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Prohibiting Medical Method Patents: A Criticism of the Status Quo

Mark S. Wilke*

Methods of medical treatment are not patentable in Canada. This means that inventions involving the performance of surgery, administration of medicine, or extraction of fluids or tissue for diagnostic tests cannot directly be protected under the current patent regime. However, this prohibition is not an absolute ban. Many medical innovations are patentable, including surgical tools and devices, drugs and other chemical compounds, medical “uses”, diagnostic assays and methods of treating “natural” conditions. The practical reality is that the distinction between what is and what is not patentable is poorly defined. This uncertainty presents a steep challenge for inventors and patent agents in preparing patent claims that appropriately encapsulate a particular medical invention without claiming prohibited subject matter. This confusion also hinders the public and would-be inventors wishing to navigate the patent landscape.

Part I of this paper entitled “*Legal Basis for the Prohibition*” summarizes the statutory and jurisprudential basis for prohibiting medical method patents. Part II entitled “*Patentability of Medical Methods in Practice*” discusses how this prohibition has been applied by courts and the Commissioner of Patents. Inconsistencies in its application are highlighted and practical guidance is provided on how to protect aspects of medical inventions without triggering the prohibition. Part III entitled “*Criticism of the Status Quo*” argues that the rationale for prohibiting medical method patents is tenuous, based more on public policy than the *Patent Act*.¹ Based on the irregular application of the prohibition revealed in Part II and the criticisms raised in Part III, legislative reform is recommended.

I. LEGAL BASIS FOR THE PROHIBITION

Methods of medical treatment are not expressly prohibited in the *Patent Act*. In fact, it is not obvious from the wording of the *Patent Act* that medical methods were intended to be banned at all. As will be discussed below, the leading common law authority for the prohibition is primarily based on a repealed provision of the *Patent Act*. What remains is the somewhat tenuous decision to exclude medical methods as non-commercial activities which do not fit within the statutory definition of “invention”.

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¹ *Patent Act*, RSC 1985, c P-4.

(a) Patentable Subject Matter

A patent grants the exclusive right to make, use, sell, and import a patented invention for twenty years.² In exchange for this valuable monopoly, the patentee must disclose how to make and use the patented invention. This *quid pro quo* is intended to encourage innovation by facilitating the prompt sharing of new technology with the public; the public may immediately learn from the invention as well as freely exploit the invention once the patent expires.³

In Canada, these patent rights arise from the *Patent Act*. As expressed by the Supreme Court of Canada, “There is no inherent common law right to a patent. An inventor gets his patent according to the terms of the *Patent Act*, no more and no less”.⁴ For an invention to be eligible for a patent it must not only be *novel*, *non-obvious*, and *useful* (or have *utility*),⁵ it must also fall within appropriate statutory *subject matter* for a patent. The definition of “invention” in section 2 of the *Patent Act* suggests that patentable subject matter includes “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.” In *Harvard College v. Canada (Commissioner of Patents)*, the Supreme Court of Canada noted that this definition reveals that certain subject matter is excluded from patentability:

[T]he definition of “invention” in the *Patent Act* is broad. Because the *Act* was designed in part to promote innovation, it is only reasonable to expect the definition of “invention” to be broad enough to encompass unforeseen and unanticipated technology. I cannot however agree with the suggestion that the definition is unlimited in the sense that it includes “anything under the sun that is made by man”. In drafting the *Patent Act*, Parliament chose to

² Section 42 of the *Patent Act* grants the exclusive right to make, use, and sell the invention. The exclusive right to *import* patented products or products prepared using patented processes or machines is not expressly provided by the *Patent Act*, but is clearly accepted at common law (e.g. *Société des usines chimiques Rhône-Poulenc v. Jules R. Gilbert Ltd.* (1967), 35 Fox Pat. C. 174 at para. 73 (Can. Ex. Ct.); affirmed [1968] S.C.R. 950, 69 D.L.R. (2d) 353). Sections 44 and 45 of the *Patent Act* specify that patents filed on or after 1 October 1989 last for twenty years from the filing date, while patents filed before 1 October 1989 expire seventeen years from the date on which the patent was issued.

³ There is some debate as to whether or not or to what extent patents actually foster innovation in society (see Bronwyn H. Hall, “Patents and Patent policy” (2007) 23(4) Oxford Rev. Econ. Pol. 568). Two prominent questions are (1) whether patents, while helpful in investment heavy industries such as the pharmaceutical and biotechnology sectors, are perhaps less productive in other industries, such as the information technology sector; and (2) how do patent laws affect technology transfer to developing countries?

⁴ *Farbwerke Hoechst A.G. v. vormals Meister Lucius & Bruning v. Canada (Commissioner of Patents)*, [1964] S.C.R. 49 at 57, 41 C.P.R. 9.

⁵ The requirements for novelty and utility (or “usefulness”) are derived from s 2 of the *Patent Act*, which defines “invention” as “any new and useful art” [emphasis added]. The requirement for non-obviousness (or “inventiveness”) is derived from s. 28.3 of the *Act*.

adopt an exhaustive definition that limits invention to any “art, process, machine, manufacture or composition of matter”. Parliament did not define “invention” as “anything new and useful made by man”. *By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act.*⁶

Similarly, the Supreme Court of Canada commented in *Monsanto Canada Inc. v. Schmeiser* that “[c]laims that would otherwise be valid may be limited by statutory provisions or by jurisprudence”.⁷ The only explicit statutory exclusion of subject matter is found in section 17(8) of the *Patent Act*, which identifies a “mere scientific principle or abstract theorem” as non-patentable subject matter. In addition, the courts have identified various other subject matter as inappropriate for patenting, including professional skills,⁸ arts or processes lacking in commercial value,⁹ higher life forms,¹⁰ and methods of medical treatment.¹¹

(b) Art & Process

From the definition of “invention” in section 2 of the *Patent Act*, any “art” or “process” may be patentable, so long as it is new, useful and not obvious. However, neither the term “art” nor the term “process” is defined in the *Patent Act*. From case law, the term “art” has a broad meaning that includes the term “process”.¹² The bygone Exchequer Court of Canada defined “art” as follows:

An art or operation is an act or series of acts performed by some physical agent upon some physical object and producing in such object some change either of character or of condition. It is abstract in that, it is capable of contemplation of the mind. It is concrete in that it consists in the application of physical agents to physical objects and is then apparent to the senses in connection with some tangible object or instrument.

In the earlier development of patent law, it was considered that an invention must be a vendible substance and that unless a new mode of operation created a new substance the invention was not entitled to a patent, but if a new operation created a new substance the patentable invention was the sub-

⁶ *Harvard College v. Canada (Commissioner of Patents)*, 2002 SCC 76, [2002] 4 S.C.R. 45 at para. 158, [2002] S.C.J. No. 77 [emphasis added].

⁷ *Monsanto Canada Inc. v. Schmeiser*, 2004 SCC 34, [2004] 1 S.C.R. 902 at para. 132, 239 D.L.R. (4th) 271 [Schmeiser].

⁸ *Lawson v. Canada (Commissioner of Patents)* (1970), 62 C.P.R. 101 (Can. Ex. Ct.) [Lawson].

⁹ *Shell Oil Co. v. Canada (Patent Commissioner)*, [1982] 2 S.C.R. 536, 142 D.L.R. (3d) 117 [Shell Oil cited to SCR]; *Progressive Games Inc. v. Canada (Commissioner of Patents)* (1999), 3 C.P.R. (4th) 517, (sub nom. *Progressive Games Inc. v. Commissioner of Patents*) 177 F.T.R. 241 (Fed. T.D.) [*Progressive Games* cited to C.P.R.], affirmed 9 C.P.R. (4th) 479, 265 N.R. 392 (Fed. C.A.).

¹⁰ *Harvard College*, *supra* note 6; *Schmeiser*, *supra* note 7.

¹¹ *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*, [1974] S.C.R. 111, 33 D.L.R. (3d) 459 [*Tennessee Eastman* cited to SCR].

