

Note

An Unacceptable Exception: The Ramifications of Physician Immunity from Medical Procedure Patent Infringement Liability

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Medical procedure patents first drew political attention in 1993 after Samuel Pallin sued fellow doctor Jack Singer for infringing his cataract surgery procedure patent.¹ The lawsuit resulted in an outcry from the medical community,² culminating in a vote of the American Medical Association (AMA) House of Delegates to condemn medical and surgical procedure patents.³ In response to the AMA's lobbying,⁴ Congress passed 35 U.S.C. § 287(c), which did not change the patentability of medical procedures, but instead made medical professionals and their associated healthcare entities immune from infringement liability.⁵

With the passage of § 287(c), Congress created significant problems. First, because medical procedure patents are now unenforceable,⁶ they are effectively useless.⁷ It is impossible to

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1. Bradley J. Meier, Note, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. LEGIS. 265, 265 (1997); see *Pallin v. Singer*, No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996).

2. William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 651 (1995). One physician stated that a victory by the plaintiff in the lawsuit could cause "profoundly devastating and mind-boggling consequences." *Id.* The AMA called these patents "horrendous." *Id.*

3. *Id.*

4. See Eric M. Lee, *35 U.S.C. § 287(c)—The Physician Immunity Statute*, 79 J. PAT. & TRADEMARK OFF. SOC'Y 701, 707 (1997).

5. See 35 U.S.C. § 287(c) (2000).

6. Beata Gocyk-Farber, Note, *Patenting Medical Procedures: A Search*

determine how many medical procedures have gone undeveloped as a result of lost funding due to unenforceable patents.⁸ Even for developed procedures, doctors may now be resorting to trade secrecy to obtain protection because Congress has eliminated the benefits of patent protection.⁹ Second, § 287(c) violates the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).¹⁰ Any TRIPS violation sets a precedent for other nations to apply similar exceptions to other technologies.¹¹ The United States must take the lead in intellectual property enforcement,¹² because reduced intellectual property protection results in lost jobs and increased costs to U.S. consumers.¹³ Thus, the growing importance of intellectual property protection abroad warrants further review of any provision in which U.S. compliance with TRIPS is questionable.¹⁴

This Note argues that because § 287(c) violates TRIPS, Congress must find an alternative solution that appropriately balances the ethical and economic concerns regarding medical

for a *Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, 1557 (1997) (describing how the statute renders “patents unenforceable against the most frequent users of the patented procedures”).

7. See 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (“A patent without a meaningful remedy against infringement is like no patent at all.”).

8. Cf. *id.* (stating that it is unknown whether medical procedures develop swiftly without patent protection).

9. See Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN’S L. REV. 329, 365 (1997). These arguments are equally applicable against § 287(c). See Cynthia M. Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 613 n.54 (2000).

10. See 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (arguing that the statute raises questions about compliance with TRIPS); Ho, *supra* note 9, at 655–70 (detailing § 287(c)’s noncompliance with TRIPS).

11. See Ho, *supra* note 9, at 671–72.

12. Susan C. Schwab, U.S. Trade Representative, Remarks to the U.S. Chamber of Commerce (Sept. 28, 2006), at 12, available at http://www.ustr.gov/assets/Document_Library/Transcripts/2006/September/asset_upload_file794_9872.pdf?ht=.

13. Cf. 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch) (“Virtually every trade expert believes that worldwide adherence to TRIP [sic] means jobs for American workers, and lowered costs for American consumers as piracy of products is reduced and others pay their fair share of research and development costs.”).

14. Tackling the problems of intellectual property enforcement abroad is a priority of the United States. Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317, 317 (2006); Schwab, *supra* note 12, at 2.

procedure patents. Part I describes the general patentability of medical procedures under U.S. law and the debate over these patents. Part II discusses the problems that § 287(c) poses under TRIPS. Finally, Part III addresses potential solutions and proposes a TRIPS-compliant compulsory licensing system. This Note concludes that the most appropriate way to address the ethical concerns regarding medical procedure patents while providing an incentive to innovate is to adopt a compulsory licensing scheme that meets the TRIPS criteria.

I. THE DEBATE OVER MEDICAL PROCEDURE PATENTABILITY

The patent system derives from Congress's constitutional power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹⁵ Patents are considered necessary to encourage innovation by protecting the capital investments required to develop new technology.¹⁶ Thus, the function of patents is not to reward inventors,¹⁷ but to "secure the invention for public benefit."¹⁸

It is well established that medical procedures are patentable under U.S. law.¹⁹ Since 1954, when the Patent Office held that medical and surgical methods were patentable,²⁰ numerous medical and surgical procedure patents have been issued.²¹ After the Pallin litigation, however, the AMA called for Congress to abolish these patents.²² The following sections describe the arguments for and against patentability of medical

15. U.S. CONST. art. I, § 8, cl. 8.

16. Noonan, *supra* note 2, at 656.

17. See NUNO PIRES DE CARVALHO, *THE TRIPS REGIME OF PATENT RIGHTS* 2 (2d ed. 2005).

18. Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139, 1148 (1987).

19. Ho, *supra* note 9, at 611.

20. See *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107, 110 (1954) (rejecting prior holdings that prohibited medical procedure patents). For one such holding, see *Morton v. New York Eye Infirmary*, 17 F. Cas. 879, 883–84 (1862).

21. See Noonan, *supra* note 2, at 653–55.

22. See AMA COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, CEJA REPORT 1-A-95, *ETHICAL ISSUES IN THE PATENTING OF MEDICAL PROCEDURES* 8 (1995), available at http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_1a95.pdf [hereinafter *AMA REPORT*] (describing the various ethical objections to medical procedure patents and urging Congress to outlaw the practice).

procedures and the congressional response to the AMA's concerns.

A. THE ARGUMENTS FOR AND AGAINST PATENTABILITY

The AMA argued that medical procedure patents compromise patients' rights to privacy, practitioners' freedom, the dissemination of information, and access to procedures at reasonable costs.²³ However, many academics consider patents necessary to encourage investment in the invention and development of new technologies.²⁴ These proponents argue that the AMA's ethical objections have no force because, in the absence of patents, innovation is stymied.²⁵ Thus, more people are harmed in the absence of patent protection because many beneficial procedures go undeveloped.²⁶

1. Patients' Rights to Privacy

Opponents of medical procedure patents argued that monitoring medical activity for infringement would compromise physician-patient confidentiality.²⁷ This confidentiality benefits public and individual health because "it encourages the patient to fully disclose his condition[, which makes] diagnosis more accurate and therapy more effective."²⁸ Yet, even opponents noted that it is possible to enforce patents without compromising confidentiality.²⁹ Infringement litigation does not require disclosure of confidential patient information.³⁰ Moreover, in practice, patient confidentiality is not absolute even in the absence of patent infringement litigation.³¹ Thus, most scholars have dismissed this confidentiality argument.³²

23. *See id.* at 3–7.

