

Legal issues relating to patent litigation in Portugal

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In Portugal, as in many jurisdictions, there is often debate over certain legal issues in litigation involving enforcement of patents, especially chemical/pharmaceutical patents.

The scope of protection of patents changed in Portugal in 1995 from a situation where only processes were patent protected to the current position, where both processes and products are protected. This article provides a summary analysis of the key issues involved in patent protection in Portugal, including the validity of patents, the reversal of the burden of proof and the doctrine of equivalents, and aims to contribute to an understanding of the Portuguese legal system in relation to these issues.

PROTECTING PROCESS PATENTS AND PRODUCT PATENTS

Under the Portuguese Industrial Property Code of 1940 (*Decree 30 679, 24 August 1940 (Código da Propriedade Industrial)*) (CPI 1940) it was only possible to patent the processes used to, among other things, produce pharmaceutical products and not the pharmaceutical products themselves (*Article 5(4), CPI 1940*).

However, this changed with the following two events, as both provided for the patentability of chemical and pharmaceutical products:

- On 1 June 1995, the Industrial Property Code of 1995 (approved by Decree-Law 16/95 of 24 January) (CPI 1995) entered into force.
- On 1 January 1996, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was ratified.

The result of these events was that:

- Patent claims, that is, the extent of protection covering only the processes for obtaining pharmaceutical products that had been submitted under CPI 1940, was changed to include product claims (around 3,000 patent applications were in this situation).
- Once granted, now under CPI 1995, the patents included the new product claims. Therefore, these patents, which were applied for under the CPI 1940 legal framework, were granted in accordance with CPI 1995.

The application of CPI 1995 at the time of granting of patents that had been applied for under CPI 1940 has been supported by practically all subsequent case law dealing with that issue. This issue has in fact remained undisputed since the Lisbon Court of Appeal's Judgment of 16 March 2006 (*Collection of Case-Law, Volume II/2006, 69 and following*). (This judgment addressed the question of the application of law in time; the court concluded that the applicable law is the law that is in force when the intellectual property (IP) right is granted and not the law in force when the IP right is applied for.) The change from process claims to product claims has however raised other issues including the validity of the corresponding product patents under CPI 1995.

Validity of product claims

The validity of product claims under CPI 1995 has caused some debate. Changes to claims were not required to be published under CPI 1940. However, some argued that those patents were therefore null and void, due to the lack of publication of the changes, following the enactment of CPI 1995.

Under CPI 1995, for authorisation of changes that did not affect the essential elements of a patent, utility model or registration (trade marks and designs) all that was required was that these changes were published (*Article 26(1), CPI 1995*). This legal provision was however only applicable to industrial property rights that were already granted and not those that were still at the application stage. As applications for patents (just as applications for registrations), are of course different from granted patents it follows that when the law refers to a patent it clearly means the right that has already been granted (by the Portuguese Patent and Trade Mark Office (*Instituto Nacional da Propriedade Industrial* (INPI)) and not the corresponding application stage.

On this basis, according to the jurisprudence it became clear that the changes of process claims to product claims were not legally subject to publication. Therefore the granted patents, including the new product claims, were perfectly valid.

Application summaries

Patent applications in Portugal must be filed with the claims, the description, the designs and the summary of the invention (*Article 58, CPI 1995 and Article 62(1), CPI 2003*); however, only the summaries are published. Applications themselves were never published under CPI 1995 and are not currently published under CPI 2003 (*approved by Decree-Law 36/2003, 5 March (and amended by Decree-Laws 318/2007, 26 September; 360/2007, 2 November; 143/2008, 25 July) and by Law 16/2008, 1 April*).

The essential purpose of the publication of the summary is the disclosure, in brief, of an invention for the information of the interested scientific community (and of the applicant's competitors themselves) in the sector to which the patent application belongs. This is one of the ways technological innovation in all fields can evolve. That same scientific community, and in particular the competitors, should always access the patent claims (as applied for and as granted), so that they can exercise their rights if:

- They feel they have been harmed by the patent application (in this case, by filing an opposition).
- They do not want to breach the patent.
- They feel they are harmed by the patent granted (in this case by submitting a judicial appeal regarding the INPI's grant decision (*see below, Changes in claims: Judicial appeals and administrative oppositions*)).

