16 Tex. Intell. Prop. L.J. 299

Texas Intellectual Property Law Journal
Winter 2008

Article

REVISITING THE COMPROMISE OF 35 U.S.C. § 287(C)

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"There is always an easy solution to every human problem--neat, plausible, and wrong." ~H.L. Mencken

*300 I. Introduction

Over a decade ago, Congress enacted 35 U.S.C. § 287(c) to protect medical practitioners from liability for infringement of medical or surgical procedure patents.[1] Legislators sought a compromise designed to appease both the medical community, who were advocating for a complete ban on the patentability of medical procedures, and the biotechnology community, who feared judicial interpretation of such a ban would erode their patent rights.[2] Despite the legislature's best efforts at a statutory solution, these questions remain: What aspects of the practice of medicine are patentable and for those aspects that remain patentable, should they be?

Whether the practice of medicine is patentable may depend on how the issue is framed. In Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., the Supreme Court denied further review of a patent claim directed at a process for correlating test results with potential vitamin deficiencies.[3] The lower courts found Laboratory Corporation of America Holdings (LabCorp) liable "for inducing infringement of the claim when it encouraged doctors to order diagnostic tests for measuring homocysteine."[4] Justice Breyer dissented from the dismissal of certiorari arguing that the claim at issue amounted to an invalid effort to patent a phenomenon of nature.[5] According to Justice Breyer, the respondents simply could not avoid the fact that the claimed process was "no more than an instruction to read some numbers in light of medical knowledge."[6] Justices Stevens and Souter joined Breyer's dissent from the dismissal of the writ of certiorari.[7] It appears that LabCorp's failure to argue that the claim at issue was not patentable subject matter pursuant to 35 U.S.C. § 101 resulted in this denial of further Supreme Court review.[8] Although not explicitly dealing with a medical or surgical procedure, the controversy in this case helps to illustrate the difficulties in identifying the proper scope of patentability as applied to the practice of medicine.

Consider the surprise of a doctor who is told that by correlating the total homocysteine level of his patient to a cobalamin/folate deficiency he is directly ***301** infringing a patent.[9] Or imagine the shock of a doctor, who employs a special incision during surgery, finding out this surgical technique is patented, and he now owes its "inventor" a royalty.[10] Whereas LabCorp could have framed its defense to emphasize the exclusion of phenomena of nature from patentable subject matter,[11] many medical and surgical procedure patents could not be so characterized.[12] Thus, much of the practice of medicine remains patentable. A doctor may presume that the medicines he prescribes and the devices he employs are likely patented, but should he have to worry that the methods he uses to treat patients are too?

One might argue that whether medical methods fall within patentable subject matter does not matter because § 287(c) exempts medical practitioners from liability for "performance of a medical activity that constitutes an infringement."[13] However, the current Congressional solution to this controversy creates new problems and fails to resolve ethical dilemmas unique to medical process patents.

This Note intends to stimulate the public policy debate over whether medical and surgical procedures should be removed from the scope of patentability. Discussion is limited to the patentability of the practice of medicine utilizing a "pure" medical or surgical procedure--that is, "a medical diagnostic procedure or treatment, or a method or process, where the 'invention' is independent of the use of a medical device and drug."[14] Part II outlines the historical treatment of medical and surgical procedure patents in the United States. Part III traces the legislative response to enforcement of medical process patents in the 1990s. In light of the current state of affairs in both healthcare and patent law, Part IV evaluates the arguments for and against the patentability of medical procedure patents. Finally, Part V concludes that medical and surgical procedures should be removed from the scope of patentable subject matter.

*302 II. Historical Treatment of Medical Procedure Patents in the United States

Over time, the patent system's treatment of medical process patents has evolved from complete rejection to complete acceptance. This historical transition provides an important background to the current debate over the patentability of medical

and surgical procedures.

A. General Requirements for Patentability

The United States Constitution provides that Congress shall have the power "[t]o Promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[15] Since 1790, Congress has utilized this constitutional power to enact patent statutes designed to promote invention by giving the patentee the right to exclude others from "making, using, offering for sale or selling the invention."[16] This exclusionary right is valid for a limited time--twenty years from the filing date of the patent application.[17] However, not every invention deserves such protection; the patent statutes protect only inventions which are useful,[18] novel,[19] and nonobvious.[20]

Furthermore, the patent statutes explicitly define protectable subject matter as "any new and useful process, machine, manufacture, or composition of matter."[21] "The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to 'include anything under the sun that is made by man.'"[22] However, courts have interpreted this statutory requirement to prohibit the patenting of laws of nature, physical phenomena, and abstract ideas.[23] Thus, the statutory subject matter requirement excludes very few inventions from the scope of patentability, and medical and surgical procedures currently constitute patentable inventions (provided they meet the other statutory requirements).

*303 B. Patentability of Medical and Surgical Procedures

Prior to the 1950s, medical and surgical procedures were not considered patentable.[24] In Morton v. New York Eye Infirmary, the Federal Circuit Court for the Southern District of New York held that a method for anesthetizing patients by using ether was not patentable subject matter.[25] For the next fifty years or so, "the Commissioners of Patents' propounded the Morton rule that 'the methods or modes of treatment [by] physicians of certain diseases are not patentable.'"[26] For example, in Ex parte Brinkerhoff, the United States Patent and Trademark Office (USPTO) firmly stated that "the methods or modes of treatment by physicians of certain diseases are not patentable."[27] Thus, medical and surgical procedures were considered outside the scope of the patent system.

However, in the 1950s, amendments to the Patent Act and judicial reversal of prior case law led to the general understanding that medical and surgical procedures now fall within the realm of patentable subject matter. In 1952, Congress replaced the term "art" with "process" in 35 U.S.C. § 101.[28] Thus, the legislature clarified that processes in general were patentable. At this time, the judiciary was also moving toward including medical and surgical processes within patentable subject matter. In 1952, the Board of Patent Appeals allowed a patent claim on a "process of injection of medication through intact skin," thus opening the door for medical process patents.[29] In Ex parte Scherer, the Board of Patent Appeals overruled Ex parte Brinkerhoff "to the extent that [it] holds or implies that all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body."[30] While legislative and common law changes to the doctrine of patentable subject matter appeared to allow for patents on medical and surgical ***304** procedures, until Pallin v. Singer,[31] few believed physicians would enforce such patents against other physicians.[32]

