) (*citing* Gary W. Matkin, *Technology Transfer and the American Research University* (1989) (unpublished Ph.D. dissertation, University of California (Berkeley))). See generally Reid G. Adler, *Technology Transfer, Government Research, and the Frontiers of Science: Intellectual Property Protection in the Biotechnology Industry*, 39 FED. BAR NEWS & J. 270 (1992); Brian J. Reichel, *Regulating Conflicts of Interest in the Technology Transfer Age: Promoting Public Trust Or Defeating Public Interest?*, 40 DRAKE L. REV. 385, 398-402 (1991) (summarizing the history of private, public and federal technology transfer administrations).

213. See 60 Fed. Reg. 12,771 (1995) (National Institutes of Health's (NIH) Uniform Biological Materials Agreement (UBMTA)). See also Richard Stone, . . . While NIH Unveils a Tech Transfer Treaty, 268 SCIENCE 19 (1995) (discussing the NIH-UBMTA and claiming it will speed the transfer of proprietary materials); Arthur George et al., *The Commercial Campus*, THE RECORDER (SAN FRANCISCO, CA), INTELLECTUAL PROPERTY SUPPLEMENT, Mar. 6, 1995, at 38 (discussing evolving role of university technology transfer administrations) (on file with author).

must constantly license "in" a variety of patented technologies for their own members to use, they are far less likely to refuse to license "out" any single patented technology than an independent physician-inventor with a narrow specialty would be.<sup>214</sup> Also, institutional technology transfer administrators are subject to the scrutiny of academic researchers, who may value and enforce the "sharing norm."<sup>215</sup> For these reasons, and because institutional technology transfer may be a more efficient means of recovering the costs of research and development than independent inventors licensing their own patent rights, nearly all major research centers now have some form of technology transfer administration.<sup>216</sup>

## VI. A PROPOSAL: MANDATORY ASSIGNMENT OF PHYSICIANS' PATENT RIGHTS

The central dilemmas facing independent physician-inventors, then, are that the patent system provides incentives for them to disregard the "sharing norm" of medical science and to overlook their ethical and fiduciary duties to patients. The "sharing norm" and the concerns raised by breaches of a fiduciary duty do not confront the inventors of most medical products because "sharing" is no longer a strong ethical norm in the industries most often involved with the development of pharmaceuticals or medical devices. Likewise, these inventors owe no meaningful fiduciary duty to individual patients. The enforcement of patent rights may also lead physicians to disregard their ethical obligations to preserve patients' privacy and autonomy.

The pending legislation and the current AMA Principles of Medical Ethics tacitly recognize that only non-physicians are responsible for the development of medical products, by admitting that patenting such inventions is ethical and in fact should be encouraged. In seeking to impose a "sharing norm" on *only* physician-inventors, the medical community has overreacted, attempting either to outlaw all the patents physician-inventors would typically own or to prevent the enforcement of their patent rights. In so doing, the medical community has overlooked a far less drastic alternative: entrusting the enforcement of the "sharing norm" and the associated ethical and fiduciary duties to organizations subject to the oversight of the medical community.

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214. I am not aware of any empirical evidence that supports this assertion, but I suggest the underlying logic is compelling.

215. *See supra* part II.A.

216. MATKIN, *supra* note 212. *See also* Adler, *supra* note 212, at 270.

In June of 1914, the House of Delegates of the AMA gave permission to the association's Board of Trustees "to accept, at their discretion, patents for medical and surgical instruments and appliances and to keep these patents as trustees for the benefit of the profession and the public; provided neither the [AMA] nor the patentee shall receive remuneration from these patents."<sup>217</sup> At that time few (or no) medical process patents were issued by the PTO, and the AMA strongly disapproved physician-owned patents of any kind. Nevertheless, the AMA could have held itself out as a repository for medical patents developed by concerned non-members. It appears that too few of these generous inventors stepped forward and that even fewer physicians were willing to offer evidence that they had violated the AMA's ethical code. Thus, the AMA never became the national medical patent clearinghouse the House of Delegates may have envisioned.

