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Patent Litigation 2022

Portugal: Trends & Developments
Manuel Durães Rocha, António Andrade
and Ricardo Henriques
Abreu Advogados

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Trends and Developments

Contributed by:

Manuel Durães Rocha, António Andrade and Ricardo Henriques Abreu Advogados see p.8

Introduction

In Portugal, as 2021 came to an end, although it was an exhausting year for everyone in court, the number of patent disputes was decreasing.

The remaining litigation was focused on two particular topics.

The first involved disputes related to the validity of supplementary protection certificates (SPCs), notably concerning the question of whether a product is covered by the basic patent and the question of a second SPC for the basic patent in combination products.

The second involved lawsuits and decisions related to patents protecting pharmaceutical products and disputes with generics companies under Portuguese Law No 62/2011 of 12 December, in its current version adopted in 2018.

There was no litigation concerning other economic sectors where patents are essential, notably in the mechanical and telecommunications sectors

Notwithstanding the smaller number of cases, important rulings were issued in 2021 that may have a significant impact on substantive law, particularly concerning SPCs.

The following paragraphs try to accurately present the panorama of patent litigation in Portugal in 2021.

The Validity of SPCs

The main legal questions in dispute in the Portuguese courts concerning SPC litigation focused

on the fulfilment of the legal conditions – established either by Article 3 a) or Article 3 c) of EU regulation No 469/2009 – by patented pharmaceutical products aiming to obtain the extension term of protection granted by an SPC. Judgments were essential to decide on the protection by a second SPC on the same basic patent of combined pharmaceutical products.

All the three different levels of Portuguese courts were involved in clarifying these questions.

The Intellectual Property Court, where lawsuits are initiated and judged, as well as appeals from the decisions of the Portuguese Patent and Trademark Office (INPI), handed down decisions. The Lisbon Court of Appeal, which represents the first degree of appeal for lawsuits, but it is the final degree of appeal for decisions issued by INPI to grant or refuse registration to intellectual property rights, was also involved. One case before the Portuguese Supreme Court concerned discussion of the validity of an existing SPC; namely, whether the product protected by the SPC in question fulfilled the conditions established in Articles 3 a) and c) of EU Regulation number 469/2009.

Is the product contained in the claims of the basic patent in the sense of Article 3 a) of EU Regulation number 469/2009?

A significant number of cases were related to fulfilling the condition established by Article 3 a) of EU Regulation number 469/2009. Notably, whether the basic patent covers the product benefiting from SPC protection or whether the basic patent contains the active principle identified in the product benefiting from an SPC.

In these cases, the Portuguese courts followed guidance from ECJ decisions that analysed and ruled on these questions.

The Portuguese courts decided that a product protected by an SPC is protected in the basic patent in the following cases:

- where the active principle is claimed in the basic patent;
- where the active principle is not directly claimed in the basic patent but the functional definition formulae of the claims, interpreted in light of the description of the basic patent, implicitly contain and necessarily identify the active principle in a specific form.

Consequently, in these cases, the law must be interpreted in the sense that when the product's active principle is identified and protected in the basic patent, protection through an SPC should be granted. The judgment of the Supreme Court of Justice of 19 March 2021 concluded as follows:

“ I – Article 3 a) of the EU Regulation (CE) No. 469/2009 of 06-05-2009, [...] must be interpreted in the sense that a product composed of different active principles of combined effect is protected by a basic patent in force, when the combination of the active principles is expressly mentioned in the claims of the basic patent or although not explicitly claimed in the basic patent when it is implicitly and necessarily targeted in the claims of the basic patent...

II – The combination is implicit but necessarily targeted in the claims upon the fulfilment of three cumulative conditions: the combination of active principles must correspond to the functional definition contained in the claims; the combination of active principles must be necessarily covered by the description and drawings of the patent; each active principle must be specifically identifi-

able based on all the elements disclosed by the basic patent.

III – It is sufficient that the product results from the set of disclosed elements considered by a skilled person based on his common and general knowledge in the domain in question.

IV – Article 3 c), of EU Regulation No. 469/2009 must be interpreted in the sense that once a basic patent covers different products, in principle, it is possible to obtain more SPCs related with each one of the identified products provided that each one is protected per se in the basic patent in the sense of Article 3 a) of that Regulation interpreted in connection with Article 1 b) and c). “

On the contrary, on 20 May 2021, the Supreme Court decided that if a product is not contained in the basic patent in the sense of Article 3 a) it cannot benefit from SPC protection if, even though the active principle may be contained in the functional definitions of the claims of the basic patent, it is not specifically identified thereto.