C. Enforcement of Medical Procedure Patents in the 1990s: Pallin v. Singer

When Dr. Samuel Pallin, a surgeon emboldened by a patent on his process for creating a sutureless incision during cataract surgery, brought an infringement action against a fellow doctor, the consequences of allowing patents on medical and surgical procedures crystallized and sparked a heated debate.[33] The patented invention was an incision that: "(a) substantially self-seals; (b) is located 1.5 to 3.0 millimeters from the limbus; and (c) diverges from the limbus from a central location to form a shape resembling a chevron or frown."[34] Essentially, Dr. Pallin obtained a patent on making a frown-shaped incision that heals without the need for sutures. The defendants presented evidence of cataract surgeries involving both a sutureless technique made with a straight line and a sutureless, inverted-V-shaped, scleral incision.[35] In addition, Dr. Singer presented evidence that he had performed corneal surgery using a frown-shaped incision prior to the "invention" of this technique by Dr. Pallin.[36] Despite this overwhelming evidence that Dr. Pallin's technique would have been obvious to any other ophthalmic surgeon, the court denied the defendants' motion for summary judgment.[37] In subsequent settlement talks, "Dr. Pallin demanded a royalty of $2,500 to $10,000 per year, which could have been increased annually at his discretion."[38] Ultimately, the federal district judge issued an order invalidating the claims at issue and preventing Dr. Pallin from

attempting to enforce his patent against any physicians.[39] Notably, the judge released this order[40] after congressional debate on an exemption from patent infringement for medical practitioners performing a medical or surgical procedure[41] ***305** but before enactment of 35 U.S.C. § 287(c).[42] Regardless of the outcome in the Pallin case, this litigation intensified the debate over whether medical and surgical procedures should be patentable and led directly to legislative action.[43]

Although Pallin was the instigating case in this debate, other factors contributed to the medical community's demand for immediate action. Opponents of medical procedure patents could point to two other controversial patents as demonstrating the need for reform.

First, the USPTO granted a patent to Dr. John D. Stevens for a method of using ultrasound to detect fetal gender.[44] Despite the development of ultrasound in 1958 and its widespread use by the 1970s, the USPTO still granted Dr. Stevens a patent for this method.[45] Contributing to the controversial granting of this patent, Dr. Stephens, like Dr. Pallin, filed his patent application only after a medical journal had deemed his method unoriginal.[46] Pointing to a second controversial patent, opponents of medical procedure patents emphasized that even if patent claims are ultimately found invalid, the patent-holder may hold the healthcare industry hostage in the meantime.[47] The USPTO issued a patent to Dr. Alvaro La Torre for the treatment of male impotence by directly injecting vasodilators into the penis.[48] After re-examination, all claims were found invalid due to obviousness, but before this determination, the patent's assignee had sent cease and desist letters to over 500 urologists demanding $350 in royalty fees from each of them.[49] At this point in history, the possibility that the USPTO would improvidently grant patents on obvious medical methods was rapidly increasing, and estimates predicted the USPTO was granting 100 medical procedure patents every month.[50] The combination of the Pallin case, the high-profile, controversial patents, and the overall increase in the USPTO's issuance of medical procedure patents fueled the debate over the appropriateness of patenting medical methods.

*306 III. Legislative Response to Pallin--Enactment of 35 U.S.C. § 287(c)

The outrage within the medical community over the enforcement of medical process patents extended into the legislature and ultimately resulted in the enactment of 35 U.S.C. § 287(c), which exempts medical practitioners from liability for infringement of medical process patents.[51] The intervening time frame--between identification of the problem and passage of the Omnibus Consolidated Appropriations Act of 1997--represented a significant departure from the ordinary legislative process.[52]

A. Representative Ganske's Proposal

In response to the debate over the patentability of medical and surgical procedures, Representative Greg Ganske of Iowa introduced House Bill 1127 to prohibit the issuance of patents "for any invention or discovery of a technique, method, or process for performing a surgical or medical procedure, administering a surgical or medical therapy, or making a medical diagnosis."[53] His version allowed for the issuance of patents where the medical procedures were performed as an essential component of a machine, manufacture, or composition of matter.[54] While the medical community supported this bill, the ABA and the biotechnology industry opposed the bill.[55] The primary criticism offered by the biotechnology sector was the failure of the bill to distinctly "define the meaning of 'surgical or medical procedure, surgical or medical therapy, or making a diagnosis.'"[56] In addition to these objections, the Clinton administration voiced its opposition to the bill by sending G. Lee Skillington to generically testify that excluding medical and ***307** surgical procedures from the scope of patentable subject matter was not the proper response to the concerns of the medical community.[57]

To address these criticisms, Representative Ganske offered an amendment to House Bill 1127.[58] The new version explicitly defined medical procedure and surgical procedure, as well as offering two exceptions to the prohibition against issuing patents for such procedures.[59] First, the USPTO could issue patents on a "procedure performed by, or as a necessary component of a patentable machine, manufacture, or composition of matter."[60] This exception would have ensured the patentability of biotechnology that involves use of a medical procedure within an otherwise patentable invention. The second exception offered by Representative Ganske would allow patents to be issued for "a new use of a composition of matter or biological process."[61] Despite these changes, House Bill 3814 (the amended version of House Bill 1127) died in the Senate.[62]

B. The Senate's Version--A Compromise is Reached

While unwilling to accept the legislative solution proposed by House members, the Senate ultimately did pass a bill attempting to address the medical process patent controversy.[63] The Senate's consideration of the issue began with the introduction of Senate Bill 1334 by Senator Bill Frist of Tennessee.[64] Acknowledging that the issuance of medical method patents conflicts with broader health policy goals, Senator Frist offered a bill designed to provide an exemption for medical practitioners from liability for patent infringement, rather than prohibiting the issuance of patents on medical methods.[65] Senator Frist claimed that this solution was preferable because biotechnology companies would still be able to enforce "their patent rights against commercial users with respect to any patentable advancements in areas such as gene therapy, cell therapy, or with respect ***308** to new uses for well-known drugs."[66] Although recognizing that eighty other countries prohibit the issuance of medical method patents, Senator Frist emphasized that his legislative solution would "limit the enforcement of medical method patents against physicians, while preserving the rights of the biotechnology industry."[67] The Senate failed to pass Senate Bill 1334, but undeterred, Senator Frist offered a similar bill (Senate Bill 2105) on September 24, 1996.[68] That bill likewise died, but the Senate incorporated the substantive portion of Senator Frist's compromise solution into House Bill 3610.[69] From here, the bill avoided the normal legislative process and was fast-tracked to passage within the Omnibus Consolidated Appropriations Act of 1997.[70]

C. Passage Without True Debate

A bill that drastically changed the United States patent system made it through the legislature without substantial debate.[71] House Bill 3610 passed during an all-night session of the House without even a committee hearing.[72] When sent to the Senate, it was linked to House Bill 4278 as a conference report, which obligated the Senate to vote on these bills without amendments.[73] The Senate passed this bill package on September 30, 1996, and the President signed it that evening.[74] Thus, a bill that had repeatedly failed to pass both the House and Senate made it to the President's desk without much discussion.

