SHOULD PATENTING OF SURGICAL PROCEDURES AND OTHER MEDICAL TECHNIQUES BY PHYSICIANS BE BANNED?

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I. Introduction

On March 3, 1995, House of Representatives Bill 1127 (H.R. 1127), entitled "Medical Procedures Innovation and Affordability Act," was introduced in the House of Representatives by Representatives Greg Ganske (R-IA) and Ron Wyden (D-OR). [n.1] H.R. 1127 would prohibit the U.S. Patent and Trademark Office (PTO) from granting patents on surgical procedures and other medical techniques unless such procedures were claimed in combination with a patentable medical drug or device. [n.2] *256 The introduction of H.R. 1127 was a result of lobbying efforts by the American Society of Cataract and Refractive Surgery (ASCRS). The ASCRS sought to amend current patent legislation when Dr. Pallin, a physician and holder of a no-stitch incision method patent, initiated enforcement of his patent against ophthalmologists who allegedly infringed his patented surgical procedure. [n.3] It appears that Dr. Pallin is the first party ever to file an infringement suit involving a patented surgical procedure. [n.4]

H.R. 1127 already has the support of many medical organizations, such as the American Medical Association (AMA) and the American Academy of Ophthalmology (AAO). This support was prompted by serious concerns regarding the present state of the law. Currently, U.S. law allows the patenting of medical procedures. [n.5] The AMA has argued that, unlike other inventors, physicians have certain ethical obligations to which they should be held. [n.6] Similarly, the AAO has taken the position that medical method patents are "contrary to the fundamental tenets of medicine." [n.7]

Since the introduction of H.R. 1127, there has been considerable debate on the desirability of medical method patents among members of the medical community. Advocates believe that patenting of medical procedures provides motivation for innovation and that it is no different than the patenting of medical drugs and devices. [n.8] Opponents argue that *257 such practices violate a physician's ethical obligations as avowed under the Hippocratic oath. [n.9] Using Dr. Pallin's no-stitch incision patent as an example, this article attempts to set forth the differing opinions and examines the debate surrounding patenting of medical procedures.

To understand the nature of the debate, one must have a general understanding of the patent law system. Accordingly, Section II discusses patentability and infringement issues as they pertain to medical procedures. Section III examines the debate by setting forth the primary objections raised by opponents of medical method patents and, in turn, offers answers by proponents to those objections. In conclusion, Section IV suggests alternatives to banning medical method patents and proposes that, in lieu of striking current legislation, a mandatory licensing provision should be enacted.

II. Patentability and Infringement Issues Pertaining to Medical Procedures

A. Are Medical Procedures Included Under Patentable Subject Matter?

There is no question that medical procedures currently fall under the Congressional definition of patentable subject matter. The Patent Act explicitly states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." [n.10] Thus, as far back as 1876, a process has been considered within the realm of *258 "patentable subject matter." [n.11] The term "process" is defined in the Patent Act to mean any "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter or material." [n.12] Surgical procedures and medical techniques are "methods" for performing certain procedures or techniques. Thus, since methods are included under the term "process," surgical procedures and medical techniques constitute patentable subject matter. For purposes of this article, surgical procedures and medical techniques will subsequently be referred to as "medical methods."

Many patents have been granted for medical drugs and devices which also claim the method of using such drugs and devices. More recently, however, patents have issued for "pure" medical methods that do not claim the drug or the instrumentation with which the method may be used. Dr. Pallin's medical method patent for a no-stitch incision is one such example. [n.13] Despite Dr. Pallin being the first to litigate a "pure" medical method patent, the issues surrounding the alleged infringement are likely to be similar to those in any other patent infringement lawsuit.

B. Brief Discussion of Infringement Issues

A person may be liable directly or indirectly for infringing a patent, [n.14] provided that the infringer has been provided with sufficient notice. [n.15] If a patent is found to be infringed, the patent owner is entitled *259 to ask for both damages [n.16] and injunctive relief. [n.17] An alleged infringer can either deny infringement [n.18] or defend the alleged infringement on several grounds including: (1) that the patent is invalid; [n.19] (2) that the patent owner is misusing the patent; [n.20] (3) that an equitable defense is available to the defendant; [n.21] or (4) that the use was experimental in nature. [n.22]

Also, if a patent owner commits fraud on the PTO in obtaining a patent, the defendant may claim the patent is unenforceable. That is, although the patent is technically valid, courts are likely to refuse to enforce a fraudulently obtained patent.

