

Patents for Second Medical Indications and Their Potential Impact on Pharmacare in Canada

*Teresa Scassa**

Introduction

The practice of granting patents for second medical indications of known drug compounds is not new in Canada. However, a recent court decision has brought into focus the implications of this practice for pharmacare programs in Canada. In *Apotex v. Ontario (Minister of Health)*,¹ the Superior Court of Ontario upheld a decision by the Ministry of Health and Long-Term Care (hereinafter Health Ontario) to list a generic formulation of sertraline hydrochloride as interchangeable for only one of the brand name drug's three approved indications. The decision by Health Ontario, which was unprecedented in Canada, came following pressure by Pfizer Canada, the maker of the brand name version of sertraline hydrochloride called Zoloft™. While the patent on Zoloft™ for treatment of depression had expired, a valid patent remained on Zoloft™ for use for other approved indications. The subsisting patent formed the basis for Pfizer's opposition to full interchangeable status for Zoloft™. Although the case is currently under appeal, it is expected that similar pressure may be brought to bear on other provincial health departments to begin listing drugs in formularies as being only partially interchangeable where one patent on a given drug has expired but others remain in effect.

This issue of second medical indication patents and their implications is an important one, as it has the potential to raise costs significantly for already cash-strapped provincial drug programs. It may also have implications for privately funded drug plans, and hence for the cost of private drug insurance programs. At the very least, it may impose costs on provincial health departments to defend themselves in any potential patent infringement actions taken against them. It has also been argued that to list drugs as only partially interchangeable in provincial drug formularies will place difficult burdens on pharmacists and those who prescribe drugs, and may expose them directly to patent infringement liability. This paper considers both the issues raised by the decision in *Apotex v. Ontario*, and the implications for health departments, doctors and pharmacists.

*Teresa Scassa is Associate Dean, Professor and Associate Director of the Law and Technology Institute at Dalhousie University, Halifax, Nova Scotia. This article is based upon a report written by the author for Health Canada. The author is grateful for the assistance of Dr. Ingrid Sketris, Dr. Timothy Pollak, Eleonar Hubbard, Holly Rasky, and the Research Group of the College of Pharmacy at Dalhousie University. The author would also like to thank Charles Sanders, and research assistant Josephine Asmah. Any errors in the text of this document are the author's.

¹[2000] O.J. No. 4834.

The first part of this paper explores the relevant patent issues. These issues do not receive any direct coverage in *Apotex v. Ontario*; nevertheless, they underlie the decision in that case. The bar on patenting of medical treatments is considered as well as the means by which drug patents are distinguished from methods of treatment. The legal basis for granting second medical use patents is also assessed. These issues are considered with some comparison to other jurisdictions and in light of Canada's international obligations.

The second part of the paper consists of a closer look at *Apotex v. Ontario* and its implications for provincial pharmacare programs. It includes a consideration of the relevant legislative and regulatory scheme in Ontario, and incorporates a consideration of the various liability issues that may arise for provincial health departments, doctors and pharmacists.

I. Patent Issues

A. Methods of Medical Treatment under Patent Law

In Canada, methods of medical treatment of humans and animals are not patentable.² This is not expressly stated in the *Patent Act*,³ but rather has evolved as a matter of interpretation. The leading case on the issue is *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*.⁴ In *Tennessee Eastman*, the Supreme Court of Canada found that the discovery that a known adhesive compound could be used to close wounds was a method of medical treatment, and therefore not patentable. There are policy reasons underlying the exclusion of medical treatments from patentability, as explained by David Vaver:

The exception for medical treatment springs from ethical or emotional reasons based on a desire not to hamper the saving of life and the alleviation of suffering. Medicine is also a profession whose members

²*Tennessee Eastman Co. v. Canada (Commissioner of Patents)* (1970), 62 C.P.R. 117 (Ex.Ct.), aff'd [1974] S.C.R. 111, 8 C.P.R. (2d) 202 [hereinafter *Tennessee Eastman*, cited to C.P.R.]. D. Vaver, *Intellectual Property Law* (Concord, Ont.: Irwin Law, 1997) at 130. As Vaver notes, this bar on patenting methods of treatment extends to "methods of using medicine or similar substances to diagnose, prevent, or cure ailments in humans or animals" (at 130). See also: Canadian Patent Office, *Manual of Patent Office Practice*, (Ottawa-Hull: Industry Canada, March 1998), online: <http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop/mopop_dnl-d-e.html> (date accessed: 20 February 2002) [hereinafter *MOPOP*] at para. 16.04(b), which reads: "Subject matter related to a process of surgery or therapy on living humans or animals is not considered to be within the scope of 'invention' as defined by section 2 of the Patent Act."

³R.S.C. 1985, ch. P-4, as amended by R.S.C. 1985, c. 33 (3rd Supp.); S.C. 1992, c. 1; 1993, c.2; c.15; c. 44; 1994, c. 26; c.47; 1995, c.1; 1996, c.8.

⁴*Supra* note 2. Although s. 41 of the *Patent Act*, which was in effect in *Tennessee Eastman*, has since been repealed, the case has been affirmed as still standing for the proposition that methods of medical treatment are not patentable subject matter. See *Imperial Chemical Industries Ltd. v. Commissioner of Patents* (1986), 9 C.P.R. (3d) 289 (FCA) at 296; *Re Application of Regents of the University of Minnesota* (1988), 29 C.P.R. (3d) 42 (P.A.B. and Commissioner of Patents).

should share their skills and should not foreclose others from applying them; an operating surgeon or prescribing physician should not have to worry about patent infringement.⁵

It has been argued that, in a publicly funded health care system, it would also impose significant costs if doctors were required to record and pay royalties for the methods they used to treat patients, or if hospitals were required to obtain a licence for the treatments that they provide.⁶

In New Zealand, where, as in Canada, the relevant patent legislation is silent on the issue, the courts have found methods of medical treatment to be non-patentable.⁷ In the United Kingdom, the *Patents Act 1977* provides that a “method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human body is not to be taken as capable of industrial application and is therefore not patentable.”⁸ However, this exception is construed narrowly.⁹

⁵Vaver, *supra* note 2, at 131. In *Pharmaceutical Management Agency Ltd. v. Commissioner of Patents*, [1999] N.Z.C.A. 330 at para. 26 [hereinafter *Pharmaceutical Management Agency Ltd.*], the New Zealand Court of Appeal concluded that: “it seems that the exclusion from patentability of methods of medical treatment of humans is now supported only on ethical grounds. Yet patents are granted for pharmaceutical and surgical products.” In *New Zealand Commissioner of Patents v. The Wellcome Foundation Ltd.*, [1983] N.Z.L.R. 385, F.S.R. 593 (N.Z. C.A.) at 392 [hereinafter *Wellcome Foundation*], Cooke J. raised the concern that the economic costs of allowing patents for medical treatments might be significant and should be taken into account by Parliament in deciding whether to alter the general prohibition. In *Anaesthetic Supplies Pty Limited v. Rescare Ltd.* (1994), 50 F.C.R. 1 [hereinafter *Rescare*], Lockhart J. of the Federal Court of Australia conducted an extensive review of Commonwealth case law relating to the prohibition on patenting of medical treatments. While noting that decisions of English courts on the issue had been described as being based on “primarily grounds of ethics rather than logic, and they are not the subject of any fully developed reasoned considerations” (at para. 65), he took the view that the particular wording of such decisions had been based on the statute at the time, which had since been amended. He noted the New Zealand Court of Appeal decision in *Wellcome Foundation (supra)*, and in particular the comments of Davison C.J. to the effect that “there was a lack of logic in any distinction which produced the result that a product for treating the human body would be patentable but not a method of treating the human body” (*Rescare* at para. 66).

⁶In *Rescare, ibid.*, Sheppard J. raised concerns about the possible effects of granting a monopoly over a life-saving treatment to a doctor or group of doctors (at para. 58 of his reasons). However, on this point, Sheppard J. was in the minority.

⁷Like Canada, New Zealand’s patent legislation does not expressly prohibit the patenting of methods of medical treatment. However, in *Wellcome Foundation, supra* note 5, the New Zealand Court of Appeal held that patents were not available for methods of medical treatment. The definition of what constitutes a method of medical treatment has been interpreted restrictively by the New Zealand Patent Commissioner. Currently, claims are allowed for methods of treatment of humans where they do not relate to illness or disease, but relate to health and hygiene, treatment of minor conditions, and elective treatments such as quitting smoking or contraception. See *Pharmaceutical Management Agency Ltd., supra* note 5, at para. 24.

⁸*Patents Act 1977* (U.K.), 1977, c. 37, s. 4(2).

⁹*Bristol-Myers Squibb v. Baker Norton Pharmaceuticals Inc.* [1999] R.P.C. 253 (Patents Ct).

The *European Patent Convention*¹⁰ also prohibits the patenting of medical treatments.¹¹

In contrast to the general trend, patents on methods of medical treatment are allowed in Australia.¹² The United States also allows for the patenting of medical and surgical methods of treatment.¹³ However, the backlash following a recent case¹⁴ in which one doctor sued another over a patented medical procedure has led to amendments to the *Patent Act* in the United States to make patents for medical treatment unenforceable against doctors or the medical facilities with which they are associated. Section 287 of the *Patent Act* reads:

(1) With respect to a medical practitioner's performance of a medical activity that constitutes and 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.¹⁵

¹⁰*European Patent Convention* of 5 October 1973, as amended by the act revising Article 63 EPC of 17 December 1991, and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996 and 10 December 1998, art. 52, online: <<http://www.european-patent-office.org/legal/epc/e/ar52.html>> (date accessed: 20 February 2002). The *European Patent Convention* came into force in 1977. It represents a means of filing a single, centralized application in order to obtain patents in specified signatory states under the Convention. The members of the *EPC* include the member states of the European Union, Cyprus, Liechtenstein, Monaco and Switzerland.

¹¹Article 52 of the *European Patent Convention*, *ibid.*, provides that "patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step." However, article 52 also contains a series of exceptions to this general rule, including 52(4), which reads: "[m]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods."

¹²*Bristol-Myers Squibb Co. v. F.H. Faulding & Co. Ltd.*, [2000] F.C.A. 316 (Fed. Ct. Aus.) at para. 15.

¹³In the United States, methods of medical treatment are not excluded by the U.S. *Patent Act*, 35 U.S.C. (1984), nor have they been expressly excluded by the courts. In the United States, surgical techniques, as well as methods of diagnosis or treatment have been found to be patentable, as long as the requisite novelty is present: *Re Sherer*, 103 U.S.P.Q. 107 (1954) (U.S. Pat. Off. Bd. App.). See also T. Orlhac, "How to Draft Use Claims in the Pharmaceutical Field or Overcoming a Dichotomy of Interpretation" (1994) 11 C.I.P.R. 185 at 187. It is worth noting, perhaps, that the United States courts have not recently considered the issue of patentability of methods of medical treatment, and the view that such methods are patentable depends largely upon the decisions of the U.S. Patent and Trademark Office. See T. Martin, "Patentability of Methods of Medical Treatment: A Comparative Study" (2000) 82 J.P.T.O.S. 381 at 401.

¹⁴*Pallin v. Singer*, 36 U.S.P.Q. 2d (BNA) 1050 (1995).

