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COMMENTS

MEDICAL PROCESS PATENTS AND PATIENT PRIVACY RIGHTS

I. INTRODUCTION

If Henry J. Heimlich had patented his medical technique¹ and received royalties every time someone applied his maneuver, he would have been a very wealthy man. Historically, very few physicians patent their medical processes to protect proprietary rights in their work.² Instead, physicians argue that immediate publication of their results in medical journals and implementation of their procedures accelerates the use of the advances by the medical community.³ Recently however, physicians have sought to protect new medical processes and diagnostic and treatment methods by patenting their discoveries.⁴

Throughout the history of the United States, medical technology has continuously expanded through inventions such as vaccines, insulin, penicillin, and organ transplantation.⁵ In the last twenty years, the

^{1.} The New Encyclopedia Britannica 804 (15th ed. 1992). Doctor Heimlich invented the Heimlich maneuver. *Id.* The Heimlich maneuver is an emergency procedure whereby foreign objects are thrust out of the windpipe of a choking victim due to sudden upward pressure on the upper abdomen. *Id.* The maneuver is applied only when the choking victim's airway is totally blocked rendering the person unable to speak, breath, or cough out the foreign object. *Id.*

^{2.} Allan Bloomberg, et. al., Patenting Medical Technology: "To Promote the Progress of Science and Useful Arts," 317 New Eng. J. Med. 565 (Aug. 1987) ("Bloomberg"). In the first month of 1987, only 423 of 6418 patents filed were classified as medical patents. Id. Specifically, only twenty-three were granted to hospitals, universities or colleges, or nonprofit research groups. Id. "Relatively few patents are in the field of medicine. A recent survey disclosed that of the U.S. patents issued during the survey period, 6.6 percent related to medicine and 0.4 percent were filed on behalf of hospitals, universities, and not-for-profit research institutions." Id.

^{3.} Id. at 566.

^{4.} Edward Felsenthal, Medical Patents Trigger Debate Among Doctors, Wall St. J., August 11, 1994, at B1, B6.

^{5.} See Larry Thompson, Medical Technology - 20 Years of Heart Transplants; Explosion of This Technology Raises Questions of Cost and of Who Gets Scarce Organs, Wash. Post, Dec. 1, 1987, at Z16. The vaccine was invented in 1796, insulin created in 1921, penicillin came into existence in 1943, and the first organ transplantation occurred in 1955. Id.

transplantation of hearts, livers, and lungs has become a common occurrence.⁶

Today, with the aid of computer technology, physicians are able to plan and create medical techniques more effectively.⁷ For example, physicians use computers to take an image of the patient's body and create a map.⁸ This technique allows the doctor to invent new ways to operate before he even makes an incision.⁹ By enabling the doctor to plan his surgery, computer imaging reduces operating time and increases the chances of a successful operation.¹⁰

Recently, Doctor Samuel Pallin invented a medical technique whereby he shortened the overall length of cataract surgery and eliminated the use of stitches. ¹¹ Dr. Pallin, seeking financial reward for his newly developed medical technique, patented the process. ¹² Subsequently he filed a patent infringement ¹³ suit against a medical group for unauthorized use of his newly discovered medical process. ¹⁴

In response to physicians seeking patents and collecting royalties for new medical processes, medical associations and physicians are expressing concern about the patenting of medical processes. Namely, the American Medical Association ("AMA") alleges that patenting medical processes will discourage physicians from disclosing their new discoveries, thereby excluding other physicians from using their patented medi-

^{6.} Id. In 1967, Dr. Christian N. Barnard performed the first successful heart transplant. Id. Since then, doctors have performed well over 4000 heart transplants. Id.

^{7.} Rebecca Fowler, Computers May Drive Revolution in Neurosurgery Techniques, Wash. Post, Aug. 15, 1994, at A3.

^{8.} Id. The process commences with the doctor placing the patient's head in a frame to measure the size of the brain. Id. Then, the computer scans the brain to gain valuable information and produces a three dimensional image of the brain. Id.

^{9.} Id.

^{10.} Id. Moreover, the latest trend in surgery is laparoscopic surgery. See John V. White, Registry of Laparoscopic Cholecystectomy and New and Evolving Laparoscopic Techniques, 165 Am. J. Surgery 536 (April 1993). Laparoscopic surgery is a process of inserting a scope into the body and taking images of the body so the doctor may plan his surgery. Id. This eliminates the pain and suffering of incisions. Id.

^{11.} Felsenthal, supra note 4 at B1, B6. The surgery involves an incision "shaped like a facial frown that automatically seals itself after surgery. Unlike traditional incisions, it doesn't require stitches." Id.

^{12.} Id.

^{13. 35} U.S.C. § 271(a) (1994). This statute provides, in relevant part, "[e]xcept as otherwise provided in this title, whoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefore, infringes the patent." Id.

^{14.} Felsenthal, supra note 4 at B1. Doctor Pallin filed suit against a Vermont physicians' group which Pallin claimed infringed his patent for an operating procedure for cataracts. Id.

^{15.} Id.

cal techniques.¹⁶ Additionally, the AMA fears that patent-owning physicians, in order to enforce medical process patents, will intrude into the privacy of patient medical records to uncover possible patent infringement.¹⁷ Through effective lobbying, the AMA has influenced members of Congress to propose a bill seeking to prohibit the patenting of medical processes.¹⁸

This comment examines the patentability of medical processes and the impact patentability has on the right to privacy inherent in a physician-patient relationship. Part II examines the Constitutional background and development of the Patent Act through statutory enactment and case law. Part III focuses on the effects of enforcing medical process patents and the impact disclosure of medical records has upon the privacy of the physician-patient relationship when patent owners attempt to uncover patent infringement. Part IV proposes a solution that allows a patient to maintain his privacy while allowing a doctor to reap financial benefits from his patented medical process.

II. BACKGROUND

Even though the courts and the Board of Patent Appeals and Interferences ("Patent Board") approved the patentability of medical process patents today, both at first did not adhere to this concept. Before 1952, the courts and the Patent Board held that medical process patents were not patentable subject matter. ¹⁹ In 1952, Congress codified the patent laws establishing the elements an inventor must prove to obtain a patent for a particular innovation. ²⁰ Therefore, to comprehend the patentability of medical processes and the impact patents have on the privacy of a physician-patient relationship, one must examine the Constitutional

^{16.} Id.

