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Medical Process Patents: Can We Live Without Them? Should we?

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MEDICAL PROCESS PATENTS: CAN WE LIVE WITHOUT THEM? SHOULD WE?

"Imagine if somebody held the patent on taking a patient's temperature under the tongue and charged a royalty of $1 each time this was done."

I. INTRODUCTION

Throughout history, the United States Patent and Trademark Office (PTO) has liberally granted patents for inventions that did not meet the statutory definition of a patentable subject in past decades. Congress, pursuant to its constitutionally derived power, granted the PTO the authority to issue or deny patent applications. With the advent of the United States Court of Appeals for the Federal Circuit, more patents have been held valid than were valid prior to its creation. The PTO has interpreted the Patent Act as allowing patents for medical procedures

4 U.S. CONST. art. I, § 8, cl. 8.
6 The Federal Circuit Court of Appeals was created in 1982 and has been deemed a "propatent" court by commentators. Roger M. Milgrim, Milgrim on Licensing § 2.67, at 2-66 (1990). See also Gerald Sobel, The Court of Appeals for the Federal Circuit: A Fifth Anniversary Look at Its Impact on Patent Law and Litigation, 37 AM. U. L. REV. 1087, 1089 (1988). Important changes since the advent of the Court as the sole appellate court for patent cases include "a climate more favorable to upholding the validity, and particularly the non-obviousness of patents." Id. "The court has strengthened the statutory presumption of validity. . . . [thereby increasing] the likelihood of relief against infringement." Id. "The new court is upholding patents 80% of the time vs. 30% under the previous system." Paula Dwyer et al., The Battle Raging Over 'Intellectual Property,' 3106 Bus. WK. 78, 79 (May 22, 1989).
and has granted at least twenty-eight medical process patents since 1975.  

Patents secured for medical processes are unnecessary because the goals of the Patent Act\(^8\) can be achieved without producing a monopoly that deprives the public of useful and potentially life-saving procedures. The dispensibility of the patent system in regard to medical process patents is apparent upon examination of the availability and cost of medical processes in other countries. For example, in Great Britain and New Zealand, where medical process patents are prohibited,\(^9\) all of the medical processes and procedures available to the public were developed without patent protection. The lower cost and availability of numerous procedures demonstrate that medical process patents are not necessary for the development of medical technology. The lack of need for patent protection of medical processes is also illustrated by the numerous medical developments in the United States that were not protected.\(^10\)

Other inventions, including computer programs, were also successfully developed without the aid of patent protection. Many programs are not patentable for reasons that apply to medical processes. However, software has increasingly been held patentable subject matter as a result of the industry mushrooming during the 1980's. The plight of the computer industry, resulting from increased patentability of processes, should serve as a warning to those advocating medical process patents without first looking at the consequences that lay ahead.

These medical process patents are also unethical, not only in a

\(^7\) Burch, supra note 3, at 1143.

\(^8\) The goals of the patent system are to promote science and advance the arts “looking to the general welfare of the Nation.” Burch, supra note 3, at 1147 n.48 (quoting Sinclair & Carrol Co. v. Interchemical Corp., 325 U.S. 327, 331 n.1 (1945)). “The patent system aims to promote scientific and technological progress by granting exclusive rights in new discoveries.” Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. CHI. L. REV. 1017, 1086 (1989) [hereinafter Progress of Science].

\(^9\) Counter to the English system, the United States has allowed medical-method patents since the 1950s. Edward Felsenthal, Medical Patents Trigger Debate Among Doctors, WALL ST. J., Aug. 11, 1994, at B1.

\(^10\) See infra notes 65-72 and accompanying text (discussing medical developments in United States not protected by patents).
societal context where patients will be denied a superior treatment, but also in a professional context. Doctors will be faced with conflicts of interest not present in the traditional treatment of patients where the doctors have no patent infringement worries. The ethical considerations not only effect the doctor-patient relationship, but the patenting of these processes also impacts the research undertaken by physicians and universities because these patents are at odds with the goals and beliefs of the scientific community.

Because medical process patents are unlikely to be prohibited in the United States, despite successful prohibition in foreign nations and successful development of unpatented procedures in this country, this Note offers a temperate approach. This Note will show that the effect of medical process patents can be minimized through the licensing agreements many patentees seek as a means of cashing in on their invention. Although the effect might be minimal, the American Medical Association and other physicians' organizations could set standards and issue opinions regarding proper licensing practices. Because licensing agreements are a matter of state contract law, any dispute arising under the agreement could be brought into a state court that may not have such a pro-patent bias as the Federal Circuit Court of Appeals. This would increase the chance that the process patent would be invalidated.

The harsh effect of these process patents, therefore, can be softened by ensuring reasonable fees for and availability of licensing agreements through action by state physician licensing boards. Professional organizations and doctors, many of whom disagree with process patenting, can administratively encourage their colleagues to respond ethically and responsibly to the temptation of patenting. Limits placed on licensing agreements will be an effective way to control health care costs that normally

11 Patients will be denied treatment for various reasons including: their doctor is not licensed to perform the procedure; the cost of the newly patented procedure is substantially more than the cost of an older procedure, which is now considered riskier or less efficient; and, the patentee has not granted a license to anyone while the wait for the new procedure is too long for an acute illness requiring immediate treatment.

12 "The [American Medical Association] and several other physicians groups have passed resolutions urging Congress to bar method patents." Felsenthal, supra note 9.
increase with patent protection.\textsuperscript{13}

Hospitals could amend by-laws to include licensing provisions expressing a reasonable license fee and possible sanctions for exorbitant fees. They could also use physician employment contracts as a means of controlling the patent process.

This Note advocates a moderate approach to reducing the number and effect of medical process patents through responsible licensing and contract law. Yet, the grim destiny of these patents, as illustrated by the PTO's and court's treatment of computer program patenting, demands that prohibition become a goal in the near future.

