

COMPULSORY LICENSING PROPOSAL FOR
SURGICAL AND MEDICAL PROCEDURE PATENTS,
An Alternative to the Limitations of Remedies for Patent Infringement
under § 287(c) of the Patent Act

Introduction

Recent events of the past year have once again sparked the debate over whether patents should be issued for surgical procedures¹ This debate is not new; rather, it has been going on for over 150 years.² There are passionate, justifiable, and convincing arguments on both sides of the issue. In response to this debate, Congress enacted legislation which eliminates one remedy a surgical or medical procedure patent owner might seek against an infringer of her or his patent.³

The purpose of this paper is not to engage in a justification for or against the patentability of surgical and medical procedure patents. On the contrary, this paper is written from the premise that these procedures should remain patentable and enforceable. The objective of this paper is to suggest one possible solution that redresses the concerns that people have regarding the patenting of surgical procedures without sacrificing the goals of patent law. Before we can see where we should go, it is important to see where we have been.

History of Patents

The Framers of the United States Constitution knew of the importance of technological progress.⁴ The Constitution reads:

The Congress shall have the power...

(8) To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.⁵

¹ William D. Noonan, MD, JD, *Patenting Medical and Surgical Procedures*, 77 J. Pat & Trademark Off. Soc'y 651, 651 (1995).

² *Id.* at 2.

³ 35 U.S.C. § 287(c)(1) (1996) as amended by Public Law 104-208, the Omnibus Consolidation Appropriation Act for 1997.

⁴ Paul Gormley, *Compulsory Patent Licenses and Environmental Protection*, 7 Tul. Envtl. L.J. 131, 2 (1993).

⁵ U.S. Const. art. I, §8, cl. 8.

This provides inventors with an incentive to create new products and processes.⁶ Congress has limited the duration of the monopolistic protection.⁷ In return for the protection, the inventor must disclose his invention to the Patent Office which, in turn, discloses the information to the general public.⁸

The Patent Act was drafted to accomplish two goals.⁹ First, it encourages innovation and discovery through its incentive of limited monopoly¹⁰ Second, the patent system promotes the disclosure of useful technology to the general public by putting it in the public domain.¹¹

Surgical procedure patents are not a new phenomena.¹² One of the earliest medical procedure patents was Morton's 1846 patent for the use of ether as anesthesia during surgery.¹³ Although his patent was eventually found to be invalid due to insufficient inventiveness, the court failed to prohibit the genre of medical process patents.¹⁴

The right granted to the patent owner is the right to exclude others from making, using, or selling his or her invention without his or her permission.¹⁵ The inventor can exercise several options relating to his patented invention. He or she can practice the art himself, permit someone else to practice the art, both practice the art himself and permit someone else to practice the art, or decide not to practice the art and not allow any one else to practice the art.

The inventor may license his or her patent to another. The license could permit the recipient the privilege to make, use or sell the inventor's invention. A license is a contractual promise, a covenant, by the inventor not to sue the licensee for using, making, or selling (depending on the license) the inventor's invention. In return for the license, the inventor is permitted to be compensated in the form of payment or royalties.

⁶Paul Gormley, *Compulsory Patent Licenses and Environmental Protection*, 7 Tul. Envtl. L.J. 131, 2 (1993)

⁷35 USC § 154 (1994)

⁸Paul Gormley, *Compulsory Patent Licenses and Environmental Protection*, 7 Tul. Envtl. L.J. 131, 2 (1993)

⁹Earl Kintner & Jack Lahr, *An Intellectual Property Primer*, 10, (2d ed., 1982)

¹⁰*Id.* @ 10-11

¹¹*Id.* @ 10-11

¹²William D. Noonan, MD, JD, *Patenting Medical and Surgical Procedures*, 77 J. Pat & Trademark Off. Soc'y 651, 652 (1995).

¹³U.S. Patent No, 4,848.

¹⁴*See Morton v. New York*, 17 F.Cas. 879 (No. 9865) (S.D.N.Y.1862)

¹⁵35 U.S.C. § 154

While a patent owner has the option to license his or her invention, in most cases, he or she is not obligated to do so.¹⁶ It is not an abuse to refuse to license a patent.¹⁷ If the inventor chooses to sit on his or her rights and not practice the patent nor license it to another, that is his or her right under the United States' Patent Act barring a few notable exceptions.¹⁸ The general rule is to allow for free market transactions to insure proper compensation.¹⁹ The size, diversity, and wealth of the population of the United States all lead to attractive market incentives to exploit intellectual property through market transactions.²⁰

Compulsory Licenses in the United States

Although rare, there are three categories of exemptions in the United States when a patent owner may be obligated to license his or her invention. First, there may be provisions in specific statutes passed by Congress that mandate mandatory licensing of relevant inventions.²¹ Second, there are cases where the failure to not permit licensing would result in antitrust violations.²² Third, there are cases where a court decides not to issue an injunction after finding infringement, whereby the court allows the infringing act to continue.²³

Congress has enacted a few statutes which contain provisions for mandatory, compulsory licensing of relevant patented inventions. A compulsory license is “[a] permission to use intellectual property, compelled by the government in order to accomplish some political or social objective.”²⁴ Three such statutes are the Clear Air Act,²⁵ the Atomic Energy Act²⁶, and the statute to protect plant varieties (Plant Protection Act).²⁷ The underlining justification for compulsory licensing in these statutes is that the health, safety, and welfare of the citizens of the United States would be compromised if the patented invention were not adequately licensed.

¹⁶Donald S. Chisum and Michael A. Jacobs, *Understanding Intellectual Property Law*, § 4E[7] (1992).

¹⁷35 U.S.C. § 271(d)(4)

¹⁸ *United States v. Studiengesellschaft Kohle*, 670 F.2d 1122 (DC Cir. 1981).

