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During 2012, a significant change has occurred in Mexico regarding the wording of the first medical use claims that are acceptable by the Mexican Institute of Industrial Property (IMPI).

In the past, IMPI used to grant first medical use claims similar to the so called “Swiss type claims”. That is, any patent application for a first medical use could have allowable claims drafted in the following way:

“Use of a compound X for the manufacture of a medicament for the treatment of a disease or condition Y"

Now, IMPI has changed its criterion and first medical use claim must be drafted as follows:

"Compound (or substance) X for use as a medicament useful in the treatment of a disease or condition Y".

This wording is similar to what it is currently accepted by European Patent Office (EPO). However, no change has occurred regarding the accepted wording for the second medical use claims which are still allowable drafted in the Swiss type use claims style. The reasons behind these new criteria will be explained in this article.

Legal Frame.

In accordance with the Industrial Property Law (IPL), its Regulations and the applicable rules for patent application, pharmaceutical patents are allowed when contains:

- Pharmaceutical product claims

- Formulation and composition claims.

- Pharmaceutical combination claims.

- Dosage claims.

- Salt claims.

- Polymorph claims

- Pharmaceutical use claims

In spite that the present article will be focused on first and second medical use claims, patent applicants in Mexico must consider that all the types of claims mentioned in this list usually face objections involving lack of novelty and inventive step, when there is not a clear explanation or support in the description of the advantages of the invention. Therefore, in order to meet the provisions of article 47 of the Mexican Industrial Property Law (IPL), and 28 and 29 of its Regulations, the applicant shall take into account that said claims must be written in terms of its technical features, and not based on its function or result. In addition, the description must contain examples providing support to the claims.

Moreover, dosage and polymorph claims are usually objected under the argument that they do not involve an inventive step and thus, it is necessary to point out in a clear and concise manner in the description the unexpected effect of said dosage or polymorph, which must be duly supported by examples and comparative examples.

On the other hand, applicant shall avoid claiming:

- Method of treatment applicable to human/animal body.

- Product by process, in the majority of the cases.

- Omnibus claims

- Biological and genetic material as found in nature

Is it possible to amend methods of treatment applicable to human body to Swiss type use claims?

Regarding methods applicable to the human/animal body which are considered non-patentable matter under the provisions of, article 19 section VII of IPL provides that:

"For the purposes of this Law, surgical, therapeutic and diagnostic treatment methods for the treatment of the human body and those related to animals are not inventions."

Upon this provision, IMPI changed its criteria, arguing that Swiss type claims are structured to indirectly fall in the category of process due to these are addressed to the preparation of a medicament. The fact that the claims are always narrowed to the use of a known active ingredient (compound) directed to "a treatment" of an specific disease or medical condition ("Use of a compound X for the manufacture of a medicament for the **treatment of a disease or condition Y**") has lead IMPI to the conclusion that this wording triggers the prohibition mentioned above.

In order to protect this subject matter, IMPI resolved the discussion first by accepting the Swiss type claims and now accepting medical use claims in accordance with the new wording as mentioned at the beginning of this article. The reasoning behind this is the result from the Enlarged Board of Appeal of EPO and the following:

Article 45 of IPL provides a list of type of claims that may be included in one single patent or patent application, namely:

I.- Claims of an specific product and those related to processes specially devised for its manufacture or <u>use</u>;

II.- Claims of an specific process and those relative to an apparatus or to any means specially devised for its application, and;

III.- Claims of a determined product and those of a process specially devised for its manufacture and those of an apparatus or means specially devised for its application.

Therefore, use claims are provided in the Mexican legal frame and Mexican Examiners should not object them. But this is not the issue: while use claims are provided and therefore allowable, the way in which section I of the above provision is drafted has created confusion in some examiners in the sense that use claims are construed as process or method claims.

Moreover, section H of article 4 of the Paris Convention states that:

"Priority may not be refused on the ground that certain elements of the invention for which priority is claimed, do not appear among the claims formulated in the application in the country of origin, provided that the application documents as a whole specifically disclose such elements."

Section H solved the problem regarding the divergences on IP between the different legislations of the countries of the Union, because if certain subject matter is considered as not patentable in one country, it may be patentable in other(s) country(ies) since the application must be examined based on both the description and the claims as a whole and not only based on the claims in an isolated manner.

