Questions

I. Summary

A patent application for a second medical might be allowed if it presents novelty, inventive step and industrial application, in a manner that does not depend on the features of a therapeutic method.

Swiss-type use claim is mostly accepted.

Both direct and indirect infringement is applicable. Litigation involving second medical use infringement is very low.

It is important to encourage research into new medical use of a known substance, and the medical use of a known substance for a known indication but with different dosage forms, dosage regimes or patient populations via patent system.

International harmonization is desirable to provide a greater certainty to originator and generic companies, and Swiss type claim and purpose-limited product claim should be permissible.

When establishing infringement of a further medical use patent, all relevant circumstances that indicate infringing use despite “skinny labeling”, “cross-label” or “off-label” should be taken into account before the court.

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.

Second or further medical uses of known substances claims are accepted by the Brazilian Patent Office (BPO) and the Courts, and even by ANVISA in some specific cases (ANVISA is the Brazilian Agency in charge of the analysis and granting of market approvals for drugs in Brazil, corresponding to the U.S. Food and Drug Administration – FDA and the EMA in Europe). It is important to note that, in Brazil, pharmaceutical patents need the prior consent from ANVISA before their granting by the BPO (see Article 229-C of Brazilian IP Law # 9.279 of May 14, 1996).

So, in short, if the patent application for a second medical use presents novelty, inventive step and industrial application, it might be allowed in Brazil.

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

a) What is the basis for patent protection?

The Brazilian IP Law does not contain any provision allowing or denying second medical use claims. However, the BPO’s guidelines for the examination of patent applications state that these claims are acceptable (BPO’s resolution 124/2013 and BPO’s guideline for the examination of patent applications in Biotechnological and Pharmaceutical fields filed after December 31, 1994).

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

Any new therapeutic use of a known substance is patentable as long as it is new and inventive in a manner that does not depend on the features of a therapeutic method in view of the fact that a therapeutic method applied to the human or animal body are not considered to be an invention based on article 10 (VIII) of the Brazilian IP Law.

A claim directed to a known substance for preparing/manufacturing a medicine for treating a known disease/condition in a new dosage form or new dosage regimen may be objected by the BPO and ANVISA under the allegation that this claim is in fact related to a therapeutic method. In attempt to surmount this objection, the claim could be redrafted in a suitable format.

In a nutshell, the analysis of which types of second medical use are acceptable in Brazil has to be performed on case-by-case basis.

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

A second medical use is not allowable when it is new and inventive in a manner that depends on the features of a therapeutic method. However, as above indicated, it might be a matter of drafting the claim in a suitable format.

d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.
According to the BPO’s examination guidelines (BPO’s resolution 124/2013 and BPO’s guideline for the examination of patent applications in Biotechnological and Pharmaceutical fields filed after December 31, 1994), the acceptable format for a second medical use claim is the classic Swiss-type use format, as follows:

*Use of (substance X), characterized in that it is for manufacturing/preparing a medicament for the treatment of (disease/condition Y).*

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

The following forms are not permissible according to the Brazilian IP Law (article 10, VIII) and the BPO’s examination guidelines:

- *Use of substance X for the treatment of a disease/condition Y;*
- *Method of treating a patient suffering from a disease/condition Y comprising administering substance X to the patient;*
- *Administration of substance X for treating a disease/condition Y;* and
- *Substance X for treating a disease/condition Y.*

The above claims are understood as related to a therapeutic method, which is not considered to be an invention.

**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.

No. Nevertheless, we believe that the Brazilian court would interpret the term “treatment”, “treating” and “use to treat” on the basis of what the patent application or patent teaches in view of the fact that, under article 41 of the Brazilian IP Law, the scope of protection conferred by a patent is determined by the content of the claims, interpreted in the light of the specification and drawings.

3) If your country permits second medical use claims:

Since there is very little number of case law in Brazil regarding second medical use infringement, our comments to the questions regarding this issue are based on our interpretation of the Brazilian IP Law. Therefore, the answers should not yet be considered established case law.