¹⁹Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[2] (1994)

²⁰*Id.*

²¹Alan M. Fisch, *Seeking the Intersection of Two Legal Sets: A review of the Commercial Law of Intellectual Property*, 19 Colum. VLA J.L. & Arts 301, 307 (1995)

²²Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[1] (1994)

²³*See Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir), *cert denied* 293 U.S. 576 (1934)

²⁴J.T. McCarthy, *McCarthy's Desk Encyclopedia of Intellectual Property* 51-52 (1991)

²⁵42 U.S.C. § 7608

²⁶42 U.S.C. § 2183(g) (1995)

²⁷U.S.C. § 2404 (1995)

The tremendous benefit to the public through mandatory licensing outweighs the interest of the patent owner not to license.

The Clean Air Act permits mandatory licensing whenever the Attorney General finds (1) an otherwise unavailable patent is needed to accomplish the goals of the Clean Air Act, (2) no reasonable alternative methods exist that satisfy its goal, (3) the unavailability of such license “may result in a substantial lessening of competition.”²⁸ If the Attorney General does find the patented invention satisfies these three conditions, the patent owner is required to license his or her invention “on reasonable terms and conditions.”²⁹

Similar to the Clean Air Act, the Atomic Energy Act contains provisions for compulsory licensing.³⁰

The Commission may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (1) the invention of discovery covered by the patent is of primary importance in the production or utilization of special nuclear material or atomic energy; and (2) the licensing of such invention or discovery under this section is of primary importance to effectuate the policies and purposes of this chapter.³¹

Although, a patent is deemed to be in the “public interest,” this does not necessarily guarantee that the inventor will be obligated to license his or her invention to anyone.³² It only permits the Commission to use the invention covered by the patent in performing its powers under the Atomic Energy Act.³³ First, the potential licensees must apply to the Commission for a license.³⁴ Then, a hearing must be conducted whereby the Commission must determine if the applicant is entitled to a license.³⁵ If the Commission finds (1) the invention covered by the patent is of primary importance [as defined by goals of the Act], (2) the licensing of such invention is of primary importance to the activities of the applicant, (3) the applicant’s proposed use for the patent license is in furtherance of the goals of the Act, and (4) “such applicant cannot

²⁸42 U.S.C. § 7608

²⁹*Id.*

³⁰42 U.S.C. § 2183(g) (1995)

³¹42 U.S.C. § 2183(a)

³²*Id.*

³³42 U.S.C. § 2183(b)(1)

³⁴42 U.S.C. § 2183(c)

³⁵*Id.*

otherwise obtain a patent license from the owner on terms which the Commission deems to be reasonable... the Commission shall license the applicant to use the invention.”³⁶ Conversely, regardless of the “public interest” of the invention, if the applicant is able to negotiate with the patent owner for a fair and equitable license, as determined by the Commission, then the Commission will not issue a license.³⁷

If the Commission does issue a license, it will be narrow in scope.³⁸ The use will be limited to that which was stated in the application.³⁹ It will be a non-transferable, non-exclusive license with reasonable royalty fees paid to the patent owner.⁴⁰

A third statute which contains provisions for compulsory licenses is the Plant Protection Act.⁴¹ The Secretary of Agriculture may grant a compulsory license for a patent protected plant, if he or she determines that it is

“necessary in order to insure an adequate supply of fiber, food, or feed in this country and its owner is unwilling or unable to supply the public needs...at a price which is reasonably deemed fair.”⁴²

As in both the Clean Air Act and the Atomic Energy Act, there must be (1) a showing of some strong public interest or need for the patented invention, (2) no other appropriate substitute available and (3) no other way to license the patent. All three of these elements must be met before the Secretary will issue a compulsory license.⁴³ As in the prior two statutes, a reasonable royalty rate shall be paid to the patent owner.⁴⁴

A second category of exceptions to the general rule against compulsory licensing of patents is seen when the failure to not permit licensing would result in antitrust violations.⁴⁵ “Judicial decrees in antitrust cases...may have the effect of compulsory licensing.”⁴⁶ One such

³⁶42 U.S.C. § 2183(e)

³⁷*Id.*

³⁸42 U.S.C. § 2183(f)

³⁹*Id.*

⁴⁰42 U.S.C. §§ 2183(a)(2) & (g)

⁴¹7 U.S.C. § 2404.

⁴²*Id.*

⁴³*Id.*

⁴⁴*Id.*

⁴⁵Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[1] (1994)

⁴⁶Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[2][d] (1994)

case is *United States v. Glaxo Group* where the court imposed a compulsory license as a remedy to its finding an antitrust violation.⁴⁷ Like the Atomic Energy Act's statutory compulsory license provision, each grant of permission will be done on a case-by-case basis against proven antitrust violators.⁴⁸

A third category when the United States may impose compulsory licensing is through a court's decision not to grant an injunction after finding an inventor's patent was infringed.⁴⁹ Although the general rule is to provide injunctive relief⁵⁰ in intellectual property infringement cases, there are exceptions.⁵¹ A court may permit the infringing activity to continue, if an injunction would result in immense detriment to a public interest.⁵² Normally, the public has an interest in insuring intellectual property rights are enforced.⁵³ However, there are instances when denying an injunction is in the best interest of the public.⁵⁴ The terms of the permission to continue to use the patented invention will be limited to what is necessary to prevent the harmful effect. For example, in order to protect the public welfare, the court in *Milwaukee v. Activated Sludge, Inc.*, failed to issue an injunction. In accordance with the rules of equity, a court can impose compensation in the form of reasonable royalties to be paid from the infringer to the patent owner.⁵⁵

The general prohibition on compulsory licensing of intellectual property is also seen in the 1976 Copyright Act (Copyright Act).⁵⁶ Like the patent laws, the copyright laws contain no general provisions for compulsory licensing.⁵⁷ In contrast to the Patent Act, the Copyright Act does contain provisions for compulsory licenses in several, specific situations.⁵⁸ These provisions were deemed necessary as a remedy to the impasse which had occurred in the

⁴⁷ 410 U.S. 52, 60-63 (1973)

⁴⁸ *Id.*

⁴⁹ Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.06[2] (1994)

⁵⁰ *See* 35 U.S.C. 283

⁵¹ Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.06[2] (1994).