^{17.} *Id.* at B6. Doctor George Annas asserts that to monitor medical processes, doctors and patients' privacy interests will be invaded. *Id.* In addition, medical groups and doctors fear increasing health care costs and legal fees. *Id.*

^{18.} H. R. 587, 104th Cong., 1st Sess. (1995). The American Bar Association's Section on Intellectual Property Law adopted a resolution in opposition to the bill at its annual meeting in June 1995. Patents on Surgical Methods, A.B.A. Sec. Int. Prop. L. Res. 101-8 (action taken June 21-25, 1995); see also Sabra Chartrand, Medical Community Disputes Procedure Patents, Plain Dealer, July 11, 1995 at § 10-E.

^{19.} Morton v. New York Infirmary, 17 F. Cas. 879 (S.D.N.Y. 1862) (disallowing a patent for administering anesthetics during surgery); Ex Parte Brinkerhoff, 24 Off. Gaz. Pat. 349 (Comm'r. Pat. 1883) (denying a patent for a surgical method) reprinted in 27 J. Pat. Off. Soc'y 797 (1945).

^{20.} Act of July 19, 1952, Pub. L. No. 950-593, § 1, 66 Stat. 797, reprinted in 1952 U.S.C.C.A.N. 2394. Congress passed the first patent laws in 1790. See, e.g., Graham v. John Deere Co., 383 U.S. 1, 6 (1966). Since 1790, Congress modified the patent laws nearly fifty times before officially codifying them in 1952. Id. at 10.

background and development of the Patent Act through statutory enactment and case law.

Federal patent protection is derived directly from the Constitution, which authorizes Congress "to promote the advancement of science and the useful arts." In accordance with this provision, Congress enacted the Patent Act ("Act") of 1790.22 Under the Act, the United States Patent and Trademark Office ("PTO") grants an inventor the exclusive right to an invention for a limited time period.23 Consequently, everyone but the patent-holder is excluded from "making, using, or selling, the invention."24 In return for the grant of the exclusive right, the inventor discloses to the public a novel, "non-obvious and useful invention."25

Since Congress enacted the first Patent Act in 1790, there have been four major revisions.²⁶ One change was made when, in 1952, Congress replaced the word "art" in the Act with the word "process."²⁷ The Act now includes "a new use of a known process or material."²⁸ However, long before this change in the statute, a "process" was patentable.²⁹ For example, in *Cochrane v. Deener*,³⁰ the Supreme Court stated "it cannot

^{21.} U.S. Const. art. 1, §8, cl. 8. This section provides in relevant part that Congress is empowered "to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." *Id. See also Graham*, 383 U.S. at 6 (stating that the above-mentioned standard is expressly stated in the Constitution and it must not be ignored).

^{22.} Graham, 383 U.S. at 6. The Patent Act of 1790 granted a patent for fourteen years to anyone who invented or discovered any useful art, or device, or any improvement not known or used before. Id. at 7. The first Act spawned the creation of an agency headed by the Department of War and the Attorney General. Id. The guiding spirit behind this agency was Thomas Jefferson, the "first administrator of our patent system." Id. Also, Jefferson was the author of the Patent Act of 1793. Id. Jefferson was himself a great inventor, as he made improvements on plows that gained him notoriety on both sides of the Atlantic Ocean. Id. Jefferson noted in a letter to Isaac McPherson that the patent monopoly is not granted for frivolous devices, improvements, or small details. Id. at 9. Rather, he stated that the patent monopoly "was a reward, an inducement, to bring forth new knowledge." Id.

^{23.} Timothy J. McCoy, Biomedical Process Patents: Should They Be Restricted by Ethical Limitations?, 13 J. Leg. Med. 501, 502 (Dec. 1992).

^{24.} Id.

^{25.} Id.

^{26.} Gregory F. Burch, Ethical Considerations in the Patenting of Medical Processes, 65 Tex. L. Rev. 1139, 1145 (May 1987). The most recent occurred in 1952. Id.

^{27. 35} U.S.C. § 100(b) (1994). The statute reads: "The term process means process, art, or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." *Id.*

^{28.} Id.

^{29.} See Diamond v. Diehr, 450 U.S. 175, 182 (1981). The Court determined the meaning of the word "process" from the Committee Reports accompanying the 1952 Statute. Id.

^{30. 94} U.S. 780, 787-88 (1876). In *Cochrane*, the appellant, William F. Cochrane, sued on six patents which were granted to him relating to a new method of bolting flour. *Id.* at 781. The first patent was issued for the general process, while the remaining five were for

be disputed that any process is patentable." Moreover, the Court held that a process, if new and useful, is a term of art in the language of the patent law.³¹

Since the adoption of the word "process" in the Act, the Supreme Court has held that the subject matter of a patent "include[s] anything under the sun made by man."³² For instance, in *Diamond v. Diehr*, ³³ the Court, in finding that a process for curing synthetic rubber employing a mathematical equation was patentable subject matter, stated that a common and ordinary meaning must apply to all words. ³⁴ Because the Supreme Court instructs lower courts not to limit or restrictively define words when interpreting patent laws, "process" today receives a broad construction. ³⁵

Medical processes have been patentable since the landmark case of Ex Parte Scherer.³⁶ In Scherer, the Patent Board ruled that medical

improvements made on different parts of the machinery carrying on the process. Id. The invention was to produce the finest quality of flour. Id. at 785. The process involved separating superfine flour from the meal and regrinding and rebolting the remaining flour portions to make pure white flour. Id. This, when added to the superfine flour, improved the quality of the flour. Id. While the process is more detailed and complex, generally this was the process described. Id. The Court held Mr. Cochrane's process patentable. Id. at 788. The Court defined a process as "a mode of treatment of certain materials to produce a given result." Id. The Court went further to state that "[i]t is an act, or series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." Id. "If new and useful, it is just as patentable as is a piece of machinery." Id.

