Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)

Cynthia M. Ho *

TABLE OF CONTENTS

* Assistant Professor, Loyola University of Chicago School of Law. J.D., Duke; B.A., Boston University; Registered to Practice Before the United States Patent and Trademark Office. I wish to thank John Blum, Dan Burk, Margaret Chon, Robert Danforth, Elaine Drager, Mark Janis, Christian Johnson, Susan Kuo, Roberta Rosenthall Kwall, Patrick McFadden, David Ross, A. Samuel Oddi, Neil Williams, and Alfred Yen for their suggestions on a prior draft of this Article. I am also grateful for the excellent research assistance provided by Kelly Tautges and Gretchen Prochaska. Any comments are welcome at cho@luc.edu.

INTRODUCTION

What do patents,[1] patients, and public policy have in common? Public policy goals are the foundation for both the patent and the health care systems. A fundamental policy of the patent system is to foster innovation.[2] The patent laws encourage innovation by giving patent holders[3] the right to exclude all others from using a patented invention during the term of the patent.[4] At odds with this right to exclude is a fundamental policy of the medical system to provide patients with access to medical treatment.[5]

---

[1] A patent is a type of intellectual property that functions similarly to a deed or title for other types of property. *See, e.g.*, Kearns v. General Motors Corp., 94 F.3d 1553, 1555 (Fed. Cir. 1996) (quoting Consolidated Fruit-Jar Co. v. Wright, 94 U.S. 92, 96 (1876)) (noting that "a patent for an invention is as much property as a patent for land"). Like those items, the patent confers legal rights regarding an object that is physically separate. In the case of a patent, the right conferred to the patent owner is the right to exclude all others from making, using, selling, offering to sell, or importing the patented invention in the United States for a limited period of time in exchange for full disclosure to the public of the invention such that the invention will be available for public use once the term expires. *See* 35 U.S.C. § 112 (1994); *id.* § 261 (1994), *id.* § 271 (1994 & Supp. IV 1998).

[2] Although there are various theories for justifying the patent system, fostering of innovation is often cited as fundamental. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989) (noting that Constitution and Patent Act are intended to encourage innovation); Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-81 (1974) (noting that patent laws are intended to provide incentives to invent); Paulik v. Rizkalla, 760 F.2d 1270, 1276 (Fed. Cir. 1985) (noting that purpose of patent system is "to encourage innovation and its fruits"); *see also* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (Newman, J., concurring) ("The patent law is directed to the public purposes of fostering technological progress, investment in research and development, capital formation, entrepreneurship, innovation, national strength, and international competitiveness."), *aff'd sub nom.* Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 40-41 (1997). *See generally* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024-46 (1989) [hereinafter Eisenberg, *Patents and the Progress of Science*] (discussing various theories for justifying patent system).

[3] Technically, a patentee is the inventor of the patent, but not necessarily the owner if the patentee has assigned her rights in the patent. *See* 35 U.S.C. § 152 (1994) (noting that patent may be issued to assignee of inventor); *id.* § 261 (noting that patents have "attributes of personal property" and are therefore assignable). However, this Article uses the term "patentee" interchangeably with the terms "patent owner" and "patent holder."

[4] *See, e.g., id.* § 271. However, the right to exclude others only exists for the limited duration of the patent term, which generally ends 20 years after the patent application is filed. *See id.* § 154 (1994 & Supp. IV 1998).

[5] *See, e.g.*, AMERICAN MEDICAL ASSOCIATION, CODE OF MEDICAL ETHICS: CURRENT OPINIONS xii (1992) (noting that patients have rights to adequate health care and that physicians should work toward fulfilling that goal regardless of patient's inability to pay for care). Although no health care law expressly states this policy, access to health care is a core principle of medical ethics. *See id.*

The underlying policies of these two systems — one that promotes limited access and another that promotes increased access — conflict where the systems intersect: medical procedure patents. Nonetheless, the tension between the two systems has been long dormant, in part because patent holders traditionally have not enforced their rights against doctors.[6] Recently, however, the conflict became readily apparent in a patent infringement suit[7] concerning a patented medical procedure. In 1994, Dr. Samuel Pallin sued another doctor for using his patented method of performing cataract surgery.[8] This case drew national attention because it was believed to be the first instance in which a doctor sued another doctor[9] for patent infringement.[10] Moreover, the case demonstrated

---

[6] *See, e.g.*, Sabra Chartrand, *Why Is This Surgeon Suing?*, N.Y. TIMES, June 8, 1995, at D2; Robert L. Lowes, *Are You Stealing from Other Doctors?*, MED. ECON., Mar. 11, 1996, at 195, 206-07.

[7] A patent infringement action is a civil action that may be initiated by the patent owner against someone that is using patented technology without authority in contravention of the patent owner's right to exclude all others during the term of a patent. *See* 35 U.S.C. § 271 (providing that one who "without authority makes, uses, offers to sell, or sells any patented invention within the United States, or imports into the United States any patented invention during the term of the patent thereof, infringes the patent."); *id.* § 281 (1994) (providing that patent owner "shall have remedy by civil action for infringement of his patent").

[8] *See* Chartrand, *supra* note 6, at D2; *see also* U.S. Patent No. 5,080,111 (Jan. 14, 1992) ("Method of Making Self-Sealing Episcleral Incision"). It should also be noted that the circumstances that led to Pallin's actual infringement suit may be unique. Pallin sought a patent after he failed to obtain the usual sign of professional recognition in the form of publication of his invention in a peer-reviewed journal. *See, e.g., Legislation: PTO Assails Bills to Limit Patents on Medical Procedures*, 50 BNA'S PAT. TRADEMARK & COPYRIGHT J. 731, 737 (1995); Lowes, *supra* note 6, at 206; *see also* Jeffrey I.D. Lewis, *Medical Patents: How Far Can They Go?*, HEALTH SYSTEMS REV., Sept.-Oct. 1995, at 22, 23 (noting that journal rejected his article as being of "very little importance"); Ron Stodghill, *First, Do No Harm. Then, Get a Patent*, BUS. WK., July 24, 1995, at 86 (noting that Pallin received terse rejection letter that noted his research was of "little importance"). Although the journal that initially rebuffed him did eventually publish an article by Pallin on this surgical method, Pallin still believed that he had been denied his due recognition because his publication was merely one in a slew of articles concerning the same issue and he could not duly claim to be the inventor. *See* Lowes, *supra* note 6, at 206; Samuel L. Pallin, *Chevron Sutureless Closure: A Preliminary Report*, 17 J. CATARACT & REFRACT. SURG. 706 (Supp. 1991). Moreover, the incentive to sue Singer in particular, may have arisen because Singer published an article discussing the invention Pallin believed that he invented, without citing Pallin. *See* Jack A. Singer, *Review of Incision and Closure Techniques for Cataract Surgery*, 10 OPHTHALMIC PRAC. 152 (1992). Pallin is said to believe that Singer was taking credit for his idea; litigation ensued after Singer refused to pay royalties on Pallin's patent. *See* Chartrand, *supra* note 6, at D2 (quoting Pallin as stating, "Dr. Singer has largely taken credit for my idea and I resent it.").

[9] Less notable was that the hospital where the doctor worked was also charged as a defendant. *See* Pallin v. Singer, No. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28,

that a doctor could be personally liable for patent infringement by performing a routine medical procedure without actual knowledge of a patent.[11]

Although the defendants in that suit ultimately prevailed by establishing that the patent was invalid,[12] many doctors remained concerned about the implications of medical procedure patents.[13]

1996); *see also* Mallinckrodt, Inc. v. Medipart, Inc., 976 F.2d 700, 701 (Fed. Cir. 1992) (involving infringement suit against hospital rather than doctor).

[10] *See, e.g.*, Lewis, *supra* note 8, at 24; Brian McCormick, *Just Reward or Just Plain Wrong?*, AM. MED. NEWS, Sept. 5, 1994, at 3, 32. However, more than a century ago, dentists apparently found themselves in a similar position to doctors today when they were pressured for royalties by a colleague with a patent on a dental device. *See, e.g.*, William S. Deeley, *Dentistry in the US: Struggle, Disputes, Lawsuits*, DENTAL STUDENT, Mar. 1978, at 67, 74; Malvin E. Ring, *The Rubber Denture Murder Case: The True Story of the Vulcanite Litigations*, 32 BULL. HIST. DENTISTRY 3, 5-17 (1984); *see also* William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 652-53 (1995) (describing Vulcanite denture litigations of 1860s and 1870s as one of earliest American controversies concerning patented medical procedures).

[11] *See generally* 35 U.S.C. § 271(a) (containing no intent requirement for direct patent infringement).

[12] *See Pallin*, 1996 WL 274407, at *1 (prohibiting Pallin from enforcing patent claims against "the parties, any physician, health care provider, hospital, clinic, teaching institution, or other entity or person of any kind"); Carolyn Lederman, *Pallin Patent Is Invalidated*, OPHTHALMOLOGY TIMES, June 1, 1996, at 10.

Although patents are presumed valid, medical procedure patents, as well as other patents, may have been improperly issued. *See* 35 U.S.C. § 282 (1994 & Supp. IV 1998) (providing that patent is "presumed valid" and providing that defendant can establish invalidity of patent as complete defense to infringement action); Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574 (Fed. Cir. 1992) (noting that presumption of validity is one of administrative correctness). A patent may be invalid if it fails to comply with the technical requirements of patentability. *See* 35 U.S.C. § 282 (noting that invalidity may be based on failure to comply with any condition for patentability required by §§ 101-104, 112, or 251 of Patent Act).

Though not reported in *Pallin*, the court agreed with Singer that Pallin had not been the first to invent what he patented because other doctors, including Singer himself, had preceded Pallin. *See, e.g.*, Sally Squires, *AMA Condemns Patents for Medical Procedures*, WASH. POST, June 20, 1995, at A1 (noting that Singer claims that he actually developed and published Pallin's patented procedure before Pallin did so). Because Pallin's "invention" was not new, his patent was invalid for failing to meet the statutory requirement of novelty. *See* 35 U.S.C. § 102(a) (1994); *see also infra* notes 32-36 and accompanying text (describing requirements for patentability).

[13] Although the American Medical Association ("AMA") noted that the new and nonobvious requirements for patentability should theoretically prevent "improper" patents from being issued, the AMA believed that the Patent and Trademark Office ("PTO") was not abiding by these requirements, or at least was applying them too loosely. *See* AMERICAN MEDICAL ASSOCIATION COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, ETHICAL ISSUES IN THE PATENTING OF MEDICAL PROCEDURES 59, 67-68 (Report A-95 1995) [hereinafter AMA REPORT]. Moreover, some argued that even if the PTO attempted to adhere more strictly to the statutory requirements, it would not be able to do so either because the PTO does not have access to relevant prior art, or because examiners are incompetent to examine the relevant art. *See id.*; Lowes, *supra* note 6, at 197-98. *But see Hearings on H.R. 1127 and H.R. 2419 Before the Subcomm. on Courts and Intellectual Property of the House*

Some doctors were troubled by the potential for personal liability because they perceived that medical procedure patents were becoming commonplace[14] and that there was no easy method to determine whether a procedure was patented.[15] They argued that the threat of patent liability might compromise medical treatment and result in a disincentive to share new technology.[16] These concerns prompted doctors to lobby Congress for immunity from potential liability for patent infringement.[17]

In response to the strong medical lobby,[18] Congress amended the Patent Act as part of the 1996 appropriations bill, adding section 287(c) to the Patent Act.[19] Congress passed the new law over objec-

---

Comm. on the Judiciary, 104th Cong., 1st Sess. (1995) [hereinafter *Congressional Hearings on H.R. 1127 and H.R. 2419*] (dismissing proposition by ABA representative Don Dunner). The *Pallin* litigation, however, reinforced the perception that the PTO could not distinguish new inventions. *See* AMA REPORT, *supra*, at 68.

[14] Doctors were concerned by what appeared to be an increasing number of medical procedure patents, as well as the perception that more commonplace technology was being patented — both of which would increase the probability of personal liability. *See, e.g.*, AMA REPORT, *supra* note 13, at 60; Lewis, *supra* note 8, at 24. However, there was no firm evidence of an increasing number of such patents. *See, e.g.*, Lowes, *supra* note 6, at 195-96 (alleging that "today, the Patent Office is awarding about 100 pure procedure patents each month — roughly double the number in 1985," but not providing any support for these empirical figures); McCormick, *supra* note 10, at 3 (stating that "what began as a trickle less than 20 years ago is becoming a flood, with one [unnamed] lawyer estimating that as many as 15 medical procedures are patented every week").

[15] *See, e.g.*, AMA REPORT, *supra* note 13, at 62; *see also infra* notes 141-42 and accompanying text (explaining that doctors may use older procedures because they cannot easily determine what is patented).

[16] *See* AMA REPORT, *supra* note 13, at 62-65; *see also infra* notes 103-06, 134-42 and accompanying text (discussing sharing norm among doctors and need for access to new technologies).

[17] In 1994, while the *Pallin* lawsuit was still pending, the AMA adopted a resolution "vigorously condemning" patents directed to "medical and surgical practices." AMA, House of Delegates Annual Meeting, Substitute Resolution No. 2 (1994). Furthermore, the resolution asserted that the AMA should "work with Congress to outlaw" the patenting of medical procedures. *See id.* Similarly, in July, 1995, the AMA Council on Ethical and Judicial Affairs issued an opinion in which it concluded that the patenting of medical procedures was ethically improper. *See* AMA REPORT, *supra* note 13, at 68.

[18] *See, e.g.*, Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 789, 790 (1996) (noting that broad coalition of medical groups was formed, including American Society of Cataract and Refractive Surgery and other surgical and specialty associations).

[19] *See* 35 U.S.C. § 287(c) (Supp. II 1996). Congress passed this amendment after debating and rejecting several bills that specifically dealt with medical procedures. *See* H.R. 3814, 104th Cong., 2d Sess. (1996); S. 1334, 104th Cong. § 2 (1995); H.R. 1127, 104th Cong., 1st Sess. (1995); *Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13; Public Hearing on Patent Protection for Therapeutic and Diagnostic Methods, May 2, 1996, <http://www.uspto.gov/web/offices/com/sol/notices/diaghear.txt> (on file with author) [hereinafter Public Hearing]. This Article will not reiterate the complete process of legislative proposals as these have already been extensively discussed in other

tions concerning the substance of the amendment as well as the inadequacy of congressional consideration.[20] Section 287(c) prevents patent owners from suing doctors for infringing medical procedure patents such as Pallin's.[21] This section effectively grants a royalty-free, compulsory license[22] to the most likely users of patented medical procedures — doctors.

Although the medical lobby was successful in prompting Congress to enact the immunity provision, the medical lobby failed to immunize physicians completely from patent liability.[23] In particular, although the amendment provides immunity to doctors performing a "medical activity," the definition of the critical term "medical activity" is vague and riddled with exceptions that make

---

articles. *See, e.g.*, Richard P. Burgoon, *Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. 287(c)*, 4 U. BALT. INTELL. PROP. L.J. 69 (1996); Joseph M. Reisman, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355 (1995).

[20] For example, Orrin Hatch noted:

> I express my opposition to the medical patents provision which was included in this bill. This measure was added notwithstanding the fact that there were no Senate hearings, and over the objections of myself, the chairman of the Finance Committee and the United States Trade Representative. It is an unprecedented change to our patent code . . . .

142 CONG. REC. S11,843 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch). In addition, the objection echoed similar criticism of an amendment to a prior appropriations bill which failed to pass. *See id.* at H8277 (daily ed. July 24, 1996) (statement of Rep. Moorhead) (noting that amendment is "attempt to strip the Judiciary Committee of its jurisdiction" over subject matter and for that reason alone should be rejected); *id.* at H8279 (daily ed. July 24, 1996) (statement of Rep. Schroeder) ("We have no business legislating radical changes in U.S. patent law on an appropriations bill. . . . We are not only bypassing the Judiciary Committee with this amendment, but we are also engaging in a very hasty process that does not bode well for developing good policy."); *id.* (statement of Rep. Eshoo) (noting that "this is a complicated issue that deserves greater consideration than 10 minutes of debate on an appropriations bill"); *id.* at H8278 (statement of Rep. Mollohan) (noting that appropriations bill is not appropriate forum for amending patent laws).

[21] *See* 35 U.S.C. § 287(c).

[22] Some governments, including the United States, grant individuals or government entities permission to use a patented invention without consent of the patent holder. Although patent owners often license their patents, this situation is unique in that the patent owner is forced to accept the license. Accordingly, it is referred to as a "compulsory license."

[23] *See infra* notes 183-201 and accompanying text. Doctors, however, may believe that they are now free of liability for use of patented processes in the routine course of practice. *See, e.g.*, Mark S. Hughes, *Medical Patent Bill Gives Doctors New Protections*, OPHTHALMOLOGY TIMES, Jan. 15, 1997, at 28 (noting that section 287(c) "frees physicians from procedure patent lawsuits").

the immunity very narrow.[24] The amendment, thus, fails to achieve the fundamental goal of eliminating the specter of patent infringement suits against doctors.[25]

At the same time, section 287(c) departs from the fundamental patent policy of promoting innovation by granting exclusive rights. Because the control associated with the right to exclude is critical to fostering innovation, compulsory licensing of patents is typically disfavored.[26] Section 287(c) departs from this tradition by effectively requiring holders of medical procedure patents to license their inventions at no cost. By so doing, the amendment threatens to undermine the incentive to create innovative new medical procedures.

Section 287(c) is also problematic because it establishes a precedent for creating exceptions to patent enforcement based upon a person's status. This could result in additional exceptions in response to lobbying by special interest groups. Accordingly, section 287(c) threatens the patent system's ability to promote innovation in all areas.

Moreover, because Congress passed the new law with only cursory consideration of international obligations, the United States now stands at risk of violating the international trade and intellectual property agreements that it has aggressively advocated. Section 287(c) potentially conflicts with the United States's international obligations under the World Trade Organization Agreement[27] and the related Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS").[28]

---

[24] The new amendment defines "medical activity" as:

> [T]he performance of a medical or surgical procedure on a body, ***but shall not include*** (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

35 U.S.C. § 287(c)(2)(A) (emphasis added); *see also infra* notes 165-92 and accompanying text (explaining exceptions and limitations of § 287(c)).

[25] *See infra* notes 194-201 and accompanying text.

[26] *See infra* notes 202-14 and accompanying text (discussing traditional policy of protecting right to exclude inherent in patent protection by limiting compulsory licensing).

[27] *See* World Trade Organization, *About the WTO* (visited Jan. 20, 2000) <http://www.wto.org/about/about.htm> (on file with author).

[28] *See* Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 1 (1994), 33 I.L.M. 1125 (1994); Agreement on Trade-Related Aspects of Intellectual

This Article argues that section 287(c) should be repealed because it not only failed to achieve its intended purpose, but has also endangered domestic and international policies. Although there has been some discussion of medical procedure patents from a domestic perspective, commentators have not analyzed the international impact of section 287(c).[29] This Article provides a comprehensive analysis of section 287(c)'s effects on domestic medical and patent policies from a domestic perspective, as well as its international impact.

Part I of this Article discusses patent law and the policy behind the patent system. Part II examines whether enforceable medical procedure patents create a unique conflict with the practice of medicine such that those that practice medicine should be excused from the patent laws. Part III highlights the main provisions of section 287(c), including some of its deficiencies. Part IV argues that Congress should repeal the immunity provision because it compromises the patent policy of encouraging innovation, establishes a questionable precedent for restricting patent rights in other areas, and may violate international obligations.

I. BACKGROUND

A. Patent Law and Policy

The Constitution explicitly authorizes Congress to promote the progress of science and useful arts by granting inventors the exclusive right to their discoveries for a limited time.[30] Consistent with this mandate, Congress enacted the Patent Act, which gives inventors the right to exclude all others from their patented inventions

---

Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, LEGAL INSTRUMENTS — RESULTS OF THE URUGUAY ROUND vol. 31; 33 I.L.M. 81 (1994) [hereinafter TRIPS].

[29] *See, e.g.*, Burgoon, *supra* note 19, *passim* (describing legislation leading to adoption of section 287(c) without addressing any international implications). The few articles that mention TRIPS in conjuncture with section 287(c), do so in a cursory fashion. *See, e.g.*, Mossinghoff, *supra* note 18, at 796-97 (noting that TRIPS issue has been raised and arguing that "real-world practices" would result in no violation, but providing no analysis of pertinent articles of TRIPS); Robert M. Portman, *Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress*, 4 U. BALT. INTELL. PROP. L.J. 91, 118-19 (1996) (noting that various groups have raised TRIPS issue, but have summarily dismissed it).

[30] *See* U.S. CONST. art. 1, § 8, cl. 8.

during the term of the patents[31] if they meet the Patent Act's requirements.[32] In particular, the Patent Act requires that a patentable invention (1) constitute patentable subject matter,[33] (2) satisfy the technical requirements of being new, useful, and nonobvious,[34] and (3) contain a written description that discloses the invention and enables others to practice it.[35] These requirements are designed to further the constitutional mandate of promoting innovation.[36]

The United States Supreme Court has explained that the federal patent system reflects a "carefully crafted bargain" — a social contract between the inventor and society — that encourages innovation and promotes increased knowledge in the public domain.[37] The subject matter requirement encourages innovation by protecting a broad array of subject matter.[38] Although a patent must disclose an invention that fits within at least one statutory class of subject matter, the classes are very broad and are expansively interpreted.[39]

---

[31] *See* Patent Act of 1790, 1 Stat. 109 ("An Act to Promote the Progress of Useful Arts."); *see also* EDWARD C. WALTERSCHEID, TO PROMOTE THE PROGRESS OF USEFUL ARTS: AMERICAN PATENT LAW AND ADMINISTRATION, 1798-1836, at 35-36 (1998) (noting that framers elected for system of providing exclusive rights, rather than other types of rewards known at time such as medals, titles or bounties).

[32] *See* 35 U.S.C. §§ 154, 272 (1994 & Supp. IV 1998). Exclusivity is considered essential to "stimulate ideas and the eventual development of further advances." Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 481 (1974).

[33] *See* 35 U.S.C. § 101 (1994).

[34] *See id.* (providing useful requirement); *id.* § 102 (1994) (providing novelty requirement); *id.* § 103 (1994 & Supp. IV 1998) (providing nonobvious requirement).

[35] The application that becomes a patent must disclose the invention with sufficient definiteness such that someone of like ability — usually referred to as a person of "ordinary skill in the art" — could replicate the invention by following the patent. *See id.* § 112 (1994). In addition, the application must disclose the best way of practicing the invention known to the inventor at the time the application is filed. *See id.*

[36] *See, e.g.*, Patent Act of 1790, 1 Stat. 109 ("An Act to Promote the Progress of Useful Arts") (current version in scattered sections of 35 U.S.C.); Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 146 (1989); *Kewanee Oil*, 416 U.S. at 481.

[37] *See Bonito Boats*, 489 U.S. at 149; *see also* Cover v. Hydramatic Packing Co., 83 F.2d 1390, 1392-93 (Fed. Cir. 1996) (noting that patent system is balance between providing incentives to create and commercialize without undue public costs such as inflated prices).

[38] *See* Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (noting that Congress intended statutory subject matter to "include anything under the sun that is made by man," based upon committee reports accompanying 1952 Patent Act).

[39] *See* 35 U.S.C. § 101 (stating that patentable subject matter includes any process, machine, manufacture, or composition of matter); *Chakrabarty*, 447 U.S. at 308-09. In particular, it has been noted that the "subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting 'the

The technical patentability requirements ensure the validity of this social contract by mandating that the inventor disclose something of value to society in exchange for the patent.[40] The Patent Act, thus, requires that an invention be not only new, but nonobvious.[41] The disclosure requirement ensures that the public will be informed of the invention. Further, because an issued patent is a public document, it immediately benefits the public by, for example, aiding the innovation of others that become informed of the innovation.[42] In addition, the disclosure requirement, together with the limited patent term, ensures that the invention will ultimately be in the public domain.[43]

B. Patent Law, Policy, and Medical Procedures

Allowing patents on medical procedures is consistent with the policy of encouraging innovation in all fields[44] and with the specific categories of patentable subject matter in the Patent Act.[45] Because a medical procedure constitutes a process[46] — one of the categories of patentable subject matter[47] — it is patentable. Further, that medical procedures fall within the scope of patentable subject matter is now well established.[48] Although medical procedure patents

---

Progress of Science and the useful Arts' with all that means for the social and economic benefits envisioned by Jefferson." *Id.* at 315.

[40] *See, e.g., Kewanee Oil*, 416 U.S. at 480-81. (noting that patent protection requires public disclosure by inventor).

[41] *See* 35 U.S.C. § 102 (1994); *id.* § 103 (1994 & Supp. IV 1998); *see also Bonito Boats*, 489 U.S. at 156 (noting that "both the novelty and the nonobviousness requirements of federal patent law are grounded in the notion that concepts within the public grasp, or those so obvious that they readily could be, are the tools of creation available to all").

