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Medical treatment method patents are issued not for the drugs or devices used for treating a patient, but for the actual steps taken by a doctor during diagnosis or treatment. These patents are usually issued to doctors who invent the method in the course of their practice. A medical treatment method patent may be issued, for example, for a method of making incisions for cataract surgery, for a regime of dosage for administering a drug that overcomes the drug’s side effects, or for computer software interpreting the images obtained by a radiologist. With an enforceable medical treatment method patent, the patentee could charge other doctors for the privilege of using the method on patients or obtain an injunction against the use of the method by others.

Section 616 of the Omnibus Consolidated Appropriations Act of 1996, codified as 35 U.S.C. § 287(c), is generally considered to...
create a liability exception for medical practitioners infringing medical treatment method patents while performing a medical activity with the goal of treating a human being. Under 35 U.S.C. § 287(c), a medical practitioner who infringes a medical treatment method patent is immune from liability to the patentee if he infringes the patent during the performance of a medical activity.

35 U.S.C. § 287(c) was enacted with the goal of harmonizing U.S. law with international and foreign laws. International treaties permit exclusion of medical treatment methods from the categories of patentable subject matter and the patent laws of most countries make medical treatment methods unpatentable. The medical doctors' lobby in the U.S. argued for a similar provision which would have prevented

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3 "(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281 [providing a civil remedy for patent infringement], 283 [allowing for injunction in the event of patent infringement], 284 [providing for damages in the event of patent infringement] and 285 [providing for attorneys fees] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity. (2) For the purposes of this subsection ... (E) the term 'body' shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans." 35 U.S.C. 287(c)(1)-(2) (2004); Omnibus Consolidated Appropriations Act of 1996 § 616, Pub. L. 104-208, 110 Stat., 3009 (codified as 35 U.S.C. § 287(c) (1994) Supp. II 1996 & Supp. IV 1998).

4 "The proponents of H.R. 1127 and S. 1334 have argued that many countries exclude therapeutic and diagnostic methods from patent protection and that the United States should follow their lead and 'harmonize' our law with theirs." U.S. Patent and Trademark Office, "Notice of Hearings and Request for Comments on Issues Relating to Patents Protection for Therapeutic and Diagnostic Methods," 61 Fed. Reg. at 10320-23 (March 13, 1996). H.R. 1127 was introduced to exclude such methods from patentability and S. 1334 was to grant limited immunity from patent infringement to certain persons. S. 1334 resulted in 35 U.S.C. § 287(c). See also Testimony of Charles D. Kelman, M.D., President American Society of Cataract and Refractive Surgery, before the House Judiciary Subcommittee on Courts and Intellectual Property Hearing on H.R. 1127, "Medical Procedures Innovation and Affordability Act", October 19, 1995, http://web.archive.org/web/20031222171101/ http://www.ascrs.org/advocacy/testimony.html ("H.R. 1127 follows the lead of over 80 other countries that have banned medical procedure patents.").

5 Under the General Agreement on Tariffs and Trade ("GATT") (Trade-Related Aspects of Intellectual Property Rights, Including Trade In Counterfeit Goods Final Act Embodying The Results Of The Uruguay Round Of Multilateral Trade Negotiations, Apr. 15, 1994, art. 27 § 3(a), 33 I.L.M. 1, 83-111 (1994), and the North American Free Trade Agreement ("NAFTA") (Dec. 17, 1992, art. 1709, § 3(a), 32 I.L.M. 605, 670-81), member states are allowed to exclude medical procedures from patentability. Also by the time of passage of the law leading to enactment of 35 U.S.C.§ 287(c) in 1996, more than 80 countries in Europe, Asia, Africa, North America, South America and Central America, exempted medical methods from patent protection. Robert M. Portman, Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress, 4 U. BALT. INTELL. PROP. L.J. 91, 98 (1996).
granting patents to medical treatment methods in the U.S. as well. An unpatentability provision was fiercely opposed by other lobby groups such as the trial lawyers and biotechnology and pharmaceutical industries who depend on patenting. As a compromise, medical treatment methods remained patentable under U.S. law, but the patents granted on such methods were declared unenforceable against infringing doctors.

The debates leading to the enactment of the statute indicate a focus on immunity against infringement of medical treatment method patents. The commentators who have discussed 35 U.S.C. § 287(c)

6 The statute was enacted in the aftermath of a lawsuit by one doctor against another for infringing a medical treatment method patent and it was brought about by lobby efforts of physicians' organizations that found such lawsuits, hence the existence of medical treatment method patents, offensive to their profession. Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995). As an example of the concerns raised regarding this lawsuit, see e.g., Wendy W. Yang, Note, Patent Policy and Medical Procedure Patents: The Case for Statutory Exclusion From Patentability, 1 B.U. J. Sci. & Tech. L. 5, 2 (1995) ("Dr. Samuel Pallin, who held a patent on a procedure for performing cataract surgery without sutures, initiated what legal experts think is the first American patent infringement suit involving a medical procedure patent and a physician defendant. If he prevails in court, Dr. Pallin plans to charge ophthalmologists nationwide a royalty for using his procedure. If the estimates are correct that up to half of all cataract procedures performed in the United States involve Dr. Pallin's technique, a decision in Dr. Pallin's favor could result in a significant cost increase to patients and the health care system in general.") (footnotes omitted).

7 See, e.g., Robert M. Portman, Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediments to Medical Progress, 4 U. BALT. INTELL. PROP. L.J. 91, 113 (1996) ("[35 U.S.C. § 287(c)] was championed by two physician-legislators: Congressman Greg Ganske of Iowa and Senator Bill Frist of Tennessee, and passed over the vigorous opposition of Senator Orrin Hatch, who, as Chairman of the Senate Judiciary Committee, had primary jurisdiction over the patent statute.")

8 "Amending section 287(c) greased organized medicine's squeaky wheel. Section 287(c) statutorily immunized licensed medical practitioners from infringement of medical process patents. Section 287(c) did not affect the biotechnology industry because the patenting of medical processes survived unmolested." Weldon E. Havins, Immunizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, Or What? 77 U. DET. MERCY L. REV. 51, 69 (1999) (footnotes omitted). This commentator, perhaps correctly, states that the true and main impetus behind 35 U.S.C. § 287(c) was the fact that doctors did not appreciate the specter of one doctor suing another: "[I]n an overall sense, all this legislative maneuvering amounted to 'much ado about nothing.'" Weldon E. Havins, Immunizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, Or What? 77 U. DET. MERCY L. REV. 51, 69 (1999); Duane Nash, Recommended Response for Human Cloning
after its enactment also seemingly take for granted that the statute was meant to limit the enforceability of medical treatment method patents.\textsuperscript{10} The legislative history hints at the same.\textsuperscript{11} If the statute was indeed intended to pertain to medical treatment method patents alone, then writing it with language in accord with foreign laws would have given the courts and others tasked with interpretation of the statute the benefit of the interpretations already on record in other countries. The straightforward language of most foreign law that is patterned after the same international treaty approximately states that methods for treatment of the human body by surgery or therapy or methods of diagnosis shall not be regarded as inventions. Instead, the language of 287(c) states: "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement ... the provisions of sections [on various infringement remedies] shall not apply against the medical practitioner ...." This novel language, introduced by the U.S. legislature under pressure from lobby groups, forces the courts and practitioners to guess at the meaning without the aid of any authoritative or persuasive precedent.