- 31. Id. at 788.
- 32. Diamond, 450 U.S. at 182. In Diamond, the Court defined the word "process" from the Committee Reports accompanying the 1952 Statute. Id. "The Patent Act of 1793 defined statutory subject matter as 'any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereof]." Id. quoting Act of Feb. 21, 1793, Ch. 11, § 1, 1 Stat. 318.
- 33. Id. at 187. The respondent's process involved "installing rubber in a press, closing the mold, recalculating the appropriate cure time through the use of a formula and a digital computer, determining the temperature of the mold, and opening the press automatically at cure time." Id.
 - 34. Id. at 182.
- 35. Id. Furthermore, the Diamond Court found that a "process is a manner of treatment of certain materials to produce a given result." Id. at 183. In addition, the Court ruled that a process "is an act or series of acts, performed upon the subject matter to be transformed and reduced to a different state." Id.
- 36. 103 U.S.P.Q. 107, 109 (Board of Patent Appeals and Interferences 1954). At issue was whether a surgical method was patentable. *Id.* Specifically, Scherer applied for a patent for surgical method of injecting fluid into the human body through the epidermis. *Id.* The process involved "placing a jet orifice against the epidermis to provide a hydraulic seal between the edge of the orifice and the epidermis." *Id.* Meanwhile, the body serves passively as it does not react in any manner. *Id.* The accurate "placing of the fixed quantity of medicament at a predetermined position beneath" the skin layer is the expressed result and therefore useful within the statute. *Id.*

processes are patentable subject matter.³⁷ Specifically, the Board held that the medical process of injecting fluid through human epidermis was patentable.³⁸ Furthermore, the Board stated that surgical methods involving the human body are not unpatentable simply because the human body is involved.³⁹ Thus, because the change in the Patent Act of 1952 allows the patenting of a process, new medical processes are subject matter capable of being patented.⁴⁰

While Scherer paved the way for the patenting of medical processes, many physicians and medical associations fear that the investigation of patients' medical records to uncover patent infringement will effectively destroy patient privacy in medical records.⁴¹ While patients have a right to keep their medical records private,⁴² there are exceptions to this right.⁴³ For example, the government may obtain patient medical records when public health or other public concerns are at issue.⁴⁴ Particularly in Walen v. Roe,⁴⁵ the United States Supreme Court stated that disclosures of medical information to public health agencies is essential even though such disclosures exhibit a patient's private information.

^{37.} Id. at 110.

^{38.} Id.

^{39.} Id. The Patent Board refused to exclude the surgical method of injecting fluid into the human body through the epidermis stating that the patent statute does not categorically exclude surgical methods. Id.

^{40.} See, e.g., Burch, supra note 25, at 1145 (explaining the hesitancy to allow the patenting of medical processes). Initially, patents were not extended to medical processes, despite early judicial recognition of process patentability. Id. at 1146. See, e.g., Brinkeroff, 24 Off. Gaz. Pat. at 349 (disallowing a patent claim for a medical procedure for treating piles). The Commissioner of Patents rejected the medical procedure because results could not be established with medical or biological processes. Id.

^{41.} Felsenthal, supra note 4, at B1. See supra notes 17, 18 and accompanying text for a discussion of privacy-related matters and other fears of medical associations and physicians.

^{42.} See United States v. Westinghouse Elec. Corp., 638 F.2d 570 (3rd Cir. 1980) (acknowledging a privacy interest in medical records). Westinghouse involved the disclosure of a patients examination records to the National Institute For Occupational Safety and Health ("NIOSH"). Id. at 572. NIOSH demanded medical records of the patients to test for possible allergy symptoms of employees to Hexahydrophalic anhydride. Id. at 572-3. The company filed suit on behalf of the employees claiming an invasion of privacy. Id. The court weighed the public interest in opening the medical records against the privacy issue to find that disclosure was permitted to protect the health of the employees. Id. at 578-80. However, the court stated that the need to disclose medical records will not always outweigh the privacy interest of the employees. Id. at 581.

^{43.} Walen v. Roe, 429 U.S. 589, 602 (1977). In Walen, the Supreme Court held that allowing disclosure of a patient's medical records does not automatically violate a patient's privacy. *Id.* at 602. The New York Legislature enacted a law requiring a patient's name, address, and age to be disclosed in order to fill prescriptions with the State Health Department. *Id.* at 591.

^{44.} Westinghouse, 638 F.2d at 578.

^{45. 429} U.S. at 602.

While the courts in Walen v. Roe, United States v. Westinghouse, and Doe v. DiGenova allowed patient records to be disclosed to persons besides physicians, 46 society promotes the privacy of a doctor-patient relationship to encourage patients to fully disclose all symptoms and illnesses. 47 Thus, confidentiality in the doctor-patient relationship encourages patients to speak openly with their physicians to receive better treatment. 48 As a result of this relationship, physicians diagnose illnesses, prescribe medicine, and treat patients more effectively. 49 Therefore, "[doctor]-patient confidentiality is a means for achieving greater general health. 750

III. ANALYSIS

The United States Supreme Court mandates that patentable subject matter includes anything "made by man under the sun."⁵¹ Thus, it follows that physicians should be able to patent new medical processes. Patents reward inventors for their innovation and contribution to society by granting them an exclusive right in return for disclosure of the new invention.⁵² Nonetheless, opponents of medical process patents fear that physicians and surgeons, in hopes of furthering their own monetary goals, will fail to report results or will report their results in a biased manner.⁵³ In addition, the AMA and some physicians fear medical process patents will invade the privacy of the doctor-patient relationship

^{46.} Id. at 599; Westinghouse, 638 F.2d at 578; Doe v. DiGenova, 642 F. Supp. 624 (D.D.C. 1986) (all allowing disclosure of a patient's medical records). In Doe, the plaintiff's medical records were sought for production by the United States Attorney. Doe, 642 F. Supp. at 626. The records containing the plaintiff's psychiatric treatment at a Veterans Administration clinic were released to two Metropolitan Police Department Officers. Id. The plaintiff filed suit alleging violation of the physician-patient privilege. Id. at 628. The court applied the balancing test of Walen and held that disclosure of the medical records was permitted. Id. at 634.

^{47.} Burch, supra note 26, at 1155. "Although the principle of confidentiality seemingly mandates that only the patient and the physician know of the procedures performed, some accepted legal practicalities do invade the physician-patient privacy." Id. For example, the patient's insurance company and some Government sponsored health care programs require a sufficient amount of disclosure of medical records. Id.

