A method of medical treatment is not patentable in Canada. This rule arises out of a concern that granting a monopoly over a method of medically treating a patient could interfere with physicians’ skill and judgment when treating patients.\textsuperscript{1}

Method versus Use

In contrast to claims for a method of medical treatment, a claim for a use of a compound or device to medically treat a disorder may be valid, so long as the claim does not limit the skill and judgment of a physician. For example, the following claim is considered to be patent-eligible subject matter in Canada:

\textit{1. The use of compound X to treat disorder Y.}\textsuperscript{2}

The above claim goes to the use of a vendible product (i.e. compound X) to treat disorder Y and does not encompass any exercise of discretion by a physician during treatment. Instead, any decision of the physician to prescribe compound X properly lies outside of the scope of the claim.

Contrast claim 1 above with claim 2, which is invalid as a method of medical treatment:

\textit{2. Use of compound X to treat disorder Y in a range of 13 to 15 mg/kg/day.}\textsuperscript{3}

Claim 2 may be considered to encompass the skill and judgment of a physician, who is required
to decide upon an appropriate dosage of compound X from the claimed dosage range when treating a patient having disorder Y.

Where a claim such as claim 2 formally recites a “use”, but in substance incorporates within its scope the skill and judgment of a physician, courts have held the claim to be invalid as a method of medical treatment. Additionally, if a claim includes one or more specific or implied steps (i.e. “how” to implement the use), then it may no longer be considered a “use” claim. Therefore, reciting “use” language in the preamble of a claim will not be determinative of patentability. One must instead construe the full scope of the claim to determine whether it impinges on a physician’s discretion and may be considered a method of medical treatment.

Various Canadian court decisions have applied the above-outlined distinction between valid use claims and invalid method claims for medical treatments. Figure 1 highlights some of these cases. Short summaries and links to full decisions can be viewed by clicking on the respective numerical indicators in the figure.

*One of the claims at issue in decision 10 was determined to be for a use, while the other claims were determined to be for a method of medical treatment.

**Figure 1.** Decisions distinguishing between method and use claims. All decisions deal with a medical treatment of a patient (represented by left circle). Method claims (represented by right circle) are not patentable, while use claims are patentable.
Medical Treatment v. Non-Medical Treatment

Of course, a claim is not invalid simply because it recites a method instead of a use. A method claim is invalid as a method of medical treatment if it includes a step of medical treatment (i.e., medical prevention, medical treatment or surgery). Method claims which in substance define non-medical treatments or manipulations such as a method of cosmetic treatment or a diagnostic method are valid. Claims for a method of treating a natural condition (as opposed to a pathological condition) such as aging or pregnancy are also valid, as are claims for methods of manipulating animals for economic benefit.

Similar to the method versus use distinction, one must look to the substance of the claim when determining whether a method claim is for a medical treatment. For example, in one case the Federal Court of Appeal found that the claimed “method of cleaning dental plaque or stains” included both a cosmetic treatment (i.e., cleaning teeth) and a medical treatment (i.e., reduction of the incidence of caries and/or periodontal disease). The claim was held invalid for including within its scope a method of medical treatment.

Figure 2 highlights decisions distinguishing between claims for methods of medical treatment and claims for methods of non-medical treatment. Short summaries and links to full decisions can be viewed by clicking on the respective numerical indicators in the figure.

![Figure 2](image-url)

Figure 2. Decisions distinguishing between method claims for medical treatments and non-medical treatments. All decisions deal with method claims (represented by right circle). Medical treatments (represented by left circle) are not patentable, while non-medical treatments...
are patentable.

Figure 3. Figures 1 and 2 combined. The left circle encompasses claims for medical treatments and the right circle encompasses method claims. The overlapping portion of the two circles represents unpatentable subject matter.


**Decision – Dec. 22, 1972**

Claims for a surgical method of bonding of body tissues by applying glue-like compounds were directed to non-statutory subject matter. The Supreme Court noted that methods of medical treatment are not contemplated in the definition of invention as a kind of “process,” and thus the same must be true for a method of surgical treatment. Although the decision was based on s. 41 of the Patent Act which is now repealed, Tennessee has been favorably cited by the Federal Court of Appeal and the Supreme Court.


