Brazil

Contributing firm
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Selection, clearance and registration

Relevant national regulatory bodies and requirements

The Brazilian Patent and Trademark Office (BPTO) is responsible for granting trademark registrations in Brazil, in accordance with the Industrial Property Law (Law 9.279/96).

The National Agency of Health Control (ANVISA) controls the production and marketing of products and services in the health sector, including pharmaceutical drugs.

According to Law 6.360/76, only drugs registered with ANVISA may be imported and marketed in Brazil. When registering with ANVISA, the interested entity must:

- describe the mark being applied for; and
- submit a sample of the label.

When selecting a pharmaceutical trademark, a company must consider which of the following types of medicine the mark will apply to, as this will affect what type of mark is suitable:

- Reference medicine – a prescription drug protected by a patent. Reference drugs may be identified by a fanciful or suggestive trademark, or their active ingredient.
- Similar medicine – a drug that is no longer protected by a patent and which contains the same active ingredient, pharmaceutical form, dosage and therapeutic indications as a reference product, although it may differ in characteristics such as size and shape, shelf life, packaging, labelling and excipients. Similar medicines must be identified by a fanciful trademark or trade name sufficiently distinct from the reference medicine.
- Generic medicine – a drug that is no longer protected by a patent and which has the same active ingredient, pharmaceutical form, dosage and therapeutic indication as a reference medicine. Generic medicines cannot be identified by a fanciful trademark, but must be identified by their active ingredient – accompanied by the expression '*G genérico*' (in English, 'G generic') – and the pharmaceutical company's house mark.
- Over-the-counter (OTC) medicine – a drug that requires no prescription. OTC medicines may be identified by a fanciful or suggestive trademark.

ANVISA recently issued Resolution 71/2009, which deals with packaging for medicines. Opinions are being sought from interested parties in order to publish a new regulation on the selection and use of pharmaceutical trademarks.

Confusion with international non-proprietary names

Pharmaceutical trademarks are usually composed of elements, diluted or in common use, deriving from their:

- active ingredient;
- international non-proprietary name; or
- therapeutic indication.

The BPTO grants limited protection to trademarks of this kind, allowing similar trademarks to coexist based on their weak distinctiveness.

For this reason, a trademark clearance search is advisable to verify whether the selected mark is inherently distinctive under local practice and ensure that it does not conflict with senior trademarks.

Registration requirements

The Industrial Property Law foresees that any visually perceptive distinctive sign is eligible for registration as a trademark, provided that it is not prohibited under law. Non-traditional trademarks, such as sound or colour marks, are not registrable as trademarks.

Under administrative rules, the registration of pharmaceutical trademarks follows the same rules and proceedings as for any other trademark. However, the analysis of likelihood of confusion or association between similar pharmaceutical trademarks follows a different reasoning.

Where products are for different purposes, this tends to diminish the likelihood of confusion between the trademarks under comparison. However, if the possible conflict involves marks that identify drugs with different therapeutic purposes, the BPTO believes that this increases the possibility of harm to consumers. This is because if a consumer mistakenly chooses one medicine intended for a particular purpose over another intended for a different purpose, this represents a greater risk to the consumer's health.

Parallel imports and repackaging

Parallel imports

Article 6 of the Agreement on Trade-Related Aspects of Intellectual Property states that the exhaustion of rights was not discussed as part of the agreement. Consequently, signatories can choose to implement any of the following regimes:

- International exhaustion regime – the right to oppose the circulation of goods containing a mark, patented product or product manufactured using the patented process expires once the product is placed on the market by the rights holder or an authorised party. In this case, the rights holder may not object to parallel imports.
- Regional exhaustion regime – the right to oppose the circulation of goods containing a mark, patented product or product manufactured using the patented process expires once the product is placed on the market of a regional bloc by the rights holder. In this case, if the product was placed on the market by the rights holder or an authorised party in any country from the regional bloc, the rights holder may not object to the import of the product to its country (should the product come from a country that is not part of the bloc, the holder may object to the import).
- National exhaustion regime – the right to oppose the circulation of goods containing a mark, patented product or product manufactured using the patented process expires once the product is placed on the domestic market by the rights holder. In this case, any parallel import of the product is forbidden.