^{48.} *Id*.

^{49.} Id.

^{50.} Id.

^{51.} Diamond, 450 U.S. at 182.

^{52.} McCoy, supra note 23 at 506. "[T]he Constitutional grant of authority, congressional enabling legislation, and judicially created case law all clearly recognize the validity of biomedical process patents." Id. Furthermore, the United States patent system fosters many technological advancements, and with the widespread growth of biomedical and medical technology in the late twentieth century, the patent system is fundamental to the medical profession and its developments. Id. at 502.

^{53.} Burch, supra note 26 at 1139.

when patent-owning physicians examine patient medical records to uncover potential patent infringement.⁵⁴ These fears are unfounded as demonstrated in the following sections.

A. Society Benefits From Medical Process Patents

The basic premise behind the patent system in the medical field is to promote the disclosure of new medical processes by granting patent protection to the doctor.⁵⁵ Procedurally, the Patent Act requires the doctor to disclose in detail his new medical process and how it works before the PTO may grant a patent.⁵⁶ Some medical associations and physicians argue that publication of medical discoveries, instead of patenting, provides a quicker mode of advancement of the discovery to the community.⁵⁷ However, this argument fails because the publication of a newly-discovered medical process can occur immediately with no affect upon the patentability of the process so long as the application is filed within a year of initial disclosure.⁵⁸ Consequently, when medical journals receive a description of a new medical process, it may be published immediately.⁵⁹ Thus, the patenting of medical processes does not inhibit or slow down the disclosure of information to the public.

In Sinclair & Carrol Company v. Interchemical Corp., the Supreme Court stated that patents are for the benefit of the public, not the private inventor, as patents encourage disclosure of inventions which might otherwise be kept secret.⁶⁰ Similarly, in Kewanee Oil Corp. v. Bicron,

^{54.} Id. at 1154. See also supra note 43 and accompanying text for a discussion of the possibility of legally forced disclosure of a patient's medical record.

^{55.} Bloomberg, supra note 2 at 566.

^{56. 35} U.S.C. § 112 (1994).

^{57.} Bloomberg, supra note 2 at 567. Bloomberg comments that publishing medical discoveries instead of patenting them may delay its availability to the medical community. *Id.* Furthermore, "the Department of Health and Human Resources ("DHHS") requested that the U.S. Patent Office expedite the examination of a . . . patent application, partly because a major pharmaceutical company informed the DHHS that it would be more interested in manufacturing the product if it were patented." *Id.* at 566.

^{58.} Id. See also 35 U.S.C. § 102(b) (1994) (providing that a patent may not issue if the invention was described in a printed publication more than one year prior to the date of application).

^{59.} Id.

^{60. 325} U.S. 327, 330-31 (1945). The Sinclair court held that the patent system induced disclosure of advances which are beneficial to society. Id. "It is the promotion of science and the advancement of the arts looking to the general welfare of the Nation that the patent laws hope to accomplish." Id. The defendant, Interchemical Corporation, claimed that the plaintiff infringed its patent. Id. at 327. Interchemical Corporation was an assignee on a patent of printing ink and other smooth non-absorbent paper. Id. The process involves ink drying instantaneously on the heating of the printed materials. Id. at 328. When one side of the paper is printed, it absorbs the ink, and the remaining side prints immediately without a smear or smudge. Id. The ink contains certain solvents

the Court stated that while the PTO grants patent owners exclusive rights to their inventions for a limited period of time, this grant operates as an incentive to introduce new products and processes into the mainstream.⁶¹

While the public is the primary beneficiary of patented medical processes, Congress also rewards the doctor, surgeon, or researcher for his individual effort and creativity.⁶² Financial rewards encourage new research, while stimulating further development in the medical profession.⁶³ As new discoveries are made, patent-seeking physicians will disclose their new processes as soon as possible to reap the anticipated financial reward.⁶⁴ In turn, this disclosure enhances medical science and produces a high social value by increasing the quality of medical care.⁶⁵

The issuance of patents for medical processes brings about "[i]nnovation, advancement, and things which add to the sum of useful knowledge."66 When physicians and surgeons patent new medical

- 63. Id.
- 64. Id.

which allows magazines to print on high speed rotary presses furnished with heating devices without interruption for drying. Id. at 329.

^{61. 416} U.S. 470, 480 (1974). In Kewanee Oil, employees of an unincorporated division of the Kewanee Oil Corporation, signed a non-disclosure agreement for consideration of employment. Id. at 473. Some employees left Kewanee Oil Corporation and went to work for Bicron Corporation and revealed trade secrets regarding the manufacture of a synthetic crystal, useful in detecting a certain form of radiation. Id. The plaintiff sought to enjoin its former employees from disclosing the trade secrets. Id. The Court stated in a rather colorful depiction that society prospers from the introduction of new materials. Id. at 480. In addition, the Court stated that inventors are offered a right of exclusion for a limited time period because of their enormous time and cost in researching and developing a "new and useful" invention. Id. At the end of this limited time period "the knowledge of the invention inures to the people, who are thus enabled without restriction to practice it and profit by its use." Id. at 481.

^{62.} Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980). In this case, the Court stated that the patentee produced his own invention without the characteristics common in nature. *Id.* at 310. Therefore, the Court held the discovery to be patentable subject-matter under section 101 of the Patent Statute. *Id.* The respondent, Chakrabarty, a microbiologist, filed a patent application of a human-made bacterium. *Id.* at 305. This bacterium could break down crude oil components and treat oil spills. *Id.* The Court stated that the discovery was one with potential significant utility to society. *Id.* at 310. Thus, it was held that live, human-made micro-organisms were subject matter capable of patentability under § 101 of the Patent Statute. *Id.*

^{65.} Burch, supra note 26 at 1142. Burch discusses the deontological and instrumentalist views regarding the ethical concerns of patenting medical processes, suggesting that medical process patents improve the quality of society's health care. *Id.*