II. BACKGROUND

A. HISTORY OF PATENT LAW

The United States Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."\textsuperscript{14} While this clause includes the Copyright Clause, the Patent Clause has generally been regarded as "[the promotion of] ... the Arts ... by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries."\textsuperscript{15}

\textsuperscript{13} Pamela Samuelson, Arguing for Patents; Innovation and Competition: Conflicts over Intellectual Property Rights in New Technologies, in OWNING SCIENTIFIC AND TECHNICAL INFORMATION: VALUE AND ETHICAL ISSUES 169 (Vivian Weil & John W. Snapper eds., 1989) [hereinafter Innovation and Competition]. "[Private research firms] will have no compunction about charging prices for the medical invention considerably in excess of what would prevail if there was no patent. Given the risk they took and the capital they invested in research and development, the companies may feel these high prices are well justified." \textit{Id.} at 183-84.

\textsuperscript{14} U.S. CONST. art. I, § 8, cl. 8.

\textsuperscript{15} At least one physician/inventor has noted that there is a fine line distinguishing copyright protection from patent protection in the field of biotechnology. Telephone Interview with Lee D. Kaplan, M.D. (March 8, 1995). Kaplan explained the difference from an inventor's standpoint, "If I were to publish a paper about a new surgical technique, it would be copyrighted. People would have to cite to my paper if they used it. If I invent a surgical technique and patent it, I will get paid every time someone uses it." \textit{Id.} The fine line Kaplan refers to is essentially the difference between recognition and royalties. See infra notes 121-129 and accompanying text (discussing conflict between goals of scientific community and those of patent system). See also Pamela Samuelson et.al., \textit{A Manifesto}
The practice of granting patents to inventors dates back to the Middle Ages in Europe. Patent law in the United States is largely derived from the English patent system which dates back to 1623. Ironically, those countries from where the United States' patent system was derived have consistently denied and prohibited such patent protection.

Congress enacted the first Patent Act in 1790. Despite the lack of express language conferring patent protection on processes, the courts interpreted the statute as allowing for process patent protection. The current Patent Act grants an inventor the exclusive right to maintain a monopoly on the invention for 17 years from the date the patent issues in exchange for full disclosure of the novel, useful, and nonobvious invention. The evolution of the Patent Act, through its subsequent amendments, liberalized the definitions and interpretations for patentable subject matter. As an example, the 1952 revision replaced the word “art” with “process” so that the Patent Act currently allows patentable processes. This change in terminology simply requires less...
interpretation by the courts, since process patents enjoyed judicial protection under the 1793 Act.  

Despite the broad language of the Patent Act, those promoting process patents for biotechnology argue that Congress should modify the test for obtaining process patents. The Biotech Process Patent Protection Act of 1995 would overrule a case frequently cited by the Patent Office as grounds for denying biotech patents, making it easier to obtain a biotechnology process patent.

Currently, the patent laws in the United States broadly view the requirements for a proper patentable subject. After the 1952 revision to the Patent Act, the courts became even more liberal in upholding process patents. In *Ex parte Scherer*, the court held that medical or surgical techniques were not categorically excluded by the statutory definition of "process." The trend, both judicially and legislatively, "is towards increasing availability of patent protection for biotechnology-related inventions."  

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24 A process was considered a form of "art" under the 1793 Act. McCoy, *supra* note 16, at 505 n.22.

25 141 CONG. REC. E129-02 (daily ed. Jan. 19, 1995) (statement of Hon. Moorhead), available in WESTLAW, 1995 WL 190448. Notably, Hon. Moorhead, of California, justified the bill by emphasizing that it will put people to work and save lives, as well as protect against foreign competitors. Id. "The biotech industry is an immensely important industry started in the United States with many labs housed in California." Id.

26 Id. The court in *In re Durden* held that "a new process may still be obvious, even when considered 'as a whole,' notwithstanding the specific starting material or resulting product, or both, is not to be found in the prior art." 763 F.2d 1406, 1410, 226 U.S.P.Q. (BNA) 359 (Fed. Cir. 1985).

27 Congress, in 1952, noted the breadth of patentable subject matter by stating "everything under the sun invented by man [is patentable]." See also MILGRIM, *supra* note 6, § 2.14, at 2-20 (noting that notion of process is construed broadly enough to encompass electromagnetic forces and surgical accomplishments).

28 103 U.S.P.Q. 107 (P.O. Bd. App. 1954). *Ex parte Scherer* expressly overruled *ex parte* Brinkerhoff, 24 Off. Gaz. Pat. 349 (Comm'r Pat. Off. 1883), "to the extent that Brinkerhoff [held] . . . that all medical or surgical methods [were] unpatentable subject matter merely because they involve treating the human body. . . ." Id. at 110.


30 Rebecca S. Eisenberg, *Norms of Science*, *supra* note 16, at 190. "The PTO 'now considers nonnaturally occurring nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. [§] 101' " according to the Commissioner of Patents. Id. at 189.
Three categories of patents are recognized in the United States: utility, design, and plant.\textsuperscript{31} Utility patents\textsuperscript{32} deal with how useful an invention is—"the way it operates or works to achieve a useful end."\textsuperscript{33} Generally, process\textsuperscript{34} patents are categorized as utility patents. Biotechnology patents, which are usually utility patents, protect "three types of patent claims: the process by which a product is made, the product itself, and its use."\textsuperscript{35} Much of the controversy surrounding process patents, particularly medical process patents, is a result of the economic importance of utility patents and the frequency with which they are granted.

