

7.2.3 Patents & Dissemination of Research Products

A patent grants the holder the right, for a limited time, to prevent others from commercializing his or her inventions. By requiring full disclosure of the invention, and thus enabling another trained in the art to replicate it, the patent system protects the holder's discovery, yet also fosters information sharing. Patenting is also thought to encourage private investment into research.

With respect to genetic research, patenting raises unique questions. Arguments have been made that the patenting of human genetic material sets a troubling precedent for the ownership or commodification of human life. However, DNA sequences are not tantamount to human life and it is unclear where and whether qualities uniquely human are found in genetic material. Moreover, while genetic research holds great potential for developing new medical therapies it remains unclear what role patenting will play in ensuring such development.

Physicians who develop medical innovations may ethically patent their discoveries or products but should uphold the following guidelines:

- (a) Not use patents (or other means, such as trade secrets or confidentiality agreements) to limit the availability of medical innovations. Patent protection should not hinder the goal of achieving better medical treatments and technologies.
- (b) Not allow patents to languish. Physicians who hold patents should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.
- (c) For patents on genetic materials recognize that:
 - (i) patents on processes, e.g. to isolate and purify gene sequences, are ethically preferable to patents on the substances themselves;
 - (ii) patents on purified proteins (substance patents) are ethically preferable to patents on genes or DNA sequences.

Descriptions for (substance) patents on proteins, genes, or genetic sequences should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question.

AMA Principles of Medical Ethics: V,VII

Background report(s):

CEJA Report 3-I-07 Amendment to Opinion E-9.095, Trademarks, patents, copyrights, and other legal restrictions on medical procedures

CEJA Report 2-I-97 Patenting the human genome

CEJA Report 1-A-95 Ethical issues in the patenting of medical procedures

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS*

CEJA Report 3-I-07

Subject: Amendment to Opinion E-9.095, “Trademarks, Patents, Copyrights, and Other Legal Restrictions on Medical Procedures”

Presented by: Mark A. Levine, MD, Chair

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(Jane C.K. Fitch, MD, Chair)

1 INTRODUCTION

2
3 At the 2006 Annual Meeting of the AMA House of Delegates adopted Resolution 1, “Trademarks,
4 Patents, Copyrights, and Other Legal Restrictions on Medical Procedures,” as introduced by the
5 Missouri Delegation. This resolution requested the Council on Ethical and Judicial Affairs (CEJA)
6 to study and evaluate whether there is an ethical difference between the use of patents for medical
7 procedures and the use of various other legal devices to limit access to new medical procedures, a
8 term that includes medical techniques and technical maneuvers. The resolution also asked CEJA to
9 study and evaluate whether to affirm Opinion E-9.095, “Patenting of Medical Procedures,” or to
10 amend it to prohibit the use of other means, in addition to patents, to limit access to medical
11 procedures.

12 BACKGROUND

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14
15 Resolution 1 is broad in scope and requests CEJA to study a number of intellectual property
16 regimes that can affect the use of new medical procedures. The report focuses primarily on trade
17 secrecy and confidentiality agreements because of the limited application that copyright or
18 trademark law could have on medical procedures, including medical techniques.

19
20 Copyright law generally protects the expression of an idea, rather than the underlying idea itself.
21 In the context of medical procedures, a copyright allows for the protection of a document or video
22 or audio aid that explains a procedure, but it does not pertain to the procedure itself. Copyright law
23 specifically exempts from protection any “idea, procedure, process, system, method of operation,
24 concept, principle, or discovery, regardless of the form in which it is described, explained,
25 illustrated, or embodied in such work.”¹ For example, a physician may teach students a procedure
26 using the information contained in a textbook, but cannot photocopy extensive portions of the
27 textbook for sale to students without permission from the copyright holder.

* Reports of the Council on Ethical and Judicial Affairs are assigned to the reference committee on Constitution and Bylaws. They may be adopted, not adopted, or referred. A report may not be amended, except to clarify the meaning of the report and only with the concurrence of the Council.

