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**EARLIER THIS YEAR THE SUPREME COURT ISSUED WELCOME CLARIFICATION ON HOW THE LINKAGE REGULATION APPLIES TO FORMULATION PATENTS AND THEIR PUBLICATION IN THE LINKAGE GAZETTE.**

On 13<sup>th</sup> January 2010 the Supreme Court issued a groundbreaking decision on the interpretation of the Linkage Regulation, which has been in force for six years. The decision focused on whether the linkage system is limited to compound patents or whether it extends to product patents that cover pharmaceutical formulations. The Supreme Court ruled that formulation patents should be listed in the *Linkage Gazette*, as only process patents are excluded from the regulation.

#### *BACKGROUND*

On 19<sup>th</sup> September 2003 the Health Law Regulation and the Industrial Property Regulation were amended to enact the Linkage Regulation in two articles: Article 47bis of the Industrial Property Regulations and Article 167bis of the Health Law Regulations.

The main purpose of these amendments was to establish coordinating rules between the two separate administrative agencies, one empowered to approve the commercialisation of medicines based on safety and efficacy standards and the other responsible for granting patents for inventions. The rationale behind linking these two agencies was to prevent the grant of marketing authorisations that violated exclusive rights.

#### *ARTICLE 47BIS OF THE INDUSTRIAL PROPERTY REGULATIONS*

This article obliges the Mexican Institute of Industrial Property (IMPI) to publish

a special gazette listing patents that cover allopathic drugs, along with their corresponding non-proprietary names. The *Linkage Gazette* includes products that are the subject of industrial property rights according to their active ingredients and chemical names.

Patents covering manufacturing and formulation processes are expressly excluded from this gazette.

Under the regulation, IMPI must publish and update the *Linkage Gazette* every six months, listing those patents in force that cover allopathic medicines and containing the following information for each patent:

- The medicament's generic name.
- A description of the medicament.
- The medicament's chemical name.
- The patent number.
- The patent's expiration date.
- The annuities paid.
- The patent owner.

- The main claims.
- Any general comments.

Products are listed in alphabetical order according to their generic name.

#### *ARTICLE 167BIS OF THE HEALTH REGULATION*

This article dictates that applicants for marketing authorisations for allopathic medicines must indicate whether they own a patent or have a licence for a patented active ingredient.

Alternatively, applicants must declare, under oath, that their application does not violate the list of products published in the *Linkage Gazette* and observes patent law. This declaration is made before the Federal Commission for the Protection and Prevention of Health Risks (COFEPRIS).

Before granting marketing authorisations to third parties other than the title holder, COFEPRIS must also check the listed patents, first by compound and then by the list of patented products issued by IMPI in the *Linkage Gazette*, which is organised according to the active ingredient's generic name. COFEPRIS must also establish the possibility of requesting additional information from the applicant. If it suspects that patent rights may be violated, COFEPRIS can request technical support from IMPI regarding the scope of the rights.

If COFEPRIS requests technical assistance, IMPI then has 10 days in which to produce an opinion on the scope of the patent and whether the product for which market authorisation is sought falls within it. If IMPI is of the opinion that the product in question falls within the scope of a published patent, the Ministry of Health shall give the applicant an opportunity to show that it has a right to make and sell that product. In the absence of convincing evidence, the application shall be dismissed.

## THE ROCHE-BOLAR EXCEPTION

A generic company may apply for a marketing authorisation for a patented medicine listed in the *Linkage Gazette* without having any rights to it if the patent is within three years of expiring. This provision allows applicants to begin safety and efficacy tests, interchangeability test, and experiments so that they can be ready to enter the market as soon as the patent expires.

This provision also recognises the confidential nature of the dossier filed with the application for marketing authorisation and states that only the applicant may access this dossier supporting the clinical trials or interchangeability tests.

## IMPI'S MISINTERPRETATION OF THE LINKAGE GAZETTE

The wording of the Linkage Regulation clearly states that IMPI must publish a gazette every six months that lists all patents in force covering allopathic medicines, according to active ingredient and regardless of whether these patents covered a compound *per se* or a pharmaceutical composition that includes an active ingredient.

However, since the first *Linkage Gazette* was published in October 2003, it has included only patents covering compounds *per se* and has not included patents that cover pharmaceutical compositions and medical – use patents. We consider that IMPI has erred in its interpretation of the regulation.

Olivares and Cia has fashioned a litigation strategy to address this misinterpretation through constitutional actions to obtain the publication of patents covering formulations and second uses. From publication of the first *Linkage Gazette* to that of the most recent in December 2009, the firm has obtained over 42 precedents from district and circuit courts ordering IMPI to include and publish formulation and medical – use patents in the *Linkage Gazette*.

The main argument we put before courts when petitioning for the inclusion of such formulations and patents in the gazette rests on the legal and technical definitions of key words in the Linkage Regulation: “allopathic medicines”; “patented products” as opposed to “process patents”; and the interpretation of “according to its active ingredient”, where the active ingredient is a reference to the organisation of a list of products and not the subject matter of the list, which is not limited to patents covering active ingredients but covers allopathic

medicines with patents in force or products subject to protection based on the Industrial Property Law (as literally stated by the Linkage Regulation and the full name of the *Linkage Gazette*, which is the *Linkage for Allopathic Medicines with Patents in Force*).