^{66.} Graham, 383 U.S. at 5. The Court stated that "[i]nnovation, advancement, and things which add to the sum of knowledge all inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts." Id. The invention in Graham was a "clamp for vibrating shank plows" that involved a combination of old

processes for the benefit of society, they receive a financial reward for a limited time as an incentive for the disclosure of innovations which add information and knowledge to the public domain.⁶⁷ Therefore, society as a whole should welcome the patenting of new medical processes as a vehicle to greater overall health.⁶⁸

B. THE IMPACT MEDICAL PROCESS PATENTS HAVE ON THE PRIVACY OF THE PHYSICIAN-PATIENT RELATIONSHIP

The AMA and others fear that the enforcement of medical patents may create the possibility of an intrusion into the privacy of the doctor-patient relationship.⁶⁹ These opponents argue that patent holding physicians will require the production of a patient's medical records in their attempts to prosecute patent infringement claims.⁷⁰ When medical records are disclosed, an intrusion into the privacy of the doctor-patient relationship occurs.⁷¹

Today, the maintenance of medical records⁷² is a sophisticated science.⁷³ Medical records contain sensitive medical (as well as nonmedi-

elements of mechanical devices whereby these elements are designed to absorb the shock from the vibrating plow through rocky soil. *Id.* at 4. The result is that the plow remains intact. *Id.* In *Graham*, the Court held that the invention involved a combination of elements that were not new results and therefore was invalid pursuant to the Patent Act's test of obviousness. *Id.* at 4.

- 67. Griffith Rubber Mills v. Hoffar, 313 F.2d 1, 3 (3rd Cir. 1979). The court stated that patents grant a monopoly for a limited time as an incentive to the disclosure of innovations which in the end will add to the fund of freely available knowledge. *Id.*
- 68. Burch, supra note 26 at 1154 (benefitting from new medical processes, society has the opportunity to receive medical attention in areas that were once unavailable in medicine).
- 69. Felsenthal, supra note 4, at B6. See supra note 17 and accompanying text describing George Annas' fear regarding invasion of privacy.
- 70. Burch, supra note 26 at 1154. See supra note 42 and accompanying text for a discussion regarding judicial enforcement of disclosing patient files.
 - 71. Burch, supra note 26 at 1154.
- 72. MARCIE A. LEWIS & CAROL D. WARDEN, LAW AND ETHICS IN THE MEDICAL OFFICE 94-95 (F.A. Davis Co. 1988). Medical records vary in all shapes and sizes. *Id.* For example, some doctors who see patients on a limited basis may keep patients' information on an index card. *Id.* However, a doctor who sees a patient frequently may have numerous file folders on that particular patient. *Id.* at 94-95. "Whatever type is utilized, each patient needs a medical record." *Id.*
- 73. Tom Christoffel, Health And The Law 330 (The Free Press 1982). Today, medical records contain a vast amount of information regarding a particular person. *Id.* Medical records are a product of communication and documentation recorded between a patient and a doctor. *Id.* at 331. The medical record guides and serves the less able practitioners and "facilitates retrospective quality review and other record-based research." *Id.* Finally, the medical record helps to resolve disputes regarding the treatment of a particular patient if any problems arise concerning a doctor or surgeon's treatment during a certain period. *Id.*

cal) information about a person.⁷⁴ Consequently, when a patient's medical record is accessed, a great deal of information concerning that patient is disclosed.⁷⁵ Therefore, health care employees with access to medical records must protect the privacy of patients.⁷⁶ However, physicians routinely permit computer database services to obtain patients' medical records in cases of state and national security.⁷⁷ Most often, patient information is exchanged by these services without either the knowledge or consent of the patient.⁷⁸ In fact, the AMA notes that numerous information agencies invade the privacy of the doctor-patient relationship by the opening of medical records without consent.⁷⁹ Several reasons exist to ensure the confidentiality of a patient's medical record.

First, a doctor can only provide adequate diagnostic and treatment methods if the patient openly discusses his problems.⁸⁰ Physicians must be able to assure patients that their relationship is confidential and privileged in order to provide necessary treatment.⁸¹ Patients may hesitate

^{74.} Sherri Alpert, Smart Cards, Smarter Policy: Medical Records, Privacy and Health Care Reform., 23 Hastings Ctr. Rpt. 13, 14 (Nov/Dec. 1993). In addition to a patient's name, age, and address, medical records may contain highly secretive information that the patient revealed to the doctor in conference or treatment. Id. at 16. Complaints of diagnosis, personal incidents involving treatment and recovery, and other sensitive information are commonly found in a patient's medical record. Id.

^{75.} Id. at 17. Most federal and state agencies access a patient's medical record through the social security number of the patient. Id. Also, most banks and credit lending institutions use the social security number as the method of identifying certain persons. Id. Therefore, using the social security number as the identifier, companies and agencies can access a persons file and learn much about a person without that person knowing unless injury occurs. Id.

^{76.} Id. No information concerning the patient should be released without the consent of the doctor and the patient. Id. at 85. Then, only relevant information that is authorized should be provided. Id. In some instances, medical offices create release forms that must first be signed by the patient before the office releases any information. Id. All in all, patients and doctors should receive notification before any information is released. Id.

^{77.} Id. at 19. In addition, medical records can also be accessed by the Medical Information Board ("MIB"). Id. at 20. This association works to prevent insurance companies from committing fraud. Id. MIB consists of over 700 life insurance companies and claims that they all work together to make the disclosing of medical records a difficult task. Id. However, when an individual applies for life, health, or disability insurance, he receives an MIB form whereby he is put on notice that the insurance company may release reports to the MIB. Id. In turn, the MIB can exchange information to all its member organizations. Id.

^{78.} Id.

^{79.} Alpert, supra note 74 at 18.

^{80.} Burch, supra note 26 at 1155. In explaining the instrumentalist approach, Burch comments that society seeks to secure the private relations of a physician and patient. Id. This private relationship encourages a patient to tell his doctor every detail, both relevant and irrelevant, during diagnosis and treatment. Id.