24. *See, e.g.,* Noonan, *supra* note 2, at 656–57.

25. *See* Burch, *supra* note 18, at 1142; *see also* 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) ("It is impossible to state categorically . . . that tomorrow's advances in 'pure' medical procedures will take place as expeditiously as possible absent patent protection.").

26. *See* Burch, *supra* note 18, at 1142 (describing the link between medical procedure patents and increased quality of health care).

27. *See* AMA REPORT, *supra* note 22, at 5.

28. Burch, *supra* note 18, at 1155.

29. *See* AMA REPORT, *supra* note 22, at 5.

30. Lee, *supra* note 4, at 715.

31. Burch, *supra* note 18, at 1155.

32. *See, e.g.,* Ho, *supra* note 9, at 633–34; Lee, *supra* note 4, at 715.

2. Practitioner Freedom and Doctors' Duties to Patients

The AMA also expressed concern that a patent could influence a doctor's medical judgment.³³ Some physicians might perform an inferior procedure rather than license the patented procedure or risk an infringement suit.³⁴ Thus, these patents decrease physician autonomy³⁵ and compromise a doctor's duty to provide the best medical care to the patient regardless of cost.³⁶ On the other hand, proponents of medical procedure patents noted that absolute discretion of the physician is unrealistic notwithstanding patent considerations.³⁷ Furthermore, the fiduciary duties that doctors already face alleviate any potential compromise to patient care.³⁸ Because doctors have a duty to fully disclose all of their interests when giving the patient a choice of procedures, the patient is able to make an informed decision, taking the costs of licensing and alternate procedures into consideration.³⁹

3. Incentives to Disclose: Preventing Secret Procedures

The AMA argued that medical procedure patents encourage physicians to withhold information—an incentive which violates the obligation of the medical profession to “share techniques as needed.”⁴⁰ Physicians believe that patenting these procedures slows the dissemination of information about new techniques to the public.⁴¹ Thus, opponents of medical procedure patents argued, when a physician has the option of patenting a medical technique, she will be more likely to refrain from publishing that technique in a medical journal until she files her patent application or even until the patent is issued.⁴²

This contention ignores the fact that publication does not preclude patentability in the United States if the patent appli-

33. See AMA REPORT, *supra* note 22, at 3.

34. See Lee, *supra* note 4, at 703; Burch, *supra* note 18, at 1152–53.

35. Burch, *supra* note 18, at 1141.

36. See Gocyk-Farber, *supra* note 6, at 1547.

37. See Burch, *supra* note 18, at 1154.

38. Meier, *supra* note 1, at 267.

39. *Id.*; see also Joseph M. Reisman, Comment, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355, 371 (1995) (noting that a doctor owes a fiduciary duty to her patients).

40. AMA REPORT, *supra* note 22, at 2.

41. Meier, *supra* note 1, at 268.

42. See AMA REPORT, *supra* note 22, at 4; see also Gocyk-Farber, *supra* note 6, at 1548.

cation is filed within one year of publication.⁴³ In fact, proponents of medical procedure patents argue that these patents reduce secrecy by *requiring* disclosure,⁴⁴ which is one of the primary purposes of patent law.⁴⁵ Without this protection, physicians could choose to protect their inventions as trade secrets.⁴⁶ This alternative would be detrimental to the health system,⁴⁷ because many procedures would not be available to the general public.⁴⁸

4. Access to Procedures and the Incentive to Innovate

The argument the AMA stressed most heavily was that medical procedure patents would result in reduced availability of procedures.⁴⁹ A patentee could restrict the number of licenses or charge a high price for licensing—actions which would decrease patient access to the treatments and increase patient costs.⁵⁰ Additionally, patented procedures are not peer-reviewed—unless they are licensees, other physicians cannot study patented procedures without infringing the patent.⁵¹ These arguments are compelling; however, they only apply if innovation would continue to occur absent patent protection.⁵²

43. See 35 U.S.C. § 102(b) (2000); Meier, *supra* note 1, at 268.

44. See Gocyk-Farber, *supra* note 6, at 1539.

45. See *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186–87 (1933) (“In consideration of [the inventor’s] disclosure and the consequent benefit to the community, the patent is granted. An exclusive enjoyment is guaranteed him for seventeen years, but upon the expiration of that period, the knowledge of the invention enures to the people, who are thus enabled without restriction to practice it and profit by its use.”), *amended by* 289 U.S. 706 (1933).

46. See Katopis, *supra* note 9, at 365; *cf.* Christopher T. Kent, Note, *Reducing the Scope of Patent Protection and Incentives for Innovation Through Unfair Application of Prosecution History Estoppel and the Recapture Rule*, 10 GEO. MASON L. REV. 595, 625 (2002) (noting that “if the value of the patent monopoly is reduced,” inventors may “resort to trade secrets”).

47. See Burch, *supra* note 18, at 1142 (stating that the advancement of medical knowledge increases the quality of society’s healthcare system).

48. See J.H. Reichman, *Legal Hybrids Between the Patent and Copyright Paradigms*, 94 COLUM. L. REV. 2432, 2507 (2006) (describing the social costs of trade secrecy to include the obligation to hide valuable information from the public).

49. See AMA REPORT, *supra* note 22, at 3–5.

50. *Id.* at 3; *see also* 142 CONG. REC. S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist) (“[H]ealth care costs would explode if doctors charged licensing fees for every new surgical or medical techniques [sic] they developed.”).

51. AMA REPORT, *supra* note 22, at 4.

52. See Burch, *supra* note 18, at 1142.

If eliminating medical procedure patents removes the incentive to innovate, the result would be a decrease, rather than an increase, in the availability of medical procedures.⁵³ Thus, the AMA's argument only has force if the medical procedures would have been developed in the absence of patent protection.⁵⁴

The AMA supported its claims by suggesting that patenting medical procedures was unnecessary to promote innovation because "the development of medical processes usually relies on intellectual curiosity rather than the availability of capital for research and development."⁵⁵ This argument reflects an assumption that physicians develop medical procedures, unlike medical devices and pharmaceuticals, during the course of practice.⁵⁶ Additionally, the AMA asserted that professional rewards such as recognition, respect, and publication were sufficient to encourage invention.⁵⁷

No empirical study has determined the developmental costs of medical procedures.⁵⁸ While it is true that, unlike medical devices and pharmaceuticals, medical procedures do not require the investment necessary to gain FDA approval,⁵⁹ it is impossible to state categorically that these procedures are inexpensive to develop. Indeed, several notable medical procedures required significant funding to develop.⁶⁰ The Surrogate

53. See 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) ("It would be really quite tragic if we were to find that a very large loophole were to be opened in the patent system that would cause investment in some of the most important technology—not just from an economic point of view but from a life-saving point of view, to cause that investment to dry up."); Katopis, *supra* note 9, at 385 ("[The] lack of benefit for these investors would lead to limited patient access to new discoveries as people would be reluctant to invent.").

