Brazil

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Selection, clearance and registration

In Brazil, pharmaceutical trademarks must comply with the requirements established by both IP and regulatory law. Therefore, they must comply with:

- the IP Law (9,279/96) and the regulations enacted by the Patent and Trademark Office (PTO), which is in charge of examining trademark applications; and
- the Food and Drug Law (6,360/76) and the regulations enacted by ANVISA, the food and drug agency, which is in charge of supervising the manufacture and marketing of pharmaceutical products.

The IP Law includes no provisions specifically related to pharmaceutical trademarks. The statute establishes that "visually perceptible distinctive signs are eligible for trademark registration" and defines a 'trademark' as "a sign used to distinguish products and services". In view of these rules, non-traditional trademarks such as sounds, smells and colours (with the exception of three-dimensional trademarks) are not subject to registration – although the provisions regarding unfair competition may provide some sort of protection for non-traditional trademarks.

Of particular relevance for pharmaceutical trademarks, the IP Law establishes that the following are not eligible for registration:

- "signs of generic, necessary, common, usual or merely descriptive nature, when related to the products to be distinguished";
- "technical terms used in the industry, science or art related to the product to be distinguished"; and
- "reproductions or imitations, in whole or in part, even with additions, of a trademark registered by a third party (or which the applicant should be aware of in view of his activity) [that] are likely to lead to confusion or false association".

However, even if a pharmaceutical trademark is duly registered before the PTO, its use depends on compliance with the Food and Drug Law. That statute provides that

pharmaceutical products "cannot have names or designations that may lead to error", and prevents companies from using trademarks that are "identical or similar to products with different composition, even if manufactured by the same company". The focus of the law is always the protection of public health.

In addition, ANVISA Resolution 333/03, which remains in force with regard to the pharmaceutical trademark provisions, establishes that a pharmaceutical trademark cannot be similar to or create confusion in regard to other pharmaceutical trademarks and designations. Although the resolution establishes the possibility of using a similar denomination by including, modifying or subtracting three letters, a trademark that creates a risk to public health cannot be accepted for registration. In addition, the resolution clarifies that a trademark cannot create confusion or be similar to a generic denomination such as an international non-proprietary name or a national non-proprietary name.

In light of this, pharmaceutical trademarks must be sufficiently different from such generic denominations and from other pharmaceutical trademarks to avoid violating both the IP and the food and drug legislation.

Although case law provides little guidance in this area, in 2011 the Superior Court of Justice – the highest court in Brazil other than the Supreme Court – ruled on pharmaceutical trademarks. Such decision provided clarification and demonstrates a higher tolerance for similar pharmaceutical trademarks, especially if they comprise elements that derive from the name of the compounds used to make the drug – at least in circumstances where there is no risk to public health.

In *Ache v Pharmascience* (Special Appeal 1.105.422/MG) the Superior Court of Justice considered an infringement lawsuit filed by Ache, holder of the pharmaceutical trademark SORINE, against Pharmascience, holder of the pharmaceutical trademark SORINAN. The court upheld the lower courts' decision and found that there was no infringement since both trademarks were used for products made of sodium chloride, informally known in Brazil as 'Soro' – therefore, 'Sor' was generic and not subject to exclusive rights. The court noted that the standards for establishing a likelihood of confusion with regard to pharmaceutical trademarks are higher, not only in light of the circumstances, but also because consumers buy drugs based on either the price or the reputation of the company that manufactures the product.

Therefore, pharmaceutical companies should take extra care when selecting trademarks, and ideally should seek local assistance in order to check for conflicts with other pharmaceutical trademarks and to ensure that the trademark is sufficiently distinctive.

Finally, even after registration, a rights holder should bear in mind that it risks losing its rights at the request of any party with a legitimate interest if the mark has not been used in Brazil within five years of the PTO granting the registration, unless there is a legitimate reason for non-use. There is no clear definition of what constitutes 'use', but the use must be effective and must include the products or services mentioned on the registration certificate. If this is not the case, partial forfeiture may occur. Although there is no settled case law regulating this matter, delay in the regulatory approval should be accepted as a legitimate reason to justify a lack of effective use.

Parallel imports and repackaging

The IP Law establishes a system of national exhaustion and does not tolerate parallel importation. Although there is no settled case law regarding repackaging, this is possible only after an agreement has been reached with the rights holder and if all regulatory rules enacted by ANVISA governing the repackaging of pharmaceutical products – notably Resolution 71/09 – are met.

Anti-counterfeiting and enforcement

Counterfeit drugs are a significant problem in Brazil and preventing the infringement of IP rights demands serious, ongoing efforts. One of the most effective ways to prevent counterfeiting is to implement border measures. For example, Customs may seize products suspected of trademark infringement and warn the rights holder, which must file an infringement lawsuit within 10 days to avoid release of the products by Customs. Accordingly, a rights holder should keep

Customs informed about its rights. The rights holder should be vigilant and take the necessary measures to protect its rights actively, such as sending warning letters and informing the authorities of any wrongdoing.

With regard to the enforcement of pharmaceutical trademarks, the rights holder can bring a criminal complaint, with the potential penalties ranging from imprisonment of between three months and one year to a fine, or a civil complaint.

A civil complaint usually includes requests for an injunction to prevent the defendant from continuing the infringement and for damages. Protection extends to translated or conceptually identical but graphically different trademarks. Further, dilution may be an additional cause of action, since a lawsuit may be filed in order to maintain "the material integrity or reputation" of a registered trademark, as expressly established by the IP Law.

