

**Question Q238**

**National Group:** Israel

**Title:** Second medical use or indication claims

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**Reporter within**

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**Note:** The positions expressed in this document do not reflect the positions of the Israeli Group, as such. Due to differences of opinions among the group members as to the state of the law in domains where no decisions have been issued, the text below attempts to reflect the different opinions.

**Date:** June 1, 2014

## 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. The concept of allowing patent protection for second medical use patents is long established and is anchored in a Supreme Court ruling of the early seventies, which allowed a second indication patent with regard to alopurinol, a drug previously known for the treatment of cancer, which was discovered to be useful for the treatment of gout.  
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?  
Second medical use claims may be granted protection as either a product claim or a process claim, and provided that such claim will not constitute a method for treatment of the human body as such. Thus, such claims may be granted as Swiss type claims or purpose limited product claims, provided that all other patentability requirements are met.
  - b) What types of second medical use are patentable? See, for example, paragraphs 14) - 17) above/WGLs.

New uses of known pharmaceutical compounds as well as new dosage regimens, The group is divided as to whether new modes or routes of administration and new patient groups would be considered subject matter eligible of patent protection. In practice such claims are granted by the patent office, provided that the invention meets the patentability criteria. According to one opinion new modes or routes of administration and new patient groups may not be eligible subject matter for second medical use-.

- c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.  
Any method for treatment of the human body as such (i.e. as distinct from a purpose bound product or processes for manufacturing same) is an impermissible subject matter.
- d) What forms of second medical use claims are permissible? See, for example, paragraphs 26) - 33) above/WGLs.
- Use of substance X in the manufacture of a medicament for the treatment of disease Y.
  - Substance X for use in the treatment of Y
  - A kit for use in the treatment of Y comprising substance X and instructions for using same are permissible in practice.
  - In addition, dosage regimen claims may, where appropriate, also be permissible, provided that the claim is directed to a product.
- e) What forms of second medical use claims are not permissible? See, for example, paragraphs 26) - 33) above/WGLs.  
A method of treating a patient suffering from disease Y by administering substance X.  
A naked use claim (namely not formed as either a process or a product), e.g. Use of substance X for the treatment of disease Y, would not be allowed. ", Similarly "Use of X as a medicament...", which are directed to a method for treatment of the human body and do not relate to either a product or a process
- 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. However, according to one opinion, second medical use claims may not limit the discretion of treating physicians.
- 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;  
Yes. According to one opinion, such liability exists provided that the claim relates to a product and the drug is marketed for the use covered in the claim.
  - ii) the physician prescribing the drug for such use;  
It is unclear whether the act of prescribing the drug by a physician amounts to an infringing act.
  - iii) the pharmacist dispensing a drug for such purpose;  
Yes. According to one opinion, such liability exists provided that the claim relates to a product and the drug is marketed for the use covered in the claim.