In 2021, the Lisbon Court of Appeals also analysed and enacted an important and innovative ruling on SPCs. This judgment was published in the official journal of 29 October 2021 and is innovative in Europe.

In fact, a judgment of the Lisbon Court of Appeals decided that Articles 1 b) and 3 a) of EU Regulation No 469/2009 can be interpreted in the sense that, in principle, they do not oppose the grant of an SPC when an excipient can be qualified as the active principle in the sense of Article 1 b) if it is demonstrated that it produces a pharmacologic, immunologic or metabolic effect per se covered by the therapeutic indications contained in the marketing authorisation. According to the authors' interpretation of this judgment, in princi-

ple, an excipient can be included in the definition of the product established by Articles 1 b) and 3 a) of EU Regulation 469/2009 in the case that the excipient of a pharmaceutical product per se has therapeutic efficacy on its own covered in the marketing authorisation.

Consequently, the court decided to grant SPC protection to that pharmaceutical product overturning the decisions of the INPI and the judgment of the Intellectual Property Court.

Although this is the first and the only judgment issued by the Portuguese courts on this question, one may conclude that the future of the admissibility of SPC protection to products in which excipients per se have pharmacological or metabolic effects, such as active principles, is a possible new path.

In September 2021, courts judged a different question relating to active principles not directly or implicitly identified in the basic patent claims by a skilled person but developed after the date of priority of the basic patent. In these cases, following the decisions with regard to the Eli Lilly and Teva/Gilead cases at the ECJ, courts refused SPC protection because, at the priority date, it was not possible for a skilled person to identify or disclose information on the active principle in the claims of the basic patent. Thus the requisites of Article 3 a) were not fulfilled.

Is the product contained in the claims of the basic patent for a second SPC on the same patent in the sense of Article 3 c) of EU Regulation No 469/2009?

The second relevant question addressed to the Portuguese courts and decided in 2021 concerning the validity of SPC is especially important for combination products, namely in the case of the association of two active principles. The Portuguese courts were called to decide in what circumstances the combination of products is

contained in the claims of the basic patent in the sense of Article 3 c) of EU Regulation No 469/2009 and when, therefore, the owner of the combined product is entitled to obtain a second SPC from the basic patent.

In these cases, the Portuguese courts, once again, followed the guidance of the decisions of the ECJ that analysed and ruled on this question.

In two different rulings, the courts declared that if the second active principle is directly identified or is identified under a functional formula in the claims of the basic patent, then Article 3 c) of the EU Regulation No 469/2009 should be interpreted in the sense that the combined product is eligible for a second SPC. Because the new combined product defined under Articles 1 b) and c) resulting from the association of two active principles are protected in the basic patent and has not yet per se benefitted from an SPC.

This was declared in two different cases by the Lisbon Court of Appeals (AstraZeneca) and the Supreme Court (Sandoz/Merck), which confirmed judgments of the Lisbon Court of Appeals.

The reasoning in these decisions was that:

“a product is protected in the basic patent in the sense of Article 3 a) of the EU Regulation even though not expressly mentioned in the claims of the basic patent provided that the product is necessarily and explicitly targeted by a claim of that patent.

The combination of the two active principles, both protected in the basic patent, fulfil the conditions of Article 3 c) and is entitled to a second SPC because the combined product has not yet been granted an SPC. “

In its judgment, the Supreme Court declared a general definition of the product, although covered by a functional definition, was not enough. This has to be sufficiently clear and specific to conclude that the claim implicitly and necessarily targeted the product at stake. This judgment, published on 23 August 2021, is also important because it decided on the specific object of the inventive step in the sense of ECJ C-121/17 and C-650/17. The court declared that the combination of two products covered by the basic patent fulfils the requisite of Article 3 c) because the combined product has not yet obtained an SPC. There is no need to demonstrate that the combined products represent an advantage or innovation.

As said in the introduction of this text, there were no cases of actual patent infringement. This leads to the second group of patent litigation cases in Portugal.

Patent Litigation under Portuguese Law No 62/2011

This law, enacted on 12 December 2011, established and implemented a system of mandatory arbitration to solve disputes between patentees and generics companies in Portugal.

Law No 62/2011 established that once a new marketing authorisation for a generic product is published in the database of the Portuguese Health Regulatory Authority (Infarmed) patent and SPC owners have the right to initiate an arbitration against the generics company to decide whether the generic product encompassed by the new marketing authorisation infringes the patent or not. This was also applicable to the registration in Portugal of centralised marketing authorisations (MAs) granted by European Medical Authority (EMA).