[42] *See* 35 U.S.C. §§ 10-11, 13 (1994) (discussing availability of patents to public).

[43] *See id.* §§ 112, 251 (1994); *see also supra* note 35 (explaining disclosure requirements of § 112).

[44] *See supra* notes 37-39 and accompanying text.

[45] *See* 35 U.S.C. § 101 (1994).

[46] A patentable "process," as defined in the Patent Act constitutes a "process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *Id.* § 100 (1994).

[47] *See id.* § 101.

[48] The prohibition against medical procedure patents stemmed from the eighteenth-century patent infringement case of *Morton v. New York Eye Infirmary*. *See* 17 F. Cas. 879 (S.D.N.Y. 1862). Although *Morton* became viewed as establishing that medical procedures were unpatentable subject matter, the case did not so hold. Rather, *Morton* held that the patent on the use of ether for anesthesia to be invalid because the chemical composition of ether had been previously known. *See id.* at 882. Moreover, others have suggested that *Morton* was wrongly decided, or at least is no longer applicable in light of post-*Morton* amendments to the Patent Act, clarifying that new uses of previously known compositions could constitute a patentable process. *See* A. Samuel Oddi, *Un-Unified Economic Theories of*

were once believed to be improper based on the 1862 case of *Morton v. New York Eye Infirmary*,[49] the patentability of medical procedures has been unchallenged, until *Pallin*, because the Patent Office Board of Appeals held that medical procedures are patentable in the 1954 decision of *Ex parte Scherer*.[50] The *Scherer* court clarified that: "it cannot be categorically stated that all such methods are unpatentable subject matter merely because they involve some treatment of the human body . . . . There is nothing in the patent statute which categorically excludes such methods, nor has any general rule of exclusion been developed by decisions."[51] Although some commentators have occasionally questioned the authoritative value of this opinion,[52] neither the courts nor the Patent and Trademark Office ("PTO") have since questioned the patentability of medical procedures that satisfy the technical requirements of patentability.[53]

Patents — The Not-Quite-Holy Grail, 71 NOTRE DAME L. REV. 267, 296-97 (1996) (noting that prior to *Morton*, patents for new uses of known compounds were approved and codification of definition of "process" under 1952 Patent Act further clarified appropriateness of medical process patents).

[49] 17 F. Cas. 879 (S.D.N.Y. 1862).

[50] 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954).

[51] *Id.* at 109-10. The Board also clarified that the *Morton* decision, holding the patent on the use of ether was invalid and was based on a lack of novelty, rather than improper statutory subject matter. *See id.* at 110. Therefore, *Morton* was not a sound basis to justify the exclusion of medical procedures from patentability. *See id.*

[52] *See* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.03[3] (1998) (noting that *Scherer* is "only a decision within the Patent Office" and "cannot be taken as strong authority for the patentability of medical and surgical treatment methods generally"); Portman, *supra* note 29, at 96.

[53] *See, e.g.*, *In re* Cortright, 49 U.S.P.Q.2d 1464, 1466-69 (Fed. Cir. 1999) (discussing whether claims to method of treating baldness through use of previously known compound met written description requirement, without questioning patentability of subject matter); Shearing v. Iolab Corp., 975 F.2d 1541, 1544-47 (Fed. Cir. 1992) (addressing defendant's counterclaim to declare patent for method of inserting artificial lens into eye invalid based on prior invention, obviousness, and failure to disclose best mode, without questioning patentability of subject matter); C.R. Bard, Inc. v. Advanced Cardiovascular Sys., Inc., 911 F.2d 670, 672-75 (Fed. Cir. 1990) (finding method of using catheter in coronary angioplasty invalid based on prior art, but not questioning patentability of subject matter); *In re* Marshall, 578 F.2d 301, 304-05 (C.C.P.A. 1978) (reversing rejections based on §§ 102 and 103 without addressing statutory subject matter); *In re* Ferens, 417 F.2d 1072, 1073-74 (C.C.P.A. 1969) (affirming rejection of claims to method and composition for hair growth for lack of utility, without raising statutory subject matter as issue); Mehl/Biophile Int'l Corp. v. Milgraum, 8 F. Supp. 2d 434, 441-49 (D.N.J. 1998) (finding patent for method of hair removal invalid because invention was anticipated by prior art, without addressing whether patent was unpatentable subject matter); *Ex parte* Balzarini, 21 U.S.P.Q.2d 1892, 1898 (P.T.O. Bd. Patent App. & Interferences 1991) (holding claims to methods of treating human cells indefinite, and thus unpatentable, without addressing patentability of subject matter); Chemetron Corp. v. Airco, Inc., 198 U.S.P.Q. 119 (N.D.

II. RECONCILING PATENT POLICY WITH THE PRACTICE OF MEDICINE

Although patent protection for medical procedures fulfills fundamental patent policies, it nonetheless has been argued that medical procedures should be denied complete patent protection because innovation in medical procedures does not need encouragement.[54] In addition, it has been argued that patents, while fostering innovation, conflict with countervailing policies that are important to the medical community. It has also been argued that the sharing norm and the policy of promoting access are irreconcilable with patent protection.[55] However, despite these criticisms that patents for medical procedures distort medical policies, these policies are not so unique that a special exemption should apply to the field of medicine.

A. Patent Policy

1. Domestic

Critics of patent protection for medical procedures assert that these patents are unnecessary because innovation already occurs in absence of the patent system.[56] Notably, the American Medical

---

Ill. 1976) (finding patent for method of removing drainage from bodies of patients recovering from gastro-intestinal surgery invalid under §§ 102 and 103, without addressing whether unpatentable as medical procedure in patent infringement action); Moraine Prods., Inc. v. Block Drug Co., 318 F. Supp. 1064, 1065 (N.D. Ill. 1970) (finding simethicone patent invalid based on public sale bar, without questioning that method of treating flatulency symptoms was patentable subject matter).

[54] Complete patent protection is denied if patents are not allowed or if patents are not fully enforceable; for example, section 287(c) precludes complete patent protection by denying full enforceability of patents. *See* 35 U.S.C. § 287(c) (Supp. II 1996). Accordingly, arguments against the patenting of medical procedures are equally applicable to arguments against enforcing medical procedure patents and will be treated as such in this section. In particular, it is noted that although most of the arguments advanced by the AMA focused on patentability, they are equally applicable to whether section 287(c) is justifiable because the section may indirectly affect whether patents are obtained by substantially lessening or eliminating the incentive to obtain a patent.

[55] *See infra* notes 103-06, 127, 134-36 and accompanying text.

[56] However, even if patents are not necessary to enable the development of medical procedures, patents can nonetheless be useful for medical research because patents may provide funding for additional medical research in all areas. The financial benefits of patent protection may be of interest to doctors as a means to enhance limited research funding or operational expenses. This is particularly true as medical research has become substantially more expensive, and public funding has become increasingly scarce. *See, e.g.*, Kenneth Sutherlin Dueker, *Biobusiness on Campus: Commercialization of University-Developed Biomedical Technologies*, 52 FOOD & DRUG L.J. 453, 458 (1997); Rebecca S.

Association ("AMA") has argued that patent protection for medical procedures is unnecessary because professional rewards and norms outside the patent system already encourage inventive activity.[57] To this end, the AMA has noted the prohibition of medical procedure patents in other countries.[58] In addition, the AMA has asserted that

---

Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 196-97 (1987) [hereinafter Eisenberg, *Proprietary Rights*]. Indeed, the medical community has previously recognized the potential for patents to finance research. *See, e.g.*, Gilbert Dalldorf, *Self-Support of Medical Science Through Patents*, 235 JAMA 29 (1976); *see also* American Medical Association, Council on Ethical and Judicial Affairs, *Ethical Issues in the Patenting of Medical Procedures*, 53 FOOD & DRUG L.J. 341, 348 (1998) [hereinafter AMA, *Ethical Issues*] (admitting that "once a process is patented and licensed . . . it is possible that the royalty fees can be used to support the hospital and its investigators in further research"); Coe A. Bloomberg et al., *Patenting Medical Technology: "To Promote the Progress of Science and Useful Arts,"* 317 NEW ENG. J. MED. 565, 567 (1987) (noting that "in these times of decreasing grant allocations and reductions in federal and state medical insurance reimbursement, the income derived from a hospital's research efforts when a royalty is charged is often a welcome addition to a medical facility's budget"); Bernard D. Davis, *Profit Sharing Between Professors and the University*, 304 N. ENG. J. MED. 1232 (1981); William D. Noonan, *Patenting Medical Inventions*, PHAROS, at 6, 8 (Summer 1990).

[57] *See* AMA, *Ethical Issues*, *supra* note 56, at 349. However, the AMA's position regarding whether patents are unnecessary for innovation has vacillated throughout history. At the beginning of this century, the AMA opposed patenting of pharmaceuticals, medical devices and medical procedures. *See, e.g.*, F.E. Stewart, *Is it Ethical for Medical Men to Patent Medical Inventions?*, 29 JAMA 583, 585 (1897). Accordingly, the AMA supported legislation prohibiting not only medical procedures, but also medical apparati from patentability. *See* H.R. 12451, 57th Cong. (Mar. 12, 1902) ("prohibiting patents on any 'art' of treating human disease . . . or upon any device adapted to be used in treatment of human disease"). This opposition was founded largely on the fact that medicine was still an undeveloped science; the AMA feared that the public would improperly perceive a patent to be a stamp of government approval. *See, e.g.*, Noonan, *supra* note 56, at 7-8; *see also* William H. Edgerton, *Medical Associations and Physicians' Patent Policies*, *in* THE ENCYCLOPEDIA OF PATENT PRACTICE AND INVENTION MANAGEMENT 563 (Robert Calvert ed., 1964) (noting that origin of controversy over patenting medical inventions is commonly attributed to "patent medicine men," who sold cure-alls). Then, as medicine became more of a certain science, the AMA softened its opposition to patents. *See, e.g.*, *id.* at 564; Noonan, *supra* note 56, at 8; *see also* Joel J. Garris, *The Case for Patenting Medical Procedures*, 22 AM. J.L. & MED. 85, 95 (1996) (analogizing AMA's drive to ban medical patents to AMA's earlier view of surgical devices); William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 654-55 (1995) (discussing AMA's vacillation regarding ethics of medical patents); Reisman, *supra* note 19, at 376-85 (explaining historical context of medical patents debate).

[58] *See* AMA, *Ethical Issues*, *supra* note 56, at 349. Although the AMA's specific arguments regarding medical procedures are discussed here, it should also be noted that the argument that patents are unnecessary has been made more generally with other technologies. *See, e.g.*, ERIC SCHIFF, INDUSTRIALIZATION WITHOUT NATIONAL PATENTS 34-41, 96-106 (1971) (finding little evidence that lack of patent system hampered industrialization in comparative study of nations with and without patent systems in nineteenth and twentieth centuries); C.T. TAYLOR & Z.A. SILBERSTON, THE ECONOMIC IMPACT OF THE PATENT SYSTEM 331-50 (1973) (noting that in survey of various industries, importance of patent protection varied); *see also* William Kingston, *Patent Protection for Modern Technologies*, 1997 INTELL. PROP. Q. 350, 357-58 (citing several industry studies showing "very little" of industry research and development depends on patent

patent protection impairs traditional methods of encouraging innovation in the medical community.[59]

It has been suggested further that patent protection for medical procedures is unnecessary because they are not costly to develop.[60] This suggestion presumes that, in contrast to medical devices and pharmaceuticals, medical procedures are developed during the usual course of practice and, thus, require little investment of time and resources.[61] Medical procedure patents, the argument goes, result in a windfall to inventors that invest little but receive the financial benefit of a patent.[62]

But the presumption that medical procedures are distinct from other medical innovations in their development costs is unsupported. Although the development costs of new pharmaceuticals are well documented,[63] similar data on medical devices are not. Those who have argued that medical devices are different from, and more costly to develop than, medical procedures have cited little evidence.[64] Moreover, it may be difficult to determine

---

of industry research and development depends on patent protection). However, the results or conclusions derived from such studies have been criticized. *See, e.g.*, Eisenberg, *Patents and the Progress of Science*, *supra* note 2, at 1032-33. Moreover, the continued existence of the U.S. Patent Act, as well as enhanced patent protection world-wide through means such as TRIPS, establish that patents are nonetheless believed to confer a net benefit to society.

[59] *See infra* notes 103-06 (noting AMA's argument that patents interfere with publication process that typically serves as professional incentive to innovate).

[60] *See* AMA REPORT, *supra* note 13, at 67 (noting that development of medical procedures relies more on intellectual curiosity and creativity than capital for research and development).

[61] *See, e.g., id.* (stating that "it is reasonable to claim that this level [of incentive] would be significantly lower for procedures than it would be for devices and pharmaceuticals"); Portman, *supra* note 29, at 111 (arguing that development of new medical procedures occurs during physician's practice such that there is much less need for capital investment).

[62] *See, e.g.*, 142 CONG. REC. S12,024 (daily ed. Sept. 30, 1996) (statement of Sen. Frist) (noting that allowing fees for use of new techniques to innovative would be "windfall" to doctors because innovations would have occurred anyway); 142 CONG. REC. H8277 (daily ed. July 24, 1996) (statement of Rep. Ganske) (suggesting that medical procedure patents allow few doctors to get "windfall profits" at expense of patients).

[63] The cost of developing a single drug is notoriously high, with estimates exceeding 200 million dollars. *See* 141 CONG. REC. S15,221 (daily ed. Oct. 17, 1995) (statement of Sen. Hatch) (noting that cost usually exceeds 230 million dollars); PhRMA, *Facts About Pharmaceutical Industries* (visited Feb. 6, 2000) <http://www.phrma.org/publications/value/facts.html> (on file with author) (estimating that it takes average of 500 million dollars to discover and develop single medication).

[64] *See, e.g.*, Silvy A. Miller, *Should Patenting of Surgical Procedures and Other Medical Techniques by Physicians Be Banned?*, 36 IDEA 255, 267 (1996) (outlining arguments by opponents of medical patents that royalties are justified for patents on devices for which re-

whether medical devices are more costly to develop than medical procedures because many medical inventions involve both a medical device and a procedure for using the device, so the two categories are actually interrelated.[65]

In addition, even if the cost of creating medical procedures were less than the cost of creating new pharmaceuticals or medical devices, this would not be an adequate legal justification for denying patent protection to medical procedures. The patent laws do not distinguish between inventions that require a substantial outlay of capital investment and those that do not.[66] Moreover, the Constitu-

---

search and development costs are justified, as well as manufacturing or distribution costs); Portman, *supra* note 29, at 111. Portman asserts that although development of drugs and medical devices requires financial incentives, academic and career recognition have been sufficient for developing medical process patents. *See id.* Further, unlike devices, the development of procedures occurs during the course of a doctor's practice; therefore, there is much less need for significant capital investment. *See id.*; *see also* Beata Gocyk-Farber, Note, *Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1554 (1997) (stating that "[b]ecause of the high research and development costs of new drugs and medical devices, the rationale for drug and medical devices patents is rarely questioned"); Wendy Yang, Note, *Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion from Patentability*, 1 B.U. J. SCI. & TECH. L. 5, 26 (1995) (stating that incentives for innovation and investment in research, development and marketing are necessary for drugs and devices, but not procedures, based solely on statement of one doctor). *But see* Steven L. Nichols, Note, *Hippocrates, the Patent-Holder: The Unenforceability of Medical Procedure Patents*, 5 GEO. MASON L. REV. 227, 245 (1997) (noting that paradox exists in distinction between patentability of devices versus processes because arguments against medical procedure patents could also apply to medical device and drug patents).

[65] *See supra* note 39 and accompanying text (noting that inventions may fit within at least one statutory class of subject matter such that medical patents may claim both medical procedures and devices).

[66] The patent statute provides one uniform standard for all inventions — they must be new, useful, and nonobvious. *See* 35 U.S.C. § 101 (1994) (providing useful requirement); *id.* § 102 (1994) (providing novelty requirement); *id.* § 103 (1994 & Supp. IV 1998) (providing nonobvious requirement). These provisions do not, however, include any requirement regarding commercial expense. *See id.* §§ 101-03; *see also* Panduit Corp. v. Dennison, 810 F.2d 1561, 1573-74 (Fed. Cir. 1987) ("The law must be the same for all patents and types of inventions. A level playing ground for the marketplace of ideas is as necessary for technological innovation as it is for politics and social policy."). One could argue that patents should be linked to amount of investment. However, such an argument would apply to all inventions and not just medical procedures. Moreover, an analysis of whether the patent system should consider this is tangential to the scope of this Article. However, this idea has been suggested. *See, e.g.*, Gocyk-Farber, *supra* note 64, at 1558-61 (proposing amendment to Patent Act requiring applicants seeking to patent medical procedures to demonstrate that development of procedure would require substantial funding in research and development). *See generally* Mark D. Janis, *Second Tier Patent Protection*, 40 HARV. INT'L L.J. 151 (1999) (suggesting that patent protection be tied to innovation and proposing shorter patent term for inventions having lower levels of innovation). In addition, such distinction might create problems with international

tion — the foundation of the United States patent system — does not make the economic value of an inventor's discovery a predicate for patent protection.[67]

Although the patent system was never intended to be the sole inspiration for the creation of inventions, it may encourage and accelerate innovation in the medical procedure area. As the Supreme Court has noted, innovation will occur regardless of patent protection,[68] but patent protection is nonetheless important because it "may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives. . . ."[69] Thus, while the development of some medical procedures may not require capital funding, other medical procedures could remain underdeveloped or develop at a slower rate without the patent incentive.[70] As former PTO Commissioner Bruce Lehman noted: "[H]istorically, surgical procedures are not patented. When they are, it is usually because it is required as part of a business plan to attract the necessary capital for research and development."[71] Even the AMA has admitted that, without the patent incentive, some procedures might not become available.[72]

The best-known example of a medical procedure that could not have been developed without patent protection is Surrogate Embryo Technology ("SET"). SET is a procedure for assisted reproduction that received funding from a private company that eventually patented the process.[73] Without that financing, the necessary

---

agreements requiring that patents be issued if they satisfy the patentability requirements of being new, useful and nonobvious. *See* TRIPS, *supra* note 28, art. 27(1).

[67] *See* U.S. CONST. art. I, § 8, cl. 8 (containing no qualification to types of useful arts that are to be promoted by exclusive protection).

[68] *See* Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980) (noting that "[t]he large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides").

[69] *Id.*

[70] *See* AMA REPORT, *supra* note 13, at 65.

[71] *See, e.g., Hearings on S.507 Before the Senate Comm. on the Judiciary*, 105th Cong., 1st Reg. Sess. (1997) (statement of Bruce Lehman, PTO Commissioner). Similarly, Cedars-Sinai Medical Center noted that "products and medical processes that might otherwise have languished in the published literature have been patented and made available to the community by patent licensees." Bloomberg, *supra* note 56, at 567.

[72] *See* AMA REPORT, *supra* note 13, at 65.

[73] Carol Cancila, *First Embryo Transfer Baby Born*, AM. MED. NEWS, Feb. 17, 1984, at 3, 17; *Embryo Transfer Technique Patent Questioned by Rep. Gore*, BLUE SHEET, Aug. 22, 1984, at 4.

research that led to SET could not have been accomplished because government funding was not available, and the doctors involved in the research were reluctant to pass the cost of the research to the individual patients.[74] The development of SET illustrates the importance of patent protection in the area of medical procedures.[75] Without this protection, the pace of innovation may be slowed or altogether halted.

2. International

Critics of medical procedure patents have also argued that because other countries prohibit such patents to some degree, the United States should follow suit.[76] The practices or policies of other nations, however, are not directly applicable to United States domestic policy. Moreover, even in countries that restrict medical procedure patents, the restrictions are not as absolute as the literal exclusions suggest,[77] and the policy justifications are questionable.[78]

Although many countries restrict the patentability of medical procedures to some extent, the manner and scope of that restric-

---

[74] *See, e.g.*, George J. Annas, *Surrogate Embryo Transfer: The Perils of Patenting*, 14 HASTINGS CENTER REP. 25, 25 (1994).

[75] *See, e.g.*, AMA REPORT, *supra* note 13, at 65-67 (acknowledging that SET example demonstrates that patents can provide necessary incentive). One doctor who patented a new method of heart bypass surgery discovered that the patent enabled him to attract the attention and funding needed to explore the patented idea. *See, e.g.*, Chartrand, *supra* note 6, at D2. Although the idea ultimately was discovered to be unworkable on a large scale, the doctor did note that "the idea was only explored because . . . I patented . . . so this company felt they could expend themselves because if it were proven successful they would be able to recoup their money and make a lot more." *Id.*; *see also* Paul Tarini, *Inventive Approach May Be The Answer: Some Physicians Turn Ideas Into Patents*, AM. MED. NEWS, Oct. 6, 1989, at 13, 16 (describing one doctor whose perspective on patenting changed after he realized that royalties from one patent allow more research opportunities and also because patents are known to be more attractive to companies which are needed to bring invention to attention of medical community).

[76] *See, e.g.*, Reisman, *supra* note 19, at 360-61; *see also Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 56 (statement of Charles Kelman, President, American Society of Cataract and Refractive Surgery) (noting that over 80 countries have banned medical procedure patents); Notice of Hearings and Requests for Comments on Issues Relating to Patent Procedures For Therapeutic and Diagnostic Methods, 61 Fed. Reg. 10320, 10322-23 (Mar. 13, 1996) (noting Rep. Moorhead's statement that many industrialized countries exclude medical procedure patents). According to the AMA, medicine advanced rapidly between World War II and the late 1970s despite an alleged lack of patents for medical procedures. AMA REPORT, *supra* note 13, at 66. However, patent protection was indeed available at that time. *See supra* note 31 and accompanying text (noting that Congress enacted Patent Act in 1790).

[77] *See infra* note 96 and accompanying text.

[78] *See infra* notes 87-93 and accompanying text.

tion is far from uniform.[79] Some countries have determined medical procedures to be per se unpatentable,[80] while other countries have declared that these procedures are not inventions as a legal matter.[81] Moreover, identically worded exclusions are subject to different interpretations from nation to nation.[82]

The exclusion of medical procedures first became well established in Europe when a number of European nations signed the European Patent Convention ("E.P.C.") in 1974.[83] Article 52(4) of the E.P.C. explicitly provides that medical procedures do not have "industrial applicability,"[84] which is defined as something capable of use in any industry.[85] The E.P.C. requires that a patented invention have industrial applicability;[86] therefore, the E.P.C. excludes medical procedures from patentability based on the premise that medicine is not an industry. Both the medical exclusion and its underlying presumption that medicine is not an

---

[79] Although the statutory exception may be identically worded, courts have interpreted the exclusion differently. *See, e.g., infra* notes 95-96 and accompanying text.

[80] *See generally* German Patent Act 2(b)(2); French Patent Act 4(2); British Patent Act; Willy De Smet, *Patentability in the Area of Therapy and Diagnosis Under Belgian Law*, 22 INT'L REV. INDUS. PROP. & COPYRIGHT L. 888, 889 (1991) (noting that although Belgian law does not literally exclude medical procedures, it has de facto excluded them because it requires that invention be "susceptible of exploitation as an industrial or commercial product" and medicine is deemed not industrial or commercial).

[81] *See, e.g.*, Denmark Patent Act 1(3) (stating that "[m]ethods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall also not be regarded as inventions"); Italian Patent Act 12(4) (excluding from definition of invention "methods for surgical or therapeutical treatment of the human or animal body and diagnostical methods applied to the human or animal body"); Swedish Patent Act 1 (excluding from definition of invention "[m]ethods for surgical or therapeutic treatment or diagnostic methods, practiced on humans or animals").

[82] *See infra* notes 95-96 and accompanying text (noting inconsistent case law under E.P.C. regarding interpretation of exclusion).

[83] *See* Convention on the Grant of European Patents, Oct. 5, 1973, 13 I.L.M. 270 [hereinafter E.P.C.]. The E.P.C. is a procedural convention for obtaining patents in E.P.C. member countries with only one patent application. *See id.* art. 1. Although patents can still be obtained through a national patent office, the European Patent Office, which governs applications pursuant to the E.P.C., provides a more efficient mechanism. However, enforcement is still governed by national laws. *See id.* arts. 64(3), 138.

[84] *Id.* art. 52(4) (stating that "[m]ethods for 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").

[85] *See id.* art 57; *see also* EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, ch. IV, pt. C, ¶ 4.1 (1994) [hereinafter EPO GUIDELINES] ("An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.").