⁵² *See Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 593 (7th Cir), *cert denied* 293 U.S. 576 (1934)

⁵³ Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.06[2] (1994)

⁵⁴ *Id.*

⁵⁵ *Foster v. American Machine & Foundry Co.*, 492 F.2d 1317, 1319 (2d Cir), *cert denied* 419 U.S. 833 (1974)

(based infringement damages measured as reasonable royalties under 35 U.S.C. § 284

⁵⁶ 17 U.S.C. §§ 101-1010. (1994)

⁵⁷ Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[2][b] (1994)

⁵⁸ 17 U.S.C. §§ 111, 115, 116, 119 (1994).

negotiations between interested parties.⁵⁹ In most cases, the compulsory licensing provisions only take effect after there is a failure of private bargaining.⁶⁰ Therefore, in these instances, compulsory licensing is only implemented as a last resort when other methods of negotiations have proven to be futile.

The Copyright Act also provides for “fair use” exemptions whereby the use of the copyrighted material would not be an infringement.⁶¹ Although, technically not a compulsory license, it does provide users, other than those authorized by the copyright holder, to enjoy some rights that would otherwise be an infringement.⁶² The drafters of the Copyright Act, designed it to be an “equitable rule of reason.”⁶³ Therefore, each case is very fact intensive and requires a balancing of equities.⁶⁴

The purpose of the “fair use” exemption is to protect “certain” people who engage in what otherwise would be infringing activity.⁶⁵ The Copyright Act provides fair use exemptions under particular circumstances for certain activities including research, education, scholarship, and reporting.⁶⁶ The rationale behind these exemptions is to promote the dissemination of information and knowledge by individuals without the fear of being sued for infringement.⁶⁷ Therefore, the fair use exemption of the Copyright Act makes concessions to the public’s interests over the rights of the copyright holder.

Compulsory Licenses Internationally

There is a sharp contrast in compulsory licensing statutes of foreign countries compared to those of the United States.⁶⁸ Compulsory licenses tend to be the rule rather than the exception in many foreign countries’ intellectual property statutes.⁶⁹

⁵⁹Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[2][b] (1994)

⁶⁰*See* 17 U.S.C. § 118(d)(1), (d)(2)

⁶¹17 U.S.C. § 107

⁶²*Id.*

⁶³H.R. Rep No. 1476, 94th Cong., 2d Sess. 65-74 (Sept 3, 1976) reprinted in 1976 U.S. Code Cong. & Admin. News 5678-5688.

⁶⁴*Id.*

⁶⁵*Id.*

⁶⁶17 U.S.C. 107

⁶⁷H.R. Rep No. 1476, 94th Cong., 2d Sess. 65-74 (Sept 3, 1976) reprinted in 1976 U.S. Code Cong. & Admin. News 5678-5688.

⁶⁸Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[1][a] (1994)

⁶⁹*Id.*

Many international treaties and conventions contain provisions for compulsory licenses of patents. For example, under the Paris Convention, if a patent is not ‘worked’ within the patent granting country, that member state’s government may enact legislation permitting that government to issue a compulsory license to a firm working in that country.⁷⁰ A reasonable royalty paid to the patent owner is the compensation for using the invention.⁷¹ The purpose of having a compulsory licensing statute is to protect intellectual property from being suppressed or neglected within the country of interest simply because the owner is unwilling or unable to exploit it.⁷²

The GATT TRIPs Agreement imposes strict limitations on the issuing of compulsory licenses.⁷³ Member states will have to modify their compulsory licensing statutes to be in compliance with GATT-TRIPs.⁷⁴ The GATT-TRIPs Agreement permits member states’ governments the authority to issue a compulsory license only after the proposed user’s reasonable effort was unsuccessful in getting authorization from the patent owner.⁷⁵ This provision may be waived “in the case of national emergency or other circumstances of extreme urgency, or in cases of public non-commercial use.” The terms of the compulsory license will be very narrow.⁷⁶ It shall be a non-exclusive, non-transferable license with limited authorization to the “supply of the domestic market of the Member [state] authorizing such use.”⁷⁷ The patent owner will receive “adequate remuneration” based on the economic value of the authorization.⁷⁸

⁷⁰International Convention for the Protection of Industrial Property, Art. 5(2), (4) done at Paris on March 20, 1883, 25 Stat. 1372, TS No. 379, as revised at Stockholm on July 14, 1967, 21 U.S.T. 1629. 1636-1637, TIAS 6923 (Stockholm text).

⁷¹The Paris Convention for the protection of Industrial Property, Art 5(A) §§ 2, 4 (amended 1967)

⁷²*Id.*

⁷³Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), Art. 31(a), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

⁷⁴Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[1][a] (1994)

⁷⁵Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), Art. 31(b), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

⁷⁶*Id.* at Art. 31

⁷⁷*Id.* at Art. 31 §§ (c)-(f)

⁷⁸*Id.* at Art. 31(h).

Any decision relating to the remuneration is subject to judicial review or other independent review in that Member.⁷⁹

History of Surgical and Medical Procedure Patents

Medical procedure patents have been around since the middle of the 19 century. What has triggered the current debate over whether medical procedures should be patentable subject matter at all was an infringement suit filed by Samuel Palin, MD.. against Jack Singer, MD.. This is believed to be “the first infringement action litigation involving one physician suing another to enforce a pure medical method patent.”⁸⁰ Pallin alleged that Singer infringed Pallin’s patent (Pat # 5,080,111) on self-sealing, chevron-shaped scleral incisions, used in cataract surgery.⁸¹

Both Palin and Singer gave testimony in front of the House Committee on Judiciary Subcommittee on Courts and Intellectual Property.⁸² Pallin claimed his surgical procedure patents should not be treated any different from any other procedure patent.⁸³ Therefore, if a new procedure saves money, should not the inventor be rewarded like any other inventor?⁸⁴ Consequently, if someone practices your patented procedure without your authorization, the other person has infringed your patent.⁸⁵

Doctor Jack Singer, as well as the American Medical Association, took an opposing view.⁸⁶ Singer claimed he did not infringe Pallin’s patent.⁸⁷ Singer first attacked the validity of the patent by saying that the procedure was a “natural outgrowth of various methods including

⁷⁹ *Id.* at Art. 31(j).