54. See Burch, *supra* note 18, at 1142 ("If the grant of a medical process patent decreases the availability of a health care process, an ethical objection may arise. This ethical objection fails, however, if patent protection is necessary to make the medical procedure possible in the first place.").

55. AMA REPORT, *supra* note 22, at 7; see also 142 CONG. REC. S12,024 (daily ed. Sept. 30, 1996) (statement of Sen. Frist) ("[U]nlike innovations in medical devices or drugs, pure-procedure innovations do not require huge investments of capital.").

56. Ho, *supra* note 9, at 615–16.

57. *Id.* at 614; see also AMA REPORT, *supra* note 22, at 6 (describing how the "prospect of publication" provided an incentive for Dr. Pallin to develop the new cataract surgery procedure).

58. Ho, *supra* note 9, at 615.

59. See Todd R. Miller, *The International Suture: A Comparative Approach to Patenting Methods of Medical Treatment*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 443, 446 (1996).

60. See Lee, *supra* note 4, at 716.

Embryo Transfer procedure research required a \$500,000 capital investment because the National Institutes of Health would not provide financial support.⁶¹ This funding would not have been available were there no chance that the invention could be patented,⁶² because private investors view patents as important for securing returns on their investments.⁶³ Thus, the arguments against patenting medical procedures hold no force if eliminating these patents “kill[s] the ‘goose that lays the golden egg.’”⁶⁴ The costs of patenting are warranted if the procedure would never have been developed in the absence of patent protection.⁶⁵

B. THE CONGRESSIONAL RESPONSE: THE MEDICAL PRACTITIONER IMMUNITY STATUTE

After the AMA’s protest, Congress considered legislation designed to address the ethical concerns of the AMA and opponents of medical procedure patents.⁶⁶ Senator Greg Ganske first proposed a bill that excluded medical procedures from patentability.⁶⁷ Senator Bill Frist responded by introducing the Medical Procedures Innovation and Affordability Act, which provided that it is not infringement for a patient, physician, or licensed healthcare practitioner to use or induce others to use a patented medical procedure.⁶⁸ In the debate over these bills, legislators decided early on to focus on the available remedies

61. 142 CONG. REC. S11,847 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (citing Noonan, *supra* note 2, at 656–57); Lee, *supra* note 4, at 716.

62. *See* 142 CONG. REC. S11,847 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (citing Noonan, *supra* note 2, at 656–57); Lee, *supra* note 4, at 716.

63. *See* Gocyk-Farber, *supra* note 6, at 1541 (“Private investors are attracted by the promise of a reasonable return on their investment and patents are the equivalents of such a promise.”).

64. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (quoting Commissioner Lehman).

65. *See* Burch, *supra* note 18, at 1142 (“Medical process patents therefore are justified insofar as they encourage the advancement of medical knowledge, which in turn increases the overall quantity and quality of society’s health care.”).

66. *See* Ho, *supra* note 9, at 606–07.

67. Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J. PAT. & TRADEMARK OFF. SOC’Y 789, 790 (1996); *see* Medical Procedures Innovation and Affordability Act, H.R. 1127, 104th Cong. (1st Sess. 1995).

68. Mossinghoff, *supra* note 67, at 794; *see* Medical Procedures Innovation and Affordability Act, S. 1334, 104th Cong. (1st Sess. 1995).

for infringement rather than on patentability.⁶⁹ This compromise between the Ganske and Frist proposals was appended to the Omnibus Consolidated Appropriations Act and signed into law on September 30, 1996.⁷⁰

The resulting statute exempts medical practitioners and their employers from liability for infringing a medical procedure patent filed after September 30, 1996.⁷¹ Thus, the patentee has no remedy for a medical practitioner's or related healthcare entity's infringement.⁷² Although the inventor has a patent on his procedure, it is the equivalent of "no patent at all."⁷³ This solution is problematic. It provides no means for a patentee to collect royalties, and thus creates no financial incentive to innovate.⁷⁴ Moreover, without patent enforcement, doctors are encouraged to protect their innovations as trade secrets.⁷⁵ Finally, the amendment violates TRIPS and may have serious implications for intellectual property protection abroad.⁷⁶ This final concern is the focus of this Note.

II. THE INTERNATIONAL ASPECT OF THE DEBATE OVER MEDICAL PROCEDURE PATENTS

The World Trade Organization (WTO) was established in 1995, and TRIPS is a mandatory component of the WTO sys-

69. Mossinghoff, *supra* note 67, at 795.

70. Lee, *supra* note 4, at 708; *see* Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009, 3009-67 to 3009-69 (1996).

71. *See* 35 U.S.C. § 287(c) (2000).

72. Lee, *supra* note 4, at 708.

73. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch).

74. *See id.* at S11,847 (describing the Surrogate Embryo Transfer procedure and arguing that patents are necessary for innovation when the costs of research are high).

75. *See* Katopis, *supra* note 9, at 365. It follows that if the amendment results in medical procedure patents being the equivalent of "no patent at all," 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch), the same trade secrecy could result from § 287(c). *Cf.* Ho, *supra* note 9, at 613 n.54 ("[A]rguments against the patenting of medical procedures are equally applicable to arguments against enforcing medical procedure patents . . .").

76. *See* 142 CONG. REC. S11,843-44 (daily ed. Sept. 30, 1996) (letter from Jennifer Hillman, Office of the U.S. Trade Representative) (describing the international implications of the proposed limitation); *id.* at S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (describing the complicated issues the statute raises under TRIPS and stating that "[t]here is no consensus on these issues").

tem.⁷⁷ Thus, as a member of the WTO, the United States is subject to TRIPS, a comprehensive agreement on intellectual property protection.⁷⁸ TRIPS has been extremely successful, providing the United States with “new tools with which to badger recalcitrant countries, especially in the developing world.”⁷⁹ As members of the WTO, many important developing countries are subject to the TRIPS provisions.⁸⁰ These countries are of great economic concern to the United States because of their underdeveloped intellectual property regimes and their potential for economic, political, and social power.⁸¹

During the debate over § 287(c), Senator Orrin Hatch, Chairman of the Senate Finance and Judiciary Committee, repeatedly expressed concern that Congress had failed to adequately address TRIPS compliance.⁸² Others, including the U.S. Trade Representative⁸³ and the American Intellectual Property Law Association,⁸⁴ voiced similar concerns. The following sections detail how § 287(c) violates TRIPS and the potential impact of that violation.