- iv) the patient using the drug for such purpose?  
No (private non-commercial use).
- b) Are any parties exempt from infringement or liability for infringement of such claims. If so, what classes of party?  
No.  
Exemptions are determined by reference to the activity, not to a class or a party.
- c) Are such claims enforceable on the basis of direct or indirect infringement? Please provide details.  
Second medical use claims may be enforceable on the basis of direct and indirect infringement. The question with respect to indirect infringement of second medical indication patents has not yet been addressed by the Israeli courts. In general, in connection with a mechanical patent for a combination, the court held that in order to impose liability with respect to contributory infringement, the following conditions must be fulfilled:
- a) the defendant sold a component of a patented machine, combination or composition, or material or apparatus for use in practicing a patented process, constituting a material part of the invention;
- b) the defendant knew or should have known, under the circumstances, that the article sold was especially made or especially adapted for use in infringement of the patent,
- c) the article sold is not a staple article or commodity suitable for substantial non-infringing use,
- The contributors could not agree on whether actual knowledge is accordingly not a requirement for establishing liability for indirect infringement; namely whether a reasonable assumption that the article will be used in an infringing manner is sufficient. It is still unclear whether the plaintiff must show that the patent has been directly infringed by someone other than the defendant.
- 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.  
Subject to the exemptions existing in law for any otherwise infringing activity, and having regard to the scope of the specific claim, the commercial manufacture, supply or use, directed to a patented indication, may be considered infringing.  
With respect to "Swiss type" claims, while there is no Israeli case law on this question, it is believed that the manufacturing of a generic version of the drug for any use may be infringing, if such manufacturing includes at least the packaging of the drug with instructions for use in the treatment of the patented indication. There is a difference of opinions within the group regarding the question whether in the eventuality where a manufacturer had reasonable basis to believe that the drug will be used for the patented indication (e.g. off label or cross label use) and did not take reasonable steps to prevent the use of the drug for the patented indication, such action (or inaction) would constitute an infringement.
- 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.  
See answer to Question 4.
- 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?  
See answer to Question 4.
- c) If yes to b), is it necessary that the party knows that their actions are in connection with the infringing use?  
Yes (knows or should have known).
- d) If yes to c), what standard of knowledge is required? See, for example, paragraphs 38) and 47) above.  
Direct infringement does not require any knowledge. Indirect infringement (if applicable), requires that the defendant knew, or should have known under the circumstances, that its product will be put for infringing use.
- 6) How do the courts determine infringement of a second medical use claim? What are the legal tests and evidentiary requirements?  
While there is no Israeli case law on this question, it is believed that infringement of a second medical use claim is generally considered by applying the same legal tests and evidentiary requirements as those applied for other patents.
- 7) What relief is available for infringement of a second medical use claim:
- a) at a preliminary / interim / interlocutory level?  
While there is no guidance in the Israeli case law on this question, it is believed that the reliefs that are available for infringement of a second medical use claim at a preliminary level are the same reliefs that are available with respect to other patents.
- b) by way of final relief?  
While there is no guidance in the Israeli case law on this question, it is believed that the reliefs that are available for infringement of a second medical use claim by way of final reliefs are the same reliefs that are available with respect to other patents.
- 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?  
Two different answers were given: (1) Such statements may be sufficient to establish the infringing use or purpose of the product. Assuming that the other claim elements are exploited and that any additional tests for the granting of a preliminary injunction (e.g. balance of convenience) are satisfied, a preliminary injunction will be granted. (2) No. The plaintiff must prove the alleged infringement with respect to all the components of the particular claim. In addition, the relevant claim must be found valid (although the validity of registered patents is not usually considered when hearing a motion for an interlocutory injunction). The criteria for the grant of a preliminary injunction further include the balance of convenience and equity considerations
- 9) In respect of Question 7)b), what level of proof is required to obtain a final injunction?  
The same level of proof that is required with respect to other patents: preponderance of evidence.

## 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?  
Two different answers were given: (1) Encouraging research in the field of additional medical uses for known drugs.  
(2) On the one hand, the need to encourage research in the field of additional medical uses for known drugs by granting patents for inventions whose subject matter concerns second medical uses. On the other hand, preserving the principle that the scope of patent claims must not exceed the scope of novelty and inventive step embodied in the teaching of the patent, and that the public must be free to use unpatented technologies. In addition, second medical use claims may not limit the professional discretion of treating physicians.
- b) Are such claims as are currently permissible in your country considered to strike the right balance between the interests of relevant stakeholders?  
There has been very little debate, or analysis in the case law, whether the current scope of protection strikes the right balance. Two different answers were therefore given: (1) In general, second medical use claims may strike the right balance to the extent they are properly drafted so as not to prevent the public from exploiting unpatented technologies. (2) In general, second medical use claims may strike the right balance to the extent they are properly drafted so as to reflect the inventive contribution of the patentee.
- c) Is it considered that such claims better serve the interests of some stakeholders and/or are detrimental to other stakeholders?  
Two different answers were given: (1) Second medical use claims provide incentive for research and development of novel medicines for the benefit of mankind, as they reduce human suffering and improve the quality of life. Such novel medicines also promote economic growth and as such serve the interests of both the innovator companies and the generic companies, which can manufacture and sell the drugs after the expiration of patents. In other words, fostering of innovation is to the benefit of all parties involved; (2) Second medical use claims provide patent protection to further medical uses of active pharmaceutical ingredients, that would have otherwise been denied as anticipated. Therefore, such claims serve the interests of the originator pharmaceutical industry. Second medical use claims may be detrimental to generic manufacturers if such claims result in preventing them from exploiting unpatented technologies, in particular, the other medical uses of the active pharmaceutical ingredient. In addition, dosage regimen claims – if permissible in the appropriate cases – may also cause difficulties to generic manufacturers if they are prevented from exploiting unpatented dosage regimens.
- 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?  
We are not aware of any such published data.

- ii) What is the profile of patentees for second medical use claims in your country?  
Based on our experience, second medical use claims are sought mainly by innovator drug manufacturers.

