Question Q238

National Group: Russian Federation National Group

Title: Second medical use or indication claims

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Date:

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, almost every type of second medical use claims is allowed in Russia and Eurasia.

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?

In Russia the standards are set forth by the Civil Code. In particular pursuant to Art. 1350 a technical solution in any field related to a product or process is subject to patent protection. The Civil Code does not contain any explicit provisions related to the “use” claims. However, as a matter of the existing practice of the Russian Patent Office, “use” claims can find patent protection.

In Eurasia, the standards are set by the Eurasian Patent Convention (EAPC) and Regulations under the EAPC. Use of a device, process, compound, biotechnological product for a new purpose is recognized as a patentable subject matter.

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

- Method of treatment or prevention
- Swiss-type
- German type
- Medicament (for Russia only)
c) Are any types of second medical use impermissible subject matter? See, for example, paragraphs 14) - 17) above/WGLs.

EPC 2000 claims as such are impermissible. Medicament claims that are allowed in Russia (see below) can be regarded as an analogue to EPC 2000.

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

Save to EPC2000 claims as such, any type of second medical use claims is permissible such as.

“A method of treating/preventing disease X, said method comprising administering to a patient an effective amount of compound Y”

“Use of compound Y for manufacturing a medicament for treating/preventing disease X”

“Use of compound Y for treating/preventing disease X”

“A medicament for treating/preventing disease X, said medicament comprising compound Y as an active ingredient” (for Russia only).

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

EPC 2000 claims as such are not allowable in Eurasia. Swiss or German type claims are not allowed provided that patentability of the invention resides merely in a new dosage regimen. Such claims may be protected as method of treating/preventing claims.

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 differences in the meaning associated with the use of such terms as 'treatment', 'treating' or 'use to treat' have been established by court and Russian/Eurasian Patent Offices. These terms are all being construed as pertinent to the treatment and therefore corroborating the feasibility of accomplishment of the intended use is of crucial importance for supporting the compliance of the claimed invention with the requirement for industrial applicability. The general approach towards these terms consists in that at least some efficacy in the treatment of a particular disease or condition should be demonstrated.

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

ii) the physician prescribing the drug for such use;

Yes, the physicians are not exempted from patent infringement. However, there is no case law on this subject.

iii) the pharmacist dispensing a drug for such purpose;

Yes, provided that this is not one-time preparing of a drug per physician’s prescription that is exempted from patent infringement.

iv) the patient using the drug for such purpose?
No, as such use is intended for personal need that is exempted from patent infringement.

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

The following acts exempted from patent infringement and liability:
- conducting a scientific research of a product or a process or conducting an experiment on such product or process;
- use of an invention under extraordinary circumstances (natural calamities, catastrophes, wrecks etc.);
- non-commercial use (use of the invention for personal needs that is not associated with generating profit or revenue) – applies for patients using the drug for patented purpose;
- one-time preparation of a medicament in a pharmacy as per a physician’s prescription – may apply for a pharmacist;
- importation, use, offer for sale, selling, other introduction into civil circulation or storage for the above purposes of a product that has been put on the local market by a patent holder or upon his consent.

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

Such claims are enforceable on the basis of direct infringement or threat of infringement. The patent law lacks indirect infringement concept.

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?

Such act shall be deemed to constitute an infringement to the extent that the generic drug is supplied for any use including the one that is covered by the patent.

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, each of these acts is infringement, provided that those acts are exempted therefrom as pointed 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, it necessary that the party committing those acts does so in connection with the infringing use.

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

No, the party does not need to know that its actions infringe to be held liable.

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

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

The court would determine infringement of the of a second medical use claim along the rules of determining infringement of any asserted patent.
It is to be proven that (a) the patented invention is being used in the generic product; and (b) the defendant has been supplying the generic product for the infringing use.

(a) Under the patent law, the scope protection is determined by claims. A patented invention is deemed used in a product, if the product contains each (or equivalent) feature of the independent claim.