In almost every infringement case, a defendant will raise the defenses of invalidity, unenforceability, or both. Therefore, it is no surprise that the defendant in Dr. Pallin's infringement suit, Dr. Singer, raised the defense of invalidity. [n.23] Dr. Singer asserted that Dr. Pallin did not disclose to the PTO (implying fraud) the pertinent prior art necessary to determine whether or not the novelty and non-obviousness requirements of the Patent Act were met. [n.24] Dr. Singer also questioned the PTO's procedures in ascertaining and evaluating pertinent prior art for an invention claiming a new medical or surgical procedure.

The legitimate concern here is that a patent Examiner relies upon the knowledge and honesty of the applicant to supply all of the relevant prior art in the field to make a determination as to the novelty and non-obviousness of the invention. [n.25] Dr. Singer stated: "there are so many new methods that are freely exchanged in the medical and surgical fields, that *260 it is virtually impossible for a patent Examiner to know whether any one method of treating the human body deserves patent protection." [n.26]

In the alternative, Dr. Singer denied infringement of Dr. Pallin's "Chevron" incision. Dr. Pallin's specific allegation was that an incision used by Dr. Singer to make a wound self-sealing, which Dr. Singer calls a "frown," infringed his "Chevron" incision patent. However, Dr. Singer stated that he uses a combination of the "frown" incision with either an internal corneal lip, which was a contribution of Dr. Paul Ernest, or another stitch that is widely used in the medical community to enhance cataract incision strength and safely eliminate sutures. Thus, Dr. Singer claimed that his procedure does not include Dr. Pallin's "Chevron" incision. [n.27] Dr. Pallin contended that regardless of the corneal lip, and regardless of what Dr. Singer calls his incision, Dr. Singer used the incision described in his patent, which constitutes infringement.

C. Difficulties of Proving Infringement of a Medical Method Patent

To understand why infringement of a "pure" medical method patent is difficult to prove, one must look at how a medical method patent that is used in conjunction with a drug or device is enforced. Generally, it is easier to prove infringement where a patent claims a drug or device because the patent holder can track the sale or manufacture of the particular drug or device in question. However, with respect to patents which only cover a method, there is no drug or device to track, thus, making it more difficult to prove that the patented method is being infringed.

Where the patented method is used in a surgical procedure, as in Dr. Pallin's case, one way to prove infringement is to question patients directly. This may not prove very useful, especially if a patient is unwilling to speak or does not know exactly what surgical method was used. An alternative would be to check information in a patient's operative

report, which provides an in-depth surgical report indicating the procedure that was used on the patient. However, a patient's operative report is generally confidential and not available to third parties. [n.28]

*261 Alternatively, the patent holder can turn to insurance companies, clinics, or health maintenance organizations, which maintain extensive patient records and statistics on computer, to determine the method a physician used in a given surgical procedure. [n.29] However, the patent holder may have to subpoena the insurance companies, clinics or health maintenance organizations to obtain any relevant records. [n.30] Finally, a patent owner may be able to rely on licensees to bring infringement to their attention, but often licensees may be reluctant to do so. [n.31]

D. Infringement Remedies

If a patent owner can prove infringement, then the owner is entitled to ask for money damages, injunctive relief, or both. With respect to the no- stitch incision procedure, Dr. Pallin stated that he did not plan to seek injunctions or stop other physicians from using the technique. [n.32] Thus, if infringement is proven, the remedy Dr. Pallin would seek is strictly monetary. [n.33] If Dr. Pallin's patent is held to be valid and enforceable, it leads to the more practical question of whether such a patent can, in reality, be legally enforced since infringement of medical methods is so difficult to police.

