Questions

I. Current law and practice

Groups are invited to answer the following questions under their national laws. If those national and regional laws apply to a set of questions, please answer the questions separately for each set of laws. Please number your answers with the same numbers used for the corresponding questions.

1) Does your country permit patents covering any aspect of new uses of known pharmaceutical compounds (hereafter referred to as second medical use claims)?

Yes.

If yes, please answer Questions 2) to 7) inclusive before proceeding to the questions in Parts I and II. If no, please proceed directly to the questions in Parts II and III.

2) If the answer to Question 1) is yes, please answer the following sub questions.

a) What is the basis for patent protection?

The statutory definition of patent eligible subject matter under Canadian law is limited to “art, process, machine, manufacture or composition of matter, or any new and useful improvement ...” thereto. The statutory regime is silent on the patentability of second medical uses.

Case law has held that new uses for old compounds are patentable (Shell Oil Co v Commissioner of Patents, [1982] 2 S.C.R. 536).
At the same time, case law has pronounced that methods of medical treatments are not patentable eligible. (Tennessee Eastman Co. v. Commissioner of Patents, [1974] S.C.R. 111).

Nevertheless, second medical uses, when appropriately claimed, are patent eligible (Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77).

b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

Notwithstanding the bar to claims to methods of medical treatment in Canada, second medical uses of pharmaceutical compounds have been considered patentable in most circumstances, provided they are new, non-obvious, and useful.

For example, claims to the use of a known compound for a new therapeutic use have been upheld by the Supreme Court, including when the first known medical use of the compound did not succeed (see by way of example Apotex Inc v Wellcome Foundation Ltd, 2002 SCC 77 at paras. 10, 48-50).

c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

There are no categorical prohibitions on the patentability of certain types of second medical uses, provided they meet the other statutory requirements for patentability.

Claims to second medical uses may still be excluded from patent eligibility, if they are presented as method claims, or if they otherwise resemble methods of medical treatment.

Second medical use claims will be rejected as impermissible where the claims cover subject matter for which a physician’s skill or judgment is required, in which case they will be held to be methods of medical treatments.

The Canadian Intellectual Property Office’s (CIPO’s) Examination Practice Respecting Medical Uses released June 10, 2013, asserts that “use” claims may be patentable where the claims are directed towards “what” to use to treat patients, but not “how” to treat the patient. The latter are considered unpatentable methods of medical treatment.

The guideline states:

Where an essential element only serves to instruct a medical professional “how” to treat a patient, rather than “what” to use to treat the patient, this will lead to the conclusion that the claimed use encompasses a method of medical treatment.

Therefore, essential elements that point to a limitation of a physician’s professional skill or judgment include those that provide details of a dosing schedule, those that represent a range of potential dosages that a patient may receive (as distinct from a range of dosages forms), and those that narrow treatment to a patient sub-population (rather than bring treatment to a new population) or administration site.

For medical inventions, the problem faced by the inventor may relate to “what” to use for treatment. Generally the solution to such a problem will be provided by an element or set of elements in a claim that embody a treatment tool. This tool may include a compound, composition, formulation, or a dosage unit form.
Alternatively, where the emphasis is not on “what” to use but instead relates to “how” to administer or refine a treatment, the solution (as embodied by the essential elements of the claim) will likely place a limit on the professional skill or judgment of a physician. An emphasis on “how” (as distinct from “what”) may include details of when or where a treatment is to be administered or who is to receive a treatment.

Canadian Courts have not endorsed or commented on these CIPO guidelines. Two recent Court decisions, issued after the publication of the guidelines, have held that second medical use claims that cover a physician’s skill or judgment were invalid. In particular, in these cases, the Court focused on whether the claimed “use” affords a physician any discretion, relying on a theory that such discretion would require the physician to exercise skill and judgment. For example, second medical use claims that recited a range of dosages or a variety of components from which a physician may chose were found to be invalid. At the same time, a “use” claim to a dosage regime that afforded no discretion was considered patentable. (Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company, 2013 FC 985 at paras. 92-99; Bayer Inc. v. Cobalt Pharmaceuticals Company, 2013 FC 1061 at paras. 160-162).