[86] *See* E.P.C., *supra* note 83, arts. 52(1), 57.

industry have been roundly criticized as being inconsistent with the realities of modern medicine.[87]

Despite this criticism, the medical procedure exclusion has become entrenched, effectively precluding legislatures of many European countries from reexamining the exclusion despite its dubious rationale.[88] Countries that are signatories to the E.P.C.[89] have amended their patent laws to be consistent with the E.P.C. without necessarily considering the implications of the exclusion.[90] But the E.P.C. provision does not necessarily reflect an independent determination by its drafters to exclude medical procedures as a matter of policy.[91]

---

[87] *See, e.g.*, Case N-116/85 (Pigs I), 1989 OFFICIAL J. EUR. PAT. OFF. 13, *reprinted in* 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 188, 191 (EPO Tech. Bd. App. 1989) (noting that "the wording of paragraph 4 [of article 52] implicitly recognizes that such methods are susceptible of industrial application as a matter of reality, but provides that they 'shall not be regarded as' inventions which are susceptible of industrial application by way of legal fiction"); *see also* Clement Payraudeau, *Recent Decisions of the EPO Technical Boards of Appeal*, 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 362, 365 (1989) (noting that distinction between medical and industrial applications is inherently subjective one that is difficult to determine).

[88] Before the enactment of the E.P.C., some countries included provisions in their patent acts to limit patenting such procedures. Although some courts questioned whether this was appropriate, they felt constrained to follow the statutory exclusion, regardless of whether the policy implications seemed justifiable. *See, e.g.*, Eli Lilly & Co.s Application, 1975 Rep. Pat., Design, & Trademark Cases 438, 438-39 (1974) (noting that "[t]he reasons for such an exclusion appear to us to be based in ethics rather than in logic but if there is to be a change in policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation"); Upjohn Co. Application, 1977 RPC 94 (1977) (noting that if law should be changed, legislature must do so).

[89] Although membership in the E.P.C. and European Union ("EU") overlaps, the E.P.C. and the EU are not identical. *Compare* European Patent Office, *EPO Member States* (visited Apr. 7, 2000) <http://www.european-patent-office.org/epo/members.htm> (on file with author) (listing countries governed under E.P.C.), *with* The European Union, *The Member States* (visited Apr. 7, 2000) <http://www.eurunion.org/states/index.htm> (on file with author) (listing European Union countries).

[90] *See, e.g.*, Alan W. White, *Patentability of Medical Treatment: Wellcome Foundation's (Hitching's) Application*, EUR. INTELL. PROP. REV., Nov. 1980, at 364 (noting that UK patent act was amended to be consistent with E.P.C. "without any consideration of the question whether it is in the national interest to grant, or not to grant, patents for this type of invention."); *see also* EPO GUIDELINES, *supra* note 85, at 42 (stating that "the intention of Art. 52(4) is only to free from restraint non-commercial and non-industrial medical and veterinary activities").

[91] Rather, this limitation was one of several E.P.C. articles based primarily on the previous Strausbourg Convention. The Strasbourg Convention, in turn, contained provisions that some members had previously adopted without evaluating policy reasons anew. *See, e.g.*, EDWARD ARMITAGE & IVOR DAVIS, PATENTS AND MORALITY IN PERSPECTIVE 16-17 (1994).

Although E.P.C. countries have adopted the medical procedure exclusion, the appropriateness of the exclusion has been questioned and limited by judicial interpretation.[92] One commentator recently stated that it is "difficult . . . to find sufficient justification for the prohibition on patenting medical methods" and thus concluded that "[f]or valid reasons legal experts have therefore repeatedly demanded that the prohibition on patenting medical methods be dropped."[93] Although the exclusion is unlikely to be eliminated entirely from the E.P.C. because of the well-known difficulties in securing the necessary consensus for any E.P.C. amendment,[94] patents for medical procedures are nonetheless granted in some instances through narrow interpretation of the exclusion.[95] However, this has yielded inconsistent decisions and unpredictability in the area of medical procedures.[96]

---

[92] *See infra* note 95 (citing cases allowing medical procedure patents through narrow interpretation of exclusion).

[93] Rainer Moufang, *Methods of Medical Treatment Under Patent Law*, 24 INT'L REV. INDUS. PROP. & COPYRIGHT L. 18, 48-49 (1993) (arguing that prohibition against patenting medical procedures is unsound and should be eliminated in E.P.C. system); *see also* Richard Apley, *Letter to the Editor Regarding: William D. Noonan, MD, JD, "Patenting Medical and Surgical Procedures," 77 JPTOS 651 (1995)*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 900, 901-02 (1995); Jochen Pagenberg, *Commentary on T 245/87 (Siemens Ag — Flow Measurements)*, 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 882 (1989) (noting that in era when WIPO is attempting to minimize subject matter restrictions on patentability, E.P.C. should at least be interpreting its exclusions restrictively, rather than broadly); White, *supra* note 90, at 367 (suggesting that appropriateness of E.P.C. provision be revisited in light of decision of New Zealand court in Wellcome Foundation that method of treating leukemia was properly patentable as method of new manufacture).

[94] In addition, section 287(c) further reduces this likelihood because those who advocated eliminating the medical procedure prohibition used to rely on United States patent laws that allowed full patentability and enforceability. *See* Moufang, *supra* note 93, at 48.

[95] T 329/94, *Blood Extraction Method*, 1998 OFFICIAL J. EUR. PAT. OFF. 241, *reprinted in* 29 INT'L REV. INDUS. PROP. & COPYRIGHT L. 694, 696-97 (1998) (finding that blood extraction method was not precluded from patentability under article 52(4) because there was no therapeutic purpose or effect where purpose was to improve "efficiency of taking blood from a donor"); T 143/94, *Trigonelline*, 1996 OFFICIAL J. EUR. PAT. OFF. 430, *reprinted in* 28 INT'L REV. INDUS. PROP. & COPYRIGHT L. 95 (1997) (finding no prohibition against patentability under article 52(4) where claim was for use of composition in production of compound even if compound would have therapeutic use); T 74/93, *Contraceptive Method/British Technology Group*, 1995 OFFICIAL J. EUR. PAT. OFF. 712, *reprinted in* 27 INT'L REV. INDUS. PROP. & COPYRIGHT L. 99, 101-102 (1996) (finding patent on method of contraception not excluded under article 52(4) because pregnancy is not illness and its prevention is not therapy).

[96] The determination of patentability often depended on narrow construction of patent claims. *See, e.g.*, T820/92, *Contraceptive Method*, 1995 OFFICIAL J. EUR. PAT. OFF. 113, 114, *reprinted in* 26 INT'L REV. INDUS. PROP. & COPYRIGHT L. 543 (1995) (finding contraceptive method unpatentable because portion of claim, although not main part, constitutes method of eliminating negative consequences, despite authority that there is

Finally, even if other nations had sound reasons for excluding medical procedures from patentability, those policies do not necessarily justify denying these patents in the United States. The United States has traditionally favored stronger patent protection than other nations.[97] In fact, the United States has often departed from international norms to serve its own domestic policies.[98] For example, in the recent TRIPS negotiations, the United States proposed that all subject matter be patentable, including medical procedures, although most other nations opposed that concept.[99] Promoting domestic policies, rather than directly applying policies of other nations, is more consistent with the United States patent policy of encouraging innovation by providing exclusive rights within the nation.

B. Medical Practice

Although patent protection may be necessary to foster innovation, a closer examination of the impact of patents on medical practice is necessary to determine whether medical procedure pat-

---

no prohibition for inventions that have both therapeutic and cosmetic purpose); T290/86, *Cleaning Plaque/ICI*, 1992 OFFICIAL J. EUR. PAT. OFF. 414, 420-21, *reprinted in* 23 INT'L REV. INDUS. PROP. & COPYRIGHT L. 815 (1991) (finding method of cleaning plaque unpatentable as method of treatment because it had curative effect, although it also had cosmetic effect, despite some authority that method with both cosmetic and therapeutic effect patentable on basis that prior case only claimed cosmetic effect, and not therapeutic effect); T144/83, *Appetite Suppressant/Du Pont*, 1986 OFFICIAL J. EUR. PAT. OFF. 301, 304, *reprinted in* 18 INT'L REV. INDUS. PROP. & COPYRIGHT L. 258 (1987) (finding product for promoting weight loss patentable despite its cosmetic and therapeutic effect). In addition, prior to *Ex parte Scherer*, a similar problem of inconsistency was found in the United States. *See, e.g., In re* Kettering, 35 U.S.P.Q. 342, 342 (Pat. Off. Bd. App. 1936) (finding process and apparatus for creating fever patentable because method of creating fever had no direct relation to curing specific disease); *Ex parte* Wappler, 26 U.S.P.Q. 191, 191 (Pat. Off. Bd. App. 1934) (reversing examiner's rejection of claim to method of shrinking living tissue by heating because claims were not directed to treatment of any specific disease).

[97] *See United States Draft Agreement on the Trade-Related Aspects of Intellectual Property Rights*, GATT Doc. MTN.GNG/NG11/W/70 (May 11, 1990) [hereinafter *United States Draft Agreement*], *reprinted in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 420, 428 (Carlos M. Correa & Abdulqawi A. Yusuf eds., 1998).

[98] *See infra* notes 328, 331 and accompanying text (describing United States efforts to promote intellectual property protection worldwide). For example, one requirement under United States patent law that does not appear likely to change in the near future is the requirement that patent application disclose an inventor's "best mode" at the time an application is filed. *Compare* 35 U.S.C. § 112 (1994) (requiring best mode be revealed), *with* TRIPS, *supra* note 28, art. 29 (suggesting, but not requiring, that best mode be included).

[99] *See United States Draft Agreement*, *supra* note 97, at 428.

ents can be reconciled with the practice of medicine. Of course, patent protection has some impact on the medical practice and its norms; however, the very nature of the patent system is a compromise between public access and exclusivity to maximize the public welfare.[100] Patents may actually have less impact on medical practice than the AMA alleges.[101] Moreover, doctors' concerns regarding medical procedures are similar to those raised by other scientists;[102] therefore, special rules, such as section 287(c), are questionable without considering the impact of patents in all fields of technology.

1. The Sharing Norm

a. The Medical Profession

The AMA has argued that because medical ethics require doctors to share information, medical procedures should not be patentable or enforceable against doctors.[103] In particular, the AMA has noted that sharing of scientific knowledge with colleagues and others is fundamental to medical ethics.[104] This sharing norm is

---

[100] *See* Part I.A (discussing policies of U.S. patent system).

[101] In addition, medical procedure patents impact other scientists because doctors are not the only ones to invent medical procedures. Although doctors would seem to be obvious inventors, research scientists can and do conceive of patentable methods; just because a research scientist may not be able to "treat" a patient does not mean the scientist could not have a patentable procedure, or work with other doctors to create a patentable procedure. *See, e.g.*, Annas, *supra* note 74, at 25 (describing research team that developed SET to include both researchers and medical doctors); Thomas C. O'Dowd & Nick Bourne, *Inventing a New Diagnostic Test for Vaginal Infection*, BRITISH MED. J., July 2, 1994, at 140 (describing medical test invented by research scientists, rather than doctors). However, scientists are not addressed separately because, as explained in this Section, the issues essentially overlap with respect to patent concerns.

[102] *See* Eisenberg, *Proprietary Rights*, *supra* note 56, at 181-84 (discussing sharing norm typical of scientists).

[103] The textual basis for this argument is derived from the AMA Principle of Medical Ethics and the AMA Code. In addition, the AMA believes that fully enforceable patents endanger the sharing of information because doctors may fail to disclose new inventions in order to secure the financial reward of a patent. This belief relies on two presumptions. First, it presumes that doctors would forgo the professional recognition inherent in publication for potential financial reward. More importantly, it presumes that if a doctor wants to obtain a patent, publication is precluded. However, publication and patenting may occur concurrently, as will be addressed in this section. Therefore, this undermines the first presumption, as well as the argument that patents reduce the sharing norm.

[104] The Principles of Medical Ethics states that: "A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public . . . ." American Medical Association, PRINCIPLES OF MEDICAL ETHICS (1996).

considered critical for the dissemination of new improvements and the resulting enhancement of patient care.[105] Patents are said to encourage violations of medical ethics because the Medical Ethics Code ("Medical Code") prohibits withholding knowledge "for reasons of personal gain."[106]

A patent, however, does not necessarily result in a personal gain that violates the Medical Code. First, the Medical Code does not condemn personal gain per se.[107] Rather, the Medical Code criticizes personal gain only if it compromises the dissemination of knowledge.[108] Even though the patent system provides the opportunity for financial benefit,[109] the patent system shares the same goal as the Medical Code in promoting knowledge dissemination.[110] Patents, by statute, must sufficiently describe the invention to en-

---

[105] The Code of Medical Ethics states that:

> Physicians have an obligation to share . . . knowledge and skills and to report the results of clinical and laboratory research . . . . This tradition enhances patient care, leads to early evaluation of new technologies, and permits the rapid dissemination of improved techniques. The intentional withholding of new medical knowledge, skills and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.

New Medical Procedures, AMA Code of Medical Ethics § 9.08 (1998) [hereinafter AMA Code].

[106] AMA REPORT, *supra* note 13, at 61.

[107] AMA Code, *supra* note 105, § 9.08 (providing that "intentional withholding of new medical knowledge . . . for reasons of personal gain . . . is to be condemned" but not condemning all types of personal gain).

[108] *See id.*

[109] While the patent system provides an opportunity for personal gain, there is no requirement that a patentee use a patent for personal gain. In fact, patentees of medical inventions have been known to dedicate their patents to the public, or use licensing fees to further additional medical research. For example, Cedars-Sinai has granted royalty-free licenses to the American Red Cross for a method to inactivate acquired immunodeficiency syndrome viruses in factor VIII concentrate. *See* Bloomberg, *supra* note 56, at 567; *see also* Dueker, *supra* note 56, at 486 (citing Harvard Licensing Report FY 1977-87 as showing that Harvard has maintained policy of dedicating patents in area of medical therapeutics to public). In addition, while the AMA assumes that patenting will result in personal gain, the AMA seems to discount the fact that doctors can economically benefit from their inventions exclusive of the patent system. *See, e.g.*, Robert Rosenberg & Bruce L. Gewertz, *Issues and Debate: The Usefulness of Medical Patents for Surgical Procedures*, 10 ANNALS OF VASCULAR SURGERY 1, 3 (1996) (noting that "some surgeons offer their techniques on confidential basis as part of exclusive and expensive seminars or promote proprietary clinics where specially trained surgeons provide advanced care for those willing to pay for 'the best'").

[110] *See supra* notes 30-39 and accompanying text (discussing patent policies of encouraging innovations).

able others to replicate the invention without undue experimentation.[111]

In a related context, the Medical Code recognizes that patents are not inconsistent with the sharing norm by explicitly authorizing doctors to patent medical devices.[112] The Medical Code states that: "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."[113] In addition, no one, including those that object to medical procedure patents, disputes whether medical devices are proper subject matter for patents.[114]

b. Other Professions

The argument that patents on medical procedures negatively affect the sharing norm is not unique to the medical profession. Traditionally, all scientists and physicians share the results of their research.[115] This sharing primarily occurs in peer-reviewed journals. In the past, scientists argued that the sharing norm would be eroded by patent protection.[116]

---

[111] *See* 35 U.S.C. § 112 (1994); *see also* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) (noting that use of invention must be sufficiently disclosed such that "undue experimentation" is not required).

[112] *See* AMA Code, *supra* note 105, § 9.09.

[113] *Id.* Notably, whether a medical device is developed during the routine course of medical practice is not raised as an issue.

[114] *See supra* notes 50-53 and accompanying text (noting that patentability of medical devices has been unquestioned since *Ex parte Scherer* decision in 1954).

[115] *See, e.g.*, Eisenberg, *Proprietary Rights*, *supra* note 56, at 183-84 (describing sharing norm within scientific community).

[116] For example, prior to Congressional action that encouraged universities to patent inventions, there was a widespread belief among scientists that patents would preclude traditional sharing of information via peer-reviewed publications. *See, e.g.*, *Franklin Pierce Law Center's Sixth Biennial Patent System Major Problems Conference*, 37 IDEA 623, 637 (1997) [hereinafter *Franklin Pierce Debates*] (quoting Norman Balmer, chief patent counsel of Union Carbide Corporation, who argued that AMA position is analogous to that of university professors in 60s and 70s who opposed patents, but that this opposition has since died down); Eisenberg, *Proprietary Rights*, *supra* note 56, at 181-82, 195-97 (noting that prior to commercialization of biotechnology, universities were averse to patenting discoveries); *see also* GARY W. MATKIN, TECHNOLOGY TRANSFER AND THE UNIVERSITY 56-76 (1990) (describing history of patent policy at universities). The prior perception about the perils of patenting is less prevalent, although it has not entirely been eliminated. *See, e.g.*, Dueker, *supra* note 56, at 465 (quoting HARVARD UNIVERSITY, RESEARCH, DISCOVERY AND THE REWARD OF INVENTION (1995)) (noting number of misperceptions including one that patenting "creates an atmosphere of secrecy"); Ronald Kotulak, *Taking License with Your Genes; Biotech Firms Say They Need Protection*, CHI. TRIB., Sept. 12, 1999, at 1 (noting that

Outside of the medical field, however, patents have become commonplace alongside publications in peer-reviewed journals. Many universities and companies today have in-house patent counsel and licensing departments, as well as uniform procedures for patenting inventions and providing incentives to inventors.[117] In addition, and although still somewhat controversial in the scientific community, patent protection of basic technology has not completely eroded the sharing norm or hindered research.[118]

Patenting and publication, in fact, may coexist. Inventors may patent an invention and publish an article regarding the same invention. The United States patent laws do not require that an invention never be available in another forum, such as a journal, although they do deny patents to inventors that unduly delay filing of a patent application after publication.[119]

---

there is concern that patents on genes and gene sequences will unduly restrict access to genetic information).

[117] *See, e.g.*, MATKIN, *supra* note 116, at 81-99 (describing in-depth patent policies at four major universities, including Penn State, which provides 1000 dollar bonus to scientists that provide patentable invention); Dueker, *supra* note 56, at 464 (noting that enactment of Bayh-Dole Act spurred creation of university technology transfer offices).

[118] For example, the Cohen-Boyer patent, one of the early patents in the area of biotechnology is routinely used by all who deal in the area of biotechnology because it relates to basic gene-splicing and cloning techniques. *See* U.S. Patent No. 4,237,224 (Dec. 2, 1980) ("Process for Producing Biologically Functional Molecular Chimeras"); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1710 (1996) [hereinafter Eisenberg, *Public Research and Private Development*] (stating that "[t]he Cohen-Boyer patents have been widely licensed to biotechnology firms and pharmaceutical firms"). Accordingly, many biotechnology companies had to pay royalty fees, under terms that were not onerous and permitted continued sharing of research. *See, e.g.*, Eisenberg, *Public Research and Private Development*, *supra*, at 1710; *see also* Robert M. Cook-Deegan, *Origins of the Human Genome Project*, 5 RISK: HEALTH SAFETY & ENV'T 97, 117 (1994) (noting that Cohen-Boyer patent covered central technique of molecular biology, but was licensed at relatively low fees). In fact, companies developed other new technologies and flourished despite the royalty payments. *See* Eisenberg, *Public Research and Private* Development, *supra*, at 1710 (noting that licensing was "on terms that have been set low enough that they have generated few complaints from industry and have probably not created significant impediment to commercial development"). However, whether this model is the exception rather than the rule and whether it continues to be viable is the subject of some debate. *See, e.g.*, Rebecca S. Eisenberg, *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, 5 RISK: HEALTH SAFETY & ENV'T 163 (1994) [hereinafter Eisenberg, *Technology Transfer*]; Arti Rai, *Regulating Scientific Research*, 94 NW. U. L. REV. 77 (1999).

[119] *See* 35 U.S.C. § 102(b) (1994) (providing grace period of up to one year after publication to file patent application). However, it should be noted that the United States is more lenient in this respect than other nations. *See, e.g.*, E.P.C., *supra* note 83, arts. 54-55, 158; *see also* IAN MUIR ET AL., EUROPEAN PATENT LAW: LAW & PROCEDURE UNDER THE E.P.C. AND P.C.T. 152-62 (1999) (discussing novelty requirement). Nonetheless, it has been questioned whether there may be an incentive to withhold research results until a

Although publication may not negatively affect patent protection, patents are perceived to compromise the sharing norms inherent in publication. For example, some fear that dissemination of information may be delayed because drafting and filing a patent application may take a significant amount of time.[120] However, a potential publication delay does not eviscerate the sharing norm. In fact, one recent study found that only a minority of researchers thought that patent applications unduly delayed the normal publication process and concluded that any delay was insignificant.[121] Thus, an inventor can obtain a patent while achieving professional recognition through journal publication.[122]

In addition, patent protection actually promotes the sharing of information by providing another avenue of information dissemination where publication is not possible.[123] Under the Patent Act, the PTO must issue patents if the application meets the technical requirements of patentability.[124] In contrast, publications have page limits and other editorial considerations that may limit the

---

patent has been granted. *See* Eisenberg *Proprietary Rights*, *supra* note 56, at 216-17 (noting that applicants may still be disinclined to publish in event that patent is denied).

[120] *See* AMA REPORT, *supra* note 13, at 64.

[121] *See generally* David Blumenthal et al., *Withholding Research Results in Academic Life Science: Evidence From a National Survey of Faculty*, 277 JAMA 1224 (1997) (finding that about 20% of researchers reported that publication of their results had been delayed by more than 6 months because of patent issues, but concluding that there is no general problem with delayed publication due to patenting).

[122] Theodore Cooper & Joseph E. Galligan, *The Anomaly as a Necessity: Academic-industrial Collaboration in Research*, 1 INT'L J. CARDIOLOGY, 449, 450-51 (1982). *But see Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 46 (statement of Dr. Jack Singer) (asserting that "free exchange of medical and surgical methods cannot coexist with the monopoly-dependent exchange of the patent system," because of different values and incentives, but providing no empirical support); Eisenberg, *Proprietary Rights*, *supra* note 56, at 216-17 (noting risk to secrecy protection involved in publishing prior to receipt of patent).

[123] *See* McCormick, *supra* note 10, at 32 (suggesting that in some cases information can only be disseminated through patent, such as when scientists are denied traditional publication); *supra* note 8 and accompanying text (describing this very situation for Dr. Pallin); *see also* Lee Bowman, *Physicians Stake Claims to their Art of Healing*, S.F. EXAMINER, July 16, 1995, at B1, B7 (asserting that there are "numerous reports of information and papers withheld due to disputes over credit or fears of helping a research competitor at a crucial moment").

[124] *See generally* 35 U.S.C. § 102 (1994) (stating that "[a] person *shall* be entitled to a patent" unless technical patentability requirements are not met) (emphasis added). The one exception to this provision is if issuance of a patent on an invention threatens national security. *See id.* § 181 (1994). However, even in this case, the statute presumes that a patent will eventually issue. *See id.* (describing procedure that must be followed in ordering secrecy of invention: PTO may only withhold grant for designated one year period, and additional extensions must be approved).

number and type of articles they publish.[125] For example, the *Journal of the American Medical Association*, a well-respected peer-reviewed journal in the medical community, reports that it only publishes about ten percent of unsolicited manuscripts.[126]

2. Peer Review

Even if patents do not preclude publication, some argue, they may effectively prohibit publication because of the potential for liability. In particular, there is a concern that peer reviewers will not review articles on patented medical procedures for fear of being sued for patent infringement.[127] Peer review is particularly important for medical procedures because there is no governmental agency that monitors their safety and effectiveness.[128]

But patents are unlikely to preclude peer review. Because the patent application process is lengthy,[129] peer review is likely to occur before a patent issues, provided that the patent and the corollary article are submitted simultaneously. A patentee does not have

---

[125] *See, e.g., Information for Contributors*, SCI. MAG. (visited Apr. 29, 2000) <http//www.sciencemag.org/misc/con-info.shtml> (on file with author). *Science Magazine*, a peer-reviewed journal, notes that not only are manuscripts evaluated for "technical merit," but also that an attempt is made to "balance subject matter" of a particular issue. *See id.*; *see also Information for Authors*, J. CATARACT & REFRACTIVE SURGERY (visited Jan. 25, 2000) <http://www.ascrs.org/publications/jcrs/auth-info.html> (on file with author) (stating criteria as suitability of subject matter, "originality" of content, and timeliness); *Getting Published in* Nature, NATURE (visted Jan. 25, 2000) <http://www.nature.com/author/htgpin.html> (on file with author) [hereinafter *Nature* Publication Guidelines] (noting that one of requirements was "interest to an interdisciplinary readership" as well as originality and outstanding scientific importance).

[126] *See Authors Instructions*, JAMA (visited Jan. 25, 2000) <http://www.jama.ama-assn.org/info/auinst.html> (on file with author); *see also Nature* Publication Guidelines, *supra* note 125 (noting that only 10% of submitted papers are published).

