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Pharmaceutical IP and competition law in Brazil: overview

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PATENTS

1. What are the legal conditions to obtain a patent and which legislation applies? Which products, substances and processes can be protected by patents and what types cannot be patent protected?

Conditions and legislation

The requirements to obtain patent protection are:

- Novelty.
- Inventive activity.
- Industrial application.
- Descriptive sufficiency.

The IP Law (*Law No. 9,279/96*) sets out the requirements to obtain patent protection.

Scope of protection

All pharmaceutical products and processes inventions can be patent protected (*Law No. IP Law*), except for:

- Those that are contrary to morals, good customs, public security, public order or health.
- Any substances related to atomic nucleus transformations.
- The whole or parts of living beings, except transgenics.

Patents can only be issued for a pharmaceutical product or process with ANVISA's prior consent (*Article 229-C, IP Law*). ANVISA's role in providing prior consent is controversial. Resolution RDC No. 45/2008 regulating the administrative proceedings on prior consent analysis initially set out (*section 4, Resolution RDC No. 45/2008*) that the analysis was directly related to assessing whether a pharmaceutical invention complies with the requirements for patentability (*see above, Conditions and legislation*). Some jurists and judges believe that ANVISA's prior consent is limited to assessing whether a patent is contrary to public health (*section 18, I, IP Law*).

Two legal opinions, that bind ANVISA, were rendered by the Attorney General's Office to limit ANVISA's examination to public health factors.

On 24 May 2012, the final report on the prior consent proceeding prepared by an inter-ministerial working group composed, among others, of representatives from the Attorney-General's Office, Ministry of Health, INPI and ANVISA, was published in the *Official Gazette*. In theory, this group should set out guidelines for co-operation between ANVISA and INPI in the prior consent proceeding. Although the report prepared by this group is not very clear about ANVISA's role, its contents can lead to the interpretation that ANVISA must limit its analysis to their legal attribution (that is, the Brazilian population's health issues).

However, after a public consultation on ANVISA's role in the prior approval procedure (held between October and December 2012), Resolution RDC No. 21 was published on 15 April 2013, provisions of which amend Resolution RDC No. 45/2008 and establish that ANVISA's analysis is to be carried out "in light of public health". According to the text introduced by this new resolution, prior consent will be denied for pharmaceutical patent applications that are contrary to public health, which are those when either:

- The claimed subject matter poses health risk, which is understood as the product being, or pharmaceutical process resulting in, a substance of which use has been banned in Brazil.
- The claimed subject matter is of interest to the policies on medicines or pharmaceutical assistance within the SUS and does not meet the patentability requirements and legal conditions. Being of interest to the SUS means that the application involves a product listed as one of the strategic products according to ordinances of the Ministry of Health, currently Ordinance No. 978/2008 and its update, Ordinance No. 1,284/2010.

The role of ANVISA established by Resolution No. 21/2013 is very controversial and may be understood as contrary to the law. Therefore, it is likely that the current trend of challenging ANVISA's negative decisions in the courts will continue and grow.

2. How is a patent obtained?

Application and guidance

Patents are issued by the Brazilian Patent and Trademark Office (INPI) (*see www.inpi.gov.br*). Guidance is available in Portuguese only.

Fees are due:

- When the application is filed: about US$60.
- When the technical examination is requested: about US$190 (application with up to ten claims).
- Annually, before the patent is not issued: about US$100.
- If and when the patent issued: about US$80.
- Annually, from the third year of the patent validity until its final term:
- from year three to year six: about US$250;
- from year seven to year ten: about US$385;

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- from year 11 to year 15: about US$530;
- from year 16 onwards: about US$650.

These fees are for when using INPI's electronic platforms. For some services, if the petitions are filed in paper instead of using the electronic means, the official fees are higher.

Process and timing

The key stages are:

- The applicant files the application. After its filing, the patent application is kept secret for 18 months and then published for opposition purposes.
- A technical examination of the patent application must be requested within 36 months from the filing date. Otherwise, the application is dismissed.
- Once requested, INPI conducts the technical examination.

  INPI then makes its decision and, if it is satisfied with the application, will issue the patent.

Applications pertaining to the pharmaceutical field often take more than ten years from filing to be granted (nowadays 12 years on average), due to the significant backlog of pending work at INPI's corresponding technical divisions.