Brazil has chosen to adopt the national exhaustion regime. This means that parallel imports are prohibited under Articles 43.IV (patents) and 132.III (trademarks) of the Industrial Property Law.

Repackaging

Repackaging products that contain a certain mark or seeking to include another mark on the label of a product, either together with the original mark or replacing it, is allowed only if authorised by the holder of the original mark.

Article 130.III of the Industrial Property Law guarantees the rights holder the right to care for its material integrity or reputation.

Although the principle of exhaustion of rights prevents the rights holder from opposing the circulation of goods containing its mark in the national territory, it is entitled to prevent third parties from changing its mark without consent.

In the case of drugs, not only trademark registration issues but also regulatory issues involving the labelling and marketing of drugs are pertinent. Any change to the mark or to the labelling must be approved by ANVISA, upon modification of the product's health registration.

Therefore, a third party that simply markets a drug may not repackage it so as to include its mark on the product, since:

- the drug can be marketed only under the conditions defined in its health registration; and
- any change to the drug's original mark and label would violate the regulatory and trademark rights of its holder.

Anti-counterfeiting and enforcement

Preventive measures

The first step in any anti-counterfeiting programme is to ensure that the holder's IP rights are fully protected. In Brazil, a trademark is protected under the Industrial Property Law and the rules against unfair competition.

Border enforcement

According to the Industrial Property Law and the Customs Regulation (Decree Law 6.759/2009), Customs, *ex officio* or at the request of an interested party, may seize any product that infringes IP rights. Also, a rights holder may file a petition with Customs including a list of IP rights and a request to trigger the surveillance of illegal imports. Such a request can also be directed to major Brazilian ports to overcome any lack of communication with the local customs authorities. In addition to filing a written request, rights holders should arrange a meeting with Customs.

Regulatory enforcement

As drugs are subject to health surveillance, it is possible to require ANVISA to adopt measures to prevent:

- drugs being repackaged in Brazil;
- the rights holder's mark being altered; or
- any other changes being performed contrary to the product's health registration.

On verifying that infringement has taken place, ANVISA may apply penalties from warnings and fines to cancellation of the product's health registration, which would prevent its import into and marketing within Brazil.

Civil remedies

Civil action is worthwhile only if the defendant is likely to have substantial assets available to pay damages. A rights holder can file injunction and indemnification actions to obtain search and seizure orders, restraining orders, recovery of damages, destruction of infringing products and reimbursement of court expenses.

Criminal remedies

The police may carry out an inquiry independently and may use search and seizure measures to seize counterfeit products and to proceed with interrogations. Once the search and seizure has been carried out and the criminal action commenced, the judge may order the destruction of all infringing goods.

Criminal search and seizure is usually carried out before any judicial procedure or during the police inquiry. In principle, only materials that are necessary to substantiate the crime will be seized. The judicial experts

must prepare an opinion containing all information necessary to ascertain the defendant's level of responsibility. The experts must answer questions formulated by the rights holder, the public prosecutor and the judge. The defendant has no opportunity to ask questions or intervene in any way during this preliminary proceeding. IP crimes are punishable by imprisonment or fine. Prison sentences can vary from one month to one year, depending on the crime.

Internet issues
Copyright violations, trademark infringements, domain name misappropriations and extensive trade in counterfeit products are the most common illegal activities in Brazil. Although Brazil does not have a specific internet regulation that clearly defines online crimes, the Civil Code, Criminal Code, Consumer Protection Code, Copyright Law, Industrial Property Law and other relevant regulations protect rights holders against counterfeiting activities. Disputes are analysed on a case-by-case basis and, depending on the type of involvement, those involved will be subject to civil and/or criminal prosecution. Depending on the circumstances of the case, liability can be extended to website administrators and internet service providers (ISPs). In such cases, the rights holder must prove an effective connection between the active or inactive behaviour of the website administrator or ISP and the violation in order to initiate a court action.