Despite the lack of formal debate, the passage of the exemption for medical practitioners from patent infringement of medical and surgical procedures did meet some opposition. Senator Orrin Hatch vigorously opposed the attachment of the medical patents provision (section 616) into the spending bill.[75] He protested to the "unprecedented change to our patent code" that was "added notwithstanding the fact that there were no Senate hearings, and over the objections of [himself], the chairman of the Finance Committee and the U.S. Trade Representative."[76]

***309** Senator Hatch's objections fell into two categories. First, the amendment on medical process patents may be inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property (TRIPs).[77] This international trade agreement requires that patent rights be enjoyed without discrimination based on the field of technology.[78] Section 616 potentially violates this requirement by providing that medical and surgical procedure patents may be issued, but that those patent rights are not enforceable against medical practitioners.[79]

Second, Senator Hatch opposed the addition of this provision on the ground that there should be a heavy burden on those advocating major change to patent policy, which was not met by the proponents of this provision.[80] Procedurally, the "Ganske/Frist amendment circumvent[ed] the normal Committee process by misusing the appropriations mechanism to amend a highly technical and very complex area of substantive patent law."[81] In a letter to his colleagues opposing the medical procedure patent provision, Senator Hatch quoted H.L. Mencken, "There is always an easy solution to every human problem-- neat, plausible, and wrong."[82] Furthermore Senator Hatch was "afraid that this is the case with the Ganske/Frist amendment on medical procedure patents."[83] Despite Senator Hatch's opposition, the compromise proposed by Senator Frist (to grant patent rights in medical procedures, yet deny their enforceability) ultimately passed both the House and Senate and was codified at 35 U.S.C. § 287(c).

D. The Enacted Compromise--35 U.S.C. § 287(c)

35 U.S.C. § 287(c) provides that an inventor or its assignees may not enforce patent rights against either a medical practitioner or a related health care entity if infringement is based on "a medical practitioner's performance of a medical activity."[84] While a seemingly clear statement of the unenforceability of medical method patents, the statute further defines the terms used and establishes several exceptions.

To invoke this provision and avoid liability, a defendant in a patent infringement suit must establish that his actions, as a medical practitioner, ***310** constituted a medical activity. Regarding who is a medical practitioner, the statute defers to state

law and provides that "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" meets the definition.[85] Thus, the law applies to nurses, medical students, and technicians as well as physicians and dentists.[86] According to § 287(c)(2)(A), "'medical activity' means the performance of a medical or surgical procedure on a body."[87] "Body" is further defined as "a human body, organ or cadaver, or a nonhuman animal used in medical research or instruction directly relating to the treatment of humans."[88] Hence, by its plain terms, activities such as manipulation of cells outside the body would fall outside the protective scope of the medical activity definition.

Even if a defendant establishes that he was performing a medical activity, he must prove such activity does not fall within one of three exceptions. First, the term medical activity does not include "the use of a patented machine, manufacture, or composition of matter in violation of such patent."[89] This exception protects medical device and pharmaceutical patents from unenforceability.[90] Second, the statute excludes "the practice of a patented use of a composition of matter in violation of such patent."[91] Thus, this legislation protects the pharmaceutical industry and allows for the enforcement of patents on new uses of unpatented drugs.[92] For example, "the conventional use of an anaesthetic in a novel method for surgically transplanting a healthy heart 'would not cause the surgical procedure to be treated as a patented use of a composition of matter.'"[93] On the other hand, if a novel anaesthetic or novel dosing schedule were used, such use would not constitute a protected medical activity.[94] Third, "the practice of a process in violation of a biotechnology patent" is not a medical activity sufficient to invoke the protective provisions of § 287(c).[95] This exception protects patents on gene ***311** therapy and similar biotechnological processes.[96] Thus, the statute narrows the definition of protectable medical activities to those generally understood as "pure" medical and surgical procedures.

In addition to carving out exceptions under the definition of medical activity, the statute provides further protections for the biotechnology and pharmaceutical industries. Section 287(c) does not apply to persons 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.[97]

This exception serves to prevent pharmaceuticals, device manufacturers and non-physician laboratories from invoking the provisions of the statute.[98] Hence, a pharmaceutical company may sue its competitor for infringing activities without fearing that the court will hold their patent unenforceable under § 287(c). As a final protection, the legislature made this statute prospective only--it only applies to patents issued based on applications subsequent to September 30, 1996.[99] Thus, § 287(c) provides a narrow exception to the enforceability of patents, reserved only for medical practitioners performing medical activities that do not involve a patented machine, manufacture, or composition of matter.

IV. Revisiting the Compromise--Arguments For and Against the Patentability of Medical Procedure Patents

Both sides in the medical process patent controversy have valid arguments. Proponents of medical process patents typically rely on economic justifications--contending that the patent system's incentives are necessary to the development of new medical and surgical procedures.[100] On the other hand, opponents of the patentability of medical methods look to ethics to justify their position.[101] ***312** Additionally, some commentators offer practical reasons why medical procedures should be excluded from patentability.[102] These arguments form the basic framework for the public policy debate on whether medical and surgical procedures should be included within the scope of patentable subject matter.

A. Economic Arguments

Proponents of medical procedure patents argue that the patent system provides necessary economic incentives to promote

investment in research that otherwise might go unfunded.[103] For example, private investors funded research that resulted in the Surrogate Embryo Transfer (SET) technique, whereby an embryo from a donor woman is transferred into a recipient, after the National Institutes of Health declined to fund the project.[104] Approximately 30,000 to 50,000 women a year benefited from treatment involving SET before alternative treatment options were available.[105] "In the absence of patent protection, it is unlikely that SET technology would have developed."[106]

Some suggest that the only alternative to patent protection for these types of medical procedures is government funding.[107] While not suggesting that all medical research would cease without patent protection, these proponents argue that in the current managed health care environment, "competitiveness and economic advantage become increasingly important."[108] Without the prospect of intellectual property protection, private investors may shy away from medical process research and funnel their capital into other types of ventures.[109] Thus, patent protection ensures that, absent government funding, companies and individuals have an incentive to devote time and resources to the development of new medical and surgical techniques.

The medical community argues that the development of medical and surgical procedures depends on "intellectual curiosity and creativity rather than the availability of capital for research and development"; therefore, there is no need for the economic incentives offered by the patent system for this type of new ***313** technology.[110] One commentator stressed that there is "no empirical data to support the proposition that research into and investment in new methods of medical treatment would proceed in the same manner and to the same degree without a patents incentive as they would with one."[111] Most advancements in medical procedures develop gradually through on-the-job improvements to known techniques.[112] Although SET is a convenient example for proponents of medical process patents, opponents can point to the low costs of development for most medical and surgical procedures, including the example of Dr. Stevens' method for detecting fetal gender using ultrasound.[113]

Medical process patent opponents further contend that such patent protection unnecessarily increases medical costs.[114] The American Academy of Orthopaedic Surgeons (AAOS) argues that expensive litigation over whether a medical procedure patent should have been issued in the first place increases the cost of health care.[115] Physicians will invariably pass these litigation costs onto patients, which the American Medical Association (AMA) asserts violates a physician's ethical obligation not to place additional financial burdens on her patients.[116] Furthermore, even a modest royalty associated with the licensing of a patented medical procedure drastically raises the cost of health care.[117] For example, Dr. Pallin requested a $4 to $5 royalty per cataract surgery for the use of "his" frown-shaped incision.[118] With over 1.3 million cataract surgeries performed yearly, Dr. Pallin's patent would have raised health care costs by between $5.2 and $6.5 million.[119] That is just one example.

