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Ethical Issues in the Patenting of Medical Procedures

INTRODUCTION

The patenting of medical procedures has been criticized on general grounds. Commentators have argued that it raises the cost of the patented procedures, thereby limiting patient access to the procedures. In addition, patenting restricts access in the research community, thereby limiting opportunity for peer review and for further research that would build on or use a patented technique. The patenting of medical procedures, although not a new phenomenon, has recently been raised as a concern in relation to litigation in which the holder of a patent on a specific type of ophthalmic surgical incision has sought to enforce the patent.^{1,2,4}

In order to avoid any potential confusion, the Council would like to clarify at the outset of this report the terms that will be employed. "Medical process patents" refers to those patents taken out on medical procedures and techniques. According to the statutory language of the United States Code, a patent on a medical procedure is legally characterized as a patent on a medical process. For the purposes of this report, "medical process patent" should be taken as equivalent to "patent on a medical procedure".

BACKGROUND

The United States Constitution grants Congress the power to make laws "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."⁵ Accordingly, beginning with the Patent Act of 1790, Congress established a system whereby, in return for full disclosure of a novel, non-obvious and useful invention, an inventor is given broad exclusive rights to the invention for a period of 17 years from the grant of the patent. As a result of a provision in the General Agreement on Tariffs and Trades, effective June 1995, the period of patent protection increased to 20 years from the date that an application is first filed.⁷ Patent holders may use the invention themselves or license the invention in exchange for royalties. An unauthorized person, even one with no knowledge of the patent, who "makes, uses or sells any patented invention, within the United States during the term of the patent thereof, infringes the patent."⁹ Currently, under legislation passed in 1952, patents are applicable to any new or useful "process, machine, manufacture or composition of matter"¹⁰ where "process" means "process, art or method and includes a new use of a known process, machine, manufacture, composition of matter or material."¹¹ This definition, while not directly addressing the question of medical procedures, leaves open the possibility of the legitimacy of medical process patents. Furthermore, in a 1980 decision, the Supreme Court granted patent protection to the inventor of an artificial life form on the grounds that "man-made" bacterial plasmids qualify as a new "manufacture" or "composition of matter."² This decision to broadly interpret the statutory scope of patentable inventions makes it highly unlikely that medical procedures can be legally excluded from the legal definition of process without additional legislative action.¹³ While such a statutory exception has previously been created only for nuclear warfare technologies, legislation was recently proposed to prohibit patents "for any invention or discovery of a technique, method, process for performing a surgical or medical therapy, administering a surgical or medical therapy, or making a medical diagnosis" independent of an otherwise patentable device or pharmaceutical.^{14,15,11}

The Patent and Trademark Office (PTO) has approved a number of patents for "pure" process claims as well as the more common claims in which method is combined with some form of novel instrumentation.^{11, 17, 18} Throughout the 1980s, these patents tended to be granted to procedures which were rarely used or constituted extraordinary health care.^{17,18} However the patenting of medical procedures has recently expanded both in terms of volume of patents issued and the subject matter of the approved process patents. One estimate places the rate of approval of medical process patents at 15 per

week, although this figure does not distinguish between pure process claims and patent claims which involve both a device and a method. In addition, the trend appears to be moving towards the patenting of common and widely used medical procedures, as evidenced by the PTO's decision to grant a patent to a stitch-free incision for cataract removal that is used by an estimated 40% of ophthalmologists.^{1,2,4} Equally disturbing is the fact that the patent holder on this procedure has commenced the first infringement litigation involving a physician as co-defendant, defense costs had already reached \$125,000 a year ago and, if the suit is successful up to 2000 surgeons could be subject to similar prosecution.¹⁵ In light of these developments, this report will examine the use of pure medical process patents, including patents for diagnoses, imaging techniques, off-label uses of a pharmaceutical, and methods of administering a biomedical therapy. Medical process patents which involve the patenting of a procedure in conjunction with a device or drug fall outside the scope of this report, as do patents for devices without which a procedure cannot be performed.

ETHICAL ISSUES

Since the time of Hippocrates, physicians have relied on the open exchange of information without the expectation of financial reward for advancing medical science. The medical profession has a longstanding obligation not to withhold information but rather to share techniques as needed.^{19,20,21,22,23} This well-established tradition is in large part reflected in Principle V of the *Principles of Medical Ethics* of the American Medical Association and in Opinion 9.08 of the *Code of Medical Ethics* of the AMA:

V. A physician shall continue to *study, apply and advance scientific know edge, make relevant information available to patients, colleagues, and the public, obtain consultation and use the talents of other health professionals when indicated.* [Emphasis added.]^(p.xiv)

9.08: New Medical Procedures. In the ethical tradition expressed by Hippocrates and continuously affirmed thereafter, the role of the physician has been that of a healer who serves patients, *a teacher who imparts knowledge of skills and techniques to colleagues*, and a student who constantly seeks to keep abreast of new medical knowledge.