**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?

Considering that (i) the acceptable claim format for a second medical use in Brazil (i.e. use of substance X for preparing a medicament for the treatment of
The patentee can prevent an unauthorized third party from manufacturing, using, offering for sale, selling or importing for such purposes a patented process, and a product directly obtained by a patented process (article 42 (II) of the Brazilian IP Law); and infringement can be by way of either direct or indirect infringement (article 42 (1st paragraph) of the Brazilian IP Law), the owner of a second medical use patent can act against:

- the party manufacturing a medicament specifically for the patented use - in this case, we have a **direct infringement**;

- any party contributing for the above manufacturer to commit the infringement (for instance, someone sells the active principle ingredient of the medicament for the manufacturer) - in this case, we have a **indirect infringement**;

- the party marketing (offering for sale, and/or selling) the medicament with label instructions encompassing the patented use - in this case, we have a **direct infringement**;

- the drug dealer, drug store and galenic lab dispensing the medicament for the patented use, or conducting the infringing act of selling and delivering the product for the patented use - in this case, we have a **direct infringement**.

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

Yes.

According to article 43 of the Brazilian IP Law, the following actions do not constitute an infringement of a second medical use patent:

- the manufacturing of a medicament specifically for the patented use for individual cases by an unauthorized pharmacist according to a medical prescription;

- the manufacturing of a medicament specifically for the patented use for experimental purposes, related to studies or to scientific or technological research; and

- the manufacturing of a medicament specifically for the patented by an unauthorized third party privately and without commercial purposes, provided they such manufacturing does not result in prejudice to the economic interests of the patentee.

In other words, exceptions to infringement are determined by reference to the activity in question rather than the person doing the activity.

Therefore, in principle, the patentee could not take action against (i) the physician prescribing the medicament for the patented use; (ii) the patient using the medicament for the patented purpose; and (iii) the pharmacist selling the medicament (professionals who practice in pharmacy).
Furthermore, those using a substance for a patented further medical use in the context of experimental studies and/or clinical trials may also be exempted.

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

Yes.

According to article 42 of the Brazilian IP Law, both direct infringement and indirect (contributory) infringement may be enforceable based on second medical use claims, especially because this claim is understood as a process patent.

Furthermore, since a use claim is considered a process claim, the burden of proof lies on the potential infringer (article 42 (2nd paragraph) of the Brazilian IP Law). In this situation, the accused third party will bear the burden of establishing that it is not manufacturing a product to be used according to the patented use.

Generally, the patient information leaflet, which contains information regarding the composition of the medicament, such as the active ingredient and its amount and excipients, as well as the intended therapies, may be used as basis for alleging direct infringement of a medical use claim, and the marketing of the compound by a distributor permits to allege indirect infringement (contributory infringement).

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?

Yes.

If an unauthorized third party manufactures, offers for sale, sells or imports for such purposes a generic version of a medicament for a use that falls within the claims of a second medical use patent, such acts constitute a direct infringement even though such generic medicament can also be used for others non-patented uses.

On the other hand, if an unauthorized third party manufactures, offers for sale, sells or imports for such purposes a generic version of a medicament for a use that does not fall within the claims of a second medical use patent, such acts in principle would not constitute a direct infringement.

Nevertheless, in our view, manufacturing, offering for sale, selling or importing for such purposes a generic version of a medicament for a non-patented use, whilst knowing that the physician will (also) use the drug for a use that falls within the claims of a second medical use patent, such acts constitute a contributory infringement, especially if the alleged infringer (i) knows, or it is evident considering the circumstances, that the medicament is suitable and intended for the patented use; and (ii) does not take any steps to prevent this infringing use (for instance by warning doctors or pharmacists of the infringing nature of such acts).

It is important to highlight once more that we are not aware of any case law on this point.

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. Such acts are foreseen in article 42 of the Brazilian IP law.

It is important to highlight that the application of the medicament for the patented use in a patient by a medical practitioner or by the patient does not constitute of an infringement in view of the provisions of aforementioned article 43 of the Brazilian IP Law, and because therapeutic methods are not patentable in Brazil (article 10, VIII, of the same Law).

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. The scope of protection of a second medical use patent extends only to the claimed use.