On the other hand, commentators advocating for the use of the patent system to protect medical methods note that managed health care reduces the cost of patent enforcement and that in many instances, patented procedures are cheaper than the unpatented alternatives.[120] Taking Dr. Pallin's patent as an example, his sutureless ***314** incision saves approximately $12 to $17 per procedure in materials.[121] Thus, Dr. Pallin claimed his procedure saves between $12 and $17 million in medical costs per year, far outweighing any additional costs to the health care system brought on by his demand for royalties.[122] Additionally, proponents argue that patented procedures result in "shortened hospital stays, less intensive care treatment, and general efficiency," which all contribute to decreasing the overall costs of healthcare.[123]

B. Ethical Arguments

Opponents of the issuance of medical procedure patents highlight the ethical conflicts that granting these patents creates for physicians. Both the AMA and the AAOS advocate against the patenting of "pure" medical and surgical procedures.[124] For the purposes of their stance, the AAOS defines a pure medical or surgical procedure as "a medical diagnostic procedure or treatment, or a method or process, where the 'invention' is independent of the use of a medical device and drug."[125] Thus, the medical community does not oppose granting patents on medical devices or pharmaceuticals, but simply opposes granting patents for methods that physicians use to treat their patients. The ethical concerns brought forth by these organizations accordingly only apply to this narrow context of medical and surgical procedures.

The medical community argues that medical procedure patents create disincentives for physicians to share the results of their professional experiences.[126] The patent system encourages inventors to keep an invention secret until the patent is granted.[127] Additionally, the enforcement of medical procedure patents discourages the sharing of information amongst physicians

because such openness may result in the targeting of these physicians for infringement suits.[128] Moreover, the medical community fears that medical schools may have to choose between ***315** teaching the latest techniques and raising the cost of medical education to cover the royalties owed on medical procedure patents.[129]

These disincentives directly conflict with the ethical obligations of physicians to share techniques openly. Principle V of the Code of Medical Ethics of the AMA reflects the long-standing tradition of physicians openly exchanging information without the expectation of financial reward for advancing the medical profession: "A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation and use the talents of other health professionals when indicated."[130] The AMA's Code of Medical Ethics further defines the ethical role of a physician--in the tradition of Hippocrates--as that of

a healer who serves patients, a teacher who imparts knowledge of skills and techniques to colleagues . . . . Physicians have an obligation to share their knowledge and skills and to report the results of clinical and laboratory research. . . . The intentional withholding of new medical knowledge, skills and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.[131]

Despite the belief that medical procedure patents violate these ethical obligations by encouraging the intentional withholding of information for reasons of personal gain, the AMA recognizes that there is a counterargument that patents promote full disclosure.[132] However, the AMA asserts that disclosure of a technique without giving full access to the performance of the technique "does not constitute availability in any substantial sense."[133]

Proponents of medical procedure patents contend that patents provide greater disclosure than that revealed by publication of research in medical journals because of the patent system's enablement requirement.[134] That is, to obtain patent rights in a medical method, the inventor must fully disclose the technique such that a person of ordinary skill in the art would understand it.[135] Medical journals do not impose this stringent level of disclosure.[136] In addition, the peer review process of medical ***316** journals necessarily narrows the spectrum of published research such that not all inventions are publicly disclosed.[137] Further, in the absence of patent protection, many physicians may turn to trade secret law to protect their investment in new technologies, thus resulting in incomplete disclosure within medical journals or within the profession.[138] As a historical example, proponents offer the case of the obstetrical forceps, which the Chamberlen family kept a secret through four generations of physicians.[139] The patent system thus provides additional incentives to those physicians who would otherwise be tempted to violate their ethical obligations of disclosure; however, the AMA argues that "it is inappropriate to reward their unethical behavior by providing an economic benefit to disclosure."[140]

Physician guidelines, like the AMA's Code of Ethics, also raise a second ethical argument--the acquirement and enforcement of medical procedure patents results in a decrease in professionalism amongst physicians.[141] "The patenting of medical procedures, with its emphasis on individual reward, selective sharing, and ownership, undermines the coherence of the profession."[142] A patient depends on her doctor to put her health above all other concerns, including economic.[143] "To the extent that economic goals are elevated above those of patient health, the integrity of the profession is severely weakened."[144]

Further, medical procedure patents serve to unacceptably restrict clinical access.[145] Where no alternative exists for a patented procedure, physicians are effectively forced to obtain a license to meet their ethical obligations of patient care.[146] The patent-holder has the right under the patent system to restrict the number of licensees or charge a high license fee, which has the effect of limiting patient access by erecting barriers to needed treatments.[147] However, a patent-holder who asserts these rights violates his ethical obligation to promote patient care above all other considerations.[148] Another concern is that the existence of a patent on a treatment may influence a doctor to choose an inferior treatment rather ***317** than paying the licensing fee or referring the patient to a licensed physician.[149] Moreover, physicians may choose not to use new procedures or modifications of existing procedures for fear they may covered by a valid patent.[150] This creates a chilling effect on the use of advances in medical procedures because physicians simply do not have the time to investigate whether these new advances are covered by patents and will simply avoid these procedures until they can be certain they are not infringing a valid patent.[151] Opponents of medical process patents often pose the hypothetical--what if the Heimlich maneuver was patented?[152] Would a fellow diner risk patent infringement by performing the technique on a choking fellow patron or forego this necessary procedure?[153]

Proponents of medical process patents contend that these phenomena are not unique to medical and surgical techniques.[154] Physicians face choices daily on whether to prescribe a new, costly, patented drug, which holds new promise for treatment, or to resort to the standard treatment.[155] Regardless of cost, a physician must choose the drug that is most likely to improve the

health of their patient. The conflict for the physician faced with a medical process patent is analogous, and thus no differentiation should be made within the patent system between these types of inventions.[156]

Finally, enforcement of medical procedure patents raises substantial patient privacy concerns.[157] Monitoring of a physician's use of a patented technique is significantly more difficult than tracing the sales of medical devices and pharmaceuticals.[158] A patent-holder who suspects a physician is performing his patented medical procedure without a license, or in excess of his license, will need access to patient information to identify those patients upon which the technique may have been performed. This enforcement behavior necessarily voids a patient's privacy. Those advocating medical procedure patents counter that simple redaction of a patient's name would protect a patient's privacy.[159] Further they point out that a patient's treatment is not absolutely privileged and is divulged in other ***318** instances--for example, when complying with government health care regulations.[160]