This paper admits that the language of 287(c) achieves the intended goal of the legislature in immunizing doctors against liability for infringement of medical treatment method patents. The paper also admits that, in practice and under most likely fact scenarios, the reach of the statute will end at immunizing doctors against liability for infringement of medical treatment method patents alone. But the paper points out that, under the language of this statute, a doctor may be immune from liability for infringement of any type of process patent, however unlikely a corresponding fact scenario.\textsuperscript{12} The text of the statute


\textsuperscript{10} See infra section III.C.


\textsuperscript{12} Of course, the patents that are expressly excluded by the statute are spared. However, not all the industries whose patents may someday be implicated were present during the debate in order to obtain an exception.
does not specify the type of patent whose infringement is immune from liability and the associated conference report uses the same general language of the statute, failing to explain that the immunity is limited to infringement of medical treatment method patents.13

Under subsection (c)(2), infringing use of a patented machine, manufacture, or composition of matter, and infringing use of a drug use process patent or a biotechnology process patent are expressly excluded from the immunity granted,14 leaving the infringement of other patented processes subject to immunity. Apparently, at no point did anyone involved consider that a doctor may need or wish to infringe a process patent other than a drug use process or biotechnology process patent or a medical treatment process patent during the performance of a medical activity.15 As a result, nowhere did the legislature state that, aside from the expressly excluded process patents, it was considering medical treatment method patents only and that it did not intend to extend the immunity to infringement of other process patents.

The text of the statute allows a medical practitioner to evade liability for infringement of a process patent in any art area, not just the medical arts, as long as he does so in the course of performing a medical activity, and as long as the process patent infringed is not found to be a drug use or a biotechnology patent. As such, 35 U.S.C. § 287(c) was written more broadly than the legislature intended and the commentators foresaw. Considering that nothing to the contrary is found in the main piece of legislative history, the current textualist tendency of the courts16 will likely cause a literal interpretation of the statute.17 Passage of time and changing circumstances or certain fact

13 Refer to Appendix B of this paper including § 616 of the Conference Report to accompany H.R. 3610, 104th Cong. (1996).

14 "For the purposes of this subsection: (A) the term 'medical activity' means the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent." 35 U.S.C. § 287(c)(2).

15 Cf. Gunfest, Joseph A. and A.C. Pritchard, Statutes with Multiple Personality Disorders: The Value of Ambiguity in Statutory Design and Interpretation, 54 STAN. L. REV. 627 (2002) (Explaining that the legislature intentionally introduce ambiguity into a statute as a means of compromise and exploring the dynamics of exploiting the ambiguity).

16 See infra section IV.C.

17 Refer to Appendix B of this paper including § 616 of the § 616 of the Conference Report to accompany H.R. 3610, 104th Cong. (1996).
patterns may prompt a judge to construe this overbroad statute according to its express language. For example, a medical practitioner may be held liable for infringement of a patent drawn to a method of hypnotism because practicing the method is not deemed a medical activity. The same medical practitioner, however, may evade liability for using the same patented method if he calls the practice of the method performance of a medical activity or if he embeds the patented method into a medical activity. The same holds true for any nonmedical cosmetic procedure.

This paper includes five sections in addition to this Introduction. Section II creates the proper perspective by presenting the well-developed international and foreign laws regarding medical treatment method patents that were the true target of 35 U.S.C. § 287(c). Section III presents the national background against which 35 U.S.C. § 287(c) was enacted, the proponent and opponent lobbies, and the national debate preceding and succeeding the statute. Section IV looks at the language of 35 U.S.C. § 287(c) that came about as a result of lobbyists pushing and pulling at the tried and true foreign examples. This section points out some of the challenges facing a judge attempting to construe the statute as well as the potential role of the legislative history. Section V shows that while the statutory language covers medical treatment method patents, it is not specific to them and may reach farther than that intended by the legislature or contemplated by the commentators. Section VI concludes the paper by arguing that the far reach of 35 U.S.C. § 287(c) immunizes medical practitioners from liability for infringement of not just treatment method patents but process patents in any area other than those expressly excluded.

II. HOW FOREIGN COUNTRIES TREAT MEDICAL TREATMENT METHODS

Medical treatment methods are not patentable in most other countries. Because 35 U.S.C. § 287(c) was enacted to bring U.S. law more in step with laws of other countries, this paper begins with the international law that influenced the enactment of 35 U.S.C. § 287(c) and with an

18 A case in point is the evolution of the requirement of enablement under 35 U.S.C. § 112 into two distinct requirements of enablement and written description in more recent years due to the progress made first in the chemical and later in the biotechnical arts. "New interpretations of old statutes in light of new fact situations occur all the time." Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F3d 956, 971 (Fed. Cir. 2002) (Lourie, J., concurring on denial of petition for rehearing en banc).
overview of EPO law as an example of a well-developed foreign law regarding treatment methods.

A. TRIPs Provisions on Patentability of Medical Treatment Methods

In 1994, the signatory nations to the General Agreement on Tariffs and Trade ("GATT") signed the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPs") that creates an international baseline for patent, trademark, and copyright protection. TRIPs provides procedures for settlement of property disputes and harmonizes the world patent laws. In harmonizing world patent laws, TRIPs makes it permissive but not mandatory for signatory countries to exclude treatment methods from the categories of patentable subject matter. "Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals." By 1996, the time that 35 U.S.C. § 287(c) was signed into law, more than 80 countries had excluded the methods of treatment of people or animals from patentability.
B. The EPO Example

The European Patent Office (EPO) grants European patents for the contracting states to the European Patent Convention (EPC), which has been in force since 1977. The EPC is the executive arm of the European Patent Organization, an intergovernmental body whose members are the EPC contracting states. A European patent can be obtained by filing a single application in one of the official languages of the EPO (English, French or German) and is valid in as many of the contracting states as the applicant cares to designate. A European patent affords the same rights in the designated contracting states as a national patent granted in any of the member states.

EPC Article 52, which takes into account the permissive exclusion of treatment patents by TRIPs, recites in relevant sections:

European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.

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

patentable, whereas, a process or method of treatment practiced on animals and not humans is recognized to have patentability. Methods of treatment or diagnosis or surgical methods applicable to the human or animal bodies are not considered inventions according to Article 19, point VII of the Mexican patent law. Subsection 25(11) of the South African patents act provides that a method of treatment of human or animal body by surgery or therapy or of diagnosis is not a patentable invention. One notable exception to the foreign pattern is Australian law that does not include any provisions against patenting of methods of treatment of humans or animals. In contrast, New Zealand does not permit issue of patents to methods of medical treatment for humans while allowing methods of treatment of animals to be patented, available at http://www.med.govt.nz/buslt/int_prop/patentsreview/cabinet/part1/section5.html

23 EPC's contracting states as of June 2003 are: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hellenic Republic, Hungary, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom, available at http://www.mewburn.com/Mewsletter%20Aug%202003.pdf.
24 The EPC language "being susceptible of industrial application" is parallel to the "utility" requirement under 35 U.S.C. §101 (2004) and the EPC language "involving an inventive step" is parallel to the "nonobvious" requirement under 35 U.S.C. §103 (2004). Further, the "novelty" requirement of EPC is parallel to the "novelty" requirement under 35
The EPC expressly excludes treatment methods of both humans and animals from patentability. The EPC refers to "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on human or animal body." This wording is patterned after TRIPs terminology of "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." EPO technical boards of appeal have interpreted and applied this provision in numerous cases. In particular, "what constitutes a method for treatment" has been the subject of much litigation before the EPO, giving rise to a considerable body of law.