#### A. Patent Clearinghouses for Physician-Invented Patents

I have argued that the current debate over the patentability of medical processes and the ethical and conflict-of-interest objections raised by these patents are, by and large, merely objections to the ownership and enforcement of patents by practicing physicians.<sup>218</sup> A mandatory assignment system limited to physician-inventors, therefore, could resolve much of the current debate. Such a mandatory assignment system, in which incentives to invent coexisted with safeguards against the violation of ethical norms, can be easily envisioned.

Organizations subject to the governance of a significant portion of the medical community (much like the AMA) could manage patent clearinghouses for the rights of otherwise independent physician-inventors. To ensure that all physicians participated in a clearinghouse, each organization would have to be approved by various state medical licensing boards. Furthermore, as a requirement to licensure, every physician would be required to assign any patent rights to one of the several state-approved clearinghouses. A university-affiliated physician would have the option of assigning her patent rights to the university, if it had been approved by the state.

Certain uniform rules would apply to all of the clearinghouses. Each would be required to offer all of its rights as a package to

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217. Fishbein, *supra* note 6, at 1317 (discussing proposal of 1914). Also described in Sperry, *supra* note 27, at 372 and in PALMER, *supra* note 27.

218. See *supra* part V.D.

medical centers throughout the country. While each could employ different formulas to determine licensing rates, those rates would reflect only the size, location, or specialty of a potential licensee medical center, *not* the number of times a specific invention has been used by that hospital in the past. Meanwhile, member physician-inventors would be reimbursed on a per-use basis, and only medical records containing no identifiable information about individual patients (e.g., physicians' medical malpractice insurance records or hospitals' operating room logs) would be used to confirm the number of times a specific product or process was used. In this way, the invasions of patients' rights to privacy that most often result from enforcement of a patent could be avoided.<sup>219</sup>

However, the details of each clearinghouse's licensing and enforcement scheme could be left to the individual organizations. For example, universities likely would simply retain their present technology transfer offices, but other organizations could look to their membership to strike an appropriate balance between profits and generosity. This variety would allow each physician to select an appropriate clearinghouse for his particular needs and desires. For example, if a physician wishes to license any future invention freely, he would select an appropriate clearinghouse. If, however, he wishes to recover research costs through patent rights, he could choose a clearinghouse with an appropriate licensing structure. Thus, by modeling their activities on existing technology transfer administrations, the proposed patent clearinghouses could become players in a dynamic market.

This proposal finds support in the basic fact that the PTO, when judging the patentability of an invention, is no longer inclined or empowered to enforce society's (much less a given profession's) ethical norms.<sup>220</sup> At the administrative level, such determinations are now

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219. Comment, *Medical Process Patents and Patient Privacy Rights*, 14 J. COMPUTER. & INFO. L. 131, 147 (1995) (noting that Montana and Washington have recently enacted modified versions of the 1985 Uniform Health-Care Information Act to protect the confidentiality of medical records). See also MONT. CODE ANN. §§ 50-16-501 to 553 (1987) (Uniform Health Care Information); WASH. REV. CODE ANN. §§ 70.02.005-904 (West 1991) (Medical Records-Health Care Information Access and Disclosure).

220. Merges, *Controversial Technologies*, *supra* note 90, at 1062-68 (concluding that patent protection for a new technology "normally should not be denied on the basis of speculation about potential negative consequences" and that other agencies such as the FDA are better suited to evaluate the potential deleterious effects of new medical technologies). For a more current analysis of the appropriate roles of the PTO and FDA, see *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995) (citing the PTO's "Guidelines for Examination of Applications for Compliance with the Utility Requirement," 60 Fed. Reg. 97 (1995)).

often left to the FDA,<sup>221</sup> an agency not answerable to the medical community. The direct control exercised by the medical community over the patent clearinghouses, however, should make the proposed system far more attractive to physicians than either the present system or the proposed legislation's inelegant barriers to the patenting of "pure" medical processes. Additionally, under the proposed system the AMA would play an active role in promoting and assessing new medical technologies. Under both the present system and that of H.R. 1127, the AMA plays no such role.

