



Should Medical Methods Be Patented?

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The patent system has played a critical role in promoting the progress of science and technology since its inception by providing incentives to invent, to disclose, to design around and to invest. These incentives encourage the progress of science and technology in turn contributing to the economic development and prosperity of mankind. Though the patent system has played a critical role in the progress of science generally, its benefits have not been extended to medical methods. (The term 'medical methods' used herein after shall mean surgical, therapeutic and diagnostic methods of treatment except methods of administering drugs).

Most countries in the world have excluded methods of medical treatment from the scope of their patent systems. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) under Paragraph 3 of Article 27 allows members to exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals from the scope of patentable subject matter. Similarly, US patent law allows methods of medical treatment to be patented but denies a remedy for its infringement, thus nullifying the right insofar as there is no enforceability. The nullification provision was hurriedly enacted in 1996 after wide dissatisfaction was provoked in the medical community by *Pallin's* case. The European Patent Convention under Article 52 Clause 4 excludes from the scope of patentable subject matter methods of treatment of the human or animal body by surgery and therapy and diagnostic methods practiced on humans. The issue has been litigated to a considerable extent in the European courts. Instead of excluding medical methods completely, the judges have found *In vitro* diagnostic methods and cosmetic surgeries or therapies to be patentable.

The patent law of Japan also excludes methods of medical treatment from the scope of patentable subject matter. Part II of the Examination Guidelines for Patent and Utility Models provides extensive guidelines for patenting methods of medical treatment similar to European law. The Examination Guidelines permit patenting of *In vitro* diagnostic methods and cosmetic methods. China and India also explicitly exclude methods of medical treatment from patentability. Contrary to the world trend, Australian patent law does not exclude methods of medical treatment from patentability. In *Bristol-Myers Squibb Co v F H Faulding & Co Ltd*, the Federal Court of Australia in a case involving the validity of petty patents that claimed a method of administering the anti-cancer drug Taxol opined in dictum that a method of medical treatment is patentable. This court has validated the statute by positively allowing methods of medical treatment to be patentable. With the exception of Australia and perhaps a few other countries, most

nations of the world exclude methods of medical treatment from the scope of patentable subject matter and in doing so they have taken away the incentives offered by the patent system. Such a policy has been adopted in light of the ethics inherent in the practice of medicine.

The American Medical Association Council on Ethical and Judicial Affairs is very concerned about the effects of patenting a medical method with regard to ethics inherent in the practice of medicine. (Ethical Issues in the Patenting of Medical Procedures at page 341, Food and Drug Law Journal, 1998). The AMA is worried that the duty of a doctor to disclose information about a medical method which has been laid down under Principle V of the Principles of Medical Ethics of the AMA will be restricted by the patent system. It is also afraid that the health care of the patient, which should be the basic concern of the doctor, will be driven by an economic motive if medical methods are patented. Furthermore, it fears that patenting a medical method will restrict clinical and academic access to that method. Additionally, the AMA is concerned that patenting a medical method will increase the financial burden on the patient if royalties must be paid, in addition to the doctor's fee, for undergoing the patented method. Moreover, it is concerned that patient confidentiality and privacy may be hampered if the enforcement of the patent right involves identifying the patient who has undergone the patented method. Finally, it is apprehensive that the physician autonomy may be compromised if the doctor is motivated to maximize his profit as a patentee or a licensee.

These concerns of the AMA indicate a conflict between the incentives offered by the patent system and ethics inherent in the practice of medicine. Best results can be achieved by neutralizing this conflict. All the concerns enunciated by AMA have alternatives that can be employed to balance the conflict. The issue of a doctor being guided by an economic motive while treating a patient can be partially neutralized by fixing royalty rate on licenses based on the importance of the medical method employed. For example, a method of treating cancer can have a lower royalty when compared to a method of performing a plastic surgery. Furthermore, a compulsory licensing scheme can be enforced to ensure broad practice of the method. The duty of a doctor to disclose information will not be affected because the patent system mandates disclosure of information in order to obtain a patent. The AMA's concern that patenting a medical method impedes clinical and educational access is not true because the patent system does not restrict access; it makes it conditional on obtaining a license. This condition is also only temporary, as the method will fall into the public domain after the patent term expires at which time access is available to all. Academic access is not affected because exemptions have already been provided in the patent laws of most nations for academic use and research. The disadvantage to the patient who may have to pay a high fee to get access to the patented medical method can be neutralized by government action. The government may subsidize payments to patients who cannot afford the treatment. Further, this concern of the AMA is not completely true because invention of a new method reduces the overall cost of treatment. Dr. Pallin's self-healing incision saved 17 dollars per stitch that was required in the absence that method. (Point made by senator Hatch of the United States Congress while opposing the medical procedures reform legislation).

Patient confidentiality can be protected by conducting in camera proceedings when privacy issues are involved.

Finally, the concern of physician autonomy can be balanced by mandating payment to the patent holder in the form of a running royalty i.e. making royalties payable after the patented method is practiced on the patient. The doctor who practices a method for his selfish financial interests can be controlled by severe disciplinary or other legal sanctions for violating ethical norms.

Thus, all concerns cited by the AMA except the first can be neutralized. The patent system has to be adopted despite the first concern of the AMA because it provides marked advantages to society. The desirability of patenting medical methods outweighs concerns over the ethical issues surrounding a doctor's financial motivation.

Surrogate embryo transfer, retinal implants and other new medical methods that integrate technology with medical treatment can be developed only under a patent regime. New medical methods that integrate technology require huge investment in research which is possible only through protection afforded by the patent system. The pace of invention of medical methods which has been very slow compared to the invention of drugs and medical implements which are patentable can be increased only by allowing them to be patented. Inventing new methods of treating a disease is as important as inventing new drugs and implements, therefore, allowing drugs and implements to be patentable and not allowing medical methods is not sensible. Furthermore, incentives to promote the development of alternative healing methods such as acupuncture, ayurveda, homeopathy, magneto therapy and so on whose development has been stunted due to lack of adequate economic incentives can be promoted by allowing them to be patented.

The patent system provides great impetus to the development of new and efficient methods of treatment and all ethical issues can be neutralized. Therefore, the policy makers of various nations should consider allowing medical methods to be patentable.