A process patent claim is typically easier to draft than other types of claims because it is analogous to writing a recipe for a cookbook.\textsuperscript{36} "[T]he elements of a method claim . . . are . . . acts or manipulative steps that are performed upon an article, workpiece or chemical substance."\textsuperscript{37}

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\textsuperscript{31} 21 ENCYCLOPEDIA AMERICANA 526 (Int'l ed., 1993).
\textsuperscript{33} 21 ENCYCLOPEDIA AMERICANA 526 (Int'l ed., 1993).
\textsuperscript{34} "A process consists of an act, operation, or step, or a series of thereof, performed upon specified subject matter to produce a physical result." ROSENBERG, supra note 29, § 6.01[1].
\textsuperscript{36} ROBERT C. FABER, LANDIS ON MECHANICS OF PATENT CLAIM DRAFTING 99 (3d ed. 1990).
\textsuperscript{37} Id. at 99-100. An example of a claim drafted for a process which was granted a patent in 1993 follows:
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\begin{quote}
A method of anesthetizing a patient comprising the steps of providing a plurality of gas permeable tubes, providing means for injecting an anesthetizing gas into the tubes, inserting the tubes within a blood vessel and injecting an anesthetizing gas into the tubes so that the gas can diffuse through the tubes into the blood steam [sic] to anesthetize the patient.
\end{quote}

A. COUNTRIES PROHIBITING MEDICAL PROCESS PATENTS

Banning all process patents would be within Congress' authority, but it is inadvisable and unlikely that Congress will take such a broad stance. Yet, Congress should consider a prohibition on medical process patents alone. While medical devices would maintain their patentable status, medical procedures, which are nearly intangible because they last only as long as the doctor is performing the procedures, would return to their pre-Scherer status. Through the prohibition of medical process patents, Congress would respond to society's and the medical profession's desire to make available effective health care at a reasonable cost to the largest number of people requiring treatment.

Other nations have already taken this step. "Methods of diagnosis and medical treatment ... cannot be patented under European law." Great Britain denies patent protection to medical processes. The British Parliament and the British

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38 See Burch, supra note 3, at 1162-63 (discussing Congress' progressive approach to ensure patentability of all processes).

39 R.S. CRESPI, PATENTS: A BASIC GUIDE TO PATENTING IN BIOTECHNOLOGY 122, 122-23 (Sir James Baddiley et al. eds., 1988). Proving infringement is often a problem where process patents are concerned. Id.

[I]t is [sometimes] difficult or impossible to tell from an examination of the product what process has been used .... In biotechnology this difficulty may be enhanced by the variability of living matter which offers more scope for argument over the identity of biological systems and the derivation of one from another.

Id. at 123.

40 Ex parte Scherer, 103 U.S.P.Q. 107 (P.O. Bd. App. 1954). See supra note 28 and accompanying text (discussing court's holding that medical and surgical methods are not rendered unpatentable because they involve human body).

41 Innovation and Competition, supra note 13, at 183 (arguing that without applying United States patent system to biomedical technologies, "the level of investment needed to bring about the advances that will provide cures may fall off, and there may consequently be fewer advances and, overall, fewer people cured"). Samuelson noted the irony in American culture that our citizens "are often indifferent to the plight of the poor but find their heartstrings pulled at the thought of the poor being denied a chance of survival or cure that the rich can afford." Id.

42 Felsenthal, supra note 9, at B6. See generally Burch, supra note 3, at 1162-63.

43 CRESPI, supra note 39, at 75.

44 Burch, supra note 3, at 1163.
Courts have adhered to this outright prohibition. In 1914, a British court declined to protect a method of extracting metals from “living bodies.” The court relied on ethics in reasoning that medical processes were not patentable. As recently as 1975, the English courts found no reason to depart from this rule which has endured over the years. The court admitted that the reasons for excluding these medical process claims from patent protection were grounded in ethics and not logic, but noted that if societal policies were to change, the law should be revised by legislation and not by judicial interpretation.

The British Parliament revised its patent laws in 1977, modeling the laws after the European Patent Convention. However, these laws still reflect a prohibition on medical process patents. New Zealand also denies patent protection for medical processes. The New Zealand Court of Appeals, grounding its decision on ethics like the English courts, overruled a lower court’s decision to allow a patent claim for a new use of a known drug. Although this case did not involve a surgical procedure, a new use of a known drug is analogous to allowing a patent on a procedure used to cure a person.

The similarity lies in the fact that no new tangible invention is involved, only the process of using an existing drug to treat an ailment not previously known to be affected by a particular dosage.
of that drug. The court noted that the "art of . . . alleviating human suffering does not belong to the area of economic endeavor or trade and commerce." The court recognized that the United States' patent system values industry and invention over humanity.

B. COMPARISON OF PROCESSES

One major objection to a prohibition on medical process patents is that no one will invent new processes because the inventor will not be able to recoup his or her costs without a guaranteed period of monopoly. However, a study of firms in the United States found patents were not a significant factor in research and development decision making—"except when patent lawyers prepared the responses."

Yet, two industrialized nations have prospered without this patent protection, one for almost a century. Further, researchers in the United States have successfully and effectively developed countless medical procedures without the aid of patent protection. In contrast to those procedures developed in the United States without patent protection, Surrogate Embryo Transfer (SET) is a

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54 See generally ROSENBERG, supra note 29, at 6-10 (discussing validity of patent covering new use for known drug in United States). Rosenberg illustrates how the United States patent system requires that the method of use must be new.

Although the analgesic properties of aspirin have long been recognized, it is only recently that the effectiveness of aspirin in preventing heart attacks has been established. If the dosages of aspirin and the intervals of its administration to ward off a heart attack are the same as that for which aspirin has been taken as an analgesic, such is but the discovery of a heretofore unrecognized benefit which however meritorious would not be patentable, as the method itself is old.

Id.


56 Id.

57 Burch, supra note 3, at 1164. "[E]lementary economic principles dictate that reducing the potential reward to medical researchers will reduce concomitantly the pace of such research." Id. But see Progress of Science, supra note 8, at 1031-32 (discussing studies comparing countries with and without patent systems to determine effect on investment in research and development).

58 Progress of Science, supra note 8, at 1032.
procedure patented in 1987. This procedure ultimately results in a sterile woman giving birth to a child. The corporation that funded and developed the now-patented procedure will derive its profits from clinics licensed to use the process. Each time a doctor at a licensed clinic performs this procedure during the next 17 years, this company will profit as a result of the licensing agreement.

Proponents of medical process patents argue that the types of processes under patent protection which currently exist in the medical field are unnecessary or “rarely used” and, therefore, do not detrimentally impact society in the way opponents of such patents fear. However, we take many basic procedures for granted in today’s high-tech society. Yet, substantial examples exist where these procedures were born and developed without patent protection. In fact, if open heart surgery were patented, it would not have become a realistic option of treatment for most Americans as quickly as it did.

