Life Sciences 2021

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Mexican patent linkage according to the USMCA and the new IP Law

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Mexican patent linkage according to the USMCA and the new IP Law

By **Alejandro Luna Fandiño** and **Alejandro Torres**

Since 19 September 2003, Mexico has been managing a patent linkage system. The system consists mainly of the Mexican Patent Office's (IMPI) biannual publication of the list of allopathic medicines covered by patents (*Linkage Gazette*), as well as the intra-governmental communication between COFEPRIS, the Mexican health authority in charge of granting sanitary registrations, and IMPI, prior to the granting of sanitary registrations for allopathic medicines.

Linkage Regulation

The Mexican Linkage Regulation is made up of Article 47*bis* of the Mexican IP Regulations and Article 167*bis* of the Health Law:

- Article 47*bis* of the IP Regulations established the publication of IMPI's *Linkage Gazette*, which contains information on patents in force that cover allopathic medicines, excluding those patents covering processes of both formulation and production.
- Article 167*bis* of the Health Law establishes that a marketing authorisation applicant must prove it is the owner or licensee of the corresponding patent. The law also allows COFEPRIS to request technical information from IMPI regarding the scope of protection of the published patents.

The main purpose of the Linkage Regulation is to prevent the granting of marketing authorisations to non-authorised third parties in violation of patent rights. The system has been governed at a regulatory level by both the regulations of the abrogated Industrial Property Law and the Health Supplies Regulation.

In the past, the linkage system was wrongly interpreted by the authorities, which were corrected by the judiciary, through decisions on legal actions filed by patent owners to secure complete compliance with the original function and nature of the patent linkage system to prevent violations of exclusive rights covering the technology of allopathic medicines, including active ingredients, formulations and their medical uses.

Case law precedents and jurisprudence of the Supreme Court were necessary to secure the inclusion of formulation patents in the *Linkage Gazette* and their observance in the marketing authorisation or regulatory approval processes. The courts studied patent owners' arguments that, according to a broad and correct interpretation of the past linkage regulations, patents covering medicines in the *Linkage Gazette* should be included, except for process patents, which are expressly excluded from publication. Case law obtained from the Supreme Court in 2010 has been observed by IMPI since 2012 but is limited in relation to the inclusion of formulation patents in the *Linkage Gazette*.

Other remarkable precedents have been obtained from the courts regarding the consideration of formulations and use patents in the process of granting marketing authorisations, as well as granting the patent owners hearing rights derived from the processes.

The previous linkage system involved listing patents covering active ingredients and formulations in the *Linkage Gazette* via a request without the need for litigation. Use-limited and purpose-limited product patents, however, required litigation by titleholders.

"The IP Law establishes that IMPI and COFEPRIS participate jointly in the design and implementation of the new patent linkage system related to allopathic medicines"

Benefits of the system

The main benefit of the linkage system is its preventative effect. IMPI's inclusion of patents in the *Linkage Gazette* and their consideration by COFEPRIS should, in theory, prevent the grant of approvals to non-authorised third parties or should put patent owners in a better position to defend themselves against violations of valid patents included in the *Linkage Gazette*, avoiding the long road of patent enforcement (ie, with the infringing product in the market). It is not necessary to have an approved product for the corresponding patents to be listed in the *Linkage Gazette*.

USMCA

After more than 17 years of patent linkage, the ratification of the protocol of amendments of the United States-Mexico-Canada Agreement (USMCA) entered in force in Mexico on 10 December 2019.

Regarding linkage provisions, the USMCA establishes that Mexico may maintain its own administrative system, based on patent-related information submitted to COFEPRIS by a patent owner or an applicant for marketing approval, or based on direct coordination between COFEPRIS and IMPI, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent owner. In addition, the USMCA establishes:

If Mexico maintains the system, Mexico shall ensure that in administrative proceedings under that system:

(a) a person of another Party that is directly affected by the proceeding is provided, whenever possible and, in accordance with domestic procedures, with reasonable notice of the initiation of a proceeding, including a description of the nature of the proceeding, a statement of the legal authority under which the proceeding is initiated and a general description of the issue in question;

(b) a person of another Party that is directly affected by the proceeding is afforded a reasonable opportunity to present facts and arguments in support of that person's position prior to any final administrative action, when time, the nature of the proceeding, and the public interest permit; and

(c) the procedures are in accordance with its law.

IP Law

According to the new IP standards established by the USMCA, the new Federal Law for the Protection of Industrial Property entered in force in Mexico 5 November 2020. The linkage system has been elevated to the rank of federal legislation. The IP Law includes general definitions of characteristics similar to those used in the former linkage system:

- The biannual publication of the list of allopathic medicine patents in the IMPI *Gazette*.
- The publication occurs as a result of a coordinated effort between IMPI and COFEPRIS in the operation of the linkage system, coordinating with the competent health authority to provide the necessary information for obtaining marketing authorisation for allopathic medicines.
- The IP Law establishes that the publication of the list must be carried out in accordance with current health regulations, in the terms provided in Article 167*bis* of the Health Supplies Regulation.