At yet another level, the proposal creates an enforcement mechanism for the medical community's ethical stance on medical patents. Because boards composed of members of both the medical and research communities could determine rates of compensation for physician-inventors, a physician-inventor's licensing profits need never be so great as to "retard or inhibit research or restrict [social] benefits."<sup>222</sup> The rates at each clearinghouse could be set to strike an appropriate balance among three competing parameters: (1) physician-inventors' desire to recover costs of research and development, (2) physician-inventors' desire to profit from their inventions by extracting a portion of the savings their inventions have afforded society, and (3) the "local" community's desire to provide medical services at the lowest possible cost while still spurring inventions that lead to greater cost savings. The third factor may be seen as a means by which the patent clearinghouse could promote the development of technologies needed to serve society's most basic medical needs by encouraging the development of cost-saving technologies while discouraging the development of certain cost-intensive technologies.

Applying this three-factor rate-setting analysis to the controversial case of Dr. Samuel Pallin,<sup>223</sup> his clearinghouse might have considered: (1) that Pallin expended virtually no resources in developing his patented incision; (2) that Pallin justifiably desires to extract some of the \$17 his procedure saves each patient; and (3) that there are societal and economic values in reducing the cost of cataract surgery. Balancing these interests in a meaningful way, the clearinghouse could arrive at a reasonable fee at which to reimburse Pallin each time his operation is performed. Such a fee (set, for example, at \$1) would be multiplied by the number of times Pallin's incision is performed over the course of a year (100,000), netting Dr.

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221. *See supra* part IV.

222. AMA PRINCIPLES OF MEDICAL ETHICS, 11-12, § 7 (1955) ("Patents and Copyrights").

223. *See supra* part II.

Pallin a handsome reward (nearly \$2 million) during the term of his patent.

Of course, the proposed collection of patent clearinghouses would not resolve all of the ethical and conflict-of-interest concerns raised by medical patents. Pharmaceutical and medical device manufacturers, with justifiable interests in recovering large investments, are often forced to price the latest innovations beyond the financial reach of many patients. Likewise, physicians' conflicts of interest are only partially allayed by the proposed system. While many perverse incentives created by physician-owned patents are eliminated under the proposed system, ties between physician and other holders of medical patents will still raise considerable concerns. The proposal, nonetheless, accomplishes its goal. It reconciles the medical community's need to enforce ethical and professional norms on its members while preserving many incentives to invent and disclose new and more effective medical technologies.

### B. ASCAP as a Model for the Patent Clearinghouses

The reader may have already observed that the proposed medical patent clearinghouses closely resemble current copyright clearinghouses, such as the American Society of Composers, Authors, and Publishers (ASCAP) and Broadcast Music, Inc. (BMI). The ASCAP model,<sup>224</sup> a more appropriate model for the proposed patent clearinghouse system, offers four distinct benefits aside from allowing the medical community to enforce its own ethical and professional norms. The proposed system, if closely modeled on ASCAP, will provide for the selling of "blanket" licenses (so called because a single license covers an entire portfolio of rights) to physicians and medical centers. The cost of these licenses would be based only on a medical center's size, specialty, or location. Such a pricing structure would better protect the privacy of patients, for there would be no need to inspect licensee operating rooms for potential infringements. Just as ASCAP uses radio station play lists to calculate only correct disbursements to its members, the medical patent clearinghouses would collect anonymous operating room or laboratory reports to

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224. ASCAP represents more than 40,000 members and controls a repertoire of approximately 3 million compositions. Composers, authors and publishers who are members of ASCAP assign their copyrights to the organization in exchange for perpetual royalties, ASCAP's licensing and enforcement services, and representation in ASCAP's governance. For a brief description of ASCAP, its competitor BMI, and their respective methods of operation, see Janet L. Avery, *The Struggle Over Performing Rights To Music: BMI and ASCAP vs. Cable Television*, 14 HASTINGS COMM. & ENT. L.J. 47, 51-53 (1991).

calculate disbursements to physician-inventors. This efficient means of calculating royalties and enforcing patients' privacy rights could compensate inventors such as Dr. Pallin for the correct number of times his procedure was used, while not requiring that hospitals be secretly monitored.<sup>225</sup>

A secondary, but compelling, benefit lies in the patent clearinghouse's ability to reduce transactional costs and, in so doing, potentially reduce the cost of medical care in general. All of the individualized licensing, disbursement and enforcement costs that would discourage an otherwise capable physician-inventor from pursuing a new technology would virtually disappear under the proposed system. This physician-inventor, no longer concerned by the costs or stigma of enforcement and assured an equitable return for successful innovative efforts, could focus on developing new, less-costly medical procedures. Additionally, the removal of independent patent holders from licensing negotiations would reduce the number of "hold-outs" who refuse to license technology for a reasonable fee, while eliminating many of the costs of repetitive negotiations.