A. MEDICAL PRACTITIONER IMMUNITY VIOLATES TRIPS

TRIPS requires that patents confer on their owners the right to exclude others from making, using, or selling the patented invention.⁸⁵ In addition, patent rights must be available without discrimination by field of technology.⁸⁶ However, under

77. Howard C. Anawalt, *Intellectual Property Scope: International Intellectual Property, Progress, and the Rule of Law*, in *ECONOMICS, LAW AND INTELLECTUAL PROPERTY* 55, 59 (Ove Granstrand ed., 2003).

78. See PIRES DE CARVALHO, *supra* note 17, at 28 (describing the unique “comprehensiveness” of TRIPS).

79. BÉNÉDICTE CALLAN, *PIRATES ON THE HIGH SEAS, THE UNITED STATES AND GLOBAL INTELLECTUAL PROPERTY RIGHTS* 16 (1998).

80. See John F. Delaney, *IP Aspects of Outsourcing*, in *12TH ANNUAL INSTITUTE ON INTELLECTUAL PROPERTY LAW*, at 363, 368 (PLI Patents, Copyrights, Trademarks, & Literary Prop., Course Handbook Series No. 8821, 2006).

81. See Bird, *supra* note 14, at 317–19 (describing developing countries’ weak intellectual property schemes and expanding economic markets).

82. See, e.g., 142 CONG. REC. S11,843, S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch).

83. See *id.* at S11,843 (letter from Jennifer Hillman, Office of the U.S. Trade Representative).

84. See *id.* at S11,845 (letter from Sen. Hatch).

85. See Agreement on Trade-Related Aspects of Intellectual Property Rights art. 28, Dec. 15, 1993, 108 Stat. 4809, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

86. *Id.* art. 27.

Article 30, member countries may provide exceptions to these rights if the “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.”⁸⁷ Article 31 also allows exceptions in the form of compulsory licensing, but imposes certain requirements on those exceptions.⁸⁸ For example, the license must be based on individual merits,⁸⁹ the potential licensee must attempt to negotiate a license with the patentee prior to obtaining a compulsory license,⁹⁰ and the patentee must receive adequate remuneration.⁹¹ This section examines how medical practitioner immunity from infringement liability violates these TRIPS mandates.

1. The Right to Exclude

TRIPS Article 28 requires that a patent provide the patentee with the right to exclude others from making and using the patented invention.⁹² With an infringement exemption for medical procedure patents, patentees have no way of enforcing that right in the United States.⁹³ Patentees cannot sue medical practitioners, the most likely infringers of their product,⁹⁴ for either damages or an injunction prohibiting use of the patented device.⁹⁵ As a result, any medical practitioner can use the patented product without paying royalties. Prohibiting such unauthorized use is the essence of the right to exclude.⁹⁶ Thus,

87. *Id.* art. 30.

88. Ho, *supra* note 9, at 668–69; *see also* TRIPS Agreement, *supra* note 85, art. 31.

89. TRIPS Agreement, *supra* note 85, art. 31(a).

90. *Id.* art. 31(b).

91. *Id.* art. 31(h).

92. *See id.* art. 28.

93. *See* 142 CONG. REC. S11,843 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch) (“The amendment would preclude a certain class of patent-holders from enforcing their patent rights against infringement, a change that renders these patents virtually meaningless.”).

94. *See id.* at S11,845 (letter from Sen. Hatch) (noting that medical practitioners are “the most likely class of infringers” of medical procedure patents).

95. Under 35 U.S.C. § 287(c) (2000), patentees may not sue a medical practitioner or associated healthcare entity for either damages or injunctive relief for performing a medical activity.

96. *See* TRIPS Agreement, *supra* note 85, art. 28 (describing the right to exclude for a process as the right “to prevent third parties not having [the owner’s] consent from the act of using the process”); PIRES DE CARVALHO, *supra* note 17, at 247–51 (describing the scope of the exclusive rights).

§ 287(c) undermines patentees' rights to exclude others from using their inventions, in contravention of TRIPS.

2. Availability Without Discrimination as to the Field of Technology

Under TRIPS, patent rights must be available without discrimination as to the field of technology.⁹⁷ This rule against discrimination is subject to the exclusions from patentability,⁹⁸ but these exclusions apply to *patentability*, not *enforcement*.⁹⁹ Thus, a country may exclude medical procedures from patentability, *but all patents that it grants must be enforceable*.¹⁰⁰ The TRIPS drafters added Article 27 to address concerns that patents would be granted but not enforced,¹⁰¹ which is precisely what Congress authorized in § 287(c).¹⁰² Some critics argue that this discrimination is justified because of ethical concerns,¹⁰³ but TRIPS categorically prohibits all discriminatory acts, whether justifiable or not.¹⁰⁴ Thus, an exception based on enforcement rather than patentability violates TRIPS unless the exception meets the requirements of Article 30 or 31.

3. Acceptable Exceptions

TRIPS Article 30 allows countries to make exceptions to patent rights provided that the 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.”¹⁰⁵ TRIPS allows for only a very narrow exception to patent rights;¹⁰⁶ it does not permit undermining the substantive TRIPS provisions entirely.¹⁰⁷ An earlier draft of Article 30 sug-

97. See TRIPS Agreement, *supra* note 85, art. 27.

98. PIRES DE CARVALHO, *supra* note 17, at 167.

99. Ho, *supra* note 9, at 657–58.

100. *Id.*

101. *Id.* at 659.

102. See *id.* at 613 n.54 (“[S]ection 287(c) precludes complete patent protection by denying full enforceability of patents.”).