The patent system gives patent owners the right to exclude others from making, using or selling their inventions, but third parties can do what they want until the patent owners enforce their rights. This enforcement requires time, commitment and money. [n.34] Dr. Pallin has *262 sought to enforce his patent rights against other physicians, and this lawsuit has sparked a heated debate within the medical community.

III. The Debate Surrounding the Patenting of Medical Methods

The patenting of medical methods by physicians, such as Dr. Pallin's patenting of his no-stitch cataract incision, raises several issues. Opponents of medical method patents argue that such patents are likely to:

(1) restrict physician autonomy;
(2) adversely affect the physician-patient relationship;
(3) impede the free flow of information in the medical profession and restrict access to new technology; and
(4) contribute to the rising cost of health care.

Proponents of medical method patents disagree on all points. Each of the above four issues is set forth in the context of Dr. Pallin's patent in a point- counterpoint debate

A. Physician Autonomy

1. Point

Opponents of medical method patents argue that medical method patents restrict a physician's autonomy, or more specifically, that they do not allow physicians to practice medicine according to their best ability and judgment. In Dr. Pallin's case, a physician who determines that a patient must undergo cataract surgery has four options from which to choose:

(1) pay a royalty and obtain a license from Dr. Pallin;

(2) refer the patient to another physician who is licensed or authorized to use the patented method;

(3) perform the surgery using the patented method without the authorization of Dr. Pallin; or

(4) perform the cataract surgery using some other method.

The first coerces the physician to pay a fee; the second coerces the physician to forego a patient's business; the third imposes liability on the *263 physician; and the fourth coerces the physician to use a substitute, and possibly inferior, technique. [n.35]

This also raises the possibility that if a patented method is superior to other non-patented alternatives, then those physicians who use the higher risk alternative methods may be faced with a greater number of malpractice suits. After all, physicians who use the higher risk alternatives may be violating their ethical obligation to use the best treatment available.

2. Counterpoint

There are many factors that restrict a physician's autonomy. Some examples include: contractual relationships between physicians and hospitals that allow some physicians, but not others, to practice in the hospitals; contractual limitations in a patient's insurance policy; and familial relationships that call into play the issue of consent for a minor or incompetent patient. [n.36] In most cases there are other alternatives, and a physician is no more restricted than any other party who refuses to pay a royalty to use, for instance, a patented medical instrument. Furthermore, the opponents' argument assumes that a physician will charge other physicians an unreasonably high royalty, thus inhibiting others from obtaining a license to use the patented method. [n.37]

The proponents rebut the opponents' concern regarding malpractice liability risks by stating that a physician has a duty to inform the patient of all the options, including that there is a superior patented method. A physician who is not licensed to use a patented method should advise the patient of this fact and leave the decision to the patient whether they want to proceed with the alternative method. If the patient chooses to forego the patented procedure in order to have the physician perform an alternative method, then the

patient has assumed the risk. In this manner, the physician is better protected from a malpractice suit since the physician has not violated any duties owed to the patient.

*264 B. Physician-Patient Relationship

1. Point

The next argument made by opponents is that the physician-patient relationship may be adversely affected given that a physician/patentee must show evidence of infringement. Opponents believe that if a patentee suspects infringement, the patentee may directly or indirectly contact sources, such as medical staff members, who have access to a patient's operative records to obtain medical information. Thus, this may violate the physician-patient confidentiality as well as the patient's expectations of privacy. A patient may not want a third party to know of a cataract condition, in which case, it is that patient's right to keep such information private. The patient's privacy interest should not be measured by an objective standard. Thus, the current practice not only affects the patient's privacy expectations, but also affects the physician-patient confidentiality.

2. Counterpoint

The above argument assumes that a patentee who seeks a patient's operative records will be able to obtain confidential information from the medical staff. If the entire medical staff is bound by patient confidentiality, then it is unlikely that a patentee will be able to improperly access confidential records. Moreover, this argument assumes that the cataract method used on a patient entails a serious privacy expectation. Although some patients may consider this type of inquiry into their operative records as a degree of invasion of privacy, this invasion is minimal and does not reach as high a level as it may in cases such as reproductive technology. [n.38]

Moreover, proponents argue there is a way to obtain information concerning a patient's operative records without intruding into a patient's confidential records. This is accomplished by serving subpoenas [n.39] to insurance companies, who keep detailed information of all of its patients' medical records, usually on a computer database. An insurance company's records could disclose the physician's diagnosis, the procedure that was performed, and the costs of the procedure. In such a case, the *265 only information that would remain confidential would be the name of the patient. Further, a patentee could utilize a subpoena to obtain information from the insurance company as to how many patients a certain medical procedure was performed on, and by whom. In this manner, the patient's identity would remain private andthe patentee does not need to resort to other, more intrusive means to obtain important infringement data.