The opinion on the use of the patented invention in the generic product is produced by a technical expert appointed by the court.

(b) Evidence should be provided that the defendant has been directly commercializing the generic product for the intended use. The burden of proof lies on the plaintiff.

7) What relief is available for infringement of a second medical use claim:
   a) at a preliminary / interim / interlocutory level?

   Under our procedural law a PI is available before Russian Court in general and in particular if a second medical use claim is asserted. However PIs are quite rare. There is no obligation for the court to grant a PI, and judges are in general quite reluctant to do so in practice. This is especially true for non-material disputes, e.g. for patent infringement trials, when the purpose of a PI is to stop infringing the asserted patent. In other words, there is a low likelihood of obtaining a PI that would prevent a generic maker from launching its infringing product or marketing it for the patented indication.

   b) by way of final relief?

   A final relief including a permanent injunction, damage collection, destruction of infringing goods, as well as publication of the court decision in the relevant sources are available under Russian law.

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?

   Under Russian law PI can be granted if its lack can result in complications or impossibility of execution of the court judgement, or in order to prevent substantial damages to the PI applicant.

   According to the general approach of Russian courts, generic activity in commercializing its product on the market is not considered to be sufficient ground for granting PI.

   The statements provided in the product packaging or based on the writing prescription cannot be a basis of granting a PI, as under our practice those issues relating to examination of infringement of the asserted patent are resolved during the main proceedings, and they are irrelevant for a PI application.

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

   The patentee should submit in first place evidence that the defendant has been commercializing the generic product for the patented indication. Such evidence may include the label that would refer to the patented indication and also identify the manufacturer being sued. Invoices, sales receipt, documents confirming participation of the defendant in the bids would also serve as proof of commercialization of the generic product by the defendant.

   Thereafter, it is required to prove that the product infringes the asserted patent. For this, the court would appoint an expert to produce the opinion. The court can impose a final relief if the court appointed expert decides that the asserted patent covers the generic product.
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?

"Use of a known product for a new purpose" along with "method of treatment/prevention" have been the claim types that were historically recognized by Russian/Eurasian laws since their adoption in early 90-ies.

As noted above, in 2008 when the Russian Patent Law was replaced by the Civil Code, the explicit reference to “use” as a patentable subject matter was removed. Nevertheless, since use type claims were not recognized as non-patentable subject matters, the Patent Office continued examining the applications and granting patents directed to use claims.

This arguable uncertainty around patentability of use claims is expected to change on October 1, 2014 when the amendments in the Civil Code will become effective, whose Article 1350.1 will explicitly comprise a use of a product or a process for the specified intended purpose as an allowable subject matter.

In our opinion these latest amendments show importance of the use claims, including second medical use claims for Russia.

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

It is generally accepted that allowance of the second medical use claims strikes the right balance between the interests of relevant stakeholders – patent owners at one side and third parties at the other. Availability of the second medical use claims provides for a substantial incentive to discover new indications for the known drugs. Furthermore, it is considered that second medical use claims can be much valuable for small R&D entities that may not have enough resources to develop a new compound, but that can focus on discovering new indications for the known drugs and secure patent protection thereto.

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

Due to the limited case law in enforcement of the second medical use claims, there is a great deal of uncertainty relating to enforceability of those claims. Therefore, it may be concluded that the value of the second medical use for securing exclusivity for the patented indication, and hence currently those patents do not fully serve the interests of their owners.

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?

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

There is no statistics on the prevalence of the second medical use claims in Russia.
The second medical use claims are used by both originators and generics. Originators may be more active in using those claims if the basic compound patent has not expired, while for the compounds that are a public domain the second medical use claims can be use by both originators and generics.

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

Not applicable

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?