1 Likewise, trademark law provides no protection for the underlying medical procedure, only its
2 distinct name. Generally, trademark law provides protection to words or symbols to identify the
3 source of goods or services. A physician may call an invented or improved procedure by his or her
4 own name, such as “The Smith Procedure,” but protection extends only to rights associated with
5 use of that name. In general, the procedure cannot be given a different name by a third party, nor
6 can this name be assigned to another procedure, but there are no restrictions on using a procedure
7 that is trademarked.

8
9 Neither copyright nor trademark presents an absolute obstacle to dissemination of information
10 concerning medical procedures, although they may limit such dissemination. It is likely for this
11 reason that the *Code of Medical Ethics* has always focused on patents rather than these other forms
12 of intellectual property.

13
14 Until the middle of the 20th Century, the *Code of Medical Ethics* contained a prohibition on the
15 patenting of medical devices. The original 1847 edition of *The Code of Ethics of the American*
16 *Medical Association* provided that “[e]qually derogatory to professional character is it, for a
17 physician to hold a patent for any surgical instrument, or medicine....” Similarly, in 1903, 1912,
18 and 1947, the AMA reaffirmed the prohibition against patents on surgical instruments, appliances,
19 and medicines.

20
21 Subsequently, the AMA began to recognize the benefits of allowing physician-inventors to retain
22 rights in inventions and the policy was revised to allow patents for devices by the mid-1950s, and
23 later to allow for certain patents related to human genes. Notably, the Opinion permitting patents
24 on devices did not mention procedure patents. In fact, Opinion E-9.08, “New Medical
25 Procedures,” added in the mid-1980s, provided that physicians should share knowledge, an
26 indication that the medical profession remained somewhat ambivalent regarding the restrictions
27 entailed by patents.

28
29 At the 1995 Annual Meeting of the House of Delegates, amid growing concern for the effect that
30 procedure patents would have—especially in light of increasing numbers of these patents and
31 lawsuits seeking enforcement—CEJA submitted a report entitled “Patenting of Medical
32 Procedures.” This report carefully laid out the basis for prohibiting the patenting of medical
33 procedures and concluded that the best interest of patients and the profession militated against
34 allowing such patents. The corresponding Opinion E-9.095, “Patenting of Medical Procedures,”
35 prohibits procedure and technique patents because such patents pose “substantial risks to the
36 effective practice of medicine by limiting the availability of new procedures to patients and should
37 be condemned on this basis.”² Principle V of the AMA’s *Principle of Medical Ethics*, which lays
38 out physicians’ ethical responsibility to contribute to and share scientific knowledge, is the
39 foundation of this Opinion. Preventing the dissemination of knowledge for financial gain or fame
40 can have a negative impact on patients and would contravene Principle VIII.

41
42 U.S. patent law allows for the patenting of medical procedures. Essentially, “any new and useful
43 process, machine, manufacture, or composition of matter, or any new and useful improvement
44 thereof” may be patented.³ However, in 1996, Congress passed legislation⁴ that protects medical
45 practitioners and related entities from claims of infringement in specified circumstances. This

1 provides limited protection for physicians and hospitals in the clinical use of patented medical
2 procedures.

3
4 TRADE SECRETS AND MEDICAL PROCEDURES

5
6 Protection for the discovery of a new medical procedure or improvement of an existing procedure
7 is not limited to patents. Trade secret law, including contractual arrangements to prevent the
8 dissemination of knowledge under what is known as a confidentiality agreement, can also be
9 employed to limit the dissemination of new medical knowledge.

10 Trade secret law is based primarily on state law rather than a comprehensive federal act. It can be
11 used to protect the same information as patent law—such as a device, procedure, or method of
12 use—but it does not require the public disclosures that patents do. Essentially, if the person
13 maintaining the trade secret can keep it out of the realm of public knowledge, he or she in effect
14 can prevent another from using the subject of the trade secret. If the trade secret is made known
15 through improper means, such as corporate espionage or a departing employee violating a
16 confidentiality agreement, the person holding the trade secret may pursue damages for violation of
17 this right and still be able to prevent the use of any information gained through the improper
18 disclosure.