^{81.} Commonwealth v. Kyle, 533 A.2d 120, 126 (Pa. 1987). In this case, the court held that the interest in protecting the victim's file outweighed disclosure. *Id.* at 129. The appellant was convicted of rape, robbery, involuntary deviate sexual intercourse and other

or even refuse to seek treatment if it is possible that their medical information could be disclosed to persons other than their doctor.⁸² Hence, the doctor-patient relationship serves the public by "promoting a society in which the general well-being of the citizenry is protected."⁸³

Second, physician-patient confidentiality serves to protect the privacy interest of the individual patient.⁸⁴ Due to the extremely personal nature of medical records, and the confidential relationship in which the information is shared, a patient's medical privacy would be virtually destroyed by a compelled disclosure.⁸⁵ As a result of this disclosure, the patient may suffer humiliation, embarrassment, and disgrace.⁸⁶ By preventing public dissemination of a patient's medical record, the doctorpatient relationship provides effective diagnostic and treatment methods, while securing the patient's personal information.⁸⁷

related offenses for attacking a female at a sewing goods store. *Id.* at 122. The appellant physically and sexually assaulted the victim after tying her down with a rope. *Id.* The court weighed the public's interest of maintaining the privacy of the doctor-patient relationship and the appellant's interest in reviewing useful information protected by the relationship. *Id.* at 129. The court recognized that the practicing medical doctor had a special need to keep the privacy of his patients. *Id.* If the patient feels that the information he shares with the doctor is capable of disclosure to others, he will hesitate to "talk freely" with the doctor. *Id.* This weakens the possibility that effective treatment will be given. *Id.* Thus, the court stated that the physician-patient relationship could compare to the relationships shared by the priest and penitent or the attorney and client. *Id.*

- 82. Id.
- 83. Id. at 126.
- 84. Kyle, 533 A.2d at 127. "The privacy interest of the client may have constitutional underpinnings." Id. The Pennsylvania Supreme Court recognizes that the physician-patient confidential relationship has a Constitutional basis. Id.
 - 85. Id. at 128
- 86. Id. The court stated that society encourages clients to seek professional help in getting treated for psychological help. Id. Furthermore, the court commented that the doctor's records of the victim were privileged communications pursuant to a Pennsylvania Statute which states that a doctor licensed under the Pennsylvania License Act of March 23, 1972, cannot without the written consent of his client or patient reveal any communications, whether examined in any criminal or civil context, arising from the professional services in behalf of the client. Id. at 123. Moreover, the Act reads, "The confidential relations and communications between a psychologist and client shall be on the same basis as those provided or prescribed by law between an attorney and client." Id. This act provides a privilege between doctors and clients designed to prevent a clients' innermost thoughts from public disclosure. Id. at 128.
- 87. Kyle, 533 A.2d at 129. The court "reviewed the language of the statutory privilege enacted by our legislature and having given consideration to the public policies underlying the absolute privilege as well as the relevant cases in this and other jurisdictions, we find that the interests protected by the privilege are substantial." Id. Furthermore, the court commented that those communications made to the doctor during the course of treatment are confidential and privileged. Id. at 130. However, the court treated these communications as "circumstances requir[ing] absolute confidentiality." Id. at 131.

Though the doctor-patient relationship mandates that only the doctor and patient know of the medical process performed, the courts have compelled the opening and disclosing of a patient's medical record when public health concerns are at issue.⁸⁸ While courts acknowledge that patients' medical records are entitled to privacy protection, there are some instances in which the government obtains permission to view medical records.⁸⁹

For example, courts have allowed disclosure of medical records where an individual patient's welfare or the public health is in jeopardy. In order to disclose a patient's medical record, the courts balance the social interest in producing the information against the privacy interest of the patient. For instance, in Walen v. Roe, the United States Supreme Court stated that disclosing medical records does not automatically violate a patient's privacy interest. The Court ruled that the disclosure of medical records to the New York Department of Health did not constitute an invasion of privacy. 93

^{88.} Burch, supra note 26 at 1154.

^{89.} Walen, 429 U.S. at 599; Westinghouse, 638 F.2d at 578; DiGenova, 642 F. Supp. at 634 (holding that disclosure of the medical records of the respective parties was allowed).

^{90.} Westinghouse, 638 F.2d at 578. The Court stated that sometimes the disclosure of medical information, private as the information may be, is essential when the information is given to doctors, other hospital personnel, insurance companies, and public health agencies. Id. at 577. When the patient's information is given to doctors, hospital personnel, insurance companies and/or public health agencies, all representatives of the state, an invasion of privacy does not necessarily take place. Id. These representatives have responsibility in maintaining the health of citizens. Id. In these instances, the government recognizes the necessity of obtaining pertinent information of a person in order to commence or improve treatment programs for the benefit of the citizens. Id. at 578. Also, the information disclosed to the state's representatives may help to diminish or stabilize medical problems that are threatening the public's general health. Id.

^{91.} Id. To prevent unnecessary intrusion into the privacy of a certain individual, many factors are taken into consideration in order to decide whether release of the information is proper. Id. Such factors are the records for request and whether the information it contains justifies the disclosure, the potential harm that may result from subsequent production of information that the patient did not consent to, the relationship between the injury resulting from disclosure and the records accessed, and the safeguarding methods providing protection from unauthorized disclosure. Id. Further factors for consideration are "the degree of need for access, and whether there is an express statutory mandate, articulated public policy, or other recognizable public interests militating toward access." Id.

^{92.} See Walen, 429 U.S. at 602 (reasoning that some level of disclosure of a patient's private medical information contained in the record is essential). The Court stated that disclosure is essential when it is made to doctors, to other hospital personnel, to insurance companies, and to public health agencies even though the disclosure reflects negativeness in the character of the patient. *Id.* Invasion of the patient's privacy does not automatically result because state representatives have a duty to provide good health in the community. *Id.*

^{93.} Id. at 603. The Court held that there was no invasion of privacy protected by the Fourteenth Amendment with the patient-identification requirements of the New York

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Also, in *United States v. Westinghouse*, the court upheld disclosure of employees' medical records to protect the collective health of all of the workers.⁹⁴ The court stated that the social interest in determining an employee's allergies under certain situations outweighed the employees' interest in protecting personal matters from disclosure.⁹⁵

Similarly, in *Doe v. DiGenova*, the court balanced the public's interest in disclosing the patient's medical records with the privacy of the patient. Ultimately, the court permitted the disclosure of the medical records to the grand jury. Hence, the judicial system allows and often requires the disclosure of a patient's medical record. Consequently, the enforcement of medical process patents will invade the confidentiality of the doctor-patient relationship because the patent holder will have to investigate the files of the doctor's patient during the discovery process of a patent infringement action. The real question then, is whether the prospect of patent enforcement surpasses the level of disclosure already tolerated.