Arguably this analysis confounds claim scope, with required intervention by a physician.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.

The following claim forms are generally considered acceptable:

Use of substance X for the treatment of condition Y. (German-style use claim.)

Use of substance X in the manufacture of a medicament for the treatment of condition Y. (Swiss-style use claim.)

Substance X, for use in the treatment of condition Y. (Product-for-use claim.)

If appropriate, all three forms can be included in the same application.

e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.

In Canada, method of treatment claims are not permissible. This includes claims that clearly recite “a method” (e.g., US-style method claims) as well as use claims that are deemed to include method steps.

That is, any use that implies an active step by the person performing the use is deemed to be a method rather than a use, even when written in use form. For example, the claim “Use of substance X for the treatment of condition Y wherein X is administered intravenously” is considered to include a method step since it indicates that someone is performing the action of administering X. This reading of the claim can be circumvented by re-wording, for example “Use of substance X for the treatment of condition Y wherein X is formulated for intravenous administration”; such language is usually interpreted to be referring to a characteristic of X rather than an action being performed.

As well, both recent case law and patent office guidelines have indicated that certain qualifications on a medical use are considered methods of medical treatment, as such qualifications are seen either to limit how a physician can act or, conversely, to require discretionary decisions to be made by a physician. Claim features that appear to limit characteristics of substance X or of condition Y may be acceptable. However, claim features such as a dosage range for substance X, a dosage schedule or regimen for the
administration of substance X, definition of site of administration, selection of a drug component from a variety of components, or selection of a sub-population of subjects from within a previously known broader population have all been deemed to convert a use claim to a method of medical treatment (see, e.g., Novartis Pharmaceuticals Canada Inc v. Cobalt Pharmaceuticals Company, 2013 FC 985 at paras. 92-99; Bayer Inc. v. Cobalt Pharmaceuticals Company, 2013 FC 1061 at paras. 160-162). Arguably this analysis confounds claim scope, with required intervention by a physician.

f) Has any guidance been provided by courts or the national patent office in relation to the meaning, scope and/or effect of ‘treatment’, ‘treating’ or ‘use to treat’ integers in second medical use claims? See, for example, paragraphs 34) - 39) above WGLs.

There has been little specific guidance on the meaning, scope and/or effect of the “treatment”, “treating” or “use to treat” integers in “use” claims.

Of note, the term “treatment” has been considered in case law dealing with the threshold question of whether a method of treatment is patent ineligible as a method of medical treatment. The case law has required that a medical treatment result in curing or preventing a disease or condition in human or animals. In Apotex Inc. v. Wellcome Foundation Ltd., 2002 SCC 77, the Supreme Court of Canada specifically considered prophylaxis/prevention to be a form of treatment. Conversely, methods relating to conditions in humans that are not considered diseases or disorders, such as pregnancy, are not considered methods of medical treatment, since pregnancy is a natural state rather than a disease condition. Likewise, industrial processes in animals that do not cure or prevent disease have not been considered methods of medical treatment.

Additionally, case law has considered the utility requirement of use claims “for the treatment of condition Y”. In those cases, a mere scintilla of utility has been required to uphold validity, unless the patent promises more. Thus, it appears that any level of cure or prevention should meet the utility requirement.

3) If your country permits second medical use claims:

   a) Who may be liable for infringement of such claims? For example:

      i) the party marketing the drug with label instructions which describe the patented use;
      ii) the physician prescribing the drug for such use;
      iii) the pharmacist dispensing a drug for such purpose;
      iv) the patient using the drug for such purpose?

The Canadian Patent Act grants a patentee the following monopoly: “the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used.” A patent claim is infringed by a party who encroaches upon the patentee’s monopoly, i.e., by making, constructing or using the invention, or selling the invention to others to be used without the patentee’s permission. Such infringement is commonly referred to as direct infringement.