At one extreme of the spectrum of cases deciding whether a treatment method is at issue lie surgical procedures and methods of alleviating pain and suffering that are for the most part unpatentable. Under the EPC, surgical procedures are not patentable whether or not their intended purpose is therapeutic, cosmetic, or otherwise. Non-therapeutic treatment methods are patentable if the non-therapeutic effect is distinct and separate from any therapeutic effect. Thus, for example, purely cosmetic treatment methods, that are not surgical either, are patentable. But if the cosmetic effect is linked to a therapeutic effect that may also be occurring, then the treatment method is not purely cosmetic and is not patentable. All methods practiced on the human or animal body which are related to diagnosis or which are of value for the purpose of diagnosis, irrespective of whether a physician could immediately decide on a course of treatment on the basis of the results obtained, are banned from patentability.

U.S.C. §102 (2004). Making the analogy to U.S. law, methods of treatment are rejected by the EPC as unpatentable subject matter for failure to meet the industrial "utility" requirement.

25 EPC art. 52(4) http://www.european-patent-office.org/legal/epc/e/ar52.html#A52.
26 Id.
27 TRIPs art. 27(3).
Diagnostic methods performed on cells in a culture, or a sample obtained from a patient are both patentable. Neither prophylactic nor curative methods are patentable, and arguing that a method should be patentable because it is preventative and not curative is not persuasive in Europe. At the other extreme lie pharmaceuticals or surgical devices that are clearly patentable.

Cases that come before a tribunal generally involve middle of the spectrum categories such as cosmetic methods, methods for curing baldness, infertility, or obesity, use of contraceptives, methods of reducing the desire to smoke, or diagnostic testing methods. Case law of the EPO and other foreign jurisdictions that consider treatment methods unpatentable, often decides whether or not such middle of the spectrum categories should be considered unpatentable treatment methods. For example, contraceptive methods are patentable because they are not considered to be therapeutic. Yet, claims to a method of

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36 At times a method of treatment may be merely a new use for a known pharmaceutical. In these circumstances, whether a claim is found patentable or not depends on the format of the claim. If the method sets forth a use for a compound for the first time, it is called a first use claim. For the first medical use of a known compound, which has not been previously disclosed as having medical utility, the claim would generally recite: "A compound of formula X for use in a method of treatment of the human or animal body by therapy." A method of use of a compound, already known to treat a certain medical condition, to treat yet another medical condition is called a second or subsequent use claim and generally uses a format as follows: "Use of compound X in the manufacture of a medicament for the treatment of condition Y." An example of this second medical use is the use of aspirin to reduce the risk of heart attacks. Second use claims are also called Swiss-type claims and are patentable in the EPO. Case Gr. 5/83, Second Medical Use, 1985 O.J. EPO 64, 16 IIC 83 (1985) (EPO Enlarged Tech. Bd. Of App.); Case T 143/94, Trigonelline, 1996 O.J. EPO 430, 28 IIC 95, 96 (1997); Case T 128/82, Pyrrolidine Derivatives/Hoffman- La Roche, 1984 O.J. EPO 174, 15 IIC 520 (1984). The term Swiss comes from a 1984 decision of the Swiss Intellectual Property Office to allow claims in this form. Therefore, the protection that cannot be achieved through the use of a "medical treatment" claim can sometimes be achieved through a "new use of a pharmaceutical" claim.
37 Form of the claim may be important in some situations. A claim to a blood extraction method for facilitating sustained venous blood flow through a limb to an extraction point wherein limb stimulus means were activated to provide a stimulus was found patentable. EPO TBA, T 0329/94. The technical board found that the method did not cure an ailment and was thus not a therapeutic method, it did not involve reaching a diagnosis and was not a diagnostic method, and the method itself did not involve surgery either. The technical board, therefore, decided that the claim was essentially a product claim to a stimulus means. Had it found the claim drawn to a blood extraction method, it would not have allowed the claim as patentable.
contraception were refused where the treatment involved the administration of two different hormones at different times in the menstrual cycle, one of the hormones being included so as to have a prophylactic effect to counter adverse effects that had been associated with the use of the other.38 The fact that the use of one of the required elements was clearly unpatentable rendered the whole method of use claim unpatentable.

Certain indicators are used by the EPO in deciding patentability. For example, if a medical practitioner is required to carry out the method, it is a likely indicator that a method of treatment is being performed which is not patentable.39 However, a method that can be carried out by non-medical practitioners may still be an unpatentable method of treatment.40 Or, in contrast to procedures whose end result is the death of the living being "under treatment," either deliberately or incidentally (e.g., the slaughter of animals or methods for measuring biological functions of an animal which comprise the sacrificing of said animal41), those physical interventions on the human or animal body which give priority to maintaining the life or health of the body on which they are performed are, "in their nature," methods for treatment by surgery within the meaning of Article 52(4) EPC.42

III. THE NATIONAL SCENE

This section skims the U.S. law regarding patentability of treatment methods prior to enactment of 35 U.S.C. § 287(c), the people and policies that formed the statute, and the consensus of the commentators regarding what the statute meant to accomplish.

A. Patentability of Treatment Methods Prior to 35 U.S.C. § 287(c)

In 1994, Congress passed the Uruguay Round Agreement Act to implement changes to the U.S. patent law required by TRIPs. Prior to the passage of the Uruguay Round Agreement Act and adoption of TRIPs, whether medical and surgical methods constituted patentable subject matter had long been controversial in the U.S.43 As TRIPs does

38 Case T 820/92, Contraceptive method/The General Hospital, O.J. EPO 113 (1995).
40 Id.
not make it mandatory to categorically exclude treatment methods from patentability, while the EPC and most other signatories chose to make this category unpatentable, U.S. did not choose to do the same.

Chisum presents a history of treatment method patents in the U.S. that follows. The seminal case involved a patent claiming performance of surgical operations by combining the surgical operation with the application of ether. The language of this case created the notion that medical and surgical methods were not patentable processes and this notion lasted until the 1930s. In 1930 the courts started upholding patents on medical diagnosis and treatment methods. In 1951, the Fourth Circuit, while invalidating the challenged patents, confirmed the patentability of treatment methods. In 1954, the Board of Appeals of the Patent Office permitted patenting of some treatment methods. In doing so, the Board overruled an earlier decision that had had the impact of excluding all medical treatment methods from patentability.

In more recent years, patents issuing to medical treatment methods have become more common. By 1996 it was estimated that the Patent Office had been issuing as many as 15 medical procedure patents per week.

In Pallin v. Singer, the case that triggered the concerns of the medical community, one doctor filed a patent infringement case against another alleging infringement of a patent issued to the plaintiff for a

Id.

44 Morton v. New York Eye Infirmary, 17 F. Cas. 879 (S.D.N.Y 1862).
46 Martin v. Wyeth, 193 F.2d 58 (4th Cir. 1951).
48 Ex Parte Brinkerhoff, 24 Comm'r's MS Decision 349, 27 J. PAT. OFF. SOC'Y 797 (1883).
surgical technique used during cataract surgery.\textsuperscript{52} The court in Pallin v. Singer, invalidated some of the claims of Pallin’s patent and enjoined him from enforcing the rest. This case, nonetheless, created the political impetus which resulted in enactment of 35 U.S.C § 287(c).\textsuperscript{53}

\textbf{B. Proponents and Opponents of 35 U.S.C. § 287(c)}

This section lists the lobby groups on opposing sides of H.R. 3610, passed in September of 1996 which gave rise to Public Law 104-208 that was in turn codified into 35 U.S.C. §287(c), and summarizes some of their arguments.