¹² *Progressive Games*, *supra* note 9 at para. 13.

stance and not the operation by which it was produced. This was the confusion of the idea of the end with that of means. However, *it is now accepted that if the invention is the means and not the end, the inventor is entitled to a patent on the means.*¹³

The Supreme Court of Canada case of *Shell Oil Co. v. Canada (Commissioner of Patents)* is considered the leading Canadian authority on the meaning of the term “art” for the purposes of the *Patent Act*. According to the Court, the term “art” has the following characteristics:

- (i) it is not a disembodied idea but has a method of *practical application*;
- (ii) it is a new and innovative method of *applying skill or knowledge*; and
- (iii) it has a result or effect that is *commercially useful*.¹⁴

Most medical methods arguably fit this definition. A medical method is not a disembodied idea. Surgical procedures, drug administration, tissue extraction, etc. all have the practical application of either treating a medical condition or modifying a patient’s body for cosmetic or other reasons. Assuming novelty, a medical method requires the skill or knowledge of a medical practitioner or other person to be performed. In some cases, only a minimal degree of skill or knowledge will be necessary and in others, a high level of expertise will be required. The trickiest stage of the test is part (iii), but it is at least arguable that a medical method “has a result or effect that is commercially useful”. There is a clear commercial result in that a medical practitioner is paid for performing a medical method. This is true both within the public health care system (where government funds employ medical practitioners) and private clinics (where individuals and insurance companies pay for certain medical services). For example, a new method for performing a rhinoplasty appears to do something that is commercially useful; it facilitates creating a new nose for a paying customer, regardless of whether that customer is the patient or the government.

A “process” is more specific than an “art” in that “[a] process implies the application of a method to a material or materials.”¹⁵ Moreover, a process that consists of applying a known method to known materials may still be patentable provided it is non-obvious and produces a new and useful result.¹⁶ The *Manual of Patent Office Practice* (“MOPOP”), prepared by the Canadian Intellectual Property Office (“CIPO”), describes a “process” as “a mode or method of operation by which a result or effect is produced by physical or chemical action, by the operation or application of some element or power of nature or one substance to another.”¹⁷ As with the more general term “art”, methods of medical treatment appear to fit

¹³ *Lawson*, *supra* note 8 at 109-10, cited in *Shell Oil*, *supra* note 9 at para. 42.

¹⁴ *Shell Oil*, *ibid*, rephrased in *Progressive Games*, *supra* note 9 at para. 16.

¹⁵ *Canada (Commissioner of Patents) v. Ciba Ltd.*, [1959] S.C.R. 378 at para. 15, 18 D.L.R. (2d) 375 [*Ciba* cited to S.C.R.].

¹⁶ *Ibid*.

¹⁷ Canadian Intellectual Property Office, “Manual of Patent Office Practice” (December 2010), s 12.02.02 [MOPOP] (the author is well aware that the opinions of CIPO do not constitute law in Canada, but the legal interpretation of CIPO is at least helpful in delineating the scope of the law).

within the definition of “process”. For example, a surgical procedure can be described as the application of a method to the materials of the human body, namely human organs or tissues.

Given the above discussion, medical methods *arguably* fit within “art” and “process” and could therefore be considered appropriate statutory subject matter for a patent. The courts apparently disagree; they have consistently found medical methods non-patentable on the basis that they do not fit within the definition of “invention” in section 2 of the *Patent Act*. The most authoritative statement on this matter was made by the Supreme Court of Canada in *Tennessee Eastman Co. et al. v. Canada (Commissioner of Patents)*.¹⁸

(c) Professional Arts

Tennessee Eastman concerned claims for a method of sealing surgical incisions or wounds in living tissue with a known chemical compound; an application of the compound that was novel. At the Exchequer Court level, the application was refused as being directed to a non-economic endeavour:

In my view the method here does not lay in the field of the manual or productive arts nor, when applied to the human body, does it produce a result in relation to trade, commerce or industry or a result that is essentially economic. The adhesive itself may enter into commerce, and *the patent for the process, if granted, may also be sold and its use licensed for financial considerations, but it does not follow that the method and its result are related to commerce or are essentially economic in the sense that those expressions have been used in patent case judgments. The method lies essentially in the professional field of surgery and medical treatment of the human body, even although it may be applied at times by persons not in that field.* Consequently, it is my conclusion that in the present state of the patent law of Canada and the scope of subject-matter for patent, as indicated by authoritative judgments that I have cited, the method is not an art or process or an improvement of an art or process within the meaning of s. 2(d) of the *Patent Act* [R.S.C. 1952, c. 203].¹⁹

Accordingly, the Exchequer Court distinguished processes that produce a product or a commercially useful result from non-economic professional arts, which includes methods of medical treatment. The former method is patentable, while the latter method is not.

This decision mirrored another decision of the Exchequer Court, *Lawson v. Canada (Commissioner of Patents)*, which was decided the same year as *Tennessee Eastman*.²⁰ In *Lawson*, the Exchequer Court rejected a patent application for a method of subdividing parcels of land into “champagne glass” configurations, as opposed to the usual rectangular lots. Citing from a decision of the High Court of Australia dealing with a method of eradicating weeds, the Court noted that only economically useful arts or methods are patentable and surmised in *obiter* that

¹⁸ *Tennessee Eastman*, *supra* note 11.

¹⁹ *Tennessee Eastman Co. v. Canada (Commissioner of Patents)* (1970), 62 C.P.R. 117 at para. 49, [1970] Ex. C.J. No. 14 (Can. Ex. Ct.) [emphasis added].

²⁰ *Lawson*, *supra* note 8.

medical methods were essentially non-economic:

The point is that a process . . . must be one that offers some advantage which is material, in the sense that the process belongs to a useful art as distinct from a fine art . . . that its value to the country is in the field of economic endeavour. (The exclusion of methods of surgery and other processes for treating the human body may well lie outside the concept of invention because the whole subject is conceived as essentially non-economic . . .).²¹

The Court ultimately concluded that professional skills are generally non-patentable art:

It is obvious . . . that professional skills are not the subject-matter of a patent. If a surgeon were to devise a method of performing a certain type of operation he cannot obtain an exclusive property or privilege therein. Neither can a barrister who has devised a particular method of cross-examination or advocacy obtain a monopoly thereof so as to require imitators or followers of his methods to obtain a licence from him.²²

Likening the process of subdividing land to a professional skill, the Court held that the claims at issue did not constitute patentable subject matter.²³ Accordingly, *Lawson* stands for the proposition that professional skills, such as a method of subdividing land, the oratory skills of a barrister and the medical know-how of a surgeon, are essentially “non-economic” arts and thus outside the statutory definition of “invention”.

(d) Repealed Subsection 41(1) of the Patent Act

Tennessee Eastman was appealed to the Supreme Court of Canada.²⁴ The Court pointed out that methods of medical treatment often include factors such as determining proper drug dosages, methods of drug administration and the consideration of counter-indications. The Court decided that methods incorporating these factors were not appropriate subject matter for a patent on the basis of subsection 41(1) of the 1952 *Patent Act*,²⁵ a provision that has since been repealed:

In the case of a drug, the desirable effects must be ascertained as well as the undesirable side effects. *The proper doses have to be found as well as methods of administration and any counter-indications.* May these therapeutic data be claimed in themselves as a separate invention consisting in a method of treatment embodying the use of the new drug? I do not think so, and it appears to me that s. 41 definitely indicates that it is not so.²⁶

Subsection 41(1) of the 1952 *Patent Act* reads as follows:

In the case of inventions relating to substances prepared or produced by

²¹ *Ibid* at 110-11, citing from *National Research Development Corporation's Application*, [1961] RPC 135 at 145 (Australia).

²² *Ibid* at 111.

²³ *Ibid*.

²⁴ *Tennessee Eastman*, *supra* note 11.

²⁵ *Patent Act*, R.S.C. 1952, c. 203.

²⁶ *Tennessee Eastman*, *supra* note 11 at 207 [emphasis added].

chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents.

This meant that one could only claim chemically produced medical substances to the extent that they were prepared by the specific *process* actually described in the patent application, *i.e.* so-called product-by-process claims. In the view of the Supreme Court of Canada, this provision implied that a new *method* of using a known compound cannot be claimed because a method claim cannot be made apart from the substance itself. To view it otherwise would provide a way of circumventing subsection 41(1) because the patentee would have a monopoly on how the substance was used, regardless of how it was made:

In my view, this necessarily implies that, with respect to such substances, the therapeutic use cannot be claimed by a process claim apart from the substance itself. Otherwise, it would mean that while the substance could not be claimed except when prepared by the patented process, *its use however prepared could be claimed as a method of treatment*. In other words, if a method of treatment consisting in the application of a new drug could be claimed as a process apart from the drug itself, then the inventor, by making such a process claim, would have an easy way out of the restriction in s. 41(1).²⁷

Accordingly, the Supreme Court of Canada did not reject the claimed medical method on the basis that it was a “professional skill”, as reasoned in the two aforementioned Exchequer Court decisions. Instead, the Court interpreted the patentability of medical methods in the context of subsection 41(1). This would appear to limit the applicability of *Tennessee Eastman* to a narrow subset of medical methods which relate to products that are both (1) made by a chemical process and (2) intended for medicine. Furthermore, since subsection 41(1) was repealed in 1991,²⁸ it bears asking whether *Tennessee Eastman* remains good law at all.

