**Question Q238**

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| **National Group:** | Hungarian AIPPI Group |
| **Title:** | **Second medical use or indication claims** |
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| **Reporter within Working Committee:** | Zsolt **SZENTPÉTERI** |
| **Date:** | April 4, 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, it does.*

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?

*Act No. XXXIII of 1995 on the Protection of Inventions by Patents (Hungarian Patents Act). (For the sake of completeness it is noted that based on Articles 84/A to 84/N of this Act a European patent can be validated as of January 1, 2003 in Hungary and revoked pursuant to the relevant rules of the European Patent Convention and in some aspects of the Hungarian Act. However, there is no practice yet in respect of validated patents; therefore, we will deal only with the practice under the Hungarian Patents Act.)*

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

*Theoretically any type of second medical use is patentable, even if the first medical use was only mentioned in the state of the art but the given compound did not become a medicinal product with the first medical use. However, a compound having a first non-pharmaceutical use is the subject of a first pharmaceutical use type invention.*

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

*According to our best knowledge there is no specific type of second medical use which could form an impermissible subject matter provided that it corresponds to all other preconditions of patentability.*

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

*Forms according to paragraphs 27 and 30 are allowable. However, if the Hungarian Patent is a validated European Patent, any form allowed by the EPO is permissible.*

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

*Method of treatment type claims are not permissible.*

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.

*We are not aware of any court or national patent office guidance in the context of paragraphs 34) - 39) above/WGLs.*

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?

*According to the Hungarian Patents Act and the patent practice only the party manufacturing, offering for sale or marketing the pharmaceutical product with label instructions which describe the patented use is liable.*

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

*Article 19 on rights conferred by the patent, section (6), paragraph (a) of the Hungarian Patents Act ["The exclusive right of exploitation shall not extend to acts done privately or not involved in an economic activity"] exempts the phy-*

*sician and the patient from any liability and paragraph (c) of the same section ["The exclusive right of exploitation shall not extend to preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription, or acts concerning the medicine so prepared"] exempts the pharmacist and (again) the physician as well. The Bolar exemption is also valid in Hungary in view of paragraph (b) of this very same section.*

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

*There is no doubt that any type of second medical use claim is enforceable in Hungary in case of direct infringement, relevant court decisions exist.*

*As regards indirect infringement, article 19 on rights conferred by the patent, section (3) reads as follows: "On the basis of the exclusive right of exploitation, the patentee shall be entitled to prevent any person not having his consent from supplying or offering to supply a person, other than a person entitled to exploit the invention, with means (instruments, appliances) relating to an essential element of the invention, for carrying out the invention, when such person knows, or it is obvious from the circumstances, that those means are suitable and intended solely for carrying out the invention."*

*Based on this regulation the patentee of a second medical use type patent is entitled to sue for infringement the manufacturer of an active ingredient who supplies another pharmaceutical manufacturer or a wholesaler with the active ingredient for an infringing use. Thus, said producer commits indirect infringement. We must confess that we are not aware of a respective court decision yet.*

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, but only if the patented indication appears on the label.*

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. Infringement is realized merely with the indication of the second use on the product or PIL.*

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.*

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

*No.*

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

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

*Based on a very small number of legally binding cases, it seems that the labeling determines the outcome, and no general consequences can be concluded.*

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

a) at a preliminary / interim / interlocutory level?

*i) the civil remedies applicable in case of infringement of patents [c.f. Article 35, section (2) of the Patents Act]:*

- *declaration of the fact of infringement by the court;*
- *injunction to cease the infringement or any acts directly threatening with it;*
- *providing information by the infringer on the identity of persons involved in the production and distribution of the infringing goods or the provision of infringing services and of their channels of distribution;*
- *satisfaction from the infringer by way of a declaration or by other appropriate means; if necessary, the declaration shall be made public by the infringer or at his expense. The court may order the publication of its decision at the expense of the infringer;*
- *surrender of the enrichment obtained by the infringement of the patent;*
- *seizure, transfer to a specific person, recall and definitive removal from the channels of commerce, or destruction, of the infringing products, as well as of the means and materials exclusively or principally used for infringement. The court may also order at the request of the patentee the removal of the infringing nature of the infringing products or, if this is not possible, the destruction thereof. In justified cases it is possible to auction the means and materials seized.*