As early as the 1920’s surgeons were developing techniques to cure patients with severe heart problems. In Boston, Edward D. Churchill treated and cured a patient suffering from chronic

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60 McCoy, supra note 16, at 507.

61 Id.

62 “Unnecessary” in that bearing children is not considered as important as saving a life or curing an ailment; and, there are other more affordable, more traditional means to become a parent, i.e. adoption.

63 McCoy, supra note 16, at 508 (citing Annas, Surrogate Embryo Transfer: The Perils of Patenting, 14 HASTINGS CENTER REP. 25 (June 1984)). Examples of medical processes that are “rarely” used include: “method and apparatus for direct electrical injection of gold ions into tissue such as bone”; “cranial insertion of surgical needle utilizing computer assisted tomography”; “method for maintaining the reduction of a sliding esophageal hiatal hernia”; and “surgical method of fixation of artificial eye lenses.” Id. at 508 n.40.

64 McCoy, supra note 16, at 511 (noting that most medical process patents issued do not relate to basic health care requirements). McCoy further argues that biomedical process patents are not well suited “for the typical basic health care needs for which access limitations would appear most unjust,” because these basic health care measures would not meet the statutory requirements of non-obviousness and novelty. Id.

65 Cf. supra notes 57-58 and accompanying text (discussing effect of patent protection on industry research and development decisions).
constrictive pericarditis.66 Robert E. Gross, another Bostonian, performed the first successful heart operation in 1938 where “a patent (open) ductus arteriosis was ligated (tied off).”67 During World War II, surgeons were able to perfect their techniques as a result of the number of casualties requiring open heart surgery.68

Had the procedure been patented, the large number of physicians performing these surgeries would have taken the procedure out of the experimental use exemption. Therefore, in order to maintain a patentable status, the physicians would not have been permitted to employ this procedure to save the soldiers. The experimental use exemption allows a patentee to ascertain “the sufficiency of the machine [or the procedure] to produce its described effects.”69

After World War II, Dwight Harkin and Charles Bailey continued to develop open heart surgery to treat other ailments.70 In the late 1940’s the surgeons opened a narrowed mitral valve by inserting a surgeon’s finger into the valve through the left atrium.71 Throughout the following decade this surgical technique was effective “in treating pulmonary edema and congestion in thousands of patients throughout the world.”72

Although the proponents of medical process patents argue that the cost73 of the patented procedure will not affect patient access to the procedure,74 a recently patented method illustrates a

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66 Paul Dudley White, M.D., Heart Surgery, in 14 THE ENCYCLOPEDIA AMERICANA 12 (Int’l ed. 1993). The procedure was performed in 1928. Id.
67 This method “became an almost routine and safe operation, and it is still widely used today.” Id.
68 Id.
69 Progress of Science, supra note 8, at 1023 (quoting Whittemore v. Cutter, 29 F. Cas. 1120 (D. Mass. 1813)). It was only after a large number of surgeries were performed during the war that the procedure became routine. Paul Dudley White, M.D., Heart Surgery, in 14 THE ENCYCLOPEDIA AMERICANA 12 (Int’l ed. 1993).
71 Id.
72 Id.
73 See infra note 112 and accompanying text (discussing increased cost of patented medical procedures).
74 See supra note 64 and accompanying text (noting that most medical process patents do not relate to basic health care needs).
The method uses a polyp marking device to remove polyps often found in the colon, sinuses, or nose. Polyps often develop into cancer and are typically removed upon discovery. This method may not be classified as a "basic health care requirement," but many Americans would assume that most doctors could offer this procedure in light of this country's awareness of cancer, and the importance of its detection, prevention, and treatment.

Yet the cost of this patented procedure will be substantially higher than the current exhorbitant cost of health care prevailing in the United States. The reason this procedure will be cost-prohibitive for patients is because the cost reflects royalties, negotiating licensing agreements and the prosecution of infringement suits. Some commentators argue that the patenting of these medical procedures is acceptable because the patents are granted infrequently and often cover procedures seldom used in basic health care. This argument must fail in light of the aforementioned example. The recently issued polyp marking patent would help reduce bleeding in a routine polyp removal procedure. The procedure's widespread desirability is, hence, obvious. The PTO has also granted patents for two potentially life-saving methods: a method for administering insulin; and a new method for diagnosing a heart-beat disorder.

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76 A polyp is a growth projecting from the tissue, attached by a stem. Telephone Interview with Lee D. Kaplan, M.D. (March 8, 1995).

77 Id.

78 See supra note 64 and accompanying text (noting that most medical process patents do not relate to basic health care needs).

79 See supra note 64 and accompanying text (noting that most medical process patents do not relate to basic health care needs).

80 Felsenthal, supra note 9. See also infra notes 137-140 and accompanying text (discussing patent costs).

81 McCoy, supra note 16, at 506.

82 Felsenthal, supra note 9.
C. PATENTING COMPUTER PROGRAMS

At a glance, computer programs and medical procedures appear to have nothing in common. However, upon closer examination, the two have a common denominator. According to Lee D. Kaplan, M.D., computer programs and surgical procedures are essentially "like a cookbook recipe." Both involve steps one must follow to achieve the desired result; any variation may prove to be disastrous. Also, the steps in both are largely incremental, with the latest inventions building on previously discovered processes. Notably, mental steps have rarely been patentable.

The courts and the PTO have only recently struggled with the question of whether computer software is patentable. Medical processes, much like computer programs, were originally denied patent protection summarily. Both also met with substantial success despite the lack of patent protection. If advocates of medical process patenting examine the impact of patenting on the computer software industry, they might be more careful in what they wish for.