Preliminary injunctions, including *ex parte* injunctions, may be obtained provided that substantive evidence is submitted to demonstrate:

- the likelihood of prevailing in the litigation; and
- the need for an urgent preliminary decision from the courts.

Thus, urgency is an important requirement: the plaintiff must show the court that it may suffer irreparable or near-irreparable harm if an immediate decision is not granted. A judge will not grant an injunction if there is a risk that such decision is irreversible. In regard to pharmaceutical trademarks, judges' focus is on avoiding risks to public health rather than protecting the rights holder's commercial interests.

Regarding damages awards, it is usually possible to obtain indemnification for actual damages, lost profits and moral damages. Lost profits shall be determined by whichever of the following criteria is most favourable to the plaintiff:

- the benefits that the plaintiff would have earned if the infringement had not occurred;
- the benefits earned by the defendant; or
- the royalty that the defendant would have paid the plaintiff had it taken a licence for the infringing products.

Moral damages are usually available if the infringement caused damage to the reputation of the rights holder. Punitive damages are extremely rare: judges will order a defendant to pay punitive damages only in extreme circumstances.

In a typical infringement lawsuit, the plaintiff must file a complaint brief, indicating its claims, its legal arguments and the remedies sought, with a state trial court. The defendant must file an answering brief; otherwise, the case will be decided by default. The plaintiff usually then has the opportunity to file a reply brief. There is then a mandatory conciliation hearing in order to encourage the parties to settle the case. If settlement is not possible, the parties will initiate the evidence production phase, which usually includes expert examination and witness testimony. Finally, the judge will issue a decision on the merits. If the plaintiff wins, the judge will often prefer to issue the damages award at a later stage. A decision on the merits is subject to an appeal to a state appellate court. Further appeal to the Superior Court of Justice and the Supreme Court may also be available.

Advertising

The federal Constitution provides that the advertising of pharmaceutical products is subject to legal restrictions. The regulatory legal framework governing the advertising of pharmaceutical products is extensive and includes Law 9,294 and Decree 2,018/96, which specifically govern the issue, in addition to ANVISA Resolution 96/08 (amended by Resolutions 23/09 and 60/09 and Normative Instruction 5/09), Ministry of Health Resolution 344/98, Law 6,360/76, Law 8,078/90 (which deals generally with consumer protection) and the Self-regulation Advertising Code.

'Advertisement' is defined by ANVISA as techniques and activities of information and persuasion with the objectives of disseminating knowledge, making a product or brand better known and aiming to influence the public through actions intended to promote or induce the prescription, distribution, purchase and use of a medicine.

The most relevant authority in charge of supervising the advertising of medicines is ANVISA's Office of Advertising, Publicity, Promotion and Information of Products Subject

to Sanitary Surveillance. It is possible to file an appeal before the ANVISA board of directors to challenge any decision issued by that office.

Advertisements need not be approved in advance, but the authorities have the power to stop further publication of an advertisement and to order a corrective statement. The penalties for failing to comply with the rules governing the advertising of medicines are:

- a warning;
- prohibition of the advertising;
- prohibition of sales;
- a corrective message; and
- a fine.

Competitors may also take direct action through the courts.

In addition to the competent health authorities, a self-regulatory system is supervised by the Self-regulatory Advertising Council (CONAR), which verifies whether an advertisement accords with the Self-regulation Advertising Code. The self-regulatory system is very effective, since most radio stations, television channels and publishers are members of CONAR and will immediately cease the dissemination of an advertisement if CONAR so decides.

Prescription drugs can be advertised only to health professionals, provided that some mandatory information is provided. Only over-the-counter drugs can be advertised to the general public, provided that all legal and regulatory requirements are met. A product cannot be advertised before its marketing approval has been issued by ANVISA, not even to health professionals. However, it is permitted to discuss information regarding such product at scientific meetings, provided that the discussion does not aim to induce the prescription, distribution, purchase or use of such medicine. This situation is the same for off-label information.

Generic substitution

There are three different classes of product in Brazil:

- reference drugs, identified by brand names and registered by the innovator company after conducting clinical trials;
- generic products, interchangeable with the reference drug, identified by their active ingredient and registered after the expiration of IP protection covering the reference drug, relying on the clinical trials performed with the reference drug; and
- similar products, identified by brand names and registered after the expiration of IP protection covering the reference drug, based on the clinical trials made with the reference drug, but which may differ from the reference drug with regard to size, shape, shelf life, packaging, labelling and excipients.

Because a generic product is interchangeable with the reference drug, generic substitution is possible and may be suggested by the pharmacist, unless the prescription specifically disallows such substitution.

Online issues

Only regular pharmacies can sell products online and they must comply with several specific regulatory rules. Naturally, a prescription is necessary in order to request a prescription drug. Products subject to special control cannot be commercialised online.

Trademarks can be enforced against domain names, and even against metatags. Conflicts between trademarks and domains names are common and may be resolved by arbitration, among other methods.

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Luiz Leonardos helped to shape Brazil's current IP scene and gave his name to Luiz Leonardos & Cia after the split of traditional IP firm Momsen Leonardos & Cia on April 30 2012.

He has been president and member of the board of directors of the Brazilian Industrial Property Association, and is now honorary president. He has been executive president of the International Association for the Protection of Intellectual Property and is currently an honorary member. He is also an honorary member of the International Federation of Intellectual Property Attorneys.

His notable career in IP law is widely recognised in Brazil and abroad. Legal excellence makes him one of the most respected IP practitioners of his generation.

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