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GLOBAL GUIDE 2020
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Pharmaceutical IP and competition law in Portugal: 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

Patents are governed by the Industrial Property Act (*Decree-Law 110/2018, 10 December 2018*).

A patent is granted to an invention, in all fields of technology, provided it is:

- New: it does not form part of the state of the art.
- Involves an inventive step: if, having regard to the state of the art, it is not obvious to a person skilled in the art.
- Susceptible to industrial application: it can be made or used in any kind of industry or in agriculture.

Scope of protection

Patents can protect:

- Products, substances or compositions used in surgical or therapeutic methods for treating the human body.
- Diagnostic methods used on the human body.

Patents cannot protect:

- Discoveries, scientific theories and mathematical methods.
- Materials or substances already existing in nature and nuclear materials.
- Aesthetic creations.
- Schemes, rules or methods for intellectual acts, playing a game or doing business and computer programs.
- Presentations of information.
- Processes for cloning human beings.
- Processes for modifying the germinal genetic identity of human beings.
- The use of human embryos for industrial or commercial purposes.

New processes for obtaining known products, substances or compositions can also be patented.

If a patent concerns a process, the rights conferred by it will cover the products obtained directly by the patented process.

2. How is a patent obtained?

Application and guidance

Patent applications can be made in the following ways:

- Application for a national patent to the National Industrial Property Institute (*Instituto Nacional da Propriedade Industrial*) (INPI). Detailed information and guidance on the application procedure and applicable fees is available on its website at: *https://inpi.justica.gov.pt*.
- Application for a European patent to the European Patent Office (*www.epo.org*).
- Application for an international patent filed under the Patent Cooperation Treaty 1970 before the INPI, the European Patent Office or elsewhere.

Process and timing

Provisional patent application. To ensure the priority of a patent, it is possible to file a provisional application and postpone the submission of all the required elements of a full application for a maximum of 12 months.

Regular patent application. Once a regular application has been submitted, a preliminary examination follows. Once all the formal requirements are satisfied, the intention to grant a patent is published in the national *Industrial Property Bulletin* within 18 months from the date of receipt of the application (exceptions can be made where an applicant requires an urgent publication).

Patent application opposition. Proceedings can be initiated within two months from the date the application is published by INPI.

The final patent decision is notified by INPI to the applicant and published in the *Industrial Property Bulletin*.

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

Duration and renewal

Patent protection typically lasts for 20 years and is not subject to extensions, although exceptions can apply.

Extending protection

Applications for supplementary protection certificates for medicinal products can be submitted to National Industrial Property Institute (INPI), to extend protection by up to five years. The application must include:

- A copy of the first marketing authorisation for Portugal identifying the product.

- The number and date of the authorisation.
- A summary of product characteristics.

In addition, a request for an extension of a supplementary protection certificate can be submitted in relation to medicinal products for paediatric use.

Supplementary protection certificates and extensions are provided by INPI in accordance with:

- Regulation (EC) 1901/2006, as amended, on medicinal products for paediatric use.
- Regulation (EC) 469/2009, as amended, concerning the supplementary protection certificate for medicinal products.

4. How can a patent be revoked?

A patent can be revoked by a court and in specific cases by the National Industrial Property Institute (INPI), following a request by the Public Prosecutor's office or by any person, including the patentee, on any of the following grounds:

- The object of the patent cannot be protected.
- If, when granted, procedures or formalities essential to the grant of the right were omitted.
- If public rules were breached.
- If the right does not belong to the patent holder.
- Failure to pay fees.
- Renunciation by the patent holder.

If the patent is not exploited within four years of the date of the patent application or three years of the grant date, whichever is later, a third party can apply to the INPI for the grant of a compulsory licence relating to the patent.

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

Conditions for infringement

A patent holder has the right to prevent others from manufacturing, offering, storing, commercialising or using a patented product or importing or possessing it for any of these purposes without his/her consent.

A patent holder can oppose all acts constituting a violation of his/her patent, including the:

- Manufacture of products that are covered by the patent.
- Use or application of means or processes that are the object of the patent.
- Import or distribution of products obtained by any of the above.

