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MEXICO: An Introduction to Life Sciences

Consequences of a Lack of a Proper Linkage System in Mexico

More than 20 years ago, as a result of innumerable and uncontainable violations of pharmaceutical patents, and in order to publicise the patents that protect allopathic medicines, several legislative amendments, such as the Regulation of Supplies for Health and the Regulation of the Industrial Property Law, were made to the relevant legal bodies in Mexico. This introduced the Gazette of Allopathic Medicines with a Valid Patent into the scope of the linkage system, publication in which is carried out according to the active substance or ingredient.

The above was implemented to create a linkage system – ie , a co-operation and communication system between COFEPRIS (the Mexican Health Authority), in charge, among other functions, of granting marketing authorisations (MAs) for the import, production, storage and commercialisation of allopathic medicines, and the Mexican Institute of Industrial Property (IMPI), empowered to confer and protect industrial property rights, among which are the temporary privileges of exclusive use of inventions through the granting of patents.

Problems with the implementation of the system

However, the regulatory provisions of the system do not consider the patent holder – ie , the linkage system revolves around drug patents and the only subject that is not mentioned in the entire system, is the owner of the patent.

The implementation of a proper linkage system should aim to prevent COFEPRIS, from granting marketing authorisations for pharmaceutical products that infringe patents. This depends on direct co-ordination between the health authority (COFEPRIS) and the patent office (IMPI) to prevent marketing authorisations from being granted to any third party seeking to market a pharmaceutical product protected by a patent, allowing the patent owner to be heard and defend their granted rights.

Currently, once a marketing application is filed, COFEPRIS reviews the Gazette of Allopathic Medicines to determine whether there is a patent published in that Gazette that may be infringed by the granting of an MA and must conduct a so-called intragovernmental communication with IMPI, which must inform COFEPRIS if the MA could infringe a patent in force and published in the corresponding Gazette. However, some of the responses to the consultations from COFEPRIS provided by IMPI, available on the agency's website, reveal that the Health Authority is providing insufficient information, leaving IMPI without adequate information to respond effectively, as they usually respond that there is not enough technical information to determine whether the drug formulation and additives for which technical co-operation is being requested from this Institute correspond to patent-protected subject matter or not, a situation that impedes IMPI from addressing the consultation.

The impact of this inefficient linkage system not only contravenes international obligations but imposes significant difficulties and high costs on patent holders, who may be obliged to withdraw infringing products from the Mexican market after they have been introduced to it.

The effect of the USMCA

It is of the utmost important to mention that Mexico as a member of the US – Mexico – Canada Agreement (USMCA) must comply with the obligations mentioned therein, which state the following:

• a person of another party that is directly affected by the proceeding is provided whenever possible and, in accordance with domestic procedures, must be given a 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; and

• 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.

In view of the foregoing, recently, the Mexican regulatory agency published on its website, in connection with patent linkage regulation in Mexico the following:

• an updated list of generic and biosimilar applications, including general information, such as the date of application, applicant name, generic name, pharmaceutical form, and publication date; and

• a format to oppose the generic or biosimilar applications based on an existing patent or patents in force.

The above appears to be an attempt to comply with the notice requirement established in the USMCA as a condition of Mexican patent linkage regulation. However, the publications do not fulfil the legal standard of proper notice, as these publications leaves the burden of detecting and alerting COFEPRIS of an eventual patent violation on the patent holder.

Filing an opposition

If a patent holder, decides to file the "opposition", they do not have sufficient information to oppose. The list of MA applications only provides essential details, such as, the application file number, filing date, the relevant procedure type, applicant's name, product's generic name, pharmaceutical compound, and the date of publication on the COFEPRIS website. This is insufficient, especially as the interested party is due to submit comments within ten working days after the application for the marketing authorisation is published on the COFEPRIS website according to the date in the list. The obligation provided in the USMCA should consist of the proper notification by the corresponding authorities to the patent holders, prior to the approval of the generic or biosimilar application.

In view of the foregoing, the proceeding established by COFEPRIS does not comply with the mandate under the USMCA related to the notice and arguments, since the mechanism established does not provide a reasonable notice nor opportunity for interested parties to submit information supporting their position. A proper linkage system must provide due notice to the patent holder (or licensees) and sufficient information during the intergovernmental consultation, of those applications that could be relevant or related to the granting of an MA, enabling them within a reasonable term and providing sufficient information to present their arguments.

Also, due to the complexity involved in assessing potential patent infringement, the ten business days provided to submit facts and arguments are insufficient. Therefore, the timeframe should be extended at least to up to 30 days to ensure compliance with the "reasonable opportunity" requirement stipulated by the USMCA.

The implementation of a proper collaboration system between IMPI and COFEPRIS as explained above, could be introduced in the pending regulations/amendments of the new Federal Law for the Protection of Industrial Property, which entered into force since 2020 and which also imposes the obligation to create a technical co-operation system between those authorities and granted a term for doing so, which expired some time ago, since both the USMCA and the Mexican courts themselves have acknowledged the lack of a guarantee of hearing for the patent holder in the linkage system. Once a proper linkage system is implemented it will avoid patent holders being subject to the need to start several legal actions, which can take years and involve high costs, to defend their legally granted rights through their patents in force and published in the corresponding Gazette. Nevertheless, cancellation actions and infringement proceeding will continue to take place.

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