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Before the Linkage Regulation in Mexico, the health authorities granted marketing authorizations for pharmaceuticals when the applicant complied with the regulatory requirements, without reviewing possible violations of patent rights. In short, marketing authorizations granted in the past for patented pharmaceutical products to non-authorized third parties were government authorizations to infringe patents.

Briefly speaking, now the Linkage Regulation has been enacted, the Mexican Patent and Trade Mark Office (IMPI) is bound to publish and update every six months a list of patents in force covering allopathic medicines.

According to this regulation, health authorities, *inter alia*, must require from applicants of marketing authorizations a declaration under oath of whether they are the owners or licensees of the corresponding patent, if the pharmaceutical product appears in such a listing of patents by IMPI, in order to avoid the granting of marketing authorizations for allopathic medicines covered by patents.

Under a narrow interpretation of the Linkage Regulation, IMPI only publishes patents covering active ingredients, excluding patents covering pharmaceutical formulations and medical uses, notwithstanding that patents covering processes are the only ones expressly forbidden by the Linkage Regulation from the listing of patents.

We have successfully contested the non-publication of formulation and use patents and we have obtained decisions from the courts ordering IMPI to include patents covering formulations and medical uses in the Linkage Gazette. The Linkage Gazette has proven to be a useful tool, as patent rights have been recognized during public tender proceedings, easily proved in patent infringement proceedings, and recently used to cancel unlawful marketing

authorizations.

Recently, we have obtained what we believe is the first decision by the Federal Court for Tax and Administrative Affairs (FCTAA) canceling a marketing authorization granted in violation of the Linkage Regulation as the active ingredient patent was disregarded by the health authority. The same reasoning should apply to patents listed in the Linkage Gazette covering formulations and medical uses.

This decision sets an important precedent as it confirms the availability of the venue of the nullity trial before the FCTAA, overcoming the lack of an express cancellation proceeding available to third parties in the Health Law for unlawful marketing authorizations.
Finally, the precedent confirms that if the Linkage Regulation is not properly applied by IMPI and the health authorities, the courts will orer the listing of missed patents and cancellation of marketing authorizations granted in violation of the Linkage Regulation.