¹⁵*Supra* note 13, s. 287. This amendment was introduced following lobbying by the American Medical Association after a case involving a patent infringement suit brought by one doctor against another with respect to a surgical eye procedure. See *Pallin v. Singer*, *ibid.* See also Martin, *supra* note 13 at 402. One author argues that "[t]his amendment also suggests the U.S. intention to recognize the concern for ensuring that patent protection does not interfere with the public welfare." A.M. Furlanetto, "Trends in the Protection of Methods of Medical Treatment" (2000) 16 C.I.P.R. 289 at 294.

Given this amendment, the law in the U.S. is not significantly different from that in Canada in terms of practical result.¹⁶ The United States' position is thus in line with the general trend internationally to exclude methods of medical treatment from patentability. The reasons for such exclusion include: ensuring a free flow of information about medical treatments, accessibility of medical treatments, avoidance of conflicts of interest in choosing medical treatments, cost, physician autonomy, ethical conflicts and patient privacy.¹⁷

Trade agreements such as the *NAFTA*¹⁸ and the *TRIPS*¹⁹ agreement allow member states to exclude methods of medical treatment from patent protection. In article 1709(3)(a) of the *NAFTA*, for example, parties are permitted to exclude from patent protection "diagnostic, therapeutic and surgical methods for the treatment of humans or animals."²⁰ Similarly, the *TRIPS* agreement, in article 27(3)(a), permits member states to exclude from patent protection "diagnostic, therapeutic and surgical methods for the treatment of humans and animals."

B. Distinguishing Compounds for Medical Use from Methods of Medical Treatment

While methods of treatment are generally not protected under patent law in Canada or elsewhere,²¹ compounds to be used in the treatment of patients are patentable. Thus, a drug that would be used in preventing or treating a medical condition could be patented, while the treatment itself would be unpatentable. The distinction is a subtle one. Essentially, the patentable compound consists of the drug itself and its use or uses. The treatment consists of the judgment applied by the physician on a case-by-case basis as to what dose and duration of therapy is required to treat the particular patient given that patient's age, physical condition, other health problems and possible drug interactions. Thus, while the compound for a particular use or uses is patentable, the non-patentable treatment consists of the

¹⁶Martin notes that: "[o]verall the new law aligns the U.S. with the growing international trend towards protecting physicians from the consequences of patent infringement. The U.S. law deals with the issue by eliminating the remedies available for infringement, rather than perpetuating a legal fiction that medical inventions for treatment of humans or animals are not 'susceptible of industrial application'" (*supra* note 13 at 406).

¹⁷For a discussion of these issues, see Martin, *ibid.* at 383-87. There are also arguments for the patentability of methods of medical treatment, which posit that such patents would enhance the dissemination of information and promote research (*ibid.*). In *Pharmaceutical Management Agency Ltd.*, the New Zealand Court of Appeal stated that "we have considerable sympathy for the view that individual medical practitioners should not be constrained in the practice of their art in the treatment of illness and disease by concerns that procedures they might adopt in the interests of their patients might render them vulnerable to proceedings for patent infringement" (*supra* note 5 at para. 28).

¹⁸*North American Free Trade Agreement* of 1992, 17 December 1992 (Ottawa: Supply & Services, 1993) [hereinafter *NAFTA*].

¹⁹*Agreement on Trade-Related Aspects of Intellectual Property Rights Including Trade in Counterfeit Goods* (1994) 25 I.I.C. 209 [hereinafter *TRIPS*].

²⁰However, as Vaver notes, "[t]he more medicine starts looking like a business, the greater becomes the pressure to allow patenting as for any other business" (*supra* note 2 at 131).

²¹The notable exceptions are, of course, Australia and the United States.

application of the patentable compound in a particular context.²² This was the view taken in *Merck & Co. v. Apotex Inc.*²³ where it was held that:

The invention, in my opinion, is not for a method or methods of medical treatment. The specification of the patent does not purport to describe such a method. It does describe a range of consumption of the compounds claimed which are perceived as useful as antihypertensives, i.e., in treating hypertension. Yet, the descriptive text of the specification acknowledges that administration of the products within the patent can only be determined for medical purposes by a person skilled in the art of prescribing medicines.²⁴

The method of treatment, therefore, flows from the application of the skill and judgment of the prescribing physician. The drug compound is merely a substance used in this treatment.²⁵ In Canada, because a medical treatment is distinguished from the use of a compound in a treatment, there remains a great deal of latitude for patenting the compounds and devices used in medical treatments.²⁶

The Canadian position that while methods of medical treatment are not patentable, compounds used in such treatments may receive patent protection, is widely shared. The situation is more complicated, however, when one considers the status of patents for second medical indications. In some ways, such patents can be seen to lie in between methods of medical treatment and compounds used in methods of medical treatment in terms of patentability. Because, in a case of a second medical indication claim, the underlying compound is not new and therefore cannot be the subject of the patent claim, all that remains to be patented is the new *use* of that compound in a course of treatment. This must have been the view of the Federal Court of Australia in *Rescare*, for example, when, after a review of international case law on the issue, Lockhart J. noted that there were many cases where, in spite of a formal prohibition against patenting of medical treatments, some leeway was given for patenting medical treatments through “an application of old compounds for new therapeutic uses.”²⁷ Of course, the question here is whether a patent for an application of a known compound for a new therapeutic use is a method of medical treatment any more than a patent on a new compound for

²²Martin, *supra* note 13 at 383 (regarding the consequences of managed health care on this distinction in the U.S.).

²³(1994), 59 C.P.R. (3d) 133 (F.C.T.D.); *aff'd* on this point (1995), 60 C.P.R. (3d) 356 (F.C.A.).

²⁴*Ibid.* at 176.

²⁵As noted above, this distinction is fairly subtle. Furlanetto, *supra* note 15 at 300, suggests that “[t]he protection afforded to a patentee for the use of a compound in the treatment of a particular disease, in effect, is protection for the method of administration of the compound.”

²⁶As is the case in Canada, U.K. law allows claims to substances or compounds used in methods of treatment. The *Manual of Patent Practice in the U.K. Patent Office*, 4th ed., 31 December 1999, online: <<http://www.patent.gov.uk/patent/reference/mpp/index.htm>> (date accessed: 20 February 2002), provides that: “the exclusions of s. 4(2) apply only to methods and not to materials to be used in such methods” (at para. 4.24).

²⁷*Rescare*, *supra* note 5 at para. 61.

a new therapeutic use. Before considering this issue, it might be useful to consider the law in Canada on patenting new uses for known compounds.

C. Legal Basis For Patenting New Uses for Existing Compounds

As noted above, although methods of medical treatment are not patentable in Canada, patents are nonetheless available for drug compounds that are used in medical treatments. A drug compound for which a patent is obtained is protected for a period of 20 years from the date of filing.²⁸ During that period of time, should the patent holder discover a new use for that particular compound, a separate patent may be sought for that new use.²⁹ The basis for this is set out below.

Patents are available in Canada for inventions.³⁰ An invention is defined as follows:

“invention” means 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.³¹

Drug compounds are considered compositions of matter.³²

The usefulness requirement in this definition is important to this discussion. The usefulness requirement for obtaining a patent generally prevents an individual or corporation from obtaining a patent monopoly over a particular invention when it is not yet clear what application that invention might have. Such a situation would be contrary to the public policy interests behind patent law: to promote the advancement of scientific knowledge and discovery. Every invention must therefore have a demonstrable use in order to be patentable. The use must also be a practical

²⁸Section 44 of the *Patent Act*, *supra* note 3, sets this term of protection for patents based on applications filed on or after October 1, 1989. Patents filed before that date receive a term of protection of 17 years from date of issue under s. 45. Following the recent World Trade Organization ruling on this issue, (*Canada - Term of Patent Protection*, AB-2000-7, WT/DS170/AB/R, 18-09-2000), Canada is currently proposing to amend its legislation so that any patents filed before October 1, 1989 and still subsisting at the time of coming into force of the Bill will receive a term of protection of 20 years from the date of filing. See discussion below, Section F.

²⁹The ability to seek a patent for a new use of a known compound is not limited to the patent holder. However, a party other than the patent holder who seeks to patent the new use does not thereby acquire any rights to the making, selling or use of the patented compound, should a valid patent still subsist. See *Patent Act*, *ibid.*, s. 32.

³⁰*Ibid.*, s. 27.

³¹*Ibid.*, s. 2 [emphasis added].

³²Until amendments to the *Patent Act* which took effect in 1987, R.S.C. 1985, c. 33 (3rd Supp.), patents were available only for new processes of making medicines and foods (see s. 41 of the *Patent Act* prior to the 1987 amendments, R.S.C. 1985, c. P.4). Thus the medicine or food itself could not be claimed. This is no longer the case.

one; a drug that might cure headaches, but that is nonetheless highly toxic, would not be considered useful because in reality it has no practical application.³³

The requirement of usefulness therefore means that drug patents are obtained not simply for compounds but for compounds having a specified utility. The utility must be included in the patent specification.³⁴ A patent is then granted for that compound for that particular use (or for all specified uses).³⁵ A patent for a particular use may be interpreted to extend to other analogous uses. However, a completely new use would not be covered by the original claim.³⁶

There is nothing explicit in the *Patent Act* that permits the patenting of a new use for an existing and patented compound. On the other hand, there is nothing in the *Patent Act* that rules out the possibility of identifying a new use for an existing compound, and obtaining a patent for that new use. In *Tennessee Eastman Co. v. Commissioner of Patents*,³⁷ the Supreme Court of Canada was asked to rule on the validity of patent claims for an invention which essentially involved “a surgical method for joining or bonding the surfaces of the incisions or wounds in living animal tissue.”³⁸ The invention involved a known and pre-existing compound for which the inventors had discovered a new use. The claim could not be for the compound itself, which was well known. Rather, the claim, in the words of the Court, “is the discovery that this particular adhesive is non-toxic and such that it can be used for the surgical bonding of living tissues.”³⁹

In reaching its decision in the case, the Supreme Court of Canada made certain relevant statements regarding the issue of obtaining patents for new uses of known substances. The Court stated that:

There is no doubt that when a new substance is claimed as an invention of a “medicine”, it has to be shown that it is active and non-toxic in therapeutic doses. Otherwise the patent fails for lack of utility and this is so if a class of substances is claimed some of which are useful as a “medicine”, some of which are not....Here we have to deal with a substance that was known and also with its previously known essential properties...Therefore, *the only element of novelty is in its application*

³³*Tennessee Eastman*, *supra* note 2.

³⁴See s. 27(3)(a) and (b) of the *Patent Act*, *supra* note 3.

³⁵Process claims are also recognized for pharmaceutical products. In a process claim, what is claimed as the invention is the process by which the product is produced.

³⁶A claim to a particular use may be broadly interpreted so as not to allow others to easily get around the patent. See *e.g. Marzone Chemicals Ltd. v. Eli Lilly and Co.*, [1978] F.C.J. No. 213. Even where a patent is interpreted broadly to include not just the stated use but other related uses, a new patent may still be issued for a different and non-obvious use (Vaver, *supra* note 2 at 123). This result has been questioned by Vaver, *ibid.*

³⁷*Supra* note 2.

³⁸*Ibid.* at 202.

³⁹*Ibid.* at 206.