⁸⁰ *Prepared Statement of Jack A. Signer, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess. Thursday, October 19, 1995

⁸¹ William D. Noonan, MD, JD, *Patenting Medical and Surgical Procedures*, 77 J. Pat & Trademark Off. Soc’y 651, 651 (1995)

⁸² *The House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess. Wednesday, October 18, 1995

⁸³ *Prepared Statement of Samuel Lear MD.. F.A.C.S. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess. Wednesday, October 18, 1995

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Prepared Statement of Jack A. Signer, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess. Thursday, October 19, 1995

⁸⁷ *Id.*

my external incision and the internal incision developed by other ophthalmologist.” In other words, the patent should be found invalid for obviousness.⁸⁸

Singer, next, made a policy argument. He does not believe pure medical procedure patents should be patentable subject matter.⁸⁹ Singer feels that patenting pure medical procedures conflicts with the goals of the medical profession.⁹⁰

Concerns over the Patentability of Surgical and Medical Patents

There are three main concerns some people have regarding the patentability of medical procedures. First, the proliferation of these patents will lead to higher medical cost.⁹¹ Second, the quality of health care will suffer as a consequence of the patents.⁹² Finally, there will be a “chilling effect” on the free-flow of research information by physicians fearing litigation for infringement of another’s patent.⁹³

The first concern is that the proliferation of medical procedure patents will lead to higher medical cost.⁹⁴ If a physician has to pay royalties to the patent holder every time he or she performs the procedure, there will be an increase in the cost of doing the that procedure.⁹⁵

The second concern is that the quality of health care would be jeopardized as a result of medical procedure patents.⁹⁶ This could occur in one of two ways. First, there will be less peer review of the medical procedures.⁹⁷ Second, a physician may opt not to perform the patented

⁸⁸35 U.S.C. 103

⁸⁹*Prepared Statement of Jack A. Signer, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess. Thursday, October 19, 1995

⁹⁰*Id.*

⁹¹*See e.g. Prepared Statement of Jack A. Signer, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess., Thursday, October 19, 1995; *Testimony of Charles D. Kelman, MD.. Before the House Subcommittee on Courts and Intellectual Property of the Committee of the Judiciary, Hearing on H.R. 1127 and H.R. 2419, 103rd Congress, 2d Sess., October 19, 1995; Prepared Statement of H. Dunbar Hoskins, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordably Act..”* 103rd Congress, 2d Sess., Thursday, October 19, 1995;

⁹²*Id.*

⁹³*Testimony of Charles D. Kelman, MD.. Before the House Subcommittee on Courts and Intellectual Property of the Committee of the Judiciary, Hearing on H.R. 1127 and H.R. 2419, 103rd Congress, 2d Sess., October 19, 1995*

⁹⁴*Supra* n. 89

⁹⁵*Id.*

⁹⁶*Supra* n. 89

⁹⁷*Testimony of Charles D. Kelman, MD.. Before the House Subcommittee on Courts and Intellectual Property of the Committee of the Judiciary, Hearing on H.R. 1127 and H.R. 2419, 103rd Congress, 2d Sess., October 19, 1995*

procedure and use a different, less advanced, one rather than paying royalties to the patent owner.⁹⁸

The lack of peer review is based on the assumption that physicians will not be able to critique and verify another's results for fear that in doing so, they will be infringing the patent holder's procedure.⁹⁹ If a physician were to try to reproduce the patent holder's data, he may be brought up on charges of patent infringement for practicing the procedure without the authorization of the patent holder. As a result, physicians may forego this type of peer review. The consequence of this would be the proliferation of medical procedures which have not been independently tested and scrutinized for reliability, safety, reproducibility, etc.

Second, the quality of health care may be negatively affected if the patents "discourage physicians from practicing the state-of-the-art medicine"¹⁰⁰ There are any number of reasons why a physician may prefer not to practice the procedure. He or she may find it too hard to get the authorization from the patent owner. The cost of royalties may be too high to license the patent. He or she may not be confident in the procedure since it did not go through the normal scrutiny process. Regardless of the reason, the result is the same; the procedure will not be performed.

The final concern over patenting medical procedures is the potential chilling effect on the free-flow of information on research.¹⁰¹ This concept is best illustrated through an example. For instance, a physician who, without authorization, has been performing the surgical procedure patent claim. The physician, then makes a discovery relating to the patented procedure. Normally, the physician would publish his or her results. In this case, the physician may be wary to do so. Since he or she did not have authorization to practice the procedure, he or she has infringed the patent. Publishing the results may result in a lawsuit by the patent holder against the practicing physician. Rather than taking this risk, the physician may suppress his or her

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Hon. John Bryant of Texas remarks on Surgical Procedure Patents*, 140 Cong. Rec. E1754-02, E1754, 103rd Cong., 2d Sess. (1994)

¹⁰¹ *Supra* n. 91

discovery, and never disclose it to the public. Consequently, the world would be permanently deprived of ever knowing the physician's discovery.

Critique of Section 287(c)- Congress' Response to Surgical and Medical Procedure Patents

Last Fall, Congress enacted legislation amending § 287 of the Patent Act.¹⁰² Congress added § 287(c) which limits the remedies a patent owner can get from an infringer of his or her patent.¹⁰³ This subsection, § 287(c), is flawed for two reasons. First, it is in direct conflict with the goals of the Patent Act. Second, § 287(c) may be in conflict with provisions in GATT-TRIPs.