Listing formulation patents in the *Linkage Gazette* helps to prevent health authorities from granting marketing authorisations that could fall within the scope of a listed patent. In addition, publication provides the following benefits:

- A proper application of the linkage system prevents pharmaceutical patents from being infringed, especially given the poor history of enforcing such patents in Mexico.
- It establishes a valuable source of information for third parties trying to discover the full scope of opposable patents in order to obtain an authorisation for generic drugs.
- It proves that the patent is in full force and that it covers a product, namely an allopathic medicine. In the event of an infringement action, this publication will help to prove that the patent in question covers a specific pharmaceutical formulation, meaning that no expert opinion will be required during the proceeding. This will save the rights holder time and money in the eventual enforcement of its patents.
- In case the *Linkage Gazette* is not observed by the health authorities, the publication of patents is also useful for challenging marketing authorisations for patented formulations granted to third parties without the rights holder's authorisation.

- The *Linkage Gazette* is also helpful for public acquisition processes, to confirm that the product to be acquired is covered by a patent, especially when the formulation patent listed in the gazette matches the description of the product in the government's National Formulary for Purchases of Medicines.

### SUPREME COURT DECISION

Several decisions were issued in favour of rights holders in 2009. However, two out of 16 courts in the First Circuit, which has jurisdiction in Mexico City where such cases are decided, ruled that the linkage system is limited to compound patents.

As provided in the applicable law, the Supreme Court was deemed to have jurisdiction to resolve this impasse and the case was handed over to court's bench responsible for administrative cases. After receiving *amicus* briefs and memoranda from the pharmaceutical industry – from both innovators and manufacturers of generics – on 13<sup>th</sup> January 2010 the judges issued a split decision, three to two, in a public hearing declaring that formulation patents should be included in the *Linkage Gazette*, as per the interpretation of Article 47bis of the Industrial Property Regulation established in over 45 court precedents. The following is an abstract of the Supreme Court's decision: *Case law by contradictory rulings 7/2010 Industrial Property. Patents for allopathic medicines of their claims that do not represent processes for production or formulation of drugs and which in their pharmaceutical composition include an active ingredient, substance or principle, shall be included in the publication referred to in Article 47bis of the Industrial Property Regulations. These patents must be published in the gazette, since they comply with the requirements under Article 47bis of the Industrial Property Regulations, which state that in the case of patents granted to allopathic medicines, IMPI shall publish in the gazette and shall make public a list of products that should be subject to industrial protection according to the active substance or ingredient, which shall specify the duration of the patent in question. The Supreme Court decision will be considered as a binding precedent to all*

*federal circuit courts and district courts in Mexico, which means that if IMPI fails to include formulation patents in the Linkage Gazette, it would be ordered to list the patent by court orders, provided that the corresponding conditions are met.* This is a landmark case, not only because of its favourable impact on patents law, but also because few cases involving the review of IP rights ever come before the Supreme Court.

#### AFTERMATH

Under the Supreme Court's decision, all patents covering allopathic medicines, regardless of whether they are for compounds or formulations, may be published in the *Linkage Gazette*. For compound patents, the only requirement is that the titleholder or its representative petition IMPI for publication, either directly or through the Chamber of Pharmaceutical Companies. However, the impact of the Supreme Court's decision on formulation patents will remain uncertain until the relevant authorities make their position clear. Legally speaking, administrative authorities such as IMPI and COFEPRIS are not bound to follow judicial case law; however, from a moral and practical standpoint, they tend to observe such precedents.

At the time of writing, it is not yet clear whether IMPI will publish formulation patents in the *Linkage Gazette* if the rights holder requests this. We would advise applicants to pursue this possibility exhaustively. One positive indication in this regard is that IMPI's general director has talked in the media about "supporting" the Supreme Court's decision.

Any refusal by IMPI to publish a formulation patent can be contested through constitutional actions. The Supreme Court's decision binds the courts to decide on behalf of formulation patents; provided that all necessary criteria are met, these actions should be decided quickly.

Although use and second – use patents were not explicitly addressed in the Supreme Court's decision, the precedent should also help rights holders to argue in favour of these types of patent being published in the gazette.

We would like to believe that IMPI will start to include certain formulation patents as a result of the petitions. However, this will be confirmed only once IMPI issues an official communication on the subject or once it publishes the first formulation patent in the *Linkage Gazette*.

In our view, the ruling helps to clarify the second part of the Linkage Regulation

in the sense that published patents (for formulations) should be observed by the Mexican Health Authority before it grants marketing authorisations to third parties, following the linkage system described above.

As the opposing criteria reviewed by the Supreme Court were limited to IMPI's obligation to publish formulation patents in the *Linkage Gazette* as established in Article 47*bis* of the Industrial Property Regulation, but not to Article 167*bis* of the Health Regulation, we await a hard copy of the decision to discover whether the judges also studied or considered the obligations of the Linkage Regulation for COFEPRIS. This hard copy was unavailable at the time of writing; nevertheless, even if no consideration was given to COFEPRIS's obligations (under the general rules and principles for the interpretation of statutory laws), the obligation to observe formulation patents should also apply to it, as the linkage system cannot be disassociated and the obligation to observe formulation patents cannot be imposed on only one of the linked authorities. An alternative scenario would be unreasonable, impractical and, to some extent, illegal.

*Source: IAM Life Sciences 250, Formulation patents in Mexico*