103. In support of the medical practitioner infringement exemption, Senator Frist described the AMA’s various concerns regarding medical procedure patents. See 142 CONG. REC. S12,023–24 (daily ed. Sept. 30, 1996). These concerns were all ethical in nature. See *id.*

104. PIRES DE CARVALHO, *supra* note 17, at 170.

105. TRIPS Agreement, *supra* note 85, art. 30.

106. PIRES DE CARVALHO, *supra* note 17, at 306.

107. Ho, *supra* note 9, at 661.

gested prior use, non-commercial use, and experimental use as examples of acceptable exceptions.¹⁰⁸ Although these examples were not included in the final language of TRIPS, they “reveal what drafters envisioned as appropriate balances under [A]rticle 30.”¹⁰⁹

One commentator argues that because medical patents are usually not enforced against doctors, this exemption does not unreasonably conflict with the normal exploitation of patents in the medical field.¹¹⁰ However, in the case of medical procedure patents, medical practitioners are the most likely to use the patent.¹¹¹ Granting these practitioners immunity from liability prevents the patentee from making a profit by licensing technology to those who will use it.¹¹² Furthermore, the § 287(c) exception goes far beyond any of the examples the TRIPS framers suggested. None of these examples goes so far as to prohibit indefinitely enforcement against the most likely users of a patented process.¹¹³ Thus, the exemption seriously undermines the legitimate interests of the patent owner.¹¹⁴ Although patients’ interests are relevant,¹¹⁵ the exceptions cannot “emasculate the general principles established in the agreements.”¹¹⁶

One scholar also suggests that Article 30 is only appropriate in the absence of a specific Article 27 exception.¹¹⁷ Because Article 27 explicitly authorizes exclusion of medical procedures from patentability, Article 30 cannot be used to “dilute” the regular patent rules.¹¹⁸ Thus, the physician immunity statute is not an appropriate exception under Article 30. The physician immunity statute also is not an appropriate compulsory licensing system under Article 31, because it does not meet the speci-

108. See DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS* 158 (1998); see also Ho, *supra* note 9, at 666.

109. Ho, *supra* note 9, at 666.

110. See Mossinghoff, *supra* note 67, at 796–97.

111. See 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch).

112. See Ho, *supra* note 9, at 663.

113. See GERVAIS, *supra* note 108, at 158; see also Ho, *supra* note 9, at 666.

114. See Ho, *supra* note 9, at 661–63.

115. Article 30 takes third-party interests into account when considering the propriety of an exception. See TRIPS Agreement, *supra* note 85, art. 30.

116. Ho, *supra* note 9, at 661.

117. See GERVAIS, *supra* note 108, at 159.

118. *Id.* (“The general exception may thus be invoked only where no special exception exists, and not to dilute rules applying to such specific exceptions.”).

fied requirements.¹¹⁹ Most notably, the patentee receives no royalties.

B. THE IMPACT OF A TRIPS VIOLATION ON THE UNITED STATES

The failure of the United States to adhere to TRIPS may result in trade retaliation.¹²⁰ More importantly, however, it may have serious effects on the ability of the United States to increase intellectual property protection in important emerging economies.

1. The Importance of Intellectual Property Protection in Emerging Economies

Protection of intellectual property assets abroad is a topic of utmost importance to U.S. companies, inventors, and government officials.¹²¹ Intellectual property protection is important for maintaining American jobs and ensuring low costs for American consumers, because piracy results in an unfair competitive advantage for companies that do not pay the costs of research and development.¹²² Emerging economies represent some of the largest potential markets for American products.¹²³ Unfortunately, these markets also present serious difficulties for intellectual property protection.¹²⁴ The United States has led efforts to increase intellectual property protection in these countries and has made large strides toward that goal.¹²⁵ For example, China—one of the most important emerging economies—joined the WTO and became immediately subject to TRIPS.¹²⁶ However, intellectual property protection in China

119. See Ho, *supra* note 9, at 668–70. For a complete list of the Article 31 requirements, see TRIPS Agreement, *supra* note 85, art. 31.

120. Ho, *supra* note 9, at 653.

121. See Bird, *supra* note 14, at 317; Schwab, *supra* note 12, at 2.

122. See 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch).

123. See CALLAN, *supra* note 79, at 31 (“The emerging markets . . . promise an ever growing, ever richer consumer base for IP products.”); Bird, *supra* note 14, at 317–19 (describing the growth of emerging markets and their importance to American firms).

124. See Bird, *supra* note 14, at 318–19 (“The lack of intellectual property rights protection ranks for many firms as the single most significant threat to their international competitiveness.”); Schwab, *supra* note 12, at 1 (illustrating U.S. industries’ losses from piracy).

125. TRIPS has been a success, giving the United States tools with which to encourage developing countries to provide adequate intellectual property protection. See CALLAN, *supra* note 79, at 16.

126. Delaney, *supra* note 80, at 368.

and other emerging economies remains problematic¹²⁷ as underdeveloped enforcement mechanisms allow piracy to run rampant.¹²⁸

2. The Precedential Effects of a U.S. TRIPS Violation

If the United States wishes to continue strengthening its intellectual property protection abroad, it must remain a leader in intellectual property protection.¹²⁹ One of the foremost ways the United States can show leadership is by fully complying with the TRIPS provisions.¹³⁰ The § 287(c) exception is not based upon the optional exclusion from patentability, but upon ethical considerations relating to enforcement,¹³¹ which apply with equal force to pharmaceuticals and medical devices.¹³² These types of intellectual property are key technologies, the rights of which are important for the United States to protect abroad.¹³³ Should § 287(c) remain intact, it will create a dangerous precedent.¹³⁴ Other countries may argue that because of ethical considerations, the legitimate interests of third parties

127. *See id.*

128. Bird, *supra* note 14, at 334.

129. *See* Schwab, *supra* note 12, at 12 (“[I]t is important that we are out in front, that we play a leadership role and lead by example to encourage other countries to do more.”).

130. *See* 142 CONG. REC. S11,844 (daily ed. Sept. 30, 1996) (statement of Sen. Hatch); *see also* Ho, *supra* note 9, at 671 (“[E]ven 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.”).

131. *See* 142 CONG. REC. S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist).

132. The AMA was once concerned with the patenting of drugs and medical devices. *See* Katopis, *supra* note 9, at 353–54. While the incentives to innovate are arguably different, the ethical concerns over patenting medical devices are virtually the same as the ethical concerns about medical procedure patents. *See id.* at 356. Similarly, developing nations often cite access to pharmaceuticals as a justification for compulsory licensing. *See* Susan Vastano Vaughan, *Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?*, 25 HASTINGS INT’L & COMP. L. REV. 87, 101–02 (2001).

133. The loss to the pharmaceutical industry due to intellectual property infringement is estimated at twenty-two billion dollars per year. Schwab, *supra* note 12, at 1.

134. *See* Ho, *supra* note 9, at 672 (“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.”); Meier, *supra* note 1, at 276–77 (“Since the new law allows an infringement liability exception, other GATT-TRIPS members might follow this example and apply this type of exception to other technologies.”).

justify exceptions for other technologies, such as pharmaceuticals or medical devices, under TRIPS Article 30.¹³⁵ Given the growing importance of intellectual property rights abroad, especially in the field of pharmaceuticals,¹³⁶ this is a risk that Congress must seriously consider.