Claim and remedies

A civil action against the infringer can claim relief such as:

- An injunction.
- An order to deliver the infringing medicinal products.
- Payment of damages.

In addition, the unauthorised use of a patent is a criminal offence, subject to imprisonment for up to three years or a fine.

Dispute resolution and settlement

Patent disputes are dealt with by the Intellectual Property Tribunal (*Tribunal da Propriedade Intelectual*) or, in the case of an agreement by the parties, through an out-of-court Arbitration Tribunal. Settlements can be reached judicially or out of court by the parties.

Relevant international patent instruments and processes

Portugal is a contracting party to the European Patent Convention 1973 (EPC) and to the Patent Cooperation Treaty 1970 (PCT). Portugal is also a signatory of the Paris Convention for the Protection of Intellectual Property and of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPS).

A European patent application may be filed before the European Patent Office (EPO) by any natural or legal person, or any body equivalent to a legal person, irrespective of nationality and place of residence or business. Decisions adopted by the EPO are subject to a first and final judicial review by the Board of Appeals. within the framework of the EPC.

6. Are there non-patent barriers to competition that protect an originator's monopoly over an authorised medicinal product?

The Medicines Act provides exclusivity periods for medicinal products according to the "8+2+1" rule in Directive 2001/83/EC on the Community code relating to medicinal products for human use, as follows:

- For eight years after the grant of a marketing authorisation for a medicinal product, the originator company's pre-clinical and clinical data cannot be used in a generic marketing authorisation application.
- The generic medicine can only be marketed after ten years have elapsed from the initial grant of a marketing authorisation to the originator company.
- One additional year of marketing exclusivity is available if a new therapeutic indication is registered within eight years of the grant of the reference product's marketing authorisation, if it is considered of significant clinical benefit compared to existing therapies.

7. Are any restrictions placed on licensing or transferring patents to foreign parties? Are intellectual property transfers for inventions funded, or partially funded, by public investment restricted?

There are no restrictions on the licensing or transferring patents to foreign parties, or on intellectual property transfers for inventions that are funded (or partially funded) by public investment.

TRADE MARKS

8. 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?

Legislation and scope of protection

Trade marks are governed by the Industrial Property Act.

Provided a trade mark adequately distinguishes the products and services of one company from those of others, it can include:

- A sign or set of signs that can be represented graphically, such as:
  - names of persons;
  - drawings;
  - letters;
  - numbers; or
  - sounds.
- The form of the product or its packaging.

A trade mark can also consist of an advertising phrase for the products or services, provided it is distinct, regardless of protection conferred by copyright.

A trade mark application must contain the following information:

- Details of the applicant's business, tax number (if resident in Portugal) and e-mail address (if any).
- The products the trade mark is designed for:
  - grouped in accordance with the categories in the international classification of goods and services;
  - defined in precise terms; and
  - preferably using the alphabetical terms in the international classification of goods and services.
- Expressly indicate that the trade mark is an association or certification trade mark, if the applicant wants to register a collective trade mark.
- The registration number of any award featured or referred to in the trade mark.
- The colours in which the trade mark is used, if these are claimed as a distinctive element.
- The country of first application for registration of the trade mark, and the date and number of the application, if the applicant wishes to claim a right of priority.
- If applicable, the date from which the applicant has been using the trade mark.

A medicinal name can be registered as a trade mark with the National Industrial Property Institute (INPI).

The following cannot be registered as trade marks:

- Trade marks that are devoid of any distinctive character.
- Signs that exclusively consist of the form:
  - imposed by the nature of the product itself;
  - of the product necessary for obtaining a technical result; or
  - that confers a substantial value to the product.
- Signs that are exclusively made up of indications that may serve in commerce to designate the type, quality, quantity, purpose, value, geographic origin, period or means of production of the product or the service, or other characteristics of it.
- Trade marks that exclusively consist of signs or indications that have become common use in modern-day language or in the habitual and constant habits of commerce.
- Colours, unless they are combined with each other or with graphics, wording or other particular and distinctive elements.

General conditions and specific rules for naming medicines

A medicinal name can be registered as a trade mark with the National Industrial Property Institute (INPI).

