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A DRUG MARKETING AUTHORIZATION CAN BE GRANTED ONLY IF THE NAME APPLIED FOR VARIES BY AT LEAST THREE LETTERS FROM PREVIOUSLY REGISTERED NAMES. HOWEVER, THIS RULE IS NOW BEING CHALLENGED

FRAMEWORK

The Institute of Industrial Property (IMPI) is the administrative authority charged with granting trademark registrations in Mexico.
The main bodies of law governing trademarks are the Industrial Property Law and its regulations.
The procedure to obtain a marketing authorization to manufacture and commercialize a pharmaceutical product is not limited to complying with safety and efficacy requirements. The Health Law and its regulations also provide that the regulatory agency in charge of granting marketing authorizations to medicines and other supplies – the Federal Commission for the Protection against Sanitary Risks (COFEPRIS) – must approve the commercial name of the pharmaceutical product before the later is put on the market.
Although trademark registration is not a prerequisite to the launch of a pharmaceutical product on the market, the involvement of two administrative authorities in the clearance of trademarks and commercial names for drugs has become a crucial issue for the pharmaceutical industry.

GENERAL CONSIDERATIONS REGARDING LIKELIHOOD OF CONFUSION

In relation to trademark registration, the Industrial Property Law provides that IMPI must refrain from granting registrations to marks which are confusingly

similar to registrations or applications covering the same or similar products. In addition, IMPI must cancel trademark registrations that have been granted in error or that prove to be confusingly similar to senior marks used on the same type of goods.
The courts have established certain guidelines to analyze the likelihood of confusion between conflicting marks, and have been consistent in:

- ordering IMPI to take into consideration the visual, aural and conceptual aspects of the marks; and

- indicating that the examiner of judge should look at the trademarks involved as a whole, refraining from dividing or disregarding elements of the marks (non-binding precedent published in the *Federal Judicial Gazette* in February 1995, Volume XVI, p*207*).

In the case of so-called 'mixed' trademarks (ie, word and design marks), the courts have established that the word element has more weight than the design element.
In addition, distinctive (ie, fanciful or arbitrary) signs have more weight than descriptive or generic terms, which lack relevance in the analysis even though they are part of the trademark.

LIKELIHOOD OF CONFUSION BETWEEN PHARMACEUTICAL MARKS

IMPI is not bound by court guidelines. However, these are highly persuasive and IMPI usually follows them when comparing trademarks, regardless of the type or class of product or service. Therefore, the guidelines have been applied to conflicts between trademarks registered in relation to products in Class 5 of the Nice Classification, which covers pharmaceuticals.
There are few legal precedents establishing particular rules for the assessment of the likelihood of confusion between pharmaceutical trademarks. However,

the courts have ruled that I these cases, likelihood of confusion should be minimal as it could jeopardize the health of consumers (non-binding precedent published in the *Federal Judicial Gazette*, Volume CXVII, p*21*).
When part of the international non-proprietary name of the drug is included in conflicting pharmaceutical trademarks, the analysis should focus on the distinctive elements of the marks.
Although certain courts have addressed the issue, there is no definitive rule of law regarding the likelihood of confusion between trademarks for prescription drugs and over-the-counter (OTC) drugs.
According to the current law, there should be no differentiation in the likelihood of confusion analysis between conflicting trademarks for prescription and OTC drugs, as the standard provided in the law is limited to "similar products" – not to an analysis of:

- whether consumers would have access to the conflicting medicines over the counter; or

- whether the confusion would be avoided if the products were available only on prescription

THREE-LETTER RULE

The Regulation of the Federal Health Law now establishes that COFEPRIS has the authority, among other thing, to approve the commercial name of a pharmaceutical product.
In this regard, Article 23 of the Health Regulation establishes that when similarity is found between a commercial name and an earlier drug name, at least three letters should differ. This provision is known as the 'three-letter rule'. Its rationale is to avoid granting marketing authorization to a commercial name which is similar to that of a prior marketing authorization. Therefore,

COFEPRIS, as the entity in charge of admitting, prosecuting, assessing and granting marketing authorizations, should follow the three-letter rule.