In response to some people's concerns over surgical and medical procedure patents, Congress first proposed two separate pieces of legislation, one in the House and the other in the Senate. The House bill, H.R. 1127 would preclude granting patents on surgical or medical procedures.¹⁰⁴ The counter part in the Senate, S. 1334, would not preclude granting said patents. Rather, it would merely "provide an exception from the definition of patent infringement for medical and surgical procedures" performed by other physicians or other licensed health care practitioners."¹⁰⁵

Last Fall, Congress enacted a compromise bill which the President signed into law as Public Law 104-208, the Omnibus Consolidated Appropriations Act.¹⁰⁶ The law added subsection (c) to 35 U.S.C. § 287.¹⁰⁷ This subsection limits the remedies available to a surgical or medical procedure patent owner against an infringer of his or her patent.¹⁰⁸

The effect of § 287(c) is to gut the value from surgical or medical procedure patents, rendering them valueless.¹⁰⁹ A patent is a right to exclude others from practicing your invention. To enforce your right to exclude others, you have the right to bring an infringement action

¹⁰² 35 U.S.C. §§ 1-376 (1995).

¹⁰³ *Id.*

¹⁰⁴ H.R. 1127,

¹⁰⁵ *Mr. Frist statement when he introduced S. 1334, The Medical Procedure Innovation and Affordability Act*, 141 Cong. Rec. S15290-07, S15292 (1995)

¹⁰⁶ Gerald J. Mossinghoff, *Remedies Under Patents on Medical and Surgical Procedures*, 78 J.Pat. & Trademark Off. Soc'y 789, (1996).

¹⁰⁷ 35 U.S.C. 287(c) (1996).

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

against anyone who uses your invention without your permission. The penalty for infringing a patent owners patent is realized in damages sought from the infringer. It is through remedies, that a patent owner is able to enforce his or her patent rights. There is no right without a remedy to enforce that right. Without the right to receive legal or equitable relief for an infringement, a patent becomes a valueless piece of paper.

Although §287(c) addresses many of the fears that people have concerning surgical procedure patents, the subsection may create new ones. The goal of §287(c) and its predecessors, H.R. 1127 and S. 1334, was to enable all physicians the privilege to practice the state-of-the-art medical techniques without the fear of litigation.¹¹⁰ Unfortunately, just the opposite may occur.¹¹¹

There may be (1) less state-of the-art techniques invented, (2) less disclosure of the new techniques, and (3) less peer review.¹¹² Consequently, this sets up a paradox.¹¹³ The current level of health care may be hurt by the very laws which have been proposed to help it.

Section 287(c) is in direct conflict with the goals of the Patent Act. The patent system was designed to give inventors the incentive to produce new, innovative art.¹¹⁴ It was also designed to promote disclosure of new inventions.¹¹⁵ This is accomplished by granting the inventor a monopoly for a limited period of time as compensation.¹¹⁶

Section 287(c) eliminates the inventor's monopoly. Although the patent still exists and the owner retains the right to sue an infringer, the owners is unable to seek any remedy for the infringement.¹¹⁷ Without a remedy, the patent owner, de facto, cannot exclude others. Since a patent is the right to exclude others, the consequence of § 287(c) is to render a surgical or

¹¹⁰ *Mr. Frist statement when he introduced S. 1334, The Medical Procedure Innovation and Affordability Act*, 141 Cong. Rec. S15290-07, S15292 (1995); H.R. 1127.

¹¹¹ *G. Lee Skillington testifying before the Subcommittee on Courts and Intellectual Property Committee on the Judiciary*, Oct 19, 1995.

¹¹² *G. Lee Skillington testifying before the Subcommittee on Courts and Intellectual Property Committee on the Judiciary*, Oct 19, 1995.

¹¹³ *G. Lee Skillington testifying before the Subcommittee on Courts and Intellectual Property Committee on the Judiciary*, Oct 19, 1995.

¹¹⁴ Earl Kintner & Jack Lahr, *An Intellectual Property Primer*, 10, (2d ed., 1982)

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ 35 U.S.C. § 287(c) (1996).

medical procedure patent void. Consequently, the patent owner will not have the opportunity for compensation. Therefore, there is no incentive to create new art. Without this incentive, some current medical procedures may not have been and may never be discovered.¹¹⁸ These efforts to promote the free practice of the latest medical advancements may, in fact, result in fewer advancements being made.¹¹⁹

The second goal of the patent law is also in jeopardy due to §287(c). The inventor of a surgical procedure may be hesitant to disclose it, at all.¹²⁰ He or she may wish to keep it to himself or herself much like a trade secret. This way he or she can reap the rewards as the only person who performs the “secret” procedure. Once again, a paradox is formed. In an effort to promote complete dissemination on all medical advancements, the result may be less information is disclosed.¹²¹

If an inventor chooses to keep his discovery as a trade secret, there would be little or no peer review. Without the publication or dissemination of the exact technique, there would be no way for another physician to confirm the inventor’s results. This could lead to the practice of techniques which have not been adequately scrutinized by the medical community. The consequence could result in a diminution of health care.

Finally, § 287(c) may be in conflict with GATT-TRIPS. The United States is a signatory member to GATT-TRIPS.¹²² Article 27 of GATT-TRIPS says that patents “shall be available for any inventions whether product or process.”¹²³ Members may exclude from patentability “therapeutic and surgical methods for the treatment of human or animals.”¹²⁴ If the member state recognizes the product or process as patentable subject matter, i.e. the country does not

¹¹⁸William D. Noonan, MD, JD, *Patenting Medical and Surgical Procedures*, 77 J. Pat & Trademark Off. Soc’y 651, 655 (1995)

¹¹⁹*G. Lee Skillington testifying before the Subcommittee on Courts and Intellectual Property Committee on the Judiciary*, Oct 19, 1995.

¹²⁰*Id.*

¹²¹*Id.*

¹²²Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

¹²³*Id.* at Art. 27 (1).