C. Free Flow of Information and Access to Patented Technology

1. Point

The third argument posed by opponents is the impact of medical method patents on medical research. It is feared that medical method patents may inhibit the free exchange of information and the access available to the vast resources of medical colleagues. It is this free exchange and access that "leads to the early evaluation of new technologies and permits the rapid dissemination of improved techniques." [n.40] Opponents argue that this traditional goal of the scientific community to share information is in direct conflict with the values and incentives provided by the patent system. [n.41]

Further, opponents contest that patients may be denied the benefit of a potentially useful procedure if an inventor withholds disclosure while waiting for a patent to issue. In the early stages of the patent process, inventors will work in isolation and are unlikely to disseminate information regarding their new techniques or allow other physicians to try them. Consequently, new techniques will not be published or otherwise encouraged. It is also argued that patents will inhibit use of beneficial treatments in general because of uncertainty as to which methods have been patented and which have not. This fear of infringement, then, may restrict the availability of new medical methods. [n.42] Opponents further argue that ownership of a medical method patent will enable a physician to limit access of the patented method by imposition of excessive licensing fees for the life of the patent.

*266 2. Counterpoint

Mr. Longacre, Dr. Pallin's attorney, disagrees and stated that "doctors aren't going to apply in droves for method patents" and that many medical advances made by surgeons "do not rise to the level of being patentable." [n.43] Furthermore, proponents disagree by stating that the patent system encourages dissemination of information while protecting an inventor's intellectual property rights of ownership. [n.44]

This latter response parallels Professor Eisenberg's viewpoint that our patent system's objective is to give an inventor an exclusive right in exchange for the full disclosure of the invention. [n.45] An inventor is unable to obtain a patent without fulfilling the specification requirement of the Patent Act, which provides that:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, ... to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out the invention. [n.46]

This requirement ensures that the invention meets the statutory requirements for patentability and that the invention will eventually benefit society upon the expiration of the patent. Thus, the fear that medical method patents will dissuade the free flow of

information is unfounded. The patent system, in fact, assures that the invention will be fully disclosed to the public upon issuance of a patent and will become part of the public domain upon expiration of the patent term.

Finally, while the imposition of excessive licensing fees remains a possibility, this type of situation has never occurred with respect to any type of medical patent. As Dr. Pallin states, "it would be unethical to withhold the technique and it would be unethical to require license fees so large as to restrict use of the method." [n.47]

*267 D. Health Care Costs

1. Point

The final argument raised by opponents is that payment of royalties will contribute to the rising costs of health care, and that the additional cost will be passed on to patients. For instance, rural physicians may be unable to spread the license fee across enough cases to make it economically viable. Thus, physicians in rural areas would be forced to charge a high fee and deprive lower income persons of access in such areas. Dr. Singer explains that "surgical patents will produce a spiraling inflation of health care costs by inhibiting free exchange and by adding the costs of license fees, royalty payments, patent applications and legal expenses." [n.48]

Opponents contend that royalties are justified for patents on drugs and medical devices, where most of the costs for research, development and marketing are funded by private interest groups, who would not have invested had it not been for the possibility of profiting from the licensing of the patented technology. [n.49] In the case of Dr. Pallin's medical method patent, opponents find no such compelling argument. Also, there are no additional manufacturing and distribution costs as would be the case for a drug or device. Dr. Singer stated with respect to Dr. Pallin's patent, "little financial investment is needed to undertake an improved surgical technique ... where it employs available and known instruments." [n.50]