19
20 The responsibility to prevent disclosure rests with the holder of the trade secret. If the holder
21 inadvertently releases information that others can rightfully discover, the trade secret will no longer
22 exist. Additionally, if another person discovers the same device or procedure through legitimate
23 means and makes that information publicly available, the trade secret will cease to exist. The
24 primary difference between a patent and a trade secret is that the public disclosure of a trade secret
25 destroys legal protection, while the publicly available disclosure of the subject matter of a patent is
26 required. Additionally, a patent lasts for a definite time while a trade secret lasts as long as there is
27 a protected secret.

28
29 The *Code of Medical Ethics* contains policy that speaks to inhibiting the spread and use of medical
30 knowledge. Opinion E-9.08, “New Medical Procedures,” presents a strong rationale for
31 disallowing the use of trade secrets to protect medical procedures. It states that “[p]hysicians have
32 an obligation to share their knowledge and skills and to report the results of clinical and laboratory
33 research.”⁵ Moreover, “[t]he intentional withholding of new medical knowledge, skills, and
34 techniques from colleagues for reasons of personal gain is detrimental to the medical profession
35 and society and is to be condemned.” Accordingly, it could be said that trade secrets fall under this
36 Opinion, since their purpose is “intentional withholding” for “personal gain.” However, Opinion
37 E-9.08 does not explicitly address this legal means.

38
39 Likewise, Opinion E-9.095, “Patenting of Medical Procedures,” discusses the hindrance of
40 dissemination of medical procedures, but is narrow in scope and does not address any legal theory
41 other than patents. It provides that “[t]he patenting of medical procedures poses substantial risks to
42 the effective practice of medicine by limiting the availability of new procedures to patients and
43 should be condemned on this basis.”

1 The justification for designating medical procedure patents as unethical is that dissemination of
2 new medical knowledge will be inhibited, thus harming patients who might have benefited from
3 the patented procedure. This reasoning is even stronger for trade secrets: the end result of
4 maintaining a trade secret is limited dissemination or none at all. Like patents, the holder of a trade
5 secret can choose permissible uses of a procedure; unlike patents, the public can be prevented from
6 obtaining the knowledge for future innovations. This limitation on medical knowledge presents
7 additional dangers to patients by preventing others from reviewing or testing the procedure for
8 safety and efficacy.

9
10 CONCLUSION

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12 Opinion E-9.095 was intended to protect the integrity of the medical profession by ensuring access
13 to medical procedures that might benefit patients. The current Opinion applies to seeking,
14 securing, or enforcing patents, and does not address other methods to limit dissemination of
15 medical knowledge. The use of trade secrets, including confidentiality agreements, to prevent this
16 dissemination is just as detrimental, if not more so, than medical procedure patents. Although it is
17 unknown how pervasive the use of trade secrecy is in medicine, the end result of its use is to
18 prevent widespread adoption of medical procedures and techniques for personal gain, potentially at
19 the expense of patients' safety and access to quality care. The Council concludes that Opinion E-
20 9.095 should be amended to cite the use of trade secrets and confidentiality agreements, along with
21 patents, on medical procedures as unethical and to further emphasize the policy's emphasis on
22 sharing medical knowledge.

23
24 RECOMMENDATION

25
26 The Council recommends that Opinion E-9.095, "Patenting of Medical Procedures," be amended as
27 follows and the remainder of the Report be filed.

28
29 E-9.095 The Use of Patents and Other Means to Limit Availability of ~~Patenting of Medical~~
30 ~~Procedures~~

31
32 ~~Physicians have~~ A physician has the ethical responsibilities ~~responsibility~~ not only to learn
33 from but also, when possible, to contribute to the total store of scientific knowledge ~~when~~
34 ~~possible~~. Physicians should strive to advance medical science and make their
35 achievements ~~advances~~ known through publication or other means of disseminating such
36 information. This encourages physicians to innovate and to share ensuing advances to
37 patients, colleagues, and the public. This obligation provides not merely incentive but
38 imperative to innovate and share the ensuing advances.