(e) Following *Tennessee Eastman*

The Federal Court of Appeal addressed these concerns in *Imperial Chemical Industries v. Commissioner of Patents*.²⁹ The Applicant had argued that the *Tennessee Eastman* decision did not provide precedent that *all* medical methods were non-patentable: “[*Tennessee Eastman*] only prohibits the patentability of medical methods which utilize materials prohibited pursuant to subsection 41(1), namely, materials produced by chemical processes.”³⁰ The Court disagreed, quoting the fol-

²⁷ *Ibid* at para. 14 [emphasis added].

²⁸ Bill C-22, *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, 2nd Sess, 33rd Parl, 1986-1987, cl. 28 (On 17 November 1987, s 41(1) of the *Patent Act* was renumbered to s 39(1) and then repealed four years later, pursuant to s 39(1.1), which allowed pharmaceutical products to be patented directly, regardless of the process used to make them).

²⁹ *Imperial Chemical Industries Ltd. v. Canada (Patent Commissioner)*, [1986] 3 F.C. 40, 9 C.P.R. (3d) 289 (C.A.) [*Imperial Chemical* cited to FC].

³⁰ *Ibid* at para. 9.

following passage from *Tennessee Eastman*:

Having come to the conclusion that methods of medical treatment are not contemplated in the definition of “invention” as a kind of “process”, the same must, on the same basis, be true of a method or surgical treatment.³¹

According to the Federal Court of Appeal, this meant that the scope of the *Tennessee Eastman* decision extends beyond cases governed by subsection 41(1):

In my opinion, this is a clear and unequivocal statement that “methods of medical treatment are not contemplated in the definition of ‘invention’ as a kind of ‘process’”. That was the sole issue before the Court and it is here answered in unmistakable and unambiguous language. Accordingly, in my view, the force of that pronouncement cannot be restricted merely to factual situations where subsection 41(1) of the Act applies.

However, this interpretation does not acknowledge that subsection 41(1) was the only *stated* basis for finding that medical methods were not patentable. The stark omission of “professional arts” from the Supreme Court of Canada decision of *Tennessee Eastman* implies that only the result of the Exchequer Court decision was affirmed, not the reasons. The Supreme Court of Canada seemed to acknowledge this point in *Harvard College v. Canada (Commissioner of Patents)*, where it was noted that “[i]n *Tennessee Eastman Co.* . . . the determination that a method for bonding incisions and wounds was not an ‘art’ or a ‘process’ was based *primarily* on the fact that the bonding material itself when prepared for medical purposes would not be patentable under what was then s. 41 of the *Patent Act*”³² While usage of the word “primarily” here suggests that the Court did consider additional *non-stated* grounds, the Supreme Court of Canada notably did not state that this was due to the “professional skill” rationale raised by the Exchequer Court in *Lawson* and *Tennessee Eastman*.

More recently, the Supreme Court of Canada has indicated its approval of the reasoning used by the Exchequer Court in *Tennessee Eastman*. In *Shell Oil*, the Supreme Court of Canada made the following statement with explicit reference to the fact that the lower court decision was affirmed by Canada’s highest court:

In *Tennessee Eastman Co. v. Commissioner of Patents* (1970), 62 C.P.R. 117 (Ex. Ct.); aff’d [1974] S.C.R. 111 . . . The applicant appealed to the Exchequer Court and the issue there was limited to the question whether this use of the adhesive fell within the meaning of new and useful “art” or “process” within the meaning of the *Patent Act*. It was held that it did not for the reasons given by the Commissioner. *In effect, it was not patentable because it was essentially non-economic and unrelated to trade, industry or commerce. It was related rather to the area of professional skills.*³³

The above quote specifically references the Exchequer Court decision, not that of the Supreme Court of Canada. This quote was cited by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*, again indicating that the common law finds medical methods non-patentable because they are non-economic

³¹ *Ibid* at para. 11, citing *Tennessee Eastman*, *supra* note 11 at 119.

³² *Harvard College*, *supra* note 6 at para. 145 [emphasis added].

³³ *Shell Oil*, *supra* note 9 at para. 41.

professional arts:

The [*Tennessee Eastman*] decision was based on the former s. 41 of the *Patent Act*, now repealed. The Court concluded that the method (apart from the compounds) was not patentable. The policy rationale, as explained by Wilson J. in *Shell Oil* . . . was that the unpatentable claim was

. . . essentially non-economic and unrelated to trade, industry, or commerce. It was related rather to the area of professional skills.³⁴

Given these indications and the clear position of the Federal Court of Appeal, the non-patentability of methods of medical treatment appears to generally be accepted at common law. However, such a broad prohibition may encapsulate many medically-related inventions that are not necessarily professional arts or otherwise essentially non-economic in character or result. This issue is discussed in Part II.

II. PATENTABILITY OF MEDICAL METHODS IN PRACTICE

“Methods of medical treatment” is a broad term which could arguably include any specialized procedure, skill or technique performed in the course of treating a patient. Recall that “methods” are patentable in general, but that the common law draws a distinction between methods that constitute a “manual or productive art” (such as a process to produce a product) and those that are essentially a non-economic endeavour (such as a “professional skill”). The former is patentable; the latter is not. This means that some methods related to medicine are still patentable. The tricky part is discerning between a prohibited method of medical treatment and a patentable method that is merely related to medicine. The goal of this section is to assess the scope of the prohibition by reviewing case law and the decisions of the Commissioner of Patents.³⁵ Such an analysis reveals that this scope is poorly defined, making it difficult to predict whether or not a particular patent claim will be rejected.

While assessing the patentability of a claim is highly fact dependent, a claim is generally at risk of being rejected as a method of medical treatment where it recites any of the following:

1. surgery, physiotherapy, or any other manual manipulation of the patient;
2. administration of drugs or other compounds to the patient;
3. extraction of blood or other tissues from the patient for diagnostic tests; or
4. choosing proper dosages or other analytical methods.³⁶

³⁴ *Apotex Inc v. Wellcome Foundation Ltd.*, 2002 SCC 77, [2002] 4 S.C.R. 153 at para. 49, 21 C.P.R. (4th) 499 [*Wellcome* cited to S.C.R.].

³⁵ Because only a handful of such cases have come before the courts, it is instructive to additionally review decisions of the Commissioner of Patents. While Commissioner decisions have no precedential value, the Commissioner’s discussion of the relevant jurisprudence and its application to factual scenarios illustrates how these situations may play out in the courts.

³⁶ MOPOP, s. 17.02.03.

Despite this, a questionable claim may yet be patentable. For example, methods for treating “natural” conditions are not prohibited.³⁷ Unfortunately, the distinction between “natural” and “pathological” is often unclear. Furthermore, claims that do not require a medical practitioner’s skill or judgment are more likely to be found patentable than claims that do.³⁸ Even minimal discretion on the part of the medical practitioner appears sufficient to reject the claim, even where the same degree of discretion on the part of a non-medical professional would not condemn the claim. Similarly, a claim to a drug that recites a specific dosage regime may be patentable so long as there are no steps requiring professional judgment.³⁹ Additionally, diagnostic methods may be patentable, provided they are neither therapeutic nor include steps involving the collection of blood or tissue from the patient.⁴⁰ Finally, the “use” of a compound or device for treating a disease or condition is not prohibited as a medical method.⁴¹ Each of these situations is discussed in detail below; inconsistencies in the case law and Commissioner decisions are highlighted and practical advice is provided for drafting non-prohibited patent claims.

(a) Natural Conditions & Cosmetic Treatments

A number of court and Commissioner decisions have addressed the issue of whether or not methods of treating *natural* or *non-pathological* conditions are patentable. For example, is a method which is entirely *cosmetic* patentable since it possesses no *therapeutic* value?

In *Re Revici*, the Commissioner rejected claims teaching a method of preventing or reducing the desire for smoking tobacco in humans by administering a certain composition.⁴² The applicant argued that a desire to smoke was not an ailment and the composition used in the method was not a medicine.⁴³ The Commissioner held that any substance used for modifying organic functions in man or animal was a medicine in the broad sense, and thus any method involving manipulation of organic function constitutes a medical treatment.⁴⁴

Similarly, in *Commissioner Decision #1114* the Commissioner rejected claims to a cosmetic method of increasing skin cell turnover without causing skin irritation

³⁷ *General Hospital Corp. Patent Application No. 532,566, Re* (1996), 74 C.P.R. (3d) 544 (Can. Pat. App. Bd. & Pat. Commr.) [*Re General Hospital*].