It is expected that the scope of the linkage system will be modified under the new regulations due to be issued. In this regard, the IP Law establishes that IMPI and COFEPRIS participate jointly in the design and implementation of the new patent linkage system related to allopathic medicines. Implementation of these changes is expected through the issuance of a corresponding regulation by the executive and through the issuance of general guidelines by COFEPRIS and IMPI.

Requirements and obligations

In the guidelines, it is anticipated that the linkage system should include new requirements or obligations:

- Notice to be provided to the patent owner – the authorities are obliged to serve notice to the patent owner regarding the initiation of a marketing authorisation request. Specific situations or detailed forms of the notice are expected to be included in the IP regulations.
- The patent owner must be permitted to be heard – the authorities should review the arguments that can ultimately be posted by the patent owner, as established by the USMCA. This concept had been pending introduction in the local regulations since the implementation of the previous linkage system. In this regard, there is already a precedent declaring the Linkage Regulation unconstitutional, in order to grant patent owners the right to be heard during the sanitary registration approval process.

The new scheme of obligations for those participating in the marketing authorisation award process (ie, IMPI, COFEPRIS and the marketing authorisation applicant) can be summarised as follows:

- IMPI's obligations:
  - Issue a list of patents covering medicines twice a year in the *Linkage Gazette*.
  - Provide information to COFEPRIS regarding IP rights violations (technical opinions).
  - Provide notice of marketing authorisation request filings to patent owners (terms and conditions of this obligation are expected to be defined in the new IP Law regulations pending issue).
- COFEPRIS' obligations:
  - Allow patent owners to be heard in marketing authorisation request proceedings (terms and conditions of this obligation are expected to be defined in the new IP Law or the guidelines to be issued by COFEPRIS).
  - Before granting marketing authorisation to third parties other than patent title holders, check listed patents, first by compound and then by the list of patented products (organised according to the active ingredient's generic name) issued by IMPI in the *Linkage Gazette*.

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- Request technical opinions from IMPI concerning patents in force that may cover or are related to products under regulatory analysis. IMPI has a 10-day term in which to produce this opinion once requested by COFEPRIS.
- Refuse the applicant if necessary.
- Reject marketing authorisation applications submitted by those having no ownership of or patent licence for the product concerned.
- Keep dossiers confidential.

- Marketing authorisation applicant's obligations:
  - Indicate whether the applicant is the holder or licensee of the patent that covers the active ingredient of its product or, alternatively, declare under oath that the application does not violate patents listed in the *Linkage Gazette* and that it observes patent law.

The new IP Law also includes positive wording regarding the patentability of new uses, compared with the silence of the current abrogated IP Law. It was IMPI's practice to grant these patents.

The wording in the IP Law could be a positive interpretation of the linkage regulations regarding their consideration for publication in the *Linkage Gazette* and observance by COFEPRIS in the marketing authorisation request.

If the IP Law changes, and use patents are not contemplated, a constitutional action would be filed not only for the lack of publication in the *Linkage Gazette*, but also for the failure to grant them by IMPI. In this regard, it will be necessary to review the final wording because if there is an express ban on these patents in the *Linkage Gazette*, it would eventually be necessary to contest the constitutionality of the legislation itself.

In general terms, the amendment to the USMCA and the IP Law gives the Mexican linkage system more punch by providing increased transparency in the process. Notably, the obligations of the interested parties (ie, generics manufacturers and title holders) are provided in general terms in the treaty, therefore these will need to be implemented in regulations in domestic law. The Linkage Regulation does not specify the legislative process. IMPI and COFEPRIS will need to prepare a regulatory framework for the linkage system that complies with the USMCA.

Finally, there have been recent initiatives seeking to limit the scope of the linkage system established in the IP Law, with regard to certain types of patent. The main characteristics of the proposals include:

- express bans on the granting of use patents; and
- a requirement for publication in the *Linkage Gazette* to include a list of patents for reference medicines provided by COFEPRIS.

The recent amendments to the new IP Law may conflict with the Mexican Constitution, the patent system and the USMCA. It therefore seems unlikely that they will be approved and passed.

Comment

Regardless of the format and regulatory governance of the new linkage system, it is expected that title holders and agents with interests in the R&D sector will find that the system fulfils its original function and nature, which is to prevent violations of exclusive rights of allopathic drug patents, including active ingredients, formulations and medical uses – although litigation may still be necessary, particularly for use claims.

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