39
40 The use of patents, trade secrets, confidentiality agreements, or other means to limit the
41 availability ~~patenting~~ of medical procedures places significant limitation on the
42 dissemination of medical knowledge, and is therefore unethical. ~~poses substantial risks to~~
43 ~~the effective practice of medicine by limiting the availability of new procedures to patients~~
44 ~~and should be condemned on this basis. Accordingly, it is unethical for physicians to seek,~~
45 ~~secure, or enforce patents on medical procedures. (V, VII)~~

- 1 Issued June 1996 based on the report "Ethical Issues in the Patenting of Medical Procedures,"
- 2 adopted June 1995 (Food & Drug Law J. 1998; 53: 341-57).
- 3
- 4 (Modify HOD/CEJA Policy)

Fiscal Note: Staff cost estimated at less than \$500 to implement.

APPENDIX- PROPOSED OPINION AMENDMENTS (CLEAN)

E-9.095 The Use of Patents and Other Means to Limit Availability of Medical Procedures

Physicians have ethical responsibilities not only to learn from but also, when possible, to contribute to the total store of scientific knowledge. Physicians should strive to advance medical science and make their achievements known through publication or other means of disseminating such information. This encourages physicians to innovate and to share ensuing advances.

The use of patents, trade secrets, confidentiality agreements, or other means to limit the availability of medical procedures places significant limitation on the dissemination of medical knowledge, and is therefore unethical. (V, VII)

Issued June 1996 based on the report "Ethical Issues in the Patenting of Medical Procedures," adopted June 1995 (Food & Drug Law J. 1998; 53: 341-57).

REFERENCES

- ¹ United States Copyright Act, 17 U.S.C.S. § 102(b) (Matthew Bender 2006).
- ² American Medical Association. Opinion 9.095 Patenting of Medical Procedures. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/category/8542.html>. Accessed September 4, 2007.
- ³ United States Patent Act, 35 U.S.C.S. § 101 (Matthew Bender 2006).
- ⁴ United States Patent Act, 35 U.S.C.S. § 287(c) (Matthew Bender 2006).
- ⁵ American Medical Association. Opinion 9.08 New Medical Procedures. *AMA Code of Medical Ethics*. Chicago, IL: American Medical Association; 2006. <http://www.ama-assn.org/ama/pub/category/8540.html>. Accessed September 4, 2007.

CEJA Report 2 – I-97 Patenting the Human Genome

INTRODUCTION

The Human Genome Project (HGP) is a joint endeavor overseen by the National Institutes of Health (NIH) and the Department of Energy (DOE). International research efforts are coordinated through HUGO (Human Genome Organization). The 15-year HGP began in 1990 and proposes to find the location of 100,000 (or more) human genes, as well as to read the entire genetic script (approximately 3 billion base pairs) by the year 2005. Initial investments focused primarily on developing computerized tools for mapping, sequencing, storing, and handling genes. Despite this, the development of physical and genetic maps has moved forward faster than originally expected. Recently, with the development of new technologies that enable research to proceed more rapidly and efficiently, larger-scale sequencing efforts have begun.

With genetic research moving ahead at light-speed, patenting has become an important issue. Much of the concern in this area has focused on DNA sequences.¹ These sequences may be fragments of a gene (*i.e.*, they code for certain amino acids), or a full gene (*i.e.*, they code for a full protein). Patenting of the former is more controversial, both legally and ethically, than the latter. In this report the Council provides a brief explanation of patent law and its potential application to genomic sequences. After examining some of the ethical concerns regarding patenting human genomic material, it concludes that caution is warranted in this area.

