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WORLD MEDICAL ASSOCIATION STATEMENT

ON

MEDICAL PROCESS PATENTS

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PREAMBLE

1. Under the law of some jurisdictions medical procedures are patentable subject matter. Patents on medical procedures are often called medical process patents. A medical process patent or patent claim is one that only confers rights over procedural steps and does not confer rights over any new devices.
2. Over 80 countries prohibit medical process patents. The practice of excluding medical procedures from patentability is consistent with the Uruguay Round of Amendments to the General Agreements on Tariffs and Trade Agreement on Trade Related Aspects of International Property Rights (GATT-TRIPS), which states: «Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals» (Article 27). The United States still allows medical process patents, but as of July 1996 newly issued medical process patents will no longer be enforceable against medical professionals who infringe while performing a medical or surgical procedure. This law makes new medical process patents virtually worthless in the United States. However, in the United States there are still numerous medical process patents which were issued prior to 1996 and which are still enforceable.

3. The purpose of patents is to encourage private investment in research and development. However, physicians, particularly those who work in research institutions, already have incentives to innovate and improve their skills. These incentives include professional reputation, professional advancement, and ethical and legal obligations to provide competent medical care (International Code of Medical Ethics, 17.A). Physicians are already paid for these activities, and public funding is sometimes available for medical research. The argument that patents are necessary to spur invention of medical procedures, and that without process patents there would be fewer beneficial medical procedures for patients, is not particularly persuasive when these other incentives and financing mechanisms are available.
4. Another argument is that patents are necessary, not so much for invention but for product development. This argument also is not persuasive in the case of medical process patents. Unlike device development, which requires investment in engineers, production processes, and factories, development of medical processes consists of physicians attaining and perfecting manual and intellectual skills. As discussed above, physicians already have both obligations to engage in these professional activities as well as rewards for doing so.
5. Whether or not it is ethical to patent medical devices does not bear directly on whether it is ethical for physicians to patent medical procedures. Devices are manufactured and disseminated by companies, whereas medical processes are «produced and disseminated» by physicians. Physicians have ethical or legal obligations to patients and professional obligations towards each other, which companies do not have. Having particular ethical obligations is part of what defines medicine as a profession.
6. There is no *a priori* reason to believe that those holding medical process patents would make patented medical procedures widely available. Patentees might attempt to maximize their profits by making the procedure widely available through nonexclusive licensing with low fees. Alternatively, they might attempt to maximize profits by limiting availability of the procedure and charging higher prices to those for whom the procedure is extremely important and who have the means to pay. Competition between organizations providing health care could provide incentives for some organizations to negotiate exclusive licenses, or licenses which sharply limit who else could practice the procedure. Such a license might provide the organization with an advantage in attracting patients, if the organization could advertise that it was the only organization in a region which could provide a particularly desirable service. Thus, at least some of the time patentees will probably limit access to patented medical procedures.
7. Medical process patents may negatively affect patient care. If medical process patents are obtained, then patients' access to necessary medical treatments might diminish and thereby undermine the quality of medical care. Access could diminish for the following reasons:

- 7.1 the cost of medical practice would likely increase because of licensing and royalty fees, and because the cost of physicians' insurance would likely increase to cover patent litigation expenses.
 - 7.2 some physicians capable of performing the patented procedure might not obtain licenses to perform it. The number of licensed physicians might be restricted because certain physicians cannot or will not pay the licensing fees or royalties, or because the patentee refuses to make the license widely available. Limiting the number of licenses would, in some circumstances, limit patients' choice of physicians.
 - 7.3 The presence of patents may prevent physicians from undertaking even those procedures which do not infringe. Devices can be labeled if they are patented, but procedures cannot, and therefore it is not immediately obvious whether what one is doing infringes somebody else's medical process patent. However, lack of knowledge is no defense against patent infringement, so if a physician is uncertain he or she may simply refrain from performing the procedure.
8. Enforcement of medical process patents can also result in invasion of patients' privacy or in the undermining of physicians' ethical obligation to maintain the confidentiality of patients' medical information. Where physicians practice in small groups or as sole practitioners, the most expedient methods for a patentee to identify instances of infringement might be to look through patients' medical records or to interview patients. Removing obvious identifiers for the record review would not guarantee confidentiality, because identity can often be «reconstructed» with very few pieces of information. This would be particularly true in small towns or small practices.
 9. Physicians have ethical obligations both to teach skills and techniques to their colleagues, and to continuously learn and update their own skills. Medical process patents can undermine these obligations. Once a patent has issued on a process, the process would be fully disclosed (this is one requirement for obtaining a patent); however, those without licenses would not be able to practice it. Limiting who can practice the procedure undermines the spirit of the ethical mandate to teach and disseminate knowledge. It also undermines the obligation to update one's skills, because it does not do much good to acquire skills which cannot be used legally.
 10. The obligation to teach and impart skills may also be impaired if the possibility of patents causes physicians to delay publishing new results or presenting them at conferences. Physicians may be inclined to keep new techniques secret while waiting to complete a patent application. This is because public use of a procedure, or publication of a description of the procedure, prior to applying for a patent may invalidate the application.
 11. Physicians also have an ethical obligation not to permit profit motives to influence their free and independent medical judgment (International Code of Medical Ethics, 17.A). For physicians to pursue, obtain, or enforce medical process patents could violate this requirement. Physicians holding patents or licenses for procedures might advocate for the use of those procedures even when they are not indicated, or not the best procedure under

the circumstances. Physicians who are not licensed to perform a particular procedure might advocate against that procedure, even when it is the best procedure under the circumstances.

12. Finally, physicians' professional obligations to practice their profession with conscience and dignity (Declaration of Geneva) might be violated by the enforcement of medical process patents. Lawsuits are rarely dignified or respectful enterprises, and the spectacle of physicians suing each other on a regular basis is unlikely to enhance the standing of the profession.

POSITION

13. The World Medical Association

- 13.1 states that the patenting of medical procedures poses serious risks to the effective practice of medicine by potentially limiting the availability of new procedures to patients.
- 13.2 considers that the patenting of medical procedures is unethical and contrary to the values of professionalism that should guide physicians' service to their patients and relations with their colleagues. However, in light of the differences between medical procedures and medical devices discussed above, the patenting of medical devices is acceptable;
- 13.3 encourages national medical associations to make every effort to protect physicians' incentives to advance medical knowledge and develop new medical procedures.

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