The following cannot be registered as trade marks:

- Trade marks that are devoid of any distinctive character.
- Signs that exclusively consist of the form:
  - imposed by the nature of the product itself;
  - of the product necessary for obtaining a technical result; or
  - that confer a substantial value to the product.
- Signs that are exclusively made up of indications that may serve in commerce to designate the type, quality, quantity, purpose, value, geographic origin, period or means of production of the product or the service, or other characteristics of it.
- Trade marks that exclusively consist of signs or indications that have become common use in modern-day language or in the habitual and constant habits of commerce.
- Colours, unless they are combined with each other or with graphics, wording or other particular and distinctive elements.

9. How is a trade mark registered?

Application and guidance

A trade mark application is submitted to the National Industrial Property Institute (INPI). Detailed guidance on the applicable procedure and fees can be accessed at *https://inpi.justica.gov.pt*.

The standard fees are, for both an initial trade mark application and renewals:

- In one class: EUR126.17 for online submission and EUR252.33 for paper submission.
- For each additional class: EUR31.99 for online submission and EUR63.96 for paper submission.

Process and timing

Once the application is filed, there is an initial examination in accordance with the rules governing the composition of trade marks. The application is published online in the national *Industrial Property Bulletin*.

There follows an opposition period. Any opposition proceedings must be initiated within two months from the date the application is published by INPI.

If no grounds for refusal are found, the trade mark registration is granted and the approval decision is published.

10. How long does trade mark protection typically last?

A trade mark registration lasts ten years, beginning on the date of grant. It can be indefinitely renewed for subsequent ten-year periods.

11. How can a trade mark be revoked?

A trade mark can be revoked on the following grounds:

- The trade mark was not the object of serious use for a period of five consecutive years.
- The grounds for registration were not fulfilled.
- The trade mark may mislead the public, particularly as to the quality, nature or origin of the goods or services.

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

Conditions

A registered trade mark is infringed by another trade mark in the following circumstances (*Industrial Property Act*):

- The registered trade mark has priority.
- Both trade marks are designed for identical or similar products or services.
- The trade marks are so similar in graphic, figurative, phonetic or any other terms that the consumer can easily be misled or confused, or that there is a risk of association with the already registered trade mark, so that the consumer can only distinguish between them after attentive scrutiny or comparison.

The following actions constitute a criminal infringement of a trade mark:

- Counterfeiting, totally or partially, or reproducing by any other means a registered trade mark.
- Imitating a registered trade mark either as a whole or using characteristic parts of it.
- Using counterfeit or imitated trade marks.
- Using, counterfeiting or imitating well-known trade marks for which registration has already been applied for in Portugal.
- Using trade marks (even for products or services that are not identical or similar) that are an interpretation of, or are identical or similar to, previously existing trade marks for which registration has been applied for, which enjoy a prestigious reputation in Portugal or the EU (if they are Community trade marks) when such use seeks to derive unjust benefit from the distinctive or prestigious character of the prior trade marks or may be prejudicial to them.
- Using for products, services, an establishment or a company, a registered trade mark belonging to another person.

Claim and remedies

The civil and criminal penalties are the same as for infringement of a patent (*see Question 5, Claim and remedies*).

Dispute resolution and settlement

See *Question 5*.

Relevant international trade mark instruments and processes

See *Question 5*.

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

The regulatory powers relating to counterfeit medicinal products are jointly held by INFARMED (notably to execute laboratory quality tests on suspected counterfeit medicinal products), the Portuguese Tax and Customs Authority (PTCA), the Public Prosecutor's Office, and the police.

In this context, under Regulation (EC) 765/2008 on accreditation and market surveillance relating to the marketing of products, which sets out the market surveillance framework and controls of products entering the EU, the PTCA performs appropriate checks on the characteristics of medicinal products, by means of:

- Documentary checks.
- Where appropriate, physical and laboratory checks (via INFARMED) on the basis of adequate samples.

The PTCA, usually in co-operation with INFARMED, suspends the release of medicinal products when either of the following occurs during checks:

- An apparent counterfeit displays characteristics that give cause to believe that it presents a serious risk to health or safety.
- A product is not accompanied by the written or electronic documentation required by the relevant legislation, or is not marked in accordance with that legislation.