³⁸ *Commissioner Decision #1086* (15 August 1986) online: <<http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/1086/summary.html?query=1086+%3Cin%3E+comdecnumber&start=1&num=10>>.

³⁹ *Axcan Pharma Inc. v. Pharmascience Inc.*, 2006 FC 527, 50 C.P.R. (4th) 321, 291 F.T.R. 160 (Eng.) [*Axcan*].

⁴⁰ *Application for Patent of Goldenberg, Re* (1988), 22 C.P.R. (3d) 159 (Can. Pat. Commr.) [*Re Goldenberg*].

⁴¹ *Wellcome*, *supra* note 34.

⁴² *Revici, Re* (1981), 71 C.P.R. (2d) 285 at para. 1 (Can. Pat. App. Bd. & Pat. Commr.).

⁴³ *Ibid* at paras. 2-3.

⁴⁴ *Ibid* at para. 5.

by applying various formulations to the skin.⁴⁵ The Commissioner decided that even though the claims were phrased in terms of a cosmetic method, they are nevertheless primarily directed to a medical method. The basis for this appeared to be that the method comprised treating *living* skin tissue, as opposed to *dead* tissue, like hair or nails, by removing dead cells from the outer layer of the skin so as to promote new skin cell growth.

More recent Commissioner decisions have taken a narrower view of medical methods. For example, *Re General Hospital Corp.* concerned claims directed at “[a] method of preventing pregnancy in a female mammal,” which comprised of administering certain compounds at specified times.⁴⁶ The applicant argued that since pregnancy is not a disease, but a “natural condition”, a method of preventing pregnancy is not a medical method as no pathological condition is cured. The Commissioner approved the claims, citing the Supreme Court of Canada in *Burton Parsons Chemicals v. Hewlett-Packard*, where the use of a conductive cream was held not to be a medical method because use of the cream for attaching electrodes to the skin during surgery was not necessarily “the main or primary use of the product.”⁴⁷ The Commissioner stated that even where prevention of a potentially damaging pregnancy could have beneficial effects to a female, the main or primary use of the invention was not as a method of medical treatment.⁴⁸

Cosmetic claims have similarly been interpreted narrowly in more recent years. In *Re Senentek plc*, the Commissioner accepted method claims directed to reducing the adverse effects of aging so as to reduce wrinkles.⁴⁹ The following claim is representative of those at issue:

A method for ameliorating the adverse effects of aging on mammalian cells, comprising contacting mammalian cells with a cosmetic composition that contains an effective concentration of a 6-(substituted amino) purine cytokinin, wherein:

the cells are on the surface of a living animal; and
the concentration is sufficient to ameliorate the adverse effects of aging of said cells, whereby the rate of development of characteristics of said cells that are associated with cellular aging is reversed or slowed, and the growth rate and total proliferative capacity of the cells subsequent to said contacting is substantially the same as prior to said contacting.⁵⁰

The Commissioner decided that even though the claimed method causes

⁴⁵ *Commissioner Decision #1114* (20 April 1988), online: <<http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/1114/summary.html?query=1114+%3Cin%3E+comdecnumber&start=1&num=10>>.

⁴⁶ *Re General Hospital*, *supra* note 37 at para. 7.

⁴⁷ *Ibid.*, citing *Burton Parsons Chemicals Inc. v. Hewlett-Packard (Canada) Ltd.* (1974), [1976] 1 S.C.R. 555 at 570, 54 D.L.R. (3d) 711 [*Burton Parsons* cited to S.C.R.].

⁴⁸ *Ibid.* at para. 13.

⁴⁹ *Application for Patent by Senentek plc, Re* (1997), 77 C.P.R. (3d) 321 (Can. Pat. App. Bd. & Pat. Commr.) [*Re Senentek*].

⁵⁰ *Ibid.* at para. 3.

changes in skin cell metabolism which retard the aging process, aging is a natural condition, not a disease. Accordingly, the method was not considered a method of medical treatment since no pathological condition is cured.⁵¹

The judiciary appear to share the more recent view of the Commissioner of Patents. In *Visx Inc. v. Nidek Co.*, the Trial Division of the Federal Court held that claims related to a device for use in laser eye surgery were not medical methods partly on the basis that the conditions to be treated by the claimed device were not diseases: “[I]n accordance with Dr. Sher’s evidence, myopia, hypermyopia and astigmatism are not diseases, they are human conditions.”⁵²

The Federal Court of Appeal provided the most authoritative statement on this matter in *Imperial Chemical*. The invention at issue was for a method of cleaning teeth by applying aqueous compositions which were not produced by a chemical process. The method apparently had two purposes:

- (1) the *medical* purpose of removing dental plaque and reduce the likelihood of cavities and periodontal disease; and
- (2) the *cosmetic* purpose of removing stains.

Citing *Burton Parsons* as authority, the applicant argued that the claimed method was not in its “main and primary function” a medical method because it clearly had a cosmetic purpose.⁵³ The Court rejected this argument and held that the claims were directed to a medical method. The fact that one of the leading functions of the claimed method had a medical purpose was sufficient to classify it as non-patentable subject matter: “I see no error in law . . . in characterizing the invention as having a medical function simply because it may also have another leading function, namely, a cosmetic one.”⁵⁴ The Federal Court of Appeal clarified that, in its view, *Burton Parsons* was only relevant to claims subject to subsection 41(1) of the *Patent Act*. Moreover, even assuming that *Burton Parsons* did apply, the Court reasoned that it is possible to have more than one “main or primary” purpose in a product.⁵⁵

According to CIPO in MOPOP, the state of the law is such that claims will be considered methods of medical treatment where they provide “a practical therapeutic benefit to a subject, . . . cure, prevent or ameliorate an ailment or pathological condition, or treat a physical abnormality or deformity such as by physiotherapy or surgery.”⁵⁶ However, the aforementioned jurisprudence has not provided this level of specificity. It is more appropriate to conclude that claims to methods that primarily treat physiological conditions which cannot be characterized as diseases are patentable. Notably, treating a disease need only be a leading function of the invention, not the only or primary function, in order for that invention to be non-

⁵¹ *Ibid* at para. 7.

⁵² *Visx Inc. v. Nidek Co.* (1999), 3 C.P.R. (4th) 417 at para. 173, 181 F.T.R. 22 (Fed. T.D.) [*Visx* cited to C.P.R.], ; affirmed 2001 FCA 215, 16 C.P.R. (4th) 251 (although the issue of non-patentable medical methods was not raised in the appeal).

⁵³ *Ibid* at para. 5.

⁵⁴ *Ibid* at para. 8.

⁵⁵ *Ibid* at paras. 6–8.

⁵⁶ MOPOP, s. 17.02.03.

patentable.⁵⁷

Given the above, it appears that methods relating to a physiological condition which can be categorized as “natural” may be patentable. This includes methods for ameliorating human deficiencies such as myopia. This perspective marks a divergence from earlier Commissioner decisions, such as *Re Revici* and *Commissioner Decision #1114*, where method claims were not patentable for merely involving the manipulation of living organic functions. A useful practical example of this principle was presented in *Biotechnology and Chemical Patent Practice in Canada — A Practical Guide*:

[I]t is entirely natural with age for blood pressure to increase, bones to become brittle, and hair to fall out. Following this logic, a method for treating increased blood pressure in a 65-year-old would fall within the ambit of *Re Senentek* as a natural condition. However, treating high blood pressure in a juvenile may be a pathological treatment and, hence, unpatentable.⁵⁸

As this excerpt illustrates, the distinction between a “natural” condition and a “pathological” condition is decidedly unclear. This makes it hard to predict what is and what can be patented with any degree of certainty, especially where inventions have both therapeutic and cosmetic effects. At present, patent agents are recommended to direct medically or cosmetically related method claims to the treatment of natural conditions, where possible.

(b) Steps Requiring Professional Skill or Judgment

In general, a claim that recites a step requiring the skill or judgment of a medical professional will be rejected as a method of medical treatment, even if that step can be performed by a non-professional.

In *Commissioner Decision #1086*, claims to a non-surgical method of preventing pregnancy by constructing a plug in a patient’s oviduct were rejected as a medical method.⁵⁹ The applicant argued that the claim was merely directed to a method of manufacturing a commercial product *in situ* (i.e. in the patient), but the Commissioner found that the skills of a medical professional were required to tailor the plug to each patient’s individual anatomy.