IMPI has been reluctant to apply the three-letter rule in examination, cancellation and infringement actions concerning pharmaceuticals marks. IMPI claims that the rule is not mentioned in the Industrial Property Law and contradicts case law, which does not limit the likelihood of confusion analysis to a number of letters.

Some courts have held that the three-letter rule should be taken into consideration by IMPI when assessing the likelihood of confusion between pharmaceutical trademarks, under the rationale that the commercialization of pharmaceutical products is a matter of public policy regulated by the Health Law and its regulations.

Considering the split of opinion between the courts on this issue, a Supreme Court decision will be needed to clarify the applicability of the three-letter rule. Meanwhile, IMPI itself has recently showed some ambivalence towards the rule; this has added to the confusion regarding the interpretation and application of two federal provisions, and led to IMPI and COFEPRIS issuing conflicting decisions regarding the likelihood of confusion of the same marks/names.

AUTHORIZATION AND REGISTRATION

The double requirement for authorization and registration of pharmaceutical trademarks causes two main problems.

From a legal point of view, there is a conflict between the law and the faculties of the authorities to analyze the likelihood of confusion. A party affected by the application of the three-letter rule could argue that IMPI does not have the power to apply the rule, as the latter is provided in a different body of law and for a different type of proceeding. Additionally, the affected party may argue that the analysis of likelihood of confusion is not limited to a number of letters; their positions or sequence could trump any likelihood of confusion.

Further, the rule's detractors argue that the article establishing her rule is unconstitutional as the Mexican Constitution provides that trademarks and distinctive signs are governed by the Industrial Property Law; therefore, the three-letter rule in the Health Regulation is in conflict with this constitutional provision.

Pre-emption of laws is another issue. In case of conflict of laws caused by the application of the three-letter rule to a specific case, the Industrial Property Law arguably pre-empts the Health Regulation-not only because the Industrial Property Law has a specific constitutional basis to regulate trademark matters, but also due to the hierarchy of laws: the industrial property law is a federal law approved by Congress, while the Health Regulation is a lower-grade body of law issued by administrative agencies with regard to the application and interpretation of the Health Law.

From a practical standpoint, at the time of assessing a junior marketing authorization and applying the three-letter rule, COFEPRIS has neither access to updated records nor the capacity to confirm whether a marketing authorization and its commercial name are in force and the products are on the market. This is because until recent amendments to the Health Law and its regulations were made, marketing authorizations for medicines and drugs were granted for an indefinite period. Consequently, there are close to 20,000 COFEPRIS-approved drug names on record. Under the three-letter rule, any of these names may be cited against junior applications, regardless of whether:

- the products are obsolete and out of commerce; or

- the corresponding trademark registration has lapsed or is subject to a cancellation action for non-use.

OUTLOOK

Two proposals have been formulated to address the situation. Both proposals aim to remove the three-letter rule from the Health Law, but differ in the way they would regulate the approval of commercial names by COFEPRIS.

The first proposal suggests that the review and authorization by COFEPRIS of commercial names in applications for marketing authorizations be limited to

health issues. In other words, to avoid a likelihood of confusion derived from the improper use of part of generic drug names, the analysis should consider only:

- the therapeutic indications and medical uses of the products; and

- misleading names that would jeopardize consumers' health.

In this scenario, the likelihood of confusion analysis between trademarks would be an exclusive faculty of IMPI, based on its own trademark database and guidelines of comparison.

The second proposal would link IMPI and COFEPRIS approvals, in that COFEPRIS would approve the commercial name in a marketing authorization without assessing its likelihood of confusion with any other name, provided that the applicant showed the corresponding trademark registration granted by IMPI. This proposal also contemplates the possibility to change the proposed commercial name before COFEPRIS if the trademark registration were not granted.

The Health Regulation is thus expected to be amended and the three-letter rule abolished. An alternative would be for COFEPRIS to update its database. However, as this would take time and require a large governmental budget, the first proposal – to amend the Health Regulation to take advantage of the already financed, modern and publicly available trademark database managed by IMPI – is arguably more efficient.

Meanwhile, as there is no resolution in sight regarding IMPI's use (or non-use) of the three-letter rule in trademark prosecution and/or litigation, pharmaceutical brand owners are advised to conduct an analysis of their marks on a case-by-case basis to make the best legal and business decision in the circumstances.

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