The PTO should issue patents for medical processes that are new and useful to the medical profession and society in general. In the event the PTO issues a patent for a medical discovery, the patent system requires full disclosure, and effectuates full public access to the new tech-

State Controlled Substance Act of 1972 even where the patient's reputation and independence was jeopardized. Id.

^{94. 638} F.2d at 579 (concluding that the overall interest of the safety and health of current employees in the workplace, future employees, and the public at large is substantial and qualifies for the disclosure of records and information normally considered private). Id. In addition, the court stated that the National Institute for Occupational Safety and Health examination of the employees' medical records was done to protect the employees' health. Id. Furthermore, the court stated that the disclosure of the employees' medical records would not likely cause the employees to forbear from taking further periodic examinations. Id. "The strong public interest in facilitating the research and investigations of [the National Institute for Occupational Safety and Health] justify this minimal intrusion into the privacy which surrounds the employees' medical records." Id. at 580.

^{95.} Id. at 577. In Westinghouse, the court cited Walen v. Roe, where one of two types of privacy interests constitutional protections extend to. Id. The second interest noted is the liberty interest in making important decisions. Id.

^{96.} DiGenova, 642 F. Supp. at 634.

^{97.} Id. In Doe, as in Westinghouse, the court cited Walen v. Roe, and concluded that the grand jury could see the plaintiff's Veteran's Administration records because only a small amount of people view the records and the plaintiff has protection from further disclosure pursuant to the grand jury secrecy rule. Id.

^{98.} See Burch, supra note 26 at 1155 (acknowledging that other disclosures permitted are to the patient's insurance company and government funded health care benefit programs).

^{99.} Id. at 1145.

^{100.} Id.

nique.¹⁰¹ "This principle is the engine that drives innovation and capital investment in research and development."¹⁰² In turn, society benefits because new medical processes provide better diagnostic and surgical methods for the treatment of patients. Logically, when medical knowledge advances, the quality of society's health care increases.¹⁰³

Although the quality of society's health care increases with medical process patents, equally important is the private relationship that exists between a doctor and patient.¹⁰⁴ When patent owners investigate a patient's medical records, the patient is exposed to potential loss of self-respect and meaningful interaction with others.¹⁰⁵ Therefore, a solution should equally protect a doctor's right to obtain a patent and a patient's right to privacy of his medical record.

IV. SOLUTION

Recently, President Clinton unveiled his health care reform proposal. 106 This reform proposal relies heavily on computer technology for

However, both of the plans provide "insurance purchasing cooperatives, competing health plans, a standard minimum benefits package, insurance market reforms, and the provision to consumers of data on price and quality." Id.

^{101.} See McCoy, supra note 23 at 502 (stating that unavailability of access to a patent is for a limited period of time). When access to the use of the patented invention or discovery is not available, it remains so only for a limited period of time. Id. "The grant of exclusivity and potential economic monopoly on any product utilizing patented technology—including a patented medical process—is the quid pro quo for disclosure." Id.

^{102.} McCov, supra note 23 at 502.

^{103.} Burch, supra note 26 at 1142. See supra note 62 and accompanying text for a discussion of how patents for medical processes increase society's overall general health.

^{104.} See Alpert, supra note 74 at 22 (discussing intimate details of a patient's or employee's medical record). Privacy deserves the respect and notoriety as other values which society recognizes as being important. Id. Privacy is sometimes defenseless and open to attack and therefore it should receive the same protections and commitment as other values. Id.

^{105.} Id. See also text accompanying supra note 108 (explaining the importance of privacy in general). "Privacy has also been described as being fundamental to the values of respect, love, friendship, and trust; indeed, some argue, without privacy these relationships are inconceivable." Alpert, supra note 74 at 22. People appreciate the solitude and autonomy that privacy encompasses, and once this is under threat by disclosure of some sort, people tend to hide and lose some sense of individuality. Id.

^{106.} Dana Priest, For Its Omissions, Coopers Tennessee Solution' Fills Some Bills, Wash. Post, February 3, 1994, at A12. Along with President Bill Clinton's health care plan, Representative Jim Cooper has proposed a health care bill. Id. President Clinton's health care plan mandates that employers would pay for the health insurance of their employees, and the government would be able to restrict premiums on the health insurance. Id. While Representative Cooper's health care bill does not mandate the above mentioned policies, not everyone under his health bill proposal would receive private health insurance. Id. President Clinton's plan calls for more government regulation, while Representative Cooper's plan involves not only the government, but employers and others who will all contribute in paying for health coverage. Id.

listing, filing, and facilitating information on medical records.¹⁰⁷ Since health care may be undergoing reformation on a national scale, it is necessary to standardize protection for a patient's medical records.¹⁰⁸ This section proposes a solution that provides reasonable security to safeguard information a patient discloses to his doctor. Thus, when patent holders seek to uncover patent infringement of new medical processes, the patient will be secure from unnecessary embarrassment and exposure through identification.

Currently, federal and most state laws fail to adequately protect a patient's medical records. 109 In fact, few states have enacted laws to pro-

107. Alpert, supra note 74 at 22. Today, relying on computer technology is prevalent in all of the health care reform proposals put forth by the President, Congressmen, and advisors. Id. Some suggest that an individual's medical files should be contained on databases. Id. at 20. Also, these proposals institute access of a patient's medical information through telecommunications networks. Id. Currently there exist two kinds of card technologies; one being an automated teller card and the other a smart card. Id. at 21.