83 Telephone Interview with Lee D. Kaplan, M.D. (March 8, 1995).
84 "Patent law requires an inventive advance over the prior art before it grants protection." Pamela Samuelson et al., A Manifesto Concerning the Legal Protection of Computer Programs, 94 COLUM. L. REV. 2308, 2346 (1994). "Protecting incremental innovations in [computer] program behavior through patent law would thwart the economic goals of the patent system: to grant exclusive rights only when an innovator has made a substantial contribution to the art and advanced competition to a new level." Id.
86 See generally Knobbe, supra note 85, at 44-51 (discussing patentability of software).
87 MERGES, supra note 21, at 87. "It is noted that the creation of [computer] programs has undergone substantial and satisfactory growth in the absence of patent protection . . . ." Id. (quoting Gottschalk v. Benson, 407 U.S. 63, 175 U.S.P.Q. (BNA) 673 (1972)).
88 "Those [patent] cases have hung over our collective heads like vipers about to strike, diverting the energies of industry participants from developing new technologies to defending old ones in courts, and heaping new loads of fear, uncertainty, and doubt onto the backs of the user community." MERGES, supra note 21, at 88 (quoting Editorial, Patent Mania is Hurting the Industry, 5 P.C. WEEK 38, July 18, 1988).
The PTO employs a two-step analysis in reviewing patent applications for software. 89 The PTO first determines whether the claim describes an algorithm. 90 If the claim describes an algorithm, the PTO must then determine whether the algorithm is preempted. 91 When the claim defines a method or process rather than an apparatus or system, the PTO employs an extended analysis. 92 Generally, if the claim simply describes a mathematical manipulation, the subject matter is not patentable. 93

Medical process patents could be denied on a similar theory. Certain actions involving the mind, which could be classified as mental steps, are not prohibited patentable subjects by the case law relating to purely mental steps. 94 However, in In re Meyer, 95 a claim describing a method and apparatus for a diagnostic or memory aid for a neurologist was rejected. 96 The claimed invention essentially replaced a neurologist’s thinking process with a

89 Knobbe, supra note 85, at 44-51. This analysis is commonly referred to as the Freeman-Walter two-step analysis. Id. The analysis is “based upon two decisions of the Court of Customs and Patent Appeals: In re Freeman, 573 F.2d 1237 (C.C.P.A. 1978), and in In re Walter, 618 F.2d 758 (C.C.P.A. 1980).” Id.

90 Knobbe, supra note 85, at 45. “[A]n algorithm question includes both claims that recite a computer or other apparatus operating in accordance with a mathematical formula or a series of steps determined by a mathematical formula, but also claimed subject matter which indirectly claims an algorithm.” Id.

91 Gottschalk v. Benson, 409 U.S. 63 (1972). See generally supra note 84 and accompanying text (discussing requirement of inventive advance for patent protection). To avoid preemption, the claim must recite structural elements or steps apart from the algorithm elements or steps because an algorithm is not patentable. Knobbe, supra note 85, at 48-51.

92 Knobbe, supra note 85, at 44-51.

93 Id. at 51.

94 Ex parte McNabb, 127 U.S.P.Q. (BNA) 456 (Pat. Off. Bd. App. 1959). See Knobbe, supra note 85, at 44. The Patent Office Board of Appeals distinguished between “use of the human eyes for detection or determination of any condition, such as temperature, pressure, time, etc. and/or the use of the hands for the purpose of manipulating . . . as to produce a certain result necessarily involves the human mind and hence can be classed as a mental step. Such steps, however, are not purely mental or interpretive steps and are not the kind which are prohibited by the decisions relating to purely mental steps.” Knobbe, supra note 85, at 44 (quoting Ex parte McNabb, 127 U.S.P.Q. (BNA) 456 (Pat. Off. Bd. of App. 1959)).


96 Id. See generally Knobbe, supra note 85, at 44 (discussing patentability of software).
The claim also recited "a mathematical algorithm which represents a mental process that a neurologist should follow." The court concluded that the mathematical algorithm, which represented a mental process but was not applied to physical elements or process steps, was "not limited to any otherwise statutory process." Therefore, the court upheld the rejection of the patent for the claimed invention.

The United States Supreme Court has yet to "entirely eliminate the mental step doctrine from current law." Therefore, the PTO and the lower courts will subject patent claims that arguably include mental steps, such as those claiming medical processes, to a higher level of scrutiny. Because medical processes are similar to a computer program in that they both represent a mental process, the medical process claims have a higher probability of rejection. In fact, Professor Alan Newell, a "prominent computer scientist and pioneer in the field of machine or 'artificial' intelligence, [notes that] the main line of progress in psychology . . . has been to describe human behavior as computational . . . [H]umans think by means of algorithms. Sequences of mental steps and algorithms are the same thing."

Commentators have noted that the PTO does not often grant medical process patents for basic health care needs. Their conclusions could arguably be based on the courts' and the PTO's treatment of the mental steps doctrine. The fact that some medical processes are not so broad as to encompass a large number of treatments should not preclude them from the PTO's stricter

97 Knobbe, supra note 85, at 44 (quoting In re Meyer, 688 F.2d 789 (C.C.P.A. 1982)).
98 Id.
99 Id. at 44-46 (quoting In re Meyer, 688 F.2d 789 (C.C.P.A. 1982)).
100 MERGES, supra note 21, at 52. See Knobbe, supra note 85, at 46 (discussing patentability of software).
101 Knobbe supra note 85, at 46.
102 MERGES, supra note 21, at 54 (quoting Alan Newell, The Models Are Broken, The Models Are Broken, 47 U. Pitt. L. Rev. 1023, 1025 (1986)). Newell uses an example to illustrate the effect of allowing patents for algorithms. "If algorithms are patentable, [and one wanted to patent addition] the patentee could keep [a person] from doing addition with the algorithms invented for it. There would be ever so many things that the poor would not be able to do, such as add up their grocery bill." Id. at 55 (quoting Newell, The Models Are Broken, The Models Are Broken, 47 U. Pitt. L. Rev. 1023, 1027).
103 See supra notes 63-64 and accompanying text (noting that patents for medical processes are arguably only granted for "rarely used" procedures).
scrutiny. Even though the claims for these processes may recite structural elements or steps in addition to the mental step, the patent should still be rejected. The basis of the rejection could lie in a failure to meet the non-obviousness requirement of the Patent Act. A medical process invention fails to become non-obvious because the additional steps in the claim would be obvious given the underlying mental steps of the procedure. In fact, commentators arguing for protection of software beyond what the patent system offers are dissatisfied with the emerging case law on non-obviousness and its effect on biotechnological process patents. Their dissatisfaction lies in the "judicial tendency to deny protection to costly biotechnological processes that yield major commercial and societal gains." Therefore, medical processes, like software programs, may be denied patent protection. Both are created by building on incremental steps and by definition are obvious.