Physicians have an obligation to share their knowledge and skills and to re- port the results of clinical and laboratory research. Both positive and negative studies should be included even though they may not support the author's hypothesis. *This tradition enhances patient care, leads to early evaluation of new technologies, and permits the rapid dissemination of improved techniques.*

The intentional withholding of new medical knowledge, skills and techniques from colleagues for reasons of personal gain is detrimental to the medical profession and to society and is to be condemned.^{p.139}

The impact of Principle V and Opinion 9.08 on the acceptability of medical process patents is unclear. At first glance, they appear to prohibit the patenting of medical processes. On one level, it can be argued that a medical process patent amounts to "the intentional withholding of new medical knowledge. For reasons of personal gain. " However, it can also be argued that medical process patents are consistent with the AMA's *Code of Medical Ethics*. The patent system requires full disclosure of a patented invention and, once a procedure is patented, the patent holder can make it available to other physicians for a reasonable licensing fee. Therefore, it could follow that there need not be any withholding of knowledge.

Yet, even if a convincing argument can be made for the view that patenting does not necessarily entail withholding, Principle V and Opinion 9.08 provide another basis for condemning the patenting of procedures, namely the decrease in professionalism occasioned by physicians who seek and enforce

patents. Physicians who collectively engage in promoting health and patient welfare constitute the medical profession. The patenting of medical procedures, with its emphasis on individual reward, selective sharing and ownership, undermines the coherence of the profession. In addition, a profession is characterized by shared commitment to moral ideals. One of the fundamental principles in medicine is that the health of the patient is a physician's most basic concern. Much of the respect and trust accorded patients arises from the perception that economic concerns do not generally impact medical decisionmaking. In opposition, medical process patents are committed to the primacy of economic benefit and reward. To the extent which economic goals are elevated above those of patient health, the integrity of the profession is severely weakened.

Some commentators have argued that these criticisms of medical process patents are not sufficient justification for a prohibition on patenting medical procedures, that the ethical concerns raised by process patents are also raised by other kinds of health care patents which are well accepted by society as well as by the medical profession.^{12, 17, 18,20 (p.140)} For example, pharmaceutical manufacturers patent their drugs, and physicians patent their new devices. Nevertheless, as the remainder of this report demonstrates, there are compelling reasons for distinguishing between patents on medical procedures and patents on drugs and devices.

PROFESSIONAL AND PATIENT CARE CONCERNS

Restricted access to patented procedures

Restricted clinical access

The most compelling argument against medical process patents is grounded in the unacceptable picture of a patented procedure becoming unavailable to patients who require it, particularly when no alternative exists. Once procedures can be patented, physicians will not be able to use a patent procedure without obtaining a license to use the procedure. If the patent holder were to restrict the number of licensees or charge a high price for licensing, then the patent holder would be erecting significant barriers to patient access to a needed treatment.^{13,18,24} Such withholding of information to the detriment of patient care is clearly unethical, condemned in texts ranging from the Hippocratic Oath to the AMA's *Code of Medical Ethics*. An additional concern is that the patent process could influence a doctor's medical judgment as to the appropriate treatment.^{17,18} In cases in which a patented procedure would be the most advisable therapy, physicians might rationalize the performance of what could be an inferior procedure rather than become a licensee of the patent holder or refer the patient to a licensed physician.

Moreover, the patenting of medical procedures may have a profound chilling effect on the use of any advances in medical procedures. Once patenting is allowed, physicians face a substantial legal risk every time they decide to introduce a new procedure or a modification of an existing procedure into their practice. This is because use of a patented procedure without permission of the patent holder constitutes unlawful infringement of the procedure. While physicians could avoid infringement by obtaining a license, it will often not be clear whether a valid patent exists. There is no obvious way for a physician to know whether a particular procedure has been patented. Even when physicians devise a new procedure or a modification of an existing procedure on their own, they still could be at legal risk if someone else already patented the procedure or the modification. Faced with this uncertainty, physicians may decide that it is safer not to use new procedures or modifications of existing procedures until they can be certain that no patents exist. To achieve such certainty would take considerable time and effort. In the meantime, many patients will not be able to benefit from the procedure or modification. The legal risk from procedure patents exists once patents are permitted even if they are not aggressively enforced. A patent holder is free at any time to seek enforcement of the patent.