A patent claim may also be indirectly infringed by a party who induces another party to directly infringe the patent. Canadian Courts have set out the following three-part test for establishing infringement by inducement: (1) the act of infringement must have been completed by the direct infringer; (2) the completion of the acts of infringement must be influenced by the acts of the alleged inducer to the point that, without the influence, direct infringement would not take place; (3) the influence must knowingly be exercised by the inducer, namely, the inducer knows that this influence will result in the completion of the act of infringement (Corlac Inc. v. Weatherford Canada Inc., 2011 FCA 228 at para. 162).
Thus, any of the parties i), ii), iii) and iv) may be liable for infringement of a second medical use claim. As a practical matter, parties ii), iii), and iv) are rarely sued for infringement of second medical use claims.

See answer to Question 3c) below for a discussion of whether infringement by each of these parties is direct or indirect.

b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?

No classes of parties are exempt from infringement or liability for infringement of second medical use claims.

c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.

Patients may directly infringe a second medical use claim by using the claimed drug for the claimed second medical use (Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health), 2002 FCA 290 at para. 44).

Physicians and pharmacists may infringe a second medical use claim, either directly or indirectly. In particular, Canadian Courts have indicated that physicians who prescribe the claimed drug for the claimed use and pharmacists who dispense the claimed drug for the claimed use may directly infringe the claim (Novopharm Limited v. Sanofi-Aventis Canada Inc., 2007 FCA 167 at paras. 9-10). Canadian Courts have also indicated that physicians and pharmacists may indirectly infringe a second medical use claim by respectively, prescribing or dispensing the claimed drug for the claimed use and thereby inducing patients to directly infringe the claim (Aventis Pharma Inc. v. Pharmascience Inc., 2006 FCA 229 at para. 34).

Drug manufacturers may directly infringe a second medical use claim, e.g., when the claim is a Swiss-style use claim that covers use of a compound in the manufacture of a drug.

Drug manufacturers may also indirectly infringe a second medical use claim by inducing another party (e.g., a physician, a pharmacist, or a patient) to directly infringe the claim. Canadian Courts have held that infringement through inducement by a drug manufacturer may be established, for example, on the basis of “inferences reasonably drawn from the contents of the product monograph for the generic drug product, or evidence relating to the dosage form of the generic product, or its labelling or marketing” (Novopharm Limited v. Sanofi-Aventis Canada Inc., 2007 FCA 167 at para. 11). However, mere sale of a drug by a drug manufacturer, without more, does not constitute direct or indirect infringement of a second medical use claim (AB Hassle v. Canada (Minister of National Health and Welfare)), 2002 FCA 421 at paras. 56-58).

4) If a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, is it an infringement if a party makes, supplies or uses a generic version of the drug for any use?

A second medical use claim is infringed only if a party makes, supplies or uses the claimed drug for the claimed use. Canadian Courts have cautioned that a second medical use claim should not allow a patentee to “effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place” (AB Hassle v. Canada (Minister of National Health and Welfare)), 2002 FCA 421 at para. 57).
However, if a party that makes or supplies the drug takes steps to induce another party to use the drug for the claimed second medical use (e.g., by way of a product monograph, dosage form, labeling or marketing), then the party making or supplying the drug may indirectly infringe the second medical use claim.

5) If the answer to Question 4) is yes, please answer the following sub questions in that context.

a) Is each of the acts of making, supplying and using a form of infringement? If not, please specify which (or any other) acts which constitute infringement.

Yes. See answer to Question 3a) above.

b) Is it necessary for a finding of infringement that the party making, supplying or using the generic version of the drug does so in connection with the infringing use?

Yes. See answer to Question 4) above.

c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?