**Decision – Dec. 5, 2002**

Claims relating to the use of a known compound called AZT for the novel purpose of treating HIV constitute statutory subject matter. The Supreme Court found “the AZT patent does not
seek to “fence in” an area of medical treatment. It seeks the exclusive right to provide AZT as a commercial offering. How and when, if at all, AZT is employed is left to the professional skill and judgment of the medical profession.”


**Decision – May 26, 2005**
Claims relating to the use of a 70 mg tablet of alendronate taken once weekly for the treatment of osteoporosis constitute statutory subject matter, but the patent was invalid for obviousness. The Federal Court found that the claims were for a “vendible product having economic value”, and were thus distinguishable from claims requiring the specialized skill of a physician.

4. *Pfizer Canada Inc. v Apotex Inc.*, **2005 FC 1421**.

**Decision – Oct. 17, 2005**
A claim relating to the use of azithromycin to treat microbial infections where the physician need not have regard for whether the patient had eaten prior to administration constitute statutory subject matter. The Federal Court noted that the claim “merely instructs physicians and pharmacists that the azithromycin tablets can be administered to treat microbial infections without concern as to the patient's fed or fasted state. It doesn't instruct them on how to treat the patient.”

5. *Axcan Pharma Inc. v. Pharmascience Inc.*, **2006 FC 527**.

**Decision – March 30, 2006**
Claims relating to the use of a pharmaceutical composition administered in a daily dose of 13-15 mg/kg for the treatment of primary biliary cirrhosis were found to constitute a method of medical treatment. The Federal Court held “there is a distinction between the dosage in a capsule and a dosage range based on the patient's weight...the emphasis is on the dosage range, and a dosage range is not a vendable product.”


**Decision – June 5, 2009**
Claims relating to the administration of 50 to 300 units of botulinum toxin for treating pain associated with muscle disorders were directed to a method of medical treatment. The Patent Appeal Board found that “while a dosage range is claimed, it is the physician who must decide in any given case where in that range a particular use will fall.”


Decision – May 11, 2010
Claims relating to the use of 5-alpha reductase inhibitors in the dosage amount of 1.0 mg for the treatment of male-pattern baldness constitute statutory subject matter, but the patent was invalid for lack of novelty and double patenting. The Federal Court found that a “distinction must be made between claims that rely upon the skill and judgment of a medical practitioner and those that deal with a vendible product, be it a scalpel, X-ray machine or 1 mg tablet that are to be used or prescribed for use by such practitioner.”


Decision – Nov. 10, 2010
Claims relating to the use of galantamine in increasing amounts for the treatment of Alzheimer’s disease were directed to non-statutory subject matter. The Federal Court found that the claims merely outlined a recommendation to physicians involving inexact amounts of galantamine administered across inexact time periods, and that the patent “interferes with the ability of physicians to exercise their judgment in the administration of generic versions of the drug.


Decision – Sept. 25, 2013
Claims relating to the use of zoledronic acid at various dosage ranges and administration intervals for the treatment of osteoporosis were directed to a method of medical treatment. The Federal Court found that because each claim included either an imprecise dosage range or administration interval, the claims covered “that which lies in the skill of the medical practitioner and are thus invalid.” The decision was affirmed by the Federal Court of Appeal (2014 FCA 17).

Decision – Oct. 22, 2013
The patent related to a two-component contraceptive involving an estrogen and a gestogen. Certain claims encompassing a variety of molecular entities and dosage ranges were held to be non-statutory on the basis that they provided for a choice to be made by those prescribing the drug. One claim, which restricted the estrogen and gestogen to specific entities at specific dosages, was patentable on the basis that the claim defined a vendible product.