The counterfeit of medicines incurs criminal penalties of imprisonment up to eight years (*Article 282, Criminal Code*). INFARMED can also impose misdemeanour fines for circulating medicinal products that do not comply with the Medicines Act (up to 15% of the annual turnover of the infringer or EUR180,000 (whichever is the lower) per infringement).

IP and competition law issues

14. 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 Portuguese Competition Act (Law 19/2012, 8 May 2012) closely follows the EU competition law framework.

The national regime governs mergers and anti-trust. A breach of the relevant anti-trust rules can incur misdemeanour sanctions up to 10% of a company's annual turnover per infringement. The Competition Authority (*www.concorrencia.pt/vEN/Pages/Homepage-AdC-vEN.aspx*) is the public agency responsible for the enforcement of the national competition legal framework.

The Competition Authority has significant experience in merger cases in the pharmaceutical and healthcare sector, as reflected in decisions adopted in various procedures. Recent cases include:

- 52/2019: Lab Hilário de Lima / Lab São Lázaro.
- 31/2019: Chiesi / Raxone assets.
- 02/2019: Base/IMAG.
- 45/2018: Group HPA Saúde/HSGL.
- 38/2018: AH*IBERFAR/Logifarma.
- 33/2018: Essential Pharma/Priadel assets.
- 31/2018: Polski Bank/Stemlab.
- 16/2018: Riemser/Eisai assets.
- 15/2018: Unilabs/Laboratório Tâmega.
- 09/2018: Albimed/IMI.
- 08/2018: Recordati/Cystagon assets.
- 07/2018: Plural/Farmadeira.
- 06/2018: Luz Saúde/Idealmed III, Imacentro, Ponte Galante.

The Competition Authority has investigated and adopted several anti-trust enforcement decisions in the pharmaceutical sector. A recent case regarding unlawful conducts by several companies led to the imposition of fines (*National Association of Pharmacies et al v Competition Authority*), and was later judicially partially

confirmed by the Competition Court and p by the Lisbon Court of Appeal.

Another anti-trust case handled by the Competition Authority concerned abuse of dominance by a pharmaceutical company in the context of tender proposals submitted to NHS hospitals (*see Question 16*). The infringing company was fined EUR900,000.

15. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products? What compliance issues do parties to pharmaceutical technology licences and pharmaceutical distribution agreements need to consider?

Agreements on the licensing of technology and patents in the pharmaceutical sector can be caught by Article 101 of the Treaty on the Functioning of the European Union (TFEU) and by the equivalent national provisions of the Competition Act, specifically Articles 9 and 10.

Relevant competition rules are found in Regulation (EU) 316/2014 on the application of Article 101(3) of the TFEU to categories of technology transfer, which, under the Competition Act, must be closely followed by the Competition Authority.

Generally, competing companies under a licensing of technology or a patent agreement, or any other agreement, cannot directly or indirectly, in isolation or in combination with other factors under their control, have as their object to do any of the following:

- Restrict or delay the future entry of an innovative or generic medicine in the market to the detriment of patients.
- Restrict a party's ability to determine its prices when selling products to third parties.
- Allocate markets or customers.

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

Settlements regarding the generic entry of pharmaceuticals in the market can be challenging from a competition law perspective, including those settlements that may lead to a delay of generic entry in return for a payment by the innovative company to the generic company.

Other examples of potentially problematic agreements relate to settlements that contain restrictions beyond the exclusionary zone of the patent. This means that these reach beyond a patent geographic scope, protection period or exclusionary scope, as such agreements may not appear to directly relate to the IP rights granted by the relevant patents.

For example, the Portuguese Competition Authority opened an anti-trust inquiry (*Case PRC 2014/4*) after receiving information from the Secretary of State for Health regarding an agreement between pharmaceutical companies, under which the non-innovative company agreed to withdraw a generic medicine from the Portuguese market. The anti-trust inquiry was concluded in 2016, following a Competition Authority decision without the adoption of a statement of objections, deeming the companies' conduct lawful. The Competition Authority's findings in this investigation are the first in Portugal to combine competition law rules and IP law in the context of a patent settlement between originator and generic pharmaceutical undertakings. The decision provides ample guidance to economic agents regarding the requirements that must be fulfilled for such agreements to comply with competition law in Portugal.