Advertising

The Constitution establishes that the advertising of medicines and therapies is subject to restrictions in order to protect public health. Within this context, Law 9782/99 makes ANVISA responsible for regulating the advertising of pharmaceuticals in Brazil.

Advertising and other promotional practices for pharmaceuticals are regulated by Resolution RDC 96/2008, issued by ANVISA.

Advertisements to health professionals
According to RDC 96/2008, the advertising of prescription medicines is restricted to communications directed at health professionals qualified to prescribe or distribute such products. Such communications must contain essential information regarding the product, including:

- trade name;
- active ingredient;
- ANVISA registration number; and
- indications, warnings and safety measures.

Further, if the benefits of the medicine are highlighted, at least one contraindication and the most frequent drug interaction must be highlighted so as to have a visual impact on the readers (ie, it must be at least 20% of the size of the largest font used).

Any statements, quotations, tables or illustrations related to scientific information shall be obtained from clinical studies, available in scientific publications, and must be faithfully reproduced, specifying the reference.

OTC drugs
Advertisements of OTC medicines may be directed at the general public and must present the same essential information regarding the product.

However, RDC 96/2008 prohibits advertising that:

- encourages the indiscriminate use of medicines;
- suggests or encourages diagnostics to the general public; or
- uses imperatives which directly induce consumption of the medicines (eg, 'have it', 'take it', 'use it' or 'try it').

Further, advertisements of OTC drugs must carry the warning "IF SYMPTOMS PERSIST, ASK FOR YOUR DOCTOR'S HELP", as well as warnings related to the active ingredients.

The broadcast of such publicity/advertising is prohibited during television programmes or in magazines intended for children and teenagers.

Free samples
Free samples of birth control pills and drugs of continuous use must contain 100% of the contents of the original registered and commercialised presentation. As regards antibiotics, free samples must contain at least the amount sufficient for a full course of treatment. For other prescription drugs, free samples must contain at least 50% of the original content.

Scientific events and campaigns
RDC 96/2008 reinforces that support or sponsorship of healthcare professionals may not be conditional on the prescription or administration of any type of drug.

The resolution forbids advertising and mentioning drug names during social campaigns.

Term and penalties
Anyone infringing the resolution shall be subject to the penalties set out in Law 6.437/1997, which range from publicly correcting an advertisement to suspending the product's sale if no correction is made.

Generic substitution
Reference medicines may be substituted by generic medicines once the reference medicine is out of patent. All generic medicines must be clearly identified as such.

Online issues
The advertising or publicising of prescription drugs over the Internet is restricted to professionals qualified to prescribe or distribute drugs by means of an electronic registration system. A liability agreement must also be submitted carrying information about legal restrictions to access.

Package inserts of prescription drugs available on the Internet, with no access restrictions, must be up to date and precisely reproduce the inserts approved by ANVISA. In addition, they may not present designations, symbols, figures, drawings, images, slogans or any arguments designed to advertise the drugs.

Only pharmacies open to the public and with a responsible pharmacist available during business hours may distribute drugs requested remotely (eg, by phone, fax or online). The submission of the prescription and its assessment by the pharmacist is essential for the distribution of prescription-only drugs.

The website of such a pharmacy must be registered in the second-level domain '.com.br' and shall contain on its main page the following information:

- the pharmacy's corporate name and trade name;
- the corporate taxpayer's registration number, full address, working hours and telephone number, as well as a link to its name and enrolment number at the Pharmaceutical Council; and
- the responsible technician present when the service was rendered.

All remote requests for drug distribution shall be registered by the pharmacy. However, the distribution of drugs subject to special control by such means is forbidden.

Finally, pharmacies may deliver drugs by mail, provided that they conform to health conditions to ensure the integrity and quality of the products. WTR

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