*ii) The patentee may claim damages under the rules of civil liability.*

*iii) Furthermore, Article 104 of the Patents Act on rules governing patent litigation, section (5) defines three additional remedies which may be requested from the court in the request for provisional measures:*

- *"(a) ordering precautionary measures in accordance with the provisions of the Act on Judicial Execution, if he [the patentee] demonstrates circumstances likely to endanger the later satisfaction of his claim for damages or for the surrender of the enrichment obtained by infringement;*
- *(b) compelling the infringer to communicate or present his banking, financial or commercial documents with a view to ordering the precautionary measures in accordance with point (a);*
- *(c) ordering the lodging of security, if in place of demanding discontinuance of the patent infringement, the patentee consents to the continuation, by the infringer, of the allegedly infringing activity."*

b) by way of final relief?

*There are no special remedies/rules in case of the infringement of a second medical use claim; the civil remedies mentioned in 7)a)i) and ii) may be requested.*

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?

*Injunction can be granted upon the statements in the product packaging or in PIL provided that the statements expressly refer to the use of the protected second indication.*
*Article 19 on rights conferred by the patent, section (3) reads as follows: "On the basis of the exclusive right of exploitation, the patentee shall be entitled to prevent any person not having his consent from supplying or offering to supply a person, other than a person entitled to exploit the invention, with means (instruments, appliances) relating to an essential element of the invention, for carrying out the invention, when such person knows, or it is obvious from the circumstances, that those means are suitable and intended for carrying out the invention."*
*The same Article, section (4) reads as follows: "The provisions of paragraph (3) shall not apply when the supplied or offered means are staple commercial products, except when the supplier or offerer deliberately induces his client to commit the acts referred to in paragraph (2)."*
*Thus, the prescription may be served as a basis for injunction provided it can be proved that the manufacturer or the wholesaler deliberately induces the physician to prescribe the product for the off-label use.*

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

*According to the Hungarian legislation there are no special requirements regarding to the level of proof in case of infringing second medical use claims.*

## 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?

*Due to the rapid development of the pharmaceutical industry in the 1980's the preparation and designing of compounds having pharmaceutical activity became significantly easier. Also, during the theoretical and clinical researches more and more information in connection with the biological function and regulating processes of the human body were gathered which opened the way to the recognition of possible new indications of already known active substances. Consequently, there was also an urgent need for the patent protection of the relevant research results. The Hungarian Intellectual Property Office, the representatives of the pharmaceutical industry as well as the professional bodies were always of the opinion that recognizing a new pharmaceutical or biological effect of an already known substance by experimental work should be rewarded by exclusive rights. According to their standpoint second medical uses are meeting the requirements of novelty and inventive activity as set by the Hungarian Patents Act. In order to meet also the requirement of the third patentability criterion, the industrially applicable second medical indications - like in most of the countries - were initially patentable by using the Swiss-type claim format only. Over time the Hungarian legislation regarding the permissi-*

*ble claim format developed simultaneously with the practice of the EPO. As another aspect also the public health considered the use of a particular product for more purposes especially desirable, since in case of introduction of new active substances new side effects endangering the patients may occur, while the side effects of already used substances are well-known. Further, in the case of pharmaceutical compositions based on second medical indication the registration costs and the time elapsed till the grant of the marketing authorization are significantly reduced, which is also mirrored by the price of the product.*

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

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

***Answer to b) and c)**: the fact, that inventions protected by second medical indication claims are also rewarded by exclusive rights, urges the originators to conduct additional researches in connection with possible further pharmacological or biological activities of their active substances. However, the possibility for testing the original active substances for further pharmaceutical effects is also open to generic firms, which possibility is also supported by some successful generic activity.*

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?

*Since most of the patents granted in Hungary are validated European Patents, the prevalence of the second medical use claims is most probably identical with the EP prevalence.*

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

*See the answer to question i) above. At the same time we wish to note that several patents with Swiss-type use claim format may be still in force.*

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?