2. Counterpoint

In contrast, proponents argue that the overall benefit to society of medical method patents far outweighs any cost that a physician, and in turn a patient, may have to pay in royalties. As Gregory Burch points out in his article, "the 'marginal' character of medical process patenting is a function of two factors: cost of development and demand for the procedure." [n.51] Burch argues that any objection raised as far as patents restricting access is countervailed if "the only alternative is that the procedure never be developed in the first place." [n.52] Burch further explains *268 that if a physician charges a high price for an invention, this may negatively influence the decision of another physician to pay the high royalty fee; however, if the price is reasonable, a physician is more likely to pay

for the use of the patented procedure. If it is to the benefit of the licensor physician to ensure that a royalty fee is not so unreasonable that others will not want to pay it, then it is likely that the physician will charge a lower fee.

Dr. Pallin requested a fee of approximately $3 to $4 per operation from colleagues who use the procedure. [n.53] Dr. Pallin believes this cost is no different than physicians charging a royalty for a patent involving a drug or device. [n.54] Further, Dr. Pallin believes many ophthalmologists view the patenting of medical methods as "a positive development and an incentive, which holds promise to restore ... some of the motivation which has dissipated through government intervention." [n.55] Other proponents argue that royalties provide motivation for medical advances by rewarding creativity and funding for research and development costs of an invention. [n.56] In Dr. Pallin's case, it is not known what costs, if any, were involved in developing his medical method invention to justify the imposition of a royalty on other physicians. However, there are inherent risks involved in experimenting with any surgical technique. [n.57] Besides, the patent system does not consider the cost of an invention in order to issue a patent.

Finally, proponents argue that if a patented medical method reduces complications, it is likely to save money and reduce the costs of health care in the long run. For instance, Dr. Pallin stated that the $17 cost of sutures used in approximately one million surgeries per year in the United States could be saved. [n.58] This annual savings of approximately $17 million is five times greater than the royalty sought by Dr. Pallin.

*269 IV. Alternatives to Banning the Patenting of Medical Methods

Although each of the opponents' arguments mentioned in the above section raise valid concerns, they do not necessitate the outright banning of medical method patents. There is at least one other alternative that Congress should consider before banning the patenting of medical methods altogether. After all, without a patent option, the only alternatives left for a physician are to pursue disclosure through publication in academic journals, [n.59] lecture at medical symposiums, or keep the invention a trade secret. [n.60] The favored alternative is to amend the current patent law to include mandatory licensing of medical method patents. But before addressing the mandatory licensing alternative, some other alternatives are briefly discussed.

A. Disclosure Through Publication

Unsuccessful attempts by physicians to disclose their inventions via academic journals is one factor that has led physicians to patent their medical method inventions in the first place. For instance, Dr. Pallin reported to the media that he turned to patenting only after he was refused publication in the Journal of Cataract and Refractive Surgery and was ridiculed by his colleagues in ophthalmology. [n.61] In response to the inconsiderate treatment that Dr. Pallin received from the medical community, one proponent, Dr. Jarstad wrote, "the entire method patent controversy could easily have been avoided if

proper credit was given by our profession for developments and contributions." [n.62] If the publication route proves to be difficult for physicians, and if patenting is no longer an option, then physicians are more apt to keep their inventions a trade secret.

*270 B. Trade Secrets

The term "trade secret" refers to "any formula, pattern, device or compilation of information which is used in one's business, and which gives that person an opportunity to obtain an advantage over competitors who do not know or use it." [n.63] Being a matter of state law, trade secret law varies by jurisdiction. Many states follow trade secret law as set forth in § 757 of the Restatement of Torts. Under the Restatement, " o ne who discloses or uses another's trade secret, without a privilege to do so, is liable to the other if ... his disclosure of use constitutes a breach of confidence reposed in him by the other in disclosing the secret to him." [n.64] State law usually requires that the "owner of a trade secret demonstrate some measure of actual secrecy, reasonable efforts to maintain secrecy, and misconduct by the defendant in acquiring, using, or disclosing the trade secret." [n.65]

A trade secret keeps knowledge from the public domain for an indefinite period of time, [n.66] whereas a patent expressly teaches an invention to the public and, as a reward for full disclosure, gives the patent holder the right to exclude others from making, using or selling the patented invention for a limited term. Patentees can then exploit this right of exclusion by selling or licensing their patent rights to others. If the ultimate goal of the medical profession is to keep information flowing freely within the medical community, then the patent system would appear to better serve that purpose. Furthermore, if patenting is viewed as a superior alternative, then one way to resolve the various issues raised by the patenting of medical methods is to amend the existing patent laws so as to implement mandatory licensing provisions.

