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Intellectual Property - Mexico

Supreme Court decision promises more efficient linkage system

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Author

Juan Carlos Amaro Alvarado

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Since the Mexican linkage system was created in 2003 as a result of amendments to the General Health Law and the Industrial Property Law, only patents that protect an active substance *per se* have been included in the Mexican Institute of Industrial Property's special gazette (which was created to set out the patents eligible for inclusion in this system). Other kinds of pharmaceutical patent, such as those granted to protect pharmaceutical compositions or formulations, have been excluded.

The criterion on which the institute based this selective inclusion was founded on a misinterpretation of the amendments which, in turn, resulted from unclear wording. In the institute's opinion, the linkage system was intended to include only patents granted for active substances *per se.* In order to have a pharmaceutical patent of another kind included, the patent holder had to litigate, appealing the rejection decision so as to obtain a court order requiring the institute to include the patent. This caused considerable delay in the application of the linkage system, as well as a significant increase in costs for patent holders.

The institute's interpretation of the linkage provisions was considered questionable by many experts and was overturned in a number of court decisions. As a result, the Supreme Court began a study to determine whether the institute's interpretation was correct and, if not, what the proper interpretation should be.

In February 2010, following a thorough analysis, the court concluded that the proper interpretation extends the linkage system to pharmaceutical patents that do not protect an active substance *per se*, and that the system can therefore include pharmaceutical compositions.

As a result, patent holders can apply directly to the institute for the inclusion in the linkage system of pharmaceutical patents that do not protect an active substance *per se*, but protect a pharmaceutical composition or formulation. Patents that protect processes remain excluded.

This decision will improve the efficiency of the linkage system. It will ensure the faster inclusion of pharmaceutical patents for active substances *per se* and those for pharmaceutical compounds; moreover, the change will remove the need for many costly court cases. The new criterion requires the institute, on receipt of a written request formally filed by the patent holder, to include all pharmaceutical patents which were granted to protect pharmaceutical compositions or formulations, but which do not protect an active substance *per se*.

Patent holders will be particularly alert to the question of whether the health authorities observe the new provisions. The changes should help them to prevent the authorities from granting health marketing approvals for generic products to a party that is not a licensee or a patent holder, and will also be relevant in the context of public acquisition proceedings.

For further information on this topic please contact Juan Carlos Amaro at Becerril, Coca & Becerril SC by telephone (+52 55 5263 8730), fax (+52 55 5263 8731) or email (camaro@bcb.com.mx).