3. How long does patent protection typically last? Can monopoly rights be extended by other means?

Duration and renewal

Patent protection lasts for 20 years from the filing date, or at least ten years from when it is granted (*Article 40, IP Law*). It cannot be renewed.

Extending protection

There is no procedure to renew a patent or extend its term, even where there are delays to the issue of the related marketing approval. If INPI unreasonably delays examination of the patent application for more than ten years, the term of the patent is ten years from its grant (*Article 40, IP Law*).

4. How can a patent be revoked?

INPI and any other authorised body can revoke patents using a post-grant opposition procedure, within six months from the issuance of the patent, in the following circumstances:

- If the legal patentability requirements, for example novelty, inventiveness and descriptive sufficiency, have not been met.
- If the patented subject matter extends what was originally claimed.
- If any essential formal requirement was not met during the patent application process.

A patent can also be revoked by a nullity lawsuit before the federal courts at any time during the patent term. A patent can also be revoked through a forfeiture proceeding started by INPI or any interested party in cases of abuse or non-use (*section 80, IP Law*).

5. How is a patent infringed? How is a claim for patent infringement made and what remedies are available?

Conditions for infringement

Patent infringements include:

- Using a patented product or process without the patent owner's authorisation.
- Importing, for economic purposes, a patented product or a product that is obtained by a patented means or process, which has been placed on the external market by someone other than the patent owner, or without his consent.
- Supplying a component of a patented product, or material or equipment for carrying out a patented process, if the final application of the component, material or equipment necessarily leads to the exploitation of the subject matter of the patent.

Claim and remedies

When a patent is infringed, the patentee can file a civil lawsuit to seek to stop the infringement and obtain compensatory damages.

In addition, patent infringements are criminal offences punishable with imprisonment.

6. Are there non-patent barriers to competition to protect medicinal products?

Data package exclusivity (DPE) periods can be used to extend protection, or replace patent protection if there is no patent covering the product. Law No. 10,603/2002 only provides DPE for pharmaceutical products for veterinary use, fertilisers, agrochemicals, their components and similar products.

In relation to drugs for human use, the data package protection is solely based on the rules of unfair competition (*section 195, item XIV, IP Law*). Further, ANVISA must treat data packages submitted to it for marketing approvals as secret. However, the Superior Court of Justice (STJ) has suspended a court decision which granted DPE for a human drug (*Appeal #0184444-02-2011.3.00.0000*), based on the fact that, when Congress converted Provisional Measure No. 69/2002 into Law No. 10,603/2002, it intended to suppress DPE for human drugs. In addition, DPE for human drugs could jeopardise generic drugs in Brazil. Although this decision does not have binding effect, lowers courts are likely to follow the same understanding.

TRADE MARKS

7. What are the legal conditions to obtain a trade mark and which legislation applies? What cannot be registered as a trade mark and can a medicinal brand be registered as a trade mark?

Conditions and legislation

A trade mark application must be filed before INPI and it will mature into registration, if the trade mark at stake is:

- Visually perceptive.
- Distinctive.
- Not statutorily prohibited. Most statutory prohibitions are set out in Article 124 of the IP Law.

Scope of protection

Medicinal product brands can be registered as trade marks. However, the products must not have names or designations (*Article 5, Law No. 6,360/76*) that could lead to confusion between brands. ANVISA's rules relating to medicine labelling and commercial names are set out in Resolutions No. 71/2009.

8. How is a trade mark registered?

Application and guidance

Applications for trade mark registration must be filed with INPI.

Fees (through the electronic platform) are due:

- When the trade mark application is filed (if the applicant chooses the specification of product/services based on the INPI's pre-defined list): about US$170.
- Before the registration certificate is issued, when fees for the first ten-year period of registration must be paid: about US$240.
- During the last year of the ten-year registration term, when fees for any renewal application must be paid: US$350.

Process and timing

The key steps in the process are:

- The applicant files the application.
- The application is published, opening a 60-day term for eventual interested parties to file an opposition.
- If an opposition is filed in time, a notice is published, opening a 60-day term for the applicant to file a reply.
- INPI examines the application and eventual oppositions and, then, makes a decision granting or rejecting the application.
- INPI grants a registration certificate.