*to surgical use and the discovery is limited to the unobvious adaptability to such use.*⁴⁰

These comments indicate that the Court recognized the possibility that the requisite novelty and usefulness could exist in finding a new use for an existing compound. However, the end result in *Tennessee Eastman*, which was a finding of non-patentability, turned on the fact that the Court characterized the invention as being a method of surgical treatment, and therefore unpatentable.⁴¹

In *Shell Oil Co. v. Commissioner of Patents*,⁴² the Supreme Court of Canada again was faced with a patent claim that related to a new use for a known compound. In this case, the claim related to chemical compounds mixed with an adjuvant to be used to regulate the growth of plants. With respect to the patentability of new uses for old compounds, the Court stated:

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.

If I am right that the discovery of a new use for these compounds which is capable of practical application is an "invention" within the meaning of the definition, I can find nothing in the statute which would preclude a claim for these compositions.⁴³ The Supreme Court further found that this position was compatible with English law on the subject.⁴⁴

Following the *Shell Oil* decision, the Canadian Patent Office issued a bulletin that set out the following:

⁴⁰*Ibid.* at 206 [emphasis added].

⁴¹*Ibid.* at 207. The reason the patent failed therefore was not that it relied on a new use for a known compound, but that the new use itself was a method of medical treatment and therefore unpatentable. Since the repeal of s. 41 of the *Patent Act*, which was in effect in *Tennessee Eastman*, a new use for a drug compound would not be caught in the same way.

⁴²[1982] 2 S.C.R. 536, 67 C.P.R. (2d) 1 [cited to C.P.R.].

⁴³*Ibid.* at 11.

⁴⁴It is also consistent with Australian law. In *Rescare*, Lockhart J. wrote: "[a]lthough a 'mere new use for an old thing' is not patentable, a discovery which itself involves ingenuity or novelty, that an old substance may be used so as to produce a new result, may ground a patentable invention. In such a case the old substance is treated as if it were new, its hitherto unknown or unsuspected potential being revealed by the discovery which is itself a consequence of scientific ingenuity. If a process which does not produce a new substance but nevertheless results in 'a new and useful effect' so that the new result is 'an artificially created state of affairs' providing economic utility, it may be considered a 'manner of new manufacture'" (*supra* note 5 at para. 76).

In view of the Supreme Court decision *Shell Oil Company v. The Commissioner of Patents* (1982) 2 S.C.R. and recent Commissioner's Decisions, the Patent Office will accept claims of the following type:

- a) when the invention is a *novel* compound X or a *novel* composition Y:
 - 1) Compound X (composition Y) for the use of . . .
 - 2) The use of compound X (composition Y) for . . .
 - 3) The method of using compound X (composition Y) comprising . . . (set forth various steps of method).
- b) when the invention is a known compound Z or known composition W having a *novel* utility:
 - 1) Compound Z (Composition W) for the (new) use of . . .
 - 2) Use of compound Z (Composition W) for the (new) use of . . .⁴⁵

Thus the Patent Office adopted the position set out in *Shell Oil*, and established the manner in which claims for new uses of known compounds could be made.

The *Shell Oil* decision has been applied in subsequent cases before the Patent Appeal Board, including ones involving compositions for use in medical treatment. In *Application of Patent of Wayne State University*,⁴⁶ the subject matter of the claim related directly to a new medical use for an existing composition. Following *Shell Oil*, the Appeal Board found that "a new use for the known compound is an invention which may be entitled to patent claim protection."⁴⁷

These cases suggest that despite the fact that the *Patent Act* contains no explicit reference to the possibility of patenting new uses of existing compounds, it is now settled law in Canada that such patents are available. There does, however, remain a possible issue as to whether this general ability to patent a new use for a known compound extends to new medical uses for drug compounds. In a brief note on this subject, one commentator has stated: "The *Shell Oil* decision did not involve medical uses, and thus there still may be an issue here for decision in view of the *Tennessee Eastman* case, even though the statutory foundation for that decision has since been repealed."⁴⁸ The issue here is that, even though a new use for an existing compound may be generally patentable, with the novelty lying in the discovery of the new use, where there is a new use for an known drug compound, the novelty can only lie in the application of the compound to a new medical purpose. It has

⁴⁵Canadian Intellectual Property Office, *Bulletin: Canadian Patents Issued*, 9 May 1989 [hereinafter *CIPO Bulletin*], item no. 14.

⁴⁶(1988), 22 C.P.R. (3d) 407 (P.A.B.). In commenting on this decision, Orhac noted: "[t]he simultaneous allowance of composition claims distinguishing from the prior art only by reference to the novel use of the composition has confirmed this very liberal interpretation of the *Act*" (*supra* note 13 at 186).

⁴⁷*Ibid.* at 410. Note that the position of the Board in this case is in contrast to its position in *Re Application for a Patent of Talwar* (1985), 6 C.P.R. (3d) 31 (P.A.B. and Commissioner of Patents).

⁴⁸J.D. Morrow, "Patentable Subject-Matter: Emerging Technologies" in G.F. Henderson, ed., *Patent Law of Canada* (Toronto: Carswell, 1994) 23 at 33. See also Orhac, *supra* note 13.

been argued by some that what remains, in this case, is a use which is a medical treatment (as there is nothing else that is novel), which itself is unpatentable. This position was explained in the Banks Committee Report from the U.K.:

Since new chemical compounds, processes for making such compounds and even known compounds presented in a different form are already patentable, the only type of invention which would be patentable under the proposal [to allow patents for medical treatments] would be a known compound in a known form which could be used against a disease for which it was not previously thought to be effective. The extension of patent protection in this way would result, in effect, in patents for the treatment of human beings, since a claim for such an invention would have to specify the condition against which the compound was effective and to include instructions for its use. This would not, in our view be desirable.⁴⁹

In this view of things, a patent for a second medical indication, because it lacks the element of a claim for the compound itself, can only be based on the new use, and therefore would be akin to a medical treatment. However, it is doubtful that this view would be persuasive to courts today. The assumption that a claim for a new use for a known compound would have to “include instructions for its use” is not necessarily accurate. As long as the use was set out in a manner that still provided scope for the exercise of skill and judgment on the part of the treating physician, the claim would not likely be considered, at least in Canadian law, as being a claim to a medical treatment.⁵⁰

The recent decision of the Federal Court of Appeal in the so-called Harvard Mouse case, while not relating to medical treatments or second medical use patents nonetheless may have some relevance here. The approach of the Court in that case was to decide the issues based upon a reasonable interpretation of the *Patent Act*, leaving matters of public policy to the legislature. Rothstein J., writing for the majority, noted: “[i]t is not up to the Court, for policy reasons, to place limits on the scope of legislation not supported by the words. That is the role of the legislative branch of government.”⁵¹ Thus, the fact that patenting of medical treatments is not expressly prohibited by the *Patent Act* may mean that any claim that meets the basic

⁴⁹*Report of the Committee to Examine the Patent System and Patent Law in England (the Banks Committee)* (London: Departments of State & Official Bodies, 1970), at para 239. This report does not reflect the current position in the U.K.

⁵⁰Orlhaac writes: “[i]f, however, reference to the use of a product or composition is essentially made for the purpose of specifying the utility of this product and composition without implying a physical step, then such use should be claimed *per se*” (*supra* note 13 at 186).

⁵¹*President and Fellows of Harvard College v. Canada (Commissioner of Patents)*, [2000] F.C.J. No. 1213 (F.C.A.) at 92. Rothstein J. goes on to note that “the words of the definition of ‘invention’ in the Patent Act do not exclude living organisms, and the Court may not impose such a limitation on policy grounds” (*ibid.*).

criteria for patentability is likely to be accepted without the application of an unduly restrictive interpretation of *Tennessee Eastman* based on public policy concerns.

D. Second Medical Indication Patents Under the *European Patent Convention*

As noted earlier,⁵² the *European Patent Convention (EPC)* provides for the patentability of “inventions which are susceptible of industrial application, which are new and which involve an inventive step.”⁵³ The *EPC* also excludes from patentability “methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.”⁵⁴ Similar to the practice in Canada, however, patents are available for drug compounds used in the treatment of the human or animal body.

In a key 1985 decision, the Enlarged Board of Appeal under the *EPC* heard and decided a case that raised the issue of the availability of patents for second medical indications. The Board recognized that the issue of patentability of second medical indications was interlaced with the issue of distinguishing drug compounds from methods of medical treatment for the purposes of patentability. Thus the combination of these issues was addressed in the case.

The Board first found that claims for the use of a compound for treatment were nothing more than “a method of treatment of the human or animal body by therapy with the substance or composition,” and thus were not patentable by virtue of art. 52(4) of the *EPC*.⁵⁵ However, the Board distinguished between these unpatentable claims, and claims to compounds for use in particular treatment: “[c]laims directed to substances or compositions *for use in any methods for treatment* of the human or animal body, on the other hand, are unquestionably directed to inventions which are susceptible of industrial application within the meaning of Article 52(1) *EPC*.”⁵⁶

The distinction being made is between a claim to a compound for use as a treatment, and the claim to a compound for use in the course of treatment.⁵⁷ This is essentially the same as the Canadian situation,⁵⁸ where so long as the actual

⁵²See *supra* note 11.

⁵³*European Patent Convention, supra* note 10, article 52(1).

⁵⁴*Ibid.*, article 52(4). This is done by stating that such methods of treatment are not “susceptible of industrial application.” This position has been described as a “fiction”: see Martin, *supra* note 13 at 399.

⁵⁵Case number G 83/0005 (1985), Official Journal 3 at para 14.

⁵⁶*Ibid.* [emphasis added].

⁵⁷This position is clarified in art. 54(5) of the *EPC, supra* note 10, which reads: “[t]he provisions of paragraphs 1 to 4 shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art.”

⁵⁸*Merck & Co. v. Apotex, supra* note 23.

treatment involves an exercise of discretion and judgement, it can be distinguished from the compound being used as part of the treatment.

With respect to the patentability of second medical indications for compounds, the Board discussed the problem of novelty in relation to such claims. The Board noted:

Where the medicament itself is novel in the sense of having novel technical features – e.g. a new formulation, dosage or synergistic combination – the ordinary requirements of Article 54(1) to (4) EPC will be met and there will in principle be no difficulty over the question of novelty, whether the claim be directed to the medicament per se or to the use of the active ingredient to prepare the medicament. *The critical case is, however, that in which the medicament resulting from the claimed use is not in any way different from a known medicament.*⁵⁹

The Board distinguished the case where a known compound is reformulated into a different dose, composition or format for the new medical use from the case where an existing compound in its existing formulation is applied to a new medical use. The former poses little difficulty for patent law, as there is novelty in the reformulation of the known compound as well as in the use. However, in the latter case, the novelty lies only in the discovery of the new use and thus comes close to a medical treatment. However, in the view of the Board, this is still sufficient to base a claim of patentability.⁶⁰ The Board found that under the terms of the treaty, there was no discernible intention “to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim... No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention.”⁶¹

The ultimate conclusion of the Board was that:

it is legitimate in principle to allow claims directed to the use of a substance or composition for the manufacture of a medicament for a specified new and inventive therapeutic application, even in a case in which the process of manufacture as such does not differ from known processes using the same active ingredient.⁶²

⁵⁹Case number G 83/0005, *supra* note 55 at para. 20 [emphasis added].

⁶⁰The Board noted: “[i]t seems justifiable by analogy to derive the novelty for the process which forms the subject-matter of the type of use claim now being considered from the new therapeutic use of the medicament and this irrespective of the fact whether a pharmaceutical use of the medicament was already known or not” (*ibid.* at para. 21).

