por Alejandro Luna

In previous newsletters regarding Data Package Exclusivity (DPE) in Mexico we highlighted that the domestic law was silent in the recognition of DPE rights. We also commented that in January 2008, the Mexican Health Regulations were amended concerning generic medications, eliminating the requirement to prove safety and efficacy for generics, which was substituted by the need to prove interchangeability.

In short, in 2008 the regulations were modified to implement an abbreviated approval procedure for generic drugs, on the basis of bioequivalence and bioavailability studies, without setting forth any provisions containing a non-reliance period as established in the international treaties such as NAFTA and TRIPS.

Based on the hierarchy of international treaties established in the Mexican Constitution, where international treaties approved by the Mexican Senate supersede Federal Laws, our firm structured a litigation strategy to secure recognition of DPE rights in Mexico. Although we have obtained valuable preliminary injunctions, ordering the regulatory agency to refrain from grant marketing authorizations relying directly or indirectly in the dossier of the innovator or the so-called product of reference, these cases remain under prosecution and are pending to be decided on their merits by the courts.

The issue has been discussed in many forums, highlighting the limitations of our domestic law, the possibility that the amendments to the Health Law in 2008 disregarding DPE rights could be considered as a contradiction with the international treaties, and that litigating the recognition of these rights is an unnecessary burden for individuals. In consequence this past February, 2011, a publication was made in the Gazette of the Congress, containing a proposal of amendment to the Health Law to fully recognize DPE rights in the Mexican Health Law. The proposal reads as follows:

"Art. 376….

For the purposes of this article and concerning interchangeable generics for allopathic medicines, the corresponding marketing authorizations can be only granted after a period of five years running from the date of granting of the medicament considered as innovator or product of reference; unless that the applicant is be the titleholder of the marketing authorization for the innovator or reference product or, applicant has obtained an express authorization from the

titleholder."

The following issues arise from this proposal:

- The word "interchangeable" referring to generic drugs should be removed from the article, as in 2008 the amendments to the Health Regulations eliminated the previously existing distinction between generics and interchangeable generics.

- The proposal does not make specific distinctions for protection of new chemical entities, formulations and new indications.

- The proposal limits the scope of protection of DPE to five years while NAFTA establishes the five year period as a minimum.

- The proposal seems to be also limited to allopathic medicines of chemical nature, as there is no specific mention to biologic drugs. In other jurisdictions establishing DPE rights, biologic drugs obtain a longer protection period.

- The Health Regulations should be also immediately amended and modified to coincide, clarify and accomplish the amendments of the Health Law.

In short, the proposal is highly positive and welcomed, as it would put an end to the contradiction of the domestic law with international treaties and would grant certainty and incentives to investors, companies conducting clinical trials and

developers of innovative medicines. It will be important to monitor lobby efforts before the Mexican Congress, in a scenario close to the next presidential elections in Mexico and facing the opposition to this proposal by some sectors of the pharma industry.