The chilling effect of procedure patents distinguishes these patents in an important way from drug or device patents. If a drug or device has been patented, the licensing fee is incorporated into the cost of the drug or device. Accordingly, the physician does not have to worry about inadvertently infringing a drug or device patent, and physicians therefore are not discouraged from using drugs or devices by legal uncertainty about patent infringement.

The concerns about the constraining effects of a patent are especially important in light of the recent shift in patenting from fairly specialized medical procedures to processes of greater applicability, such as detection methods for breast tumors, which increases the number of potential beneficiaries who could be adversely affected by patenting.^{17,18,25} It is true that physicians have been able to practice good medicine despite many existing restraints on their autonomy, such as insurance compensation and contractual obligations. However, it does not follow that there should be more restraints.

Restricted academic access

The prospect of patenting medical procedures raises additional fears in the research community. Patented biomedical procedures may be restricted from peer review because other physicians may not be able to study the procedure without paying a licensing fee.^{17,18,26} While the Food and Drug Administration has responsibility for regulating drugs and devices, peer review serves as the primary regulatory mechanism for medical processes.²⁶ Thus, the potential barriers to peer review from patenting could lead to a decrease in the quality and safety of new procedures. Furthermore, patients who are not knowledgeable about the process of publication and peer review might not realize that patenting does not guarantee scientific merit but might mistakenly think that patenting is a statement of efficacy. As a result, they could subsequently undergo unnecessary or unwarranted procedures. Already, certain techniques have been prominently labeled as "patented" in advertising by physicians even though the techniques have little or no proven scientific merit.

Some concerns about peer review could conceivably be avoided by the application of an expanded form of "the experimental use doctrine" (allowing minimal use of the patented invention which does not interfere with the economic interests of the patent holder) to allow investigational use of patented procedures.^{12,18} Patent holders would have incentive to seek peer review, since there is no financial benefit in holding a patent on a useless or dangerous procedure.²⁷ Yet both the "restricted use" doctrine and the reliance on market forces are limited in their ability to guarantee the timely dissemination of information about the patented technique.^{12,18} Disclosure of new procedures would likely take longer in the presence of widespread patenting than when innovation is motivated solely by altruistic or scientific concerns.²³ Physicians seeking patents are frequently admonished by legal counsel not to reveal inventions before filing a patent application.²⁸ Furthermore, an inventor who is unsure about the patentability of the technique may even defer publication until the patent has been issued, a process that generally takes years.¹² Because a patent is in effect for 20 years, a patented procedure may not be available for use by medical schools in training the next generation of physicians.²⁹

Despite the effects of patents on access to new procedures in research and clinical practice, some commentators have argued that patenting may not necessarily entail the withholding of information.^{12,17,18,23} As mentioned earlier, the granting of any patent is contingent on the full disclosure of the invention in question. Nevertheless, access to patented procedures is more restricted than it would be if patenting were prohibited.^{12,17,18,23} While patenting may provide sufficient access to a description or explanation of a patented technique, it simultaneously creates additional barriers to an individual physician's application of the procedure. Disclosure of the technique without the ability to use the technique does not constitute availability in any substantial sense. Rather, before the information can be considered truly shared the recipient of the information must be able to act on the information. In short, it is difficult to see how the legal requirement to disclose the content of a patent satisfies the ethical

obligation to share information if the actual performance of the disclosed procedure is restricted. While it may be argued that current geographic and financial constraints on patient access to treatment are tolerated by the medical community,¹⁸ it does not follow that the medical profession should erect more such barriers at the expense of the patient and the integrity of the profession. Likewise, while the free flow of information may not be blocked by patenting any more than it is by concerns about dominance in a field, tenure, and prestige,^{18,23} the fact that there are such barriers to data sharing does not mean that they should exist and proliferate.

Increased Financial Burdens

An ancillary argument against medical process patents is that patenting of medical procedures may lead to an increase in the cost of health care via licensing fees or the costs of infringement litigation. While royalty fees may be "nominal" from a percentage perspective, these small percentages over a great number of procedures can substantially increase the cost of health care, especially with the widespread proliferation of patents.^{3, 4, 19, 29} In addition, it is necessary to consider the additional costs of infringement litigation as patent-holders attempt to collect on their promised monopoly. Legal costs associated with patenting and licensing are already quite high, with a recent survey showing that universities spent \$52.8 million on such fees, litigation and associated costs in 1992 alone. It is likely that an increase in these kinds of expenses resulting from biomedical process patents expenses will be carried by the patient population via an increase in the cost to the consumer undergoing the procedure. This is unacceptable; physicians have an ethical obligation not to place additional financial burdens on their patients. While in certain cases patenting may be fiscally neutral or actually economically benefit patients by leading to a decrease in the cost of treatment as new, less expensive procedures replace older ones,^{2,3} it is not clear to what extent this line of reasoning is generalizable, and there is little supporting empirical data from which to draw conclusions.