In other words, if a third party makes, supplies or uses a generic version of a medicament with the purpose to treat a disease or a condition different from that indicated in the claims, there would be no infringement by this third party.

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

As a general rule, it is not necessary that the third party knows that their actions are in connection with the infringing use in order to establish an infringement of a second medical use patent.

Nevertheless, it must be proved that the third party knows or should have known that the medicament manufactured or marketed will be used to the same purpose foreseen in the second medical use claim.

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

As comments on item (c) below, the knowledge by the potential infringer is not a requirement for alleging infringement.

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

Under article 41 of the Brazilian IP Law, the scope of protection of a patent is determined by the claims, and the specification and drawings serve to interpret those claims.

So far, there is no case law on second medical use patents, but we believe that an infringement would be determined as in other patent infringement cases, namely: that infringement may be constructed either through literal interpretation or the doctrine of equivalence.

In the context of assessing infringement, any and all circumstances can be taken into account. A copy of the patient information leaflet of a generic medicament may be used to allege infringement, since it clearly indicates the active ingredient and intended therapies.
In general, evidence is obtained by the plaintiff before the lawsuit is filed. Pieces of evidences of infringement may also be produced during the litigation such as the filing of expert opinions, opinions of scholars, documental evidence, depositions, technical examination by a court-appointed expert, etc.

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

There are no differences between any kind of preliminary and final reliefs on the basis of a second medical use claim or on the basis of a different type of patent claim.

a) at a preliminary / interim / interlocutory level?

The most common reliefs obtained by a patentee in an infringement case at a preliminary / interim / interlocutory level are:

- the grant of an *ex parte* restraining order to prevent future violations. In this situation, the defendant will not be permitted to sell the infringing goods during the civil action under the threat of a daily fine to be ascertained by the court. This injunction may be granted *inaudita altera parte* and the judge may request the plaintiff to post a judicial bond to guarantee the execution of the injunction;

- an *ex parte* search and seizure order of the infringing products at the defendant's premises, which is also quite important to avoid the continuance of the patent infringement; and

- to freeze the infringer's assets until a final decision on the merits is rendered. However, this type of court order can only be obtained if the patent owner shows that there is an actual risk of not duly recovering damages by the end of the court proceeding; and provides the court with a list of the assets of the defendant that it wishes to be frozen.

b) by way of final relief?

The most common remedies obtained by a patentee in an infringement case are the following:

- cessation of the infringement by the defendant under the payment of a daily penalty;

- the destruction of all products and material involved in the infringement;

- the recovery of damages; and

- the payment of attorney fees and judicial (official) costs.

Regarding recovery of damages, please note that the damages (i.e. loss of profits) will be determined by the most favorable to the injured party according to the following criteria:

- the benefits that would have been gained by the injured party if the violation had not occurred;

- the benefits gained by the author of the violation of the rights; or
• the remuneration that the author of the violation would have paid to the proprietor of the violated rights for a granted license, which would have legally permitted him to exploit the subject matter of the right.

Thus, even if the infringer does not keep records of his illegal operations, it is possible to determine the damages using a different criteria, such as the benefits that would have been obtained by the injured party if the violation had not occurred, or the remuneration that the infringer would have paid to the owner of the violated rights for a license.

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?

In order to have a preliminary injunction granted, the plaintiff must convince the judge of:

• the likelihood of success based on solid rights (*fumus boni juris*): the plaintiff must demonstrate that it has a good right which deserves protection and that there is a good probability that the defendant is infringing this right; and

• its rights could be severely damaged if no action is immediately taken (*periculum in mora*): the judge must be convinced that the plaintiff’s right is threatened by an activity of the defendant and could be severely damaged if no action is taken before a final decision on the merits is rendered.

Although the basis for the preliminary relief will be decided *in casu*, we believe that the statements provided in the product packaging or the writing of a prescription is powerful piece of evidence to convince the judge of the *fumus boni juris* and, therefore, it is likely that a preliminary injunction would be granted based on such information.

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

Considering that a patent litigation in Brazil is basically decided on the technical evidence, and the vast majority of local judges does not have a technical background, it is important to collect several pieces of evidence attesting the infringement and to obtain the technical reports in an attempt to convince the judge as to the existence of the infringement.