Currently, INPI is taking around three to four years to issue a trade mark registration.

9. How long does trade mark protection typically last?

Trade mark protection lasts for ten years.

Trade mark protection is renewable for successive ten-year periods, on payment of renewal fees (*Article 133, IP Law*).

Non-registered trade marks can be protected under unfair competition law.

10. How can a trade mark be revoked?

A trade mark can be revoked if it was issued contrary to any of the legal requirements, within 180 days after the issuance of the registration certificate and using the administrative procedure (administrative annulment request). After this period, a trade mark can be revoked through a nullity lawsuit, which must be filed within five years from the registration.

In addition, a trade mark registration can be revoked through forfeiture proceedings, on the request of any person with a legitimate interest if:

- After five years from its issuance, the owner has not used the trade mark in Brazil.
- The use of the mark has been interrupted for more than five consecutive years or, within that time, has been used in a modified form that implies alteration in its original distinctive character, as set out on the registration certificate.

However, the registration will not be revoked if its owner demonstrates that the non-use is due to legitimate reasons (for example, a delay in granting marketing approval by ANVISA).

11. How is a trade mark infringed? How is a claim for trade mark infringement made and what remedies are available?

Conditions

A trade mark is infringed if someone:

- Reproduces a registered mark wholly or in part, without the authorisation of the trade mark owner.
- Imitates a registered mark in a manner that could cause confusion with another mark.
- Alters the registered mark of a third party already applied to a product placed on the market.

It is also a crime to import, export, sell, offer or exhibit for sale, hide or maintain in stock either:

- A product branded with an illicitly, wholly or partially, reproduced or imitated mark of a third party.
- A product of the infringer's trade or commerce, held in a vessel, container or package and carrying a legitimate mark of a third party.

It is also prohibited to (*Article 195, IP Law*):

- Use fraudulent means to take another's clients for a person's own, or a third party's, benefit.
- Use another person's advertising expression or sign, or imitate it in such a way to cause confusion between products or businesses.
- Unduly use another's commercial name, business title or insignia, or sell, exhibit or offer for sale, or maintain in stock, a product with such references.

Claim and remedies

Infringements (*see above, Conditions*) are criminal acts punishable with imprisonment. The trade mark owner can also file a civil lawsuit.

The trade mark owner can file a civil lawsuit seeking damages. Trade mark counterfeited goods can be seized by customs authorities.

12. Outline the regulatory powers and enforcement action against counterfeiting in the pharmaceutical sector.

As the main authority responsible for regulating the pharmaceutical market, ANVISA can combat counterfeiting activities through its following powers:

- Controlling ports, airports and borders with the aim to block the exportation or importation of irregular medicines.
- Authorising the operations of companies manufacturing, distributing and importing medicines.

- Shutting down, as a sanitary surveillance measure, manufacturing plants and those premises involved in the management, importation, storage, distribution and sale of health-related products and services, if the relevant legislation is violated, or if they are a likely health risk.
- Regulating the conditions for the transportation of pharmaceutical products.
- Establishing security features (for example, stamps) in packages to help consumers to identify irregular products.

ANVISA frequently uses these powers, but sometimes their work is not very effective, due to the size of the country and to the fact that they have been understaffed for years.

IP and competition law issues

13. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector. In particular, the competition authorities and their regulatory powers, key legislation, whether pharmaceutical investigations are common, key recent activity and case law.

The Anti-trust Law is based on the following legislation:

- Federal Constitution, especially item IV of Article 170, which sets out the main economic principles.
- Law No. 12,529/2011, which establishes the rules against violations of the economic order and the Defence System of Competition.

The Administrative Council for Economic Defence (CADE) is the governmental agency empowered to prevent and repress infringements against competition, and to conduct educational efforts in this area.

Acts of concentration (such as mergers and acquisitions) must be submitted to CADE's analysis for prior approval where both (*section 88, Law No. 12,529/2011, and Interministerial Ordinance 994/2012*):

- One of the parties has more than BRL750 million of annual gross turnover.
- One of the other parties has at least BRL75 million of annual gross turnover.

CADE then assesses whether the concentration would involve the elimination of a substantial part of the competition of the relevant market, creation or reinforcement of a dominant position, or the domination of the relevant goods or services market, (*section 88, fifth paragraph, Law No. 12,529/2011*).