By contrast, the Federal Court in *Visx*, commented that claims to a surgical device, which included “means” for “shaping, focusing and directing the beam”, did not explicitly claim steps requiring surgical skills, even though the surgeon had to operate the machine:

These patents do not teach professional skills to surgeons. They deal with an apparatus, a machine, a combination of several components. . . . The invention in the *Visx* patents does not pose a limitation upon the surgeons’ skills. On the contrary, it is meant to assist a surgeon in his operation on the human eye. . . . All the surgeon does is prepare the patient and enter the basic measurements into the computer. He then steps on the pedal to start the

⁵⁷ *Imperial Chemical*, *supra* note 29 at para. 8.

⁵⁸ The Biotechnology and Chemical Patent Group, *Biotechnology and Chemical Patent Practice in Canada: A Practical Guide*, 2d ed (Canada: Borden Ladner Gervais LLP, 2008) at 84.

⁵⁹ *Commissioner Decision #1086*, *supra* note 38.

machine.⁶⁰

In *Imperial Chemical*, the applicant argued that the claimed method of cleaning teeth was not a method of medical treatment because it was not restricted to being practiced by medical professionals: “[I]ts practice is clearly not restricted to doctors . . . it is not, in its main and primary function a medical method, any more than the simple act of brushing one’s teeth is a medical method.”⁶¹ In finding the method non-patentable, the Federal Court of Appeal focused on the *result* of using the method and ignored the point that brushing one’s teeth obviously does not require the specialized skill or judgment of a medical professional. Regardless, the Court refused to overturn the rejection of the patent; so it would seem that non-patentable medical methods *do not necessarily* require the specialized skill or judgment of a medical professional in their use. At the same time, methods that *do* require medical skill or judgment are still not patentable.

CIPO has taken the view that any “methods that involve performing surgery on the human or animal body are excluded from patentability, whether the effect of the surgery is therapeutic or not.”⁶² The rationale for this position is presumably that any surgical step necessarily requires the professional skill of a surgeon.

(c) Diagnostic Methods

Diagnostic methods are related to medical methods, but they do not function to treat a disease or disorder, *per se*, but instead analyze the physiological condition of the patient. In *Commissioner Decision #144*, the Commissioner of Patents reversed the Examiner’s rejection of an *in vitro* diagnostic method which identified a pathogen in a patient by determining whether a patient’s fluids contained antibodies or antigens to that pathogen.⁶³ The Commissioner rejected the Examiner’s argument that the method was essentially non-economic for being performed on human body fluids, a non-industrial product.

In *Commissioner Decision #1108*, the Commissioner of Patents allowed claims to a method of detecting pathogens in a patient by temporarily diverting a small amount of the patient’s blood through an extracorporeal device that collects the pathogens for subsequent *in vitro* analysis.⁶⁴ The Commissioner held that the method was diagnostic, not therapeutic, and was therefore patentable:

We are persuaded that in the present arrangement the step of externally adsorbing certain elements does not amount to a treatment of a person’s blood, nor to a treatment of a human body, since no steps of treating the blood are introduced, and the blood is merely returned to the body.

⁶⁰ *Visx*, *supra* note 52 at para. 173.

⁶¹ *Imperial Chemical*, *supra* note 29 at para. 5.

⁶² MOPOP, s. 17.02.03.

⁶³ *Commissioner Decision #144* (23 March 1973), online: <<http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/144/summary.html?query=144+%3Cin%3E+comdecnumber&start=1&num=10>>.

⁶⁴ *Commissioner Decision #1108* (26 August 1987), online: <<http://brevets-patents.ic.gc.ca/opic-cipo/comdec/eng/decision/1108/summary.html?query=1108+%3Cin%3E+comdecnumber&start=1&num=10>>.

...

If we look to the end use of Applicant's process for the detection of pathogens in blood, we see no treatment of the blood is contemplated nor effected. Moreover, no curing or alteration of the metabolism of the body is obtained.⁶⁵

In *Re Application for Patent of Goldenberg*, the Commissioner allowed claims teaching a method of locating a tumour by injecting the patient with radio-labelled antibodies.⁶⁶ The Patent Examiner argued that the claims constitute a medical method because the patient's metabolism would necessarily be changed by injecting immunological agents. However, the method was held to be patentable because the radio-labelled antibodies did not have a therapeutic effect, but only functioned to assist in locating the tumour.⁶⁷

Accordingly, certain methods of diagnosing a disease or other physiological condition may be patentable, whether practised *in vitro* or *in vivo*. The caveat is that surgical steps, such as collecting blood or tissue samples, or any other steps requiring the exercise of professional art will be interpreted as medical methods and render the claim non-patentable.

(d) Medical "Use" Claims

Related to "method" claims are "use" claims. The term "use" does not appear in the definition of "invention" found in section 2 of the *Patent Act*, but it is now accepted at common law that a new "use" of a known compound, composition, or substance may be patented. In *Shell Oil*, the Supreme Court of Canada accepted the patentability of a new "composition" comprising known compounds mixed with adjuvants.⁶⁸ While a composition that comprises known compounds in combination with a mere diluent is not considered patentable subject matter *per se*,⁶⁹ the Court noted that the invention was actually the discovery of a new "use" for the compounds:

The appellant has discovered that compounds having a specific chemical structure have useful properties as plant growth regulators. *Although . . . these compounds were already known, their usefulness for this particular purpose was not known. This new use for these old compounds is therefore the appellant's "invention" with respect to these old compounds.* In order to use them for this purpose, it has mixed them with the appropriate adjuvants for their application to plants.⁷⁰

The Court then held that a new "use" is a patentable invention since it falls

⁶⁵ *Ibid* at 3-4.

⁶⁶ *Re Goldenberg*, *supra* note 40.

⁶⁷ *Ibid* at paras. 28-29.

⁶⁸ The word "adjuvant" refers to a compound for delivering, modifying or enhancing the function of the composition's active ingredient.

⁶⁹ *Farbwerke Hoechst A.G. v. Meier Lucius & Bruning v. Canada (Commissioner of Patents)* (1963), [1964] S.C.R. 49, 41 C.P.R. 9 (S.C.C.).

⁷⁰ *Shell Oil*, *supra* note 9 at para. 22 [emphasis added].

within section 2 of the *Patent Act* under “any new and useful art”:

It is not the process of mixing the old compounds with the known adjuvants which is put forward as novel. It is the idea of applying the old compounds to the new use as plant growth regulators; the character of the adjuvants follows inevitably once their usefulness for that purpose has been discovered. *What then is the “invention” under s. 2? I believe it is the application of this new knowledge to effect a desired result which has an undisputed commercial value and that it falls within the words “any new and useful art”.* I think the word “art” in the context of the definition must be given its general connotation of “learning” or “knowledge” as commonly used in expressions such as “the state of the art” or “the prior art”. *The appellant’s discovery in this case has added to the cumulative wisdom on the subject of these compounds by a recognition of their hitherto unrecognized properties and it has established the method whereby these properties may be realized through practical application.* In my view, this constitutes a “new and useful art” and the compositions are the practical embodiment of the new knowledge.⁷¹

The Supreme Court of Canada recognizes the close link between a “use” and a “method”. Indeed, a method may be viewed as the “practical application” of the discovery of a new use. While it is not obvious that claiming a “use” or a “method” in a patent significantly changes the scope of the applicant’s resulting monopoly, the Supreme Court of Canada has distinguished between these terms. In *Wellcome*, the patent at issue claimed various pharmaceutical formulations, useful in treating AIDS/HIV,⁷² which contained the active ingredient 3’-azido-3’-deoxythymidine (AZT). Several of these claims were limited by the language “for use in the treatment or prophylaxis” of AIDS or human retrovirus infections and others were limited by the language “for the treatment or prophylaxis of an AIDS infection.”⁷³ Citing *Shell Oil*, the Supreme Court of Canada clearly stated that claims directed to the use of a substance were patentable, even when that “use” was medical treatment:

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.⁷⁴

Accordingly, the use of a substance or device for medical treatment is patentable, while the practical application of that use is not.

While the language of the particular claims at issue in *Shell Oil* and *Wellcome* did not commence with the preamble “use of”, the Supreme Court of Canada made it clear that the discovery of a new use was all that was necessary for patentability:

... Having discovered the use, the appellant has then combined the com-

⁷¹ *Ibid* at para. 30 [emphasis added].

⁷² *Acquired Immune Deficiency Syndrome* (“AIDS”) is an infectious disease caused by the *Human Immunodeficiency Virus* (“HIV”).

⁷³ “Antiviral nucleosides”, Can Patent No 1238277, (14 March 1986), clms 21–23, 26–31, 34, 45, 49–73 and 74–78.

