Mexico: The Recent Decision of The Supreme Court of Justice Will Improve the Efficiency of the Mexican Linkage System

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Since the Mexican Linkage system was created in 2003 as a consequence of some amendments to the regulations of the General Law of Health and of the Industrial Property Law, the Mexican Institute of Industrial Property (MIIP) had been including in its Special Gazette *(created to compile the patents subject to be included within such system)* only those patents that protect an active substance *per-se* but not any other kind of pharmaceutical patents, as for example, those patents granted to protect pharmaceutical compositions or formulations.

The criterion, on which the authorities of such Institute based this selective inclusion, had been grounded on a misinterpretation of such amendments to the Linkage system provisions. Under their point of view, these provisions were not clear enough in their wording. Therefrom, according with the MIIP, the linkage system was created to only include patents granted for active substances per se, so they prevented the inclusion of any other type of pharmaceutical patents.

As a consequence in the application of such questionable criterion, the inclusion in the special gazette of any other type of pharmaceutical patents that were not granted to protect an active substance *per-se,* was rejected by the MIIP. To achieve the inclusion of these rejected patents in the special gazette, the patent holder had to appeal the rejection through litigation in order to obtain a Court decision that ordered the MIIP to include them.

The rejected patents were included only after the conclusion of the litigation procedure, which resolution ordered the MIIP to include them into the mentioned publication. This represented a considerable delay in the application of the linkage system, as well as a significant increase in the necessary budget of the patent holders. .

In view that the interpretation of the MIIP to the linkage provisions was highly questioned and that it was revoked through several Court decisions, which confirmed that other type of pharmaceutical patents could also be included into the linkage system, the Mexican Supreme Court of Justice (MSCJ) began a discussion in order to determine if the interpretation of the MIIP to such provisions was correct, and in case of concluding otherwise, to determine the proper interpretation of the applicable regulations for the linkage system.

On February 2010, after a thorough analysis, the MSCJ concluded that the proper interpretation of the Mexican Linkage system provisions enacted on 2003, do not refer only to pharmaceutical patents that protect active substances *per-se,* but also embraces pharmaceutical patents that do not protect an active substance *per-se, i.e. a pharmaceutical composition.*

This recent decision of the MSCJ allows the patent holders to directly obtain from the MIIP the inclusion into the linkage system of pharmaceutical patents that do not protect an active substance *per-se,* but that protect a pharmaceutical composition of formulation patent. Thus, this kind of patents may, from now on, be included withir the corresponding publication created for the linkage system. Patents that protect processes are still excluded from the linkage system.

Such a decision will improve the efficiency of the Linkage System. It will allow the patent holders to obtain the inclusion of their pharmaceutical patents granted for active substances *per-se* or for a pharmaceutical compound

(s) that protect a new product, into the linkage system in lesser time, and to avoid significant expenses for unnecessary litigations, as it used to be with the past criterion assumed by the MIIP. With this new criterion, the MIIP will be obliged to include *(from a written petition formally filed by the patent holder)* all the pharmaceutical patents granted to protect pharmaceutical compositions or formulations besides an active substance *per-se*.

The improvement of the linkage system as a consequence of this new criterion, will be extremely important, particularly for patent holders that are extremely concerned that the health authorities observe these new provisions, to prevent the granting of health marketing approvals for generic products to someone that is not a licensee or a patent holder as well as to consider them to carry on public acquisition proceedings.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.

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