

MEXICO

Applying the experimental use exception in patent infringements

OLIVARES



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For many years, the experimental and academic use exception was incorrectly applied in Mexico to declare third parties who imported raw materials while the patents that protected the correlative active principle were still in force, as infringers. This is because the companies alleged that, according to their import requests, these authorisations had been granted by the sanitary authorities for experimentation purposes without commercial aims.

Therefore, to avoid patent infringement, it was sufficient for the defendant to exhibit the import authorisation granted by the sanitary authority (Federal Commission for the Protection against Sanitary Risks COFEPRIS). The import authorisation also had to include a legend stating that the importation had been authorised for experimentation purposes.

Additionally, some infringing companies enforced the Roche-Bolar exception and the experimental use exception at the same time, generating confusion in the Mexican Institute of Industrial Property (IMPI). The institute chose to declare the raw material importing companies (trading companies) as infringers, considering that their activity was only for commercial purposes and denied the infringement if the defendants proved that they were pharmaceutical companies applying the benefit of the Roche-Bolar exception.

Recently, in cases handled by Olivares, two different circuit courts have clarified the correct interpretation of the experimental and academic use exception. The rulings

stated, in accordance with the most basic rules of the burden of proof, that it was not enough to exhibit an import permit that indicates that the destination of the raw material to consider that such exception is applicable. It stated that it was however necessary to demonstrate with another type of evidence, as they constitute their own facts and it was the defendants who asserted the said exception, which is the type of activity that was specifically carried out for purely experimental purposes. These new criteria have now caused the IMPI to correctly apply this exception for the benefit of the patent protection system and its holders.