UNITED STATES PATENT LAW

Patent law is controlled by federal legislation, federal court decisions, and decisions of the Patent and Trademark Office (PTO). The Constitution notes that Congress has the power to “promote the progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive right to their Writings and Discoveries.”²

Patent holders do not own an invention—they own merely the patent. A patent then grants the holder the right, for a limited amount of time, to prevent others from commercializing their inventions. In this sense a patent does not confer ownership rights, it confers property rights. This is an important distinction. For example, an easement (another type of property right) granting X access over Y's property to the ocean front does not mean that X owns the property, merely that X has certain rights with respect to the property.

The obverse of patent law is trade secret law. It may be more lucrative to maintain an invention as a trade secret than to disclose it under patenting requirements. For example, Coca Cola originally sought patent protection for Coke, but dropped the application in light of the disclosure requirements. The formula for Coke turned out to be much more valuable as a trade secret than if patented (since the company would have had to disclose how to make it).

Patent law is designed to allow inventors to profit from their inventions, safeguarding intellectual property. At the same time, the patent system is designed to foster information sharing since full disclosure of the invention—enabling another trained in the art to replicate it—is necessary to obtain a patent.³ One author described a patent as “a contract between its owner and the U.S. government, whereby the owner is given security in exchange for sharing knowledge with the public.”⁴ The “contract,” as such, lasts 20 years from the date of filing.

There are two aspects to consider when a patent application is filed: the first is determining whether the thing is an invention, which is potentially patentable, or a discovery, which is not. In some sense, all inventions can be reduced to naturally occurring substances that are merely discoverable. Another way to think about the difference between a discovery and an invention is to consider the distinction between basic and applied research.⁵ This distinction, however, is not always clear-cut in the realm of biotechnology. As a result, whether or not to classify a finding as a discovery or an invention often reduces to the requirement of “utility” discussed below. Second, once a finding is classified as an invention and deemed potentially patentable, it must meet the three requirements of novelty, non-obviousness and utility.

Novelty

To meet the novelty requirement, the invention cannot have been known or used by others in this country, or patented or described in a publication in this or a foreign country.⁶ In other words, the invention must not have been in the public domain. This issue becomes crucial when an inventor seeks to disseminate his or her invention before issuance of the patent. The United States grants a one year grace period from the time that the invention is disseminated to the time the patent application is filed. In theory this may keep some inventors from disclosing their inventions, or information about them, until they have met the other requirements and thus are ready to file.

Non-obviousness

To be patentable, the invention in question must not have been obvious to one working in the field at the time of the invention.⁷ If all of the elements of an invention were described in a single previous publication, even if the invention itself had not been developed, it is considered to be non-obvious. In this sense, what can be patented changes over time. As the state of the art develops, what was once considered non-obvious or novel, may become routine and thus unpatentable.

Utility

Utility requires that the invention must have a practical use beyond merely being a tool for scientific inquiry.⁸ The focus here is not on the degree of utility—if an inventor can articulate at least one use for the invention he or she will have met this requirement. This does not mean that if an inventor can articulate the natural function the test has been met—a commercial use (e.g., a therapeutic use) must be identified.

In practice, people can use a patented invention in the absence of a licensing agreement. First, there is an exception that allows the use of a patented invention for research purposes, although if a commercial product arises from the research an agreement must be negotiated between the original patent owner and the researcher. This “research exception” has never been clearly defined and it is uncertain how it would be interpreted if litigated. Second, not all patents are enforced, either because the patent holder does not mind the use or because of the financial cost of enforcement. The patent holder actively must seek either an injunction to prevent use of the patent or the payment of penalties. Third, all patents can be challenged in court, as they often are by companies who have developed the same or similar technology.