Yes. Although Canadian Courts have not expressly articulated such a knowledge requirement, in at least one case, a Court suggested that a second medical use claim may not be infringed in the absence of intentional use (H. Lundbeck A/S v. Canada (Minister of Health), 2003 FC 1333). This case involved a drug that could be used for treating depression or treating dementia, and a second medical use claim that covered only the use of the drug for treating dementia. The patentee argued that the claim was infringed even when the drug was used for the purpose of treating depression, if the patient was affected by both depression and dementia. The Court rejected this argument, ostensibly requiring use of the drug for treating dementia be intentional to find infringement.

A finding of indirect infringement requires the inducer who influences another to infringe to exercise that influence intentionally and to know that the influence will result in the completion of the act of infringement.

d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.

See answer to Question 5c) above.

6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?

The burden is on the patentee to establish infringement on a balance of probabilities. The question of patent infringement is a question of mixed fact and law. The initial construction of the claims is a question of law. However, once the claims of the patent have been construed, whether the defendant's activities fall within the scope of the monopoly thus defined is a question of fact (Whirlpool Corp v Camco Inc, 2000 SCC 67 at para. 76).

With respect to infringement of a second medical use claim, as discussed in the answer to Question 3(b), mere sale by a generic manufacturer, without more, is not sufficient to constitute infringement of claim to a second medical use. Where a generic manufacturer does not seek approval for the patented use and would not refer to that use in its product monograph, the Courts have found non-infringement (AB Hassle v. Canada (Minister of National Health and Welfare), 2002 FCA 421 at paras. 56-58). The Court of Appeal has
expressed concern that holding a generic manufacturer liable for infringement of new medical use claims could artificially extend the monopoly on the original compound or use claims:

… If there was any likelihood that a patient would consume a generic product for a patented use, then the generic product would not be approved. This would prevent new uses from being approved for existing drugs because there is always the possibility that someone somewhere will use the drug for the prohibited, patented purpose. This would result in a real injustice: since a generic company cannot possibly control how everyone in the world uses its product, the prevention of the generic from marketing the product would further fortify and artificially extend the monopoly held by the patent holders. The patent holder would, therefore, effectively control not just the new uses for the old compound, but the compound itself, even though the compound itself is not protected by the patent in the first place. The patent holders, as a result, would obtain a benefit they were not meant to have. In the end, society would be deprived of the benefit of new methods of using existing pharmaceutical medicines at a lower cost.

However, in a case where there was evidence of similar packaging and dosages between the generic and brand products, where the marketing approval would state equivalence with the patented second medical use product, and the market for the first medical use was much smaller than the second medical use, the Court of Appeal found that it was inevitable that the selling of the product would result in infringement of the patented second medical use, and therefore precluded the market approval of the generic product: Procter & Gamble Pharmaceuticals Canada, Inc. v. Canada (Minister of Health), 2002 FCA 290.

7) What relief is available for infringement of a second medical use claim:

a) at a preliminary / interim / interlocutory level?

Interlocutory and interim injunctions are available as remedies for patent infringement, but their grant is much more restrictive than permanent injunctions upon a finding of infringement. See the answer to Question 8 for the legal test.

In addition to an interlocutory or interim injunction in the context of a patent infringement suit, in Canada there is also a regulatory regime under the Patented Medicines (Notice of Compliance) Regulations (“PM(NOC) Regulations”) that provides what is, in effect, an automatic statutory stay, preventing entry of the generic product for up to 24 months, if certain requirements are met. In order for a patentee to avail themselves of the PM(NOC) Regulations the patent at issue must pertain to a medicine (this includes, inter alia, claim for the use of the medicinal ingredient), and that patent must be listed on a “Patent Register” maintained by the Minister of Health. As a matter of timing, the patent must have been filed before the regulatory submission for the drug and the patent must be submitted to be listed within 30 days of the patent issuing. If a generic manufacturer intends on relying on the safety and efficacy data submitted to Health Canada by the brand manufacturer to obtain regulatory approval to market and sell the drug, the generic manufacturer must send a “Notice of Allegation” outlining why the patent(s) on the Patent Register should not prohibit the Minister of Health from issuing a “Notice of Compliance” (i.e., regulatory approval to sell). The manufacturer of the brand product can then start a Court proceeding to prohibit the Minister of Health from issuing a Notice of Compliance. These proceedings must be completed within 24 months of commencement, but the Minister of Health will not grant the Notice of Compliance (and the generic manufacturer will therefore be prevented from entering the market) until the proceeding is resolved. Use of the PM(NOC) Regulations can result in the brand manufacturer being liable to the generic manufacturer for damages under the Regulations.