Decision – May 14, 2013
Claims relating to the use of a therapeutic enzyme “a-Gal.A” to treat a genetic disease known as “Fabry” were directed to a method of medical treatment. The Patent Appeal Board held that since the claims disclosed that changes to a patient’s dose and/or dosage frequency may be required during the course of treatment, the claims encompassed the skill and judgment of a physician. The Board also noted that claims directed to a dose per patient body mass attempt to monopolize an effective dosage regime and thus interfere with the ability of physicians to appropriately treat their patients.

2. *AbbVie Biotechnology Ltd. v. Canada (Attorney General), 2014 FC 1251.*

Decision – Jan. 20, 2015
Claims relating to the use of anti-human TNF antibodies on a fixed dosage and schedule for the treatment of autoimmune diseases and intestinal disorders constitute statutory subject matter. The Federal Court held that exercise of physician “skill or judgement to determine if the claimed use is appropriate for a patient” is acceptable, but exercise of physician skill “within the claim is not.” Since the claim at hand involved a defined dosage appropriate for all patients, the claim was statutory.

Cosmetic Effects

3. *Imperial Chemical Industries Ltd. v. Canada (Commissioner of Patents), [1986] FCJ No 1049 (FCA).*

Decision – April 21, 1986
Claims relating to a method of cleaning plaque from teeth were directed to non-statutory subject matter. The Federal Court found that although the cleaning method resulted in a cosmetic effect, it also produced a therapeutic effect, and therefore constituted a method of medical treatment. The Court noted that the Commissioner had committed no error in law by “characterizing the invention as having a medical function simply because it may also have another leading function, namely, a cosmetic one.”

**Natural Conditions**


**Decision – Oct. 28, 1996**
Claims relating to a method of preventing pregnancy constitute statutory subject matter. The Patent Appeal Board found that the claims were patentable since they did not involve the therapeutic treatment of a pathological condition, but instead were directed to a natural condition. Specifically, the Board held “…methods of preventing pregnancy are not methods of medical treatment in the strict sense as determined in the Tennessee-Eastman case and should therefore be considered allowable.”


**Decision – Jan. 23, 1997**
Claims relating to a method of treating skin cells to reduce wrinkles constitute statutory subject matter. The Patent Appeal Board noted “aging is a natural condition of the human body not a disease so that the method should not be considered as a method of medical treatment since no pathological condition is cured.”

6. *Commissioner’s Decision No. 1388 (unreported).*

**Decision – Aug. 5, 2015**
The claims as purposively construed were directed to a method for delivery of a healing substance to a targeted place in the gastrointestinal tract. The Board held the claims to be non-statutory on the basis that “[t]he clear intent of the method, taken from the use of the term “healing” in the claims as well as from the specification as a whole, is the therapeutic benefit to a subject.”

   **Decision – Dec. 16, 1999**
   Claims relating to an apparatus for performing ophthalmological surgery on the cornea of the eye constitute statutory subject matter. The Federal Court held that the claims did not pose a limitation upon the surgeon’s skills, since all that was required of the surgeon was to prepare the patient, enter basic measurements into the computer, and start the machine. The Court also noted that the apparatus was used to treat human conditions, and not diseases.

**Diagnostic Methods**


   **Decision – March 23, 1973**
   Claims relating to a method for determining the identity of antigens in an aqueous fluid of a living animal constitute statutory subject matter. The Patent Appeal Board found that the invention encompassed by the claims “lies in the field of a ‘useful art’ as opposed to a ‘fine art’, ‘abstract theorem’ or ‘scientific principle’.” Furthermore, the Board noted that the invention was “reproducible and controllable to produce the desired result whenever it is worked or used.”


   **Decision – Dec. 19, 1974**
   Claims relating to applying an electrically conducting cream in the performance of an electrocardiogram constitute statutory subject matter. The Supreme Court found that inventions whose primary use is intended for medicine are not patentable, while inventions that are primarily directed towards diagnostic methods are patentable, even if the invention has a secondary use for a medical purpose.