PATENTING DNA

While naturally occurring DNA sequences can only be discovered, and thus are not patentable, sequences that been manipulated or altered are considered inventions and thus

potentially patentable. In 1980, the Supreme Court decided the case of *Diamond v. Chakrabarty* holding that genetically engineered microorganisms are patentable.⁹ Moreover, other cases have held that a newly isolated or purified material is patentable (for example, purified: prostaglandins, acetylsalicylic acid, adrenaline composition, and bacterial strains have been granted patent protection).¹⁰ Thus a newly cloned human gene that existed naturally in an impure form in human cells (*i.e.*, it existed only in combination with other DNA), may be patentable. For example, the European Patent Office (EPO) recently allowed a patent for a synthetic gene for H2-relaxin.¹¹

DNA sequences may be classified as an invention rather than a discovery, but they must still meet the three requirements of novelty, nonobviousness and utility. Although sequences are potentially novel and non-obvious, they may not remain so.¹² Thus DNA sequences may meet this requirement in the early stages of HUGO, but later developed ones may not since the mechanisms and technology needed to establish new sequences might be obvious from the older sequences. The state of the art might have already progressed beyond the point where DNA sequences are non-obvious. In addition, the utility requirement may cause difficulty. This difficulty is what underlies the controversy between patenting partial and full sequences.¹³ While the partial sequence might have some use as a tool for scientific inquiry, in order to satisfy the utility criterion, the inventor might need to articulate the specific function of the full gene or resulting protein. In practice, however, the utility requirement has never posed a significant barrier to obtaining a patent; any proposed use generally is considered sufficient for purposes of the application.

In addition to patents on genetic substances, patents of sequencing processes are also possible. Process patents are often thought to be less economically valuable than substance patents from the standpoint of the patent holder since they do not prevent others from developing the same substance through a different process. In addition to patents on genes and gene sequences, patents may also be sought on genetic therapies or technologies. This report does not address the ethical acceptability of patents on genetic therapies.

PURPOSE OF PATENTING

Before entering into a discussion of the ethical concerns regarding patenting the human genome, it is useful to identify why patent protection is sought. Large outlays of money are necessary to conduct most biotechnology research. A substantial amount of this money comes from private sources.¹⁴ Given the present state of federal funding for science research, it is unlikely that public money will be able to make up for the loss of private funding. Patenting is thought to encourage private investment into research.¹⁵ Leaving aside for the moment the appropriateness or efficacy of a particular incentive (*e.g.*, patenting) it is important to acknowledge the need for incentives to encourage continued private support of research.

In addition, the patent system is designed to foster information sharing since a patent holder must disclose all of the information regarding his or her invention as part of the patent application. However, it is unclear whether this information sharing actually occurs. Clearly the effect of patent law on private research is different from the effect on academic research, where information sharing is generally the norm. With respect to private research, investigators may be unwilling to share information (or prevented by their company from doing so) until they are prepared to file a patent application. On the other hand, refusing to extend patent protection to DNA sequences will not necessarily result in more information sharing. Industries may choose to keep the sequence information secret until they develop a patentable product.¹⁶ As a result dissemination of information will not only be slowed, as

occurs during the period between patent application and patent approval, but possibly cut off completely.

Biotechnology inventions are more like drug or device patents—there may be no direct benefit to the inventor unless he can market it commercially. This is in contrast to medical procedures, where one can argue that the inventor will still benefit from an invention without patent protection because of increases in the number of patients who come to the inventor for the procedure.¹⁷ Moreover, although physicians may be barred from using a patented medical procedure in the course of their practice because of the potential for financial gain, researchers are not barred from using a patented biotechnology invention in the course of their research (as long as the research is not for financial gain). This is the research exception in patent law. As noted previously, the extent of this protection is unclear. There is some concern that the exception will not hold with the recent proliferation of joint endeavors between biotechnology industries and academic institutions. While a patented material may be used for research purposes, if those research purposes lead to commercial inventions, a license agreement must be negotiated between the original patent holder and the subsequent investigator. As a result, research efforts may be hindered because of high licensing fees.

ETHICAL CONCERNS

Notwithstanding the uncertainties about the benefits of patent protection, there are ethical concerns with patenting in this context. Most of these concerns focus on the idea that patenting human genomic material results in a harm to human dignity. There are a number of different arguments imbedded in this concept of harm and they will each be addressed in turn.