III. SOLUTIONS TO THE DEBATE OVER MEDICAL PROCEDURE PATENTS

Before Congress adopted § 287(c), the AMA argued for the complete exclusion of medical procedures from patentability.¹³⁷ If § 287(c) were repealed, the AMA would likely resurrect this argument. Conversely, others would argue that medical procedures should be eligible for fully enforceable patent protection. Parts III.A and III.B describe why these solutions are unsatisfactory. Part III.C proposes an appropriately designed compulsory licensing system that will address the AMA's ethical concerns while maintaining the incentive to innovate.

A. THE PROBLEMS WITH ELIMINATING PATENTABILITY

The physician immunity statute largely addresses the ethical concerns of the medical community.¹³⁸ If Congress were to repeal this exemption because of its TRIPS implications, many physicians would argue that medical procedure patents should be excluded altogether.¹³⁹ This solution is unsatisfactory. Some important medical procedures would not have been developed

135. The general exceptions can be applied to any field of technology, not just those specifically exempt. *Cf.* GERVAIS, *supra* note 108, at 159 (describing how the general exception only applies when no specific exception exists). Thus, other parties to TRIPS may apply such an exception to other technologies. Meier, *supra* note 1, at 276–77.

136. *See* Schwab, *supra* note 12, at 1 (describing the pharmaceutical industry's losses from piracy).

137. *See generally* AMA REPORT, *supra* note 22 (describing the AMA's ethical objections to medical procedure patents).

138. *See* 142 CONG. REC. S12,023 (daily ed. Sept. 30, 1996) (statement of Sen. Frist) (citing healthcare costs, invasion of privacy, the exchange of information, and peer review as reasons for the legislation); AMA REPORT, *supra* note 22, at 2–5 (citing increased costs of health care, patient confidentiality, and the availability of information as justifications for opposing medical procedure patents).

139. For instance, during the debate over the Ganske amendment, which would have forbidden the Patent and Trademark Office from issuing patents on medical procedures, “no one spoke against the basic thrust of the litigation.” Mossinghoff, *supra* note 67, at 792.

without private funding.¹⁴⁰ The AMA argues that these are rare exceptions.¹⁴¹ However, as technology develops, the cost of new medical procedures is increasing.¹⁴² At the same time, public funding for such procedures is decreasing.¹⁴³ Private funds for research are not available without patent protection,¹⁴⁴ because private investors view patentability as important for ensuring returns on their investments.¹⁴⁵ While medical practitioners may view public notoriety and the health of their patients as sufficient rewards for their innovation, these benefits will not satisfy a private investor.¹⁴⁶ Thus, without patents, venture capitalists will be unwilling to invest,¹⁴⁷ and without capital, doctors cannot afford to develop new procedures. If medical procedures are not patentable, it is impossible to determine how many innovations will be lost due to a lack of funding.¹⁴⁸

In the absence of patent protection, physicians and investors would need to protect procedures that were developed at high costs as trade secrets in order to recoup their invest-

140. For example, the Surrogate Embryo Transfer procedure required significant cost to develop. See Noonan, *supra* note 2, at 657. The researchers were forced to obtain private funding after the National Institutes of Health refused to fund the research. *Id.*

141. See AMA REPORT, *supra* note 22, at 7 (“[Surrogate Embryo Transfer] is one obvious counterexample, yet this alone does not undermine a prohibition on patenting of medical procedures, as we do not, in any context, require general rules to meet the impossible condition of working faultlessly.”).

142. See Burch, *supra* note 18, at 1143.

143. *Id.*

144. See 142 CONG. REC. S11,847 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (“It seems unlikely that the inventor of the [Surrogate Embryo Transfer] process would have gotten this private funding if the process was not patentable subject matter.”).

145. See Gocyk-Farber, *supra* note 6, at 1541 (providing that investors believe patents will ensure a return on their investments); cf. Ove Granstrand, *Innovations and Intellectual Property Studies: An Introduction and Overview of a Developing Field*, in ECONOMICS, LAW AND INTELLECTUAL PROPERTY 9, 15 (Ove Granstrand ed., 2003) (“[W]hen innovations require investments, as for most technological innovations, some laws for public or private provision of the investments are required.”).

146. See Granstrand, *supra* note 145, at 11 (“[I]ncentive structures differ among individuals, some preferring monetary rewards in the first place, some fame and social recognition, some satisfaction from achievement and so forth.”).

147. See Gocyk-Farber, *supra* note 6, at 1541.

148. See 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (providing that patent protection is a means of ensuring efficient medical procedure development); Noonan, *supra* note 2, at 656 (“[T]he patent grant is considered necessary to . . . protect large capital investments that are often required to develop new technologies.”).

ments.¹⁴⁹ Physicians could use trade secrecy to maintain monopolies and charge high prices.¹⁵⁰ This response would harm society because many procedures would remain hidden from the general public.¹⁵¹ Furthermore, other physicians might try to develop similar procedures independently, a tactic which wastes societal resources by promoting duplicative research rather than new discoveries.¹⁵² Thus, the risks of eliminating medical procedures from patentability are too great to justify the ethical concerns these patents present.

B. THE PROBLEMS WITH FULLY ENFORCEABLE MEDICAL PROCEDURE PATENTS

An alternative to eliminating medical procedures from patentability is to simply repeal § 287(c).¹⁵³ This approach would make medical procedure patents fully enforceable and reinstate incentives to innovate. However, this approach does not address the ethical concerns of the AMA and other opponents of these patents. Most significantly, fully enforceable patents on medical procedures would likely result in limited patient access to the procedures.

Patentees could control the licenses they grant through enforcement of their patents.¹⁵⁴ Although patentees would have the incentive to license their procedures to as many physicians

149. Cf. Kent, *supra* note 46, at 625 (stating that inventors may seek trade secret protection if the value of patent protection decreases).

150. Trade secrets are valuable because they are not known or ascertainable by others. See KENNETH L. PORT ET AL., LICENSING INTELLECTUAL PROPERTY IN THE INFORMATION AGE 24–27 (2d ed. 2005).

151. See Reichman, *supra* note 48, at 2507 (“The well-known social costs of trade secret protection stem principally from the innovator’s expenses in preserving secrecy and from the obligation not to disclose technically valuable information to the public.”).

152. See Kent, *supra* note 46, at 625–26 (“[I]nstead of spending their resources on improvements of a disclosed innovation, they will be wastefully spending on research that duplicates the research of their competitor. As a result, the pace of innovation will slacken.”). Scholars have expressed similar concerns in other scientific fields. See Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means?*, 7 COMP. L. REV. & TECH. J. 255, 261–62 (2003) (describing how, in the absence of gene patents, overly duplicative “research and science would lead to a most inefficient and unethical result”); Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 35 (1999) (“Scientists, instead of sharing their discoveries in a timely fashion, are protecting them as trade secrets. This has resulted in wasteful duplication of research . . .”).

