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A NEW SYSTEM LINKING THE HEALTH AND PATENT AUTHORITIES MAKES IT POSSIBLE TO CHALLENGE PHARMACEUTICAL MARKETING AUTHORIZATIONS.

Recent developments in Mexico's legal system address the relationship between health and industrial property-related provisions and now allow owners of certain types of industrial property to challenge marketing authorizations granted to third parties.

On September 19 2003, a Decree was published in the Official Gazette of the federal government, with amendments to the regulations of the Health Law as well as to the regulations of the Law on Industrial Property. The amendments aim to establish coordination rules between the Ministry of Health and the Mexican Institute of Industrial Property, in connection with granting pharmaceutical product registrations for marketing approval when making and/or selling a product might trigger the infringement of a patent.

The reform dictates that applicants of product registrations relating to "substances or active ingredients" are obliged to indicate whether or not they own a patent or have a licence on the product. If applicants do not have a patent or a licence, they will be required to declare under oath that the product (substance or active ingredient) is in "compliance with the patent laws". In that case, the health authorities will request technical assistance from the Mexican Institute of Industrial Property (IMPI) so that, within 10 working days, IMPI performs a patent clearance. If the search reveals that the product subject to

the registration falls within the scope of any patent, the Ministry of Health will give the applicant a chance to show that it has a right to make and sell that product. In the absence of convincing evidence, the application will be dismissed.

A party will be entitled to apply for registration of a product relating to a substance or active ingredient covered by someone else's patent if the application is filed in the three years before the corresponding patent expires. This provision, supported by the Roche-Bolar exception theory, would allow the applicant to start performing tests and experiments so that it is ready to enter the market as soon as the patent has expired. Obviously, the Ministry of Health will not be able to grant the product registration until the patent's expiration date.

Similarly, the regulations to the Law on Industrial Property were amended, imposing upon IMPI an obligation to publish a special gazette listing patents relating to allopathic drugs, and their correspondence to a non-proprietary name (INN) for the substance of the active ingredient. The catalogue will consider patents that cover substances or active ingredients, specifically excluding patents covering processes.

Since the Mexican Linkage Regulation was enacted in 2003, IMPI, due to a narrow interpretation of linkage provisions, has been reluctant to include in the Linkage Gazette those patents that cover pharmaceutical compositions and medical use patents, because the regulations are silent on these specific types of patent.

Despite controversial criteria from the Patent Office, the interpretation of the courts in more than 30 litigation procedures regarding the Linkage Regulation has been consistent, as the Patent Office has been ordered to publish patents that cover pharmaceutical compositions, as well as medical use patents.

Practically speaking, the publication of patents in the Linkage Gazette has proven convenient, as the health authorities have used the Gazette to award public bids to the patent owners or their licensees.

More to point, the Mexican Linkage Regulation has been a useful tool and has opened new venues for contesting marketing authorizations granted in violation of patent rights.
Before the creation of the linkage system in Mexico, health authorities did not generally observe patent rights, and rather granted marketing authorizations for pharmaceutical products (compound and formulation), regardless of patent protection.

However, with the creation of the Linkage Regulation, our firm has been able to successfully obtain a landmark court decision annulling a marketing authorization granted in breach of these regulations, in which the court clearly states that health authorities are bound to observe patent rights.

Marketing authorizations granted before the enactment of the Linkage Regulation or in breach of patents that have not been published in the Linkage Gazette:

Even though there is no specific provision forbidding health authorities from granting authorizations in breach of unpublished patents, our firm has assisted IP holders in bringing challenges before administrative courts (these have not yet been decided).

In these cases, the main argument relies on the general obligation by authorities to comply with the provisions of federal laws, and in the understanding that, for an IP system to properly function, the authorities should not authorize applicants to infringe IP rights.

Marketing authorizations granted in breach of data package exclusivity (DPE):

There is no specific body of legislation referring to data protection in Mexico, but several provisions apply to the issue in Mexico's IP Law, the Health Law Regulations, the Information Access Law and international treaties subscribed by Mexico such as Nafta and TRIPs.

The Mexican IP Law establishes that undisclosed information in applications for marketing authorizations will be considered an industrial secret. It also

mentions that information submitted to obtain a marketing authorization for producing or marketing chemical products will be protected according to the international treaties subscribed by Mexico.

Article 167 bis of the Health Law Regulations states that all confidential information filed to obtain a marketing authorization must be protected against disclosure.

The Information Access Law establishes that information will be considered confidential when a body of law expressly considers that certain information should be protected. It also mentions that industrial secrets are considered confidential information.

On the other hand, applicable international treaties such as Nafta and TRIPs state the following regarding data protection:
Nafta: Undisclosed information submitted to obtain marketing authorizations will be protected from being disclosed to, or relied upon by, third parties for at least five years.
TRIPs: Information provided to obtain a marketing authorization must be protected, and cannot be disclosed to third parties.
According to firm jurisprudence, these treaties apply in Mexico above federal and local laws as long as they don't go against the Constitution.
Regardless of these provisions, the pharmaceutical R&D industry in Mexico is aware of possible breaches to data exclusivity, especially concerning generic companies' reliance on the innovator's data, used to prove safety and efficacy of their products.
We have developed a litigation strategy that could be attempted by the affected party in case of a breach of DPE:
a) Actions against the authority in charge of issuing marketing authorizations
The main available venue for enforcement of exclusivity rights against an act of authority is the nullity trial before the Federal Court of Tax and Administrative Affairs. In this trial, the action is brought against COFEPRIS, claiming the breach is a violation of the provisions mentioned above. The object of this trial would be revocation of the marketing authorization.
In this action, the affected party can request the Court to provide a copy of the

dossier that is alleged to contain information obtained in breach of data exclusivity, and the Court can take one of the following positions:

· The Court can decide that the dossier can be accessed by the challenging party, which will have an obligation of confidentiality concerning the corresponding information. This confidentiality will include a prohibition against using this information in an eventual patent infringement action.

· The Court can determine that the information will not be accessed by the challenging party, but only by the Court and its appointed expert.

If the third party's dossier indicates that there was a disclosure of information provided in the innovator's dossier, there would be a clear-cut case for the annulment of the marketing authorization based on existing provisions in Mexican laws.

If there was no disclosure, but only reliance on information that remains confidential, the action would have to be based on a breach of obligations in international treaties, and an eventual constitutionality challenge against the provisions in Mexico's laws that do not contemplate data exclusivity, specifically those concerning generic applications.

As additional venues, an affected party could bring a specific criminal or civil action against the officer responsible of the disclosure, which should of course be analyzed on a case-by-case basis.

b) Actions against the third party using the information obtained in breach of data exclusivity

Actions against this third party have to be determined on a case-by-case basis, because the use of the information contained in the original marketing authorization in its entirety could provide basis for a copyright infringement action, an action for unfair competition, or a criminal action for the purposeful obtainment or use of confidential information.

The enforcement of data exclusivity has been sought by pharmaceutical companies through these venues but this is a new field in the Mexican legal system and so far no specific precedents indicate any of these venues as correct.

The Mexican legal system has been advancing in its adaptation to modern IP systems, especially through the establishment of linkage regulations establishing coordination between health and patent authorities in Mexico. This has allowed IP rights holders to bring actions, some successful, others yet to be decided upon, enforcing these rights, and questioning the actions of health authorities, which is a clear improvement from the mere possibility of

requesting declarations of patent infringement.
The decision obtained by our firm annulling a marketing authorization for breach of the linkage system will surely set a favourable precedent for IP holders in Mexico, for all pharmaceutical patents.