⁷⁴ *Wellcome*, *supra* note 34.

pounds with the appropriate carriers for their application to plants. *It is not, in my view, necessary in the case of the discovery of a new use for an old compound that the combination of the compound with the adjuvant be itself novel in any sense other than that it is required in order to give effect to this particular use of the compound.* This is not a case where the inventive ingenuity is alleged to lie in the combination; the combination is simply the means of realizing on the newly discovered potential of the compounds. This is a case where the inventive ingenuity is in the discovery of the new use and no further inventive step is required in the application of the compounds to that use, i.e. in the preparation of the appropriate compositions.⁷⁵

In *Re Application for Patent of Wayne State University*, the applicant successfully convinced the Commissioner of Patents that “the use of the active ingredient should be construed as extending to cover activities which can be regarded as ‘industrial’ in character but not extending to the actual treatment of disease by administration of the active ingredient.”⁷⁶

It is now common practice for patent claims to begin with the preamble, “Use of”, but CIPO warns that “[d]epending upon how a *use* claim is worded, it risks being, in form or substance, a *method*.”⁷⁷ Indeed, merely replacing the preamble, “A method of”, with the preamble, “Use of”, will not necessarily constitute a patentable claim. Two commonly accepted use claim formats are *Swiss-type claims* and *German-type claims*, which have the following forms:

Swiss-type:

- Use of compound X (or composition W) in the manufacture of a medicament for the treatment of condition Y.⁷⁸

German-type:

- Use of compound X (or composition W) for the treatment of condition Y.
- Compound X (or composition W) for use in the treatment of condition Y.⁷⁹

Since it is not clear that the different “use” claim formats provide equivalent patent rights, it is recommended that all of the various claim types be included in a patent application.

⁷⁵ *Shell Oil*, *supra* note 9 at para. 31 [emphasis added].

⁷⁶ *Application for Patent by Wayne State University, Re* (1988), 22 C.P.R. (3d) 407 at paras. 4 and 13 (Can. Pat. App. Bd. & Pat. Commr.) [*Re Wayne State*].

⁷⁷ MOPOP, s. 12.06.08d.

⁷⁸ *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, 63 C.P.R. (4th) 406 at paras. 22–23 (The Federal Court commented that Swiss-type and German-type claims were both acceptable formats for “use” claims); *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 971, 61 C.P.R. (4th) 305 at paras. 152–153; affirmed 2008 FCA 8, (sub nom. *Apotex Inc. v. Pfizer Canada Inc.*) 72 C.P.R. (4th) 141 (The Federal Court upheld both Swiss and German-type claims as valid “use” claims).

⁷⁹ *Ibid*; *Wellcome*, *supra* note 34 (The Supreme Court of Canada held Claim 21, a German-type claim, to be valid).

(e) Drug Dosages

In general, drugs that treat a disease or medical condition at one concentration are ineffective at lower concentrations and toxic at higher concentrations. Precise tailoring of drug dosages to individual patients can be crucial to the utility of a pharmaceutical invention.⁸⁰ This step may be as simple as adjusting the dosage to the weight of a patient or substantially more sophisticated, such as predicting an individual patient's responsiveness to a dosage through genetic screening or other diagnostic analyses. As such, this area of patent law is especially relevant to the growing field of personalized medicine.

In *Pfizer Canada Inc. v. Apotex Inc.*, the claim at issue was directed to a drug dosage that was appropriate for a patient that had eaten:

Use of a therapeutically effective amount of azithromycin for the preparation of a pharmaceutical dosage form which does not exhibit an adverse food effect for administration, in the treatment of an antimicrobial infection, to a patient that has eaten.⁸¹

The Federal Court held that this claim was not directed to a medical method because it does not teach “how” to treat the patient, only that the drug “can” be administered to treat microbial infections “without concern as to the patient’s fed or fasted state.”⁸²

Similarly, in *Merck & Co. v. Apotex Inc.* the Federal Court upheld claims directed to the dosage of a drug for the treatment of osteoporosis.⁸³ While the compound, method of administration and therapeutic purpose were all known in the prior art, the applicant had discovered that an undesirable gastro-intestinal side-effect was significantly reduced when the drug was orally administered once a week rather than daily. The Court found that the claims were not medical methods:

Merck submits that *where the claims of a patent are for a vendible product having economic value in trade, industry and commerce and are distinguishable from the work of a physician, which requires the exercise of specialized skill, the patent is taken out of the realm of Tennessee Eastman.* The how and when of administration is not a part of the patent. The inventors provide a new product which physicians may choose to use in treating patients, based on their own skill and judgment . . .

*I find that the patent is for a vendible product having real economic value, as demonstrated by its immediate success in the market, and is, therefore, not for an unpatentable method of treatment.*⁸⁴

In contrast, the Federal Court in *Axcan Pharma Inc. v. Pharmascience Inc.* rejected the following drug composition claim (translated from French) on the basis

⁸⁰ Recall that “utility” is a requirement for patentability (see note 5). Ascertaining the appropriate dosage can be critical for a pharmaceutical invention to be patentable.

⁸¹ *Pfizer Canada Inc. v. Apotex Inc.*, 2005 FC 1421, 43 C.P.R. (4th) 81 at para. 8, 282 F.T.R. 8 (Eng.) [*Pfizer*].

⁸² *Ibid* at para. 149.

⁸³ *Merck & Co. v. Apotex Inc.*, 2005 FC 755, 41 C.P.R. (4th) 35, 274 F.T.R. 113 (Eng.) [*Merck*].

⁸⁴ *Ibid* at paras. 29, 136-137 [emphasis added].

that it was directed to a medical method:

Pharmaceutical composition for the treatment of primary biliary cirrhosis, characterized in that it includes ursodeoxyscholic acid as well as a vehicle and if necessary pharmaceutical [excipients], the said composition being processed in a form allowing for the said treatment of primary biliary cirrhosis based on a *dose of 13 to 15 mg/kg/day*.⁸⁵

The Court held that the dosage regime was an essential feature of the invention and that determining the appropriate dosage required the physician to assess the patient's weight and metabolism, an exercise of professional skill and knowledge:

It is up to the physician based on his or her knowledge of the patient's rate of metabolism and other factors to determine the appropriate daily dosage. I cannot, for a moment, contemplate that Axcan could claim exclusive property in the dosage and sue a physician for prescribing Ursodiol for the treatment of PBC at a dosage less than 13 mg/kg/day or greater than 15 mg/kg/day. In fact, Dr. Shaffer, who was called by Axcan, stated during cross-examination that he has at times prescribed Ursodiol at dosages greater than those set out in the patent.

...

[I]n this case the number of capsules to prescribe is a matter between the patient and her doctor, and does not form part of a monopoly protected by Letters Patent. Therefore, the patent is invalid because it claims a method of medical treatment.

...

There is a distinction between the dosage in a capsule and a dosage range based on the patient's weight. As I read the claim, the emphasis is on the dosage range, and a dosage range is not a vendable product.⁸⁶

A dosage regimen was also at issue in *Janssen Inc. v. Mylan Pharmaceuticals ULC*.⁸⁷

One of the claims at issue read as follows:

A use of galantamine from a first dosage of about 8 mg/day to a final dosage of about 16 mg/day to 24 mg/day for treating Alzheimer's Disease wherein said first dosage is for use for a period from about two weeks to about ten weeks; and wherein the use of the first dosage from about two weeks to ten weeks results in a lower final dosage.

Galantamine was already known to treat Alzheimer's disease, but the patentee had discovered that slow titration of the drug resulted in a lower effective dose and reduced side effects. The Federal Court found the invention to not be patentable because the claims taught a medical method. From expert evidence, the Court held that titrating a drug required more skill and knowledge than strict adherence to the patentees dosing regimen. Accordingly, practicing the invention would require the

⁸⁵ *Axcan*, *supra* note 39 at para. 3 [emphasis added].

⁸⁶ *Ibid* at paras. 35, 46, 48 and 51.

⁸⁷ *Janssen Inc. v. Mylan Pharmaceuticals ULC*, 2010 FC 1123 [*Janssen*].

physician to practice his or her professional art:

What is clear from the evidence is that prudent physicians like Dr. Sadavoy who are attempting to manage the administration of drugs carrying side effects in the treatment of geriatric patients do so by considering a number of individualized factors. . . . [T]his does not begin and end with the manufacturer's dosing advice. In this context, the titration regimen claimed by Janssen can only be seen as a recommendation to physicians. Effective patient management may require on-going individualized surveillance and concomitant dosing adjustments.

...