The Clinton administration’s Department of Commerce (that oversees the U.S. Patent and Trademark Office), the American Bar Association (ABA), the American Intellectual Property Law Association (AIPLA), the Biotechnology Industry Organization (BIO), and the Pharmaceutical Research Manufacturer’s Association (PhRMA) lobbied against amending the patent statute.

In the debate over the pros and cons of making treatment methods unpatentable or at least limiting liability for infringement of treatment method patents, one side argued doctors had an ethical obliga-


\textsuperscript{53} See, e.g., Weldon E. Havins, "Immunizing the Medical Practitioner "Process" Infringer: Greasing the Squeaky Wheel, Good Public Policy, Or What?" 77 U. DET. MERCY L. REV. 51 (1999); Gerald J. Mossinghoff, Remedies under Patents on Medical and Surgical Procedures, 78 J. PAT. & TRADEMARK OFF. SOC’Y 789 (1996).
tion to share their innovations; the other side argued that the doctors should profit from their innovations. One side argued that doctors have been and will be innovating the same with or without an added profit incentive; the other side argued that doctors should be given the incentive of profiting from their innovations like everyone else. One side argued that U.S. law should be in step with international law which banned patenting of treatment methods; the other side argued that U.S. law should keep its differences with the laws of other countries and use them as a bargaining chip in international negotiations. One side argued patenting would add to the cost of health care; the other side argued that many factors, such as regulations, add to the cost of health care but were nonetheless necessary. These arguments reflect the policies considered during the debate and the meaning of the resulting statute. Certain other policy considerations, expressed by foreign jurisdictions in forming their respective laws, were not raised by the U.S. Commentators.

54 The AMA presented professional and ethical concerns regarding patenting of treatment methods. American Medical Association, Council on Ethical and Judicial Affairs, Ethical Issues in the Patenting of Medical Procedures, 53 FOOD & DRUG L.J. 341, 344-348 (1998). The World Medical Association agreed with the AMA and on similar grounds. World Medical Association Statement on Medical Process Patents, Adopted by the 51st World Medical Assembly, Tel Aviv, October 1999, available at http://www.wma.net/e/policy/m30.htm. Both AMA and WMA distinguished patents on medical devices and pharmaceuticals from treatment method patents. They seemed to believe that patents on medical devices and pharmaceuticals are not offensive to the medical profession because the manufacturers of the devices and the drugs are not bound by the same ethical considerations as doctors. Further, these industries need the profit incentive in order to innovate whereas the doctors’ incentives should lie elsewhere as far as the AMA and WMA were concerned. AMA was also concerned about the quality of patents issued by the Patent and Trademark Office in general. Both associations indicated distaste for exposing the image of their profession to the indignity of litigation amongst colleagues. In addition to the AMA and its various members, the lawyers who represented the coalition of medical and surgical specialty societies presented arguments in support of the limitation of liability granted by the statute. Robert M. Portman, Legislative Restriction on Medical and Surgical Patents Removes Impediments to Medical Progress, 4 U. BALTIM. INTELL. PROP. L.J. 91 (1996).

55 On the other side, AILPA considered the incentive driven patent system a constitutional mandate and argued for keeping the system intact, available at http://www.aipla.org. Most other views expressed in the literature are by patent practitioners that benefit from maximizing the number of patents filed and do not wish to see the number of patentable categories or recovery for infringement of patents, hence the incentive to sue, limited. Steven L. Nichols, Hippocrates, the Patent Holder: The unenforceability of Medical Procedure Patent, 5 GEO. MASON L. REV. 227(1997); Brett G. Allen, Left to One’s Devices: Congress Limits Patents on Medical Procedures, 8 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 837, 841 (1998); Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALTIM. INTELL. PROP. L.J. (1996). These practitioners argued that a correct balance of policy interests did not require limiting the liability of infringers.

56 Several relevant considerations were not expressed by the commentators. One
C. Consensus of Commentators

The literature commenting on 35 U.S.C § 287(c) is almost unanimous in expressing or implying that this statute grants immunity to medical practitioners against liability for infringement of medical treatment method patents only.

Some examples of the consensus are cited in this paragraph. "The current controversy over the patentability of medical procedures began in 1993 ...."57 "A concern among medical professionals is that the existence of patents on therapeutic and diagnostic methods has a chilling effect on the study of such procedures."58 "This note examines the controversial medical procedure patent legislation ...."59 The debate leading to the enactment of 35 U.S.C. § 287(c) generally argued whether "Congress should amend the patent statute to exclude medical procedures from the definition of patentable material."60 "More recently, there was a renewed effort to exclude medical procedures

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59 Supra note 57.
from the scope of the Patent Act in response to a strong medical lobby asserting that doctors should not be liable for infringement of medical procedure patents. Although these efforts did not ultimately alter the scope of patentable subject matter, the legislation Congress did enact deprives medical procedure patent owners from any remedies against doctors who infringe and may thus make the scope of patentable subject matter an empty promise for such inventions.61 “Responding to concerns raised by medical professionals over patents issued on surgical techniques … Congress in 1996 enacted 35 U.S.C. § 287(c), which provides that the remedies against patent infringement shall not apply to medical practitioners and related health entities for performance of a medical activity.”62 “On September 30, 1996, Congress included a limitation on medical procedure patent infringement in the Omnibus Consolidated Appropriations Act of 1997. The provision, section 287(c), created a safe haven from patent infringement liability under certain circumstances. Proponents of section 287(c) argue that it addresses problems with medical procedure patents and the infringement lawsuits that naturally flow from the ownership and enforcement of those patents.”63 “The intent of Public Law 104-208 [codified as 35 U.S.C. § 287(c)] is to deny these rights to a patent owner if the subject of the patent is purely a medical or surgical procedure. The result renders any such patent virtually worthless.”64 “This section amends 35 U.S.C. § 287 to prevent the enforcement of medical procedure patents against medical practitioners ….”65

According to these commentators and many more, 35 U.S.C. § 287(c) was enacted to allow medical practitioners to practice a patented treatment method without liability for infringing the patent. The fact


that only "medical treatment method patents" were on the minds of those involved in the debate leading to the enactment of 35 U.S.C. § 287(c) as well as the commentators, who have since spoken, is also apparent from the titles of the many of the journal articles referenced in this paper.

IV.
LANGUAGE OF 35 U.S.C. § 287(c)

This section provides a glimpse at some of the issues that a judge may face when attempting to construe the language of the statute.

35 U.S.C. § 287(c) recites: "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under ... this title, the provisions [providing a civil remedy, allowing for injunction, providing for damages, and providing for attorney fees in the event of patent infringement] shall not apply against the medical practitioner ...." This statute does exclude all patentable categories of inventions except for process patents: "but [immunized medical activity] shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent...." It does also exclude process patents drawn to the method of using a drug and biotechnology process patents: "the practice of a patented use of a composition of matter in violation of such patent" or "the practice of a process in violation of a biotechnology patent." In view of the language and the legislative history of the statute, drug, device, and biotechnology patents, and treatment method patents that derive their patentability from the use of a drug, device, or a biotechnological innovation, may not be infringed with immunity.