Taking into consideration article 45 of IPL and article 4-H of the Paris Convention, it is understood that the methods for treatment (surgery or therapy) or diagnosis applicable to the human/animal body, which are not patentable under article 19-VII, can be reformulated as pharmaceutical or medical use claims.

Now, article 45 of IPL may be considered as the basis on which method of treatment claims applicable to human body, duly reformulated as use claims may be patentable in Mexico; however, the Mexican practice has follwed the results from the Enlarged Board of Appeal of the European Patent Office on this matter, due to the fact that IPL and EPC contains provisions very close or similar.

Further, Article 16 of IPL states that inventions that are new, the result of an inventive step and susceptible of industrial applicability within the meaning of the Law shall be patentable, with the exception of:

I.- Essentially biological processes for obtaining, reproducing and propagating plants and animals;

II.- Biological and genetic material as found in nature;

III.- Animals breeds;

IV.- The human body and the living matter constituting it; and

V.- Plant varieties.

Legally speaking, Article 45 of IPL read along with article 16 of IPL should be interpreted as the basis for allowing claims of a specific product to be used in any of the methods of treatment pointed out in article 19-VII of IPL, provided that the use of the product for any of such methods is not comprised in the state of the art. The issue here being that the Mexican Examiner must be convinced that the technical feature to be protected is the effect of the substance relating to a different disease to which such substance was originally applied for.

In light of the above, use claims should not be consider as process (method) claims and moreover, use claims are the legal vehicle to get protection for first and second medical uses , understood as product claims.

IMPI considers that if method of treatment claims using a substance already known are drafted as a "new use" for the treatment of a different disease or condition, it overcomes the objection that methods of treatment applicable to human body are not capable of industrial application, that is, the new application of a substance already known which was tested as useful for treating some disease or condition is considered as having novelty, inventive step and industrial applicability. In other words, in order to recognize that the substance already known has a new use, it is necessary that two elements are found: that the new use effectively exists and that the new result is obtained for a different disease or condition. Therefore, the novelty lies in the "different disease or condition" to be treated with the active ingredient already known.

From the above, an immediate question would be “Is it possible to claim first and second medical uses in a single patent application?” The response should be “YES”, provided that the medical use is specific; however, as IPL is silent on this matter and no Guidelines for Examination are available to the Mexican Examiners on this matter, the acceptance of such claims discretionarily depends on the criterion of the Examiner.

Under the current Mexican practice, another question arises: “Is it possible to draft first medical use claims containing two compounds already known? The response should be “YES”, if and when the claims are drafted in the currently accepted formats, and the novelty and inventive step requirements are met. The final question is why IMPI is still accepting Swiss type claims for second medical use? There is no clear answer for this criteria, however at the light of the change regarding first medical use claims, it is only logical that the same rational should apply for the second medical use claims. However, as previously mentioned, for second medical use claims, IMPI is yet allowing the use of the Swiss type claims. The reasoning behind this is yet obscure for the practitioner, however, due to the new criteria, when establishing the scope of the claims for infringement purposes, this difference needs to be taken into account.

The Mexican legal system only recognizes literal infringement of a patent. Due to the fact that in the past Swiss type claims were allowed for both first and second medical use claims, there was no room for a different interpretation of the actual scope of the claims. However, at the light of the new criteria, it could be argued that second medical use claims are directed to protect processes rather than products and this could cause a big difference during litigation.

Conclusions

Methods applicable to the human/animal body which are considered non-patentable subject matter under the provisions of article 19 section VII of IPL, may be reformulated as first medical use, including the disease to be treated with the medicament, that is, “A compound X to use in a medicament useful in the treatment of a disease or condition Y”; and second medical uses may be reformulated as Swiss type use claims, that is “Use of a compound X for the manufacture of a medicament for treating a disease or condition Y”.

The Mexican practice allows to reformulate methods of treatment claims as first and second pharmaceutical (medical) use, provided that the same comply with the accepted wording, however, if the applicant intends to reformulate methods of treatment using a device or any other physical means to carry out such method, or to be applied on the body, wherein such device or means are introduced or applied into or on the body as an use claim, the applicant must be aware that the Mexican Examiners interpret the invasion of the device or means into the body, or the application on the body, as a method of treatment and then, the reformulated use claim(s) will probably be objected.

Finally, it is advisable to amend the wording of first medical uses originally drafted as Swiss type claims to the new wording accepted by IMPI, i.e. Compound X for the manufacture of a medicament, in order to avoid a wrong interpretation as to the scope of the claim during litigation.

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