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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 36/2003, 5 March 2003*).

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 include:

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

Patents cannot include:

- 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 *www.marcasepatentes.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 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, though exceptions can apply.



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### Extending protection

Applications for supplementary protection certificates for medicinal products can be submitted to 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 the case of medicinal products for paediatric use.

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

- Regulation 1901/2006 on medicinal products for paediatric use.
- Regulation 469/2009 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 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.
- A 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 to grant 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 consent.

A patent holder can oppose all acts constituting a violation of his 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.

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

The Medicines Act provides exclusivity periods for medicinal products according to the "8+2+1" rule in the Code for Human Medicines Directive:

- For eight years after the grant of 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 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, which is considered of significant clinical benefit compared to existing therapies.

# 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

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 the:
  - 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 product and service classification;
  - defined in precise terms; and
  - preferably using the alphabetical terms in the international product and service classification.
- 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.

### Scope of protection

A medicinal name can be registered as a trade mark with the 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 on 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.

## 8. How is a trade mark registered?

### Application and guidance

A trade mark application is submitted to the INPI. Detailed guidance on the applicable procedure and fees can be accessed at *www.marcasepatentes.pt*.

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

- In one class: EUR123.3 for online submission and EUR246.72 for paper submission.
- For each additional class: EUR31.27 for online submission and EUR62.54 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.

## 9. 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.

## 10. 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.

## 11. 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 it comprises 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, in products, services, or an establishment or 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*).

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

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

In this context, under Regulation 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 which 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 EUR44,891.81 per infringement).

## *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 Portuguese Competition Act (Law 19/2012, 8 May 2012) rules closely follow 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. 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 sector, as reflected in decisions adopted in various procedures. More recent cases include, for example:

- 06/2010: Cephalon/Mepha.
- 35/2010: Fujirebio/Innogenetics.
- 15/2011: Meda Pharma/Elidel business.
- 23/2011: Biomérieux/AES Skiva.
- 12/2012: Omega Pharma/GlaxoSmithKline.
- 18/2012: Biomet/Depuy Orthopedics business.
- 21/2013: Novo A/S/Otnortopco.

In terms of anti-trust proceedings, the Competition Authority has investigated and adopted several enforcement decisions in the pharmaceutical sector. A recent case regarding an illegal agreement between two pharmaceutical companies (following a complaint by an NHS hospital) led to fines (*Baxter and Glintt vs. Competition Authority*), later judicially confirmed by the Lisbon Commerce Court and subsequently by the Lisbon Court of Appeal.

Another anti-trust case recently handled by the Competition Authority regards the 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.

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

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 in Regulation (EC) 772/2004 on the application of Article 101(3) of the TFEU to categories of technology transfer agreements (Technology Transfer Block Exemption Regulation) 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 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.

### 15. Are there competition issues associated with the generic entry of 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 its geographic scope, its protection period or its exclusionary scope, as such agreements may not appear to directly relate to the IP rights granted by the relevant patents.

This topic has not been addressed at the national level, particularly by the Competition Authority. Most relevant enforcement actions have been centralised and performed at EU level by the European Commission, notably following the 2008 Pharmaceutical Sectoral Inquiry Report:

*http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry*

### 16. 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 grounded on a complaint lodged by a biopharmaceutical company, that was a direct competitor in public tenders which involved 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.

**17. 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.

**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?**

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 sub-licences is not provided for in the licence, these can only be granted with the written authorisation of the right holder (*Industrial Property Code*).

The licence agreements must be registered with the INPI to be made enforceable against third parties.

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