



Patent Applications Relating to Health Care Face Hurdles in Canada: Even So, They May Be Available to Inventors in The Right Circumstances

by Jacqueline Chernys

Originally published in *Blaneys on Business* (December 2010) - [Read the entire newsletter](#)

Jacqueline Chernys is a lawyer in Blaney McMurtry's Intellectual Property group. She has a Ph.D. in Genetics from Michigan State University and is a registered Canadian and U.S. Patent Agent, as well as a registered Canadian Trademark Agent. Jacqueline is involved in all aspects of intellectual property law, with a particular focus on pharmaceutical litigation, patent drafting, patent prosecution, and trademark matters.

Jacqueline may be reached directly at 416.597.4887 or jchernys@blaney.com.

Canadian patents on a wide variety of new products and processes are awarded every year. Nevertheless, a number of exceptions to patentability exist in this country, carved out over time by statute or by the courts.

Although innovations in medicine, pharmaceuticals and diagnostics have been unusually prone to such exceptions, researchers in these fields are being encouraged to take heart because, in practice, exceptions are not always clear and there may be open roads to meaningful patent protection.

A patentable invention is defined in Canada as any new and useful art, process, machine, manufacture or composition of matter, or any improvement in any of these. In order to receive patent protection, any claimed invention must meet the criteria of novelty and non-obviousness and must be described fully and particularly.

On the face of it, most inventions would appear coverable. Yet exceptions can, and do, show up readily when it comes to innovations in health care.

Consider methods of medical treatment, for example. While there is no explicit prohibition in the Canadian Patent Act or Rules against patents in this area, methods of medical treatment are not patentable.

This arises largely from a 1972 Supreme Court decision, *Tennessee Eastman Co. et al. v. Commissioner of Patents*. In that decision, the Court rejected a claim relating to a surgical procedure, holding that the methods of medical treatment do not produce a result in relation to trade, commerce or industry nor a result that is essentially economic.

At the time of the *Tennessee Eastman* decision, the *Patent Act* expressly excluded *substances* intended for medicine from the definition of invention. That provision has now been repealed. The prohibition against the patentability of *methods* of medical treatment in Canada still holds, however. The general reasoning is that a method of medical treatment involves professional skill and as such, does not produce an essentially economic result in relation to trade, industry or commerce.

Despite the continuing prohibition on patents related to methods of medical treatment, there is at least some room to argue whether a proposed method falls within the definition of a method of medical treatment. For example, the Patent Appeal Board has found that claims relating to a method of preventing pregnancy are patentable. Claims to a method of ameliorating the adverse effects of aging also have been found to be patentable. Since neither method involved treatment of disease, neither was considered a method of medical treatment.

Cosmetic methods would appear not to fall within the definition of a method of medical treatment since, arguably, these methods do not involve disease and therefore do not produce a therapeutic benefit. Accordingly, the Manual of Patent Office Practice, a guidebook for Canadian patent examiners has indicated that cosmetic methods are patentable.

As with claims regarding methods of medical treatment, whether a proposed method is cosmetic or not is not always clear. For example, in *Re Imperial Chemical Industries Ltd.*, the Patent Appeal Board rejected claims to a “method of cleaning plaque or stains, from human teeth by applying thereto an aqueous composition...” on the grounds that the method does not produce a result that is essentially economic. (The test for patentability related to economic benefit shows up in case law.) The Patent Appeal Board stated “what individuals do to their teeth as they stand before mirror in their bathrooms is not a process in the economic sense which the patent was created to protect”.

While methods of medical treatment are excluded from patentability, in certain cases it may be possible to re-draft claims regarding methods into claims regarding use. While this may seem a matter of semantics, the effect is sometimes to acquire patent protection where none would otherwise be available. This can be particularly important to inventors who have already received patent protection in the United States, where methods of medical treatment generally are patentable.

The patentability of claims regarding use (so-called “use claims”) is also important in the pharmaceutical industry where the protection of “second medical” indications is important. The patentability of use claims in Canada generally is a result of a decision of the Supreme Court in *Shell Oil Co. v. Commissioner of Patents*. In this case, the Supreme Court held that a new use of a known compound was an “invention” because, it “involved the application of new knowledge to effect a desired result which had undisputed commercial value”. (The new use was as an agricultural chemical to promote plant growth.) The outcome of this decision is that while a claim that reads “A method of treating cancer by administering drug X” is not patentable (because it is simply a method of delivering a drug that has been patented already), a claim that reads “Use of drug X in the treatment of cancer” may be patentable because the drug is being used in circumstances and ways that were unknown and not contemplated in its patent, such as the use of Aspirin, developed and patented as a pain medication, in the prevention of heart disease.

Of course, not all method claims can be re-drafted into use claims. A Canadian patent examiner will typically scrutinize claims of this sort to determine whether method steps are still present and will assess patentability based on this determination.

While methods of medical *treatment* generally are not patentable in Canada, *diagnostic* methods generally are patentable here. For example, in *Re Application of Kevin McIntyre*, the Patent Appeal Board held that claims to a method of evaluating the mechanical condition of a heart were patentable. In the method, a pulse signal, representative of arterial pulsation was provided non-invasively to the patient. The patient was then subjected to a heart straining manoeuvre. Similarly, in *Re Application of Goldenberg*, the Patent Appeal Board held that claims that involved methods of detection and localization of a tumour without medically treating the tumour are patentable. The method involved the injection of radio-labelled antibody substances into the patient’s body.

In both cases discussed above, the diagnostic methods at issue involve methods being carried out on a human body. The distinction between a surgical or medical method and a diagnostic method appears to be that the outcome of a diagnostic method must not be a therapeutic benefit to the body. That said, Canadian patent examiners will closely scrutinize claims to methods of diagnosis to assess whether a surgical step is present and may reject such claims regardless of the ultimate purpose of the method. It appears that certain procedures, such as injections or the removal of body fluid, are not considered surgical steps *per se*. (It is also important to keep in mind prohibitions against patenting of abstract theorems, scientific principles or natural phenomena, some of which may be relevant to certain diagnostic methods.)

Medical devices fall within the category of “machine” and should constitute patentable subject matter. For example, Canadian patents have been granted for a wide range of medical devices including tongue depressors, medical thermometers, blood sugar meters, artificial hearts, fibrin scaffolds, stents and X-ray machines.

Drug delivery devices, such as transdermal patches, are a sub-category of medical devices that are specialized for the delivery of a drug or therapeutic agent via a specific route. Thus, while there may be no means of obtaining patent protection to a known compound, it may be possible to patent a medical device that *delivers* the compound.

Also, such devices are often used as part of a medical treatment: while the method of medical treatment itself may not be patentable, the device for *implementing* the method may be. There may be some restrictions on the patentability of medical devices if, for example, the device includes a surgical step. A claim to such a device may fall into the prohibition against the patenting of professional skills. Similarly, a medical device that was primarily a computer-related device would be subject to patentability restrictions that apply to computer-related inventions.

To sum up, then, while there are prohibitions against the patenting of certain health care-related subject matter in Canada, the boundaries of these prohibitions are not always clear. It may be possible to seek patent protection for new uses, new methods of diagnosis and new cosmetic methods. In order to receive patent protection, however, any claimed invention will have to meet the criteria of novelty and non-obviousness, and will have to be fully and particularly described. ■