These latter two additional benefits of the ASCAP model, though more subtle, are no less important. At least part of ASCAP's appeal to its members lies in the organization's willingness to take care of the more "distasteful" business aspects of artists' lives. As far as many members are concerned, if ASCAP affords them suitable royalties while also negotiating licenses, monitoring users, and policing their rights, that is all the better. Similarly, physician-inventors, freed of the more mundane concerns of managing their patent rights, could concentrate more fully on their craft: healing the sick.

A fourth benefit of the ASCAP model is inextricably tied to the other three. One of ASCAP's principal attractions to its members is its representative form of governance. The presence of a representative board of directors, to set both fees and policy, helps guarantee equitable distribution of the proceeds of the licensing agreements while reassuring all members that they have a voice in the organization. Physician-members of the central patent clearinghouse would also benefit from such a system of governance.

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225. Of course, "spot checks" limited to verifying operating room logs might be required in exceptional circumstances. Nevertheless, an individual hospital would have no incentive to falsify its logs because the blanket licensing fee would be set independently of uses; it would be based only on the size, location, or specialty of the hospital.

## VII. CONCLUSION

The current debate over the propriety of allowing medical process patents, which has worked its way into the U.S. Congress, has provided both the medical and patent law communities an opportunity to examine their current policies. While both communities' policies may be directed toward the same goal, that of providing patients the best and most advanced care at the lowest possible cost, each community pursues distinct, often conflicting, means to that end. The patent system presents powerful incentives to invent and disclose new and useful medical technologies, but it fails to adequately address concerns regarding physicians' adherence to their own code of ethics and their respect for the fiduciary duties owed their patients. This failure indicates that a complete "sacrifice" of medical technologies to the principles underlying the patent law would be unwise.<sup>226</sup> Just as the enforcement of injunctions to enforce patent-holders' rights is always subject to the dictates of public policy,<sup>227</sup> the degree to which patent rights are vested in physician-inventors should be monitored with an eye on the concerns of medical ethics and on the avoidance of conflicts of interest. To the extent that the present patent system provides incentives for physicians to disregard their own professional code of ethics and to breach the fiduciary duties owed their patients, that system should be modified.

At the same time, the medical community values its own ethical and professional standards but disregards the long-term benefits of the patent system. By undervaluing the incentives created by medical process patents, the AMA does a disservice to physician-inventors and to society in general. By completely eliminating medical process patents, the proposed legislation would create perverse incentives for physicians to conceal their discoveries and to abandon promising, though unconventional, new treatments. The proposed legislation would introduce these harms but would address only a few of the ethical and conflict-of-interest concerns raised by medical patents.

The proposal I advance is not entirely novel,<sup>228</sup> but it does provide a viable solution to the impasse between current views in the medical community and the justifications of the patent system. It

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226. For a related analysis, suggesting that patent policy should be adapted to the special concerns raised by medical innovation, see Evan Ackiron, Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145 (1991).

227. Roche Prods. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).

228. Fishbein, *supra* note 6, at 1317. Also described in Sperry, *supra* note 27, at 372 and in PALMER, *supra* note 27.

modifies the present patent system by shifting the burden of distributing and enforcing physician-invented technologies from independent physicians to institutions better suited to that task. It also vests the power to enforce norms of medical ethics and professionalism in organizations answerable to their members, the medical community. Moreover, the proposal represents a meaningful compromise between the positions of the medical community and the strongest proponents of the patent system by placing an efficient enforcement mechanism at the disposal of the medical community. This modified enforcement structure would also safeguard the privacy concerns of patients. Thus, while the proposal does preserve many of the patent system's desirable incentives to invent, it also recognizes the role the medical community must play in enforcing the ethical norms of the profession.