*To our best knowledge there appears to be no special affect.*

## 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.*

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

*Yes, but the harmonisation of the form of permissible claims seems rather unrealistic.*

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.

*All types of second medical use should constitute permissible subject matter, e.g. those mentioned in paragraphs 14), 15) and 17) of the WGLs. May we mention that the scenario outlined in item 16) seems to cover also first medical use.*

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

*None.*

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

*To encourage: Substance X for use in the treatment of condition Y.*

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

*To discourage:*
*Method of treating a patient suffering from disease Y comprising.....*
*Use of substance or composition X for the treatment of disease Y...*

*e)* Who may be liable for infringement?

*The party manufacturing, offering for sale and/or marketing the drug with packaging or label instructions which describe the patented use. A party manufacturing and/or selling an essential element of the patented invention, e.g. the active agent of the final drug, should be liable for contributory infringement.*

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

*Medical staff, incl. physicians, pharmacists, patients, hospitals.*

*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.

*Manufacturing, offering for sale and/or marketing the drug for at least one use which falls into the scope of a patent should constitute patent infringement. The knowledge of the alleged primary infringer should not be relevant. Manufacturing and/or selling an essential element of the patented invention, e.g. the active agent of the final drug, should constitute indirect infringement in case the party manufacturing and/or selling said essential element knows the intended final use.*

h) Relief available upon a finding of infringement:

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

   *Both reliefs have to be available, like for other types of patents.*

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

   *We think that the level of proof has to be the same as in the case of other types of patents (protecting other types of inventions).*

## ***SUMMARY***

*Hungary permits second medical use claims. The basis for the protection is Act No. XXXIII of 1995 on the Protection of Inventions by Patents (Hungarian Patents Act). Theoretically any type of second medical use is patentable, provided that it corresponds to all other preconditions of patentability. Methods of treatment type claims are not permissible. For the infringement of said claims only the party producing, offering for sale or marketing the pharmaceutical product with label instructions which describe the patented use is liable. The exclusive right of exploitation does not extend to pharmacists, physicians and patients either. The Bolar exemption is also valid in Hungary. The second medical use claims are enforceable both in cases of direct and indirect infringement, although for the latter no court decision exists yet. The remedies in case of an infringement are identical with those of the infringement of other patents.*

*The policy behind permitting such claims is very similar to the general European policy, i.e. the public health considers the use of a product for more purposes desirable, due to the advantage of knowing the side effects, the reduced registration costs and reduced time elapsed till the grant of the MA, which also result in a lower price, rendering the product more affordable for the public (patients). Substantially, the claims as are currently permissible seem to strike the right balance between the interests of relevant stakeholders. According to the opinion of the Hungarian Group, it is desirable to permit second medical use claims and also harmonizing the corresponding laws, however, we believe that the harmonization of the form of permissible claims is rather unrealistic. We suggest to encourage the "Substance X for use in the treatment of condition Y." claim format and discourage the "Method of treating a patient suffering from disease Y comprising....." and "Use of substance or composition X for the treatment of disease Y..." claim forms.*

## ***ZUSAMMENFASSUNG***

*Ungarn erlaubt Verwendungsansprüche zweiter medizinischer Indikation. Basis für den Patentschutz ist das Gesetz Nr. XXXIII/1995 über den Patentschutz von Erfindungen. Theoretisch ist jede beliebige Variante zweiter medizinischer Indikation patentierbar,*

*vorausgesetzt, dass sie alle anderen Bedingungen für die Patentierbarkeit erfüllt. Patentansprüche für Behandlungsmethoden sind nicht erlaubt. Das ausschließliche Nutzungsrecht erstreckt sich nicht auf Pharmazeuten, Ärzte und Patienten. Die Bolar-Ausnahme ist auch in Ungarn gültig. Die Patentansprüche zweiter medizinischer Indikation sind sowohl bei direkter als auch bei indirekter Patentverletzung durchsetzbar, obwohl es für letztere noch kein Gerichtsurteil gibt. Die Rechtsmittel für den Fall einer Patentverletzung sind identisch mit denen bei anderen Patentverletzungen.*