⁶¹Case number G 83/0005, *ibid.* at para. 22.

⁶²*Ibid.* at para 23.

As a consequence of this decision, the European Patent Office has accepted claims to second medical indications. Such a claim, however, must be carefully worded, and is generally acceptable:

only if it is drafted in the form accepted by the practice of the Swiss Federal Intellectual Property Office, namely:

Use of a (known) product or composition X for the manufacture of a medication for the (new) therapeutic treatment of Y.⁶³

The claim described in the above passage is known as a “Swiss-type” claim, and it has been accepted in numerous jurisdictions as a valid means of claiming new uses for old compounds.⁶⁴ The Swiss-type claim is worded so as to avoid the problem of the novelty of the invention lying solely in its therapeutic use (and thus making it look a great deal like a claim to an unpatentable method of medical treatment). The reference in the claim to use of a known “composition X for the *manufacture* of a medication” inserts into the claim the element of “industrial application” required to avoid being considered a method of medical treatment.

In considering the patentability of claims to second medical indications of known substances framed as Swiss-type claims, the New Zealand Court of Appeal stated:

The Swiss form of claim has been devised to avoid claiming the method of treatment but to secure protection for use of the known compound or composition in the preparation of a medicament for the new medical use. The difficulty is that the newly discovered use which cannot be claimed represents the inventive subject matter and is where the novelty resides. It is said that by constructing the claim so as to refer to the purposes for which the medicament is made the applicant is able to invoke the novelty of the new use without claiming a method of treatment. It leaves the medical practitioner free to use the medicament without infringing the claim, yet gives protection for the innovation by furnishing the new inventor with the ability to restrain the manufacture of the medicament

⁶³Orlhac, *supra* note 13 at 188.

⁶⁴It is used in Switzerland, the United Kingdom, Sweden and Germany. In 1997, the New Zealand Patent Office issued a practice note that stated that Swiss-type claims would be accepted (*Patent Office Practice Note: “Swiss” Type Patent Claims*, 7 July 1997 [hereinafter *Practice Note 1997*], reproduced in *Pharmaceutical Management Agency Ltd.*, *supra* note 5 at para 3.) This position was challenged by the New Zealand Pharmaceutical Management Agency Ltd. The resulting decision of the New Zealand Court of Appeal confirmed that Swiss-type claims were allowed (*Pharmaceutical Management Agency Ltd.*, *ibid.*). In Australia, Swiss-type claims have also been allowed, following the decision in *Bristol-Myers Squibb Co. v. F.H. Faulding & Co. Ltd.* (1998) 41 I.P.R. 467 (Fed. Ct. Aus., T.D.), *aff’d* [2000] F.C. Aus. 316 (Fed. Ct. Aus., A.D.).

for that purpose. Continued use for any other purpose of the substance or composition remains unaffected.⁶⁵

When considered in this way, it is clear that there is a notable difference between the wording required by CIPO⁶⁶ and Swiss-type claims. In fact, the Canadian formulation comes close to being a “disembodied idea.”⁶⁷ Orlhac writes:

it would be advisable at present for practitioners to elect the second form of use claim mentioned above, namely those of the Swiss type allowed in Europe in recent years, inasmuch as in European practice as in our own practice, methods of medical treatment are considered non-patentable and the possibility of protecting a second therapeutic indication with this type of claim has been made the subject of a plurality of favourable and very sound decisions of the Enlarged Board.⁶⁸

The Swiss-type claim avoids the problems inherent in the CIPO wording, essentially that a second therapeutic use of a known compound is very close to a method of medical treatment, and the claim needs to be based on more than simply the use of the compound in a course of therapy. However, it should be noted that German courts have adopted a formulation for second medical use claims that is similar to that in the CIPO Bulletin.⁶⁹ In any event, it should be noted that the debate over claims for second medical indications is not over their patentability *per se*; rather, the dispute is largely over the appropriate wording of such claims.⁷⁰

E. Second Medical Indication Patents in Other Jurisdictions

In the United States, patents are available for second medical indications. The U.S. *Patent Act* specifically provides that “a new use of a known process, machine, manufacture, composition of matter, or material” may be patented.⁷¹ As in other jurisdictions, the patent goes to the new use, rather than to the known compound. Because there is no bar to the patenting of methods of medical treatment in the

⁶⁵*Pharmaceutical Management Agency Ltd.*, *ibid.* at para. 17. The twin problems of novelty and methods of medical treatment have been acknowledged elsewhere: “Second medical use claims should be phrased in such a way so that they steer clear of two obstacles, firstly, the requirement of novelty and the novelty conferred on second medical use claims under Article 54(5) EPC and secondly the exclusion from patentability of methods for treatment of the human body under Article 52(4) EPC.” B. Oosting, “Second Medical Use Claims: Recent Developments” (March 1999) 110 *Patent World* 22 at 22.

⁶⁶*CIPO Bulletin*, *supra* note 45.

⁶⁷Orlhac, *supra* note 13 at 189.

⁶⁸*Ibid.* at 189.

⁶⁹Oosting, *supra* note 65 at 22. The “German-type claim” is for “use of Compound X for treatment of illness Z.”

⁷⁰While the *MOPOP*, *supra* note 2, does not specifically address patents for second medical indications, the practice of the Canadian Patent Office is evident in the granting of patents for second medical indications, as occurred in the case of ZolofitTM.

⁷¹*Supra* note 13, s. 100(b).

United States, issues have not arisen as to whether what is being claimed is a method of medical treatment and, therefore, unpatentable.

The situation in New Zealand is worthy of specific consideration as the issues relating to the patenting of second medical indications for known compounds have recently received juridical consideration. Patents for methods of medical treatment are not available in New Zealand.⁷² Until recently, patents for second medical indications were similarly not available. In a Practice Note issued by the New Zealand Commissioner of Patents in 1990, it was indicated that Swiss-type claims would be rejected, not because they constituted medical treatments, but because “the pharmaceutical composition prepared is not novel unless it is materially different from previous compositions.”⁷³ In other words, the basis for rejecting the claim was lack of novelty, rather than the ground that the claim related to a method of medical treatment, which would likewise be unpatentable in New Zealand.⁷⁴ This position was reversed in a 1997 Practice Note, where the Commissioner took the view that a reversal was appropriate “in light of the continuing international trend to liberalize the definition of invention.”⁷⁵

This second Practice Note was challenged by New Zealand’s Pharmaceutical Management Agency, which is responsible for the subsidization of medicines in New Zealand. The Agency asked the courts to review and strike down the decision of the Commissioner to allow Swiss-type claims on the basis that “the grant of patents for inventions in respect of second or subsequent pharmaceutical uses will prevent competition among pharmaceutical suppliers with adverse effects on prices.”⁷⁶

In 1983, the New Zealand Court of Appeal, in *Wellcome Foundation*,⁷⁷ had ruled that a claim for a second medical indication of a known substance was not patentable because it amounted to nothing more than a claim to a method of medical treatment, which itself was non-patentable. In 1999, in the *Pharmaceutical Management Agency Ltd.* decision, the New Zealand Court of Appeal revisited that earlier case. The Court accepted that methods of medical treatment could not be patented. However, having accepted this point from *Wellcome*, they then departed from that earlier decision, stating:

⁷²See *supra* note 5.

⁷³*Patent Office Practice Note, “Swiss” Claims*, 22 March 1990, reproduced in *Pharmaceutical Management Agency Ltd.*, *supra* note 5 at para. 2.

⁷⁴Similarly, the English Patents Court has found that the problem with Swiss-type claims is that they do not confer novelty: *John Wyeth & Brother Ltd.’s Application*, [1985] R.P.C. 545 at 548. Nevertheless, for the sake of consistency within the European patent regime, the court decided to follow the decision of the Enlarged Board (at 567).

⁷⁵*Practice Note 1997*, *supra* note 64.

⁷⁶*Pharmaceutical Management Agency Ltd.*, *supra* note 5 at para. 4.

⁷⁷*Supra* note 5.

The exclusion from patentability of methods of medical treatment rests on policy (moral) grounds. The purpose of the exclusion is to ensure that medical practitioners are not subject to restraint when treating patients. It does not extend to prevent patents for pharmaceutical inventions and surgical equipment for use in medical treatment.⁷⁸

The Court then went on to determine that the Swiss-type claim was an appropriate means of patenting a second medical indication for a compound while still leaving unrestrained “the medical practitioner in the practice of his or her diagnostic, therapeutic or surgical methods.”⁷⁹ As a result, in New Zealand, while patents are not available for methods of medical treatment, they can be obtained for second medical uses of known compounds using the Swiss-type claim.

F. Consequences of Canada’s International Patent Obligations

Canada’s patent law obligations under *TRIPS* have been the subject of two recent complaints to the World Trade Organization.⁸⁰ Canada suffered a partial loss in the first case and lost the second case.⁸¹ As a result of these two decisions, legislation was recently enacted⁸² to amend the *Patent Act* by permitting the extension of the term of patent protection of those patents applied for before October 1, 1989, and still in effect at the time of coming into force of the legislation, to a term of 20 years from the date of filing in cases where this would provide a longer term of protection than 17 years from the date of patent grant. The new legislation also repeals subsections 55.2(2) and (3) of the *Act*, removing the stockpiling provisions from the *Patent Act*.

⁷⁸*Ibid.* at para. 29.

⁷⁹*Ibid.*

⁸⁰The decisions in these cases are: *Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000, online: <http://www.wto.org/english/tratop_e/dispu_e/distab_e.htm> (date accessed: 20 February 2002); and *Canada - Term of Patent Protection*, AB-2000-7, WT/DS170/AB/R.

⁸¹The first case involved two provisions of the *Patent Act* that were relevant to the early entry onto the market of generic drugs following the expiration of a patent. One provision, the “regulatory approval” exception, allowed “any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product” (*Patent Act*, *supra* note 3, s. 55.2(1)). This exception was allowed to stand. The second provision, known as the “stockpiling exception” set out limited circumstances in which articles protected by a patent could be manufactured and stored in the period leading up to the expiration of the patent (*Patent Act*, *ibid.*, s. 55.2(2)). This period was set by regulations at six months (*Manufacturing and Storage of Patented Medicines Regulations*, S.O.R./93-134). The stockpiling exception was found to violate Canada’s international obligations. The second case dealt with the shift from a term of protection of 17 years from the date of patent issue to 20 years from the date of filing. The Board ruled that by failing to guarantee that patents that issued before the change in patent term and that were still subsisting could benefit from the 20 year term, Canada violated its international obligations.

⁸²*An Act to Amend the Patent Act*, S.C. 2001, c. 10.

The legislative amendments are directly responsive to the two WTO rulings. Although both rulings and the amendments that implement them will have some impact on the entry into the market of cheaper generic drug products, that impact may be limited.⁸³ In any event, the amendments are narrowly crafted, and do not go beyond what is necessary to implement the rulings, nor do they embody a general reworking of patent law in relation to the pharmaceutical industry.