C. Mandatory Licensing

If patenting seems the preferred course, then some sort of balance must be reached in order to ensure that the free flow of information is not curtailed, that a physician's autonomy is not overly restricted, and most of all, that the health of patients is not compromised. Mandatory *271 licensing, and not the outright banning of medical methods patents, is the better solution. [n.67]

A mandatory licensing system would enable a physician who patents a medical method invention to receive reasonable monetary benefits, while ensuring that other physicians who want to use the patented method are not barred from doing so. Congress would need to pass a mandatory licensing statute, perhaps utilizing the PTO together with the court system, to determine a fair and reasonable royalty. This royalty may reflect the fair market value of the invention's utility, that is, a price that the market will bear. Mandatory licensing will serve to prohibit a physician from charging an arbitrary or

unreasonable price for the use of an invention. Prohibiting unreasonably high royalties will force a physician to market the patented invention aggressively, and a desire to profit will motivate the physician to do so. [n.68]

Mandatory licensing may also result in less biased reporting of data because more people may have access to the invention. This means that more people will have the ability to disclose whether there was any fraud committed by the inventor during the application process. Finally, mandatory licensing may reduce the need for a physician to infringe a patent in order to use a medical method, and thus, result in fewer infringement suits. Consequently, fewer infringement suits may lead to fewer inquiries into patients' medical records and, therefore, reduce invasions into the privacy of patients, which, in turn, would lessen any negative impact on the physician-patient relationship.

V. Conclusion

It is clear that medical method inventions constitute patentable subject matter. However, given the objections raised by many in the medical community, there is not a clear consensus on whether the current practice of issuing patents for medical methods should be banned. Most of the arguments presented in favor of H.R. 1127, while legitimate, do not substantiate the banning of medical method patents. This is particularly true since less drastic measures, such as mandatory licensing, can be implemented to eliminate most, if not all, of the objections.

[n.a1]. Silvy A. Miller received her J.D. degree from Franklin Pierce Law Center in May 1995.

[n.1]. H.R. 1127, 104th Cong., 1st Sess. § 2 (1995), Limitation On Issuance Of Patents, states:

> On or after the date of the enactment of this Act, a patent may not be issued 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, except that if the technique, method, or process is performed by or as a necessary component of a machine, manufacture, or composition of matter or improvement thereof which is itself patentable subject matter, the patent on such machine, manufacture, or composition of matter may claim such technique, method, or process.

H.R. 1127 would not affect existing patent holders. See ASCRS/ASOA Washington Letter, March 1995.

[n.2]. A "device" is a type of apparatus which includes an instrument and a machine. See 2 D. Chisum, Patents § 5.04[8] (1995). The term "device" is synonymous with the term "product," whereas, the terms "surgical procedure" or "medical technique" are

interchangeable with the terms "medical method" or "medical process." See infra note 11 for a definition of the term "process." In this paper, the term "medical method" is used interchangeably with terms such as "surgical procedure" or "medical technique."

[n.3]. Dr. Pallin's patent, "Method of making self-sealing episcleral incision," Patent No. 5,080,111, is also called the "Chevron" patent. His patent discloses a medical method for making an incision that does not require any stitches during cataract surgery. (Cataract is the condition where the clear, transparent lens of the eye becomes cloudy.)

[n.4]. Dr. Pallin, via his attorney, James R. Longacre, of Longacre & White of Arlington, Virginia, filed a patent infringement suit against Dr. Jack A. Singer, a member of the Hitchcock Clinic, Inc. of Randolph, Vermont, for the alleged infringement of Dr. Pallin's patent. See Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (denial of Dr. Singer's motion for summary judgment on invalidity).