¹²⁴*Id.* at Art. 27 (3).

exclude patentability under Article 27 (3), the member state “shall confer onto its owner various exclusive rights.¹²⁵ The owner of a process patent has the exclusive right to “prevent third parties not having the owner’s consent from the act of using the process.”¹²⁶ A member nation may provide limited exceptions to the exclusive rights in Article 27 “provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner.”¹²⁷

The United States continues to recognize and issue surgical and medical procedure patents. Therefore, surgical and medical procedures are patentable subject matter making Article 27 (1) applicable and Article 27 (3) inapplicable.¹²⁸ Consequently, Article 28, conferring the right to exclude, applies to surgical and medical procedure patents in the United States.¹²⁹ As stated above, by removing any remedies for infringement of one’s patent, de facto, there is no right to exclude others from practicing one’s patented invention. The purpose of §287(c) was to remove liability from unauthorized practice of the patented surgical or medical process.¹³⁰

The only thing that may save §287(c) from violating Article 28 of GATT-TRIPs is Article 30, Exceptions to Rights Conferred.¹³¹ An exception to the exclusive rights conferred will be allowed “provided that such exceptions,” one, do not unreasonably conflict with a normal exploitation of the patent and, two, do not unreasonably prejudice the legitimate interests of the patent owner.

Section 287(c) fails both one and two. It is an unreasonable conflict with a normal exploitation of the patent and it is an unreasonable prejudice the legitimate interests of the patent owner. As stated above, the owner of a surgical or medical procedure patent can no longer exclude others. The corollary of this is the patent owner cannot license or sell his or her

¹²⁵ *Id.* at Art. 28 (1).

¹²⁶ *Id.* at Art. 28 (1)(b).

¹²⁷ *Id.* at Art. 30.

¹²⁸ *Id.* at Art. 27.

¹²⁹ *Id.* at Art. 28.

¹³⁰ Legislative History of HR 3610, the Omnibus Spending Bill.

¹³¹ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), Art. 30, reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

invention. His or her patent is rendered valueless. Therefore, the patent owner cannot exploit, i.e. profit from his or her patent. Likewise, the patent owner's legitimate interest have been completely abrogated. Section 287(c) eviscerates any interest the patent owner has in the patent save his or her name. Since § 287(c) appears to unreasonably conflict with the patent owners normal exploitation of the patent and § 287(c) does unreasonably prejudice the legitimate interest of the patent owner, § 287(c) most likely violates GATT-TRIPs.

Compulsory Licensing Surgical Procedures

Compulsory licensing of medical and surgical procedure patents provides an alternative to §287(c). If drafted properly, a compulsory licensing amendment to the Patent Act, should address the concerns voiced by critics of surgical procedure patents without creating new and potentially devastating ones.

As stated above, in the United States, compulsory licenses are the exception rather than the rule.¹³² Nevertheless, in situations of large public interest, compulsory licenses are issued.¹³³ Just as the Atomic Energy Commission can declare a patent to be affected with the public interest if important to the production of certain nuclear material,¹³⁴ so too, could an appointed official declare a surgical procedure patent to be affected with the public interest if important to the promotion of state-of-the-art health care.

In drafting a compulsory licensing amendment to the current Patent Act, several sources of intellectual property rights were consulted. They included the Clean Air Act¹³⁵, the Atomic Energy Act,¹³⁶ the 1976 Copyright Act,¹³⁷ and the GATT TRIPS agreement¹³⁸.

Proposal- Amendment to the Patent Act 35 U.S.C.

§ 158 Limitations on Exclusive Rights: Surgical and Medical Procedure Patents

¹³² Jay Dratler, Jr., *Licensing of Intellectual Property*, § 3.03[2] (1994)

¹³³ See e.g. Clean Air Act, 42 U.S.C. 7608; The Atomic Energy Act, 42 U.S.C. § 2183

¹³⁴ Atomic Energy Act, 42 U.S.C. § 2183 (a)

¹³⁵ 42 U.S.C. § 7608

¹³⁶ 42 U.S.C. § 2183

¹³⁷ 17 U.S.C. §§ 101-1010

¹³⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), Art. 31(a), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

(a) The exclusive rights provided by section 154, shall, with respect to the right to exclude others from using throughout the United States, be subject to the conditions and limitations prescribed by this section.

(b) Declaration of public interest

(1) The Commission¹³⁹ may, after giving the patent owner an opportunity for a hearing, declare any patent to be affected with the public interest if (A) the invention or discovery covered by the patent claims a surgical or medical procedure of primary importance in the medical field; and (B) the licensing of such procedure under this section is of primary importance to effectuate the purpose of this section set forth in paragraph (2) of this subsection. In situations of national emergency or other circumstances of extreme urgency, the opportunity to give the patent owner an opportunity for hearing may be waived.

(2) The purpose of this section is to permit the issuing of compulsory licensing of surgical procedure patents as necessary to promote the public interest in having the state-of-the-art procedures practiced.

(c) Action by Commission

Whenever any patent has been declared affected with the public interest, pursuant to subsection (b) of this section--

(1) the Commission is licensed to use the procedure covered by such patent in performing any of its powers under this chapter; and

(2) any person may apply to the Commission for a non-exclusive, non-transferable patent license to use the procedure covered by such patent, and the Commission shall grant such patent license to the extent that it find that the use of the procedure is of primary importance to the conduct of an activity by such person authorized under this chapter.

(d) Application for patent-

Any person may at any time make application to the Commission for a patent license for the use of the procedure covered by the patent. Each such application shall set forth the nature and purpose of the use which the applicant intends to make of the patent license, the steps taken by the applicant to obtain a patent license from the owner of the patent, and a statement of the effects, as estimated by the applicant, on the authorized activities which will result from failure to obtain such patent license and which will result from the granting of such patent license. Proof of efforts to obtain a patent license from the owner of the patent may be waived in situations of national emergency or other circumstances of extreme urgency.