Enforcement and patient confidentiality

A final ethical concern involves the way in which patent claims could be enforced. While it is easy to track the sales of a device or pharmaceutical, it may be significantly more difficult to monitor a physician's use of a patented technique.^{29, 31} In addition, the monitoring of medical procedures could potentially compromise the privacy of both patients and physicians.^{17,26,29}

It may be possible to conduct enforcement in such a way as to be both effective and confidential, for example by charging doctors, insurers, group practices or health maintenance organizations fees based on yearly numbers of patients seen rather than on a case-by-case basis.³¹ However it is not clear how to ensure accuracy of reporting by these groups without compromising confidentiality in some manner.

INCENTIVE TO INNOVATE

Despite the aforementioned concerns about the potential consequence of patenting medical procedures and techniques, proponents argue that these costs are outweighed by the main benefit of patenting, namely that the procedure might not have been available at all in the absence of the patent system.^{12,17,18,23,32} It is senseless to fault patenting for restricting access to medical procedures if the procedures would not have been developed otherwise. For, although patents provide for individual benefit to inventors, either economically or in terms of recognition and respect for their discoveries, it may be argued that this is not the primary purpose of the patent system.^{17,18,32} Rather, patent policy is predicated on securing the invention for public benefit by offering a reward as an incentive to innovate and disclose, and individual reward considered in itself is a secondary concern.

Not all procedures require extensive research and development; however, some do. These procedures may never be made available to the public at all without the possibility of patent protection. For example, estimates of the total costs incurred in the development of the patented technique of Surrogate Embryo Transfer (SET) range from \$500,000²⁴ to \$1.25 million.²⁹ Furthermore, complex medical procedures are developed in an academic world in which government funding is often insufficient and the distinction between for-profit and non-profit academic research is becoming blurred.¹² Often, in order for new products to come into existence at all, there must be private funding of developmental research.²¹ Private companies may be unwilling to provide capital for research and development if they cannot expect to see an economic return on their investment.^{17, 18, 32} It may be argued that patenting, by offering broad exclusive rights, provides precisely that incentive. In addition, once a process is patented and licensed by an academic institution, it is possible that the royalty fees can be used to support the hospital and its investigators in further research.⁴

An ancillary argument for the patenting of medical procedures is that, for innovative physicians who wish to protect their interests, the alternative to patenting is non-disclosure.²³ With patenting, the physician is guaranteed some kind of reward for making the procedure public knowledge. Without such a guarantee, those physicians who wish to protect their discoveries may keep them secret, thereby hindering the dissemination of knowledge.^{17, 18, 23} While uncommon in the medical community, such non-disclosure has occurred historically (most notoriously, the refusal of four generations of the Chamberlen family to reveal their discovery of the obstetrics forceps⁵) and continues in more subtle forms today.²²

The argument that patents are needed to ensure disclosure is not adequate to justify patenting medical procedures. Given the aforementioned strong ethical prohibitions on withholding information, patenting is being inappropriately promoted to solve a dilemma that clearly should not exist. While those who violate disclosure requirements may respond to economic incentives rather than principles, it is inappropriate to reward their unethical behavior by providing an economic benefit to disclosure. Rather patenting can be ethically defensible only if it performs a function beyond merely rewarding violators for something they should have done in the first place.

While the argument that the patenting of medical processes is necessary to enable and promote procedural advances seems strong initially, there is no evidence of the argument's empirical soundness. Medical process patents have been possible since the early 1950's but were rarely issued until recently. The fact that medicine advanced rapidly from World War II to the late 1970's despite the absence of medical process patents undermines the central claim that economic incentive is needed to induce innovation in the realm of medical procedures. In addition, although patents can provide economic benefits to inventors, the medical field has, over the years, established its own internal system of rewards, including recognition and respect for discoveries through the publication of findings in respected medical journals and other media. While proponents of patenting might point out that the ophthalmologist involved in the aforementioned patent infringement suit initially attempted to publish his work, only to be rebuffed by a peer-reviewed journal, the important point is that the prospect of publication provided sufficient incentive for the ophthalmologist to develop his new procedure.