64 There are four patentable categories recognized by Title 35 of the U.S. Code: Process, machine, manufacture, and composition of matter. 35 U.S.C. § 101 (2004).
The statute does not specify the category\textsuperscript{70} or subject matter\textsuperscript{71} of a patent infringed by the performance of medical activity whose infringement has been immunized by the statute. Neither does the statute impact the patentability of treatment methods or methods for performance of a medical activity. Rather, the statute makes presumably valid process patents unenforceable vis à vis certain groups of infringers who commit their infringement during performance of certain activities.

Accordingly, the interpretation of 35 U.S.C. § 287(c) hinges not on the subject matter of the patent being infringed but on the issues of whether the infringer was a bona fide "medical practitioner," and whether the infringer's activity, which constituted infringement, also constituted a protected "medical activity." No reported U.S. cases have interpreted this statute since its enactment in 1996. While a judge could be aided by ample foreign case law in determining whether an application is drawn to a treatment method, he will have to interpret the phrases "medical activity" and "medical practitioner" anew without the aid of any authoritative or persuasive precedent.

A. Activity Focus of the U.S. Statute Contrasted to Patent Focus of TRIPs and EPC

Unlike TRIPs and EPC provisions that specify the subject matter of procedures that are unpatentable, the U.S. statute specifies the type of activity that may be performed with immunity from infringement of valid patents.\textsuperscript{72} While the category and subject matter of patents, whose infringement is immunized, are not defined in their own right, the statute alludes to them as patents that may be infringed by "performance of a medical activity."\textsuperscript{73} The focus of the language is on the type of infringing activity not the category or subject matter of the patent being infringed.\textsuperscript{74}

\textsuperscript{70} Process, machine, manufacture, or composition of matter.

\textsuperscript{71} Surgical procedure, medical device, biotechnological invention, or drug.

\textsuperscript{72} TRIPs art. 27(3); EPC art. 52(4); 35 U.S.C. 287(c) (2002).

\textsuperscript{73} Activities constituting infringement are: Making, using, offering to sell, or selling any patented invention, within the U.S. or importing into the U.S. any patented invention during the term of the patent. 35 U.S.C. § 271(a)(1999). As 35 U.S.C. § 287(c) is effectively limited to the category of process patents, the infringing activity will likely be "use" of the patented process by performing it.

\textsuperscript{74} For an example of an article correctly recognizing the activity focus of the statute, see e.g., Duane Nash, Recommended Response for Human Cloning Patent Applications, 42 IDEA 279, 279 (2000) ("[T]he patent infringement immunity given to 'medical activities' by § 616 of the Omnibus Consolidated Appropriations Act of 1996 ('Act') should not be relied upon
Courts need yet clarify, what kinds of activities constitute the protected "medical activity" of the statute. Subsection (c)(2)(A) defines "medical activity" as "the performance of a medical or surgical procedure on a body." The statute expressly excludes the use of a patented drug, device or a biotechnology system or method from the immunity granted, and the legislative history provides further guidance as to what does not constitute a "medical activity" covered by the statute. But, what does constitute a covered "medical activity" is not directly set forth in the positive.

While the identity of the proponents and opponents of a statute is not an authoritative source of statutory interpretation, identifying the interest groups that lobbied for and against a provision may shed light on whose interests may have been accommodated. For example, because plastic surgeons argued for the passage of the statute, a flag is raised indicating that the legislature had their interests in view if not in mind, and cosmetic plastic surgery was probably considered for inclusion as an immunized activity. Veterinarians did not lobby for this statute and it is clear that the statute does not consider veterinary treatment of animals to be a medical activity.

It is not clear whether the statute considers dental treatment as a medical activity. An argument may be made that "medical activity" does not include dental activity. Subsection (c)(2)(C) defines "related health care facility" and includes examples of a "related health care facility" as "including but not limited to a nursing home, hospital, uni-

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75 35 U.S.C. § 287 (2001); See generally Id. ("For purposes of this subsection ... (E) the term "body" shall mean a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans." The term "body" is defined by statute to include human or nonhuman animal or cadaver. The cadaver or the nonhuman animal, however, has to be used in research or instruction directly relating to finding a cure for treatment of humans. In other words, 35 U.S.C. 287 only applies to medical activity for the ultimate purpose of treating human bodies and the statute does not apply to veterinary medicine and treatment of animals for their own sake).

76 See H.R. CONF. REP. NO. 104-863, at 852-53 (1996) ("The term 'medical activity' as defined in subsection 287(c)(2)(A) does not include 'the practice of a patented used of a composition of matter.' ... [P]atented use of a composition of matter' does not include any claim for performing a medical or a surgical procedure on a body that recites the use of the composition of matter where the use of the composition of matter does not directly contribute to the achievement of the objective of the claimed method. ... For a 'hybrid' claim, ie., a claim with at least one step that recites the use of a composition of matter and at least one step that is not directed to the use of a composition of matter (e.g., a surgical step), [a test set forth in the statute] must be applied to determine whether the claim as a whole is exempted from the definition of a 'medical activity' because it is a patented use of a composition of matter").

77 See supra note 75 (defining "body" according to the statute).
iversity, medical school, health maintenance organization, group medical practice, or a medical clinic." Absent, not only from the language of the statute but also from its legislative history, are the terms "dentist" and "dental." The Medical Procedure Patent Coalition, that lobbied for limitation of liability, included numerous medical but no dental societies. Also, while the AMA has emphatically registered its opinion on this matter, the American Dental Association has been absent from the debate. Further, only some categories of dental procedures may be categorized as immunized surgical procedures. Patents within many subclasses of the class for dentistry\textsuperscript{78} are not directed to surgical procedures. For example, the subclass directed to the "method of positioning or aligning teeth,"\textsuperscript{79} the subclass directed to "holding or positioning denture in mouth,"\textsuperscript{80} or portions of the subclass directed to the "method or material for testing, treating, restoring, or removing natural teeth"\textsuperscript{81} are arguably not directed to medical or surgical activity covered by the statute. Infringing a patent, while performing any of these activities, is probably subject to liability.

Another example of issues that need to be addressed was raised by a commentator arguing that since 35 U.S.C. § 287(c) defines medical activity as the performance of a medical or surgical procedure, insofar as software or computer systems are not medical or surgical procedures, this section should not cover the patents drawn to such software or computer system.\textsuperscript{82} The commentator was taking for granted that only treatment method patents fall within the purview of the statute. However, his argument may be rephrased with an activity focus as: Whether using a piece of computer software or a computer system for deciphering the results of a medical test is a medical activity immunized by the statute.

A general problem with the activity focus, as opposed to the patent focus, of the statute is the order in which scrutiny and conflict occur. Inventors seeking patents on their treatment methods go through the application process of the U.S. Patent and Trademark Office before there can be any litigation over infringement. A medical practitioner


\textsuperscript{79} Id. class 433, subclass 24.

\textsuperscript{80} Id. class 433, subclass 172.

\textsuperscript{81} Id. class 433, subclass 215.

that has infringed a patent is subject to a court determination of whether he was engaged in performance of a medical activity after he has already been sued for patent infringement. There is no administrative body tasked with determining which activities constitute a medical activity and the example of EPO law indicates that lines of demarcation are not so bright.