Due to uncertainty relating to enforceability of the second medical use claims, it may be contemplated that there could be less incentive for the pharmaceutical industry both originator and generic to discover new indications of the known drugs. We think that this activity may increase if there is a case law that would give certain value for those claims.

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?

Second medical use are already permitted in many countries including Russia. It is desirable to focus on enforceability of those claims so that the entity that discovered the new indication enjoys exclusivity for it. At the same time, the third parties should not be precluded from using the drug for non-patented indications.

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

Yes, harmonization of laws relating to those claims is highly desirable. Since the pharmaceutical industry is global, the more the law is harmonized across various jurisdiction, the more pharmaceutical companies would be encourage to invest in discovering of the new indication for the benefit of the population.

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.

EPC2000 claims should be a permissible subject matter across difference jurisdictions.

Allowability of other second medical use claims can be decided at the national levels.
b) Types of any second medical use constituting impermissible subject matter. See, for example, paragraphs 14) - 17) above/WGLs.

Although in Russia any types of second medical use claims are permissible, in our view method of treatment/prevention claims can be excluded from patentability, as their value is not significant and in order to harmonize the law with the laws in other jurisdictions.

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

EPC2000 claim ("Substance X for use in treatment of disease/condition Y") should be allowable in all jurisdictions.

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

"Method of treatment/prevention of the disease/condition Y comprising administering to a patient in need thereof substance X" can be optionally removed from national patent laws.

e) Who may be liable for infringement?

Drug manufacturers, importers, distributors/wholesalers, pharmacies should be liable for infringement of the second medical use patent.

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

Doctors (practitioners) and patients should be exempted from infringement and 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 entity must be held liable if the product label contains the patented indication and it is not carved out once the alleged infringer becomes aware of the patented indication, e.g. from a patentee.

Liability for marketing the product for off label indication (e.g. if it is carved out because of the patent) should be entailed both from the IP and regulatory perspectives.

h) Relief available upon a finding of infringement:

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

ii) by way of permanent relief.

The courts should be less reluctant of granting a preliminary (interim) injunction in those jurisdictions where it is not granted as a matter of practice.

For a permanent relief, there should be established mechanisms for calculating damages for infringing for this category of patents.

i) In each case for h)i) and h)ii), the level of proof for the granting of such relief.
The courts should have harmonized tests as respect the level of proof for granting at least permanent (interim) injunction to ensure predictability of the court proceedings across various jurisdictions.

Summary

Second medical use claims are allowable for both types of patents available in Russia - (i) National Russian patents granted by the Russian Patent Office (RU PTO) in accordance with the provisions of the Civil Code and Administrative Regulation; and (ii) Regional Eurasian patents granted by the Eurasian Patent Office (EAPO) in accordance with the provisions of Eurasian Patent Convention (EAPC) and Patent Regulations under the EAPC.

Russian and Eurasian laws are quite similar in terms of requirements for validity of second medical use claims. It is worthwhile mentioning that different types of second medical use claims are allowed under both laws including method of treatment and prevention claims. However, there are some differences in Russian and Eurasian laws regarding validity of some claim types that will be specifically highlighted below.

Russian court is a venue for enforcement of both Russian and Eurasian patents, and under Eurasian law infringement of a Eurasian patent on the territory of the Contracting State including Russia should entail the same liability as infringement of a National patent.

There is a limited case law in Russia on the issue how to assess infringement of a second medical use patent, in particular, when the patented indication appears on the generic label or it is carved out from there ("skinny labelling"). There is no case law on liability for infringement of a second medical use patent, namely, whether the infringing generic product should be entirely removed from the market, or the patented indication should be carved out and/or the court must impose an injunction on marketing the generic product under the patented indication.

It would be in the interest of all stakeholders both innovators and generics as well as Health Authorities and Court to have more certainty as to the scope and enforcement capabilities of the second medical use patents to preserve the balance between innovator’s exclusivity in commercializing the product for the patented use, while allowing the generics to commercialize their drugs for the off patent indications.