By attempting to monopolize an effective titration regimen for galantamine, the '950 Patent interferes with the ability of physicians to exercise their judgment in the administration of generic versions of the drug.⁸⁸

From this limited jurisprudence, it appears as though claims involving a dosage must not be in the form of a range, such that in order to determine the appropriate dosage for a particular patient, specific knowledge of that patient is required, and judgement is required based on that knowledge; these are matters which fall within the professional art of the physician, and are therefore nonpatentable. This was the reasoning of the Commissioner of Patents in *Re Allergan Inc.*, where "use" claims that included a particular dosage range of botulinum toxin were rejected as teaching a medical method.⁸⁹ The Commissioner noted that the dose to be administered to any particular patient depended on the discretion of the physician; this included assessing the severity of the condition (e.g. the number of muscle groups requiring treatment, the age and size of the patient and the potency of the toxin).⁹⁰ Consistently, the Federal Court held in *Merck & Co. v. Pharmascience Inc.* that a "use" claim incorporating a specific dosage (i.e. not a range) was patentable:

[Incorporating all its dependencies, the claim at issue reads as follows:]

The use of finasteride for the preparation of a medicament adapted for oral administration useful for the treatment of male pattern baldness in a person and wherein the dosage is about 1.0 mg.

...

[A] distinction must be made between claims that rely upon the skill and judgment of a medial 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. In the present case, we have a 1.0 mg tablet taken as a daily dose. No skill or judgment is brought to bear. It is a vendible product and not a method of medical treatment.⁹¹

⁸⁸ *Ibid* at paras. 50–52.

⁸⁹ *Allergan Inc., Re* (2009), 79 C.P.R. (4th) 161 at para. 93 (Can. Pat. App. Bd. & Pat. Commr.) [*Re Allergan*].

⁹⁰ *Ibid* at paras. 94-95.

⁹¹ *Merck & Co. v. Pharmascience Inc.*, 2010 FC 510, 85 C.P.R. (4th) 179 at paras. 6 and 114, 368 F.T.R. 1 (Eng.) (F.C.).

Given the above, it is recommended that appropriate claims be drafted to characterize the invention as a dosage form or kit (i.e. “vendible products”) that physically embodies a dosage regime or prescribed dosage amount, and omit any steps requiring the discretion of a medical professional. For example, it would be preferable to recite a tablet containing 80 mg of the active ingredient, rather than a tablet processed in a form allowing for treatment based on a dose of 1 mg/kg body weight of a subject per day.

III. CRITICISM OF THE STATUS QUO

In Canada, the exclusion of methods of medical treatment from patentable subject matter is largely derived from common law. Following the repeal of subsection 41(1), the only legislative basis for prohibiting medical method patents is the definition of “invention” in the *Patent Act*, which has been interpreted to exclude arts and processes that are essentially non-economic (or not commercially useful) in character or result. Professional arts, including medical methods, have seemingly been viewed as non-economic because, like fine art, their societal value is not *primarily* economic even though professionals are paid for their services. As indicated by the Hippocratic Oath, the chief goal of medicine is not economic in nature, but to improve health and preserve human life.⁹² However, it must be asked whether the medical profession can really be considered a non-economic endeavour given that modern medicine is generally practiced within a highly sophisticated commercial (and arguably industrial) framework.⁹³ Indeed, courts in the United Kingdom abandoned this rationale in the 1970s, eventually opting for a specific statutory exclusion. Mitnovetski & Nicol discussed this in their paper entitled, “Are patents for methods of medical treatment contrary to *ordre public* and morality or ‘generally inconvenient’?”:

In *Eli Lilly & Company’s Application* (1975), 1975 R.P.C. 438 — for example the [UK] court . . . refused a patent application, for the first time, on the basis of the public policy proviso to section six of the *Statute of Monopolies*. . . . The court acknowledged that the prohibition [on medical method patents] was “technically anomalous and therefore illogical” stating “the reasons for such an exclusion appear to us to be based in ethics rather than logic . . .”. The court decided that, although the “generally inconvenient” exception in the *Statute of Monopolies* was never used before as the basis for refusals of medical treatment applications, it “can no more be ignored”.

. . .

[M]ethods of medical treatment were expressly excluded by the parliament of the United Kingdom in section 4(2) of the new legislation [*Patents Act 1977* (U.K.), 1977, c. 37, s. 4(2)].⁹⁴

⁹² O Mitnovetski & D Nicol, “Are patents for methods of medical treatment contrary to *ordre public* and morality or ‘generally inconvenient’?” (2004) 30 J. Med. Ethics 470 at 470.

⁹³ *Patent exclusions that promote public health objectives*, WIPO Standing Committee on Patent Law, 15th Sess, Annex 4, Doc NoSCP/15/3 (2 September 2010) at 9 [2010 Standing Committee Report].

⁹⁴ Mitnovetski & Nicol, *supra* note 92 at 471 [original references omitted].

Furthermore, the United States has allowed medical method patents since 1954, despite statutory language very similar to section 2 of Canada's *Patent Act*. Under U.S. patent law, methods of medical treatment are considered a "useful process" and fit within the scope of patentable subject matter, defined as "any new and useful process, machine, manufacture, or composition of matter".⁹⁵ These differences from Canadian jurisprudence suggest that the legal rationale for prohibiting medical method patents in Canada is tenuous.

Still, many jurisdictions prohibit the patenting of medical methods, including over 80 countries worldwide.⁹⁶ The legal basis for the prohibition in these countries varies, but there are generally three grounds:

- (1) medical methods are not patentable subject matter because they are inherently not industrial, economic or commercial in nature or result (e.g. Canada and Japan);
- (2) medical method patents violate public morality or public policy (e.g. New Zealand); or
- (3) medical methods are explicitly prohibited by statute (e.g. the United Kingdom and other members of the European Union, India and China).⁹⁷

While U.S. legislation does not prohibit medical method patents, *per se*, U.S. law has a specific defence for medical practitioners using patented methods that protect them from patent infringement.⁹⁸ With several notable exceptions (e.g. Australia⁹⁹), the above reflects a general international consensus against patenting methods of medical treatment. Many international and multinational treaties also support this view. For example, Canada is a signatory to the *Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)*,¹⁰⁰ the *North American Free Trade Agreement (NAFTA)*¹⁰¹ and the *1970 Patent Cooperation Treaty*

⁹⁵ *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107 (1954); 35 USC § 101.

⁹⁶ Robert M. Portman, "Legislative Restriction on Medical and Surgical Procedure Patents Removes Impediment to Medical Progress" (1996) 4 U. Balt. Intell. Prop. L.J. 91 at 118, cited in 2010 Standing Committee Report, *supra* note 93 at 9.

⁹⁷ For a current summary, see 2010 Standing Committee Report, *ibid* at 5–40.

⁹⁸ 35 USC § 287(c)(1) ("With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity").

⁹⁹ *Joos v Commissioner of Patents* (1972), 126 CLR 611 (HC Aus); *Anaesthetic Supplies Pty Ltd v Rescare Ltd* (1994), 50 FCR 1 (FC Aus); *Bristol Myers Squibb Co v F H Faulding & Co Ltd* (2000), 46 IPR 553 586 (FC Aus).

¹⁰⁰ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994, 1869 UNTS 299, 33 ILM 1197 [TRIPS].

¹⁰¹ *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can TS 1994 No 2, 32 ILM 289 [NAFTA].

(*PCT*),¹⁰² all of which contain provisions permitting (but not requiring) the exclusion of methods of medical treatment from patentability.¹⁰³ The reason for this broad consensus appears to be a widely shared public policy concern.

In Canada, this public policy rationale has been clearly expressed. The Supreme Court of Canada surmised in *Harvard College* that the primary policy concern was “presumably so as not to impede physicians in the practice of their profession”.¹⁰⁴ Similarly, the Federal Court recently stated in *Jenssen* that “for ethical and public health reasons, physicians should not be prevented or restricted from applying their best skill and judgment for fear of infringing a patent covering a pure form of medical treatment (as distinct from a vendible medical or pharmaceutical product).”¹⁰⁵ Considering that the overarching policy rationale for granting patents at all is to encourage innovation, it would appear that refusing medical method patents is intended to strike a balance between encouraging inventive solutions to practical problems on the one hand and promoting public health (and perhaps not offending the public sense of morality) on the other. A number of arguments have been raised in favour of this policy; patenting medical methods may (1) impede the dissemination of new methods of treatment; (2) deter physicians from performing unlicensed methods out of financial interests and for fear of infringement; (3) invade patients’ privacy during infringement lawsuits; and (4) increase health care costs and reduce access to healthcare.¹⁰⁶ While these concerns have been challenged by sceptics who argue that “every argument raised against methods of medical treatment patents could be equally raised against patents for drugs, medical devices, and cosmetic treatment,”¹⁰⁷ this same public policy rationale likely underpins the decision to deny medical method patents in each of those jurisdictions that do so.