D. ETHICAL CONSIDERATIONS

1. Societal. The most troubling aspect of patenting medical processes is that the patent inevitably denies treatment to some patients who cannot afford the procedure while it denies treatment to others whose doctors are not licensed to perform the procedure. Although the aggregate effect of the Patent Act is

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104 See supra note 91 and accompanying text (discussing how claim involving algorithm avoids preemption and becomes patentable).

105 To become patented, an invention may not be obvious at the time it was invented. 35 U.S.C. § 103 (1988). An invention fails the non-obviousness test "if the differences between the subject matter sought to be patented & the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains." Id. Cf. Brian C. Cannon, Note, Toward a Clear Standard of Obviousness for Biotechnology Patents, 79 CORNELL L. REV. 735, 736 (1994) (arguing that nonobviousness requirement is met when "a claimed biotechnology invention is unattainable through use of reasonably accessible scientific methods").


107 Id.

108 The cost of patented procedures is often elevated resulting from the collection of royalties and from the cost of prosecuting or defending actions for validity or infringement. Felsenthal, supra note 9. Legal action could cost the parties millions of dollars. Id. See also infra notes 137-140 and accompanying text (discussing patent costs).

109 See infra notes 130-154 and accompanying text (discussing licensing agreements).
to promote inventions and discoveries by granting a monopoly, one cannot ignore the impact on the discrete field of medicine and treatment of the human body. The increase in price resulting from a monopoly is simply not as offensive in other industries as it is in the medical field. Those who promote medical process patents and have adequate medical insurance may feel as though this problem of increased pricing for patented procedures does not affect their treatment. They are wrong. For instance, insurance only covers procedures costing a customary & reasonable fee. However, medical procedures that are patented involve costs much higher than what is considered customary and reasonable.

2. Doctor/Patient. Not only will society feel the financial pinch of costlier and less widely available procedures, but the individual patients could receive biased diagnoses and treatment plans. The doctor-patient relationship has been a coveted association throughout the years. The issuance of process patents could seriously undermine this relationship which is based on the mutual goals of doctor and patient to heal and to be healed.

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110 Felsenthal, supra note 9. See also infra notes 137-140 and accompanying text (discussing patent costs).
111 It is unlikely that a court in the United States would invalidate a patent or that the PTO would deny issuance of a patent on ethical grounds alone. But see supra notes 38-56 and accompanying text (discussing statutory and common law prohibition of medical process patents in foreign nations).
112 Telephone Interview with Customer Service Representative, Blue Cross/Blue Shield of Georgia (Feb. 2, 1995). To determine the amount of coverage on a particular procedure, the company employs a “procedure code” to determine the customary and reasonable fee which is based on the average cost charged by participating providers. For those with an individual policy, experimental procedures are not covered at all; however, not all patented procedures are characterized as experimental. For those covered under a group policy, the group could contract to cover experimental procedures. But, group coverage could not affect the customary and reasonable fee charged by physicians, which may not be reasonable at all if royalties are involved. Id.
113 Supra note 21.
114 Much of the trust patients have in their doctors stems from the oath every doctor must take before he begins practicing. The Hippocratic Oath requires doctors “to practice ‘for the benefit of the sick according to . . . [their] ability and judgment.’ ” Burch, supra note 3, at 1152 n.78.
115 See generally Burch, supra note 3, at 1152-57 (discussing physician autonomy and physician-patient confidentiality as ethical objections to medical process patents). For a detailed article outlining the major ethical objections to medical process patents, see McCoy, supra note 16 (concluding that ethical objections presented do not outweigh need to encourage innovation through patents).
In an ideal world, the doctor who holds a process patent, or who is licensed to perform a patented procedure, would choose a particular procedure to treat a patient solely because it would be the best and most effective way to cure that patient. However, in the world of medical process patents, that doctor's otherwise ideal judgment may be skewed in favor of a patented process.

For example, an anesthesiologist may choose a patented method to anesthetize a patient for general surgery. The only practical difference between the patented method and the traditional method is that the patented method involves a gas, instead of a liquid, anesthetizing agent. Although there is no real benefit in using the gaseous agent instead of the liquid, the doctor may use the gas because he has a license from the patentee and wants to recoup the initial cost he paid to obtain the license. In another scenario, the doctor may be the patentee and wants to gain recognition for a new method. Therefore, he uses the method on all his patients even though it is more expensive, since he is trying to recoup his research and development costs.

One district court found that the ethical objections to patenting medical processes outweighed any need for a patent monopoly. The court reasoned:

Doctors and surgeons have seldom thought it desirable to patent their new procedures for human relief. . . . The professional ethics of doctors and surgeons are more consistent with the widespread use of their medical and surgical discoveries for the benefit of mankind than in obtaining a monopoly to control their discoveries for personal commercial advantage. In this respect it would seem also that public interest is involved."