First, patenting may cause harm because it is equivalent to ownership of human beings.¹⁸ The United States Constitution forbids ownership of people (slavery).¹⁹ However, as stated previously, patents grant property rights rather than ownership rights, although this too may be disturbing. However, the property rights involved here are not rights in a full or complete human being (or even an identifiable human being), but only in parts of human material, separate from any one individual. DNA sequences are not the equivalent of a person, or even a partial person. Moreover, most DNA and even individual genes are not unique to humans—it is the combination that is crucial. Thus patenting a DNA sequence does not seem to grant property rights in another human being. Moreover, it is not clear how DNA is different from proteins or other naturally occurring substances found in human beings that are already patentable—it is just one earlier step on the chain.²⁰ The Danish Council on Ethics suggests that one concern is the lack of knowledge about DNA. Because it remains unclear where and whether certain attributes that are considered uniquely human are found in the genetic material, it is possible that granting patent rights will result in a violation of human worth.²¹ In other words, property rights will be granted in something considered fundamentally “human.” A solution to this may be to ensure that patent descriptions are carefully constructed so as to exclude the naturally occurring form, something that is not always done at this time.

Even if patenting does not confer ownership rights in a human being, there are other ethical concerns. For example, the commodification of human parts is often seen as improper.²² Even if there is continuity between DNA and patentable proteins, commodification of the former may be more problematic than the latter. For example, the manipulation of core parts, such as germ line therapy, is more ethically controversial than manipulation of somatic cells. Likewise, patenting of proteins may be more acceptable than patenting of earlier, or more fundamental elements that control (to a certain degree) who we are. Furthermore, there may be problems with using market rhetoric.²³ Discussions of patenting presuppose an ability to determine the economic value of the patentable entity. Using

market terminology in relation to DNA may be ethically troubling because it implies that human beings may be broken down into “salable” parts. Recently, a coalition of more than 100 religious leaders issued a statement asking the government to prohibit the patenting of human genes and genetically engineered animals.²⁴ The coalition, coordinated by biotech adversary Jeremy Rifkin, director of the Foundation of Economic Trends, argued that patenting reduced the history of humanity to a commodity and violates the sanctity of human life. Some commentators have argued that reducing a life form to a composition of matter that is patentable is equivalent to reducing an organism to an object and creates a troubling precedent for ownership of life, including human life.²⁵ In essence, this argument rests not on the assumption that patenting results in ownership of human beings, but that patenting results in commodification of human beings and the commodification may lead to harm to human dignity.²⁶

A final ethical issue focuses on what may be done with patented material. One element of this is a concern that human genes may be altered thus harming human genetic integrity.²⁷ Refusing patents on altered human genetic material will only indirectly control manipulation of genes—although patenting is designed to encourage investment is it clearly not the only impetus for research. A solution to this would be, instead, to regulate the research and uses of human genetic material. A second element of this concern is a fairness argument. If human genetic material is shared among all humans it should therefore “belong” to all humans. Although genomic research is being conducted on an international level, the resulting therapeutic technologies are not being distributed on a global level. For example, in one case the United States Department of Commerce filed a patent application for a cell line derived from the blood sample of a woman in Panama’s Guyami tribe. No consent had been given for isolation and patenting of the cell line, which was thought to have anti-cancer properties, nor was there any evidence that the woman, or her tribe would gain any benefits from later developed therapies.²⁸ In a recent California case, a physician-researcher failed to inform a patient that the additional travel to a distant lab and the testing done there were not required for his therapy, but were aimed at isolating a unique cell line that the investigator later sought to patent.²⁹ Allowing patents on human genetic material gives the patent holder a certain degree of control over the uses of that material. There is no guarantee that the individuals who donate the original genetic material for research will gain any benefit, nor that the resulting therapies will be distributed in a globally just manner.³⁰ As a result, allowing patent protection for human genomic material may result in greater inequities in the access to beneficial therapies. Patent holders should not be allowed to “sit” on a patent or to grant exclusive licenses to institutions which will not seek to develop the patent. Here too, the solution may be to ensure adequate informed consent or to regulate licensing agreements, not restrict patenting. Nonetheless, greater national attention needs to be paid to the implications of genomic patenting as well as to the international coordination of patenting laws.