b) by way of final relief?
The Canadian Patent Act expressly provides for an injunction as one of the remedies available for patent infringement (s. 57(1)). A permanent injunction is a discretionary remedy that is typically granted upon a declaration of infringement except in rare circumstances where there is equitable reason not to do so.

8) In respect of Question 7)a), can a preliminary / interim / interlocutory injunction be granted solely upon the statements provided in the product packaging or based on the writing of a prescription? If not, what is the basis for relief?

It is unlikely that a Canadian Court would grant an interlocutory injunction solely on the basis of statements in the product packaging or based on the writing of a prescription. The legal test applicable to motions for interlocutory injunctions in Canada asks: (i) Is there a serious question to be tried? (ii) Would the litigant who seeks the interlocutory injunction suffer irreparable harm if it is not granted? and (iii) Which party would suffer the greater harm from the granting or refusal of the interlocutory order? This is a stringent test, and often requires voluminous evidence to establish irreparable harm to the party seeking the injunctive relief, in addition to evidence to prove a prima facie case.

Establishing irreparable harm in a patent infringement suit is typically the most difficult hurdle in obtaining an interlocutory injunction due to the high threshold and that most damages are quantifiable (e.g., lost sales) and thus not irreparable. In some circumstances evidence of ‘springboarding’ – where a competitor enters the market in advance of the patent expiry causing lost market share likely to endure after patent expiry – may be sufficient to establish irreparable harm. However, springboarding arguments in the pharmaceutical context have been rejected where the Court is not persuaded that the damages in the post-expiry period are not quantifiable (Bristol Myers Squibb Co. v. Apotex Inc., 2001 FCT 1086; Bayer Healthcare AG v. Sandoz Canada Incorporated, 2007 FC 352).

As discussed in the answer to Question 7a), Canadian law also provides, in effect, a stay for up to 24 months under the PM(NOC) Regulations. Such a statutory stay, pending the determination of the Court proceeding under the PM(NOC) Regulations, would occur prior to the launch of a generic pharmaceutical product, and would be granted solely on a patent having been listed on the Minster of Health’s Patent Register, and a generic manufacturer relying on the brand manufacturer’s health and safety data to obtain regulatory approval.

9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?

Upon proving patent infringement on a balance of probabilities, a permanent injunction is a discretionary remedy that is typically granted. The permanent injunction may not be granted in circumstances where there is equitable reason not to do so, including: acquiescence, long delay, lack of clean hands, unconscionability, or triviality (Eurocopter v. Bell Helicopter Textron Canada Limitée, 2012 FC 113, aff’d without comment on this point in 2013 FCA 219).
II. Policy considerations and proposals for improvements to your current law

10) If your country permits second medical use claims, please answer the following sub questions.

   a) What are the policy reasons behind permitting such claims?

   The availability of patent protection for new uses of old compounds provides an incentive to inventors to discover and develop new, non-obvious uses of old compounds. The incentive provided for second medical uses is merely consistent with general incentives for promoting innovation.

   b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?

   Yes.

   c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?

   Some argument exists that the availability of second medical use claims is not consistent with the general prohibition against the patentability of methods of medical treatment in Canada.

   However, these arguments are countered by the observations that second medical use claims must take a particular format (discussed above) in Canada, and that the general prohibition against the patentability of methods of medical treatment is not codified, and arguably archaic.

   d) If there is any empirical or anecdotal data available, please address the following.

      i) What is the prevalence of second medical use claims in your country?