B. Who Are Medical Practitioners?

According to subsection (c)(1) of the statute: "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284 and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity." Thus, only "with respect to a medical practitioner's performance of a medical activity that constitutes an infringement" are the remedy and damages provisions of the patent statute unenforceable. Subsection (c)(2)(B) defines "medical practitioner" as "any natural person who is licensed by a State to provide the medical activity described in subsection (c)(1) or who is acting under the direction of such person in the performance of the medical activity." A person or entity not falling under the definition of medical practitioner may not practice the patented treatment method with impunity. Moreover, a person qualifying as a "medical practitioner" under the statute would not enjoy immunity if he engages in a "medical activity," other than the medical activity for which he is licensed. It is not clear whether dentists or veterinarians are medical practitioners.

83 Aside from the fact that doctors lobbied, therefore doctors are immune, the statute seems to have resolved the policy considerations behind this provision without any discussion. An interpreting court will have to guess as to the policy if the policy is to aid the construction. The U.S. law may have limited the immunity to licensed professionals out of concern for public safety. Yet, one might argue that there are other civil and criminal laws that regulate unauthorized practice of medicine. This aspect of 35 U.S.C. 287(c) is in contrast to EPO law that does not turn on the identity of the entity practicing the treatment method. European Patent Office, Decision of Technical Board of Appeal 3.2.2 (September 29, 1999) T 0035/99-3.2.2, available at http://legal.european-patent-office.org/dg3/biblio/t990035ep1.htm. In the case of mass treatment of animals mentioned supra in footnote 56, the patent applicant had argued that the method when carried out by a farmer was industrial activity and therefore patentable. The EPO technical board of appeal decided that it was "[n]ot possible as a matter of law to draw a distinction between such a method as carried out by a farmer and the same method as carried out by a veterinarian." European Patent Office, Decision of Technical Board of Appeal T 00116/85 3.3.1 (Oct. 14, 1987), available at http://legal.european-patent-office.org/dg3/biblio/t850116ep1.htm. EPO law seems to emphasize the nature of the activity over the identity of the person carrying it out.
practitioners. And, the licensing laws of a state will weigh in on determining who the "medical practitioners" of that state are. What degree of supervision would satisfy "acting under the direction of a medical practitioner" is another unknown.

C. Questionable Impact of Legislative History

As a general rule of statutory construction, a statute is construed to give effect to both the language of the statute and the intent of the legislature with language carrying the more considerable weight. "I read the statute so as to give effect to its language."84 "[T]he starting point for interpreting a statute is the language of the statute itself. Absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive."85 "As in all cases involving statutory construction, our starting point must be the language employed by Congress, and we assume that the legislative purpose is expressed by the ordinary meaning of the words used. Thus, absent a clearly expressed legislative intention to the contrary, that language must ordinarily be regarded as conclusive."86

The significance of legislative history is itself a disputed point: "Traditionally, the legislative history of a U.S. public law is looked to by federal agencies, attorneys and the courts in order to determine the Congressional intent of a particular statute or one of its provisions, especially if the plain reading of the statutory text is somewhat ambiguous.... At the very least, a legislative history will usually answer the general question about why Congress is making a particular law or particular title of a law. However, what Congress intended when they enacted a particular provision in a law or what they meant by a particular word or phrase in a law is usually harder to decipher. In recent decades, many law review articles have been written that have debated the merits of relying on documents that are not themselves legislative enactments.... Many critics, like Supreme Court Justice Antonin Scalia, advocate a strict textual interpretation of public laws. This criticism has lead [sic] to a dampening of the use of federal legislative histories in some federal courts ...."87

84 Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F3d 956, 971 (Fed Cir. 2002) (Lourie, J., concurring on denial of petition for rehearing en banc).
Although no one studying the history of the statute can doubt in good faith that the statute was enacted with medical treatment method patents in focus, there may be several problems with construing the statute to limit the granted immunity to immunity for infringement of treatment method patents. The main piece of legislative history for 35 U.S.C. § 287(c), the associated conference report, is written as broadly as the statute and does not specify that the immunity granted by the statute applies to infringement of treatment method patents alone. Further, given the textualist tendency of the recent years, the statute is susceptible of being interpreted as broadly as written.

In recent years, the interpretative paradigm has moved, quite dramatically, [in the direction of textualism].... Text, once a mere player in the broader search for legislative meaning, has now taken center stage--framed by its champions as the end of the statutory inquiry itself, rather than a subservient means to some other end. Arguments rooted in non-textual considerations, if not totally eviscerated, are not held in favor by the courts.88

V.
LANGUAGE BEYOND INTENT

The international background, the history of the statute, and the commentators all point to the same concept that 35 U.S.C. § 287(c) was enacted to make treatment method patents unenforceable in the specific circumstances articulated by the statute.89 The language of the statute achieves this goal. The language of the statute, however, goes further, making all types of process patents unenforceable against an infringing medical practitioner engaged in performance of a medical activity.90 Of course, drug and biotechnology related process patents are expressly

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90 As explained earlier, patentable categories of machine, article of manufacture, and composition of matter are excluded from the coverage of the statute leaving only process patents subject to the immunity granted for infringement. 35 U.S.C. 287(c)(2)(A)(i).
excluded from the reach of the statute. Express exceptions of the product categories91 and express exclusion of drug and biotechnology subject matters may also aid arguments in favor of the broader interpretation: Had Congress intended to exclude a particular process patent from infringement immunity, it would have done so as it did product patent or drug and biotechnology process patents.92 Under this reasoning, all other process patents would be game.

The statute as written is, therefore, overbroad. The language of the legislative history is also general and can include all process patents.93 The previous sections show that despite the narrow intent clear in the history of the statute and taken for granted by commentators, an overbroad language is in danger of overbroad interpretation. This section explains how the language stretches beyond treatment method patents while including them.

A. 35 U.S.C. § 287(c) Makes More than Treatment Method Patents Unenforceable

In a law suit asserting infringement of a patent, 35 U.S.C. § 287(c) is implicated at a point when the court has already determined that the patent at issue in the case was valid and is infringed by the acts of the defendant. The issue addressed by 35 U.S.C. § 287(c) is whether the infringer is nonetheless immune from liability for his infringing actions. Under this statute, the infringer is immune if he was a "medical practitioner" and performed a "medical activity" that constituted an infringement of this patent. The determination of whether the medical practitioner was engaged in "performance of a medical activity" is related, but not equivalent, to determining whether the patent at issue in the case is drawn to a treatment method or a method of "performance of a medical activity."

91 Machines, articles of manufacture, and compositions of matter patents are all product patents.
93 As mentioned earlier, the main piece of legislative history to be consulted by an interpreting court § 616 of the Conference Report to accompany H.R. 3610, 104th Cong. (1996), which does not contain any reference to the emphasis of the statute on treatment method patents either. This piece of legislative history is focused on discussing the exceptions granted to drug and biotechnology industries. See, e.g., Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner's Performance of a Medical Activity. The "legislative history" in a broader sense of the phrase is of course why we know the statute was truly directed at medical treatment method patents alone.
The distinction between the two related issues lies in the definition of infringement. For an accused process to infringe a patent claim, all of the claim's limitations must be present in the accused process either literally or by a substantial equivalent. In the case of a method claim, the infringer must perform each and every element of the patented claim. If what he performs lacks even one element of the claim, he is not infringing that claim. On the other hand, if he performs the claim elements and then takes additional steps, he is still infringing. Performance of a medical activity may consist of performing all of the elements of a method claim and additional steps not included in the claim. Performing this medical activity, that includes steps beyond the patented elements, is "performance of a medical activity that constitutes an infringement." The steps of this medical activity, however, are not in one-to-one correspondence with the elements of the claim being infringed. So, the claim being infringed need not itself be drawn to a method of performance of a medical activity or a treatment method.