153. See Ho, *supra* note 9, at 674–75.

154. See Gocyk-Farber, *supra* note 6, at 1544–45.

as possible to increase revenues,¹⁵⁵ licensees would not have access to any legal mechanism to ensure that these licenses are granted as widely as possible and at a reasonable price.¹⁵⁶ For example, patentees could charge high license prices for procedures that were relatively inexpensive to develop. Furthermore, patentee doctors would be tempted to refuse licenses to hospitals with which they compete so as to attract patients and reduce competition. This alternative approach could cause the very outcomes the AMA feared—increased healthcare costs and decreased availability of procedures.

C. A COMPULSORY LICENSE SYSTEM IN LIGHT OF TRIPS

Eliminating medical procedures from patentability fails to address patentees' and investors' needs, but repealing § 287(c) neglects patients' interests. A solution that balances the concerns of the medical community with incentives to innovate is necessary. Adopting a compulsory licensing scheme for medical procedure patents offers an ideal solution.¹⁵⁷ Although the United States has typically been highly skeptical of compulsory licensing systems,¹⁵⁸ the currently imposed physician immunity statute is essentially the equivalent of a compulsory license without remuneration.¹⁵⁹ Unlike § 287(c), a compulsory licensing system ensures that patentees receive financial rewards for their inventions. Thus, in light of the goals of the U.S. patent system, a compulsory licensing system that complies with TRIPS Article 31 is a preferable alternative to the current system. If designed properly, such a system will ensure that the incentive to innovate is maintained without limiting patient access to procedures.

155. Cf. Amy L. Landers, *Working Together in a Digital World: An Introduction*, 84 DENV. U. L. REV. 199, 205 (2006) (suggesting collection of royalties as an incentive to license patents).

156. Cf. Gocyk-Farber, *supra* note 6, at 1545 (“[T]he patentees may charge any price for the licenses and royalties. The prices are regulated by the market; thus, according to a basic supply and demand theory.”).

157. Other articles have suggested that compulsory licensing may be a solution, but none has offered a detailed suggestion. See Ho, *supra* note 9, at 674; Miller, *supra* note 59, at 455; Noonan, *supra* note 2, at 664.

158. See Ho, *supra* note 9, at 647 (“Congress has provided for very few statutorily imposed compulsory licenses and has restricted the scope of those licenses.”).

159. See *id.* at 607 (calling the statute a “royalty-free, compulsory license”).

1. A Proposed Compulsory Licensing System

In order to effectively address ethical concerns while providing an incentive to innovate, Congress should adopt a compulsory licensing system including the following provisions:

First, if the parties are unable to negotiate a license after reasonable effort, a potential licensee (whether an individual healthcare provider or an employer on behalf of all its healthcare providers) may apply to an administrative board for a license to use the procedure for all patients meeting specified criteria.¹⁶⁰ If the board finds that this class of patients will benefit from the procedure, it will determine a reasonable royalty based on fair market value that the licensee must pay the patentee for each procedure.¹⁶¹ Such a license will be non-exclusive and non-assignable. In the case of an emergency, however, the medical professional may use a patented procedure without prior authorization¹⁶² and must apply for a license within a reasonable time after use of the procedure, at which time the board will determine adequate remuneration.¹⁶³

Second, a patentee may waive the requirement that potential licensees individually negotiate for a license by submitting her patent to the board to determine a reasonable royalty. The board will then grant a universal license for a reasonable royalty to medical practitioners to practice the procedure on all patients meeting certain criteria. Finally, all decisions of the board shall be subject to judicial review. Any licenses granted will be available for treatment only within the United States.

A system with these features will ensure that the United States is in compliance with TRIPS. It will also maintain the incentive to innovate, while requiring that the procedure be available to all those in need.

2. TRIPS Compliance

TRIPS recognizes exceptions to patent enforceability in the form of compulsory licensing, provided the licensing scheme

160. TRIPS only permits use when the potential licensee has made previous efforts to obtain authorization from the patentee. *See* TRIPS Agreement, *supra* note 85, art. 31(b).

161. This authorization of use of the patented process is based on individual merits. *See id.* art. 31(a).

162. TRIPS allows waiver of the requirement of previous negotiation in the case of national emergency or extreme urgency. *See id.* art. 31(b).

163. *Id.* art. 31(h).

meets the requirements of Article 31.¹⁶⁴ First, an application for a compulsory license must be “considered on its individual merits.”¹⁶⁵ Thus, certain categories of inventions may not automatically become eligible for a license.¹⁶⁶ “The mere fact that the prospective licensee has unsuccessfully attempted to obtain a voluntary license from the patent owner is not a sufficient reason for the grant of a compulsory license.”¹⁶⁷ The proposed system does not automatically grant licenses. Instead, the board will grant a license only if the procedure will benefit a class of patients. Therefore, this proposed compulsory licensing regime satisfies this TRIPS requirement.

Second, a user must make reasonable efforts to obtain a license on reasonable commercial terms, except in the case of an emergency.¹⁶⁸ By allowing a potential licensee to apply for a patent only after making a reasonable effort to negotiate a license, the proposal meets this requirement. While the proposal allows the patentee to waive this requirement, this provision does not conflict with the normal exploitation of the patent or prejudice the patent owner, because the patentee is still paid adequate remuneration, but with lower transaction costs.¹⁶⁹ Finally, by allowing physicians to use the procedure without permission in the case of an emergency, the proposal addresses the realities of medical practice.

Third, “the scope and duration of such use [must] be limited to the purpose for which it was authorized.”¹⁷⁰ The proposed compulsory licensing regime allows the board to grant a license for use on a class of patients who meet certain criteria. Thus, the license is restricted to use on patients who will benefit from the procedure, meeting the requirements of Article 31(c).

164. *See id.* art. 31. This Note does not describe in detail sections (d), (e), (f), (i), or (j), as the language of the proposal on its face meets these requirements.

165. *Id.* art. 31(a).

166. GERVAIS, *supra* note 108, at 165; PIRES DE CARVALHO, *supra* note 17, at 318.

167. PIRES DE CARVALHO, *supra* note 17, at 319.

168. *See* TRIPS Agreement, *supra* note 85, art. 31(b).

169. TRIPS Article 30 states that “[m]embers may provide 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.” *Id.* art. 30.

170. *Id.* art. 31(c).

Fourth, the license must be “terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.”¹⁷¹ This termination decision may consider the interests of the licensee.¹⁷² The compulsory licensing regime permits licenses for only a class of patients who will benefit from the procedures because they meet certain criteria. When no patient meets the specified criteria, the license ceases to exist. However, if patients continue to require the procedure, the license will continue. Although this approach results in a potentially indefinite license, TRIPS does not *require* the right to be limited in time.¹⁷³ Instead, it must only be limited to the extent that circumstances require.¹⁷⁴ Thus, the proposal is consistent with TRIPS Article 31(g).