C. Other Rationales

According to the AAOS, no medical procedure is really new--every medical or surgical procedure builds upon existing knowledge.[161] The AAOS claims that sufficient prior art existed in almost every instance where the USPTO has granted a medical procedure patent.[162] Thus, these "inventions" did not fulfill the novelty or nonobviousness requirements for patentability, and these medical procedure patents never should have been issued.[163] "The U.S. Patent and Trademark Office does not have the staff or expertise to identify 'prior art.'"[164] Most medical and surgical processes are not patented and are passed down from physician to physician through hands-on training, practice seminars, and medical literature.[165]

In response to this argument, proponents argue that this problem is not unique to medical procedure patents, as compared to pharmaceutical or medical device patents.[166] "[T]he potential abuse of the patent system by non-inventors has been a longstanding problem confronting the patent system since its inception."[167] The logistical challenges faced by the USPTO in the wake of certain technologies should be dealt with by tightening guidelines on issuance requirements, rather than discriminating against a particular field of technology.[168] Moreover, problems of USPTO administration should be dealt with "through improved management and enhanced resources."[169]

Another rationale offered for excluding medical and surgical procedure patents from the scope of patentable subject matter is to bring the United States in line with most other industrialized countries.[170] More than eighty countries ban the ***319** issuance of medical procedure patents.[171] Europe and Japan exclude medical methods from patentability based on their lack of industrial applicability--a necessary requirement for patenting inventions in those countries.[172]

V. Why Removing Medical Procedures From the Scope of Patentability is the Most Appropriate Solution

Several solutions have been proposed to solve the medical process patent controversy. Some suggest that compulsory licensing for medical process patents ensures patient access to new technologies without withdrawing the economic incentives of the patent system from physician-inventors.[173] Others advocate regulating licensing agreements on medical procedure patents through state contract law such that health care costs are effectively controlled.[174] Instead of restricting licenses issued for valid patents, some propose changing patent law doctrine to allow flexibility for the unique problems associated with medical patents.[175]

Proponents of medical process patents argue that § 287(c) has provided the most appropriate resolution to this difficult public policy problem.[176] Opponents of the issuance of medical process patents contend that the best solution is to remove medical and surgical procedures from the scope of patentability by amending 35 U.S.C. § 101.[177] Each proposal has its advantages and disadvantages, but on balance, removing medical and surgical procedures from the scope of patentable subject matter offers the most reasonable solution.

A. Licensing Solutions

Compulsory licensing presents one way to avoid substantial change to this country's patent law doctrine, while still addressing the medical process patent ***320** controversy.[178] This solution ensures that the patentee may recover any capital expended on development of the new medical technique through licensing fees.[179] In addition, the compulsory nature of these licenses guarantees that patients will not be denied access to potentially life-saving procedures.[180] On the other hand, the

problem of what a reasonable royalty is still exists.[181] Further, this resolution does not address the patient privacy concerns associated with the enforcement of these compulsory licenses.

Rather than compulsory licensing, one commentator suggested that state physician licensing boards can take action to ensure reasonable access to patented medical methods at reasonable fees.[182] By seeking regulations on contractual obligations, Lara Douglass argues that any dispute arising under these licensing agreements would be brought into state court that would not have such a pro-patent bias as the Federal Circuit Court of Appeals.[183] Whether or not a court addressing a dispute between a patent-holder and a licensee has a pro-patent bias should have no impact on the enforcement of regulations regarding medical process patent licenses. The benefits of ensuring access to patented medical methods are counterbalanced by the inefficiency of seeking a solution which will vary from state to state. The United States patent system ensures consistent treatment of inventors across the country; medical process patent licensing regulations would undermine this consistency.

B. Altering Patent Doctrines

Instead of seeking broad changes to the patent system, some commentators have offered minor changes as a way to address the specific concerns raised by medical process patents without disrupting long-standing patent law traditions. For example, Todd Martin proposed that one alternative is to create a "necessity doctrine" whereby a physician who uses a patented medical procedure in an emergency is absolved of infringement liability.[184] This solution addresses the main concern that patenting medical methods will reduce patient access to necessary procedures.

Essentially, this necessity doctrine would narrow the current exemption for medical practitioners performing medical activities to remove infringement liability ***321** only where a patient's life was in danger. However, the potential abuse of this doctrine by physicians would likely expand this exemption from liability to the reaches of the current statutory compromise. That is, in the absence of a true life or death emergency, a physician may still contend that he had to use a patented medical procedure to save his patient's life. The very nature of new medical techniques is to improve the quality of healthcare, thereby saving more lives. Thus, doctors could plausibly argue that most new medical and surgical procedures are necessary to the treatment of their patients.

Alternatively, one commentator has suggested that the patent system require medical procedure patent applicants to prove that their "new" technique required substantial funding before a patent may issue.[185] This solution addresses the medical community's argument that there is no need to provide economic incentives for advancements in medical techniques, since most cost very little to develop.[186] However, this solution also runs afoul of U.S. international agreements, namely the TRIPs Agreement. Article 27.1 of the TRIPs Agreement requires member states to provide patent rights that are enjoyable without discrimination as to the field of technology.[187] By requiring a showing of substantial funding only for medical process patent applicants, this solution discriminates between patent applicants on the basis of the field of technology.

C. Section 287(c)--Allowing Patentability But Denying Enforcement

The current compromise of 35 U.S.C. § 287(c) balances the ethical concerns of the medical community against the purported need for the economic incentives of the patent system.[188] Yet, many objections exist to this statutory solution. First, § 287(c) may amount to a taking under the Fifth Amendment.[189] Providing a patent right but then preventing the remedy for infringement of that right "denies owners of all economic viable use of their property."[190] Further, § 287(c) likely violates the TRIPs Agreement.[191] In advocating against the incorporation of the medical process provision within the appropriations bill, Senator Hatch offered the most important objection to § 287(c)--its passage "circumvent[ed] the normal [c]ommittee process ***322** by misusing the appropriations mechanism to amend a highly technical and very complex area of substantive patent law."[192] This issue deserved full and complete debate, not an unsatisfactory compromise slid into an appropriations bill at the last moment.

D. Removing Medical and Surgical Procedure Patents From the Scope of Patentable Subject Matter

At a time when the U.S. faces major patent reform,[193] it is appropriate to re-examine the scope of patentable subject matter. Although Committee Reports accompanying the 1952 Patent Act suggest that Congress intended statutory subject matter to "include anything under the sun that is made by man,"[194] there is no evidence they envisioned the enforcement of medical process patents against physicians as exemplified by Pallin. As the context of these patents has evolved over time, so should

the approach of the patent system. Removing medical and surgical procedure patents from the scope of patentable subject matter provides the optimal solution to the medical process patent controversy.

