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Newsletter

# Intellectual Property Practice Group and Life Sciences Industry Group

## Mexican Circuit Court establishes scope of Bolar-type exemption for regulatory data exclusivity in landmark decision

Regulatory exclusivity for clinical data generally refers to a period -usually 5 years, but longer in some jurisdictions- in which a generic pharmaceutical product, whether a small molecule or biosimilar will not be approved, as reliance on an innovator dossier is forbidden. This type of exclusivity usually runs in parallel to -but is independent of- patent protection.

In Mexico, this exclusivity has never been sufficiently regulated; the reference in the Federal Law for Protection of Intellectual Property -and its predecessor the Industrial Property Law- is that data supporting the approval of new pharmaceutical or agrochemical products will be protected "according to provisions in international treaties", without providing clear guidance to the local regulatory agency (COFEPRIS) as to how it should be granted.

This has caused several cases -starting in 2007- in which pharmaceutical companies operating in Mexico have taken COFEPRIS to Court seeking specific protection for new drug products, combinations, indications, and orphan drugs, in cases that are usually successful.

However, the lack of clear regulations has caused the scope of rights to be determined by the Courts, upon studying specific cases -as opposed to policy discussions considering the regulators, industry, and other stakeholders-.

Our firm has obtained a favorable decision recently in which a Circuit Court establishes the specific -and, in our opinion, rational- scope of these rights. In summary, the case facts are:

- A multinational pharmaceutical company (which for confidentiality purposes will be referred to as "Plaintiff") had secured regulatory exclusivity for 3 indications associated with one of its innovative products, expiring at different periods of time.
- Once the exclusivity period had run out for the first two indications, our client -which is also a multinational company operating in Mexico ("Defendant")- filed a marketing authorization application for a generic version of the same drug, requesting approval of the two expired indications. The third indication, which still had regulatory exclusivity, was not requested.
- A constitutional challenge was brought by Plaintiff, requesting a refusal of Defendant's application, on the grounds that even if the period for protection had expired for the first two indications if bioequivalence studies were made during the period in which protection was in force, regulatory exclusivity would prevent Defendant from using said studies. This is analogous to the famous Roche v. Bolar case, where U.S. Courts determined that patent protection does not extend to activities done prior to securing a marketing authorization.
- This claim by Plaintiff would effectively extend regulatory exclusivity beyond the granted period; if a generic product applicant is forced to wait until the exclusivity period expires before being able to start bioequivalence studies, and then submit its application, it would greatly delay market entry. Whereas Mexican regulations do establish a Bolar-type exemption regarding patent rights, they are silent on whether the same exemption applies to regulatory exclusivity.
- In the first stage of litigation, a District Court dismissed the plaintiff's action, on the grounds that the marketing authorization application by our client did not affect the plaintiff's constitutional rights, as it was still under study, and a grant was not imminent.

- Both the plaintiff and defendant appealed, with the plaintiff arguing, among other points, that the mere fact that the bioequivalence studies performed by the defendant were under analysis by COFEPRIS constituted the violation of constitutional rights, warranting study of the merits of the action. COFEPRIS did not appeal the dismissal.
- In our appeal for the defendant, we requested the Circuit Court to change the reason for dismissal, by arguing that the scope of exclusivity cannot go beyond the granted 5-year term and that the bolar-type exemption existing in Mexican Law on patent protection should be extended to regulatory exclusivity.
- In its decision, the Circuit Court looked at both parties' arguments and decided to overturn the District Court decision and side with the defendant. The Court analyzed the requested indications in the dossier, along with the effective exclusivity period, and determined that upon expiration of the exclusivity period, the plaintiff lacks standing to bring an action based on the time when bioequivalence studies were made.

Whereas this decision is only mandatory for our client's specific generic product marketing authorization application, it does establish a relevant precedent that should be considered in the future by both COFEPRIS and other Courts.

In our opinion, this is a positive development in the creation of a balanced system for pharmaceutical companies operating in Mexico, where innovators should be able to obtain exclusivity in compliance with International Treaties, but generic product companies should be able to perform activities leading to securing a marketing authorization upon expiration of said exclusivity.

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