(e) Hearings

Whenever any person has made an application to the Commission for a patent pursuant to subsection (d) of this section--

(1) the Commission, within 30 days after filing of such application, shall make available to the owner of the patent all of the information contained in such application, and shall

¹³⁹refers to either the present commission at the PTO or a special commission empowered to handle compulsory licenses. Perhaps, a prevision could be amended to permit the Department of Health to administer these determinations.

notify the owner of the patent of the time and place at which a hearing will be held by the Commission;

(2) the Commission shall hold a hearing within 60 days after the filing of such application at a time and place designated by the Commission; and

(3) in the event an applicant applies for two or more patent licenses, the Commission may, in its discretion, order the consolidation of such applications, and if the patents are owned by more than one owner, such owners may be made parties to one hearing.

(f) Commission's Findings

If, after any hearing conducted pursuant to subsection (e) of this section, the Commission find that--

(1) the surgical or medical procedure covered by the patent is of primary importance in the medical field;

(2) the licensing of such procedure is of primary importance to the conduct of the activities of the applicant;

(3) the activities to which the patent license are propose to be applied by such applicant are of primary importance to the furtherance of the policies and purpose of this section; and

(4) such applicant cannot otherwise obtain a patent license from the owner of the patent on terms which the Commission deem to be reasonable for the intended use of the patent to be made by such applicant,

the Commission shall grant the applicant a non-exclusive, non-transferable license to use the surgical or medical procedure covered by the patent for the purposes stated in such application on terms deemed equitable by the Commission and generally not less fair than those granted by the patentee or by the Commission to similar licensees for comparable use.

(g) Limitations on issuance of patent

The commission shall not grant any patent license pursuant to subsection (f) of this section for any other purpose than that stated in the application. Nor shall the Commission grant any patent license to any other applicant for a patent license on the same patent without an application being made by such applicant pursuant to subsection (d) of this section, and without separate notification and hearing as provided in subsection (e) of this section, and without a separate finding as provided in subsection (f) of this section.

(h) Royalty fees

The owner of the patent affected by a declaration or a finding made by the Commission pursuant to subsection (c) or (f) of this section shall be entitled to reasonable royalty fee from the licensee for any use of a surgical or medical procedure licensed by this section. Such royalty fee may be agreed upon by such owner and the patent licensee, or in the absence of such agreement shall be determined for each patent license by the Commission pursuant to (1) of this section

(1) Standard-

In determining a reasonable royalty fee as provided for in subsection (h) of this section, the Commission shall take into consideration (A) the advice of the Patent Compensation Board; (B) any defense, general or special, that might be plead 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 surgical or medical procedure, (E) the intend use and scope of such license and (F) may consider the cost to the owner of the patent of developing such procedure or acquiring such patent.

(2) any decision relating to royalties provided in respect of such license shall be subject to judicial review by the D.C. Circuit Court of Appeals after an adverse decision by the Patent and Trademark Appeal Board.

(I) Experiment or Fair Use

Notwithstanding the provisions of section 154, the experimental or fair use of a surgical or medical procedure patent for the purposes such as criticism, comment, teaching, research is not an infringement of a patent. In determining whether the use made of the surgical or medical procedure patent in any particular case is an experiment or fair use, the following factors shall be examined: the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes.

Discussion of Proposed Amendment

The proposed amendment to the Patent Act was designed to make available the state-of-the-art medical procedures for all to enjoy. In doing so, the goal was to balance the interests of the inventor and the general public. The inventor's interest is in seeing that he or she is compensated through royalties for his or her time, energy, and investment expended while developing the new procedure. The public's interest is two fold. The public has an interest in seeing that patent holder's rights are protected. Without the protection, the public may never reap the benefits from an inventor's work. Second, the public has an interest in having the best medical technology available to them at a reasonable price. This proposal accomplishes these objectives. Furthermore, it address the three main concerns people have regarding the patenting of surgical and medical procedures.

The first concern regarding the patentability of surgical and medical procedures was the potential increase in cost of health care. This proposal helps put a "cap" on how much a patent holder can charge for his or her procedure. The prospective licensee will first attempt to get a license directly from the patent owner.¹⁴⁰ If the inventor is asking too much, the applicant can

¹⁴⁰Proposal § 158 (d)

apply for a compulsory license.¹⁴¹ It will then be left to the discretion of the Commission to set a fair royalty based on the factors set forth in the proposal.¹⁴² The inventor will not be able to abuse his or her patent by charging a disproportionate amount of money compared to the cost of making the discovery.¹⁴³

The second concern that people have regarding surgical procedure patents is the potential negative affect the patents may have on the quality of health care. They fear there will be less peer review and some physicians may prefer not to practice the procedure at all. The peer review concern is addressed by the “experiment or fair use” provision.¹⁴⁴ Based on the fair use exception in the Copyright Act,¹⁴⁵ the purpose of the experiment or fair use provision is similar. The purpose of this provision is to promote research, scholarship, education and reporting on the latest, state-of-the-art advancements in medicine without infringing the patent owner’s rights. For example, this provision would allow a physician to use the patented procedure to confirm the inventor’s results without infringing the inventor’s patent.¹⁴⁶

One common criticism of surgical and medical patents is that if the Heimlich Maneuver¹⁴⁷ or the CPR techniques were patented, anyone who used them would be infringing the patent owner’s patent. Alternatively, the one performing the procedures would be obligated to pay a royalty to the patent owner. The experiment and fair use subsection would cover just such instances.

For example, it may be deemed fair use to instruct a volunteer firefighter CPR without infringing a hypothetical CPR patent. On the other hand, using CPR in the emergency room of a private hospital, may not be deemed fair use. The key distinctions are the use and the user. Demonstrating a technique while instructing a volunteer is different from a paid professional

¹⁴¹ Proposal § 158 (d)

¹⁴² Proposal § 158 (h)(1)

¹⁴³ *Id.*

¹⁴⁴ Proposal § 158 (I)

¹⁴⁵ 17 U.S.C. 107

¹⁴⁶ *Id.*

¹⁴⁷ *Prepared Statement of Jack A. Signer, MD.. Before the House Committee on Judiciary Subcommittee on Courts and Intellectual Property Re: H.R. 1127 the “Medical Procedures Innovation and Affordability Act..” Thursday, October 19, 1995*

using a technique in a for-profit facility. Like determining fair use under the Copyright Act, each case of experiment and fair use will be based on the specific facts and circumstances surround the surgical or medical procedure's particular use. Like copyright fair use, a balance of equities will be done to determine whether the use was an infringement.