      Based on cases that have been litigated in Canada, there are many Canadian patents with second medical use claims.

      ii) What is the profile of patentees for second medical use claims in your country?

      Based on cases that have been litigated in Canada, patentees for second medical use claims are typically multi-national companies and institutions that research and develop pharmaceuticals.

11) If your country does not permit second medical use claims, please answer the following sub questions.

   a) What are the policy reasons behind not permitting such claims?

   N/A

   b) Would such claims serve the interests of relevant stakeholders?

   N/A
c) Would such claims be considered to better serve the interests of some stakeholders and/or be detrimental to other stakeholders?

N/A

12) To what extent does your country’s law in relation to second medical use claims affect the pharmaceutical industry (originator and generic) in your country?

The effects of the law in relation to second medical claims are consistent with the effects of the law in relation to pharmaceutical patents generally: innovators are rewarded with patents, and the generics must overcome the patents or wait for their expiry before bringing products covered by the patents to market.

III. Proposals for harmonisation

The Groups are invited to put forward proposals for the adoption of harmonised laws in relation to second medical use claims. More specifically, the Groups are invited to answer the following questions without regard to their existing national laws.

13) Is it desirable to permit second medical use claims?

Yes.  They are a fair reward for the discovery/development of new uses of old compounds.

14) Is harmonisation of laws relating to second medical use claims desirable?

Yes.  Harmonization begets predictability, which may be especially desirable for pharmaceutical companies—both brand and generic—that market products globally.

15) Please provide a standard that you consider to be best in each of the following areas relating to second medical use claims.

   a) Types of second medical use constituting permissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

   At least the types discussed above in the answer to Question 2b). Second medical use claims reciting dosage ranges should also be permissible provided that the other criteria for patentability are met. Possibly, other “use” claims that specify “how” to treat should also be patent eligible.

   b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

   Possibly second medical use claims encompassing methods of medical treatment. However, greater clarity on the interplay between the prohibition on patentability of methods of medical treatment, on the one hand, and the patent eligibility of second medical uses would be welcome.

   c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

   At least the forms discussed above in the answer to Question 2d).

   d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.

None.
e) Who may be liable for infringement?

At least manufacturers and physicians.

f) Any parties/institutions that should be exempted from infringement or liability for infringement.

Patients should be exempt from infringement or liability since it would be onerous for individuals to defend against patent infringement cases. Possibly, physicians and hospitals should also be exempt, so as not to inadvertently limit physician's professional judgment. Where pharmacists are merely carrying out physicians' instructions, they should also be exempt from infringement or liability.

 g) Where a drug is approved for more than one indication, one or more of which (but not all) falls within the claims of a patent, the acts that should constitute patent infringement, and in particular, the standard of knowledge of the alleged infringer.

The law as it stands in Canada, as summarized in the answer to Questions 4 and 5 above, is acceptable. It could, however, be codified.

h) Relief available upon a finding of infringement:

   i) at a preliminary / interim / interlocutory level; and
   ii) by way of permanent relief.

The law as it stands in Canada, as summarized in the answers to Questions 7 and 8, is acceptable, with the possible exception that interlocutory junctions could be made easier to obtain when entry into a market by a generic manufacturer may result in permanent market loss by a brand manufacturer.

   i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.

The law as it stands in Canada, as summarized in the answer to Question 9 is acceptable.

SUMMARY

Canadian law permits claims to new uses for old compounds if the new use is useful, novel and non-obvious. Second medical use claims are permissible provided they are not construed as a method of medical treatment, e.g. requiring a physician's skill or judgment. German-style use claims, Swiss-style use claims, and product-for-use claims are all permissible forms. Method claims or use claims that imply an active step by a person to administer use of the compound may be invalid as methods of medical treatment. Depending on the claim form and circumstances, it may be possible to establish direct or indirect infringement against a manufacturer, physician, pharmacist, or patient.