[127] *See, e.g.*, AMA REPORT, *supra* note 13, at 63 (noting that patents restrict peer review because study of patented procedures may require payment of licensing fees); *Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 58-59 (statement of Dr. Charles Kelman); Annas, *supra* note 74, at 25.

[128] *See, e.g.*, AMA REPORT, *supra* note 13, at 63 (stating that peer review acts as "primary regulatory mechanism for medical processes"). The FDA is empowered to regulate pharmaceuticals for human or animal use, as well as medical devices. *See* Federal Food, Drug & Cosmetic Act, 21 U.S.C. §§ 321(d), (g), (h), 351-60, 371(a) (1994 & Supp. IV 1998); 21 C.F.R. § 510(a)(1) (1998) (delegating functions vested in Secretary for Health by FFDCA to Commissioner of FDA).

[129] The PTO typically takes 18 months to review a patent application and generally takes considerably longer for more complex technologies. *See, e.g.*, AMA REPORT, *supra* note 13, at 64 (noting that patent process often takes years to complete).

the right to exclude others until the patent issues;[150] thus, while a patent application is pending, peer review can occur without concern for infringement.[151]

Further, peer review is common in other scientific fields despite the existence of patents. The preservation of peer review, therefore, is possible with measures less drastic than a blanket immunity provision. In addition, an exception from patent infringement for peer review could extend from the generally recognized, but presently limited exception for experimental use.[152] In any case, patent protection no more affects medical procedures than it does any discipline that encourages peer review.[153]

3. Access to Medical Care

The strongest argument for special treatment of medical procedure patents is that fully enforceable patents could limit access to necessary medical treatment.[154] Doctors have asserted that medical

---

[150] *See* 35 U.S.C. § 271 (1994 & Supp. IV 1998); *see also* Cohen v. United States, 487 F.2d 525, 527 (Ct. Cl. 1973) (noting that "there can be no infringement of a patent prior to its issuance"). Moreover, the inventor may never have a right to exclude others if the PTO determines that the invention is not patentable.

[151] The foregoing arguments presume that a doctor would desire to publish the new procedure in a peer-reviewed journal. As noted, patent protection does not foreclose that option; however, a doctor may forgo publication and attempt to keep the method as a trade secret to maintain exclusivity without utilizing the patent system. *See* AMA REPORT, *supra* note 13, at 66 (reporting precedent for keeping medical inventions as trade secrets); *see also* HAROLD SPEERT, OBSTETRICS AND GYNECOLOGY: A HISTORY & ICONOGRAPHY 270-72 (1994) (discussing refusal of several generations of Chamberlen family to reveal discovery of obstetrics forceps). Concealing an invention harms the public interest more than patent protection because a patent at least informs the public of the invention; further, the information discussed in a patent automatically becomes part of the public domain once the patent term expires. *See* 35 U.S.C. § 112 (1994); *id.* § 154 (1994 & Supp. IV 1998); Davis, *supra* note 56, at 1233 (noting that "secrecy is widespread in highly competitive fields of even the purest research" and that in long run, patents actually reduce need for secrecy); Eisenberg, *Proprietary Rights*, *supra* note 56, at 185, 194-95 (noting that patents are preferable to alternatives of trade secrecy or actual secrecy).

[152] *See* AMA REPORT, *supra* note 13, at 63; Timothy J. McCoy, *Biomedical Process Patents: Should They Be Restricted by Ethical Limitations?*, 13 J. LEGAL MED. 501, 513 (1991) (proposing experimental use doctrine as a way to allow investigational uses of patented technology to accommodate peer review); Public Hearing, *supra* note 19 (including debate over use of experimental use doctrine).

[153] *See, e.g.*, Eisenberg, *Proprietary Rights*, *supra* note 56, at 217-26 (noting that expansion of experimental use doctrine might soften exclusivity of patent rights and thereby reduce tension between patent and research interests).

[154] *See, e.g.*, AMA REPORT, *supra* note 13, at 62. Doctors have also alleged that medical education is threatened by the enforcement of patented processes because teachers and students will be restricted from access to necessary procedures. *See id.* at 64. This is essentially the same argument that has been made regarding the practice of doctors being

procedure patents may hinder their ability to use protected procedures[135] and that, at a minimum, a fear of liability will chill their treatment decisions.[136]

Total preclusion would occur if a doctor were denied a license or if a court imposed an injunction against the doctor forbidding the doctor from using a patented process. However, neither of these situations is likely to occur. First, there are no known cases in which the owner of a medical procedure patent refused to license a patent.[137] In fact, a patent owner has a financial incentive to license the invention at a reasonable cost.[138] Moreover, even if a patent

---

restricted. Accordingly, all of the arguments for reconciling patents and medical practice should be equally applicable.

[135] However, it should be noted that not all doctors agree that restricted access to patented procedures is necessarily harmful to patient care because a patent owner may assist in ensuring proper use of technology in a field in which there is no government regulation. *See* Annas, *supra* note 74, at 26.

[136] The issue of whether medical procedure patents will impact doctor decisions concerning what treatment to use is likely to arise in instances where someone other than the patentee wants to use the treatment. A doctor's decision concerning medical treatment is unlikely to be biased toward any treatment patented by the doctor himself because a doctor receives no compensation for using his own invention. Even if a doctor were to promote a use that she has patented for pecuniary reasons alone, the medical profession code of ethics would seem to prevent such a possibility because doing so would not necessarily be in the patient's best interest. *See* AMA Code, *supra* note 105, § 8.03 (noting that "[u]nder no circumstances may physicians place their own financial interests above the welfare of their patients").

[137] *See, e.g., Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 89 (statement of Michael Kirk, representing the ABA) (noting that proponents of banning medical procedure patents "have never been able to point to any concrete examples of patients who were at risk of not having the benefits of the patented surgery technique").

[138] *See* Annas, *supra* note 74, at 26 (noting that doctors working on SET believed that patent actually encouraged increased access to technology because profit motive encouraged patent owners to license); Dave Melzer, *Patent Protection for Medical Technologies: Why Some and Not Others?*, LANCET, Feb. 14, 1998, at 518, 518 (noting that opposition to surgical patents is irrational and emotional in light of reality that such patents would always be appropriately licensed due to commercial and social pressures); *see also Stem Cell Research, Patenting & Health Implications: Hearings Before the Subcomm. on Labor, Health and Human Services, Education & Related Agencies of the Senate Appropriations Comm.*, 106th Cong., 2d Sess. (1999), *available in* 1999 WL 9929, at *7 (statement of Todd Dickinson, PTO Commissioner) (noting that "[w]hile some speculate that patent owners may refuse to license or exclusively license [to] others . . . market realities and/or good will almost always resolve this problem"); *Commercialize Federally Owned Inventions: Hearings on H.R. 2544 Before the House Subcomm. on Technology of the House Comm. on Science*, 105th Cong., 2d Sess. (1998), *available in* 1998 WL 122527 (statement of Raymond Kammer, Director of National Institute of Standards and Technology) (noting that licensing of patented inventions are regulated by market forces such that exclusive licenses which hinder sharing are reduced). In addition, public pressure may also play a role in ensuring that licenses be reasonable. *See, e.g.*, Seth Shulman, *Cashing In on Medical Knowledge*, TECH. REV., Mar. 13, 1998, at 38, 42 (noting that litigation was never issue after American College of Radiology publicly condemned patent as invalid); *see also* Evan Ackiron, Note, *Patents for Critical*

owner were to attempt to enforce a patent against a doctor,[139] a court would not enforce it if public health would be compromised.[140]

The potential of restricted access is the more likely problem. In particular, the AMA suggests that fully enforceable patents would create a chilling effect that would deter doctors from using patented, or even newer, technology.[141] The AMA argues that doctors may use an older procedure because they cannot easily determine what is patented or what constitutes patent infringement.[142]

Pharmaceuticals: The AZT Case, 17 AM. J.L. & MED. 145, 146 (1991) (noting that price of AZT dropped by two-thirds after public outcry).

[139] This assumes that a patent holder both is aware of a doctor's use and elects to sue the doctor. However, patent owners typically are not aware of such use. *See, e.g.*, C. Berman & N. Lambrecht, *Medical Patents in the United States*, 10 MANAGING INTELL. PROP. (July 1991); *see also Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13 (statement of William Noonan) (noting that medical procedure patents are impractical to enforce because of both difficulties in detecting infringement and need to litigate many suits against individual doctors); Miller, *supra* note 65, at 260 (noting that there is no easy way to determine infringement although patients can be asked about surgical method, or patients' operating reports can be examined). Two exceptions to this would be if a doctor publishes an article claiming the patented invention as his own, or if the doctor sought a license from the patent holder but either was denied a license or elected not to take a license because the royalty was considered to be too high. However, the *Pallin* suit is the only one known to have occurred because of a publication. *See supra* note 8 and accompanying text. In addition, a patent owner may elect to sue a company who is contributing to or inducing a doctor's infringement by supplying the materials for infringement, rather than the individual doctor who is directly infringing. *See, e.g.*, Kendall Co. v. Progressive Med. Tech., 85 F.3d 1573 (Fed. Cir. 1996) (involving patent holder that sued supplier of replacement sleeves for contributory infringement of patented medical device, rather than doctor); Allergan Sales Inc. v. Pharmacia & Upjohn Inc., 41 U.S.P.Q.2d 1283, 1287 (S.D. Cal. 1996) (involving patent owner that sued for contributory infringement, rather than doctor); *see also* McCormick, *supra* note 10, at 33 (noting that owner of medical procedure sued manufacturers for training doctors to infringe, rather than doctors who were directly infringing). This is particularly true when the patent owner is a corporation that manufactures and sells medical supplies — in such a case, suing doctors would only result in negative relations with their key customers. *See, e.g., Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 92-100 (statement of Dr. Frank Baldino, President and CEO of Cephalon, Inc.) (noting that "[i]t would make no sense to bring an infringement action against the very people for whom we work to develop these treatments").

[140] It is within a court's equitable discretion to decide whether or not the doctor should be enjoined from using the patented procedure. Indeed, there are cases in which courts have declined to issue injunctions from use of patented inventions for public health and safety concerns. *See infra* note 208 and accompanying text (regarding imposition of injunctions).

[141] *See, e.g.*, AMA REPORT, *supra* note 13, at 62-63.

[142] *See id.* However, this situation should be precluded by medical ethics which require that the patient's best interests not be compromised. *See, e.g.*, AMA Code, *supra* note 105, § 8.03. Moreover, even if an "unethical" doctor were to choose the unpatented

Although the argument that medical procedure patents would create a chilling effect has inherent appeal, whether this is the real concern to doctors is questionable. If access were the driving force, an equally compelling argument would exist for access in all contexts; however, patented drugs have not received the same vehement objections as have medical procedure patents.[143]

This disparity may be because doctors are only "restricted" in the procedure context; in other contexts, patients, rather than doctors, are restricted. Doctors may "believe" that they enjoy free access to patented inventions other than medical procedures, such as medical apparati because they have not been threatened with infringement of such apparati. However, while it is true that doctors are generally not liable for using patented products,[144] access to the patented item is not truly free because the patent is incorporated into the purchase price.[145] Thus, their core objection is not restricted access to necessary procedures — an argument that may be arguably unique to the medical profession — but rather the potential for doctors to be financially liable. This explains why doctors have objected to paying even minimal royalties for medical proce-

---

alternative, the patent itself is still a neutral device, and regulation of the doctor, rather than the patent would seem more appropriate.

[143] *See generally* AMA REPORT, *supra* note 13, at 62-63 (discussing restricted access to patented procedures, but not mentioning restricted access to patented drugs as issue); McCoy, *supra* note 132, at 510-11 (noting that denied access is pervasive in context of modern medical care).

[144] The person that buys a patented item from an authorized user is not considered to be infringing the patent. Therefore, if a manufacturer of a patented medical device pays the patent owner a fee for making the device, the doctor who buys the device from the manufacturer is not liable to the patent owner since the patent right has been exhausted with the manufacturer. However, this only applies to products, rather than processes. Thus, doctors are generally vulnerable to suits for medical procedure patents, but not for medical device and drug patents since they buy those products from others who have paid the patentee for the privilege of using the patented technology. *See, e.g.*, 5 CHISUM, *supra* note 52, § 16.03[2][a].

[145] This distinction has been acknowledged by the AMA. *See* AMA REPORT, *supra* note 13, at 63; AMA, *Ethical Issues*, *supra* note 56, at 345 ("The chilling effect of procedural patents distinguishes these patents in an important way from drug or device patents . . . the physician does not have to worry about inadvertently infringing a drug or device patent . . . ."); *see also Congressional Hearings on H.R. 1127 and H.R. 2419*, *supra* note 13, at 81 (statement of Donald Dunner) (noting that physicians are usually indemnified from patent infringement liability because "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").

dure patents, including those that result in an overall cost savings.[146]

Personal liability, however, arises from the use of all patented processes, regardless of the field of technology. Accordingly, the AMA argument assumes that doctors should be subject to a different liability standard than all other classes of users. Doctors have alleged that their situation is unique because medical emergencies make determining patent liability unduly burdensome.[147] However, medical emergencies do not necessarily justify different liability standards because patent infringement need not be determined only during an emergency. Rather, doctors may determine liability in advance of any potential infringement, which is common in other industries, by regularly reviewing patents.[148]

4. Patient Confidentiality

Doctors have also argued that medical procedure patents inherently compromise patient privacy if patent owners monitor activity to find infringement.[149] For example, determining whether a patented process has been used could involve the monitoring of procedures in an operating room by a video camera. Or, monitoring could involve disclosure of patient medical files to indicate whether a patented procedure had been performed. In either of these scenarios, a patient potentially could be identified and confidentiality compromised.

But enforcing medical procedure patents need not compromise patient confidentiality. Even the AMA acknowledges that "[i]t may be possible to conduct enforcement in such a way as to be both

---

[146] For example, in the *Pallin* case doctors protested strenuously even though the cost in that case was relatively low — even accounting for the licensing fee, there was still a net cost savings of about 12 dollars per surgery. *See supra* note 8 and accompanying text. However, it should be noted that the restricted access argument in the *Pallin* case may have been bolstered by the strong belief that the Pallin patent was invalid. Thus, doctors thought it improper to pay any amount of money for access to what was believed to be a method long in the public domain.

[147] *See, e.g., Congressional Hearings on H.R. 1127 and H.R. 2419, supra* note 13, at 44-46 (statement of Dr. Singer) (alleging that it would be unduly burdensome to determine if patents existed before performing new or modified procedures).

[148] If, however, doctors or anyone else elect not to take such preventative measures, a judicially determined "cost" after infringement will be substantially higher than one negotiated prior to infringement — especially when the costs of litigation are accounted for.

[149] *See, e.g.*, AMA REPORT, *supra* note 13, at 65; Annas, *supra* note 74, at 26; Jeffrey A. Taylor, Comment, *Medical Process Patents and Patient Privacy Rights*, 14 J. MARSHALL J. COMPUTER & INFO. L. 131, 140-45 (1995).

effective and confidential" by charging doctors based on the number of patients seen, rather than on a case-by-case basis.[150] In addition, even if a royalty is not charged on a per patient basis, other procedures could maintain patient confidentiality. For example, identifying information in patient files may be redacted, or complete patient files could be available for review only in camera.[151] These techniques are already standard procedures in civil litigation where patient files are disclosed.[152] Similarly, situations outside of the litigation context have protected patient confidentiality by redacting personal information.[153]

III. THE IMMUNITY PROVISION

Section 287(c) of the Patent Act provides "medical practitioners" and "related health care entities" with immunity from patent infringement suits concerning patents on "medical activity."[154] Be-

---

[150] AMA REPORT, *supra* note 13, at 65; *see also* Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1 (suggesting similar limitation to reduce confidentiality issues). However, after acknowledging such a possibility, the AMA immediately dismisses it in the same breath on the basis that it is unclear how this might be accurately done, presumably based on the assumption that doctors would not accurately report usage. *See, e.g.*, AMA, *Ethical Issues*, *supra* note 56, at 347-48 (acknowledging that "[i]t may be possible to conduct enforcement in such a way as to be both effective and confidential," but maintaining that patient confidentiality will be nonetheless compromised because it is unclear "how to ensure accuracy of reporting . . . without compromising confidentiality in *some* manner") (emphasis added).

[151] *See, e.g.*, Taylor, *supra* note 149, at 147-48 (suggesting information identifying patient should be redacted or judge should perform in camera inspection of patient's file).

[152] *See, e.g.*, FED. R. CIV. P. 26(c) (describing protective orders for disclosure of confidential information).

[153] Such situations include disclosures required by the Freedom of Information Act, state and federal reimbursement regulations, and review by peer review organizations. *See, e.g.*, Garris, *supra* note 57, at 99-100 (describing how patient information has been protected in other circumstances).

[154] 35 U.S.C. § 287(c)(1) (Supp. II 1996). The full text of section 287(c) states:

> (1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.
> (2) For the purposes of this subsection:
> (A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include
> (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent,
> (ii) the practice of a patented use of a composition of matter in violation of such patent, or

cause the immunity extends to damages, injunctions, and attorney fees, medical practitioners are immune from all the effects of infringing a medical procedure patent.[155] The immunity, however,

---

(iii) the practice of a process in violation of a biotechnology patent.

(B) the term "medical practitioner" means any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity.

(C) the term "related health care entity" shall mean an entity with which a medical practitioner has a professional affiliation under which the medical practitioner performs the medical activity, including but not limited to a nursing home, hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.

(D) the term "professional affiliation" shall mean staff privileges, medical staff membership, employment or contractual relationship, partnership or ownership interest, academic appointment, or other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity.

(E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans.

(F) the term "patented use of a composition of matter" does not include a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method.

(G) the term "State" shall mean any state or territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(3) This subsection does not apply to the activities of any person, or employee or agent of such person (regardless of whether such person is a tax exempt organization under section 501(c) of the Internal Revenue Code), who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), where such activities are:

(A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services (other than clinical laboratory services provided in a physician's office), and

(B) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act.

(4) This subsection shall not apply to any patent issued before the date of enactment of this subsection.

Id.

[155] *See* 35 U.S.C. § 281 (1994) (stating that patentee "shall have remedy by civil action for infringement of his patent"); *id.* § 283 (1994) (providing courts power to grant injunctions for violations of patents); *id.* § 284 (1994) (requiring courts to award damages of at least reasonable royalty upon finding of patent infringement); *id.* § 285 (1994) (providing for attorney fees in "exceptional cases").

only applies to the performance of a "medical activity," which is subject to further definitions and exceptions.[156]

Although not explicitly stated, section 287(c) effectively operates as a compulsory licensing provision because it gives doctors a de facto license to use certain patented processes without the patent owner's consent. This compulsory license is forced upon patent owners regardless of the invention or the owner's intent to license.

A. Who Is Entitled to Immunity

There are two classes of persons to whom section 287(c) applies: medical practitioners and their related entities. A "medical practitioner" includes physicians and those who serve in a related capacity of treating patients. In particular, it includes a person "licensed by a State" to provide a "medical activity" or that is "acting under the direction" of someone that is licensed.[157] A medical practitioner could thus be a doctor or any other type of health care provider licensed by a state, such as a nurse, dentist, or physical therapist.[158] In addition, the definition includes an entity with which the

---

[156] *See id.* § 287(c)(2) (defining "medical activity").

[157] *Id.* § 287(c)(2)(B). Depending on the definition of "acting under the direction of," patients may not be provided immunity for acts that their doctors have immunity for. Patients may be vulnerable to patent infringement suits if they performed a "medical activity," although their doctor could perform the same activity with immunity because doctors are explicitly covered by this section. *See id.* For example, if a patent claims a method of treating a scalp to encourage new hair growth (i.e., a method of treating baldness), a patient performing the method in his home would be liable. However, if the patient had his doctor perform the method instead, neither the patient nor doctor would be liable, assuming that none of the 287(c) exceptions applied. This liability may be theoretical at this point because patients are typically not sued for patent infringement; however, the same was previously true for doctors. *See supra* note 10 and accompanying text. In addition, it could be inferred that Congress decided against providing immunity to patients since earlier legislative proposals concerning medical procedure patents included patients as a class of persons to be protected from patent infringement in contrast to section 287(c). *See* S. 1334, 104th Cong. § 2 (1995) ("[I]t shall not be an act of infringement for a patient, physician, or other licensed health care practitioner . . . to use or induce others to use a patented [medical procedure] . . . ."). However, given the hasty enactment of section 287(c), the omission of patients from the scope of immunity could also have been an oversight. *See supra* note 20 and accompanying text (noting lack of debate prior to enactment of § 287(c)).

[158] Also, those who work for medical practitioners are covered, although for the purposes of this paper "medical practitioner" will be used to refer to all these persons. However, because of the narrow definition of a qualifying "medical activity," not all persons who constitute "medical practitioners" will actually be entitled to immunity. For example, although both doctors and veterinarians qualify under the definition of a "medical practitioner," the requirement that the "medical activity" must be performed on a "body" ends up excluding veterinarians. In particular, animal bodies are only included within the

medical practitioner has a "professional affiliation"[159] and under which the medical practitioner conducts the activity in question.[160] Examples of such an entity include a hospital, university, medical school, and even a health maintenance organization ("HMO").[161]

B. Parameters of the Immunity

The primary problem in determining what activity will give rise to the royalty-free license under section 287(c) involves interpreting the critical phrase, "medical or surgical procedure."[162] The statute obliquely defines this term in the negative, by providing three activities that do not constitute a medical or surgical procedure.[163] In particular, the statute states that the term shall not include:

> (i) the use of a patented machine, manufacture or composition of matter in violation of such patent;

---

definition of a "body" if used in medical research or instruction "directly relating" to the treatment of humans. *See* 35 U.S.C. § 287(c)(2)(E). Treatment of an animal purely for the sake of alleviating an animal's medical condition would not be within the definition of this section. Therefore, a doctor performing a patented surgical technique on a human heart would be performing a procedure on a "body," and immune from liability. In contrast, a veterinarian performing the same patented surgical technique on a dog would not.

[159] A "professional affiliation" goes beyond employment, to include staff privileges, contractual relationship, academic appointment and any other affiliation under which a medical practitioner provides the medical activity "on behalf of, or in association with, the health care entity." *Id.* § 287(c)(2)(D).

[160] *See id.* § 287(c)(2)(C).

[161] *See id.*

[162] Another interpretive problem with section 287(c) is that it covers "performance of a medical or surgical procedure on a body" and defines "body" so broadly that it is not fully supported by prior policy arguments advanced by the AMA. *See id.* § 287(c)(2)(A). For example, a "body" is defined to include not only a live human body such as a patient, but also a "cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans." *Id.* § 287(c)(2)(E). However, the issues regarding confidentiality and compromised patient care clearly do not exist with respect to cadavers, and are probably not a major issue regarding research animals.

[163] *See id.* § 287(c)(2)(A). Section 287(c)(2)(A) provides:

> [T]he term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

Id.

(ii) the practice of a patented use of a composition of matter in violation of such patent, or
(iii) the practice of a process in violation of a biotechnology patent.[164]

These three exceptions are taken in turn below.[165]

1. A Doctor's Use of a Patented Product

Under the first exception, a medical practitioner is not provided any immunity for the "use of a patented machine, manufacture, or composition of matter in violation of such patent."[166] The "use" referred to here is that of a patented product, such as a medical apparatus.[167] The exception also embraces patents that claim both a product and a process.[168] A doctor that purchases a patented apparatus, however, is typically not liable for using that apparatus because there is an implied license to use the patented product as long as the product is purchased from a licensed manufacturer.[169] Accordingly, a doctor that uses a patented product will be liable only if the product is purchased from a vendor that is not authorized to make or sell the product.

---

[164] *Id.*

[165] Each of these exceptions refer to "the violation of a patent," which implicitly refers to patent claims. Claims are the sentences at the end of a patent that define the scope of the patentee's exclusive rights. *See id.* § 112 (1994) (noting that patents "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention"); Smithkline Diagnostics, Inc. v. Helena Labs. Corp., 859 F.2d 878, 882-85 (Fed. Cir. 1988); Constant v. Advanced Micro Devices, Inc., 848 F.2d 1560, 1567-69 (Fed. Cir. 1988). A patentee has the right to exclude others from making, using, selling, or importing the invention as claimed. *See* 35 U.S.C. § 271 (1994 & Supp. IV 1998) (prohibiting activities regarding patented invention). Anyone who performs any of these activities with regard to the claimed invention is typically liable to the patent owner for patent infringement. *See id.*; *id.* § 281 (1994); *see also infra* notes 204-06 and accompanying text (discussing limited exceptions to infringement).

[166] 35 U.S.C. § 287(c)(2)(A)(i).