A hypothetical scenario further illustrates the implications of the statutory language of 35 U.S.C. § 287(c). Suppose that a patented cosmetic procedure is not considered to be a medical activity under U.S. law. If a beautician performs this cosmetic procedure, she is infringing the patent and subject to liability for her infringement. If a medical practitioner performs this cosmetic procedure, he is also infringing the patent and subject to infringement liability. If, however, the medical practitioner adds steps that turn his activity into a medical activity, then he has infringed the patent during the performance of a medical activity or he has engaged in "performance of a medical activity that constitutes an infringement." He is immune from liability even though the procedure he intended to perform was not a medical activity and even though the patent he infringed was not drawn to a method of performing a medical activity. The added steps by the medical practitioner may be completely superfluous with the exclusive intention of abusing the immunity granted by the statute. Under this scenario, the beautician who performs the same procedure does not have the options for evading liability that are available to the infringing doctor.

95 A mirror image of this scenario was presented by one author who explores the legislative history for the purpose of advising patentees on how to evade the reach of the statute.
In such situations, a court would sort those who are legitimately within the purview of the statute from those who are not and would assure that performing the broader medical activity has not been a means of abusing the protection granted by the statute. To determine whether the infringing medical practitioner was involved in “performance of a medical activity” as opposed to an activity whose real thrust was otherwise, the court could look to the considerations of the type discussed by the legislative history of the statute in the context of distinguishing claims whose real thrust is a novel method of using a composition of matter from claims who recite a method of using a composition of matter merely as a means of falling within the exception granted by the statute.96

96 See the discussion of hybrid claims in Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. An excerpt from this discussion follows: “An example, in the case of a surgical method for transplanting a healthy heart into a patient with a diseased heart, the inclusion of a step of administering a conventional anaesthetic in a claim reciting a novel and non-obvious surgical transplantation procedure would not cause the surgical procedure to be treated as a patented use of a composition of matter within the meaning of subsection (c)(2)(A)(ii). Therefore, assuming none of the other exception is subsection (c)(2)(A) apply, the claimed immunizing infringement of their patents. Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALT. INTELL. PROP. L.J. 69 (1996). Infringement of a patent is not subject to the immunity granted by the statute, if the patent is drawn to a composition of matter or derives its utility, novelty, or nonobviousness from the use of a composition of matter included in the claims. See Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. The legislative history describes a test established by section 287(c)(2)(F) as first determining the objective of the claimed method taking into account all of the process steps set forth in the claim and second determining whether the steps involving the use of the composition of matter either alone or in combination contribute directly to the achievement of the objective of the claimed method. Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. If the use of the drug is crucial to the claim, then the claim would be one drawn to the drug or a new use of the drug and would be enforceable. The author of this article observes that because claims are reviewed “as a whole,” issued patent claims directed to process steps are not dissected to determine if each step in the process is novel, nonobvious and useful. Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALT. INTELL. PROP. L.J. 69, 86 (1996). Thus, the author continues, if a claim includes an obvious step, such as use of a patented antibiotic to prevent infection, then by definition the antibiotic contributed to the nonobviousness of the claim as a whole. Id. The author recommends that the patent applicant further buttress its position by adding statements to the specification indicating that an objective of the surgical procedure was to ensure minimizing the chance of infection and to achieve this objective the procedure mandates using an antibiotic. Id. By such maneuvering, a process claim, whose infringement is fair game for doctors, is dressed as a drug claim, whose infringement is actionable. Just as patent attorneys can turn a method claim into a drug claim, doctors can turn a non-medical activity into an immunized medical activity.

96 See the discussion of hybrid claims in Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. An excerpt from this discussion follows: “An example, in the case of a surgical method for transplanting a healthy heart into a patient with a diseased heart, the inclusion of a step of administering a conventional anaesthetic in a claim reciting a novel and non-obvious surgical transplantation procedure would not cause the surgical procedure to be treated as a patented use of a composition of matter within the meaning of subsection (c)(2)(A)(ii). Therefore, assuming none of the other exception is subsection (c)(2)(A) apply, the claimed immunizing infringement of their patents. Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALT. INTELL. PROP. L.J. 69 (1996). Infringement of a patent is not subject to the immunity granted by the statute, if the patent is drawn to a composition of matter or derives its utility, novelty, or nonobviousness from the use of a composition of matter included in the claims. See Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. The legislative history describes a test established by section 287(c)(2)(F) as first determining the objective of the claimed method taking into account all of the process steps set forth in the claim and second determining whether the steps involving the use of the composition of matter either alone or in combination contribute directly to the achievement of the objective of the claimed method. Cong. Rec. 9/28/96, H11662, § 616. Limitation on Patent Infringements Relating to a Medical Practitioner’s Performance of a Medical Activity. If the use of the drug is crucial to the claim, then the claim would be one drawn to the drug or a new use of the drug and would be enforceable. The author of this article observes that because claims are reviewed “as a whole,” issued patent claims directed to process steps are not dissected to determine if each step in the process is novel, nonobvious and useful. Richard P. Burgoon, Jr., Silk Purses, Sows Ears and Other Nuances Regarding 35 U.S.C. § 287(c), 4 U. BALT. INTELL. PROP. L.J. 69, 86 (1996). Thus, the author continues, if a claim includes an obvious step, such as use of a patented antibiotic to prevent infection, then by definition the antibiotic contributed to the nonobviousness of the claim as a whole. Id. The author recommends that the patent applicant further buttress its position by adding statements to the specification indicating that an objective of the surgical procedure was to ensure minimizing the chance of infection and to achieve this objective the procedure mandates using an antibiotic. Id. By such maneuvering, a process claim, whose infringement is fair game for doctors, is dressed as a drug claim, whose infringement is actionable. Just as patent attorneys can turn a method claim into a drug claim, doctors can turn a non-medical activity into an immunized medical activity.

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B. Infringing a Treatment Method Patent Is Medical Activity

This paper concurs that, in addition to patents on drugs and medical devices, patents that are more likely to be infringed by a medical practitioner, in performance of a medical activity, are treatment method patents. This section shows that under the language of the statute, infringement of treatment method patents by a medical practitioner is immune from liability as intended by the legislature and argued by the commentators.

As explained above, the language of the statute does not turn on the subject matter of the process patent being infringed. Rather than determining whether the process patent infringed was drawn to a method of treatment, a court examining the applicability of 35 U.S.C. § 287(c) has to determine whether the type of activity performed by the medical practitioner was a "medical activity." Nevertheless, in many cases, the issue of whether the activity performed by the practitioner was a medical activity is automatically resolved when the court determines that the patent infringed was drawn to a method of performance of a medical activity.

Medical practitioners infringing patents drawn to treatment methods or methods of "performance of a medical activity" are always immune under 35 U.S.C. §287(c) because infringing this type of patent, without doing more, is by definition an immunized "performance of a medical activity." The medical practitioner need not improvise extra steps to turn his infringing activity into a medical activity. Thus, once the court determines that the infringed patent was claiming a method of "performance of a medical activity" and that the person infringing was a medical practitioner, the infringer is immune from liability and the patentee will get no remedy.