[n.5]. See Teresa Riordan, New Legislation Seeks to Exclude Surgical Procedures from Patent Protection, N. Y. Times, March 6, 1995, at Dl.

[n.6]. See Rochelle Nataloni, AAO's patent position made public in the national press, Ocular Surgery News, December 1, 1994, at 1. Dr. Pallin states that the "Academy no more creates ethics than any organization of men can invent ethics."

[n.7]. Id. The AAO's Executive Vice President, H. Dunbar Hoskins, Jr., MD, stated in a letter to The Wall Street Journal that "[p]atents on medical methods or procedures serve no purpose other than to enrich the person or organization that holds the patent."

[n.8]. Medical professionals in favor of medical method patents have the support of the American Intellectual Property Law Association (AIPLA), which has adamantly stated its opposition to H.R. 1127. "The AIPLA categorically opposes limiting the issuance of U.S. patents on any aspect of medical or surgical procedures" (testimony October 19, 1995 of Michael Kirk, Executive Director American Intellectual Property Law Association, House Judiciary Courts and Intellectual Property Pending Legislation). See H.R. 1127, 104th Cong., 1st Sess. (1995).

[n.9]. See the Oath of Hypocrites, 400 B.C. Part of the oath is as follows:

To reckon him who taught me this art equally dear to me as my parent, to share my substance with him and relieve his necessities if required; to regard his offspring as on the same footing as my own brothers, and to teach them this art if they should wish to learn it, without fee or stipulation, and that by precept, lecture and every other mode of

instruction, I will impart a knowledge of the art to my own son and to those of my teachers, and to disciples bound by a stipulation and oath, according to the law of medicine, but to none others.

[n.10]. 35 U.S.C. § 101 (1993).

[n.11]. In Cochrane v. Deener, 94 U.S. 780, 788 (1876), the Supreme Court gave the following definition of what constitutes a patentable process:

A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery. In the language of the patent law, it is an art. The machinery pointed out as suitable to perform the process may or may not be new or patentable; whilst the process itself may be altogether new, and produce an entirely new result. The process requires that certain things should be done with certain substances, and in a certain order; but the tools to be certain substances, and in a certain order; but the tools to be used in doing this may be of secondary consequence.

[n.12]. 35 U.S.C. § 100 (1993).

[n.13]. See supra note 3. Other examples of "pure" medical method patents include: U.S. Patent No. 5,320,094, "Method for administering insulin" (involves a method for delivering insulin to the lungs); U.S. Patent No. 5,220,922, "Ultrasonic non-contact motion monitoring system" (involves a method for diagnosing a heart-beat disorder using a motion monitoring system); and U.S. Patent No. 5,190,057, "Sarfarazi method of closing a corneal incision."

[n.14]. 35 U.S.C. § 271 (1993).

[n.15]. 35 U.S.C. § 287 (1993).

[n.16]. 35 U.S.C. § 284 (1993).

[n.17]. 35 U.S.C. § 283 (1993).

[n.18]. Dr. Pallin asserted that the use and sharing of Dr. Singer's "frown" incision with colleagues infringes his "Chevron" patent. Dr. Singer claimed that his "frown" incision is

not the same as Dr. Pallin's "Chevron" incision, and thus, he does not infringe Dr. Pallin's patent.

[n.19]. 35 U.S.C. § 282 (1993).

[n.20]. 35 U.S.C. § 271(d) (1993).

[n.21]. For example, an alleged infringer may assert the equitable defenses of laches, estoppel, acquiescence or waiver if the patent owner has engaged in such inequitable conduct.

[n.22]. 35 U.S.C. § 271(e) (1993).

[n.23]. See Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (denial of defendant's motion for summary judgment of patent invalidity).

[n.24]. See AMA delegates condemn surgical method patents; surgeons take both sides in debate, Ocular Surgery News, September 15, 1994, at 1.

[n.25]. See Jack A. Singer, MD, Issue: Do method patents have a place in ophthalmology; Surgical method patents inhibit free exchange, Ocular Surgery News, July 15, 1994, at 16.

[n.26]. Dr. Singer's comments to a draft of this paper.