[167] Although the patent statute refers to four categories of subject matter — machines, manufactures, composition of matter and processes, the claims referring to these categories are denoted as product claims and process claims. Process claims include claims that describe a process or method of doing something, including a use of a previously known product. *See id.* § 100 (1994). All other claims refer to products; examples of product claims include claims that describe a tangible product such as a machine, drug, or chemical composition.

[168] The violation referred to here is probably patent "infringement" because the patent right to exclusivity is violated. *See supra* notes 1, 4 and accompanying text.

[169] *See* Joy Technologies v. Flakt, Inc., 6 F.3d 770, 773-74 (Fed. Cir. 1993) (observing infringement of method claims when steps of claimed method are performed).

2. A Doctor's Use of a Patented Composition of Matter

The second exception preserves patent liability for "the practice of a patented use of a composition of matter."[170] Unlike the first exception, this one refers to a patented process.[171] Typically, the phrase "patented use of a composition of matter" refers to a patent on the use of an unpatentable composition. In other words, although the composition itself is unpatentable, the use of the composition is patented.[172] For example, despite a preexisting patent on a composition to cure acne, the use of that composition to treat wrinkles was later given separate patent protection.[173]

The precise scope of this exception is difficult to ascertain because it is further limited by the requirement that it not include "a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not *directly contribute* to [the] achievement of the *objective of the claimed method*."[174] The Conference Report attempts to clarify when a patented use will "directly contribute" and how to determine the "objective of the claimed invention";[175] however, the definitions may be difficult to apply because they depend on what appears in each undefined step of the patent claim and on issues that were not important to determining patentability. In particular, the definitions hinge on whether each step of the claim recites the use of a composition of matter that "is itself novel or if it . . . is necessary to establish the nonobviousness

---

[170] *See* 35 U.S.C. § 287(c)(2)(A)(ii).

[171] The terms "process," "use," and "method" are interchangeable, distinct only from a product. *See supra* note 46 and accompanying text.

[172] *See* 35 U.S.C. § 100(b). A patented "new use" of a composition of matter refers to a patent on the use of a composition of matter. A common composition of matter in such a case would be a chemical composition such as a drug. Generally, patents are only sought on the use of a composition when the composition itself is not patentable. This may occur when the composition is in the public domain either because it was not patented in a timely manner, or because the patent has now expired.

[173] *See* U.S. Patent No. 4,603,146 (July 29, 1986) ("Methods for Retarding the Effects of Aging of the Skin"); Edmund L. Andrews, *Patents: University Sues Inventor of Retin-A*, N.Y. TIMES, Jan. 27, 1990, at 37; *see also* Edmund L. Andrews, *Patents: Spaghetti and Meatballs From a Fat Substitute*, N.Y. TIMES, Dec. 10, 1988, at 36 (noting issuance of patent on new uses of olestra although compound has been already patented); Edmund L. Andrews, *Patents: Ulcer Drugs May Help Mentally Ill*, N.Y. TIMES, Dec. 21, 1991, at 34 (noting issuance of patent on new use of Zantac, formerly used as ulcer medication, in treatment of schizophrenia).

[174] 35 U.S.C. § 287(c)(2)(F) (emphasis added).

[175] *See generally id.* § 287(c) (failing to provide definitions for these terms).

of the claim as a whole."[176] Patentability, however, depends on the claims as a whole rather than on their ambiguous steps.[177]

3. A Doctor's Use of a Patented Biotechnology Process

The third exception to the definition of medical activity giving rise to immunity is "the practice of a process in violation of a biotechnology patent."[178] Although section 287(c) does not directly define the term "biotechnology patent,"[179] the Conference Report states that the term includes: "a patent on a 'biotechnological process' as defined in 35 U.S.C. § 103(b),[180] [and] a patent on a

---

[176] 142 CONG. REC. H11,865 (daily ed. Sept. 28, 1996). Where each such "step" recites a use the House Report asserts that the composition will "necessarily contribute to the novelty — and therefore, to the objective — of the claimed method." *Id.* However, for claims that do not recite a use in each step, a more complex test applies, which will be referred to as the hybrid test. Under this test, the "objective" of the claimed method must first be determined, taking into account all of the steps set forth in the claim. *See id.* Second, it must be determined whether the steps involving the use of composition of matter "contribute directly" to the achievement of the objective of the claimed invention. *See id.* The second part is deemed to have been met if the use of the composition of matter represents novel subject matter, or if one or more of the steps contributes to or is necessary to establish the nonobviousness of the claim as a whole. *See id.* In addition, it has been suggested that clever drafting of claims may avoid the more difficult hybrid test. *See, e.g.*, Randall B. Bateman & M. Wayne Western, *Medical Procedure Patents, the 1996 Amendment And Who is Really Liable*, IP TODAY, Dec. 1997, at 6.

[177] These tests require determining the novelty of individual steps of claims even though such "steps" need not be deemed novel for the claims to issue in a valid patent. *See, e.g.*, *In re* Burke, Inc., 786 F. Supp. 1537, 1539 (C.D. Cal. 1992) (noting that combination of elements may be novel even though individual elements are not); *see also* Hockerson-Halberstadt, Inc. v. Converse Inc., 183 F.3d 1369, 1374 (Fed. Cir. 1999) (noting that in context of claim construction, entire claim must be reviewed, rather than examining isolated elements).

[178] 35 U.S.C. § 287(c)(2)(A)(iii).

[179] *See generally id.* § 287(c).

[180] *Id.* § 103(b)(3) (1994 & Supp. IV 1998). Section 103(b)(3) defines a biotechnological process as:

> (A) a process of genetically altering or otherwise inducing a single- or multi-celled organism to —
> (i) express an exogenous nucleotide sequence,
> (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
> (iii) express a specific physiological characteristic not naturally associated with said organism;
> (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
> (C) a method of using a product produced by a process defined by subparagraph (A) or (B), or a combination of subparagraphs (A) and (B).

Id.

process of making or using biological materials, including treatment using those materials where [they] have been manipulated ex vivo at the cellular or molecular level."[181] This exception carves a substantial hole in the immunity provision. Given the potential expansion of gene therapy,[182] a substantial number of physicians would remain fully liable for patent infringement that occurred during the practice of medicine.

C. Limitations of the Immunity

Although section 287(c) provides doctors with some immunity, that immunity is fairly narrow so that the prior argument concerning negative impacts on medical norms still exists. In particular, the section only clearly provides immunity against pure process patents — those that do not involve a patented apparatus, composition of matter, or biotechnological process.[183] Aside from this limited protection, doctors have the same liability they did before section 287(c) was enacted. In addition, the immunity provision may give rise to additional litigation to determine its scope.[184]

The only benefit that doctors obtain under section 287(c) is immunity from infringement of patented procedures that do not involve either a patented use of a composition of matter or genetic manipulation.[185] An example of a patented procedure that would satisfy all of these requirements would be Pallin's patent[186] because

---

[181] 142 CONG. REC. H11,866 (daily ed. Sept. 28, 1996).

[182] *See, e.g.*, Todd Ackerman, *Center to Offer Cell-and-Gene Therapy: New Treatment Option Expected to Become the Future of Medicine*, HOUS. CHRON., July 27, 1999, at A1 (noting establishment of gene therapy center and expectation that this treatment option is future of medicine); Shulman, *supra* note 138, at 44 (noting that NIH has patented ex vivo gene therapy method to treat genetic disorder).

For example, gene therapy has been used to insert extra genes into the heart to enable patients to grow their own bypasses in cases where patients have clogged vessels but cannot undergo traditional bypass surgery or angioplasty. *See Injected Genes Help Grow Heart Bypasses*, WASH. POST, Nov. 10, 1998, at A3; *see also* Ron Kotulak, *Glimmer of Hope in Gene Therapy*, CHI. TRIB., Mar. 28, 1999, at C1 (reporting that gene therapy holds glimmer of hope for breakthrough in genetically linked diseases and inherited conditions); Michael LaSalandra, *Prostrate Cancer Patients Band Together For Support*, BOSTON HERALD, May 18, 1999, at 2 (noting that gene therapy is looking promising).

[183] *See supra* notes 166-82 and accompanying text.

[184] *See infra* notes 195-98 and accompanying text.

[185] *See supra* notes 162-82 and accompanying text.

[186] *See* U.S. Patent No. 5,080,111 (Jan. 14, 1992) ("Method of Making Self-Sealing Episcleral Incision").

it claimed a method of suturing without stitches but did not use a composition of matter or any genetic manipulation.[187]

The immunity's scope is further narrowed because section 287(c) is not retroactive; therefore, owners of patents issued before the law's enactment retain their full panoply of remedies against doctors.[188] Accordingly, patents issued before 1996 remain enforceable against doctors, assuming they are valid.[189] Because of the term of these patents, doctors will remain subject to patent infringement suits for more than ten years after the passage of the supposed remedy.[190] Although some have proposed broadening section 287(c) to make it retroactive,[191] that would fail to address the other domestic and international policy problems that section 287(c) creates.[192] Therefore, aside from pure process patents is-

---

[187] *See, e.g., Congressional Hearings on H.R. 1127 and H.R. 2419, supra* note 13, at 58 (statement of Charles Kelman, President, American Society of Cataract and Refractive Surgery) (clarifying that opposition is only to "pure medical procedures" but not patented methods of using drugs, medical devices or biological products or processes that are subject to FDA development); *see id.* at 69 (statement of Dr. Dunbar Hoskins, Vice President, American Academy of Ophthalmology) (opposing patenting of medical procedures, but not devices). Doctors were not opposed to patents that covered both a medical apparatus and a medical procedure. *See id.*; *see also* AMA REPORT, *supra* note 13, at 60 (excluding "medical process patents which involve the patenting of a procedure in conjunction with a device or drug . . . [as well as] patents for devices without which a procedure cannot be performed" because they do not constitute type of "pure medical process patents" that AMA finds objectionable).

[188] *See* 35 U.S.C. § 287(c)(4) (Supp. II 1996) ("This subsection shall not apply to any patent issued before the date of enactment of this subsection."); Kurt Eichenwald, *Push for Royalties Threatens Use of Down Syndrome Test*, N.Y. TIMES, May 23, 1997, at A1; Brenda Sandburg, *Kaiser Case is Dismissed; Triple Marker Patent Stands*, RECORDER, Nov. 20, 1998, at 1.

[189] In addition, due to recent legislation, the scope of section 287(c) immunity is further limited. In particular, section 287(c) has been revised to expressly prevent applications of immunity to patents based on applications filed before date of enactment — regardless of when the patent issued.

[190] *See* 35 U.S.C. § 156 (1994 & Supp. IV 1998).

[191] For example, Representative Ganske, who played a pivotal role in the enactment of section 287(c), has suggested that eliminating the retroactivity component might be necessary. *See, e.g.*, Eichenwald, *supra* note 188, at A1; Shulman, *supra* note 138, at 45.

[192] In addition, such an action may raise constitutional concerns with respect to taking of property. *See, e.g.*, Courtenay C. Brinckerhoff, *Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking*, 4 U. BALT. INTELL. PROP. L.J. 147, 165-177 (1996); *see also* Thomas Cotter, *Do Federal Uses of Intellectual Property Implicate the 5th Amendment?*, 50 FLA. L. REV. 529, 530-33 (1998). However, potential constitutional consequences may not need to be tackled since most recent activity in Congress on this issue has suggested narrowing, rather than broadening the scope of section 287(c). *See* S. REP. NO. 42, 105th Cong., 1st Sess. 113 (1997) (proposing to amend section 287(c) "to narrow the scope of the ban on enforcement of medical methods patents so as to exempt those patents for which an application was pending on the date of enactment of the

sued after 1996, all other patented procedures may subject doctors to full liability for patent infringement.

In addition, because section 287(c) does not provide equal immunity from all patented processes, doctors remain restricted from using certain medical procedures. For example, a doctor that wants to use a patented gene therapy method on a fetus to eliminate a genetic defect cannot do so without the consent of the patent owner because the patented method would constitute a method covered by a "biotechnology patent" — one of the exceptions to immunity under section 287(c).[193] However, if the same doctor performs fetal surgery to cure a physical defect without the use of any genetic manipulations, patent liability would not attach.[194]

Moreover, determining which medical procedures fall within section 287(c) will likely require litigation.[195] Congress assumed that courts could determine whether this exception is met early in litigation through a motion to dismiss or summary judgment.[196]

---

ban"); *see also Legislation: Judiciary Committee Approves Bill to Reorganize PTO, Amend Patent Law*, 54 BNA'S PAT. TRADEMARK & COPYRIGHT J. 83 (1997).

[193] *See supra* notes 178-82 and accompanying text.

[194] This assumes, of course, that the patented equipment was purchased from an unlicensed vendor.

[195] Indeed, the ABA section on Intellectual Property has argued that "the number of suits may increase inasmuch as the uncertainty of the outcome will prevent parties from predicting the results of litigation in advance." *Annual Report 1996-1997*, 70 A.B.A. SEC. I.P. LAW REP. 103 (1997); *see also* Charles Craig, *Biotech Backers Fear Medical Patent Ban Will Hurt Industry*, BIOWORLD TODAY, July 26, 1996 (quoting Pharmaceutical Research and Manufacturers of America as saying that "'[m]odifying any statute as complex as the U.S. patent code on an issue as fundamental as the scope of patentability' will create uncertainty and result in more litigation").

[196] In an attempt to expedite such early resolutions, the House Report provides new standards for determining when either a motion to dismiss or a motion for summary judgment should be granted on this issue. The House Report states that dismissal of an infringement action would be appropriate if it was shown that (1) there is clear and convincing evidence that the use(s) of the composition(s) of matter lack novelty, and (2) under a preponderance of evidence standard, the steps of the claimed method that do not involve uses of compositions of matter (i.e., the medical procedure steps) are themselves novel and nonobvious. *See* 142 CONG. REC. H11,866 (daily ed. Sept. 28, 1996). However, the proposed standards of proof will not expedite the disposal of this issue because the new standards do not supersede the Federal Rules of Civil Procedure. A later-enacted Congressional statute would be controlling if there were a conflict between the Congressional statute and an earlier and inconsistent rule under the Federal Rules of Civil Procedure. *See, e.g.*, United States v. Gustin-Bacon Div., Certainteed Prods. Corp., 426 F.2d 539, 542 (10th Cir. 1970) (noting that Congress may statutorily supersede Federal Rules, but unless there is clear congressional intent to do so, subsequently enacted statutes should be construed to harmonize with Federal Rules); Burlington N. v. Consolidated Fibers, Inc., 7 F. Supp. 2d 822, 826 (N.D. Tex. 1998) (noting that subsequent con-

But determining whether section 287(c) applies involves fact-intensive inquiries, including an analysis of novelty and nonobviousness.[197] Moreover, because section 287(c) immunity depends on a new method of interpreting a patent's claims that will inherently require consultation of materials outside the patent itself, the usual presumption that claims may be construed on summary judgment motions is inapplicable.[198]

Because a doctor that is sued for patent infringement may not know whether section 287(c) immunity applies until trial,[199] the

---

gressional statute can supersede Federal Rules if there is clear congressional intent to do so). However, in this case, the federal statute — section 287(c) — is not in conflict with the Federal Rules. Rather, the "conflict" is between the standard set forth in the legislative history and the standard in the Federal Rules.

[197] *See, e.g., supra* notes 176-77 and accompanying text (discussing requirements to determine whether § 287(c) immunity applies). For example, determining nonobviousness is only possible after factual determinations that include determination of the scope of the prior art, the level of skill in the prior art, and additional considerations such as the commercial success due to the patented invention. *See, e.g.*, Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379 (Fed. Cir. 1986).

[198] It should also be noted that although a judge may interpret the meaning of claims as a matter of law in patent infringement cases by examining an essentially integrated document — the patent and its "prosecution history" (the paper history documenting correspondence between patent applicant and the PTO prior to the issuance of a patent), no such document would contain the information necessary to apply these tests. *See, e.g.*, Markman v. Westview Instruments, Inc., 517 U.S. 370, 389-90 (1996) (stating that patent is fully integrated instrument), *aff'g* 52 F.3d 967 (Fed. Cir. 1995). For example, the novelty and nonobviousness of a method of use is based on the claim as a whole, whereas section 287(c) examines individual components of claims. Because there is no statutory requirement that these individual components be independently patentable, it is unlikely that the prosecution history will be revealing. *See supra* note 177 and accompanying text (explaining that patentability is based on patent claims, not individual components).

Although the wording of claims may play a role in determining liability in other contexts, section 287(c) uses new tests for interpretation of claims that may create uncertainty in liability. Interpreting claims in the context of patent infringement typically does not give special weight to words that are reiterated in the steps of a claim; rather, claims are required to be interpreted in light of other items such as the rest of the patent. *See* Vitrionics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996); Amhil Enters. Ltd. v. Wawa, Inc., 81 F.3d 1554, 1559 (Fed. Cir. 1996); Advance Transformer Co. v. Levinson, 837 F.2d 1081, 1083 (Fed. Cir. 1988). In addition, other patent law doctrines exist in the infringement context to prevent form from prevailing over function. For example, the doctrine of equivalents allows a patent owner to establish infringement even where a defendant's activities are not literally encompassed by the strict wording of the claims. *See, e.g.*, Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 25-26 (1997); Corning Glass Works v. Sumitomo Elec. U.S.A., Inc., 868 F.2d 1251, 1258 (Fed. Cir. 1989); Texas Instruments Inc. v. United States ITC, 805 F.2d 1558, 1569-71 (Fed. Cir. 1986).

[199] One possible way this could be minimized is if the issue of immunity were bifurcated from the remainder of the action. *See* FED. R. CIV. P. 42(b). However, as experience with other bifurcated patent issues has shown, such decisions will be fact-based and unlikely subject to uniform determination by district courts. *See, e.g.*, Scientific-Atlanta v.

doctor may need to prepare a full defense, not just an argument that the section 287(c) immunity applies. Even if a doctor were ultimately found to be shielded from liability, he would nonetheless have had to bear high litigation costs typically involved in patent litigation.[200]

The above description of the immunity provision highlights some serious flaws in the precision of the statute. While many statutes often suffer from imprecise language, the problems with section 287(c) are particularly glaring because it was intended to bring clarity and certainty to patent liability for physicians.[201] In addition, the immunity provision obstructs domestic patent law policies and international obligations and policies, as the following Part explains.

IV. IMPACTS ON DOMESTIC AND INTERNATIONAL LAW AND POLICY

A. Domestic Patent Law and Policy

1. The Right to Exclude

As noted, the right to exclude is fundamental to domestic patent policy.[202] Without the right to exclude, the "express purpose of the

---

General Instrument, 24 Fed. R. Serv. 3d (Callaghan) 1239, 1241-42 (D. Md. 1993) (granting motion to bifurcate liability from damages and willfulness); Haney v. Timesavers Inc., 26 U.S.P.Q.2d 1159, 1160 (D. Or. 1992) (granting motion to bifurcate liability and damages, but not bifurcating willfulness); Air-Shields Inc. v. BOC Group, 23 U.S.P.Q.2d 1955, 1956-58 (D. Md. 1992) (granting motion to bifurcate liability from damages and willfulness); *see also* United States Gypsum Co. v. National Gypsum Co., No. 89 C 7533 1994 WL 74989, at *2-3 (N.D. Ill. Mar. 10, 1994) (trifurcating trial into patent liability and damages, willfulness, and then antitrust phases on plaintiff's motion to bifurcate patent infringement from antitrust counterclaims).

[200] *See, e.g.*, 142 CONG. REC. H8276 (daily ed. July 24, 1996) (statement of Rep. Ganske) (noting costs of defending Singer was on order of one-half million dollars prior to consent decree); John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AM. INTELL. PROP. L. ASS'N Q.J. 185, 187 (1998) (noting that litigation costs often exceed one million dollars per party). Although this may be true in other patented areas as well, the inconsistency here defeats the primary objective of the AMA in shielding all doctors from patent liability. *See supra* note 146 and accompanying text. Although some doctors will be immune under section 287(c), most doctors will suffer from the same uncertainty of litigation that they protested against prior to the enactment of section 287(c). *See, e.g.*, *supra* text accompanying note 142.

[201] *See supra* note 196 and accompanying text.

[202] *See, e.g.*, Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979) (noting that right to exclude is "one of the most essential sticks in the bundle of rights that are commonly characterized as property"); Joy Tech., Inc. v. Flakt, Inc., 6 F.3d 770, 772 (Fed. Cir. 1993); *In re* Etter, 756 F.2d 852, 859 (Fed. Cir. 1985) ("[t]he patent right is a right to exclude"); Connell v. Sears, 722 F.2d 1542, 1548 (Fed. Cir. 1983) (noting that patent act states that patent is form of property and that right to exclude is essence of concept of property); *see*

Constitution and Congress, to promote the progress of the useful arts, would be seriously undermined."[203] Accordingly, both Congress and courts have vigorously protected this right by limiting exceptions to patent infringement,[204] including limiting the availability of compulsory licenses.[205] Although compulsory licensing usually provides patent owners with some compensation, compulsory licenses are inconsistent with the exclusionary right and are therefore disfavored.[206] Accordingly, although injunctive relief for patent owners that prevail in infringement actions is discretionary, courts are inclined to grant an injunction to avoid a de facto compulsory license.[207] Courts deny permanent injunctive relief to pre-

---

also 35 U.S.C. § 271 (1994 & Supp. IV 1998) (identifying what constitutes patent infringement).

[203] Smith v. Hughes Tool, 718 F.2d 1573, 1577-78 (Fed. Cir. 1983).

[204] The Patent Act only provides a single statutory exception to infringement. *See* 35 U.S.C. § 271(e)(1); Eli Lilly & Co. v. Medtronic, Inc., 872 F.2d 402, 404 (Fed. Cir. 1989) (noting that objective of 271(e)(1) was to allow generic drugs for patented drug to be available immediately after patent expired), *aff'd*, 496 U.S. 661 (1990). In addition, even this exception was controversial when enacted and justified as a measure to prevent a patent owner from obtaining a longer period of protection, rather than concern for the infringer. *See, e.g.*, Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness*, 39 IDEA 389, 398-99 (1999) (detailing arduous path to enactment of § 271(e)); Ajay S. Pathak, *The Effect of* Lilly v. Medtronics *on the Scope of 35 U.S.C. § 271(e)(1): The Patent Infringement Exemption — Broad or Narrow*, 6 J.L. & HEALTH 175, 183-85 (1991) (noting that this provision was added to bill to extend patent term in cases of administrative delay to accommodate generic drug manufacturers who otherwise would have had nothing to gain). Similarly, courts have created few exceptions to traditional infringement. There are only two very limited exceptions — one for de minimis use, and another vaguely formulated and rarely successful exception for experimental use. The Federal Circuit has in fact called the defense "truly narrow." Roche Prods. Inc. v. Bolar Pharm. Co., 733 F.2d 858, 863 (Fed. Cir. 1984); *see also* Eisenberg, *Proprietary Rights*, *supra* note 56, at 217-26 (discussing scope and purpose of experimental use defense).

[205] *See* Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (noting that "[c]ompulsory licensing is a rarity in our patent system").

[206] Although common in other countries, the United States has never endorsed compulsory licensing for failure to use an invention and has in fact lobbied strenuously to remove such provisions on a global level. Canada and Mexico were forced to repeal compulsory licensing requirements for drug patents in order for the United States to agree to NAFTA. Similarly, articles 27 and 31 of TRIPS are the result of efforts to limit compulsory licensing world-wide based on failure to work. *See infra* Part IV.B; *cf. infra* note 306 (noting experimental use defense as one of exceptions to infringement proposed by other countries in context of negotiating TRIPS); *see also* John Giust, *Comparative Analysis of the United States Patent Law and the New Industrial Property Code of Brazil*, 21 HASTINGS INT'L & COMP. L. REV. 597, 618-19 (1998) (noting substantial exceptions to infringement under Brazilian patent act in comparison with U.S. patent act).

[207] Although the Patent Act does not mandate injunctive relief, it is generally granted once there has been a judgment of patent infringement. *See, e.g.*, Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1247 (Fed. Cir. 1989) ("It is the general rule that an injunction

vailing patent owners only in the rare instance in which an injunction would cause immediate danger to public health.[208]

Similarly, Congress has provided for very few statutorily imposed compulsory licenses and has restricted the scope of those licenses. In cases where Congress has previously allowed compulsory licensing of patents, it has not imposed those licenses without first giving patent owners the ability to obtain a voluntary license or compensation for any compulsory license.[209] For example, under the Clean Air Act ("CAA"), if a patent owner must license the patented invention because the CAA mandated use of the patented technology, the owner first has the option to license the patent and dictate the terms.[210] Only if the voluntary negotiation fails is a mandatory royalty forced upon the owner,[211] and even in these instances, the

---

will issue when infringement has been adjudged, absent a sound reason for denying it."); KSM Fastening Sys., Inc. v. H.A. Jones Co., 776 F.2d 1522, 1524 (Fed. Cir. 1985).