Revising patent policy to deny patentability for medical process patents has important international implications. Rather than violating the TRIPs Agreement, this solution falls directly within the treaty's provisions allowing for the exclusion of diagnostic, therapeutic, and surgical techniques from patentability.[195] With increased globalization of trade, the consistent protection of intellectual property rights across political boundaries is becoming more important. This solution would bring the United States' patent policy in line with that of approximately eighty other countries.[196]

Without further empirical data demonstrating the accuracy of each lobby's position, it is impossible to evaluate how much weight the economic arguments offered by each side should be given in this debate.[197] Proponents of medical process patents claim that the development of these technologies will be chilled in the absence of the economic incentives provided by the patent system.[198] ***323** Opponents of medical process patents contend that the development of these techniques requires little to no expenditure of capital, thus there is no need for these economic incentives.[199] Further, it is unclear whether patented medical methods increase or decrease the cost of healthcare.[200] Thus, without further empirical evidence, choosing to ban medical procedure patents cannot rely on economic rationales.

On the other hand, the ethical arguments presented by the medical community provide a sufficient basis to exclude medical procedure patents from patentability. Whereas the patent system depends on economic incentives, the integrity of the medical community relies on ethics. Patents on medical and surgical techniques create a disincentive for physician disclosure of new medical methods, cause a decrease in professionalism, restrict patient access to treatment and raise patient privacy concerns.[201] Banning medical methods from patentability removes these consequences to our healthcare system. Additionally, physicians would no longer have to fear that their use of new techniques potentially infringe valid patents.

From a practical standpoint, removing medical procedure patents from the scope of patentable subject matter offers additional benefits. This solution would reduce the USPTO workload and avoid litigation costs associated with improvidently granted patents. Further, instead of providing a "right without a remedy," as § 287(c) is sometimes described,[202] excluding medical procedure patents from patentability provides a bright-line rule that no patent rights will be extended for medical and surgical techniques. To address the concerns of the biotechnology community, the exception to 35 U.S.C. § 101 could specifically define the types of inventions excluded to ensure that the exception only applies to "pure" medical and surgical techniques. Thus, on balance, removing medical and surgical procedures from the scope of patentable subject matter provides the most appropriate solution to this controversy.

Footnotes

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1 35 U.S.C. § 287(c) (2006).

2 Andres Rueda, Cataract Surgery, Male Impotence, Rubber Dentures and a Murder Case--What's So Special About Medical Process Patents?, 9 U. Balt. Intell. Prop. L.J. 109, 142-47 (2001).

3 Lab. Corp. of Am. Holdings v. Metabolite Labs., Inc., 126 S. Ct. 2921, 2921 (2006) (Breyer, J., dissenting).

4 Id.

5 Id. at 2927.

[6] Id. at 2928.

[7] Id. at 2921.

[8] See id. at 2925 ("LabCorp did not refer in the lower courts to § 101 of the Patent Act ....").

[9] See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings, 370 F.3d 1354, 1364 (Fed. Cir. 2004) (finding substantial evidence of direct infringement by physicians).

[10] See, e.g., Pallin v. Singer, Civ. No. 5:93-202, 1995 U.S. Dist. LEXIS 20824, 36 U.S.P.Q.2d 1050 (D. Vt. May 1, 1995) (denying summary judgment of patent invalidity on the technique for creating a self-sealing incision during cataract surgery).

[11] See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (asserting that phenomena of nature are not patentable).

[12] See, e.g., Pallin, 1995 U.S. Dist. LEXIS 20824, 36 U.S.P.Q.2d 1050.

[13] 35 U.S.C. § 287(c)(1) (2006).

[14] Am. Acad. of Orthopaedic Surgeons, Position Statement: Medical and Surgical Procedure Patents (2000), http://www.aaos.org/about/papers/position/1131.asp. This Note uses the terms "medical procedure patent," "medical process patent," "medical method patent," and "medical and surgical procedure patents" interchangeably to mean patents on "pure" medical and surgical procedures as defined here.

[15] U.S. Const. art.1, § 8, cl. 8.

[16] 35 U.S.C. § 154 (2006); see Beata Gocyk-Farber, Note, Patenting Medical Procedures: A Search for a Compromise Between Ethics and Economics, 18 Cardozo L. Rev. 1527, 1529-30 (1997) (citing Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (1790)).

[17] 35 U.S.C. § 154 (2006).

[18] 35 U.S.C. § 101 (2006).

[19] 35 U.S.C. § 102 (2006).

[20] 35 U.S.C. § 103 (2006).

[21] 35 U.S.C. § 101 (2006).

[22] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing S. Rep. No. 82-1979, at 5 (1952) and H.R. Rep. No. 82-1923, at 6 (1952)).

[23] Id. (citing Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67 (1972); Funk Bros. Seed Co. v. Kalo

Inoculant Co., 333 U.S. 127, 130 (1948); O'Reilly v. Morse, 15 How. 62, 112-21 (1854); and Le Roy v. Tatham, 14 How. 156, 175 (1853)).

[24] 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, 52-53 (1999).

[25] Norton v. New York Eye Infirmary, 17 F. Cas. 879, 881 (C.C.S.D.N.Y. 1862) (No. 9,865).

[26] Havins, supra note 24, at 53 (quoting Donald S. Chisum, Chisum on Patents: A Treatise on the Law of Patentability, Validity and Infringement § 1.03(3), at 1-71 (1999)). One commentator has suggested that the interpretation of the Morton case so as to exclude medical procedures from patent protection was a historical mistake. Gocyk-Farber, supra note 16, at 1535.

[27] Gocyk-Farber, supra note 16, at 1535 (quoting Ex parte Brinkerhoff, 24 Off. Gaz. Pat. Office 349 (Comm'r Pat. Office 1883)).

[28] Scott D. Anderson, Comment, A Right Without a Remedy: The Unenforceable Medical Procedure Patent, 3 Marq. Intell. Prop. L. Rev. 117, 124 (1999).

[29] Havins, supra note 24, at 53 (citing Becton-Dickinson Co. v. Scherer Corp., 106 F. Supp. 665, 674 (E.D. Mich. 1952) (holding that processes are patentable even if they consist of medical or surgical methods which involve treatment of the human body)).

[30] Anderson, supra note 28, at 124 (quoting Ex parte Scherer, 103 U.S.P.Q. 107 (Pat. Off. Bd. App. 1954) (internal quotation omitted)).

[31] Pallin v. Singer, Civ. No. 5:93-202, 1995 U.S. Dist. LEXIS 20824, 36 U.S.P.Q.2d 1050 (D. Vt. May 1, 1995).

[32] Havins, supra note 24, at 53-54.

[33] Pallin, 1995 U.S. Dist. LEXIS 20824, 36 U.S.P.Q.2d 1050; Havins, supra note 24, at 54-55.

[34] Pallin, 1995 U.S. Dist. LEXIS 20824, at *4, 36 U.S.P.Q.2d 1050, 1051-52 (D. Vt. May 1, 1995).

[35] Id. at *5-*7.

[36] Id. at *7-*8.