Changes in claims

Changes introduced in claims during the patent application stage are not published by the INPI. To access claims, competitors can consult the specification of the corresponding patent at the INPI. This obligation or duty naturally falls on interested parties, especially those working in the technological sector in question, who conduct their activity with any diligence.

From 1985 (under CPI 1940) and under CPI 1995 and CPI 2003, patent claims are never published either in the patent application publication or in the publication of the notice on the grant of the patent. In fact, the only information published was (and is) the summary of the patent application, which does not contain the claims.

Judicial appeals and administrative oppositions. The issue of a patent's validity is confirmed by another relevant point, which is that a judicial appeal is, by its nature, the means through which the INPI's decisions relating to the granting or refusal of a patent, utility model or registration (trade marks and designs) are challenged. In contrast, the decisions of the INPI that are issued during the application stage for these kind of IP rights, in this case, decisions on changes to the claims in a patent application, should be challenged by means of an administrative opposition rather than a judicial appeal.

What this implies is that the appeals mentioned in Article 26(1) of CPI 1995 are, without a doubt, judicial appeals of decisions by the INPI authorising (non-essential) changes to rights that have already been granted. Therefore, Article 26(1) of CPI 1995 is not applicable to applications for the protection of industrial property rights but only to IP rights that have already been granted.

Period for oppositions. CPI 1995 provided for the publication of the notice of the grant of a patent (as does the European Patent Convention, 5 October 1973), upon which there would be a period for oppositions. However, CPI 2003 changed the system so that there is now a period for oppositions following the publication of the patent application, after which (any oppositions having been decided) the notice of the grant of the patent is published.

Publication of claims. Neither system, that is under CPI 1995 or CPI 2003, provides for publication of the claims. Additionally, neither system therefore provides for the publication of changes introduced to the claims during the patent application stage. However, both systems provide for the possibility of judicial appeals from the decisions issued by the INPI granting or refusing patents.

Confirming the legal view that changes to claims need not be published, the Portuguese Supreme Court of Justice stated that the publication of changes to patent claims made in the corresponding applications were not and are not necessary (*decision rendered on 4 November 2011 (Case n.º 772/06.9TBLRA.C1.S1-7.ª Secção)*).

REVERSAL OF THE BURDEN OF PROOF

Another issue that is regularly discussed in patent litigation in Portugal concerns the reversal of the burden of proof. In matters relating to the enforcement of process patents (the manufacturing processes of novel products) it is stipulated that there is a reversal of the burden of proof. There is therefore a legal presumption of patent infringement if the alleged offender does not prove that the manufacturing process of its product is different and not equivalent to the patented process.

The legal presumption places the patent holder in a special situation where he is not required to prove that the process used by the offender is in fact the process protected by the patent. It places

the burden of proving that the process it uses is not equal or equivalent to the protected process on the entity that produces or markets the final product of that process.

The presumption established by virtue of the reversal of the burden of proof does not constitute a simple or experience-based presumption, based on assessments of probability, on logical principles or on human intuition. It constitutes a true right that is statutorily granted to the holder of a process patent relating to the manufacture of a new product, based on international commitments taken on by the Portuguese State.

Introduction into Portuguese law

It is difficult to prove a breach of process patents without reversal of the burden of proof. As a result, it became vital to adopt the reversal of the burden of proof principle, which was set out in Portuguese law in CPI 1995 and in the current CPI 2003. This rule aims to compensate for the sometimes insurmountable difficulties in proving the use, by the offenders, of the process protected by the patent. The presumption is therefore not affected by any peripheral arguments (for example, the existence or non-existence of other processes by which the same product may be obtained that may be disclosed or covered by an application or grant of a patent and the difference in the performance of the processes used).