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

The Competition Authority has adopted a decision finding a pharmaceutical company guilty of abusing its dominant position, in the context of proposals submitted in public tenders opened by several NHS hospitals (the *Roche* case).

The Competition Authority's investigation was based on a complaint lodged by a biopharmaceutical company that was a direct competitor in public tenders involving the supply of several medicines.

Due to its market share in several relevant medicine markets, the defendant company was considered to have a dominant position in relation to part of the medicines included in the proposals submitted to the hospitals. On the basis of the submitted documentary evidence (for example, tender announcements, tender bids and award decisions), the Competition Authority concluded that the defendant abused its dominant position in relation to several relevant medicine markets by, among other things, offering mixed-bundle and loyalty rebates in its medicine tender proposals, thereby infringing the relevant provision of the Competition Act. Although it took into account the mitigating circumstances of the defendant's co-operation throughout the inquiry, the Competition Authority still ruled against the company, imposing a misdemeanour fine of EUR900,000.

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

Issues have surfaced relating to parallel imports and competition law, including in the context of marketing authorisation holders aiming to secure the adequate and continuous supply of the national market, although these have not led to formal decisions by the Competition Authority.

19. 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? Are there any formalities or other requirements that must be complied with to make the licence enforceable?

There are no requirements for either a patent or trade market licence agreement or payment of royalties to be approved or accepted by a government or regulatory body. However, licences must be drawn up in writing and if the grant of sublicences is not authorised by the licence, these can only be granted with the written authorisation of the right holder (*Industrial Property Code*).

Licence agreements must be registered with the National Industrial Property Institute (INPI) to be made enforceable against third parties.

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Areas of practice. Life sciences; public and civil law litigation; regulatory; procurement.

Recent transactions

- Practises mainly in the health sector as a life sciences lawyer.
- Advising several pharmaceutical companies.
- Coordinates the firm's Life Sciences Practice Area, including legal teams representing companies in the pharmaceutical sector, in areas such as regulation (prices and reimbursement regulation, medicine legal framework, marketing authorisation procedures, promotion activities and clinical trials), commercial policies, litigation and arbitration.

Languages. Portuguese, English, French, Spanish

Professional associations/memberships. Portuguese Bar Association.

Publications. Portuguese jurisdiction chapters in the following publications:

- *Distribution and Marketing of Drugs Global Guide, Thomson Reuters, General Editors: Eric Stupp and Markus Schott, Bar & Karrer AG and Alison Dennis, Fieldfisher, First Edition.*
- *Medicinal product regulation and product liability in Portugal: overview, Practical Law Life Sciences Global Guide, Thomson Reuters.*
- *Pharmaceutical IP and competition law in Portugal: overview, Practical Law Life Sciences Global Guide, Thomson Reuters.*
- *Healthcare Enforcement and Litigation, Getting the Deal Through.*

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Areas of practice. Life sciences; competition; EU law; litigation; regulatory.

Recent transactions

- Extensive legal assistance to companies active in life sciences.
- Advising and representing clients (both defendants and claimants) before the Portuguese Competition Authority, the European Commission, the General Court of the European Union, the Court of Justice, the Portuguese Constitutional Court and the European Court of Human Rights.
- Matters involving anti-trust practices, merger control, state aids and sectoral inquiries.

Languages. Portuguese, English, French, Spanish

Professional associations/memberships. Portuguese Bar Association.

Publications. *European Lawyer; International European Law Tax Review; International Law Office; Portuguese Bar Association; Portuguese Bank Association; The Private Competition Enforcement Review; E-competitions*, including:

- *Distribution and Marketing of Drugs Global Guide, Thomson Reuters, General Editors: Eric Stupp and Markus Schott, Bar & Karrer AG and Alison Dennis, Fieldfisher, First Edition.*
- *Medicinal product regulation and product liability in Portugal: overview, Practical Law Life Sciences Global Guide, Thomson Reuters.*
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