

POSITION PAPER

Subject:	Patenting of Medical Procedures, Gene Coding and Surgical Devices	Ref. No.	FES-FEL-013
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PATENTING OF MEDICAL PROCEDURES, GENE CODING AND SURGICAL DEVICES**Background**

Patents grant a defined monopoly to an invention and inventor. Monopolies are generally something controlled or discouraged through trade practices and anti-trust legislation, however in the case of patents monopolies are encouraged. This apparent inconsistency is reconciled for public policy purposes by the argument that the granting of a limited monopoly is a necessary incentive to promote the investment needed to produce the invention. Invention is seen as a public good as it produces new and better products and techniques and raises the general scientific base and so it is to be encouraged. It is argued that the national and international economic benefits of a patent monopoly justify the anti-competitive nature of patent rights.

An additional argument for patenting is that with the protection afforded by the patent, disclosure of the science behind the patent is more readily ensured. In this way patenting is argued to assist the expansion of public domain knowledge.

In America whilst medical procedures patents are allowed, American surgeons are exempt from infringement liability by Act of Congress. In Europe the European Patent Convention excludes medical procedures from patent protections. In all some 80 countries have some form of exemption of medical procedures from the provisions of patent law.¹ The situation in New Zealand is that the legal interpretation of the Patents Act 1953 is that medical procedures are unpatentable. New Zealand has enacted a legislative definition of the exemption of medical procedures for patent purposes. The Patents Act 2013 says...

Human beings, and biological processes for their generation, are not patentable inventions. An invention of a method of treatment of human beings by surgery or therapy is not a patentable invention. An invention of a method of diagnosis practised on human beings is not a patentable invention.²

In Australia medical procedures can be patented. In Australia the right to patent medical procedures was upheld and clarified in the Rescare³ case of 1994.

Discussion

Many of the arguments for patenting in the wider community cannot persuasively be applied to the context of medical procedures patenting. The argument that the granting of a monopoly is the necessary economic incentive to promote the development of medical knowledge ignores other incentives that exist for surgeons in this sphere. The most prominent non-economic incentive for surgeons to develop new medical knowledge is to fulfil their ethical duty...

“The health of my patient will be my first consideration”⁴

Accordingly an economic imperative is not essential to the development of medical knowledge by medical practitioners. In addition to the ethical imperative, other non-economic incentives motivate in this field. Medical research is undertaken to raise credibility with others (peers, employers, clients,

¹ Law Ethics and Medicine O Mitnovetski and D Nicol Journal of Medical Ethics 2004

² Patents Act 2013 Section 16 Other exclusions.

³ Rescare 1994 50 FCR 1

⁴ Declaration of Geneva adapting the Hippocratic Oath World Medical Association Geneva 1948 with amendments to 2006.

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regulators), to expose the research to critique and test, to share knowledge on the basis that to receive information it must be shared and to better understand the field.

The widespread, timely availability of appropriate procedures to patients can be seen to be restricted under a system of medical procedures patenting. In order to evaluate and use a patented medical procedure a surgeon may be required by the patent holder to enter into a license agreement. Failure to secure an appropriate license with a patent holder could see a surgeon infringe the intellectual property rights of another. Even where the property rights of a certain technique were of dubious quality as a defensible patent, risk mitigation would suggest some form of license agreement. One consequence of the patenting of medical procedures is that those who would not have patented a technique for economic advantage will now be motivated to patent in order that they can trade patent rights with other patent holders. The process of ascertaining the validity of a patent, negotiating a license agreement with the patent holder and building a patent portfolio for patent trading purposes restricts the timely availability of appropriate procedures to patients and diverts scarce resources from patient care.

It has been argued that the strictures of patenting are a necessary price to pay for the greater freedoms of publishing that flows with the protections of the patent. It is true that not all unpatented medical knowledge is automatically and freely shared. Researchers may wish to withhold information of value to others for reasons of professional pride or to gather other relevant information until they have critical mass. The extent of this is hard to ascertain. It should also be noted that the likely privileges afforded a prospective patent seeker also encourage restrictions on the free flow of knowledge. Information may be withheld because a patent is in prospect. There is no strong case that medical procedures patenting has the net consequence of freeing the availability of new knowledge. Furthermore the creation of new knowledge by the inclusion of patented knowledge is restrained because of the legal burdens associated.

“Allowing patents to methods of medical treatment may stifle the sharing of information between physicians, which may actually slow down the rate of innovation. Doctors and medical researchers may be unwilling to share information, because this may jeopardise their chances of getting a patent. Although it is a requirement of the patents system that there be full disclosure of the invention, this information cannot readily be used until the patent has expired.”⁵

The College position

- Medical procedures

The College is opposed to the patenting of medical procedures on ethical, practical, economic and scientific grounds.

The College view is that diagnostic methods or procedures, or methods of treatment practised on humans be exempt from patenting laws in Australia and New Zealand. However, products or devices used for diagnosis or treatment of humans may remain patentable.⁶

- Gene coding

Human and microbial genes, non-coding sequences, proteins and their derivatives, if used for diagnosis or treatment should be available in both the public and private healthcare systems in Australia and New Zealand. Current patent laws in different jurisdictions are sometimes overlapping.

⁵ Review of the Patents Act 1953: Boundaries to Patentability Ministry of Economic Development New Zealand http://www.med.govt.nz/templates/MultipageDocumentPage____1462.aspx

⁶ EPC article 53 Exceptions to patentability <http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ar53.html>

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This could lead to blocking or limiting of innovation, or to creating a monopoly over information in key research areas. The College is opposed to the use of patent law to limit availability or use of such techniques in research, diagnosis or treatment.

The College holds that the genetic sequence of a human being does not constitute an idea for patenting purposes. It is not an invention worthy of a patent but rather a discovery.

- **Surgical devices**

Surgical devices and instruments are seen as appropriate for patenting. The device designer does not have the same ethical duty, information flows are not at risk and profit is the more pervasive imperative.

Approver: Chief Executive Officer

Authoriser: Professional Development and Standards Board