

*POR [ALEJANDRO LUNA](#)*

*SOCIO*

*PATENT DOCS, 2010*

On Friday, August 13, 2010, the Mexican Trademark and Patent Office (IMPI) made available through its website the new edition of the Linkage Gazette (Mexican health and IP law regulations require IMPI to publish a gazette every six months listing patents in force that cover allopathic drugs). Regrettably, IMPI decided to exclude formulation patents, limiting the inclusion criteria to compound patents. There are formulation patents included in the list derived from individual Court orders in litigation proceedings where the non-inclusion of specific formulation patents in the Gazette was contested.

The current non-inclusion of formulation patents disregards a petition by the Pharmaceutical Association of R&D companies (AMIIF), and does not follow the jurisprudence of the Mexican Supreme Court ruling that formulation patents are to be included in the Linkage Gazette.

Legally, as an administrative authority, IMPI is not bound to follow judicial precedents; nevertheless, there is broad dissatisfaction with the political decision taken by IMPI regarding the denial to include formulation patents in the Linkage Gazette, since following the Supreme Court's criterion would have avoided further litigation from patent holders.

The non-inclusion of valuable formulation patents can be contested within the next fifteen working days. Any litigation proceeding at this point will benefit from Supreme Court precedent, which is mandatory for District and Circuit Courts and provides guidelines to decide these cases.

Of course, inclusion of formulation patents in the Linkage Gazette provides grounds to prevent or challenge marketing authorizations granted to third parties in violation of formulation patents which in many cases have expiration

dates beyond the initial compound patent.

Additionally, inclusion of formulation patents is pivotal, as the formulation of drugs is reviewed by the Regulatory Authority (COFEPRIS) upon studying applications for marketing authorizations. Since safety and efficacy of a drug reviewed by COFEPRIS is not limited to compounds, there is no rationale to limit the linkage regulation to compound patents by the linked authorities (IMPI and COFEPRIS), particularly when the highest Court in México has decided that formulation patents for allopathic medicines including an identified compound should be included in the Gazette.