Issues with the patent linkage system in Mexico

09-07-2023 Alejandro Luna and Luz Elena Elias

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Certain problems with the patent opposition process need to be addressed in order to protect patent owners, say Alejandro Luna and Luz Elena Elias of Olivares.

More than 20 years ago the Decree Reforming the Regulation of Supplies for Health and the Regulation of the Industrial Property Law was published in Mexico.

Stemming from innumerable violations of pharmaceutical patents, the purpose of this reform was to create a linkage, cooperation, and

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communication system between the Federal Commission for Protection against Health Risks (COFEPRIS), which is empowered to approve drugs, medicines, and other regulated products and services in Mexico, and the Mexican Institute of Industrial Property (IMPI).

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Erroneous interpretations

The former is in charge of granting marketing authorisations for the import, production, storage and commercialisation of allopathic medicines, while the IMPI is empowered to confer and protect IP rights.

According to the reformed system, the IMPI must publish a gazette of allopathic medicines with patents in force every six months (February and August), including patents that protect active ingredients but excluding patents for production processes and formulation processes.

Meanwhile COFEPRIS issues opinions required by the IMPI to assess and scope the protection of the patents listed in the gazette.

This was in contravention of the literal interpretation of the regulatory precept that admits the inclusion of any patent for allopathic medicines (products), as long as they are not those related to processes.

Title holders of patents granted to allopathic medicines were forced to defend their IP rights in court for the listing of formulation patents.

COFEPRIS is obliged to review the list of product patents and grant registrations to the owners or licensees of the relevant patents, or to suspend or deny marketing authorisations for the active ingredient patents published in the gazett ntil the validity of these patents ends.

Irreparable damage

From the foregoing, it is evident that, if the claims of a patent that meets the requirements of article 47 *bis* are not published, its owner will be irreparably affected.

This is because this situation will be comparable to a lack of knowledge of the right of exclusiveness granted by the patent in question.

There are more than 60 precedents issued by district judges and confirmed by circuit courts in Mexico City, where Olivares filed more than 90% of those cases in which the courts decided that formulation patents should be included in the list referred to in

article 47 *bis* of the law governing allopathic medicines.

Currently, pharmaceutical formulation patents are included in the linkage gazette without the need for litigation, but second use patents are still rejected for publication by IMPI.

The applicant for a marketing authorisation must attach the documentation that demonstrates that it is the owner of the “patent, of the substance or active ingredient, show that it has the corresponding licence” or, alternatively, declare under oath to tell the truth that it does not invade patent rights.

In this way, if the direct reference is the active ingredient by its generic name and if the applicant for the marketing authorisation that files the documentation proves to be owner or licensee of the patent that covers the active ingredient, the marketing authorisation will be granted.

Regulations

If this is not the case, the regulation itself establishes that, alternatively, the technical consultation between IMPI and COFEPRIS” must be followed, so that the IMPI can carry out an analysis of the state of the patents related to the medicine for which the marketing authorisation is to be obtained.

Based on the information provided by COFEPRIS, the IMPI must indicate whether the product’s characteristics fall within the scope of the published patents and other relevant patents that may be invaded by the product subject to approval.

the patent number, title, and validity as well as attached copies of the relevant claims of the corresponding patents that show if they are patents of active ingredients (polymorphs), formulations/compositions or use. specify the owner, the validity, if there is a licence or change of owner, and the administrative status of the patent.

If, according to the information provided by COFEPRIS, there is no patent published in the gazette or another relevant one, which may be infringed or coincides with the product subject to approval, the IMPI response must reflect that there is no relevant patent.

If IMPI responds that there is a relevant patent/s, COFEPRIS must reject or deny the application for the marketing authorisation, if the patents have a term of more than three years prior to their expiration date.

If the application was in the last three years of validity of the patents, marketing authorisation until the expiration of the validity of the patent(s) cited by IMPI.

Before the respective publication of this type of gazette is verified, in terms of the provisions that empower IMPI to carry it out, the opinion of National Chamber of the Pharmaceutical Industry (CANIFARMA) is taken into account, which integrates national and generic pharmaceutical industry associations such as the National Association of Drug Manufacturers (ANAFAM) and the Mexican Association of Pharmaceutical Research Industries (AMIIF).

Updated lists

An update to the list of medicines in the corresponding gazette will be carried out every six months and replace the publication immediately prior to it. It will contain the complete list, notwithstanding that the IMPI, if necessary, can issue an extraordinary publication before the indicated period.

Recently, COFEPRIS published the following on its website, in connection with patent linkage regulation in Mexico: 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.

It is encouraging to see the regular updating of the list of generic and bio-comparable applications, a practice which had been on pause over the last couple of years. It is considered a positive development that COFEPRIS resumed this activity, in compliance with its publicity and transparency obligations established in the legislation.

Regarding the second publication, the “opposition format”, COFEPRIS appears to be exploring ways to comply with the notice requirement established in the United States-Mexico-Canada Agreement (USMCA) as a condition of the Mexican Patent Linkage Regulation.

It was not until now that the Mexican Patent Linkage Regulation even contemplated the notice of the patent holder during the patent linkage process.

COFEPRIS seems to be demonstrating goodwill with the new opposition process currently under comment, and it appears to be attempting to comply with the USMCA notice obligation in linkage regulation.

However, when analysed, it seems that the publication of the process on its website does not comply with the required administrative and legal formalities to be valid and have legal effect.

In addition, under an in-depth review, the publications would not fulfil the legal standard of proper notice, as these publications carry the burden of detecting and alerting COFEPRIS of an eventual patent violation to the patent holder.

Whereas, in the patent linkage system, COFEPRIS has the obligation to observe the patents listed in the linkage gazette and initiate the preventive administrative mechanism of patent linkage.

A high burden

The obligation provided in the USMCA in connection with patent linkage should consist of the proper notification by the authorities (COFEPRIS and/or the Mexican Patent Office) to the patent holders, prior to the approval of the generic or biosimilar application. That is, the authority has the obligation to notify the patent holder, not the other way around.

In essence, the publications suggest an opposition system. The patent holder has the high burden to detect and alert COFEPRIS in ten working days of an eventual violation of the patent listed in the linkage gazette, by comparing a list of generic and bio-comparable applications with limited information regarding the formulation and specifics to have enough elements to claim an eventual patent violation.

Certainly, this is not a notification system wherein a proceeding impacting an interested party has been initiated by the authority, which would appear to be the rationale behind the notice obligation provided in the USMCA.

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