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116 See Faber, supra note 37 and accompanying text (discussing recently patented method for anesthetizing patient).
117 Telephone Interview with Lee D. Kaplan, M.D. (March 8, 1995).
118 See Burch, supra note 57 and accompanying text (discussing costs of research and development).
120 Norms of Science, supra note 16, at 187 (quoting Martin, 96 F. Supp. at 695). But see Felsenthal, supra note 9, at B6 ("That's where the money is. . . . This encourages people to sit down with a glass of scotch and think up new ideas," [said an attorney representing a patentee of a medical process]).
3. Impact on Research/Universities. Medical process patents also appear to be at odds with the goals and beliefs of the scientific community.\footnote{Progress of Science, supra note 8, argues for an experimental use exemption from patent infringement liability for research science. “The idea that exclusive rights in new knowledge will promote scientific progress is counterintuitive to many observers of research science, who believe that science advances most rapidly when the community enjoys free access to new discoveries.” Id. at 1017. An example of how patent protection can stifle innovation is found where a company, which owned a patent covering an enzyme that dissolves bloodclots in heart attack patients, sued companies trying to improve the clotbuster based on the enzyme. Gary Slutsker & David C. Churbuck, Whose Invention Is It Anyway?, FORBES, Aug. 19, 1991, at 114. The company owning the enzyme patent won and forced the improvers to cease their research. Id.} In general, the scientific community aims to make findings available to others for scrutiny, in order to facilitate the progress of science.\footnote{Norms of Science, supra note 16, at 182.} This attitude is especially prevalent in biotechnology, resulting from the belief that new information should be disseminated “in order to serve humanity.”\footnote{Id.} Researchers are more likely to discover or perfect a medical procedure when their colleagues can share ideas and tinker with the intricacies of the process.

Not only are subsequent discoveries more likely when free access is the norm, but also, the incentive system in place within the scientific community promotes free publication and dissemination of new observations.\footnote{Id. at 206-07.} The scientific community offers an incentive for a scientist to make his claims freely available to other researchers by awarding him recognition.\footnote{Id. at 218.} Counter to this reward structure, where the scientist gains recognition for the discovery once that discovery is publicized, the patent system “promotes investment in innovation by providing exclusive rights in inventions.”\footnote{Id.}

The following is an example of how the greed incentive of the patent system can undermine the sharing nature of the scientific community. “Two research scientists at UCLA [University of California at Los Angeles], Golde and Koeffler, gave Gallo, a researcher at the National Cancer Institute, a valuable sample of
cancerous cells they had succeeded in growing." ¹²⁷ Gallo then passed it on to "a scientist friend working for a biotech company who found a way to make use of those cells in the production of interferon." ¹²⁸ A dispute later arose which ended in an out-of-court settlement. "Golde is reported as saying, 'Everything has changed. The exchange of materials is different. They now have value. To send out a cell line for some experiment is like sending out a twenty-carat diamond to cut some glass.'" ¹²⁹

E. LICENSING

The most troubling aspect of patent law as applied to medical processes is that a monopoly is granted to the inventor for 17 years. ¹³⁰ The inventor may then withhold use of that process at his discretion. ¹³¹ In such exclusivity lies the assumption that patents will promote inventions.

Essentially, a patentee, whether a doctor, researcher or hospital, may choose to exploit an invention in different ways: “directly as a monopolist to suppress the invention entirely, or to license others to exploit the invention ... in exchange for royalties.” ¹³² The patentee, however, is not required to extend licenses. ¹³³

Some commentators have argued against mandatory licensing in the field of medical process patents. ¹³⁴ The argument for mandatory licensing is worth noting because mandatory licensing “limits the monopoly effect of a medical process patent.” ¹³⁵ However, it is too extreme to become a reality in the near future. Congress has only required mandatory licensing in two areas where detailed

¹²⁸ Id.
¹²⁹ Id.
¹³⁰ See supra note 21 and accompanying text (discussing rights available to inventors under Patent Act upon full disclosure of invention).
¹³¹ See infra notes 132-133 and accompanying text (discussing ways patentee may exploit invention).
¹³² Norms of Science, supra note 16, at 217.
¹³³ Id. See also MILGRIM, supra note 6, § 8.50, at 8-161 (stating “a unilateral refusal to license is generally not regarded as misuse or violation of the antitrust laws”).
¹³⁴ See Burch, supra note 3, at 1169-71 (discussing reasons to oppose mandatory licensing).
¹³⁵ Burch, supra note 3, at 1167.
The following discussion envisions a more attainable goal. In attempting to soften the harsh effects of the right to patent medical processes through responsible licensing, one must first examine the largest problem—soaring health care costs—caused by these patents to discern whether it is a problem worth remediying. Health care costs are generally considered too high, but they have the potential to soar as more medical processes are patented.

Increases in health care costs are inevitable when these processes are patented. Not only is there a maintenance fee to keep the patent in effect, litigation to protect the patent from alleged infringers is costly. Even assuming a moderate maintenance fee and no litigation, a patentee may still charge exorbitant royalties with the leverage of the monopoly weighing in his or her favor. The amount a patentee chooses to charge is not subject to judicial scrutiny under either antitrust or misuse.

Congress requires compulsory licensing in areas such as atomic energy (42 U.S.C. §§ 2182-90) and air pollution (42 U.S.C. § 7608 et seq.). Thomas A. Dietierich, Patents and Antitrust: An Overview, in PATENT ANTITRUST 42 (1980) (citing Wisconsin Alumni Research Found. v. Vitamin Technologists, Inc., 146 F.2d 941 (9th Cir. 1944), cert. denied, 325 U.S. 876 (1945); City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1933), cert. denied, 293 U.S. 576 (1934)). "In some instances, where a patent relates to public health or safety, courts have refused to enjoin infringement and merely permitted the patentee to recover damages .... Such decisions would seem to be equivalent to compulsory licensing at a reasonable royalty." Id.

"[T]he notion of royalty is a current payment, typically related to use, in exchange for which the patentee ... currently refrains from suing the licensee for conduct which, but for the license, would be infringement." MILGRIM, supra note 6, § 8.07, at 8-29.

Milgrim notes that patent license agreements would be an excellent cost-avoidance technique for potential litigants to resolve their differences. Id.

"The patent law seeks to stimulate innovation through reward; the antitrust law seeks to preserve innovation through competition." Id. at 51. Practices condemned under
Our nation's health care crisis, coupled with the increased likelihood for issuance and validation of medical process patents requires that influential organizations intervene.