While public policy may provide some insight into the legislative intent of Parliament in drafting the *Patent Act*, it must be remembered that the exclusion of medical methods from patentable subject matter is ultimately derived from statute, not policy. The Supreme Court of Canada has explicitly stated that the Commissioner of Patents does not have discretion to refuse a patent on the basis of public policy:

I disagree that s. 40 of the *Patent Act* gives the Commissioner discretion to refuse a patent on the basis of public policy considerations independent of

¹⁰² *Patent Cooperation Treaty*, 19 June 1970, Can TS 1990 No 22, TIAS 8733 [*PCT*]; *Regulations under the Patent Cooperation Treaty* (as in force from 1 July 2010), online: <<http://www.wipo.int/pct/en/texts/rules/#note1>> [*PCT Regulations*].

¹⁰³ Article 27.3(a) of *TRIPS* and article 1709(3)(a) of *NAFTA* explicitly permit members to exclude methods of medical treatment from patentability. Rule 39.1 of the *PCT Regulations* allows an International Searching Authority to decline to conduct patent searches relating to medical methods of treatment. Article 27.2 of *TRIPS* and article 1709(2) of *NAFTA* allow patent applications to be refused due to considerations of morality or the *ordre public*.

¹⁰⁴ *Harvard College*, *supra* note 6 at para. 145.

¹⁰⁵ *Janssen*, *supra* note 87 at para. 53.

¹⁰⁶ Mitnovetski & Nicol, *supra* note 92 at 473–75.

¹⁰⁷ *Ibid* at 473–74.

any express provision in the Act. The non-discretionary nature of the Commissioner's duty was explained in *Monsanto Co.*, supra, a case cited by Rothstein J.A. At pages 1119-20, after citing s. 40 (then s. 42) of the *Patent Act*, Pigeon J., speaking for the majority, stated:

I have underlined *by law* [in s. 42] to stress that this is not a matter of discretion: the Commissioner has to justify any refusal. As Duff C.J. said in *Vanity Fair Silk Mills v. Commissioner of Patents* (at p. 246):

No doubt the Commissioner of Patents ought not to refuse an application for a patent unless it is clearly without substantial foundation . . .

Some commentators remark that the Canadian *courts* have in the past excluded certain subject matter from patentability on moral, ethical or policy grounds . . . While it is true that certain categories of invention were excluded from patentability with these policy concerns in mind, *these exclusions were justified by reference to explicit provisions of the Patent Act*.¹⁰⁸

As the above passage implies, even the judiciary does not have the authority to reject medical method patents *purely* on public policy grounds; this is the role of Parliament.¹⁰⁹ While some jurisdictions (e.g. members of European Union,¹¹⁰ New Zealand¹¹¹ and Japan¹¹²) have statutory provisions that grant courts discretion to refuse a patent on *ordre public* or morality grounds, Canada has no such provision.¹¹³ Instead, courts may only weigh policy considerations to the extent that they can aid in interpreting the *Patent Act* and other Canadian laws. While U.S. courts have carved out a "moral utility" doctrine from the requirement for patents to have utility, this doctrine is rarely used and has never been successfully applied to medical method patents.¹¹⁴ Moreover, a "moral utility" doctrine has not developed in Canadian patent law.

Not only is the legal basis for the prohibition tenuously reasoned and the policy rationale for it controversial, the application of the prohibition by Patent Examiners, the Commissioner of Patents and the courts is often unpredictable or illogical. The fuzzy distinction between "pathological" and "natural" conditions makes it hard to confidently predict the current state of the art, particularly where inventions

¹⁰⁸ *Harvard College*, supra note 6 at paras. 144-45 [emphasis in original].

¹⁰⁹ To the best of the author's knowledge, Canadian courts have never rejected a medical method patent purely on the basis of public policy considerations.

¹¹⁰ *European Patent Convention*, 5 October 1973, 13 I.L.M. 268, art. 53 [EPC].

¹¹¹ *Patents Act 1953* (NZ), 1953/64, s 17(1)(b).

¹¹² *Patent Act* (Japan), 1959/121, art. 32.

¹¹³ While article 27.2 of TRIPS, supra note 94, contains a similar provision to article 53 of EPC, members of TRIPS are not required to implement a morality patent exclusion.

¹¹⁴ *Lowell v. Lewis*, Fed. Cas. No. 8568 (C.C. Mass. 1817), cited in *Tol-o-Matic, Inc. v. Proma Produkt-und Marketing Gesellschaft MbH.*, 945 F.2d 1546 at 1552 (Fed. Cir. 1991); US Patent and Trademark Office, Media Advisory, 986, "Facts on Patenting Life Forms Having a Relationship to Humans" (1 April 1998), online: <<http://www.uspto.gov/news/pr/1998/98-06.jsp>>.

have both therapeutic and cosmetic effects. For example, how does one reconcile that a patentable method of diagnosis would be rendered non-patentable if a therapeutic benefit results considering that the medical professional performs the same method regardless? Furthermore, it is inconsistent that methods requiring the professional art of a medical practitioner are not patentable while methods directed to non-medical fields require the same level of specialized skill and judgment. Even methods for medically related fields can be patented, such as methods of diagnosis, methods of preventing pregnancy, methods for ameliorating adverse effects of aging, and methods for medical research. Are these medically related fields more economic or commercially useful than surgery or physiotherapy? Lastly, tweaking patent claims to avoid reciting a dosage range seems like an unnecessary complication for inventors and patent agents as there may be an insubstantial degree of professional judgment in choosing an appropriate dosage. For example, weighing a patient and adjusting the dosage accordingly is not complicated. If an inventor has demonstrated that a drug is most effective at a certain dosage per kilogram of body weight, the claims should reflect that invention directly.

The above problems appear to follow from the position that *all* medical methods are not patentable. As the above issues demonstrate, many medically-related inventions incorporate aspects that could be categorized as medical methods, but are not necessarily professional arts or otherwise essentially non-economic in character or result. These issues may be avoided by replacing the concept of a general prohibition with a case-by-case assessment of whether or not a particular medical invention fits within patentable subject matter pursuant to the definition of “invention” in section 2 of the *Patent Act*. A related issue recently came before the Federal Court in *Re Amazon.com Inc.*¹¹⁵ The question was whether or not “business methods” were generally non-patentable. In holding that business methods *were* patentable in appropriate circumstances, the Court noted that each business method must be evaluated for patentability by assessing whether it fits within section 2 of the *Patent Act*:

It is noteworthy that in both the above cited cases the claimed inventions were found to be non-patentable subject matter. Not, however, because they were business methods but because they were mere “schemes” or disembodied ideas. . . . That is not the case with the business method claimed in the present case.

The approach in the USA, Australia, and as it ought to be in Canada, makes an eminent amount of sense given the nature of our legislation. It allows business methods to be assessed pursuant to the general categories in s. 2 of the *Patent Act*, preserving the rarity of exceptions. It also avoids the difficulties encountered in the UK and Europe in attempting to define a “business method”. There is no need to resort to such attempts at categorization here. Contrary to what the Commissioner suggests, to implement a business method exception would be a “radical departure” from the current regime requiring parliamentary intervention.¹¹⁶

¹¹⁵ *Amazon.com Inc., Re*, 2010 FC 1011, (sub nom. *Amazon.com, Inc. v. Canada (Attorney General)*) 86 C.P.R. (4th) 321 [*Amazon*].

¹¹⁶ *Ibid* at paras. 67-68.

Similarly, methods of medical treatment ought to be assessed for patentability on a case-by-case basis to prevent patentable methods from being unjustly rejected. Banning all medical methods merely changes the question from “what fits the definition of ‘invention’” to “what fits the category of a ‘medical method’?”

The general exclusion of medical methods from patentable subject matter has been read into the *Patent Act* by Canadian courts. While the judiciary justifies this prohibition by asserting that methods of medical treatment are inherently not patentable, this assertion may be based more on public policy than the language of the *Act*. While many jurisdictions adhere to this policy, the accuracy of it remains a controversial topic.¹¹⁷ Moreover, application of the prohibition has been unpredictable, which not only confounds patent agents, lawyers and inventors, but also serves as an impediment for medically-related industries. While some of this uncertainty may be due to a lack of Canadian jurisprudence on the matter, there appears to be some deeper logical inconsistencies, which would be better dealt with using legislative reform. For example, if the real purpose of the prohibition is to prevent doctors from being sued for treating patients, then a defence against infringement for medical practitioners, as used in the U.S., is a more direct and desirable approach.

¹¹⁷ Mitnovetski & Nicol, *supra* note 92; 2010 Standing Committee Report, *supra* note 93.