[208] *See* Continental Paper Bag v. Eastern Paper Bag, 210 U.S. 405, 424-30 (1908) (denying injunctive relief to patentee of medical test kits because of overriding public interest); City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577, 593 (7th Cir. 1934) (denying permanent injunction against city operation of sewage disposal plant in light of public health concerns); Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found., 146 F.2d 941, 946-47 (9th Cir. 1945).

In addition, courts often grant preliminary injunctions unless the public interest is harmed. *See, e.g.*, Hybritech, Inc. v. Abbott Lab., 849 F.2d 1446, 1458 (Fed. Cir. 1988) (affirming partial denial of injunction preliminarily enjoining sale of cancer test kits and hepatitis kits because of public interest in continued availability of kits); Ethicon Endo-Surgery v. United States Surgical Corp., 855 F. Supp. 1500, 1517 (S.D. Ohio 1994) (denying preliminary injunction where immediate withdrawal of devices would have "serious disruptive effect on surgical practice").

[209] One exception to the general rule that the patent owner is allowed freedom to negotiate the amount of remuneration, is with use by the federal government. The United States government is entitled to use any United States patent without consent of the patent owner. 28 U.S.C. § 1498(a) (1994 & Supp. IV 1998); *see also* 35 U.S.C. § 203 (1994) (allowing federal agency who funded invention to have right to use invention as licensee under reasonable terms). The patent owner in such cases is not given an opportunity to negotiate a license, but the owner is still entitled to bring an action to recover "reasonable and entire compensation" for the government's use. *See* 28 U.S.C. § 1498(a) (1994). *See generally* Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or Its Contractors*, 18 AM. INTELL. PROP. L. ASS'N Q.J. 349 (1991) (providing general discussion of recovery from United States government under § 1498 action). Thus, patent owners can still control the amount that they should get in exchange for the reduced exclusion right.

[210] *See* 42 U.S.C. § 7608 (1994); *see also* Plant Variety Protection Act, 7 U.S.C. § 2404 (1994) (providing licenses where "necessary in order to insure an adequate supply of fiber, food or feed . . . [if] the owner is unwilling or unable to supply the public needs . . . at a price which may reasonably be deemed fair" in area of plant variety protection, which provides similar protection to patent system for plant varieties).

[211] *See* 42 U.S.C. § 7608 (allowing district court to require patent owner to license on reasonable terms and conditions).

owner is provided a reasonable royalty as determined by a court.[212] Similarly, the owner of a patent relating to material covered by the Atomic Energy Act is entitled to a reasonable royalty, which the Commission determines only after voluntary negotiation fails.[213]

Section 287(c) is, thus, a distinct departure from patent policy that assiduously protects the right to exclude. Further, section 287(c) requires compulsory licensing in situations that are unlike other situations that justify such a license.[214] In particular, section 287(c) does not alleviate immediate public harm, nor is it necessary to prevent a patent owner from withholding critical goods. Moreover, because the license mandated by section 287(c) does not provide for any royalty to the patent holder, it is more onerous than prior compulsory licensing provisions.

2. Impact on Innovation

The automatic compulsory licensing that section 287(c) mandates may have a substantial impact on innovation. Even those that proposed compulsory licensing for medical procedures before section 287(c) acknowledged that such a scheme might discourage some inventions.[215] They further acknowledged that reduced pat-

---

[212] *See id.* § 7608(2). Before a district court mandates licensing, the Attorney General must first establish that compliance with the CAA requires use of a patented invention, that there are no reasonable alternative methods, and that without such a license there would be a substantial lessening of competition. *See id.* § 7608(1).

[213] *See id.* § 2183(g) (1994). If the Commission is establishing a reasonable royalty fee, the Commission may take into account:

> (A) the advice of the Patent Compensation Board;
> (B) any defense . . . that might be pleaded by a defendant in an action for infringement;
> (C) the extent to which, if any, such patent was developed through federally financed research; and
> (D) the degree of utility, novelty, and importance of the invention or discovery, and may consider the cost to the owner of the patent of developing such invention or discovery or acquiring such patent.

Id. § 2187(c)(1) (1994).

[214] *See supra* notes 210-13 and accompanying text.

[215] *See, e.g.*, Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1170-71 (1987) (noting that mandatory licensing may discourage development of particularly costly or risky medical procedures but rationalizing that "half a loaf is better than none" on assumption that only other solution for dealing with medical community would be complete prohibition of patents). This criticism echoes criticism of prior compulsory licensing schemes. *See* William W. Beckett & Richard M. Merriman, *Will the Patent Provisions of the Atomic Energy Act of 1954 Promote Progress or Stifle Invention?*, 37 J. PAT. OFF. SOC'Y 38, 53-59 (1955) (discussing undesirability of com-

ent protection could slow the rate at which inventions are discovered.[216] Nonetheless, they justified compulsory licensing as better than complete denial of protection, which they presumed was the only other alternative.[217] But this justification is inapplicable, as section 287(c) fails to provide any compensation — unlike other proposals[218] and compulsory licensing statutes.[219]

The impact on innovation after section 287(c) could be determined by examining the number of medical procedure patents before and after the enactment of this section;[220] however, this would be a poor gauge, as numbers alone cannot measure lost innovation. In addition, if only one invention were not discovered because of section 287(c), it nonetheless would be significant if

---

pulsory licensing and noting that compulsory licensing statute is dangerous precedent for diluting patent system that has proven successful for United States); Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1628 (1993) (criticizing "reasonable royalty" rate as illusory incentive); Warren F. Schwartz, *Mandatory Patent Licensing of Air Pollution Control Technology*, 57 VA. L. REV. 719 (1971) (criticizing compulsory licensing provision under CAA as questionable compromise of affording compensation to inventors while securing ready access because of difficulties in administration); Robert Weissman, *A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECON. L. 1069, 1122 (1996) (noting that patent monopoly probably encourages some research that would not otherwise occur under compulsory licensing regime).

[216] *See* Burch, *supra* note 215, at 1164 (noting that in absence of empirical data showing that patents do not result in increased medical research, "elementary economic principles dictate that reducing the potential reward to medical researchers will reduce concomitantly the pace of such research").

[217] *See, e.g., id.* at 1170-71.

[218] *See, e.g.*, I.J. Fellner, *Medical Patents, A Reply*, 28 J. PAT. OFF. SOC'Y 678, 682 (1946) (arguing that AMA or another organization could be charged with custody of patents issued to doctors and give those doctors royalty while assuring free use by all in medical profession); Reisman, *supra* note 19, at 396-401 (proposing that AMA or other medical organization establish patent clearinghouse to which all doctors must be required to assign their patents and that this clearinghouse could, in turn, license rights similarly to copyright clearinghouses); A.T. Sperry, *Medical Patents*, 28 J. PAT. OFF. SOC'Y 371, 372 (1946) (noting prior proposal that AMA should be custodian of all patents issued to doctors); Burch, *supra* note 215, at 1166-71 (proposing mandatory licensing of medical procedure patents at judicially determined fair price, modeled upon licensing under CAA); *see also* Melzer, *supra* note 138, at 518-19 (proposing licensing of medical procedure patents in similar manner to copyrights). However, it must be noted that none of these proposals considered the impact of TRIPS and would likely be inadequate without further modifications because of the strict requirements under TRIPS for compulsory licensing. *See infra* notes 311-17 and accompanying text (discussing requirements of article 31 of TRIPS).

[219] *See supra* notes 208-13 and accompanying text (noting that prior compulsory licensing statutes provided remuneration).

[220] *See Franklin Pierce Debates*, *supra* note 116, at 642 (quoting Jacobus Rasser, chief patent counsel of Procter & Gamble, who suggests that PhRMA conduct such study).

that invention were a method to eliminate a disease or condition affecting a substantial segment of the population.[221]

Regardless of the actual effect on innovation, which is not easily measurable, withholding full patent protection for medical procedures is inconsistent with the patent policy of encouraging research. Although there are occasional exceptions to the patent holder's exclusionary right, these exceptions are based on public policies, such as immediate public harm.[222] Section 287(c), however, does not prevent any such harm. Rather, it only limits personal liability to doctors in certain circumstances. While it is arguable that the public might be harmed if doctors considered their access to medical procedures restricted, these concerns have not traditionally been considered more important than the patent right of exclusion.[223] Moreover, because section 287(c) leaves doctors with the same issues they faced before its enactment,[224] any countervailing policy argument is questionable in light of the usual patent policy of encouraging innovation.

In addition, the uncertainty created by vague statutory language[225] may reduce innovation, because uncertain patent protection may create a disincentive to invest time and money developing an invention.[226] This problem was recently recognized in Europe, where uncertainty surrounding the patentability of biotechnology

---

[221] Although the AMA previously discounted situations where the patent system would have an impact in influencing innovation that would not otherwise occur, its position may be different in a case where a substantial population is affected.

[222] *See supra* notes 204-13 and accompanying text (discussing limited situations in which usual exclusionary patent right has been restricted).

[223] *See supra* notes 183-201 and accompanying text (noting limited scope of immunity provisions).

[224] *See supra* note 208 and accompanying text.

[225] *See supra* notes 162-82 and accompanying text (describing vague and ambiguous key terms under § 287(c)).

[226] Some have even suggested that the availability of strong patents is directly related to, or at least correlated with, strong technology development. *See People's Right to Profit from Their Own Inventions and Whether Ideas Should Be Patented as Well as the Actual Inventions* (National Public Radio broadcast, Mar. 5, 1999), *available in* LEXIS, Nexis Library, Current File (statement of Todd Dickinson, PTO Commissioner) (commenting that strength of U.S. patent system is related to United States having great technological and entrepreneurial base); *see also* Report of the Group of Independent Experts on Legislative and Administrative Simplification, COM(95)288 final/2 at 17 (noting need for proposal on new directive to clarify that biotechnological inventions are patentable as soon as possible to avoid further increasing gap between EU and its main competitive countries with respect to investment); Biotechnology in the Community, COM(83)672 final at E3, E5 (noting necessity of patent protection to stimulate biotechnology development in EU to increase competitiveness of Europe's bio-industries).

was thought to erode the incentive to invent and the ability to attract investment for development and commercialization.[227] In fact, these factors played an important role in the European Union's decision to enact a directive clarifying that biotechnological inventions are patentable.[228]

Section 287(c) may also reduce innovation because it bases the immunity on personal status.[229] Section 287(c) is, notably, the first instance of an exception to patent protection based on individual status.[230] However, the classes of individuals entitled to special treatment under section 287(c) seem to be a function of lobbying, as these groups are not distinct from other groups that section 287(c) does not protect. For example, veterinarians do not enjoy the immunity although they share the same issues with respect to restricted access to necessary technology.[231] Conversely, HMOs have immunity under the present provision although they are not typically cited as needing extra protection under the laws.[232] Sec-

---

[227] *See* Proposal for a Directive on the Legal Protection of Biotechnological Inventions, COM(95)661 final at 4 (noting that uncertainty regarding patentability will hamper investment in research and development for biotechnological inventions).

[228] *See* Council Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions, 1998 O.J. (L 213) 13. It should be noted, however, that although the Directive takes a positive step in affirmatively declaring that biological material may be patentable, it does not conclusively resolve all ambiguity, and arguably creates more ambiguity by adding new tests to determine what constitutes an invention that violates "ordre public" and "morality." *See id.* art. 3.1. (providing that inventions that concern biological material may be patentable); *id.* art. 6 (providing examples of what violates "ordre public"). For example, the Directive precludes patents for processes on cloning humans, processes for germ line therapy and processes for "modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes." *Id.* art. 6(2).

[229] *See* 35 U.S.C. 287(c) (Supp. II 1996).

[230] *See supra* Part III.A (discussing which individuals are entitled to immunity).

[231] Although veterinarians would be within the definition of a "medical practitioner," they would not be entitled to immunity because the statute requires a "medical or surgical procedure" to be performed on a human body or an animal used in research "directly relating" to human treatment. *See* 35 U.S.C. § 287(c)(2)(A), (B), (E); *see also supra* Part II.B.3 (concerning argument that enforceable patents limit access to necessary medical care).

[232] Indeed, in the last session of Congress, legislation was proposed that would have narrowed the scope of this exception to preclude providing immunity to these organizations. *See Judiciary Committee Approves Bill to Reorganize PTO, Amend Patent Law*, 54 BNA'S PAT. TRADEMARK & COPYRIGHT J. 83, 83 (1997) (noting that Sen. Hatch proposed amending section 287(c) so that corporate entities such as hospitals and HMOs would cease to be given immunity under section 287(c)).

tion 287(c) may even encourage those covered by the statute[233] — as well as other interest groups — to push for additional exceptions from patent liability.[234]

Some suggest that section 287(c) should serve as a model for restricting patentable subject matter in ways that both Congress and courts have explicitly denied.[235] For example, some have suggested that section 287(c) be used as a model to counter the Federal Circuit's position that business methods are patentable.[236] In addition, lobbyists may attack other types of patentable subject matter as im-

---

[233] Doctors may next seek to expand their immunity under section 287(c) to eliminate the present exceptions, so that they are immune from all medical procedure patents. This proposal is not as far-fetched as it may seem in light of the fact that section 287(c) fails to address most of the concerns that were raised about medical procedure patents prior to its enforcement. *See supra* notes 183-93 and accompanying text (noting limitations of immunity provisions).

[234] Other interest groups may allege that they have unique circumstances that similarly justify an exemption from patent infringement. For example, individual inventors or companies might claim that they need an exception because, in comparison to large companies, they do not have equivalent means to enforce against patent litigation suits. *See* Greg Borzo, *Royalty Relief: Procedure Patents Not Enforceable*, AM. MED. NEWS, Oct. 21, 1996, at 3 (quoting Donald Dunner, Chair of ABA Intellectual Property Law section, who states that section 287 sets dangerous precedent and "may invite other groups, such as generic drugmakers or patient-advocacy organizations, to seek similar exemptions"); N. Stephan Kinsella & Robert E. Rosenthal, *How to Operate Within the Law: Patents on Medical Procedures*, LEGAL INTELLIGENCER, Feb. 5, 1998, at 2 (noting that advocates of patent system fear that § 287(c) will result in "'open season' for exceptions to patent protection"); Warren D. Woessner & Michael A. Dryja, *US Doctors Find Swift Relief in Patent Law Amendment*, IP WORLDWIDE, Mar.-Apr. 1997, *available in* LEXIS, Nexis Library, Current File (noting that section 287(c) may encourage other industries to push for special exemptions and amendments to patent system).

[235] Congress has traditionally declined to enact legislation to ban specific areas from patentability. *See, e.g.*, S. 387, 103d Cong. § 3 (1993) (proposing two year moratorium on patenting animals, as well as certain human tissues, organs, and cells); H.R. 4989, 102d Cong. § 2 (1992) (proposing five-year moratorium on patenting animals); S. 1291, 102d Cong. § 2 (1991) (proposing to amend patent act to impose five year moratorium on patenting of animals); S. 2169, 101st Cong. § 2 (1990) (proposing five year moratorium on patenting of genetically modified animals); H.R. 3247, 101st Cong. § 1 (1989) (proposing to impose two year moratorium on patenting genetically altered animals, except for animals subject to regulatory review for commercialization); S. 2111, 100th Cong. (1988) (proposing to amend patent act to ban patenting of genetically modified animals); H.R. 3119, 100th Cong. § 2 (1987) (proposing to introduce moratorium on animal patents for two years and to revoke previously granted patents on such animals); *see also supra* note 57 (noting proposed legislation to exclude both medical procedures and apparati from scope of patentable subject matter).

[236] *See, e.g.*, Robert M. Kunstadt, *Sneak Attack on U.S. Inventiveness*, NAT'L L.J., Nov. 9, 1998, at A21; *see also* John R. Thomas, *The Post-Industrialist Patent System*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3, 47-50 (1999) (suggesting that whether this occurs is dependent on lobbying ability and noting that medical lobby is known to be one of strongest lobbying organizations).

proper for patent protection.[237] These attacks on the patent system could limit the scope of patent protection to subject matter for which there is no powerful lobby to protest patent protection.

B. International Law and Policy

In addition to impacting domestic patent policy, section 287(c) has international ramifications. In particular, the United States must maintain certain standards of patent rights as a member of the World Trade Organization ("WTO") and as a party to TRIPS. TRIPS established certain minimum standards for intellectual property protection,[238] including standards of patent protection with which all member states must comply.[239] Failure to adhere to the TRIPS standards can result in trade retaliations.[240]

Before section 287(c), certain members of Congress, the Office of the United States Trade Representatives ("USTR"), and intellectual property lawyers expressed serious concern about international repercussions.[241] Some congressional members were con-

---

[237] For example, public opinion has perceived plants, computer software, and business methods to be improper subject matter for patentability. *See, e.g.*, Scott Kilman, *Biotech Industry Shivers at Threat to Seed Patents*, WALL ST. J., Mar. 3, 1999, at B1 (noting controversy surrounding patentability of genetically modified plants).

[238] The United States is a party to the General Agreement on Trade and Tariffs ("GATT"), and must comply with related agreements such as the Agreement to Establish the World Trade Organization and the TRIPS agreement. *See supra* notes 27-28 and accompanying text.

[239] *See* TRIPS, *supra* note 28, art. 2 (incorporating Paris Convention requirements into TRIPS such that even nonsignatories to this convention must comply with it if they are parties to TRIPS); *id.* arts. 27-34 (providing provisions regarding patentability that must be complied with in addition to those incorporated via article 2). In addition, TRIPS establishes standards for dispute resolution. *See id.* arts. 41-64.

[240] In the event that the United States, or any other member state fails to comply with TRIPS, another member state may demand a consultation in an attempt to correct the problem. If the parties fail to reach a satisfactory solution, the complaining party may request an adjudicatory proceeding before a WTO panel according to the Dispute Settlement Understanding. *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, WTO Agreement, *supra* note 28, Annex 2, art. 4.5, 33 I.L.M. 1226 [hereinafter DSU]. The panel then issues a report to the parties and the dispute settlement body, which adopts the panel report unless there is an appeal to the Appellate Body. If the nonconforming party fails to implement the recommended action within an allotted time, compensation and retaliation may occur. *See* DSU, *supra*, art. 22.3. *See generally* Ernst-Ulrich Petersmann, *International Trade Law and the GATT/WTO Dispute Settlement System 1948-1996: An Introduction*, *in* INTERNATIONAL TRADE LAW AND THE GATT/WTO DISPUTE SETTLEMENT SYSTEM 54-72 (Ernst-Ulrich Petersmann ed., 1997) (discussing dispute settlement process); Terence P. Stewart & Mara M. Burr, *The WTO's First Two and a Half Years of Dispute Resolution*, 23 N.C. J. INT'L L. & COM. REG. 481 (1998) (providing overview of DSU process, as well as analysis of WTO decisions to date).

[241] *See infra* notes 242-43 and accompanying text.

cerned that the TRIPS implications had not been adequately discussed and, in particular, had not been considered by the relevant congressional committee.[242] In addition, the General Counsel of the USTR, the American Bar Association ("ABA"), and the American Intellectual Property Law Association ("AIPLA") expressed concern that section 287(c) would violate TRIPS.[243]

Determining whether section 287(c) violates TRIPS requires an in-depth examination of all the articles that it may violate, as well as potential exceptions for any violations.[244] Although such an analysis of every potential violation is beyond the scope of this Article, a brief examination of the TRIPS issues raised by section 287(c) is warranted here. In particular, section 287(c) raises a substantial question regarding the United States's compliance with two articles of TRIPS and therefore provides an additional ground for repealing section 287(c).[245]

---

[242] *See, e.g.*, 142 CONG. REC. S11,843 (daily ed. Sept. 27, 1996) (letter from Sens. Hatch and Roth to Sen. Lott) (noting that proposed section 287(c) falls under Senate Committee on Finance's jurisdiction because it implicates United States obligations under TRIPS and that "[t]he Committee on Finance has not had an opportunity to hold a hearing on this matter to consider these broader ramifications for U.S. trade policy").

[243] *See id.* at S11,843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, General Counsel of USTR, to Sen. Hatch); *see id.* S11,844 (statement of Sen. Hatch); *see id.* S11,846-47 (letter from John R. Kirk, Jr., ABA Chairman, to Sen. Hatch).

[244] Interpretation of specific provisions of TRIPS must be in "accordance with the customary rules of international law," according to the DSU that applies to TRIPS. *See* TRIPS, *supra* note 28, art. 64 (providing that GATT Articles XXII and XXIII are applicable "as elaborated and applied by the Dispute Settlement Understanding"); DSU, *supra* note 240, art. 3.2. This language has been interpreted to mean that TRIPS should be interpreted in accordance with the 1969 Vienna Convention on the Law of Treaties. *See* WTO Dispute Settlement Panel Report on India — Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/12, ¶ 7.18 (Sept. 5, 1997); WTO Appellate Body Report on United States — Standards for Reformulated and Conventional Gasoline, 35 I.L.M. 603 (1996) [hereinafter Reformulated Gasoline Appellate Body Report]; *see also* Vienna Convention on the Law of Treaties, Mar. 21, 1986, art. 31(1), 25 I.L.M. 543, 562 (1986) [hereinafter Vienna Convention] (stating general rule for treaty interpretations). Thus, the TRIPS provisions should be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose." *Id.* art. 31. In addition, the TRIPS provisions may be interpreted by using "supplementary means of interpretation" such as the negotiating history when interpretation pursuant to article 31 leaves a meaning ambiguous or obscure, or leads to a result that is "manifestly absurd or unreasonable." *Id.* art. 32.

[245] There may also be an argument that section 287(c) violates the enforcement provisions of TRIPS by failing to allow an effective remedy for patent infringement. *See* TRIPS, *supra* note 28, arts. 44-45 (requiring that judicial authority exist to allow injunctive relief and monetary compensation in cases of infringement); *see also* 142 CONG. REC. S11,843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, General Counsel of USTR, to Sen. Hatch) (noting that section 287 appeared to violate articles 27, 28, 44 and 45 of TRIPS). However, a detailed analysis of this argument will not be included here because

1. Requirements of TRIPS

Because section 287(c) limits patent rights, it must be analyzed with reference to those articles of TRIPS that govern patent rights — namely, articles 27 and 28. Article 28 specifies the rights conferred by a patent,[246] while article 27 provides that those rights be enjoyable without discrimination.[247]

a. Article 28

Article 28 delineates the minimum exclusive rights that member countries must provide to patent owners, and it is the only article devoted solely to these rights.[248] With respect to patented processes, it states: "A patent shall confer on its owner the following exclusive rights . . . where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process."[249] Article 28 thus provides that an owner of a patented process shall have an exclusive right to prevent all others from using the patented process. Article 28's exclusive right requirement is underscored by an examination of the TRIPS agreement in its entirety. Unlike other TRIPS provisions that set forth substantive requirements, article 28 itself does not include any internal exceptions to its requirement that exclusive rights be provided.[250]

Contrary to article 28, section 287(c) allows doctors, who constitute third parties, to use a patented process without the owner's consent. Section 287(c) thus fails to provide the exclusive right to owners of medical procedure patents, as article 28 requires.

---

this Article focuses on reasons for repealing section 287(c), rather than a complete examination of all the ways in which section 287(c) violates TRIPS.

[246] *See* TRIPS, *supra* note 28, art. 28.

[247] *See id.* art. 27(1); *see also infra* notes 253-58 and accompanying text (noting that article 27(1) sets forth both criteria for determining patentability and requirement for patent enforcement).

[248] *See generally* TRIPS, *supra* note 28, arts. 27-38 (relating to patent rights). In fact, article 28 is denoted as "Rights Conferred." *See id.* art. 28.

[249] TRIPS, *supra* note 28, art. 28.

[250] For example, in contrast to the patentability standard set forth under article 27, the exclusive rights under article 28 have no exceptions provided within the same article. *Compare id.* art. 27, *with id.* art. 28. Although a separate article of TRIPS does allow an exception to this exclusive rights requirement, it mandates that any exception be a limited one; moreover, additional restrictions must be satisfied. *See id.* art. 30; *see also infra* notes 274-79 and accompanying text (discussing interpretation of article 30 exception).

b. Article 27

Article 27(1) also refers to the exclusive rights that article 28 mandates. Although article 27 does not use the term "exclusive," it reinforces article 28's concept of exclusivity by stating that "patent rights [shall be] enjoyable without discrimination."[251] However, some have argued that article 27(1) can also be interpreted to justify section 287(c) by reading article 27(1) together with article 27(3)'s exception to patentability.[252] However, a review of article 27, including its exceptions, demonstrates that section 287(c) is inconsistent with this article.[253]

Article 27(1) sets forth two requirements. First, it establishes the general patentability criteria, which mirror the United States requirements for patentability.[254] In addition, article 27 requires that all patents, once issued, be entitled to the same right to exclude without regard to the subject matter of the patented technology.[255] All patent owners should therefore be entitled to the same rights under article 28. In particular, article 27 provides:

---

[251] TRIPS, *supra* note 28, art. 27(1) (specifying that there shall be no discrimination in enjoyment of patent rights based on where invention is created, produced, or subject matter of invention).