In an infringement of a second medical use patent lawsuit, since a use claim is considered a process claim, there is a reversal of the burden of proof. In this situation, the accused third party will bear the burden of establishing that its acts do not infringe the patent.

In this regard, it is important to highlight that the Brazilian legislation does not foresee discovery proceedings as in the United States. Hence, the parties are not obliged to disclose data that may jeopardize its position in the litigation.
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?

Brazil, as a developing country, does not have the ideal conditions for the development of new drugs, since the development of a new drug is a very long, costly and complex process. Thus, Brazil benefits greatly from permitting second medical use claims, since the development of a new therapeutic use is a simpler process (once the safety profile of drugs known for human use has already been established), and more companies would be encouraged to invest in research and development.

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

A fair balance between the interests of the relevant stakeholders (i.e. particularly the originator companies - usually the patent owners - and the generics manufacturers/suppliers - usually the third parties) is the goal of every patent system.

In Brazil, further medical use claims are generally considered to strike the right balance between the interests of relevant stakeholders, because such claims allow researchers to seek reward in the form of patent protection for investment into R&D into new uses of known compounds.

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

Further medical use claims are considered to better serve the interests of the innovator companies, i.e. the companies that develops new medical uses of a known substance.

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?

There is no empirical or anecdotal data available on the prevalence of second medical use claims. In addition, there is very little case law on second medical use claims.

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

The profile of patentees for second medical use claims are normally the originators (the same owner of the patent for the original use of the compound).

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?

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

There is no prohibition of second medical use claims in the Brazilian IP law, reason why no answers were provided for (a)-(c).

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?

Even though there is no data available with respect to the effects of allowing further medical use claims on the pharmaceutical industry, we could state that the extent of such allowance have been limited so far since it does not appear to have many lawsuits before the courts discussing infringement of second medical use claim.

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.

It is very important to encourage research into new medical use of a known substance, as well as the medical use of a known substance for a known indication but with different dosage forms, dosage regimes or patient populations via the patent system.

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

Yes.

An international harmonization of patent laws relating to further medical use claims would certainly be beneficial to create an effective international patent system, and bring greater international legal certainty for originator and generics companies, which operate in global markets.

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.

   Same standard as currently in practice in Brazil, namely any new medical use of a known substance is patentable as long as it is new and inventive in a manner that does not depend on the features of a therapeutic method in view of the fact that a therapeutic method applied to the human or animal body are not considered to be an invention based on article 10 (VIII) of the Brazilian IP Law.

b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.
As indicated in our comments to question (2c), new medical use is not allowable in Brazil when it is new and inventive in a manner that depends on the features of a therapeutic method.

A standard that would be best is to perform a more flexible interpretation of the new medical use claim in order to accept more this type of invention.

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

Swiss type use claim and purpose-limited product claim format should be permissible.

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

Same standards as currently in practice except for substance for use.

e) Who may be liable for infringement?

Any third party that explore the subject matter protected by a second therapeutic use patent with commercial purposes, especially if such act results in prejudice to the economic interests of the Patentee. In other words, any party conducting a prohibited act, any party unlawfully inducing a prohibited act and/or any party taking undue advantage of infringing activities.

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

Medical practitioners and patients should not be liable for infringement.

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.

First of all, infringement of a further medical use patent should be analyzed as any other type of infringement.

When establishing infringement of a further medical use patent, all relevant circumstances of a case that indicate infringing use despite “skinny labeling”, “cross-label” or “off-label” should be taken into account by the court.

Furthermore, knowledge by a third party should not be a requirement so that the act of such party constitutes an infringement of a further medical use patent.

In case there may be a “skinny label” or an “off-label”, it seems necessary to investigate if the product will be used for the patented use or not.

h) Relief available upon a finding of infringement:

i) at a preliminary / interim / interlocutory level; and

ii) by way of permanent relief.
Same standards as currently in practice (see answers to questions 7 and 8 above).

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

Same standards as currently in practice (see answers to questions 7 and 8 above).