[37] Id. at *14.

[38] Robert M. Portman, Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress, 4 U. Balt. Intell. Prop. L.J. 91, 102, 119 (1996). Mr. Portman is a partner in the law firm Jenner & Block who represented Dr. Singer in this litigation. See Pallin, 1995 U.S. Dist. LEXIS 20824, at *1, 36 U.S.P.Q.2d 1050, 1050.

[39] Portman, supra note 38, at 102 (citing Pallin v. Singer, No. 2:93-CV-202, 1996 WL 274407 (D. Vt. Mar. 28, 1996)).

[40] Pallin, 1996 WL 274407.

[41] 141 Cong. Rec. 28,297 (1995) (statement of Sen. Frist).

[42] Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009 (1996).

[43] Havins, supra note 24, at 54.

[44] Rueda, supra note 2, at 128 (citing U.S. Patent No. 4,986,274 (filed Dec. 4, 1989) (issued Jan. 22, 1991)).

[45] Rueda, supra note 2, at 128.

[46] Rueda, supra note 2, at 129.

[47] See Rueda, supra note 2, at 129 (noting the enforcement actions taken by the assignee against over 500 physicians).

[48] Rueda, supra note 2, at 129.

[49] Rueda, supra note 2, at 129-30.

[50] Rueda, supra note 2, at 126.

[51] 35 U.S.C. § 287(c) (2006); Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009 (1996).

[52] See, e.g., 142 Cong. Rec. 26,639 (1996) (statement of Sen. Hatch) ("This measure was added notwithstanding the fact that there were no Senate hearings, and over the objections of myself, the chairman of the Finance Committee and the U.S. Trade Representative. It is an unprecedented change to our patent code and it is my intention to closely scrutinize the implementation of this new law.").

[53] Havins, supra note 24, at 63-64 (quoting H.R. 1127, 104th Cong. (1995)).

[54] Havins, supra note 24, at 64 (citing H.R. 1127, 104th Cong. (1995)).

[55] Havins, supra note 24, at 64.

[56] Havins, supra note 24, at 64 (citing Medical Procedures Innovation and Affordability Act and Inventor Protection Act of 1995: Hearing Before the Subcomm. on Courts and Intellectual Property of the H. Comm. on the Judiciary on H.R. 1127 and H.R. 2419, 104th Cong. 57-58 (1995) [hereinafter Hearing] (statement of Charles D. Kalman, M.D., President, American Society of Cataract and Refractive Surgery)). See also Hearing, supra, at 97-99 (statement of Dr. Frank Baldino, Jr., President and CEO of Cephalon, Inc.).

[57] Havins, supra note 24, at 64 (citing Hearing, supra note 56, at 29 (statement of G. Lee Skillington, Counsel, Office of Legislative and International Affairs, U.S. Patent and Trademark Office)).

[58] H.R. 3814, 104th Cong. (1996).

[59] Havins, supra note 24, at 65 (citing H.R. 3814, 104th Cong. (1996); 142 Cong. Rec. H8030 (daily ed. July 18, 1996) (stating that Rep. Ganske offered H.R. 3814)).

[60] Havins, supra note 24, at 65 (citing H.R. 3814, 104th Cong. (1996)).

[61] Havins, supra note 24, at 65-66 (quoting H.R. 3814, 104th Cong. (1996)).

[62] Havins, supra note 24, at 66 (stating that H.R. 3814 failed to solve the medical process patent controversy because it operated by temporarily eliminating funding within the USPTO for medical process patents).

[63] See Omnibus Consolidated Appropriations Act of 1997, Pub. L. No. 104-208, § 616, 110 Stat. 3009 (1996).

[64] 141 Cong. Rec. 28,297 (1995) (statement of Sen. Frist).

[65] Id.

[66] Id.

[67] Id. at 28,298.

[68] Havins, supra note 24, at 67 (citing S. 1334, 104th Cong. (1995); S. 2105, 104th Cong. (1996)).

[69] Havins, supra note 24, at 67 (citing S. 2105, 104th Cong. (1996); H.R. 3610, 104th Cong. (1996)).

[70] Havins, supra note 24, at 67-68.

[71] See generally Havins, supra note 24, at 67-68.

[72] Havins, supra note 24, at 67-68 (citing 142 Cong. Rec. 26,611 (1996) (statement of Sen. Lott)).

[73] Havins, supra note 24, at 68 (citing 142 Cong. Rec. 26,611 (1996) (statement of Sen. Lott)).

[74] Havins, supra note 24, at 68 (citing 142 Cong. Rec. 26,611 (1996) (statement of Sen. Lott)).

[75] 142 Cong. Rec. 26,639 (1996) (statement of Sen. Hatch).

[76] Id.

[77] Id.

[78] Id. at 26,640 (letter from Jennifer Hillman, General Counsel, Office of the U.S. Trade Representative, to Sen. Hatch).

[79] 35 U.S.C. § 287(c) (2006).

[80] 142 Cong. Rec. 26,641 (1996) (statement of Sen. Hatch).

[81] Id. (dear colleague letter from Sen. Hatch).

[82] Id.

[83] Id.

[84] 35 U.S.C. § 287(c)(1) (2006).

[85] 35 U.S.C. § 287(c)(2)(B) (2006).

[86] Portman, supra note 38, at 114.

[87] 35 U.S.C. § 287(c)(2)(A) (2006).

[88] 35 U.S.C. § 287(c)(2)(E) (2006).

[89] 35 U.S.C. § 287(c)(2)(A) (2006).

[90] Portman, supra note 38, at 114-15 ("Thus, the statute does not allow physicians and others covered by the law to use a generic or other competing drug or device if to do so would violate a patent held by another individual or entity.").

[91] 35 U.S.C. § 287(c)(2)(A) (2006).

[92] Portman, supra note 38, at 115.

[93] Portman, supra note 38, at 116 (internal citations omitted).

[94] Portman, supra note 38, at 116.

[95] 35 U.S.C. § 287(c) (2006).

[96] Portman, supra note 38, at 116-17.

[97] 35 U.S.C. § 287(c)(3) (2006).

[98] Portman, supra note 38, at 117.

[99] 35 U.S.C. § 287(c)(4) (2006).

[100] See infra Part IV.A.

[101] See infra Part IV.B.

[102] See infra Part IV.C.

[103] See Todd Martin, Patentability of Methods of Medical Treatment: A Comparative Study, 82 J. Pat. & Trademark Off. Soc'y 381, 384 (2000) (offering the example of Surrogate Embryo Transfer (SET) that was financed by private investors after the National Institutes of Health declined to fund it).

[104] Id.

[105] Rueda, supra note 2, at 135 & n.224.

[106] Martin, supra note 103, at 384.

[107] Rueda, supra note 2, at 134.

[108] Martin, supra note 103, at 384.

[109] Rueda, supra note 2, at 132.