- 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?
- 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?  
Two different answers were given: (1) To a significant extent. Israel is home to the world's largest generic pharmaceutical industry, which might be prevented from manufacturing or marketing generic drugs if second medical use claims will be interpreted too broadly.  
(2) There is no empirical information and therefore no assumptions can be made. In any event, Israel is not only the home to the generic industry but also, and primarily, the home to thriving innovative biotech industry which depends upon strong patent protection.

### 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?  
Two different answers were given: (1) Yes, provided that such claims will not prevent or limit the exploitation of unpatented technologies.  
(2) Yes, it is important to incentivize research into new therapeutic applications.
- 14) Is harmonisation of laws relating to second medical use claims desirable?  
Yes, to promote uniformity of IP laws throughout the world.
- 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.  
New uses of known pharmaceutical compounds. There has been a debate within the contributors whether novel dosages and dosage regimens also constitute permissible subject matter. Such patents are issued in practice.
  - b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.  
Two answers were given: (1) It is a question whether methods for treatment of the human body as such should be excluded from patent protection, especially when considering that patent protection is afforded to medical devices for carrying out such treatments. It may be suggested that if no impediment is imposed on protecting methods of treatment, doctors applying such methods

would not be exposed to injunctive reliefs. (2) Methods for treatment of the human body as such, as well as claims covering dosage regimens should not constitute permissible subject matter, so that the discretion of treating physicians will not be limited by patents.

- c) Form of permissible claims. See, for example, paragraphs 26) - 33) above/WGLs.  
The form of the claim should play less of a role in allowing patent protection. It is rather the essence that matter, and the question to be asked is whether and under what conditions affording protection for medical use patents would serve the global interest of society, regardless of any form. With respect to the form of permissible claims, two answers were given: (1) Acceptable forms may be for example, "Product X for use in the treatment of Y". Swiss type claims and kit claims (which are accepted as a matter of practice, but there is no case law on this issue) (2) the acceptable forms should be Purpose-limited claims, such as "Product X for use in the treatment of Y".
- d) Form of impermissible claims. See, for example, paragraphs 26) - 33) above/WGLs.  
Two different answers were given: (1) According to present standard, Claims to methods of treatment of the human body as such ought not be allowed, but see b) and c) above.  
(2) Any form other than the "purpose-limited" product claims referred to above.
- e) Who may be liable for infringement?  
Two different answers were given: (1) Manufacturer, insurer including Sick Funds, wholesalers, pharmacists.  
(2) Whoever puts on the market a product which specifically states on the relevant product label that the generic drug is indicated for the patented use.
- f) Any parties/institutions that should be exempted from infringement or liability for infringement.  
Physicians prescribing the drug should be exempted from liability for infringement, to the extent that the physician is not jointly liable for infringement with the manufacturer; the patient using the drug for the purpose of the patented use. According to one opinion, the pharmacist dispensing a drug for the purpose of the patented use should also be exempted from liability 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.  
The commercial manufacture, supply, storing, importing, offering for sale or use, directed to a patented indication, should be considered infringement. The standard of knowledge of the alleged infringer should be any knowledge with respect to direct infringement, and intent to infringe with respect to indirect infringement (if applicable). The group has difference of opinions as to whether reasonable basis to believe that the drug will be used for the patented indication coupled with lack of reasonable measures to avoid infringement will satisfy both these requirements.
- h) Relief available upon a finding of infringement:
  - i) at a preliminary / interim / interlocutory level; and
  - ii) by way of permanent relief.

The same reliefs that are available with respect to other patents.

- i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.  
The same levels of proof that are available with respect to other patents.

**NOTE:**

It will be helpful and appreciated if the following points could be taken into consideration when editing the Group Report:

- kindly follow the order of the questions and use the questions and numbers for each answer
- if possible type your answers in a different colour
- please send in a word document
- in case images need to be included high resolution is required for good quality printing.

**Summary**

Second medical use claims may be granted in Israel for new uses of known pharmaceutical compounds. "Swiss-type" and "purpose-limited" product claims are permissible. Dosage regimen claims are also permissible, provided that such claims are directed to a product or a process for manufacturing same.

Second medical use claims may be enforceable on the basis of direct infringement. Indirect infringement of second medical claims has not yet been addressed by the courts.

Infringement of a second medical use claim is generally considered by applying the same legal tests and evidentiary requirements as those applied for other patents and may yield the identical reliefs.

In general, second medical use claims are considered beneficial to the extent that such claims do not prevent the public from exploiting unpatented technologies.