This proposal addresses the concern that some physicians may choose not to practice the procedure by eliminating some of the obstacles. First, the experimental and fair use subsection allows a physician to practice the procedure in certain instances without infringing ones patent.¹⁴⁸ Second, the cost of licensing will be kept to a reasonable level.¹⁴⁹

The final concern people have regarding the patentability of surgical and medical patents is the "chilling effect it may have on the free-flow of research information discovered while using ones patent without authorization. Reasonable royalty levels and the experimental and fair use subsection both help ease these concerns. There will be little excuse for a practitioner not to get a license. Therefore, a physician is not likely to be infringing ones patent. Furthermore, the experimental research may fall under the experiment use provision. Consequently, the proposal helps remove the "chilling effect on the free-flow of information."

Not only does the proposal address the concerns the public has considering these patents but it also addresses the possible negative consequences of §287(c).¹⁵⁰ The first disadvantage of the § 287(c) is the removal of the incentive to create new surgical and medical procedures. Unlike §287(c), the proposal permits compensation to the inventor for his or her discovery.

A compulsory license would only be issued as a last resort. The commission must first find the patent is of "public interest."¹⁵¹ Then, the Commission must conclude the intend use is of "primary importance" to the applicant's activities¹⁵² and the applicant has no other means of obtaining a license from the patent owner¹⁵³ before issuing a license. When a license is issued, it is a non-exclusive, non-transferable license, limited in to the specific purpose to which the

¹⁴⁸ 17 U.S.C. 107

¹⁴⁹ Proposal § 158 (h)

¹⁵⁰ 35 U.S.C. 287(c) (1996).

¹⁵¹ Proposal § 158 (b)

¹⁵² Proposal § 158 (f)(2)

¹⁵³ Proposal § 158 (f)(4)

applicant applied.¹⁵⁴ These provisions help to protect the inventor's patent protection by preventing the nondiscretionary issuing of licenses, which in turn, benefits the inventor.

The inventor would be entitled to adequate compensation based on his or her contribution to the medical field.¹⁵⁵ For instance, a procedure that cost one million dollars of private money to develop, that was very innovative will command a larger royalty than a procedure that cost one thousand dollars of NIH¹⁵⁶ grant money to develop and was not as innovative.¹⁵⁷ If an inventor knows that he or she will be able to recoup his or her investment through royalties, he or she is much more likely to engage in inventorship. Therefore, the adequate compensation of the proposal acts as an incentive to make new discoveries.

The second potential disadvantage § 287(c) is the possibility that inventors will opt to keep their surgical procedures as trade secrets rather than disclosing them for all to use. By providing adequate compensation in the form of royalties, there would be little gained by this. Instead of trying to recover the cost of developing the procedure by performing the procedure himself or herself, the proposal, unlike § 287(c), provides for a reasonable royalty to be paid by licensees.

Comparison of Proposed Compulsory Licensing Agreement with GATT TRIPS

Unlike § 287(c) which may violate the GATT-TRIPS agreement, the proposed patent amendment is consistent with GATT-TRIPS. Member nations do not have to provide patent protection for "surgical methods for the treatment of humans."¹⁵⁸ Therefore, if a foreign country wishes not to recognize a surgical procedure patents, it may do so. Although the inventor would not receive any patent protect for his or her discovery in that foreign country, he still would be able to enjoy patent protection in this country.

¹⁵⁴Proposal § 158 (g)

¹⁵⁵*Id.*

¹⁵⁶National Institute of Health

¹⁵⁷*Id.*

¹⁵⁸Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including Trade in Counterfeit Goods of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), Art. 27 3(a), reprinted in 47 Patent, Copyright & Trademark Rep. (BNA) 230 (Jan. 13, 1994)

The proposed amendment is also consistent with the specific compulsory licensing provisions of GATT¹⁵⁹. A compulsory license would be issued, barring national emergency, only after efforts to negotiate with the patent owner have failed.¹⁶⁰ It is to be regarded as a last resort. The purpose and scope of the license will be narrowly tailored and issued on a case-by-case basis.¹⁶¹ The compulsory licensed shall be non-exclusive and non-transferable.¹⁶² An objective standard based on equitable considerations will be used in establishing reasonable royalties.¹⁶³ Any disputes concerning the amount of royalties can be appealed.¹⁶⁴

Conclusion

The goals of the Patent Act are to provide incentive to promote innovations and to encourage disclosure. Section 287(c) frustrates these goals. It will abrogate any incentive to create new medical procedures. Moreover, § 287(c) may tend to discourage disclosure of new surgical procedures. It is important to examine other options. Although compulsory licensing is the exception to the rule, in circumstance where there is large public interest, it is justified. The proposed compulsory licensing amendment to the Patent Act reinforces the goals of the Patent Act while redressing the concerns people have. It is a happy medium, a compromise, necessary to insure the availability of state-of-the-art surgical and medical procedures in the future without sacrificing the incentives necessary to promote the innovation and disclosure of those discoveries.

¹⁵⁹GATT-TRIPS Art. 31

¹⁶⁰Proposal §§ 158 (f)(4) & (g) (comparable to GATT-TRIPS Art. 31 (b))

¹⁶¹Proposal § 158 (f) (compare with GATT-TRIPS Art. 31 (c))

¹⁶²Proposal §§ 158 (c)(2) & (f) (compare with GATT-TRIP Art. 31 (d) & (e))

¹⁶³Proposal § 158 (h) (compare with GATT-TRIPS Art. 31 (h))

¹⁶⁴Proposal § 158 (h)(2) (compare with GATT-TRIPS Art. 31 (j))