10. **Application for Patent of Goldenberg (1988), 22 CPR (3d) 159 (Commissioner’s Decision No. 1119).**

    **Decision – May 13, 1988**
    Claims relating to a method of locating a tumour through the administration of radio-labelled
antibody substances to the body constitute statutory subject matter. The Patent Appeal Board rejected the examiner's position that since the antibody modifies the metabolism of the human body, it therefore constituted a method of medical treatment. The Board noted Tennessee stands for the notion that only “patents for medical treatment in the strict sense must be excluded under the Patent Act.”

1. **Kevin McIntyre Patent Application No. 502,082 (1992), 53 CPR (3d) 532 (Commissioner’s Decision No. 1172)**

   **Decision – Feb. 7, 1992**

   Claims relating to a method of evaluating the mechanical condition of a heart constitute statutory subject matter. The Patent Appeal Board noted that the method at issue “may constitute a voluntary effort on the part of the patient being diagnosed, but there is no therapeutic method derived from this maneuver, nor does the act of expiring require any special skill or training.

2. **Commissioner’s Decision No. 1108 (unreported).**

   **Decision – Aug. 26, 1987**

   Claims relating to a process to detect blood pathogens in which the blood is drawn from a patient, passed through an adsorbent device, and is returned to the patient constitute statutory subject matter. The Patent Appeal Board found that the claimed method was not any different from any other in vitro diagnostic method. The Board noted “no treatment of the blood is contemplated nor effected. Moreover, no curing or alteration of the metabolism of the body is obtained.”

**Manipulation of Animals for Economic Benefit**


   **Decision – July 16, 2015**

   Claims for a method of administering an antibiotic to cattle, swine, sheep or goats were held to be unpatentable as a method of medical treatment. The Patent Appeal Board found that “although proposed claim 1 is directed to a method of “administering” a drug, it is our view that the skilled person would understand, in light of the specification as a whole, that the result of administration is still the treatment or prevention of a pathological condition (i.e., a
bacterial infection such as bovine respiratory disease or swine respiratory disease).

4. Application No. 862,758 (1970), 4 CPR (2d) 24 (Commissioner’s Decision No. 33).

Decision – Nov. 9, 1970
Claims relating to a process for increasing the rate of growth of swine using a dosage range of monosodium glutamate constitute statutory subject matter. The Patent Appeal Board found “the physiological process defined by [the] applicant in his claims is one that is reproducible and is capable of control within reasonable limits, and furthermore it results in an enhanced vendible product.”

5. Application No. 954,851 of Biehl (1971), 5 CPR (2d) 201 (Commissioner’s Decision No. 63).

Decision – April 13, 1971
Claims relating to a method for the timed controlled feeding of domestic animals to increase their mass constitute statutory subject matter. The Patent Appeal Board held that a method of improving the yield of a vendible product falls within the meaning of invention under the Patent Act. The Board held that the claims represented such a method, and were therefore patentable.

Surgery v. Non-Surgery

6. Commissioner’s Decision No. 1082 (unreported).

Decision – Aug. 13, 1986
Claims relating to inserting a catheter into a body for intravenous therapy and hyperalimentation were directed to non-statutory subject matter. The Patent Appeal Board found that the claims fell within the professional field of surgery and medical treatment, and thus involved the professional skill of a medical practitioner. The Board noted “the claims do contain steps of medical treatment concerning the incision of a body, insertion of a catheter, and clinical treatment of a body.”

[1] For example, see Janssen Inc v. Mylan Pharmaceuticals ULC, 2010 FC 1123 at para 51, where Justice Barnes refers to “the problem of imposing a monopoly over the prescribing practices of the medical profession”.

use claims for statutory subject-matter evaluation": https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03919.html

[3] Ibid.
[5] Ibid at section 17.02.03.
[6] See decision 13 in Figure 2.
[7] See decisions 18-22 in Figure 2.
[8] Commissioner’s Decision No. 1213 (PAB) – see decision 15 in Figure 2.
[9] Commissioner’s Decision No. 1209 (PAB) – see decision 14 in Figure 2.
[10] See decisions 23-25 in Figure 2.
[11] Imperial Chemical Industries Ltd v. Canada (Commissioner of Patents), [1986] FCJ No 1049 (FCA) [see decision 13 in Figure 2].

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