This type of appeal to non-financial incentives does not entirely address the issue of incentive for innovation, for internal recognition and respect do not necessarily generate the money to enable the creation of new procedures in the first place. The patent system provides incentive for investors as well as individual physician-inventors and the investors are neither recipients of nor concerned with internal prestige as much as financial reward. Yet this defense of medical process patents is ultimately unconvincing. While there is no substantive empirical data about the level of incentive needed to promote

innovation and disclosure in the biomedical sciences,^{17, 18, 32} it is reasonable to claim that this level would be significantly lower for procedures than it would be for devices and pharmaceuticals. Unlike the development of innovative medical instruments or pharmaceuticals, the development of medical processes usually relies on intellectual curiosity and creativity rather than the availability of capital for research and development. Especially in the case of pure medical process patents, the innovative step tends to be a novel mental step rather than the creation of a new physical entity. While this does not mean that this type of innovation is any less worthy of reward, it does imply that the need for outside funding costs that might require later recovery is generally less pressing than in the case of devices or pharmaceuticals. SET is one obvious counterexample, yet this alone does not undermine a prohibition on patenting of medical procedures as we do not, in any context, require general rules to meet the impossible condition of working faultlessly.

REGULATION VS. PROHIBITION

It may be argued that the distinction between product patents and process patents does not arise from some feature unique to medical process patents but rather results from the comparison of inappropriate medical process patents with appropriate patents on devices and pharmaceuticals. If the comparison were drawn instead between a procedure such as SET, an appropriate candidate for patenting, and a corresponding device or pharmaceutical, then the troublesome discrepancy in the strength of the incentive-to-innovate justification would likely evaporate. SET likely would not have been developed in the absence of patent protection, so the benefits occasioned by patenting are tangible and comparable to that occasioned by other kinds of acceptable patents. In addition, the costs are no more than other medical patents since SET, as a rare procedure, has relatively little impact on physician autonomy, and the scarcity of potential beneficiaries makes the potential decrease in accessibility even less than that tolerated in the case of many devices and pharmaceuticals. Because some process patents may be as justifiable as drug or device patents, it is often argued that process patents should be regulated rather than prohibited.^{17,18} Ethical codes, according to this line of reasoning, should distinguish between inappropriate and appropriate patents.

The basis on which to draw a distinction between appropriate and inappropriate patents can be found in the fundamental tenet of the patent system that a patented invention be both "novel" and "non-obvious". While the novelty condition requiring that the patented invention be new is likely too broad to discourage the patenting of procedures such as the cataract incision, the requirement that the patented invention be non-obvious may be significantly more useful. In order for a procedure to qualify as non-obvious, it must represent a substantial advance over the state of the prior art, one which could neither have been easily deduced from the background of medical knowledge at the time of the generation of the procedure,¹² nor have been readily obvious to a skilled worker in the field.³⁶ While this condition is met by procedures such as SET, other patented procedures such as the diagnosis of chronic fatigue syndrome³⁷ and the use of vasodilators for treatment of male impotence¹ fall short of this standard. Indeed rigorous application of the standard would not only remove the procedures which are currently causing an uproar in the medical community from patent protection but would ensure that procedures worthy of patent protection could come into existence. It seems reasonable to assert that generally the procedures which were non-obvious would be the ones that required additional incentives and economic investment.

Nevertheless, the option of regulation is not tenable. Unfortunately, as supported by the recent furor of the patenting of medical procedures, there is a significant gap between a strict interpretation of novel and non-obvious and the way that these terms are currently applied in assessing patent applications. As in the case of biotechnology generally, the Patent and Trademark Office (PTO) has applied the statutory rules too broadly, resulting in unduly expansive patenting decisions.³⁵ Often the PTO relies on subsequent litigation challenging the validity of issued patents to weed out those patents which are not truly novel

and non-obvious. The trend in recent years toward the widespread patenting of common medical procedures undermines the essential distinction between appropriate and inappropriate medical process patents. While inappropriate medical process patents may be particularly vulnerable to court challenge,¹⁸ this is not an acceptable solution, for it leaves unaddressed the additional costs incurred by litigation as well as the inaccessibility and professional compromises that may occur while the application and subsequent litigation are pursued. In short, while the ethical problems with patenting might be solved in theory by drawing a distinction between inappropriate and appropriate medical process patents, such a solution is not useful in practice.

CONCLUSION

A physician has the ethical responsibility not only to learn from but also to contribute to the total store of scientific knowledge when possible. Physicians should strive to advance medical science and make their advances known to patients, colleagues and the public. This obligation provides not merely incentive but imperative to innovate and share the ensuing advances. The patenting of medical procedures poses substantial risks to the effective practice of medicine by limiting the availability of new procedures to patients and should be condemned on this basis. Accordingly, the Council believes that it is unethical for physicians to seek, secure or enforce patents on medical procedures.

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