However, because the legislation will have an impact, albeit limited, on the speed at which generic drug products enter the market in Canada, and therefore on drug costs and costs to the health care system, the amendments have attracted attention, and pressure has been placed on government to respond to public concerns. Industry Minister Brian Tobin recently announced his intention to "reopen the debate about one of Canada's most controversial laws,"⁸⁴ the *Patent Act*. In particular, he was quoted as saying that he "would be open to revisiting other regulations controlling the prescription drug regime, particularly those permitting drug companies to modify their patents midway through their terms, and, in so doing extend their lives".⁸⁵ This suggests that the issue regarding patents for second medical indications may well be on the table in any future discussions on amending Canada's patent legislation.

However, in light of the emerging legal consensus among Canada's trading partners on the legitimacy of second medical indication patents, and in light of Canada's international patent obligations, it is difficult to see how Canada would be in a position to restrict patents for second medical indications. This is because both the *NAFTA* and the *TRIPS* agreement require Canada to provide protection for inventions, broadly defined. The relevant exception in both agreements to the general rule on patentability which allows states to create exemptions from patentability for methods of medical treatment would not be applicable, because there is now an established body of law across multiple jurisdictions which finds that patents for second medical indications are not patents for methods of medical treatment. Finally, patents for second medical indications have been treated among

⁸³ According to the Canadian Intellectual Property Office (CIPO), the patents to receive an extended term of protection following the proposed amendments include "some 30 commercially significant drugs." However, CIPO estimates that the amendments would extend the life of these patents by "an average of less than six months," and notes that "[i]n some cases this could delay the entry onto market of less expensive generic substitutes by a similar period of time." As a result, CIPO concludes: "[t]he World Trade Organization ruling has no significant or sustained impact on drug costs" (Canadian Intellectual Property Office, "Backgrounder: World Trade Organization Ruling on Patent Term," 22 February 2001). Arguably, the regulatory approval exception was more important as the lack of ability to stockpile ingredients would only result in minor delays in getting to market.

⁸⁴ I. Jack, "Tobin to reopen generic drug debate: Plans fall review of law critics says keeps prices high" *National Post* (22 March 2001) A6.

⁸⁵ J. Baxter, "Tobin Tells Senate: I was wrong: Minister wants drug patents extended" *Ottawa Citizen* (22 March 2001) C3.

Canada's trading partners as patents on inventions within the meaning of both *NAFTA* and *TRIPS*.⁸⁶

It is clear that should Canada attempt to further amend its patent legislation to favour the entry onto the market of generic products or to limit options for second medical use patents, its options will be very severely constrained by its international obligations. In evaluating the patentability of claims to second medical uses, the New Zealand Court of Appeal noted:

But by its accession to the TRIPS Agreement New Zealand has undertaken to make available patents "for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application": (Art 27:1). That obligation, which has been assumed by all parties to the agreement, is not to be set aside on grounds based on circumstances of convenience such as the comparatively low level of medical research undertaken in this country or the particular method by which medicines are funded.⁸⁷

Similarly, it is difficult to see how Canada would be able to limit the granting of patents for second medical uses of compounds, particularly when such claims have been distinguished from claims with respect to medical treatments, and when such patents are widely recognized in other jurisdictions, including those which prohibit the patenting of methods of medical treatment.

G. Summary

Methods of medical treatment are not patentable in Canada. This is the case in many jurisdictions including New Zealand and the United Kingdom, and under the *European Patent Convention*. In the United States, while methods of medical treatment may be patented, recent amendments to the U.S. *Patent Act* make such patents largely unenforceable against physicians or hospitals.

Even in jurisdictions such as Canada which do not allow patents on methods of medical treatment, there is still much room for patents in the health care area. In particular, drugs used in medical treatment are considered to be distinct from the medical treatment itself, and therefore patentable. The method of medical treatment tends to be defined in terms of the skill and judgment of the physician in using the drug compound. The compound is thus independently patentable.

⁸⁶This being the case, there still remains scope for determining what constitutes a legitimate claim for a second medical indication. Under the *EPC*, for example, a distinction is made between "a true new use... and not merely more information about a known use" (Oosting, *supra* note 65 at 24).

⁸⁷*Pharmaceutical Management Agency Ltd.*, *supra* note 5 at para. 64.

Patents for second medical indications occupy an awkward space in between a method of medical treatment and a patentable compound. Because, in the case of a patent claim for a new use of an old compound, the only novelty is in the new use, the claim may come close to seeming like a claim for an actual treatment. However, so-called Swiss-type claims have been relied on under the *European Patent Convention* and in New Zealand for claims to second medical indications for known drug compounds. A Swiss-type claim is distinctive because it frames the claim as the use of the known compound for the manufacture of a medicine for a new therapeutic use. The wording of the Swiss-type claim thus introduces an element of industrial application into the claim. In Canada, the CIPO has allowed claims for second medical indications to be framed as claims to compound Z for a specified new use. It is not clear whether a claim worded according to this formula may give rise to a challenge on the basis that such patents are nothing more than patents on medical treatments. However, it is unlikely that such a semantic difference would be sufficient to reject patents for second medical indications, particularly where such patents are receiving general international acceptance. The trend of the Federal Court of Canada towards a less restrictive interpretation of the *Patent Act*, the fact that the *Act* itself does not prohibit patents on methods of medical treatment, developments in jurisdictions with legislative regimes similar to Canada's, and the constraints of Canada's international patent obligations make it unlikely that the legal basis for second medical indication patents could be easily disrupted.

II. *Apotex V. Ontario (Minister of Health) and Pharmacare Programs*

A. *Apotex Inc. v. Ontario (Minster of Health)*

Central to the issues raised in this paper is the decision of Justice O'Driscoll in the case of *Apotex Inc. v. Ontario (Minister of Health)*.⁸⁸ The case is a complicated one, involving the interaction of various statutory and regulatory schemes including the *Food and Drugs Act*,⁸⁹ the *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)*,⁹⁰ the *Patent Act*, the *Ontario Drug Interchangeability and Dispensing Fee Act*⁹¹ (*DIDFA*), and the *Ontario Drug Benefit Act*.⁹²

Sertraline hydrochloride, known by its brand-name, Zoloft™, was originally protected by a patent with the treatment of depression as the identified use.⁹³ The patent holder was Pfizer Canada. Subsequently, Pfizer obtained a patent for two

⁸⁸*Supra* note 1 [hereinafter *Apotex v. Ontario*].

⁸⁹R.S.C. 1985, c. F-27.

⁹⁰S.O.R./93-133.

⁹¹R.S.O. 1990, c. P.23.

⁹²R.S.O. 1990, c. O.10.

⁹³Canadian Patent 1,130,815.

other uses of the compound: the treatment of obsessive-compulsive disorder and of panic disorder.⁹⁴ The patent for the first indicated use expired on August 31, 1999. The patent for the second indicated uses will not expire until 2010.

Apotex applied for and ultimately received a Notice of Compliance (NOC) for a generic version of Zoloft™ under the *NOC Regulations*. At the time of seeking the Notice of Compliance, it made the undertaking that it would not “make, construct, use or sell sertraline hydrochloride or compositions containing same for any use covered by the claims”⁹⁵ of the patents for sertraline hydrochloride relating to treatment of conditions other than depression. In reliance on this undertaking, Pfizer did not commence a proceeding against Apotex under s. 6 of the *NOC Regulations*.

Apotex subsequently proceeded to seek to have their generic version of sertraline hydrochloride listed as interchangeable with Zoloft™ in the Ontario Formulary under the *DIDFA* regulations. They sought to have it listed as fully interchangeable, not interchangeable only for the particular indication of depression. This was not unprecedented, as it appears that other drugs with multiple indications, some of which were still protected by patents, had been listed as fully interchangeable in the past.⁹⁶ However, in a more or less unprecedented move, the Ministry of Health and Long-Term Care (Health Ontario) listed Apo-sertraline as interchangeable only for the indication of depression. Apotex made an application for judicial review of this decision, which was heard by Justice O’Driscoll of the Ontario Superior Court on February 29 and March 1, 2000. His decision upholding the decision of Health Ontario was issued on December 20, 2000.⁹⁷

In his decision, Justice O’Driscoll found that a full interchangeable listing for Apo-sertraline would be contrary to the *Food and Drugs Act* provisions relating to the issuance of Notices of Compliance. The regulatory approval under this Act was given only for sale for treatment of depression. As a result, in his view, Apo-sertraline “does not qualify for a full interchangeable listing.”⁹⁸ Justice O’Driscoll further found that the wording of the relevant Ontario legislation and the *Food and*

⁹⁴Canadian Patent 2,029,065.

⁹⁵*Apotex v. Ontario*, *supra* note 1 at para. 10, citing Notice of Allegation from Apotex to Pfizer Canada (14 January 1997).

⁹⁶*Apotex v. Ontario*, *supra* note 1 (Evidence, Affidavit of J. Keon, 25 January 2001, Court File No. 59/2000) at para. 27. In fact, in a letter to the Associate Director of Drug Programs Management, the Director of Apotex wrote: “[f]or more than twenty years, the Ministry has added products to the Formulary regardless of differences in approved indications between interchangeable products, or patent disputes between corporations. There are numerous examples of products that were added to the Formulary under similar circumstances. Sulfonpyrazone, propranolol, ranitidine, salbutamol, enalapril and lovastatin are some of the precedents spanning this time period.” *Apotex v. Ontario*, *ibid.* (Evidence, Letter from P. Gingras to L. Babiak, 14 June 1999, Court File No. 59/2000) [hereinafter Letter from P. Gingras].

⁹⁷*Apotex v. Ontario*, *ibid.*

⁹⁸*Ibid.* at para. 31.

Drugs Act provided “ample discretion to list Apotex’s product as a restricted listing on the Formulary.”⁹⁹

Although he did not engage with the patent issues directly in reaching his decision, Justice O’Driscoll quoted at length from the Affidavit of Frank DeFelice of Health Ontario. In that Affidavit, Mr. DeFelice indicated that the Ministry had reached its decision to make a qualified interchangeable listing because of patent issues. In particular, Mr. DeFelice noted that the patents for the second indications were valid, the NOC was issued only for the indication of depression, and Apotex would be unable to get an NOC for the other indications until the patents expired. Further, he noted that “an unrestricted listing on the Formulary could place pharmacists in the position of infringing valid patents, as well as place the Ministry in the position of inducing patent infringement.”¹⁰⁰ Mr. DeFelice further noted that the reason this case was a watershed was because “this was the first case where the issue of patents being held on [second] indications was raised with the Ministry and the first time that the Ministry was put on notice by the brand manufacturer that it would be enforcing such patents.”¹⁰¹

Essentially, the decision of Justice O’Driscoll upholds the decision of the Ministry on the basis that there was ample discretion on the part of the Ministry to act as they did, and that their discretion was not improperly exercised. There is no actual decision on the issue of patent liability of pharmacists or of the Ministry should a full interchangeability listing be given. It is important to emphasize that this decision is really about whether the Ministry could act as it did. The conclusion of Justice O’Driscoll is that it could, given the wording of its legislation. It is much less clear whether the Ministry was required to act as it did. However, patent concerns were clearly motivating factors behind the decision of the Ministry to provide only a partial interchangeability listing.

B. Notice of Compliance Regulations

Before going on to consider the issues relating to interchangeability under provincial pharmacare programs in more detail, it is important first to assess the Notice of Compliance scheme under the *Food and Drugs Act (FDA)*¹⁰² and its regulations, and the *NOC Regulations*. This scheme is of fundamental importance as it underlies the relationship between patent issues and regulatory approval for pharmaceutical products in Canada.