[252] *See, e.g.*, Portman, *supra* note 29, at 118.

[253] Article 27(1) must be interpreted in light of the other paragraphs of article 27. *See* WTO Appellate Body Report on India — Patent Protection for Pharmaceutical and Agricultural Chemical Products, AB 1997-5, WT/DS50/AB/R, ¶ 56 (Dec. 19, 1997) [hereinafter WTO Appellate Body Report on India, Dec. 19, 1999] (noting that paragraphs (b) and (c) of article 70.8 constitute proper context for interpreting provision at issue — article 70.8(a)).

[254] *See* TRIPS, *supra* note 28, art. 27(1) ("[P]atents shall be available for any inventions . . . in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."). Although two of the terms stated under article 27 — "inventive step" and "capable of industrial application" — are not identical to terms under United States patent law, article 27 nonetheless intended to be roughly analogous to the standards under United States patent law. This intent is indicated by a footnote to article 27 which states that these terms should be understood to be identical to United States terms under section 101. *See id.* at n.5; *see also supra* notes 33-35 and accompanying text (describing requirements for patentability under U.S. law). *But see* Carlos M. Correa, *Patent Rights, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT, *supra* note 97, at 189, 200-01 (noting difference between United States term "utility" and narrow term of "industrial applicability," and that terms remain unharmonized after TRIPS); *cf.* J.H. Reichman, *From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11, 30-32 (1997) (noting that countries are free to adopt their own standards of novelty, usefulness, and other patent requirements).

[255] *See* TRIPS, *supra* note 28, art. 27(1) (providing that "patent rights" shall be "enjoyable without discrimination as to the . . . field of technology"). The term "field of technology" is generally interpreted as equivalent to "subject matter." *See, e.g.*, Correa, *supra* note 254, at 202-03.

> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
> 3. Members may also exclude from patentability:
>   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[256]

Most of the exceptions to article 27(1) are irrelevant to the issue of whether section 287(c) is inconsistent with article 27(1). The articles to which article 27(1) refers — articles 65 and 70 — apply only to developing countries.[257] Articles 27(2) and 27(3) do not apply to section 287(c) because they are exceptions to the patentability standard in article 27(1), not enforcement of patent rights.[258] However, a closer examination of article 27(3) is warranted because it relates to the same subject matter as section 287(c).

Some critics of medical procedure patents have read article 27(1) to allow discrimination against the enforcement of medical procedure patents because article 27(3) allows these procedures to

---

[256] TRIPS, *supra* note 28, art. 27.

[257] Article 65, paragraph 4 allows a developing country to delay compliance with providing product patents as required under article 27 if such patents were not previously provided. *See id.* art. 65(4). Similarly, article 70, paragraph 8 provides a procedure in lieu of full patent protection during this period of delayed compliance. *See id.* art. 70(8). *See generally* WTO Appellate Body Report on India, Dec. 19, 1999, *supra* note 253 (providing explanation of these exceptions); Charters Macdonald-Brown & Leon Ferera, *First WTO Decision on TRIPS*, 2 EUR. INTELL. PROP. REV. 69 (1998) (describing Appellate Body Report, as well as requirements of articles 65(4) and 70(8)).

[258] *See* TRIPS, *supra* note 28, art. 27(2) (specifying "[m]embers may exclude from *patentability*") (emphasis added).

be completely excluded from patentability in the first instance.[259] Under this interpretation of article 27, medical procedure patents with limited enforcement rights are allowable as a category of the article 27(3) exception. Section 287(c) would therefore be permissible because, although it discriminates against medical procedure patent owners, TRIPS allows nations to prohibit the patenting of the subject matter altogether.

While this interpretation is tempting, it is not consistent with the actual text of TRIPS. Article 27(1) literally requires all issued patents to be enforceable; it does not state that a country may enforce patent rights differently depending on whether the subject matter is a type that need not be allowed in the first instance.[260] Also, the portion of article 27(1) relating to patent rights should be read in its proper context, not in isolation. In this case, the proper context includes article 28 because that article similarly relates to patent rights.[261] Interpreting the patent enforcement right requirement in view of the patentability exceptions of article 27 is inappropriate,[262]

---

[259] *See, e.g.*, Portman, *supra* note 29, at 118. This could be buttressed by the argument that because the initial object of TRIPS was to reduce trade distortions, section 287(c) would be permissible because it would be unlikely to impact trade as most nations do not even patent what the United States is declining to enforce. *See supra* notes 76-81 and accompanying text (describing how other nations limit patent protection for medical procedures); *see also* Ministerial Declaration on the Uruguay Round, Sept. 20, 1986, GATT B.I.S.D. (33d Supp.) at 19 (1987) (stating that aim of including intellectual property in Uruguay Round negotiations was "to reduce the distortions and impediments to international trade"); TRIPS, *supra* note 28, preamble (noting need to provide "adequate standards and principles concerning . . . trade-related intellectual property rights"). However, the object and purpose of the concluded TRIPS agreement is not necessarily tied purely to trade. *See* David W. Leebron, *An Overview of the Uruguay Round Results*, 34 COLUM. J. TRANSNAT'L L. 11, 29 (1995) (noting that "[d]espite its name, the TRIPS is really not a trade agreement at all; it does not contain commitments regarding trade in intellectual property. The only obligation is to protect such property, and that does not necessarily entail trade."). In addition, the inclusion of intellectual property standards in the GATT regime, rather than in a freestanding international agreement, was primarily for political reasons. *See, e.g.*, Hans Peter Kunz-Hallstein, *The United States Proposal for a GATT-Agreement on Intellectual Property and the Paris Convention for the Protection of Industrial Property, in* GATT OR WIPO?: NEW WAYS IN THE INTERNATIONAL PROTECTION OF INTELLECTUAL PROPERTY 77-79 (Friedrich-Karl Beier & Gerhard Schricker eds., 1989) (noting that United States first introduced idea of intellectual property into GATT regime because it perceived GATT forum to be friendlier environment to its causes, rather than because issues were solely trade-based).

[260] *See* TRIPS, *supra* note 28, art. 27(1).

[261] *See id.* arts. 27-28.

[262] *See generally* Vienna Convention, *supra* note 244, art. 31 (requiring interpretations of treaty terms in light of context).

as article 27's exceptions expressly pertain to patentability, not enforceability.[263]

Finally, the negotiation history of TRIPS also supports a literal reading of article 27, which dictates that section 287(c) is inconsistent with TRIPS.[264] Although unenforceable medical procedure patents were not contemplated during the TRIPS negotiations, the possibility of unenforceable patents was.[265] Before TRIPS, developed countries were concerned about obtaining patents[266] and enforcing them in other countries.[267]

Article 27(1) was intended to address both of these concerns by establishing a general presumption of patentability for all subject matter and ensuring that subject matter deemed patentable would be enforceable.[268] The "field of technology" language, as well as the prohibition of discrimination based on importation, was added to article 27(1) to prevent patents from being de facto unenforceable.[269] It would thus be more consistent with the negotiation history of TRIPS to enforce equally all issued patents; otherwise, nations could defeat the intended patent scheme by refusing to enforce patents using the exceptions of article 27.[270] In particular,

---

[263] *See* TRIPS, *supra* note 28, art. 27(3).

[264] *See* Vienna Convention, *supra* note 244, arts. 31-32 (allowing ability to "supplementary means of interpretation" such as negotiating history when interpretation pursuant to article 31 leaves unclear or ambiguous meaning).

[265] For example, compulsory licensing of patents under the Paris Convention made them effectively unenforceable. *See* G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY 71 (1968).

[266] *See* Correa, *supra* note 254, at 191-92 (noting that prior to TRIPS more than 50 countries did not allow patent protection for at least one type of subject matter, with pharmaceuticals being one of most common exclusions). *See generally* World Intellectual Property Organization, *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms For the Protection of Intellectual Property*, MTN.GNG/NG11 /W/24/Rev.1, Annex II (Sept. 1988) (summarizing exclusions from patent protection for subject matter including pharmaceutical products, pharmaceutical processes, animal varieties, methods for treatment of human or animal body, food products, computer programs and chemical products).

[267] Outside the United States this was explicitly sanctioned worldwide by the Paris Convention, which allows its members to limit patent rights for failure to work a patent locally. *See* Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, *last revised*, July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305; BODENHAUSEN, *supra* note 265, at 67-73. Unenforceable patents were often the result of compulsory licensing requirements that discriminated against foreign patent owners by requiring owners to grant a license if they did not produce the patented product locally.

[268] *See, e.g.*, DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 147-48 (1998).

[269] *See id.* at 148; Correa, *supra* note 254, at 202-03.

[270] In addition, requiring equal enforcement would be more consistent with the policy of establishing uniform and certain patent protection.

countries could use article 27(3) to justify their refusal to enforce the very types of patents that article 27 was crafted to protect — biotechnological patents.[271] Moreover, because separate articles of TRIPS already address patents with limited enforcement rights — namely, articles 30 and 31 — article 27 should not be interpreted to address the same issue.[272] Because section 287(c) restricts the patent holder's right to exclude and treats medical procedure patents differently from other patents, it violates articles 27 and 28 of TRIPS.

2. Exceptions to TRIPS

Although section 287(c) is inconsistent with articles 27 and 28 of TRIPS, an actual violation of TRIPS occurs only when the inconsistency lacks an excuse under another portion of TRIPS.[273] Whether section 287(c) violates TRIPS, thus, depends on articles 30 and 31, the provisions of TRIPS that excuse noncompliance with the general requirement that all patents be provided exclusive rights. These articles, however, do not excuse section 287(c)'s noncompliance.

a. Article 30

Article 30 allows a member state to provide "limited exceptions" to the exclusive rights that TRIPS ordinarily requires as long as article 30's requirements are satisfied.[274] As noted, article 28 entitles the owner of a patented process to exclude all others from using that process; however, patent rights are subject to article 30's exception.[275] What constitutes a "limited exception" under article 30, though, is not clear.[276] Article 30 states: "Members may provide

---

[271] *See* TRIPS, *supra* note 28, art. 27(3); *supra* notes 264-69 and accompanying text (concerning negotiating history of article 27).

[272] *See* TRIPS, *supra* note 28, arts. 30-31.

[273] *See generally id.* arts. 7-8, 30-31 (providing grounds for exceptions from usual TRIPS requirements).

[274] *See id.* art. 30.

[275] *See id.* art. 28; *see also supra* notes 248-50 and accompanying text (discussing article 28).

[276] Perhaps predictably, article 30 has been invoked both to support the assertion that section 287(c) is TRIPS-compliant, and to support the assertion that section 287(c) violates TRIPS. *See, e.g.*, 142 CONG. REC. S11,845 (daily ed. Sept. 26, 1996) (statement of Sen. Hatch) (asserting that article 30 fails to save section 287(c)); *id.* at S11,843-44 (letter of Jennifer Hillman, General Counsel of USTR, to Sen. Hatch) (asserting that section 287(c) is not exempt under article 30); Burgoon, *supra* note 19, at 119; Mossinghoff, *supra* note

limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[277] The article cannot be reasonably interpreted to swallow entirely the substantive patent provisions of TRIPS. Panel decisions by the WTO, the organization responsible for enforcing TRIPS, have reinforced the idea that exceptions are intended to be just that — exceptions that do not emasculate the general principles established in the agreements.[278] Because the fundamental principle behind the patent provisions is to provide exclusive rights, allowing article 30 to provide an exception for all activity would be improper. But attempting to define an appropriate scope for article 30's limited exception is notably difficult. Whether section 287(c) is a justifiable limited exception under article 30 depends on whether it, (1) "unreasonably conflict[s] with a normal exploitation" of a medical procedure patent, and (2) "unreasonably prejudice[s] the legitimate interests of the

---

18, at 796-97 (applying "real world" gloss to interpretation of TRIPS to conclude that because most corporate patentees of medical procedures do not sue doctors, such suits would not be "normal exploitation of patents under article 30"). It should be noted that a WTO panel has addressed the scope of article 30 for the first time in a recent decision; however, it did so in an unrelated dispute and the parties still have the right to appeal the decision as this Article goes to press. *See* WTO dispute Settlement Report on Canada — Patent Protection of Pharmaceutical Products, WTO doc. WT/DS 114/R (Mar. 17, 2000). This Article is not based on this recent WTO decision; rather it is an independent evaluation of article 30 in accordance with the Vienna Convention.

[277] TRIPS, *supra* note 28, art. 30.

[278] *See, e.g.*, Reformulated Gasoline Appellate Body Report, *supra* note 244, at 16 (noting that exceptions of Article XX of GATT "should not be so applied as to frustrate or defeat the legal obligations . . . under the substantive rules of the General Agreement"). Although WTO panel decisions are not binding except with respect to the specific parties referred to in the reports, they are often considered persuasive authority by subsequent panels and create legitimate expectations among members. *See, e.g.*, WTO Dispute Settlement Panel Report on Japan — Taxes on Alcoholic Beverages, WTO Doc. AB-1996-2, WT/DS1/AB/R, WT/DS10/AB/R, WT/DS22/AB/4, at 11 (Nov. 1, 1996); *see also* David Palmeter & Petros C. Mavroidis, *The WTO Legal System: Source of Law*, 92 AM. J. INT'L L. 398, 404 (1998) (noting that "it is reasonable to presume that, absent unusual circumstances, panels will follow the decisions of the Appellate Body in much the same way that a lower court follows the decisions of a higher court"). This was recently demonstrated when a second WTO panel deferred to an earlier panel and appellate body decision, although noting that the prior decisions were not binding precedent. *See* WTO Dispute Settlement Panel Report on India — Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS79/R, ¶ 7.30 (Aug. 24, 1998).

patent owner, taking account of the legitimate interests of third parties."[279]

The first limit to the exception depends on what constitutes "unreasonable conflict with a normal exploitation" of a patent.[280] A patent provides its owner with the right to exclude others;[281] however, in the case of medical procedure patents, unless the patent is licensed, its owner is unlikely to maximize financial benefit from the patent.[282] Accordingly, it is uncommon for a patent owner to refuse to license to others because that refusal would not maximize financial return.[283] It has been suggested that normal exploitation of a patent includes typical activity, such as licensing, and excludes atypical activity, such as refusals to license.[284] The question can thus be rephrased as whether section 287(c) in fact unreasonably conflicts with a patent owner's ability to license the patent.

Although section 287(c) does not completely preclude a patent owner from licensing a patent, it does effectively preclude the owner from licensing direct users.[285] Section 287(c) theoretically still permits the owner of a medical procedure patent to exploit a patent by licensing someone that is not covered by section 287(c). That person would likely be a supplier that could be liable as a contributory infringer — in other words, someone that contributes to a doctor's direct infringement by supplying the doctor with the

---

[279] *See* Carlos M. Correa, *Implementing the TRIPS Agreement in the Patents Field: Options for Developing Countries*, 1 J. WORLD INTELL. PROP. 75, 90 (1998) (stating that article 30 should be interpreted as requiring three conditions be applied, taking into account interests of third parties, but not actually applying these conditions). In addition, it has been suggested that section 287(c) is not a "limited exception" when compared to other exceptions under the United States Patent Act. *See* 142 CONG. REC. S11,843-44 (daily ed. Sept. 30, 1996) (letter of Jennifer Hillman, General Counsel of USTR, to Sen. Hatch) (noting that precluding both damages and injunctive relief "goes far beyond other exceptions provided in title 35").

[280] *See* TRIPS, *supra* note 28, art. 30.

[281] *See* 35 U.S.C. § 271 (1994 & Supp. IV 1998); TRIPS, *supra* note 28, art. 28.

[282] *See supra* notes 137-38 and accompanying text (discussing incentives to license). This excludes the situation of blocking patents whereby a patent is obtained merely to prevent a competitor from using technology covered by the patent and the owner refuses to license the patent to essentially force the competitor out of business.

[283] *See* Hilton Davis Chem. Co. v. Warner-Jenkinson Co., 62 F.3d 1512, 1536 (Fed. Cir. 1995) (Newman, J., concurring), 520 U.S. 17, 40-41 (1997).

[284] It has been suggested that when a patentee refuses to use a patented invention or license it, such nonuse would not constitute exploitation because the term exploit implies some affirmative act, such as licensing. *See* Weissman, *supra* note 215, at 1110 (citing *Black's Law Dictionary* for definition of "exploit"); *see also Franklin Pierce Debates*, *supra* note 116, at 630-31 (presenting comments of patent attorney Robert Armitage).

[285] *See supra* notes 154-58 and accompanying text (describing how section 287(c) provides doctors — direct users — with immunity).

means to infringe.[286] Section 287(c) does not provide immunity from contributory infringement, nor does it provide immunity to any person who is not a medical practitioner.[287] Because section 287(c) provides immunity from damages but does not alter what constitutes direct infringement, it is still possible for contributory infringement to exist.[288] Because of the strict requirements for contributory infringement, it will not exist in every case in which a doctor directly infringes a medical procedure patent.[289] Therefore, a patent owner's ability to exploit a medical procedure patent through licensing is significantly reduced if the pool of potential licensees is limited to contributory infringers. It is questionable whether the limited exploitation available by licensing contributory infringers should even be considered within the definition of "normal" exploitation. A plain text reading of "normal" exploitation encompasses exploitation of the most typical users — the licensing of doctors.[290]

In addition, TRIPS does not require members to recognize contributory infringement. The exclusive rights that each member country must provide under TRIPS are limited to direct infringement, although each nation is free to provide additional rights,

---

[286] *See* 35 U.S.C. § 271(c) (1994 & Supp. IV 1998); *see also supra* note 139 (noting that contributory infringers are often sued for infringement of medical procedure patents).

[287] *See* 35 U.S.C. § 287(c) (Supp. II 1996).

[288] *See id.* In fact, the ability to sue manufacturers as contributory infringers was one reason why a prior bill failed — it declared doctors' activity as not constituting direct infringement and thereby eliminated the possibility of recovery from anyone because direct infringement must exist for contributory infringement to exist. *See* S. 1334, 104th Cong. § 2 (1995); *see also* Public Hearing, *supra* note 19, § 2 (noting sources for additional information concerning legislative history).

[289] *See* 35 U.S.C. § 271(c).

> Whoever offers to sell or sells . . . or imports . . . a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

Id.; *see also* 5 CHISUM, *supra* note 52, § 17.03 (explaining requirements of contributory infringement). The knowledge requirement that must be proven to establish contributory infringement is particularly hard to show. *See, e.g.*, Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 488-90 (1964); Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1469 (Fed. Cir. 1990).

[290] *See* THE AMERICAN HERITAGE DICTIONARY 894 (1976) (defining normal to include "regular, standard, natural, typical").

such as contributory infringement.[291] Because TRIPS only requires members to preclude direct infringement, an "unreasonable conflict with normal exploitation" may only refer to conflict with the exploitation that occurs with direct infringement.

The second limit to article 30's exception is that there cannot be "unreasonabl[e] prejudice" to the "legitimate interests" of the patent holder, keeping in mind the "legitimate interests of third parties."[292] As a preliminary matter, this Article assumes that the patent holder's legitimate interests are distinct from the normal exploitation of a patent, to avoid redundancy.[293] Consistent with the previous analysis that "normal exploitation" only includes licensing to the direct user, the "legitimate interests" of the patent holder should encompass all other interests that the owner may have in the patent. For example, legitimate interests would include licensing contributory infringers and refusing to license or even use the patented invention.[294]

The "third parties" to which article 30 refers presumably include all unauthorized users of a patent.[295] For medical procedure patents, medical practitioners are relevant third parties whose interests are relevant; however, patients should also be considered third parties. They might be third parties either based on actual use of the patented invention or because their interests are affected by whether medical practitioners can use the patented invention.[296] For this analysis, whether doctors alone or doctors and patients are

---

[291] *See* TRIPS, *supra* note 28, art. 28(1) (prohibiting third parties from directly infringing, but not prohibiting anyone from assisting in direct infringing acts); *see also id.* art. 2 (stating that TRIPS is minimum requirement).

[292] TRIPS, *supra* note 28, art. 30.

[293] At first glance, this requirement seems redundant of the previous requirement. However, the two clauses are joined by the conjunctive "and," rather than the disjunctive "or," suggesting that they are intended to be separate requirements.

[294] *See supra* notes 286-89 and accompanying text (discussing contributory infringement). Also, the patent right provides a right to exclude others and does not demand that the patent owner use the invention. *See* 35 U.S.C. § 271.

[295] Although third parties are not defined within article 30, third parties are referenced elsewhere in the TRIPS agreement with regard to a patent owner's right to exclude. In particular, article 28 states that a patent owner has a right to prevent third parties from using a patented invention without the owner's consent. *See* TRIPS, *supra* note 28, art. 28.

[296] In addition, it could be argued that patients are part of the relevant third parties even if they do not directly use the patented procedures because their interests are implicated by the exclusivity of the use of the patented procedures. *See supra* notes 134-43 and accompanying text (discussing implications of patents on patient care); *see also* Portman, *supra* note 29, at 119 (including patients, medical practitioners and general public as relevant third parties).

considered third parties should not make a difference because their interests are aligned.[297]

Once the third parties are identified, the legitimate interests of third parties must be determined. Although article 30 does not define "legitimate interests," other portions of the TRIPS agreement suggest what this term should include. For example, the interests of third parties in using technological knowledge for social and economic welfare could be read into article 30 based on language in other articles of TRIPS emphasizing the need to recognize these interests.[298] Social welfare includes the interests of medical practitioners to have unrestricted access to patented technology.[299] On the other hand, medical procedure patents do not necessarily compromise these interests.[300]

The critical question is whether 287(c) provides access to patented technologies — a legitimate interest of third parties — without unreasonably prejudicing the legitimate interest of patent holders to exploit their patents. Although article 30 itself provides no guidance, a prior draft of this provision does shed some light on acceptable limitations that balance the interests of the patent

---

[297] Both doctors and patients have interests in assuring that access to medical procedures is not restricted. *See supra* notes 134-36 and accompanying text. Although doctors have some additional interests concerning medical procedures that do not overlap with patients, they do not necessarily have to be discussed to engage in the balancing under article 30. For example, the argument that medical procedures impinge on the sharing norm of doctors will not be directly addressed here, although it is acknowledged that it would also likely constitute a "legitimate" interest under article 30.

[298] For example, article 7, which is labeled as "Objectives," emphasizes that protection of intellectual property rights should contribute to "the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." TRIPS, *supra* note 28, art. 7; *see also id.* preamble (noting that public policy objectives of nations need to be respected even though intellectual property rights are private rights). In addition, article 8 explicitly acknowledges the importance of allowing members to adopt laws as necessary to protect public health and public interest. *See id.* art. 8. Professor Reichman has suggested that articles 7 or 8, either standing alone or in conjunction with article 30, should provide developing countries with substantial leeway in "complying" with TRIPS. *See* J.H. Reichman, *Beyond the Historical Lines of Demarcation: Competition Law, Intellectual Property Rights, and International Trade After the GATT's Uruguay Round*, 20 BROOK. L. REV. 75, 100 (1993); *see also* Michael Halewood, *Regulating Patent Holders: Local Working Requirements and Compulsory Licensing at International Law*, 35 OSGOODE HALL L.J. 243, 264-65 (1997) (suggesting that article 8 factors be read into article 30).

[299] *See supra* notes 134-36 and accompanying text.

[300] *See supra* notes 137-48 and accompanying text (discussing illusory problem with restricted access).

holder and those of third parties.[301] These limitations include immunity for prior use,[302] noncommercial private use, experimental use, and government use.[303] Although these examples were not intended to be the only types of situations that article 30 covers,[304] they nonetheless reveal what drafters envisioned as appropriate balances under article 30.[305] All of these examples deal with activity that would normally constitute direct infringement but is excepted from infringement for social policy reasons, for example, to avoid hindering research by imposing liability for mere experimental uses.[306] Furthermore, section 287(c) encompasses activity much broader than these exceptions; it covers a third party's private, commercial use of a patented method.[307]

The examination of the appropriate balance here may not be done anew. Some have suggested that great deference to a member state's determination is appropriate when balancing interests under article 30.[308] But undue deference would result in the TRIPS

---

[301] *See Status of Work in the Negotiating Group: Chairman's Report to the GNG*, GATT Doc. MTN.GNG/NG11/W/76 (July 23, 1990), *reprinted in* GERVAIS, *supra* note 268, at 158 (providing less requirements for "limited exception" provision and stating "[p]rovided that legitimate interests of the proprietor of the patent and of third parties are taken into account, limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, *such as*") (emphasis added).