CONCLUSION

While the Council does not feel that patenting of naturally occurring substances is unethical *per se*, it does urge caution in this area. Genetic research holds great potential for the development of new beneficial therapies. However, it is unclear what role patenting may play in ensuring such development. While an outright ban on patenting of genomic material is unlikely and may be unwise, the Council makes the following recommendations:

- 1) Patents on processes—for example, processes used to isolate and purify gene sequences, genes and proteins, or vehicles of gene therapy—do not raise the same ethical problems as patents on the substances themselves and are thus preferable.

- 2) Substance patents on purified proteins present fewer ethical problems than patents on genes or DNA sequences and are thus preferable.
- 3) Patent descriptions should be carefully constructed to ensure that the patent holder does not limit the use of a naturally occurring form of the substance in question. This includes patents on proteins, genes, and genetic sequences.
- 4) One of the goals of genetic research is to achieve better medical treatments and technologies. Granting patent protection should not hinder this goal. Individuals or entities holding patents on genetic material should not allow patents to languish and should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.

REFERENCES

1. For example, Dr. Venter while at NIH filed, but subsequently withdrew, a patent application for a number of cDNA sequences. See, e.g., Paul Riley, Comments: Patenting Dr. Venter's Genetic Findings: Is the national institutes of health creating hurdles or clearing the path for biotechnology's voyage into the twenty-first century? *J. Con. H. L. & Policy* 10:309 (1994).
2. U.S. Const. art. I, 8, cl.8.
3. 35 U.S.C.112 (1988) ("The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.").
4. Riley, *supra* note 1.
5. Rebecca Eisenberg, Patents and the Progress of Science: Exclusive rights and Experimental Use, *University of Chicago Law Review* 56:1017-1086 (1989).
6. 35 U.S.C. 102(a)(1988).
7. 35 U.S.C. 103 (1988).
8. 35 U.S.C. 101 (1988). *Brenner v. Manson*, 383 U.S. 519 (1966).
9. 447 U.S. 303 (1990).
10. Rebecca Eisenberg, "Patenting the Human Genome." *Emory Law Journal* 39:721-745, fn. 27, 1990.
11. The Danish Council of Ethics, "Patenting Human Genes," at 16, 1994.
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17. American Medical Association Council on Ethical and Judicial Affairs, Report 67: "Ethical Issues in the Patenting of Medical Procedures."
18. Baruch Brody, "Protecting human Dignity and the Patenting of Human Genes," Draft Paper Baylor College of Medicine, January 22, 1997 (there are four arguments that patenting human genes harms human dignity: (1) it is equivalent to ownership of humans, (2) it commercializes body parts which should not be commodified, (3) it cheapens that which defines human identity, and (4) it leads to inappropriate modifications in our genetic integrity.).

19. U.S. Const. Amendment 13.
20. There are some opponents of patenting who claim that no naturally occurring substances should be patentable. See, e.g., Kathleen Day, "Church Groups to Fight Patenting of Life Forms," *Washington Post*, Saturday, May 13, 1995.
21. The Danish Council of Ethics, *supra* note 14 at 27.
22. See, e.g., Brody, *supra* note 12.
23. See, e.g. Margaret Radin, *Contested Commodities* (1996).
24. "Religious Leaders Prepare to Fight Patents on Genes." *New York Times*, Saturday, May 13, 1995
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26. See, e.g., Radin *supra* note 16 and Brody, *supra* note 12.
27. Brody, *supra* note 12.
28. "Life for Sale: Europe says no to patenting life forms, but the US moves ahead." *Utne Reader*, June 1995.
29. *Moore v. Regents of the University of California*, 793 P.2d 479 (Ca. 1990).
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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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