It was not easy to introduce the reversal of the burden of proof principle into the Portuguese legal system. It was considered impossible, in concrete terms, for the holder of the process patent to prove a breach of a patent in the context of judicial proceedings relating to such breach, notably due to not having access to the premises of the potential offender. Therefore, when in 1980, in the wake of WIPO, the legislator decided to reverse the burden of proof (*Article 3(b)*, *Decree-Law 176/80, 30 May*) the lobbies (groups attempting to influence government officials' decisions) immediately set about trying to get this principle repealed and it was actually repealed in June 1983 (*Decree-Law 285/83, 21 June*). The principle was however reinserted into Portuguese law due to Portugal's accession to the European Communities on 1 January 1986 and the accession to the European Patent Convention on 1 January 1992. Currently, the reversal of the burden of proof is addressed under Article 98 of CPI 2003.

Provision of evidence

Another special rule on the reversal of the burden of proof exists, which has been invoked (currently within mandatory arbitration proceedings) and that may be applied in cases concerning other patents that are not process patents, namely formulation patents. When the evidence relating to the qualitative and quantitative composition of the medicine is in the defendant's possession, and that defendant chooses to not make all of this information available to the claimant, the proof of facts that are only in the defendant's possession is considered to have been intentionally not provided.

The consequences of such behaviour should be framed within the reversal of the burden of proof rule set out in Article 344(2) of the Portuguese Civil Code, which states that: "*reversal of the burden of proof also occurs when the opposing party has intentionally made it impossible for the burdened party to provide proof, without prejudice to the penalties that procedural law specially imposes on disobedience or false representations*".

In these cases, the defendant would therefore have to prove that its medicines did not infringe the patents invoked in a lawsuit. If he fails to prove this it results, by law, in a presumption that such patents were infringed.

DOCTRINE OF EQUIVALENTS

Another important issue, even if only in the sense that it should be more frequently applied in patent litigation in Portugal, concerns the doctrine of equivalents. The doctrine of equivalents allows the patent holder to invoke the doctrine against the producer of a device or a process that (*Graver Tank & Mfg. Co. vs Linde Air Prod. Co. Graver Tank & Mfg. Co. vs Linde Air Prod. Co. (case 339US605, 1950)*):

- Performs substantially the same function.
- In substantially the same way.
- Obtains substantially the same result as the invention claimed in the previous patent.
- This is known as the triple test.

According to theories developed about the doctrine of equivalents, and in its most widely accepted understanding, the means or process protected by the patent covers all equivalent means or processes that constitute the "heart of the invention", for example, the:

- Essential elements.
- Significant features.
- Principal object of the patented means or process.

According to the major jurisprudence the doctrine of equivalents is applicable where:

- The patented invention and the questioned invention are both within the context of the same technical problem.
- Both present an identical solution and the modified elements (or variations) are known by a person skilled in the art.

Currently, the doctrine of equivalents, with some minor differences in formulation, is universally accepted and taken into account by the courts and the arbitral tribunals. This principle was already valid in Portugal under CPI 1940 and continues to be valid. The doctrine has been recently applied in Portuguese case law, both in judicial proceedings (*see Judgment of the Lisbon Court of Appeal of 17 September 2009*) and in arbitral proceedings, which are mandatory for pharmaceutical patent litigation (*Law 62/2011, 12 December*).

PATENT PROTECTION: BROADER SCOPE

Patent protection in Portugal has broadened in scope over the years; from a time when processes only were patent protected to the current position where both processes and products, and other patents such as formulation and use patents, are protected, notably for their enforcement against infringers.

Patent infringements are evidently not limited to the direct and literal infringement of patent claims. They should also be tested against the doctrine of equivalents, the application of which can lead to the existence of a real infringement that is no "less serious", for all purposes, than a literal infringement. The doctrine of equivalents and the reversal of the burden of proof are among the issues that must be considered in relation to infringement of patents.

The scope of patent protection is therefore not limited to its literal claims. It also covers all the technical solutions to the problem that the patent seeks to solve and that, even though they are not literally claimed, can be considered to be equivalent to the technical solution that is specifically claimed by the patent in question.

Practical Law Contributor profile



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Publications

- *The Intellectual Property Review, chapter 21 regarding Portugal (3 editions, 2012/2014).*
- *Several opinion articles in the press.*
- *Speaker and delegate on several conferences, seminars and workshops regarding IP.*