On the other hand, medical practitioners infringing a patent that is not inherently drawn to a method of "performance of a medical activity" may or may not be immunized by the statute. After the court determines that the infringed patent did not claim a method of "performance of a medical activity" and that the infringer was a medical practitioner, the court must still determine whether the medical

surgical method would necessarily qualify as a medical activity. In contrast, where the administration of anaesthesia was accomplished, for example, using a novel anaesthetic or a novel dosing schedule, the objective of the claimed method would include the provision of a novel use of an anaesthetic in transplantation surgery and the use of the composition of matter (i.e., the anaesthetic) would directly contribute to the achievement of the objective."
practitioner infringed the patent in the course of "performance of a medical activity." If the medical practitioner infringed the patent not in the course of performance of a protected "medical activity" within the meaning of the statute, then he would be liable for infringement. If the medical practitioner infringed the patent in the course of performing a "medical activity," then even though the patent itself is not drawn to a treatment method and even though the patent is infringed, the medical practitioner is nonetheless immune.

VI.
CONCLUSION

This paper explores the boundaries of immunity from liability for infringement of process patents that was created by the enactment of 35 U.S.C. § 287(c) in 1996. The paper examines the language of the statute in the absence of relevant U.S. case law. The paper shows that based on the language of the statute, a medical practitioner engaged in performance of a medical activity is immune from liability for infringing treatment method patents as well as any other kind of process patent except expressly excluded drug and biotechnology process patents. A court deciding the applicability of the immunity may decide to first resolve whether the claims infringed are drawn to a treatment method, or a method of performance of a medical activity. If the claims infringed are treatment method claims, the infringing medical practitioner is immune because by the very infringement of the claims, he did engage in performance of a medical activity. However, as long as the claims infringed are process claims, even if not drawn to a treatment method, the medical practitioner may still be immune if he infringed the claims in the course of performance of a medical activity.

As such, the reach of 35 U.S.C. § 287(c) may go further than that intended by Congress and further than EPO law that prohibits patenting of treatment methods but does not immunize medical practitioners from liability for infringement of valid process patents in other areas. 35 U.S.C. § 287(c) was thought to reach a compromise between opposing sides by leaving the patentability of treatment methods intact. However, in the light of the overbroad statutory language, opting to make treatment methods unpatentable in accord with most foreign laws would have been advantageous for some opponents of the statute.
35 U.S.C. § 287(c)

(c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281 [providing a civil remedy for patent infringement], 283 [allowing for injunction in the event of patent infringement], 284 [providing for damages in the event of patent infringement] and 285 [providing for attorneys fees] of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

(2) For the purposes of this subsection:

(A) the term "medical activity" means the performance of a medical or surgical procedure on a body, but shall not include

(i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent.

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

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

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

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

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

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

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

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

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

(4) This subsection shall not apply to any patent issued before the date of enactment of this subsection."
Selected portions of Section 616 of the Conference Report [to accompany H.R. 3610], September 28, 1996, follow:

"The conference agreement includes section 616, which includes language not in either the House or Senate-reported bill. The provision included in this conference agreement precludes the filing of civil action for damages or injunctive relief against a medical practitioner licensed by the State to provide the medical activity that would otherwise constitute an infringement or inducement to infringe under 35 U.S.C. § 271(a) or (b) for patents issued after its enactment.

The term "medical activity" as defined in subsection 287(c)(2)(A) does not include "the practice of a patented used of a composition of matter." The term "patented use of a composition of matter" as used in subsection (c)(2)(A)(ii) is limited by subsection (c)(2)(F). Subsection (c)(2)(F) provides that the term "patented use of a composition of matter" does not include any claim for performing a medical or a surgical procedure on a body that recites the use of the composition of matter where the use of the composition of matter does not directly contribute to the achievement of the objective of the claimed method. A use of a composition of matter as a step in a claim will direct [sic] contribute to the achievement of the objective of the claimed method if it is itself novel or if it contributes to or is necessary to establish the non-obviousness of the claim as a whole.

For a method claim in which each of the method steps recites a "use of a composition of matter" the claim cannot represent a "medical activity" because the use of a composition of matter must necessarily contribute to the novelty – and, therefore, to the objective – of the claimed method. "Uses of compositions of matter" include, without limitation, novel uses of drugs, novel uses of chemical or biological reagents for diagnostic purposes, novel method for scheduling or timing administration of drugs, novel methods for combining drug therapies, and novel methods for providing genetic or other biological materials to a patient (including gene therapies.” A particular example would be a claim that recites only the novel use of a drug for the treatment of diabetes that involves the administration of a drug at a particular time of day on/or at a specified dose and/or with a specified concomitant medicinal therapy could not be construed as a "medical activity."
For a "hybrid" claim, i.e., a claim with at least one step that recites the use of a composition of matter and at least one step that is not directed to the use of a composition of matter (e.g., a surgical step), the test established by subsection (c)(2)(F) must be applied to determine whether the claim as a whole is exempted from the definition of a "medical activity" because it is a patented use of a composition of matter. The first step in this test is to determine objective of the claimed method taking into account all of the process steps set forth in the claim. The second part of this test is to determine whether steps involving the use of one or more compositions of matter either alone or in combination contribute directly to the achievement of the objective of the claimed method. It is interesting [sic] that this part of the test will have been met if the uses of the compositions of matter, either individually or collectively, represents novel subject matter, or if one or more of these steps contributes to or are necessary to establish the non-obviousness of the claim as a whole. Thus, even where the steps involving used of one or more compositions of matter are not novel individually or in combination with each other, these uses may still directly contribute to the achievement of the objective of the claimed method if, in combination with the steps that involve collectively obvious medical or surgical techniques, they produce a novel and non-obvious method.

An example, in the case of a surgical method for transplanting a healthy heart into a patient with a diseased heart, the inclusion of a step of administering a conventional anaesthetic in a claim reciting a novel and non-obvious surgical transplantation procedure would not cause the surgical procedure to be treated as a patented use of a composition of matter within the meaning of subsection (c)(2)(A)(ii). Therefore, assuming none of the other exception is subsection (c)(2)(A) apply, the claimed surgical method would necessarily qualify as a medical activity. In contrast, where the administration of anaesthesia was accomplished, for example, using a novel anaesthetic or a novel dosing schedule, the objective of the claimed method would include the provision of a novel use of an anaesthetic in transplantation surgery and the use of the composition of matter (i.e., the anaesthetic) would directly contribute to the achievement of the objective.

It is intended that the applicability of the exception in (c)(2)(A)(ii) for a patented use of a composition of matter can usually be decided by a motion to dismiss or summary judgment under Rule 12(b) or Rule 56, respectively, of the Federal Rules of Civil Procedure.
For example, an accused infringer seeking to invoke the relief from remedies afforded under 287(c)(1) would ordinarily prevail under such a motion if the following conditions are met: (1) the movant shows by clear and convincing evidence that the recited uses of the compositions of matter, both individually and collectively, lack novelty, and (2) the movant also shows by a preponderance of evidence that the steps of the claimed method that do not involve uses of compositions of matter (i.e., the medical or surgical procedure steps) are, by themselves, novel and non-obvious, provided, however, that the movant may concede the non-obviousness in lieu of making the required evidentiary showing."