Fifth, and perhaps most important, is the requirement that “the right holder . . . be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”¹⁷⁵ This remuneration should be approximately what a license would cost if the patent owner were to grant it.¹⁷⁶ This provision is the most evident reason that the royalty-free license created by § 287(c) cannot pass muster as a compulsory license under TRIPS.¹⁷⁷ In contrast, the compulsory licensing approach requires the board to determine an appropriate licensing fee. Thus, it provides remuneration and is consistent with TRIPS.

3. Effects on the Incentive to Innovate

The primary concern with eliminating medical procedure patents is that private investors will refuse to invest in non-patentable procedures.¹⁷⁸ Compulsory licensing addresses this concern by providing patentees with royalties at fair market value. While compulsory licensing with minimal compensation may have deleterious effects on innovation, providing royalties

171. *Id.* art. 31(g).

172. *See id.* (providing that liability is “subject to adequate protection of the legitimate interests of the persons so authorized”).

173. *See id.* (requiring termination only “*if and when*” it is no longer necessary, not *when* it is no longer necessary (emphasis added)).

174. *See id.*

175. *Id.* art. 31(h).

176. GERVAIS, *supra* note 108, at 166.

177. *See Ho, supra* note 9, at 669.

178. *See* 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch); Noonan, *supra* note 2, at 656.

at fair market value provides adequate incentives.¹⁷⁹ Although patentees will not get the monopoly benefit that they could get by refusing licenses, this result is justified by the public benefit of wide access to procedures.¹⁸⁰ Since the purpose of patent law is not individual reward,¹⁸¹ “[t]he essential needs of the society as a whole may outweigh the exclusive rights of an individual patentee.”¹⁸² As with individual licenses, investors in this system will recoup their investments through royalties. Thus, this system provides the necessary incentive that patent law strives to maintain.

4. Financial Costs of Licensing

Opponents claim that licenses will raise the cost of health care, because the licensing fees will be passed on to the patients.¹⁸³ However, as described in Part III.A, the cost to patients is far greater if the procedure had never been developed or freely shared in the first place. Under a compulsory licensing regime, patentees will not be able to abuse patents by refusing licenses or by demanding exorbitant fees. Instead, the board will determine a reasonable royalty to encourage innovation without placing unreasonable costs on the public. Thus, a compulsory licensing scheme ensures that procedures will be developed and shared while preventing unreasonable excess costs.

5. Transaction Costs and the Chilling Effects of Potential Litigation

Some commentators are concerned that healthcare costs will increase because doctors will need to research patents to avoid infringement.¹⁸⁴ While this compulsory licensing regime requires a patentee to take reasonable steps to negotiate an in-

179. See Vastano Vaughan, *supra* note 132, at 104.

180. *Cf. id.* at 101 (“U.S. Congress balanced human need for access to medical procedures against the potential damper on innovation and concluded that human need was paramount.”).

181. See PIRES DE CARVALHO, *supra* note 17, at 2–6; Burch, *supra* note 18, at 1148.

182. Kirby W. Lee, *Permitted Use of Patented Inventions in the United States: Why Prescription Drugs Do Not Merit Compulsory Licensing*, 36 IND. L. REV. 175, 181 (2003).

183. See Miller, *supra* note 59, at 445–46; Meier, *supra* note 1, at 266–67.

184. See, e.g., AMA REPORT, *supra* note 22, at 3 (“[P]hysicians face a substantial legal risk every time they decide to introduce a new procedure or a modification of an existing procedure . . . because use of a patented procedure without [a license] constitutes unlawful infringement.”).

dividual license, as required by TRIPS,¹⁸⁵ the patentee may waive this requirement to decrease transaction costs. Patentees therefore have an incentive to waive this requirement so they will receive the same remuneration without the expense of negotiating with multiple individual licensees. Thus, universal licenses will cover most procedures. The patentees will also have an incentive to inform all doctors and healthcare entities about the procedure and universal license. If patentees teach more doctors about the procedure, they gain potential licensees. This approach will reduce the onus on physicians to research patented procedures.

Even in the rare case that a patentee does not submit her patent for a universal license, incentives for innovation justify the small risk of litigation. Although the AMA expressed concern over litigation, the “economic realities of modern American patent infringement litigation do not suggest that a wave of medical procedure patent litigation is about to sweep over the country.”¹⁸⁶ The risk of litigation from unintentional infringement is relatively small, because the people most likely to enforce their patents are those attempting to recoup significant investments.¹⁸⁷ It is also unlikely that a court will award an injunction if ethical concerns suggest that the patented procedure should be available to the public.¹⁸⁸ Thus, the incentives to in-

185. See TRIPS Agreement, *supra* note 85, art. 31(b).

186. Noonan, *supra* note 2, at 661.

187. Cf. 142 CONG. REC. S11,845 (daily ed. Sept. 30, 1996) (letter from Sen. Hatch) (“Historically, 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.”).

188. The U.S. Supreme Court recently held that traditional principles of equity are applicable in intellectual property disputes. See *Ebay Inc. v. Mercexchange*, 126 S. Ct. 1837, 1839 (2006). In doing so, the Court rejected the rule that a court will award permanent injunction in patent disputes upon a showing of infringement and validity. See *id.* at 1841. Thus, in order to receive a permanent injunction:

A plaintiff must demonstrate: (1) that it has suffered irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

Id. at 1839. If withholding a patented procedure from the public is unethical, the public interest would be disserved by a permanent injunction, so this four-factor test will not be satisfied.

novate that patents provide justify these slight risks, which are required by TRIPS.¹⁸⁹

CONCLUSION

In its implementation of 35 U.S.C. § 287(c), Congress failed to address compliance with TRIPS. This omission resulted in a TRIPS violation with a potentially huge impact for the United States. Trading partners could use the United States as an example to justify other exceptions to patent enforcement, creating problems for intellectual property enforcement abroad. However, repealing the statute creates serious ethical problems. Alternatively, excluding medical procedures from patentability will not provide the necessary incentive to innovate in an increasingly expensive field. A compulsory licensing scheme addresses the ethical concerns while providing an incentive to innovate and remaining consistent with TRIPS. Ensuring that the United States is in full compliance with TRIPS will set an example to its trading partners, encouraging them to do the same. This approach strengthens the ability of the United States to enforce intellectual property rights abroad at a time when patenting those rights is of the utmost importance for United States companies and legislators.

189. See TRIPS Agreement, *supra* note 85, art. 31(b) (requiring an attempt to individually negotiate a license).