⁹⁹*Ibid.* at para. 33.

¹⁰⁰*Apotex v. Ontario*, *supra* note 1 (Evidence, Affidavit of F. DeFelice, 18 February 2000), cited in *Apotex v. Ontario*, *ibid.* at para. 30.

¹⁰¹*Ibid.*

¹⁰²*Supra* note 89.

In 1993 Canada introduced a Notice of Compliance scheme through the *NOC Regulations*.¹⁰³ These regulations under the *Patent Act* are intended to work in conjunction with the regulations relating to Notices of Compliance issued under s. C.08.004 of the *Food and Drugs Regulations (FDA Regulations)*,¹⁰⁴ pursuant to the *Food and Drugs Act*. Under the *FDA Regulations*, an NOC is issued in respect of a new drug once the Minister is satisfied that the safety and effectiveness of a new drug is established. Until an NOC issues, the new drug may not be advertised or sold.¹⁰⁵ A new drug submission for the purposes of obtaining an NOC must contain a detailed compilation of information, data and research to satisfy the Minister.¹⁰⁶

The *FDA Regulations* make provision for speedier approval of new drugs where “the new drug is the pharmaceutical equivalent of the Canadian reference product,” where it is bioequivalent with the Canadian reference product, where “the route of administration of the new drug is the same as that of the Canadian reference product,” and where “the conditions of use for the new drug fall within the conditions of use for the Canadian reference product.”¹⁰⁷ In other words, where a generic company wishes to enter the market with a product that is the equivalent to an existing brand name drug, it may rely upon much of the research used in the approval process for the brand name drug. This can significantly reduce both the time and cost of entry into the market of the generic product.

The *NOC Regulations* are meant to ensure respect for patents in relation to the *FDA* Notice of Compliance process. They are of particular importance where a generic drug company is seeking regulatory approval for a generic version of a brand name drug and is seeking to rely upon the research of the brand name drug company in the approval process. According to the Regulatory Impact Analysis Statement, they were enacted “to ensure that second and subsequent entry manufacturers who apply for a notice of compliance (NOC) for their version of a patented drug will not obtain a NOC until the relevant patent expires, or until disputes respecting patent infringement or invalidity are resolved by the courts.”¹⁰⁸ Thus, a drug company that wishes to sell a generic version of a brand name drug

¹⁰³*Supra* note 90, as. am. by S.O.R./98-166; S.O.R./99-379. These regulations were introduced in the same time period in which compulsory licences for pharmaceuticals were abolished. Also, ss. 55.2(1) and (2) of the *Patent Act*, *supra* note 3, recently challenged before the WTO by the European Union, were also introduced as part of the new overall scheme for the regulation of the pharmaceutical industry. Under s. 55.2(1), it is legal to manufacture or use a patented invention for the purposes of seeking regulatory approval such as a Notice of Compliance. This provision remains valid following the WTO ruling discussed *supra* note 81.

¹⁰⁴*Food and Drug Regulations*, C.R.C., c. 870.

¹⁰⁵*Ibid.*, C.08.002 (1).

¹⁰⁶*Ibid.*, C.08.002 (2).

¹⁰⁷*Ibid.*, C.08.002.1 (1)(a).

¹⁰⁸*Regulatory Impact Analysis Statement for Regulations Amending the Patented Medicines (Notice of Compliance) Regulations*, SOR/99-379, 13 October 1999, C. Gaz. 1999.II, Vol. 133, No. 21.

“must address that company’s patents before obtaining marketing approval to sell the generic version.”¹⁰⁹

The *NOC Regulations* provide for the Minister of National Health and Welfare to maintain a register of patents relating to drugs for which NOCs have been issued.¹¹⁰ Where a registered patent exists on a product for which a generic company is seeking approval under the *FDA Regulations*, the generic drug applicant who has filed a submission for a Notice of Compliance, and who wishes to rely upon the research and other data relating to the approved drug for which a patent is listed, must address the patent issues. The generic company may:

- (a) state that the person accepts that the notice of compliance will not issue until the patent expires; or
- (b) allege that
 - (i) the statement made by the first person pursuant to paragraph 4(2)(c) is false,
 - (ii) the patent has expired,
 - (iii) the patent is not valid, or
 - (iv) no claim for the medicine itself and no claim for the use of the medicine would be infringed by the making, constructing, using or selling by that person of the drug for which the submission for the notice of compliance is filed.¹¹¹

Thus, the *NOC Regulations* introduce patent considerations into the regulatory approval process. In *Merck Frosst Canada Inc. v. Minister of National Health and Welfare*¹¹² Hugessen J. made the following comment:

In this appeal the court is again called upon to struggle with the difficult task of interpreting the newly adopted Patented Medicines (Notice of Compliance) Regulations, SOR/93-133. In large measure, the difficulty is due to the fact that those regulations, whose clear intention is to facilitate the protection of private commercial patent rights, have been grafted onto a regulatory scheme, the Food and Drug Regulations, C.R.C. 1978, c. 870, as amended, whose sole purpose is the protection of public health and safety. The union is not a happy one.¹¹³

¹⁰⁹P.R. Wilcox & D.C. Ripley, “The Patented Medicines (Notice of Compliance) Regulations” (2000) 16 C.I.P.R. 429 at 429.

¹¹⁰Patent holders are entitled, under the regulations, to submit a patent list, which sets out “any Canadian patent that is owned by the person, or in respect of which the person has an exclusive licence...that contains a claim for the medicine itself or a claim for the use of the medicine and that the person wishes to have included on the register” (*NOC Regulations*, *supra* note 90, s. 4(2)(b)).

¹¹¹*Ibid.*, s. 5(1).

¹¹²(1994), 55 C.P.R. (3d) 302 (F.C.A.).

¹¹³*Ibid.* at 304.

These comments are also appropriate in light of the issues that have arisen in *Apotex v. Ontario*, where a generic drug is approved for sale as the bioequivalent of a brand name drug, yet cannot be used for the same indications as the brand name drug because of patent issues.

The regime under the *NOC Regulations* and its relationship with the *FDA Regulations* pose real problems for the administration of provincial pharmacare programs. A generic drug company can get an NOC for a drug on which a patent has expired. It can do so even where other unexpired patents exist in respect of the same drug. Further, the NOC in the case of the generic indicates a finding of bioequivalence. Thus, a generic product is found to be bioequivalent to the brand name drug when it is approved for use and sale. It is not surprising that approval of use of a generic drug for one indication but not for another, where the drug is the bioequivalent of another drug which is approved for both purposes, causes confusion and disruption in the prescribing and dispensing of drugs and in the administration of pharmacare programs.

C. Patent Implications

In its Notice of Motion for leave to appeal the decision of Justice O'Driscoll, Apotex argued that:

Patent disputes or potential disputes are common in the pharmaceutical industry. If Mr. Justice O'Driscoll's decision is permitted to stand, the effect will be that patent-related assertions to the Minister may limit or delay the designation of many generic products as interchangeable under DIDFA, defeating the purpose of DIDFA, and greatly reducing the availability of generic drugs.¹¹⁴

While it is true that patent disputes or potential disputes are common in the industry, the *Apotex v. Ontario* case did not involve a disputed patent. Rather, it involved the issue of whether the use of a generic drug for medical indications for which a Notice of Compliance had not yet issued could be the subject of an interchangeability listing on a provincial formulary.

It may well be that health departments customarily take the position that in the case of patent disputes between brand name and generic drug companies, an approved generic will remain listed as interchangeable unless and until the case is finally resolved against the generic. However, the issues in the situation under discussion are somewhat different. In seeking the NOC, the generic drug company has an opportunity to challenge the validity of the brand name patents. Where an NOC issues, it is because such a challenge has not been made, and the generic drug

¹¹⁴*Apotex v. Ontario*, *supra* note 1 (Notice of Motion for Leave to Appeal, 3 January 2001, Court File No. 59/2000) at para. 32.

company has agreed to respect the patents. In such circumstances, the issue becomes whether still subsisting patents on the brand name drug impose obligations on health departments, prescribers and/or dispensers of drugs to respect the patents in making decisions about interchangeability.

It is clear that until a Notice of Compliance is issued, a drug cannot be marketed or sold in Canada. It is further true that the *NOC Regulations* are tied to the *Patent Act*, and a Notice of Compliance is only issued either to the holder of a valid patent for the particular drug, or to a generic company if, and only if, the term of patent protection on the brand name drug has expired. Thus it seems clear in this regard that the issuance of Notices of Compliance is, in fact, closely tied to patent issues.

D. Provincial Health Departments and Drug Interchangeability

Because the drug approval process can result in generic products being approved for only one of multiple possible indications due to still subsisting patents, issues of liability for patent infringement may arise among those who use or dispense the drug products. The example of Ontario is used to illustrate where these issues might arise.

1. Ontario

The *Ontario Drug Benefit Act*¹¹⁵ gives the Lieutenant Governor in Council the power to make regulations "prescribing conditions to be met for a drug product to be designated as a listed product"¹¹⁶ for the purposes of the Drug Benefit scheme. These regulations refer to the "Drug Benefit Formulary/Comparative Drug Index"¹¹⁷ (Formulary), which is the list of drug products along with interchangeable drugs. The *Drug Benefit Act*, in its definition of "interchangeable," refers to a drug product designated as interchangeable under the *Drug Interchangeability and Dispensing Fee Act (DIDFA)*.¹¹⁸ Under the latter Act, an interchangeable product is defined as "a drug or combination of drugs in a particular dosage form and strength identified by a specific product name or manufacturer and designated as interchangeable with one or more other such products."¹¹⁹ Under s. 14(1) of the *DIDFA*, the Lieutenant Governor in Council is empowered to make regulations "prescribing conditions to be met by products or by manufacturers of products in order to be designated as interchangeable with other products." The regulations enacted pursuant to this section are key.¹²⁰ They provide that:

¹¹⁵*Supra* note 92 [hereinafter *Drug Benefit Act*].

¹¹⁶*Ibid.*, s. 18(1)(b).

¹¹⁷*Ontario Drug Benefit Act (Regulations)*, O.Reg. 201/96, amended to O.Reg. 358/01, s. 1.

¹¹⁸*Supra* note 92, s. 1.

¹¹⁹*Supra* note 91, s. 1.

¹²⁰*Drug Interchangeability and Dispensing Fee Act (Regulations)*, O. Reg. 935 (amended to O. Reg. 359/01).

6.(1) It is a condition for each strength and dosage form of a drug product to be designated as interchangeable with other products that the manufacturer of the drug product submit to the Minister,

(a) evidence that the Health Protection Branch of Health Canada has approved the product for sale in Canada, the product's drug identification number and, subject to subsection (2), a copy of the product monograph approved by the Health Protection Branch of Health Canada;

...

8. The following conditions must be met in order for a drug product that has been designated as interchangeable to continue to be designated as interchangeable:

...

(2) The product must be authorized for sale under the Food and Drugs Act.

These sections link the interchangeable listing directly to the *FDA* approval process. Presumably, where Health Canada has approved a generic drug for sale only for one of a number of possible indications for patent reasons, the documentation submitted under these regulations will so indicate. Although the regulations do not expressly require that the drug be listed as interchangeable only for approved indications, it is arguable that that is implicit in these regulations. However, it is also possible to argue that the reference in s. 6(1)(a) to approval for sale is a general one, and does not require approval for sale for all indications.