*Der Grundsatz hinter der Genehmigung solcher Patentansprüche ist der allgemeinen europäischen Richtlinie sehr ähnlich, d.h. das öffentliche Gesundheitswesen berücksichtigt die Anwendung eines Produktes für mehrere wünschenswerte Zwecke aufgrund der Kenntnis der Nebenwirkungen, der verringerten Anmeldungskosten und der geringeren Zeitdauer bis zur Arzneimittelzulassung, was auch einen niedrigeren Preis und für die Verbraucher (Patienten) den Zugang zu einem erschwinglicheren Produkt zur Folge hat. Im Wesentlichen scheinen die gegenwärtig akzeptierbaren Patentansprüche einen rechtlichen Mittelweg zwischen den Interessen der betroffenen Anspruchsberechtigten ermöglichen. Nach Meinung der Ungarischen Gruppe ist es erstrebenswert, Ansprüche zweiter medizinischer Indikation zu genehmigen und auch mit den entsprechenden Gesetzen in Einklang zu bringen, jedoch glauben wir, dass eine Anpassung der Form der zulässigen Ansprüche ziemlich unrealistisch ist. Unser Vorschlag ist, die Anspruchsform „Substanz X zur Verwendung in der Behandlung des Zustandes Y“ anzuregen und von der Anspruchsform „Methode zur Behandlung von an Krankheit Y leidenden Patienten beinhaltend …“ und „Verwendung der Substanz oder Komposition X zur Behandlung der Krankheit Y beinhaltend …“ abzuraten.*

## ***RÉSUMÉ***

*La Hongrie autorise les revendications concernant une deuxième utilisation médicale. Cette protection est fondée sur la loi No XXXIII de 1995 portant sur la protection des inventions par le brevet (Loi Hongroise des Brevets). En théorie, n'importe quel type de deuxième utilisation médicale est brevetable, à condition de satisfaire à toutes les autres conditions préalables de la brevetabilité. Les revendications portant sur les méthodes de traitement ne sont pas autorisées. (Seule la partie produisant, mettant en vente ou commercialisant le produit pharmaceutique muni d'un descriptif expliquant l'utilisation brevetée est responsable pour la contrefaçon des revendications mentionnées.) Le droit exclusif d'exploitation ne s'étend ni aux pharmaciens, ni aux médecins, ni aux patients. L'exemption Bolar est également valable en Hongrie. Les revendications de deuxième utilisation médicale sont exécutoires aussi bien en cas de contrefaçon directe qu'indirecte, bien que pour cette dernière il n'existe pour l'instant aucune décision judiciaire.*

*Les recours en cas de contrefaçon sont identiques à ceux concernant la contrefaçon d'autres brevets. La conception qui sous-tend l'autorisation de telles revendications est très similaire à la conception européenne générale, c'est-à-dire que les autorités de la santé publique considèrent comme souhaitable l'utilisation multiple d'un même produit en raison de l'avantage qu'il y a à en connaître les effets secondaires, des frais d'enregistrement réduits ainsi que de la durée de temps réduite jusqu'à l'autorisation de mise sur le marché, ce qui se traduit aussi par un prix plus bas qui rend le produit plus accessible au public (aux patients). En fait, les revendications qui sont autorisées actuellement semblent créer l'équilibre nécessaire entre les intérêts des différents acteurs concernés. Selon l'opinion du Groupe Hongrois, il est souhaitable d'autoriser les revendications portant sur la deuxième utilisation médicale et d'harmoniser les lois correspondantes, cependant nous pensons que l'harmonisation de la forme des revendications autorisables semble peu réaliste. Nous suggérons de promouvoir un format de revendication du type « Substance X à utiliser dans le traitement d'un état Y », et de dissuader de l'utilisation des formats de revendication du type « Méthode pour traiter*

*un patient souffrant de la maladie Y qui comprend… » et « Utilisation d'une substance ou d'une composition X pour le traitement d'une maladie Y ».*