Every now and then CADE carries out an investigation into the pharmaceutical sector, especially cases involving acts of concentration. The most recent key activity of CADE in connection with the pharmaceutical sector refers to sham litigation claims against a group of pharmaceutical companies. The investigations led to a formal complaint against them, which is still pending a decision.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Brazil: overview.*

14. Briefly outline the competition issues that can arise on the licensing of technology and patents in a pharmaceutical context.

At present, the obligation of submitting technology licensing agreements to CADE's analysis is rather controversial.

Acts of concentration can be considered when two or more companies execute an associative agreement, consortium or joint venture (*item IV, section 90, Law No. 12,529/2011*). Based on this definition some licensing agreements have been submitted to CADE. However, CADE still does not have a clear position whether these agreements must be submitted to it or not.

In a case involving a non-exclusive patent licensing agreement (*Procedure # 08700.003898/2012-34*), CADE's members asserted, among other arguments, that:

- The anti-trust authorities must analyse this sort of contract to better understand how they work.
- A prima facie refusal to analyse a case by CADE must be exceptional and must be clearly allowed by law.
- The association of two or more companies, even without involving a merger and acquisition, can give rise to economic domination, especially in the high technology field.

Therefore, CADE decided to analyse the contract and it approved it. However, amendments to the agreement were ordered, such as the deletion of clauses that granted powers to the licensor to control decisions related to the business and the partnership structure of the licensee. This position tends to be followed by CADE in other cases.

15. Are there competition issues associated with the generic entry of pharmaceuticals in your jurisdiction?

Research activities involving third party patented products are allowed in Brazil (in Brazilian law, there are both experimental use and Bolar exemptions). Further, third parties (generic entrants) can study the subject matter of a third party's patent, with the aim to produce information, data and test results to be sent to ANVISA to obtain registration for manufacturing and marketing the product in question, immediately after expiration of the patent term (*item VII, section 43, IP Law*).

Some pharmaceutical companies have been trying to prevent generic entrants from entering the market by filing lawsuits seeking exclusive marketing rights (EMRs), data package protection exclusivity, patent term extension, and so on.

These issues are rather controversial in Brazil. Procedures currently handled by CADE have been filed by generic entrants against a group of pharmaceutical companies. According to these complaints, a group of pharmaceutical companies has been filing sham lawsuits to prevent generic entrants from launching generic drugs (*Procedures #08012.011508/2007-91, #08012.006377/2010-25 and #08012.007147/2009-40*).

16. Have abuse of dominance issues arisen in the pharmaceutical sector in your jurisdiction?

Abuse of dominance issues have not arisen in a way to oblige the break-up of a company. However, these issues are always mentioned in the context of any procedure before CADE that involves large research-based pharmaceutical companies.

17. Have parallel imports of pharmaceuticals raised IP and competition law issues in your jurisdiction?

Parallel imports of pharmaceuticals have not raised IP and competition law issues in Brazil. This is probably because most medicines in Brazil are already less expensive than in highly developed countries, due to the generally lower purchasing power of the Brazilian public and strong price control on medicines exercised by the government.

18. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved or accepted by a government or regulatory body? How is such a licence made enforceable?

It is mandatory to obtain approval for patent, trade secrets and trade mark technology transfer licences to remit royalty payments abroad. The approval procedure, which is lodged with INPI, is straightforward, but can take several months.

There are a number of limitations imposed on the amount of royalties that can be sent abroad, particularly between corporations exercising the same control, such as a parent and its subsidiary.

Patent and trade mark licencing agreements must be registered with INPI to be enforceable against third parties. For instance, if it is necessary for the licensee to take action against an infringer on behalf of the right holder (if the licence allows it). Such registration is also mandatory for the remittance of royalties to foreign licensors, as well as for tax deduction of royalties as operating expenses.

For information on pharmaceutical pricing and state funding, manufacturing, marketing, clinical trials, advertising, labelling, and product recall and liability, visit *Medicinal product regulation and product liability in Brazil: overview*.

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Recent transactions

- Succeeded in two lawsuits representing a major Brazilian jeweller unduly accused of copyright infringement.
- Negotiated an agreement for the construction of a new shipyard in Brazil.
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