The *DIDFA* requires pharmacists to advise patients that they are "entitled to request that the prescription be filled with a less-expensive, interchangeable product (where an interchangeable product is listed on the Formulary)."¹²¹ The legislation also sets limits on the prices that can be charged to patients where there are interchangeable products, unless the patient requests the brand-name product, or a physician has indicated no substitution. Interchangeable products are those listed in the provincial Formulary. Pharmacists rely on the Formulary in making their decisions regarding interchangeability. Indeed, "[i]f a product is listed in the Formulary, the pharmacist need only rely on the Formulary to establish whether a product is interchangeable and to ensure that the requirements for interchangeability are met."¹²² This reliance upon the Formulary is a key element in assessing the potential patent liability of Health Ontario, which is responsible for the creation of the Formulary. It is also a key element in assessing the patent liability of the pharmacist for dispensing a drug that infringes upon a patent. Pharmacists who follow the statutory rules and abide by the interchangeable designations in the Formulary can benefit from s. 8 of *DIDFA*, which reads:

If an interchangeable product is dispensed in accordance with this Act,
no action or other proceeding shall be instituted against the person who

¹²¹*Apotex v. Ontario*, *supra* note 1 (Evidence, Affidavit of G.M. Ujiye, 23 February 2000, Court File No. 59/2000) at para. 8.

¹²²*Ibid.* at para. 12.

issued the prescription, the dispenser or any person who is responsible in law for the acts of either of them on the grounds that an interchangeable product other than the one prescribed was dispensed.

Thus, the legislation shields from liability a pharmacist who dispenses according to the statutory rules and the Formulary. Presumably, this provision would also protect pharmacists from patent liability. However, it cannot remove the issue of patent liability entirely. In a sense, if the pharmacist is allowed the defense that he or she was merely complying with provincial legislation, then assuming there is infringement, liability for that infringement must lie elsewhere. Most likely it would lie with the Health Ontario for having approved of and encouraged the patent violation by making the listing of full interchangeability. These issues will be discussed in the section on patent infringement below.

The exemption from liability in s. 8 of the *DIDFA* is for any legal action taken “on the grounds that an interchangeable product other than the one prescribed was dispensed.” However, where the Formulary provides that certain drugs are interchangeable for only one of a range of possible indications, it does seem to place an onus on pharmacists to ensure that the interchangeable drug is only dispensed for the permitted indications and not for others. In other words, the shield from liability would not apply if a drug were dispensed for an indication for which it was not listed as interchangeable. The decision of the Health Ontario to provide listings with only partial interchangeability places pharmacists in the position of needing to request the indication from the physician in order to dispense the appropriate drug. This would be necessary to allow them to benefit from the shield from liability provided for in s. 8 of the *DIDFA*. It is a separate issue whether they would be liable for patent infringement, for example, for dispensing Apo-sertraline for panic disorder in these circumstances.¹²³

2. Provinces Other than Ontario

Currently no other province in Canada gives anything other than full interchangeability listings for generic products that are approved for at least one indication. However, there is evidence that other provincial ministries of health have been given notice by Pfizer that these issues will be pursued in their jurisdictions.¹²⁴ Whether they will respond in the same manner as did Ontario’s Ministry of Health and Long-Term Care remains to be seen. A key factor in reaching any such decision may be whether there are, in fact, serious patent issues, and the extent to which medical and pharmacy professionals and even the health departments may be held responsible for any patent violations.

¹²³For a discussion of liability issues, see the section on patent infringement below.

¹²⁴Application for Leave to Appeal the decision of Justice O’Driscoll in *Apotex v. Ontario* (Minster of Health (Affidavit of J. Keon, President of the Canadian Drug Manufacturers Association, 25 January 2001) at para. 45.

While Pfizer has been the lead player in this regard, and Zoloft™ has been the “test case” product,¹²⁵ there are currently many other brand-name drugs with second medical indications subject to valid patents, but which are listed as fully interchangeable on provincial formularies.¹²⁶ The practice of getting new patents for existing compounds is widespread enough to be known as “evergreening.”¹²⁷ Thus the potential implications for provincially funded pharmacare programs are significant.¹²⁸

E. Prescribing and Dispensing Practices

Doctors often prescribe, and pharmacists often dispense drugs for non-approved indications. It could be argued, therefore, that there is nothing wrong with prescribing any drug that has been approved for at least one indication for any other indication if it is known to have therapeutic effect in regard to that other indication. To be better able to assess the merits of this argument, particularly in the patent context, it is useful to first gain some understanding of the practices that lead to the prescribing and dispensing of drugs for non-approved indications.

A patented drug for which an NOC has been obtained is approved for sale for certain indications. Those indications are the only ones for which the patent holder may legally promote or market the drug. The patent holder may choose to pursue further research to determine if there are any other uses for the particular compound. If such uses are discovered, the company may seek and obtain separate patents for those second medical indications.

It sometimes occurs in medical practice that a particular drug becomes known among doctors as having beneficial uses other than those for which it is approved. Doctors apparently do regularly prescribe medication for uses that are not formally approved. In some cases, the patents on the drug in question have expired, and there is no party interested in going to the expense of seeking both a patent and FDA

¹²⁵Perhaps not surprisingly, Zoloft™ is the 11th most prescribed pharmaceutical in the U.S., and is likely, by extension, to be a top seller in Canada. See RxList, “The Top 200 Prescriptions for 2000 by Number of U.S. Prescriptions Dispensed,” online: <<http://www.rxlist.com/top200.html>> (date accessed: 20 February 2002). According to Pfizer, the “Ontario Drug Benefit Program reimbursed approximately 300,000 claims for Zoloft during 1998. This resulted in an expenditure by ODB of \$22 million for drug cost, not including markup or dispensing fee.” *Apotex v. Ontario*, *supra* note 1 (Evidence, Letter from T. Firestone to M.C. Lindberg, 18 March 1999, Court File No. 59/2000) [hereinafter Letter from T. Firestone].

¹²⁶See Letter from P. Gingras, *supra* note 96.

¹²⁷Second medical indication patents are just one of a number of ways in which brand name drug companies extend the lives of their pharmaceutical products. For a discussion of some of the different techniques, see D. Robertson, “Pharma strategies extend drug lives” (1999) 17 *Nature Biotechnology* 220.

¹²⁸In a letter to the Assistant Deputy Minister for Health Insurance and Related Programs (Ontario), a Pfizer Vice-President indicated that in 1998 alone, \$22 million in drug cost was paid under the Ontario Drug Benefit Program for Zoloft™. Of that amount, Pfizer estimates that 12% of claims were for panic and obsessive compulsive disorder. Letter from T. Firestone, *supra* note 125.

approval. In such circumstances, the use of the drug for purposes other than those approved can become widespread, although not officially sanctioned. As a patent can only be obtained for a new use that is non-obvious, once it is known in the medical community that a particular compound has a particular therapeutic effect, then it would be impossible to obtain a patent for that particular use of the compound. It is also possible that a drug still covered by a patent becomes used for a new and non-patented indication. In such circumstances the brand name company may tolerate this use without seeking an additional patent either because there would be problems with establishing novelty or non-obviousness, or because there is insufficient economic interest to incur the costs of complying with the relevant patent and drug approval processes.

Where doctors prescribe medication for non-approved indications, pharmacists will fill the prescription. In many, if not most cases, they will not know the purpose for which the drug is being prescribed, and thus are not in any way complicit in prescribing a drug for a non-approved indication. However, in other circumstances they may be aware of the indication for which the drug is prescribed. In such cases, the pharmacists also engage in the practice of dispensing a drug for a non-approved indication. Issues of tort liability may arise where a patient suffers harm after being treated with a drug for a non-approved indication.

Thus, although it might be argued that it is not unusual for a drug to be prescribed for a non-approved indication, and that therefore there is no harm in dispensing a generic drug for an indication for which that drug has not been formally approved, the issues are different where the patent on one indication for use has expired but patents for other indications have not. In such circumstances, it is not simply a matter of doctors and pharmacists choosing to prescribe and dispense drugs for uses for which they have not received formal approval. Rather, the issue is complicated by the fact that the *Patent Act* prohibits the use and sale of items in violation of a valid patent.

F. Patent Infringement

Section 42 of the *Patent Act* provides that:

Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, *the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used* subject to adjudication in respect thereof before any court of competent jurisdiction.¹²⁹

¹²⁹*Supra* note 3 [emphasis added].

Thus, the exclusive rights of the patentee are to exclude others from making, constructing and using the invention and from selling it to others to be used. Any infringement of the patent, therefore, must result from another person engaging in one of these protected activities. Where the patent is with respect to a new use for a known compound, and that compound is in the public domain, there cannot be a monopoly in the making or construction of the invention. The monopoly rights can therefore only reside in the use of the invention, and in the sale of it to others to be used.

In a letter to the Assistant Deputy Minister for Health Insurance and Related Programs (Ontario), a Pfizer Vice-President stated the company's view of the patent infringement situation with respect to Zoloft™. Theresa Firestone wrote:

It is therefore our position that under the current environment in Ontario, if the generic sertraline were designated interchangeable with ZOLOFT, each and every time a prescription was filled for the indication of either panic disorder or obsessive compulsive disorder, the pharmacist would be violating Pfizer's patent. In so designating this product, it is also our position that the Ontario Drug Benefit Program would indeed be facilitating this violation. This is also the case for payment of claims for generic sertraline for what in effect would be a combination of claims for all indications.¹³⁰

The discussion that follows will consider issues of infringement with respect to use of a known compound for a second medical indication, and the sale of the known compound for that use. It will also consider liability issues for inducing infringement. For the sake of convenience, Zoloft™ will be used to illustrate the discussion.

1. Infringement through Use

Sertraline hydrochloride is no longer covered by a patent for its use in the treatment of depression. However, sertraline hydrochloride under the name of Zoloft™ is protected by a patent for use in treating panic disorder or obsessive compulsive disorder. In order to determine who might be liable for infringement for improper use of the patented product, it is worth considering who could be said to "use" the drug. Patients who are prescribed the drug arguably use it, as they actively take the medication in order to be cured of a particular illness or condition.¹³¹ However, they are only using the drug under the directions of their physician. It is the physician who has prescribed the drug, and who is more appropriately said to be using the drug to treat the patient's illness.

¹³⁰Letter from T. Firestone, *supra* note 125.

¹³¹In any event, it would be practically impossible for drug companies to pursue individuals for infringing uses of the medication. Not only would such law suits be impossibly costly to pursue, the uses would be difficult to detect because of doctor-patient confidentiality.

A doctor who prescribes Zoloft™ for a patient to treat the patient's depression is not using the drug in violation of any patents. A doctor who prescribes Zoloft™ by brand name for treatment of panic disorder or obsessive compulsive disorder is similarly not using the drug contrary to patent law. A doctor who prescribes sertraline hydrochloride for the second medical indications is also doing nothing to infringe patent law – the chemical name is a perfectly acceptable form (and a more accurate one) for describing the product to be dispensed. A doctor who wrote the prescription using the generic name for the drug, such as Apo-sertraline for panic disorder, might be infringing patent law, as he or she is “using” the generic drug product in a treatment where use of the brand name product is protected by a valid patent. However, it is unlikely that many doctors prescribe using the specific generic drug name. Even if they did, doctor-patient confidentiality would make it difficult for a pharmaceutical company to detect any infringing conduct. It is unlikely, therefore, that any serious infringement issues arise at the level of a doctor prescribing a particular medication.