The influence of organizations such as the American Medical Association will undeniably be limited. They could, however, campaign for more reasonable licensing agreements and encourage licensing of all patented inventions. Nonetheless, state contract law, with the cooperation of state licensing boards and individual hospitals, can more effectively lessen the effects of medical process patents.

State contract law, by governing licensing agreements, is one way to bypass review by the pro-patent United States Court of Appeals for the Federal Circuit. A patent's validity is normally determined by the federal judiciary. Yet, licensing agreements between a patentee and a licensee that determine amount of royalties and the scope of use are contracts. These contracts are subject to scrutiny under state contract law when a dispute arises. The state court, given jurisdiction over the dispute, may determine issues of patent infringement and patent validity.

the antitrust laws include "tying the sale of patented products to the purchase of unpatented material, agreements to refrain from challenging the validity of patents under which no license has been granted, agreements not to deal in goods which compete with products covered by the patent, and the like." Id.

42 MILGRIM, supra note 6, § 8.06, at 8-27 (citing Brullotte v. Thys Co., 379 U.S. 29 (1964), reh'g denied, 379 U.S. 985 (1965)).
43 Supra note 12.
44 MILGRIM, supra note 6, § 2.68, at 2-67.
14 Id.
In addition, state physician licensing boards could encourage reasonable licensing agreements. The patent laws, and judicial interpretation thereof, allow a patentee broad discretion in setting the price and limiting the method of sale of the patent.\footnote{148} Because the state licensing board controls the number of doctors admitted to practice in the state and has the power to suspend or revoke licenses, the board's views on reasonable licensing provisions are persuasive. The board might enlist a committee to review agreements regarding a medical patent solely consisting of a process. The board might also offer an administrative remedy to licensees challenging an oppressive agreement. The board should also encourage widespread licensing at a reasonable cost, as opposed to limiting licenses to the few doctors who have the resources to engage in licensing opportunities.\footnote{149} Although the board can only reach physician patentees, it is a small step in the right direction.

Individual hospitals may also encourage responsible licensing. Most non-research/teaching hospitals could include a provision regarding the patenting of medical processes in the employment contract granting physician privileges to a doctor or group of doctors. The provision could specify that any discoveries made during the course of employment would be made for the benefit and use of the hospital.\footnote{150} The theory behind the hospital receiving of the patent could potentially be decided by a foreign court if the license agreement contains a forum selection clause. \textit{Id.} at 2-70 n.217 (citing Warner & Swasey Co. v. Salvagnini Transferica S.p.A., 633 F. Supp. 1209, 1211-14 (W.D.N.Y. 1986) (holding that "purported patent infringement action...was essentially a contract dispute and public policy favored selection of the bargained-for venue provisions"—venue selected was Italy)).

\footnote{148} United States v. General Elec. Co., 272 U.S. 476 (1926) (holding that patentee may set price and limit method of sale). \textit{See also} MILGRIM, supra note 6, \S 7.11, at 7-19 (stating that "[T]he [Department of Justice] has concluded that licensing principles permit the owner of patents and other technology to enjoy a wide latitude of restrictive practices in...economic implementation").

\footnote{149} Although the patentee, "once he embarks on a licensing program, [does not retain] absolute discretion in deciding to whom he shall license, the general rule is that a patentee has the discretion to grant or withhold a license as he sees fit." United States v. Huck Mfg. Co., 227 F. Supp. 791, 800, 140 U.S.P.Q. 554 (E.D. Mich. 1964), aff'd per curiam, 382 U.S. 197, 147 U.S.P.Q. 404 (1965) (4-4) (quoted from MILGRIM, supra note 6, \S 8.04, at 8-20 n.42).

\footnote{150} The doctor actually making the discovery would, of course, receive a nominal bonus. Companies that regularly patent tangible goods often offer a bonus when the patent is issued. \textit{See infra} note 151 and accompanying text (discussing bonus systems employed by larger corporations).
the benefits of the patent is that the institution provided the facilities that allowed the doctor to experiment.151

By allowing the hospital to hold the patent, licensing fees could decrease because the hospital is in a better position to market and license to other hospitals nationwide. A hospital is less likely to exploit the patent as a monopolist because the hospital would gain the most recognition by training licensees at the hospital's direction. Training could be available through nationwide conferences and seminars. Doctors across the nation would then attribute a higher level of expertise to the patentee/hospital.152 Also, a hospital does not have a personal attachment to the procedure and would be less likely to deny another doctor or hospital a patent for personal or arbitrary reasons.

Another benefit of allowing the hospital to hold the patent is that it could reduce the ultimate cost of the procedure. Typically, the most expensive phase of obtaining a patent is encountered at the research and development stage.153 A hospital, rather than an individual physician, would have easier access to equipment, funds, and personnel. Also, many companies were trimming their research and development budgets before the advent of the United States Court of Appeals for the Federal Circuit because patents were not treated favorably.154 Although the treatment of patents has become more favorable since 1982, with the creation of appellate patent jurisdiction, companies are now more likely to hoard their own resources than to invest in an outside physician because this is the most efficient way to recoup research and development costs.

151 Telephone Interview with Gary W. Douglass, Project Engineer, Pratt & Whitney (Mar. 11, 1995). Pratt & Whitney is a company that manufactures gas turbine engines for aircraft. Douglass said that inventors within the company receive a bonus of $1000 for a patentable invention. The company, however, collects royalties well in excess of any employee bonus.

152 This notion of gaining recognition in the scientific community often conflicts with the goals of the patent system. Norms of Science, supra note 16. But, by giving hospitals control of the patent, these conflicting views are a step closer to compromise.

153 MILGRIM, supra note 6, § 2.59, at 2-62.

154 Id.
The importance of health care, the traditional sharing nature of the scientific community and the successful development of medical procedures without patent protection, call for an incremental movement toward reducing the effects of the issuance of these patents. The first step is to encourage responsible and reasonable licensing. The ultimate goal of prohibition on medical process patents will certainly meet resistance. Prohibition may not become a reality for years or even decades. However, reasonable licensing will at least pacify those who currently realize the value of patent-free medical processes until the goal of prohibition is realized.

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