The automated teller card is similar to a credit card as the front of the card is embossed with the patient's name and health care identification number. *Id.* Analogous to a credit card, the automated teller card has a magnetic strip on the back of the card which contains information about the patient. *Id.*

On the other hand, smart cards are comparable to microcomputers and contain integrated circuit chips or employ laser technology. *Id.* The smart card is said to be able to store the equivalent of a hundred pages of information while only the size of a credit card. *Id.* Unlike the automated teller card which only stores general information about the patient, the smart card would contain detailed medical and insurance information regarding the card holder. *Id.*

Since medical records contain extensive amounts of information about a person, the government needs to consider the privacy implications relating to the automated teller card and the smart card. *Id.* These cards could possibly provide limited access to a patient and allow the patient to control the information. *Id.*

These proposals would be linked to databases and "[i]ndeed electronic cards may do nothing to control access to data once the information resides in a data base. So, in reality, the cards could provide a false sense of security to a patient trying to control how much of his or her records someone else sees." *Id.*

108. Id. at 21. Today, Congress continues to discuss problems regarding the United States health care system. Id. Policymakers need to find a solution to curtail the increasing costs of our nation's health care bill. Id. In the last decade, several legislative proposals were made to further cut costs of administering health care. Id. at 23. These proposals included one made during the Bush Presidency which turned out as a non-legislative proposal. Id. Also, four legislative proposals were introduced by Senators Mitchell (D-Maine) and Kennedy (D-Massachusetts), and Representatives Russo (D-Illinois) and Cooper (D-Tennessee). Id. Similar proposals were introduced in Congress earlier this past year. Id.

109. Id. at 23. Most states have not enacted any privacy protection laws for medical records. Id. Only a few have implemented privacy protections for medical records, but their laws vary in scope and applicability. Id. Some states provide protections for only insurance transactions or for highly sensitive information, while California, Montana, and Washington have adopted laws concerning the accessibility of health information. Id. Shockingly, some states have enacted laws that provide greater privacy protection to information exchange than a patient's privacy. Id. "[V]ideo rental records are afforded more

tect these records.¹¹⁰ Therefore, to prevent further disclosure of medical records, Congress should revise the Patent Act to provide reasonable security protections between physician and patient. Such protections will allow a patient to disclose all medical problems without the fear of subsequent identification.

Congress should revise the Act to include medical record protection similar to that of Montana and Washington. 111 These states attempt to prevent unnecessary intrusions into a patient's medical record. 112 The revised Patent Act should include a clause requiring all physicians and hospitals to protect medical records and health care information of all patients. 113 As a preliminary measure, this new clause should require all physicians to provide a notice to each patient stating the doctor will not disclose any medical records unless the patient consents or the courts compel disclosure of the medical records. 114 If the patient consents to a disclosure of his medical record, any information identifying the patient should be redacted. 115 After the removal of identifying information, the patient should have the opportunity to review the file. By allowing primary patient review, the doctor will not improperly disclose identifying information. This process would limit disclosure of the patient's identification regardless of whether the medical records are automated or simply filed in a cabinet.

Alternatively, if the law compels the opening of a patient's file for patent infringement purposes, this new clause should require a similar

federal protection than are medical records. As the law now stands, while the unauthorized disclosure of medical records may be ethically reprehensible, in the majority of states in this country it is not illegal." *Id.* at 14.

- 110. Alpert, supra note 74 at 14.
- 111. See Mont. Code Ann., Title 50, Ch. 16 (1994); see also Wash. Rev. Code, Title 50, Ch. 70.02 (1994).
- 112. Mont. Code Ann., Title 50, Ch. 16, Pt. 5 concedes that disclosure of a patient's medical record is proper when it: "[i]s of sufficient importance to outweigh the intrusion into the privacy of the patient that would result from the disclosure; and contains reasonable safeguards to protect the information from improper disclosure." *Id.*

Furthermore the statute aims to protect the identity of the patient by requiring "reasonable safeguards to protect against directly or indirectly identifying any patient in any report . . . [and] procedures to remove or destroy at the earliest opportunity . . . information that would enable the patient to be identified." *Id*.

- 113. Id.. The statute reads in relevant part: "[h]ealth care information means any information, whether oral or recorded in any form or medium, that identifies or can readily be associated with the identity of a patient and relates to the patient's health care." Id.
- 114. Wash. Rev. Code, Title 50, Ch. 70.02. The statute provides that health care providers must post a notice stating that "[w]e keep a record of the health care services we provide you . . . [w]e will not disclose your record to others unless you direct us to do so or unless the law authorizes or compels us to do so." *Id*.
- 115. Id. In Washington, an auditor will "remove or destroy at the earliest opportunity, consistent with the purposes of the project, information that would enable the patient to be identified." Id.

process for limiting disclosure of patient identification. However, court compelled disclosure should include one more step. This new step involves a judge performing an *in camera* inspection of the patient's file to decide if the medical record contains any information that may cause the patient unnecessary humiliation or degradation by disclosure.

Congress should revise the Patent Act in conjunction with recent attempts at health care reform. This new revised Act would promote society's overall health care and allow a doctor to receive a financial reward through the patenting process. Patients would continue to comfortably disclose to their doctor all information regarding their condition or illness. As a result, the doctor would be able to provide adequate diagnosis and treatment, the keys to greater general health.

V. CONCLUSION

Congress passed the Patent Act pursuant to the United States Constitution which provides that patent law exists "to promote the progress of science and the useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." Ambiguous language in what is patentable subject matter prompted Congress to recodify the Patent Act to include processes as patentable subject matter. Today, the courts are liberal in their interpretation of what is patentable subject matter. As a result, new medical processes invented by physicians are patentable subject matter within the statute.

However, medical process patents may lead to unacceptable privacy violations as patent-owning physicians, suspecting unauthorized use of their medical processes, investigate patient medical records to uncover patent infringement. Consequently, this investigation subjects the patient to unnecessary personal scrutiny whereby the patient fears speaking freely with his doctor, hence jeopardizing effective diagnosis and treatment.

A viable solution to this problem is for Congress to revise the Patent Act to protect patient privacy rights when infringement is investigated. If Congress adopts this proposal, patients will not fear disclosing information to their physicians. In turn, physicians will be able to provide effective diagnostic and treatment methods in all areas of medicine, while maintaining the right to patent their new medical processes. Finally, economic incentives behind the concept of patenting are essential for innovation in society. While the fair return in the marketplace is yet to be determined, the essential need for medical process patents cannot be disputed. Moral and ethical arguments notwithstanding, the public

benefits immeasurably by receiving new medical discoveries, as newly patented medical processes promote better overall health.

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