AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Opinion on Ethics and Professionalism

Medical and Surgical Procedure Patents

An AAOS Opinion on Ethics and Professionalism is an official AAOS statement dealing with an ethical issue, which offers aspirational advice on how an orthopaedic surgeon can best deal with a particular situation or circumstance. Developed through a consensus process by the AAOS Ethics Committee, an Opinion on Ethics and Professionalism is not a product of a systematic review. An AAOS Opinion on Ethics and Professionalism is adopted by a two-thirds vote of the AAOS Board of Directors present and voting.

Issue raised

Is it unethical for an orthopaedic surgeon to patent a medical and/or surgical procedure?

Background

For more than a century, medical and surgical methods and processes for diagnosing and treating disease were not considered patentable. In 1952, Congress amended the patent law, adding to the list of subject matter that could be patented "new and useful processes." At the time, the clear legislative intent was to codify existing policy, not change it. Regardless of this intent, since 1952, the U.S. Patent and Trademark Office ("PTO") has routinely issued method or process patents for purely medical and surgical procedures not associated with any drug or medical device (hereinafter referred to as "Medical Procedure Patents"). In fact, the PTO has estimated that as many as 100 medical procedure patents are issued every month. Until recently, such patents were rarely enforced. However, over the past few years, the holders of some of these Medical Procedure Patents actively have sought to enforce them, and consequently the number of Medical Procedure Patents has continued to increase

In October 1996, President Clinton signed into law legislation involving Medical Procedure Patents. The legislation permanently precludes the filing of infringement suits against physicians and other medical practitioners for the performance of "medical activities" that would otherwise violate patents on medical or surgical procedures. A "medical activity" is broadly defined to include the performance of a medical or surgical procedure on a human body, organ or cadaver or on an animal used in medical research. The Act does not apply to patents issued before October, 1996 and it does not affect enforcement of biotechnology patents, patents on drugs or devices or patents on new uses of drugs or other compositions of matter.

Ethical Issues

The patients who we serve are assured a higher quality of care if innovations in medicine and surgery are openly discussed and disseminated by physicians and other health care professionals. Medical Procedure Patents may inhibit these discussions on both legal and financial grounds. In addition, with costs of health care rising, orthopaedic surgeons have an

obligation to support and participate in cost-effective musculoskeletal care. Medical Procedure Patents potentially may increase the costs of new procedures and devices, as the "inventor" would be entitled to compensation over and above the on-going accepted cost of the new procedure or device. They may also limit the access of providers to technology that is more cost effective than the procedures currently used.

The training of future orthopaedic surgeons and continuing medical education for practicing orthopaedic surgeons are based on the free sharing and passing on of knowledge, methods, and procedures. Since it would be in the patent holder's interest to keep an "invention" a secret until the patent is granted, Medical Procedure Patents may discourage orthopaedic surgeons from openly sharing developing medical information. In addition, the enforcement of Medical Procedure Patents is a strong disincentive for orthopaedic surgeons to share the results of their professional experiences and/or independent discoveries of similar existing methods with their colleagues, since this sharing may identify themselves as a potential target for infringement suits. Thus, the granting of Medical Procedure Patents may undermine the process of peer review, evaluation, and critical appraisal of medical innovation within orthopaedics.

If the PTO continues to grant Medical Procedure Patents, medical education similarly may be compromised. Medical schools, medical societies (including the Academy) and other entities providing medical education might either be prohibited from teaching certain patented procedures or would be required to pay a licensing fee to the inventor before teaching a course that includes the patented method. The cost of medical education would also increase if medical schools were required to pay royalties to patent holders to teach patented surgical and medical techniques.

In addition, Medical Procedure Patents may unreasonably interfere with the practice of medicine and the physician-patient relationship. Orthopaedic surgeons have a fiduciary duty to patients to provide the best possible care without outside influence. With Medical Procedure Patents, patients may be denied access to certain procedures, or their choice of physicians may be restricted to only those doctors who are paying royalties to the original "inventor" of the process. Moreover, enforcing such Medical Procedure Patents may compromise patient confidentiality since all procedures will have to be recorded. Thus, granting Medical Procedure Patents may adversely affect the quality of care, jeopardize patient confidentiality, and contribute to the increasing cost of health care.

Medical Procedure Patents may impede the advancement of medicine, curtail academic access, compromise peer review, place unreasonable limits on the research community, directly interfere with the education of new physicians, and interfere with the physician-patient relationship and the quality of medical care provided to the patient. Under these circumstances, the patenting of "pure" medical procedures or techniques would be unethical.

Legal and Other Issues

The consensus in the medical community is that no medical process is really new. Other professional organizations, including the American Medical Association (AMA), have opposed Medical Procedure Patents as unethical. Every procedural innovation is largely based on "prior art." Every advancement in medicine builds on existing knowledge. Sufficient "prior art" exists in almost every instance where the PTO has granted a Medical Procedure Patent. Seen in this light, the PTO should not grant these patents. Also, a real possibility exists of expensive litigation over whether a Medical Procedure Patent should have been granted in the first place. Such litigation has already occurred in this country and further increases the cost of health care.

The PTO has neither the staff nor the expertise to identify "prior art." Moreover, most medical methods and procedures have not been patented, and consequently, the PTO is ill-equipped to determine whether a process is new. In most instances, these medical and surgical processes have existed for years, and have been transferred from teacher to student through practice seminars, actual "hands-on" training, and through the medical literature.

Recommendations

Consistent with the *Principles* and *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons,* the American Academy of Orthopaedic Surgeons believes that it is unethical for orthopaedic surgeons to seek, secure, or enforce patents on medical or surgical procedures.

The granting of Medical Procedure Patents may pose a serious threat to medical advancement, medical education, and patient care, as well as contribute to the spiraling costs of health care. Furthermore, the Academy believes that the granting of Medical Procedure Patents conflicts with the Academy's mission of fostering and assuring the highest quality and most cost-effective musculoskeletal health care.

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References:

Applicable provisions of the *Principles of Medical Ethics and Professionalism in Orthopaedic Surgery*

> **"VI. Medical Knowledge.** The orthopaedic surgeon continually must strive to maintain and improve medical knowledge and to make relevant information available to patients, colleagues, and the public."
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> **"X. Societal Responsibility.** The orthopaedic surgeon has a responsibility not only to the individual patient, to colleagues and orthopaedic surgeons-in-training, but also to society as a whole. Activities that have the purpose of improving the health and well-being of the patient and/or the community in a cost-effective way deserve the interest, support, and participation of the orthopaedic surgeon."

Applicable provision of the *Code of Medical Ethics and Professionalism for Orthopaedic Surgeons*

> **"IV. A.** The orthopaedic surgeon must continually strive to maintain and improve medical knowledge and skill, and should make available to patients and colleagues the benefits of his or her professional attainments."

Other references:

American Medical Association Council on Ethical and Judicial Affairs: *Code of Medical Ethics.* Chicago, IL, 2014-2015 edition.

Opinion 9.095 - The Use of Patents and Other Means to Limit Availability of Medical Procedures. 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); updated June 2008 based on the report *Trademarks, Patents, Copyrights, and Other Legal Restrictions on Medical Procedures*, adopted November 2007. http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion9095.page

U.S. Constitution, Art. 1, Section 8, cl. 8. 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 respective Writings and Discoveries."

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