[302] Although not defined in the prior draft, "prior use" is a term that is recognized in some countries as an equitable principle under patent law that essentially immunizes prior users of technology that elected to forgo patent protection from being sued as infringers by someone that later patents what he has been using. Although not presently an aspect of the United States patent system, Congress recently enacted a limited prior use provision applicable only to business method patents that is a defense to patent infringement. *See* First Inventor Defense Act of 1999, Pub. L. No. 106-113, § 4301, 113 Stat. 1501 (1999).

[303] *See id.*

[304] *See supra* note 301 (indicating that situations are intended to be merely illustrative only by denoting "such as").

[305] It has also been suggested that the categories proposed in prior drafts of article 30 would be properly within the scope of article 30. *See* Correa, *supra* note 279, at 91.

[306] It is presumed that no compensation is required under article 30 because of the omission of language concerning compensation or reasonable compensation, especially because such language is included under article 31. *See* TRIPS, *supra* note 28, arts. 30-31; *see also* WTO Dispute Settlement Panel Report on Indonesia — Certain Measures Affecting the Automobile Industry, WT/DS54/R, ¶ 14.210 (July 2, 1998).

[307] Prior use includes commercial use, but commercial use prior to the existence of a patent whereas 287(c) allows people to use the patented invention. *See* 35 U.S.C. § 287(c) (Supp. II 1996).

[308] It has been suggested, that to the extent the panel and appellate body have authority to review whether article 30 applies, they should exercise extreme deference to member states. *See* J.H. Reichman, *Enforcing the Enforcement Procedures of the TRIPS Agreement*, 37 VA. J. INT'L L. 335, 337 (1997) (noting that dispute settlement panels should "show a high degree of respect for, or deference to, good faith applications of local laws to the facts

provisions' having no meaning because great deference would justify, under article 30, almost any national law.[309] In addition, section 287(c) deserves little deference because Congress engaged in minimal debate concerning TRIPS compliance before enacting it.[310]

---

and issues in dispute."); *see also* Judith Bello, *Some Practical Observations About WTO Settlement of Intellectual Property Disputes*, 37 VA. J. INT'L L. 357, 364-65 (1997) (noting that WTO panel should not usurp role of government negotiations); Rochelle Cooper Dreyfuss & Andreas F. Lowenfeld, *Two Achievements of the Uruguay Round: Putting TRIPS and Dispute Settlement Together*, 37 VA. J. INT'L L. 275, 304-05 (1997) (suggesting that TRIPS violation require some additional showing of violation of nondiscrimination because TRIPS is intended as minimum, rather than "optimum" requirement of intellectual property standards); Peter Lichtenbaum, *Procedural Issues in WTO Dispute Resolution*, 19 MICH. J. INT'L L. 1195, 1233-37 (1998) (suggesting that standard for review in cases other than in anti-dumping context are to be less deferential in light of specific language in Anti-Dumping Agreement, as well as requirement under DSU that panels make "objective assessment" of both legal and factual issues); Neil Weinstock Netanel, *Asserting Copyright's Democratic Principles in the Global Arena*, 51 VAND. L. REV. 217, 311 (1998) (noting that WTO panel should accord more deference to allegedly noncomplying member's good faith interpretation of TRIPS when member state's efforts attempt to accommodate free speech values). *But see* Steven P. Croley & John H. Jackson, *WTO Dispute Procedures, Standards of Review, and Deference to National Governments*, 90 AM. J. INT'L L. 193, 211-12 (1996) (arguing for more balanced standard of review to maintain credibility of WTO system).

[309] *See* Lichtenbaum, *supra* note 308, at 1237 (noting that "[i]f panels deferred to national interpretations, this could result in a number of diverging permissible interpretations . . . [that] 'could transform the WTO into a "tower of Babel" and conflict with the declared object of the WTO dispute settlement procedures to protect legal security'"). Further, undue deference would also contravene the Dispute Settlement Understanding agreement (DSU) that applies to TRIPS. This agreement requires that WTO panels "make an objective assessment of the matter . . . including an objective assessment of the facts of the case and the application of and conformity with the relevant covered agreements." DSU, *supra* note 240, art. 11; *see also* Stewart & Burr, *supra* note 240, at 635-36 (noting that during negotiations United States suggested and then rejected deference to member states). In addition, the Appellate Body has thus far refused to rubber stamp all actions that member states bring under TRIPS. *See, e.g.*, WTO Appellate Body Report on India, Dec. 19, 1999, *supra* note 253, ¶ 66. The Appellate Body, for example, considered Indian law to determine whether it had complied with TRIPS. *See id.* It recognized that to give India the benefit of doubt regarding whether its administrative instructions adequately complied with TRIPS "would be to say that only India can assess whether Indian law is consistent with India's obligations under the WTO Agreement." *Id.* According to the Appellate Body, "[t]his, clearly cannot be so." *Id.*

[310] *See supra* note 20 and accompanying text; *see also* 142 CONG. REC. S11,843 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch) (noting that "[t]he Committee on Finance has not had an opportunity to hold a hearing on this matter to consider these broader ramifications for U.S. trade policy").

b. Article 31

Article 31 applies when a member country allows use of a patented invention not allowed under article 30.[311] Although it does not use the phrase "compulsory license," article 31 essentially governs compulsory licensing of patents. In particular, article 31 states:

> Where the law of a Member allows for other use [other than that allowed under article 30] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected . . . .[312]

The activity that article 31 describes is much more like that to which section 287(c) applies than that described in article 30. Section 287(c) is, literally, a "law . . . [that] allows for other use"[313] of a patent without authorization of the patent holder, and it contemplates use by "third parties authorized by the government."[314] Medical practitioners are the third parties, and the government authorizes their unrestricted use of medical procedure patents under section 287(c).[315] Although section 287(c) does not provide medical practitioners with an affirmative right to use, its provision of immunity is tantamount to that right.[316]

---

[311] *See* TRIPS, *supra* note 28, art. 31 (noting that it applies where member's laws "allows for other use of the subject matter of a patent without the authorization of the right holder"; *id.* art. 31 n.a (defining "other use" as "use other than that allowed under Article 30").

[312] *Id.* art. 31. In addition, article 31 has been presumed to cover compulsory licensing. *See, e.g.*, FREDERICK ABBOTT ET AL., THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS 710-11 (1999); GERVAIS, *supra* note 268, at 165.

[313] It is unclear whether the definition of "other use" for article 31 means that the subject matter under article 31 must be subject matter never included under article 30, or that it means that the subject matter has failed the requirements of article 30. In either event, because the former section concluded that article 30 was ambiguous at best concerning whether it exempted article 287(c), as well as the fact that neither article explicitly has a subject matter requirement, it seems appropriate at this juncture to continue the analysis for article 31.

[314] TRIPS, *supra* note 28, art. 31.

[315] *See generally supra* notes 154-61 and accompanying text (noting that section 287(c) provides doctors with de facto compulsory license).

[316] This reading also seems consistent with patent law, which provides patent owners with a right to exclude, rather than an affirmative right to use. *See* 35 U.S.C. § 271 (1994 & Supp. IV 1998) (providing right to exclude all others, rather than right to use). Accordingly, exemptions from patent doctrine provide immunity from infringement, rather

Article 31 allows noncompliance with the substantive articles of TRIPS — including articles 27 and 28 — where a compulsory license satisfies the following requirements:

(1) the licensed use must be based on its "individual merits,"
(2) the proposed user must first attempt to obtain authorization from the patent owner on "reasonable commercial terms and conditions" within a reasonable period of time (unless in cases of extreme urgency, in which the patent owner must be notified as soon as "reasonably practicable")
(3) the scope and duration of use must be limited to the purpose for which it is authorized,
(4) the use must be non-exclusive,
(4) the use must be non-assignable,
(5) the use must be authorized predominantly for the supply of the domestic market,
(6) the authorized use must be subject to termination when circumstances that led to it cease to exist and are unlikely to occur,
(7) the right holder must be paid "adequate remuneration,"
(8) the legal validity of a determination relating to authorization of use should be subject to judicial review,
(9) any decision relating to remuneration shall be subject to judicial review.[317]

Section 287(c) fails to comply with article 31's requirements on several grounds. First, section 287(c) allows all medical practitioners to use patented inventions that fall within section 287(c) and does not grant the authorization on its individual merits.[318] Article 31 requires that the allowed use be determined on a case-by-case basis, not for entire categories of inventions.[319] Based on this re-

---

than affirmative right to use. *See, e.g., id.* § 271(e). To do otherwise would result in providing more under an exemption than under the original grant of a patent.

[317] TRIPS, *supra* note 28, art. 31. Compulsory licenses as remedies for antitrust violations are subject to additional requirements. *See id.* art. 31(k). Similarly, article 31 provides additional requirements where compulsory licensing is authorized to allow exploitation of a patent that cannot be exploited without infringement. *See id.* art. 31(l).

[318] *See* 35 U.S.C. 287(c) (Supp. II 1996).

[319] *See* GERVAIS, *supra* note 268, at 165 (stating that "compulsory licenses under which certain categories of inventions automatically become eligible for a license would seem to violate this provision"); Correa, *supra* note 254, at 213 (stating that compulsory licenses cannot be "based on *general* rules (e.g., all patents relating to certain kinds of technology) . . ."); *see also* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT, *supra* note 97, at 430 (reprinting Communication from United States (May

quirement alone, section 287(c) fails to comply with article 31 because it treats all medical procedure patents uniformly, rather than looking at the merits of each medical procedure patent.[320] In addition, section 287(c) does not require medical practitioners to attempt to negotiate a license or even inform the patent holder after an emergency use where there is no time to seek prior permission.[321] Furthermore, section 287(c) does not provide any remuneration, much less the "adequate remuneration" that article 31 requires.[322] Because section 287(c) does not comply with the requirements of articles 30 and 31,[323] its failure to comply with articles 27 and 28 is not permissible.[324]

11, 1990) that states that "[e]ach case involving the possible grant of a compulsory license shall be considered on its individual merits" in proposed article 27).

[320] *See* 35 U.S.C. 287(c).

[321] *Compare id.* (allowing medical practitioners to use patented inventions without any need to try to negotiate licenses on reasonable terms), *with* TRIPS, *supra* note 28, art. 31(b) (contemplating that proposed users will attempt to negotiate licenses with patent holders prior to use). Further, article 31 should only be triggered after efforts to achieve licenses on "reasonable commercial terms and conditions" have been unsuccessful within a reasonable period of time. *See* TRIPS, *supra* note 28, art. 31(b). This requirement may be waived in the event of "circumstances of extreme urgency." *Id.* But, even in such situations the right holder must still be notified "as soon as reasonably practicable" of the use. *Id.* In contrast, section 287(c) does not require the medical practitioner to ever notify the patentee of use either before or after the patented invention is used. *See* 35 U.S.C. § 287(c) (providing no requirements for negotiation).

[322] *Compare* 35 U.S.C. § 287(c) (providing no remuneration requirement), *with* TRIPS, *supra* note 28, art. 31(h) (requiring "adequate remuneration"). Granted, it is conceivable that a patent owner may obtain monetary relief from persons other than medical practitioners, such as contributory infringers who are not included under the terms of section 287. *See* 35 U.S.C. § 287(c) (providing exception only to direct infringement and inducement to infringe); *see also supra* note 139 and accompanying text (describing how manufacturer may be sued). However, article 31 does not state that the right holder should be entitled to remuneration for some unauthorized uses of the patent. *See* TRIPS, *supra* note 28, art. 31. Rather, article 31 specifies what must apply for every use of a patent that is not authorized. *See id.* Thus, section 287(c) would still fail to comply with this reasonable remuneration requirement even if the patentee were able to obtain remuneration from those who are not medical practitioners.

[323] *See* TRIPS, *supra* note 28, art. 31(i)-(j) (requiring judicial review of decision authorizing compulsory licensing).

[324] In addition, it would be difficult to revise section 287(c) such that it would comply with article 31 while still addressing the concerns of the medical community. For example, TRIPS requires that the patent owner be notified prior to or as soon as possible after the unauthorized use. *See id.* art. 31(b). For a doctor to notify the patentee concerning use, the doctor must as a threshold matter at least be aware of the existence of a patent. Thus, a doctor would have the burden of both (a) determining whether there was a relevant patent, and (b) seeking out the patent owner. However, doctors have objected to patenting and enforcing medical procedure patents on the very ground that they do not want to be involved in determining whether patents exist that they must be aware of. *See supra* note 15 and accompanying text. Thus, doctors would probably find such a requirement to be an onerous one. In addition, although it has been suggested that blan-

3. Implications of a TRIPS Violation

Regardless of whether section 287(c) is ever adjudged to violate TRIPS, it raises important international policy implications.[325] While there is a serious question as to whether section 287(c) violates TRIPS, even an appearance of a TRIPS violation may impact how other member nations implement TRIPS and how they react to the United States in future discussions regarding intellectual property protection. The United States has always aggressively en-

---

ket royalty rates could be used to assure access with minimal intrusion into patient confidentiality, such rates would not necessarily comply with TRIPS. A license based solely on the number of uses may not comport with the TRIPS requirement that the license be based on "the circumstances of each case" that take into account the "economic value of the authorization." *See* TRIPS, *supra* note 28, art. 31(h).

[325] Although this section has concluded that there is at least a viable argument that section 287(c) is presently in violation of TRIPS, the United States is not necessarily in immediate danger of being subject to formal action under TRIPS. So far, official disputes under TRIPS have been raised by member states that are directly and adversely impacted by the failure of another member state to comply with TRIPS. In each case where a nation has asserted a TRIPS violation, the complaining nation's own intellectual property rights were at stake; in particular, the complainants' intellectual property rights were negatively affected because inadequate protection resulted in free riding and loss of revenue to the complaining party. *See, e.g.*, Request for Consultations by Canada Concerning EC — Patent Protection for Pharmaceuticals and Agricultural Chemical Products, WT/DS153/1 (Dec. 2, 1998) (alleging European Community's ("EC") failure to comply with TRIPS article 27(1), on basis that EC regulations discriminate with respect to subject matter because they only apply to pharmaceuticals and agricultural products); Request for Consultations by EC Concerning Canada — Patent Protection of Pharmaceutical Products, WT/DS114/1 (Dec. 19, 1997) (alleging Canada's failure to provide adequate protection to pharmaceuticals in violation of TRIPS articles 27(1), 28, and 33); Request for Consultations by United States Concerning Portugal — Patent Protection Under the Industrial Property Act, WT/DS37/1 (Apr. 30, 1996) (alleging Portugal's failure to provide adequate term of patent protection in violation of TRIPS articles 33, 65 and 70); Request for Consultations by United States Concerning Pakistan — Patent Protection for Pharmaceuticals and Agricultural Chemical Products, WT/DS36/1 (Apr. 30, 1996) (alleging Pakistan's failure to provide adequate patent protection or mailbox rights for pharmaceuticals in violation of TRIPS articles 27, 65 and 70). The section 287(c) violation does not fit the same mold. Because TRIPS explicitly allows medical procedures to be excluded from patentability and most other nations deny such patentability, there may be no adverse impact on other states. Thus, other member states may lack the motivation to raise a formal challenge despite the existence of technical noncompliance. *See, e.g.*, Portman, *supra* note 29, at 119 (noting that countries who already *ban* patents on medical and surgical procedures are unlikely to complain about TRIPS violation regarding this subject matter). *See generally* Reichman, *supra* note 308, at 347 (suggesting that WTO "should insist on a showing of material injury to the complainant state as a prerequisite to intervention at the international level" in context of suggestion for some doctrine of ripeness for WTO disputes). This may suggest that TRIPS is an inadequate mechanism for enforcing international norms of intellectual property protection. However, a discussion of whether such norms should be enforced through a means that is less tied to trade impacts is beyond the scope of this Article.

forced its intellectual property rights;[326] further, the United States has taken an aggressive posture in both negotiating and enforcing the TRIPS agreement.[327] Other nations may be less likely to uphold the TRIPS provisions if they perceive that the United States, a major proponent of the TRIPS agreement, ignores its provisions.[328] Accordingly, former PTO Commissioner Bruce Lehman noted that section 287(c) "is troubling on the international front" because it makes it more difficult to require other countries to fully implement the TRIPS agreement.[329]

Moreover, an actual or perceived TRIPS violation might undermine any future United States arguments for stronger intellectual property protection. For example, the United States may lose bargaining power in future TRIPS discussions concerning the scope of patentability. In particular, it may put the United States in a poor negotiating position with respect to TRIPS article 27(3)(b), which currently allows countries to preclude patentability of genetically

---

[326] For example, the United States has used various trade acts to negotiate intellectual property trade disputes. *See, e.g.*, 2 THE GATT URUGUAY ROUND: A NEGOTIATING HISTORY (1986-1992), at 2255-59 (Terrence P. Stewart ed., 1993) (describing United States's use of section 301 of 1984 Trade Act prior to initiation of Uruguay Round to improve intellectual property protection outside of United States); C. O'Neal Taylor, *The Limits of Economic Power: Section 301 and the World Trade Organization Dispute Settlement System*, 30 VAND. J. TRANSNAT'L L. 209, 225-42 (1997); *see also* James McIlroy, *American Enforcement of Intellectual Property Rights: A Canadian Perspective*, 1 J. WORLD INTELL. PROP. 445, 445-57 (1998) (providing overview of approaches that United States has used to unilaterally enforce its intellectual property rights).

[327] Beginning with the Tokyo Round of GATT the United States began introducing the idea of intellectual property rights into the GATT regime. At that time, the idea was limited to counterfeited trademarks and their adverse impact on trade. *See Agreement on Measures to Discover the Import of Counterfeit Goods*, GATT Doc. L/4817 (July 31, 1979). The United States initially stood alone in its desire to link trade with intellectual property. *See* HUGO PAEMEN & ALEXANDRA BENSCH, FROM THE GATT TO THE WTO: THE EUROPEAN COMMUNITY IN THE URUGUAY ROUND 84-85 (1995) (noting that United States was initially alone in desiring all intellectual property to be included in Uruguay Round). The United States continued to persist and eventually succeeded in putting intellectual property on the Uruguay Round agenda. *See, e.g.*, GERVAIS, *supra* note 268, at 10-28; Michael L. Doane, *TRIPS and International Intellectual Property Protection in an Age of Advancing Technology*, 9 AM. U. J. INT'L L. & POL'Y 465, 466-76 (1994).

[328] *See* 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, General Counsel of USTR, to Sen. Hatch); *see also id.* at S11,846 (statement of John Kirk, chair of ABA) (cautioning against enacting legislation that would send dangerous precedent to other countries with respect to weakening patent protection); *id.* (letter from AIPLA) (noting that enacting section 287 would "clearly be inimical to the interests of American industry for the United States to take the lead in weakening the patent protection required under Articles 28 and 30 of the TRIPS").

[329] *See Hearings on S. 507 Before the Senate Comm. on the Judiciary*, 105th Cong., 1stss Reg. Sess. (1997) (statement of Bruce Lehman, PTO Commissioner) (responding to question from Chairman Hatch about § 287(c)).

modified plants and animals.[330] Although the United States wants broader subject matter patentability,[331] it consented to article 27(3) as part of enacting TRIPS as a package deal.[332] This provision hurts the United States because it is narrower than the United States patentability standard and thus fails to protect American inventors abroad.[333] In addition, the language in article 27(3) can lead to unpredictable patentability of plants and animals, which is similarly troubling.[334] Indeed, language similar to TRIPS article 27(3) has resulted in inconsistent case law concerning whether genetically modified plants are patentable.[335] Although the United States ultimately wants to eliminate the article 27(3) exemption, its position may now be undermined by its perceived failure to comply with TRIPS.[336]

---

[330] *See* TRIPS, *supra* note 28, art. 27(3)(b).

[331] *See, e.g., United States Draft Agreement, supra* note 97, at 428 (proposing article 23 that states that "patents shall be granted for all products and processes which are new, useful, and nonobvious" without any subject matter restrictions); *GATT: Intellectual Property Provisions Hearings on H.R. 4894 Before the Subcomm. on Intellectual Property and Judicial Administration of the House Comm. on the Judiciary and S. 2368 Before the Subcomm. on Patents, Copyrights, and Trademarks of the Senate Comm. on the Judiciary*, 103d Cong. 403 (1994) (statement of biotechnology company Genentech regarding biotechnology industry's desire for broad definition of patentable subject matter); International Chamber of Commerce, Policy Statement: The Review of TRIPS article 27.3 <http://www.iccubo.org/Commissions/Intellectual_property/Review_of_TRIPS.htm> (on file with author) (noting that article 27(3)(b) arose out of fierce controversy over clause).

[332] *See, e.g.*, David G. Scalise & David Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT'L L. 83, 114 (1995). In addition, the United States would like this provision to be deleted. *See* WTO Implementation Report: Trade-Related Intellectual Property Rights, Mar. 11, 1996 <http://www.ustr.gov/reports/wto/intellectual_property.html> (on file with author).

[333] Piracy is a particular problem for the biotechnology industry because typically substantial expenditures are required for development, but replication is inexpensive. *See, e.g.*, Elizabeth Henderson, *TRIPS and the Third World: the Example of Pharmaceutical Patents in India*, 11 EUR. INTELL. PROP. REV. 651, 659-60 (1997); *see also* Sudhir D. Ahuja, *IP Treaties Show Little Effect in India*, IP WORLDWIDE, Jan.-Feb. 1999, *available in* LEXIS, Nexis Library, Current file (noting this problem of piracy in India). Although United States patents can compensate for an initial investment of capital, the compensation is not complete if the invention can be easily duplicated abroad.

[334] *See, e.g.*, Harvard/Onco-mouse, 1991 Eur. Pat. Off. Rep. 525 (Examining Div.), 1990 Eur. Pat. Off. Rep. 501 (EPO Tech. Bd. App.), *rev'g* 1990 Eur. Pat. Off. Rep. 4 (Examining Div.).

[335] *See, e.g.*, Robin Nott, *The Novartis Case in the EPO*, 21 EUR. INTELL. PROP. REV. 33 (1999); Ingeborg Voelker, *Europe Won't Reverse Controversial EPO Ruling*, IP WORLDWIDE, July-Aug. 1997 <http://www.ljx.com/patents/7-8europe.html> (on file with author).

[336] United States negotiating power in the context of TRIPS may also be undermined by a recent enactment to United States copyright laws. In fact, a formal complaint against the United States has already been raised by the EC regarding United States amendments to the Copyright Act that allow public places to play music without payment of royalties;

CONCLUSION

Congress should repeal section 287(c) because the statute not only fails to accomplish the main objective of the medical community in eliminating the specter of litigation against doctors, but also has negative ramifications for domestic and international policies. Until section 287(c) is repealed, the ability of the United States patent system to promote innovation will continue to be compromised. Moreover, the immunity provision leaves the United States vulnerable to international criticism and diminishes its ability to raise the level of intellectual property protection worldwide.

At a minimum, section 287(c) should be revised to comply with TRIPS and to foster innovation in accordance with patent law and policy. Even if compulsory licensing of medical procedure patents is to be maintained, the present system that automatically licenses all of these patents without compensation violates article 31 of TRIPS. A more nuanced system that considers the individual nature of each medical procedure patent is necessary to comply with TRIPS and to fulfill the patent system's policy of promoting innovation.

The repeal or revision of section 287(c) is only a necessary first step in resolving the tension between the medical and patent systems. As previously noted, section 287(c) does not entirely address the issues of conflict between the two systems; personal liability for doctors continues to exist under section 287(c), and the principles of sharing and access to health care that section 287(c) was intended to preserve are still compromised. While repeal is warranted, it would merely return the parties and policies to their prior positions.

The conflict between the medical and patent policies must therefore be revisited and addressed in conjunction with similar conflicts. While this Article argues that patents can be reconciled with medical policies just as patents were reconciled with the norms of the scientific community, reconciling policies would not entirely eliminate conflict. In particular, although the scientific community has adjusted to the concept of patents, the use and

---

this has been contended to be in violation of TRIPS art. 9(1). *See* Request for Consultations by EC Concerning the United States — Section 110(5) of U.S. Copyright Act, WT/DS160/1/IP/D/16 (Jan. 26, 1999). Regardless of whether the United States is eventually found adjudged to violate either provision of TRIPS, both situations undermine the United States claim to strong intellectual protection.

enforcement of patents has not been without criticism. In addition, recent developments in the area of patenting biotechnology have raised renewed objections to patents that mirror those of the medical community — harm to the sharing norm and restricted access to medical procedures.

These similar conflicts should be addressed together because piecemeal discussion will likely result in disparate treatment of different technologies by the patent system. Accordingly, to truly resolve the tension between patent and medical policies, the underlying conflicts must be addressed along side similar issues raised in other technological fields. Hopefully, next time patent policies intersect with other social policies, such a comprehensive approach will lay the groundwork for a complete consideration of all relevant interests and thereby serve the interest of all parties.