[n.27]. Rochelle Nataloni, Pallin vs. Singer still at stalemate; offer made, refused, Ocular Surgery News, September 15, 1994, at 23.

[n.28]. Physicians have a duty to respect the privacy interests of their patients. Generally, everything said by a patient to a physician in the context of a medical diagnosis and treatment is confidential and may only be revealed in certain cases. A physician can, however, safely release medical information to a third party if the patient consents in writing.

[n.29]. See Gregory F. Burch, Ethical Considerations in the Patenting of Medical Processes, 65 Tex. L. Rev. 1139 (1987). Patients who are on welfare need to have their physicians certify the medical necessity of procedures to be performed.

[n.30]. To facilitate the acquisition of the data, Dr. Pallin has named the Hitchcock Clinic as one of the co-defendants in the alleged infringement suit, since the Hitchcock Clinic has data on the procedures performed by its physicians. See Samuel L. Pallin, MD, Issue: Do method patents have a place in ophthalmology; Method patents benefit information dissemination, Ocular Surgery News, July 15, 1994, at 1.

[n.31]. As already mentioned, if a patent owner sues an infringer, it is likely that the infringer will defend the alleged infringement by raising the defense of patent invalidity. If the infringer wins, the patent is declared invalid and the licensees of the patent owner are free from having to pay any royalties. Thus, a licensee stands to benefit by bringing other infringers to the patent owner's attention.

[n.32]. See supra note 24.

[n.33]. Id.

[n.34]. James R. Longacre, Pallin Action No Indication of Method Patent Avalanche, Ocular Surgery News, December 1, 1994, at 4.

[n.35]. See Burch, supra note 29, at 1145.

[n.36]. See Burch, supra note 29.

[n.37]. See infra Part D for a discussion on health care cost issues.

[n.38]. See Burch, supra note 29.

[n.39]. A "subpoena duces tecum" is a court process initiated by a party in the litigation. It can compel the production of books, papers and other materials relevant to facts at issue in a pending judicial proceeding that are in custody and control of the party served with process.

[n.40]. See Singer, supra note 25.

[n.41]. Id.

[n.42]. Id.

[n.43]. Longacre, supra note 34.

[n.44]. See Pallin, supra note 30.

[n.45]. See Rebecca S. Eisenberg, Proprietary Rights and the Norms of Science in Biotechnology Research, 97 Yale L.J. 177, 195 (1987).

[n.46]. 35 U.S.C. § 112 (1993).

[n.47]. See Pallin, supra note 30.

[n.48]. See Singer, supra note 25.

[n.49]. See Nataloni, supra note 6.

[n.50]. Id.

[n.51]. Burch, supra note 29.

[n.52]. Id. at 1148.

[n.53]. See Nataloni, supra note 6.

[n.54]. See Pallin, supra note 30. Dr. Pallin stated that "it seems reasonable to charge a $5.00 license fee for the use of a technique that earns a surgeon $1,000.00."

[n.55]. Id.

[n.56]. See Brian McCormick, Just reward or just plain wrong? Specter of royalties from method patents stirs debate, American Medical News, September 5, 1994, at 3.

[n.57]. Telephone discussion with Dr. Pallin on November 30, 1994.

[n.58]. Id.

[n.59]. Id. Dr. Singer stated that "this choice of pursuing disclosure through academic journals and academic symposiums is clearly the choice made by the vast majority of the medical profession."

[n.60]. The term "trade secret" refers to "any formula, pattern, device or compilation of information which is used in one's business, and which gives that person an opportunity to obtain an advantage over competitors who do not know or use it." Restatement of Torts, § 757(b) (1939).

[n.61]. See Pallin, supra note 30.

[n.62]. John S. Jarstad, MD, Letters to the Editor, Ocular Surgery News, December 1, 1994, at 3.

[n.63]. Supra note 60.

[n.64]. Id.

[n.65]. See Eisenberg, supra note 45 nn. 71-74.

[n.66]. By the same token, if an invention is kept as a trade secret, and a third party discovers the invention by reverse engineering, that third party is free to use the invention.

[n.67]. See Burch, supra note 29.

[n.68]. Id. at 1153.