2. Infringement through sale

A pharmacist who fills a prescription for a brand name drug with the brand name drug has not run afoul of any patent issues. Where the patent has expired, and the same prescription is filled with a generic product, there are similarly no patent issues. However, in the case of patents for second medical indications, the pharmacist may be in the difficult position of not knowing whether the generic can legally be dispensed without knowing the indication for which the drug has been prescribed. It is not currently the practice of physicians in Canada to note indications on drug prescriptions.

When a pharmacist fills a prescription for sertraline hydrochloride with the generic product, and the drug has actually been prescribed by the doctor for the treatment of panic disorder, then the pharmacist has arguably either used the drug, or, more likely, sold it to others to be used within the meaning of s. 42 of the *Patent Act*. As the pharmacist may not know the use for which the drug has been sold, this may raise questions about the pharmacist's liability under the *Act*, as intent to infringe is not a requirement.¹³² While it could be argued that the pharmacist has not *used* the particular invention, he or she may be argued to have sold the drug for an infringing use. The question will be whether the pharmacist can be liable for infringement where she or he is ignorant of the particular use. It could be argued that any such ignorance is willful, as the pharmacist could ask the patient, or could contact the doctor for clarification.

Ultimately, the liability of the pharmacist may depend on the legislative scheme in place in a given province. In most cases, legislation will require the pharmacist to dispense the least expensive version of the drug, particularly under

¹³²Vaver, *supra* note 2 at 152.

a pharmacare scheme. In the case of Nova Scotia, for instance, the law directs the pharmacist to do just that:

When a drug is prescribed by its “generic” or proper name the pharmaceutical chemist shall supply the lowest priced brand of the drug listed in the formulary which he has in his inventory.¹³³

Pharmacists who act in this way may not be liable for patent infringement, as they might have a defense that they were complying with the law regulating their profession. Because the pharmacist is merely complying with a rule of law when he or she fills the prescription, the issue becomes one of whether the liability lies at the level of the maker of the particular rule – in other words, the health department.

This is in part what lay behind the *Apotex v. Ontario* decision. In that case, presumably out of concern over patent issues, the Ontario Ministry of Health and Long-Term Care began to list drugs such as Zoloft™ as only partially interchangeable, where the first patent had expired but a second patent remained for a second medical indication. The decision by the Ontario Ministry did not remove any potential patent liability issues; rather, it shifted them from the Ministry to the pharmacists. Pharmacists are placed in the position of having to ensure that they dispense only the proper drug for the particular indication. They remain bound by rules of interchangeability on the one hand, requiring interchangeability where a generic drug exists for an indication not covered by a patent, but they are not insulated from liability where they dispense a generic product for an indication that is covered by a valid patent.¹³⁴

It is not entirely clear how pharmacists could be held to account to the drug companies for breaches of the patent laws in relation to dispensing of medications. Physician-patient confidentiality would make it quite difficult in practice for a drug company to determine if and when generic products were being illegally dispensed in substitution for the brand name drug. However, where pharmaceutical corporations generate contact with patients through organizing support groups or networks, or through providing internet or telephone hotline support for people with particular medical conditions, it may well be that they create a means through which individuals may provide them with information about the drugs they have been prescribed or that have been dispensed. In any event, the threat of possible

¹³³*Pharmacy Regulations*, O.I.C. 81-1312 (October 27, 1981), N.S. Reg. 148/81 as am. to O.I.C. 2000-563 (November 9, 2000), N.S. Reg. 189/2000, s. 12:3:1. Section 5 of *DIDFA*, *supra* note 91, has the same effect, although it is less direct in its wording than the Nova Scotia provision. Section 5 of *DIDFA* provides: “[i]f a prescription directs the dispensing of a drug for which there are interchangeable products without identifying a specific product name or manufacturer, the dispenser shall dispense an interchangeable product of that drug.”

¹³⁴See the wording of s. 5 of *DIDFA*, *ibid.*

liability is causing a great deal of concern within the Ontario Pharmacists Association.¹³⁵

The practical result of the situation in Ontario is that pharmacists are now in a position of either disregarding the possibility of patent infringement or of calling doctors to clarify the indication where a drug such as Zoloft™ is listed as only partially interchangeable. This situation has been criticized as being largely unworkable.¹³⁶ Although the situation could be eased by having doctors write the indication on the prescription itself, there is nothing in the law to compel doctors to do this, and the OMA has proven resistant to doing so on its own due to concerns about doctor-patient confidentiality. One solution would be to require the specification of indication by legislation or by regulation. However, there may be a legislative reluctance to interfere with what is regarded as a largely self-regulating profession.

3. Inducing Infringement

Inducing infringement of a patent is itself considered to be an infringement of the patent.¹³⁷ In this regard, a provincial health department that lists a generic drug in the formulary as fully interchangeable, when valid patents still subsist for one or more indications, might face liability for inducing the infringement of the patent by pharmacists. Inducement by inducement has been described as follows:

Patent infringement by inducement occurs when a person does something that leads another person to infringe a patent. This form of infringement requires that the defendant knowingly induce or procure another to infringe a patent. Inducement requires an invitation, instruction, or control by the inducing party.¹³⁸

It is likely that requiring a pharmacist to act in a particular way through legislative or regulatory means would be considered an "instruction or control" on the part of the relevant health department. Thus where regulations like the *Pharmacy Regulations* in Nova Scotia provide that "[w]hen a drug is prescribed by its 'generic' or proper name the pharmaceutical chemist shall supply the lowest priced

¹³⁵This concern is evidenced by the application of the Ontario Pharmacists' Association for leave to intervene in the appeal of *Apotex v. Ontario* (Motion for Leave to Intervene by the Ontario Pharmacists' Association, Court File No. 59/2000).

¹³⁶The problems identified have been numerous. In his affidavit as part of the *Apotex v. Ontario* case file, Arthur Ito of Pharma Plus Drug Marts stated that the need to contact physicians to determine the indication for which Zoloft™ had been prescribed resulted in delays of "hours or days" in dispensing the necessary medication. In some cases, no indication could be obtained, either where doctors were unavailable or where they objected to providing the information because of concerns about confidentiality. *Apotex v. Ontario*, *supra* note 1 (Evidence, Affidavit of Arthur Ito, 31 January 2000 Court File No. 59/2000).

¹³⁷*Reading & Bates Construction Co. v. Baker Energy Resources Corp.* (1986), 13 C.P.R. (3d) 410 (F.C.T.D.).

¹³⁸R. Howell et al., *Intellectual Property: Cases, Notes and Materials* (Toronto: Emond Montgomery, 2000) at 980.

brand of the drug listed in the formulary which he has in his inventory,”¹³⁹ and where the formulary lists a generic as fully interchangeable for a drug such as Zoloft™, then there is arguably a case of inducement to infringe by the health department.

One possible response to this, on the part of a provincial health department, might be that doctors must only prescribe drugs which are approved by Health Canada for the treatment of particular indications, so the responsibility lies with the doctor to write the appropriate prescription, and that the health department therefore has no specific knowledge of, or has given no specific direction to infringe any patent. However, given that substitution is directed even where the doctor writes a prescription using the brand name of the drug, this argument is not likely to carry much weight.

A health department might also be entitled to rely upon the NOC process in support of its position. Because the *NOC Regulations* provide an opportunity to address patent issues as between brand name and generic drug companies before the NOC is issued, it is arguable that after the NOC has been issued, health departments are entitled to rely upon the NOC as an indication that there are no outstanding patent issues. However, in reality, there are no outstanding patent issues where an NOC is given for one indication but not for others protected by valid patents. In such a circumstance, the generic company is likely to have accepted the validity of the still subsisting patents, as was the case of Apotex with Zoloft™. All that the health department could reasonably rely on in this regard is that there are no outstanding issues of validity regarding the relevant patents. They would not be entitled to disregard relevant unexpired patents.

G. Summary

Although it would seem that until recently drug companies have not taken an active role in defending their patents for second medical indications when it comes to the listing of generic drugs as interchangeable in drug formularies, the case of Zoloft™ has squarely raised issues of patent liability where generic drugs are dispensed in violation of still subsisting patents. In Ontario, the Ministry of Health and Long-Term Care responded to pressure from Pfizer, the maker of Zoloft™, and listed the drug as only partially interchangeable. They did so out of concern that failure to do so might lead to a finding that they were liable for inducing patent infringement. The result is that pharmacists in Ontario must determine the indication for which Zoloft™ has been prescribed in order to dispense the appropriate drug in compliance with patent law and obligations under provincial drug dispensing legislation.

¹³⁹*Pharmacy Regulations*, *supra* note 133, s. 12:3:1.

Although the issue has not yet come to a head in other provinces, it is clear that the same problems can and do arise under other pharmacare regimes. Where there exists a valid patent for a second medical indication, it would infringe that patent to use or sell, or to induce the use or sale, of a generic drug in place of the patent-protected drug for that indication.

III. Conclusions

In Canada, patents are available for second medical uses of known compounds. Such patents are not caught by the general prohibition against patenting methods of medical treatment. The situation is the same amongst Canada's major trading partners. Patents for second medical uses of known compounds are widely recognized. Issues of validity of such patents may turn on the wording of the patent claims, and on the degree of novelty of the new use. However, in principle, such new uses may be patented. It would be difficult to see how Canada could step back from this position without running afoul of international trade obligations.

The Federal Court of Canada has recently proven itself unwilling to interfere with the language of the *Patent Act*, and in particular, to interpret it narrowly on policy grounds. The stated preference of the Court is to leave matters of patent policy to Parliament. There have been recent indications that the federal government is willing to open a policy discussion regarding patents for second medical uses. However, any such discussion will be constrained by Canada's international trade obligations, particularly under the *NAFTA* and the *TRIPS* agreement. Although under these agreements, Canada may legislate exceptions to patentability for methods of medical treatment, the international consensus is that second medical use patents do not relate to methods of medical treatment. In addition, the agreements require member states to provide protection for all inventions. In the wording of the *TRIPS* agreement, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."¹⁴⁰ The international consensus appears to be that second medical indication patents are for inventions in this sense.

The existence of patents for second medical indications poses problems for provincial health departments in their administration of drug dispensing formularies. The issue is currently coming to a head in Canada as a result of attempts by Pfizer to aggressively defend its patents for second medical indications on its product ZoloftTM. Because patents for second medical uses of known compounds are available, complications may arise where a first patent has expired with respect to one indication, while second or third patents remain in effect for other indications. The expiry of the first patent means that a generic product may

¹⁴⁰*TRIPS*, *supra* note 19, art. 27.1.

be approved for use and sale for the first indication but may not be used or sold for the indications still protected by valid patents. In such circumstances, a provincial health department that lists the generic product as fully interchangeable with the brand name may be in the position of inducing patent infringement by pharmacists who would then be permitted, and in some circumstances required, to dispense the generic drug in place of the brand name drug in violation of valid patents.

Although one option for provincial health departments is to list a generic drug as only interchangeable for a specific indication, this can lead to confusion and disruption in the prescribing and dispensing of medications. It raises concerns about delays in drug dispensing, problems of physician-patient confidentiality and concerns about increased costs to provincial pharmacare programs. Unfortunately there is no easy or obvious alternative to this situation.