[110] Am. Med. Ass'n Council on Ethical and Judicial Affairs, Ethical Issues in the Patenting of Medical Procedures, 53 Food & Drug L.J. 341, 349 (1998).

[111] Martin, supra note 103, at 384 (quoting Patricia Loughlan, Of Patents and Patients: New Monopolies in Medical Methods, Austl. Intell. Prop. J. 5, 13 (1995)).

[112] Gocyk-Farber, supra note 16, at 1552.

[113] Gocyk-Farber, supra note 16, at 1552-53.

[114] See, e.g., Rueda, supra note 2, at 135.

[115] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[116] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 347.

[117] Rueda, supra note 2, at 135.

[118] Rueda, supra note 2, at 135.

[119] Rueda, supra note 2, at 135.

[120] Martin, supra note 103, at 387 (citing Joel J. Garris, The Case for Patenting Medical Procedures, 22 Am. J.L. & Med. 85, 98 (1996)).

[121] Rueda, supra note 2, at 135 (citing Jeffrey I.D. Lewis, Congressional Legislation Would Restrict Medical Patents, N.Y.L.J., Apr. 8, 1996, at S1).

[122] Rueda, supra note 2, at 135 (citing Jeffrey I.D. Lewis, Congressional Legislation Would Restrict Medical Patents, N.Y.L.J., Apr. 8, 1996, at S1).

[123] Anderson, supra note 28, at 138.

[124] Council on Ethical and Judicial Affairs, supra note 110, at 351; Am. Acad. of Orthopaedic Surgeons, supra note 14.

[125] Am. Acad. of Orthopaedic Surgeons, supra note 14. This is the definition also adopted by this Note. See supra note 14 and accompanying text.

[126] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[127] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[128] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[129] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[130] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 343 (quoting Am. Med. Ass'n Council on Ethical and Judicial Affairs, Code of Medical Ethics: 1994 Edition, at xiv (Principle V) (1994)).

[131] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 343 (quoting Am. Med. Ass'n Council on Ethical and Judicial Affairs, Code of Medical Ethics: 1994 Edition, at 139 (Opinion 9.08) (1994)) (emphasis omitted).

[132] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 343-44.

[133] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 346.

[134] Martin, supra note 103, at 384-85.

[135] Martin, supra note 103, at 385; see also 35 U.S.C. § 112 (2006).

[136] Martin, supra note 103, at 385.

[137] Martin, supra note 103, at 385.

[138] Martin, supra note 103, at 385.

[139] Rueda, supra note 2, at 132.

[140] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 349.

[141] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[142] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[143] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[144] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[145] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[146] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[147] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344.

[148] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 344-45.

[149] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 345.

[150] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 345.

[151] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 345.

[152] Havins, supra note 24, at 51-52.

[153] Havins, supra note 24, at 51-52.

[154] Rueda, supra note 2, at 139.

[155] Rueda, supra note 2, at 139.

[156] Rueda, supra note 2, at 139.

[157] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 347.

[158] Am. Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 347.

[159] Martin, supra note 103, at 387.

[160] Anderson, supra note 28, at 134 & n.114.

[161] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[162] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[163] See generally 35 U.S.C. § 102 (2006); 35 U.S.C. § 103 (2006).

[164] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[165] Am. Acad. of Orthopaedic Surgeons, supra note 14.

[166] Rueda, supra note 2, at 135-36.

[167] Rueda, supra note 2, at 136.

[168] Rueda, supra note 2, at 136.

[169] Rueda, supra note 2, at 138.

[170] See, e.g., Am. Acad. of Orthopaedic Surgeons, supra note 14 (stating that medical procedure patents should be prohibited in order to be in full compliance with international trade agreements signed between the U.S. and European countries).

[171] See, e.g., Am. Acad. of Orthopaedic Surgeons, supra note 14. For a comparison of current U.S. law with that of other countries, see Martin, supra note 103.

[172] Toshiko Takenaka, The Best Patent Practice or Mere Compromise? A Review of the Current Draft of the Substantive Patent Law Treaty and a Proposal for a "First-To-Invent" Exception for Domestic Applicants, 11 Tex. Intell. Prop. L.J. 259, 339 (2003).

[173] Martin, supra note 103, at 419.

[174] Lara L. Douglass, Medical Process Patents: Can We Live Without Them? Should We?, 3 J. Intell. Prop. L. 161, 163-64 (1995).

[175] See Martin, supra note 103, 420 (suggesting a "necessity doctrine" allowing doctors to use patented procedures in emergency situation without fear of infringement consequences); see also Gocyk-Farber, supra note 16, at 1558 (advocating the addition of a fourth prong to the patentability requirements for medical process patents requiring the applicant to prove that substantial funding was required to develop the new technique).

[176] Portman, supra note 38, at 119.

[177] Shawn J. Kolitch, The Proper Scope of Patentability in International Law, 11 Marq. Intell. Prop. L. Rev. 149, 174, 177 (2007).

[178] Martin, supra note 103, at 419.

[179] Martin, supra note 103, at 419.

[180] Martin, supra note 103, at 419.

[181] Martin, supra note 103, at 420.

[182] Douglass, supra note 174, at 163-64.

[183] Douglass, supra note 174, at 163.

[184] Martin, supra note 103, at 420.

[185] Gocyk-Farber, supra note 16, at 1558.

[186] See supra Part IV.A.

[187] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments--Results of the Uruguay Round, 33 I.L.M. 81, 93-94 (1994) (available at http://www.wto.org/english/docs_e/legal_e/27-trips.pdf (in particular, see pages 320-21)).

[188] See supra Part III.C-D.

[189] Courtenay C. Brinckerhoff, Medical Method Patents and the Fifth Amendment: Do the New Limits on Enforceability Effect a Taking?, 4 U. Balt. Intell. Prop. L.J. 147, 147-48 (1996).

[190] Anderson, supra note 28, at 144.

[191] See supra notes 77-79 and accompanying text.

[192] 142 Cong. Rec. 26,641 (1996) (dear colleague letter from Sen. Hatch).

[193] See, e.g., Patent Reform Act of 2007, S. 1145, 110th Cong. (2007), available at http://www.patentlyo.com/patent/files/PatentReform2007.SENATE.pdf (offered simultaneously in the House and Senate on April 18, 2007).

[194] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

[195] See 142 Cong. Rec. 26,640 (1996) (letter from Jennifer Hillman, General Counsel, Office of the U.S. Trade Representative, to Sen. Hatch).

[196] 141 Cong. Rec. 28,298 (1995) (statement of Sen. Frist).

[197] A full debate of this issue should include such empirical data; however, it is outside the scope of this Note.

[198] Martin, supra note 103, at 384.

[199] Am Med. Ass'n Council on Ethical and Judicial Affairs, supra note 110, at 349.

[200] Rueda, supra note 2, at 135; Martin, supra note 103, at 387.

[201] See supra Part IV.B.

[202] Anderson, supra note 28, at 138.