Upon the provisions of the law, the patent holder has the right to initiate arbitration against the

generics company in thirty days, counted as of the date of publication. The generics company has thirty days to oppose. If no opposition is filed, the generics company is immediately prohibited from launching the generic product.

Some court judgments ruled that, if the patentee fails to initiate the arbitration proceedings within the thirty-day window, the patentee could no longer enforce its patents rights. However, other judgments decided the contrary in the sense that since the patent or the SPC remains in force, the right holder is always entitled to enforce the right against infringers.

The different senses of the courts' decisions on the same legal question led to significant doubts for patentees, who decided not to take the risk of their rights being left unprotected. They have always initiated arbitration even though in the cases where there was no conflict to prevent the impossibility of the future enforcement of their patents.

As a result, in Portugal, hundreds of new cases were initiated and decided under this compulsory arbitration system. Many of these cases corresponded to actual discussions of patent infringement, including preliminary injunctions related thereto, but many cases were merely formal disputes between patentees and generics companies. This happened because there was no real dispute between the parties. Still, in these cases, compulsory arbitration lawsuits were only initiated due to the official publication of a new application for marketing authorisations without actual infringement or threat of patent infringement.

In 2018, Law No 62/2011 was modified by Decree Law No 110/2018 of December 10th to abandon the compulsory arbitration system and replace it with a voluntary arbitration system to solve the same type of disputes. That law also

established the right to solve these disputes in court. In this case, the Portuguese Intellectual Property Court.

The first consequence arising from modifying the law was the abandonment of the arbitration system. It has been impossible to obtain the agreement of patentees and generics companies to enter into voluntary arbitration to discuss and decide these cases.

The second consequence corresponds to an increasing number of judicial lawsuits based on this specific law.

In these judicial lawsuits at the IP Court, as previously occurred in the compulsory arbitration system, once a new marketing authorisation for a generic product is published in the Infarmed database, patent and SPC holders have the right to initiate a judicial lawsuit against the generics company. This judicial lawsuit is intended to decide whether the generic product encompassed by the new marketing authorisation infringes the product or not. This is also applicable to the registration in Portugal of centralised MAs granted by the EMA.

Under the provisions of the modified law, the patent holder has the right to initiate a judicial lawsuit against the generics company within thirty days, counted as of the date of publication of the application or registration of the MA. The generics company has the right to respond in thirty days, calculated as of the service date. Failure to oppose immediately prohibits the generics company from launching the generic product in the market regardless of any other discussions, notably those concerning validity and infringement.

The problem of the risk for the patentee arising from not filing within this 30-day term (not yet solved by jurisprudence) has led to the strategy

of patent holders always initiating new judicial cases. The patent and SPC holders fear that if they do not file a lawsuit, they will be prevented in the future from enforcing the patent against an actual patent infringement. Although this strategy is understandable from the IP right-holders' perspective, it has led to an increasing number of merely formal lawsuits pending at the IP Court in cases where there is no actual conflict.

Unlike the arbitration system, this very short thirty-day term to prepare and file a judicial lawsuit based on patent infringement prevents the carrying out of negotiations between the parties to settle the case. Nevertheless, creative solutions – based on the provisions of the civil law aiming to suspend such terms – have been used.

Far from being a consensual solution on the part of the lawmakers for settling disputes between patent holders and generics companies, discussions now also continue between the Intellectual Property Court and the IP section of the Lisbon Court of Appeals.

The Intellectual Property Court usually dismisses these lawsuits on the following grounds:

- the grant of an MA to a generic company for a product whose origin is patent-protected does not represent patent infringement;
- the regulatory proceedings undertaken to obtain an MA are exempt from the exclusivity granted by patent law;
- therefore, there is no actual conflict between the patent holder and the generics company over the MA granted;
- courts exist to settle disputes between parties, and if no conflict exists, courts cannot be called on to decide; and
- there is therefore no procedural interest in this case.

Patentees have been filing appeals from these judgments, and the Lisbon Court of Appeals has usually overturned the rulings of the IP Court in its judgments.

The Lisbon Court of Appeals has a different interpretation of the law:

- the grant of an MA to a generics company for a product whose origin is patent-protected does not represent patent infringement;
- the regulatory proceedings undertaken to obtain an MA are exempt from the exclusivity granted by patent law;
- Law No 62/2011, however, establishes the right for the patent holder to file a lawsuit to enforce its IP rights based on the publication of a new application for a generic medicine;
- there is therefore an explicit procedural interest of the patentee in filing this special lawsuit to enforce its rights; and
- the Court of Appeals has ruled that this is a special lawsuit designed to defend patentees and quickly solve the eventual disputes between patentees and generics companies.

The following judgment of the Court of Appeals delivered on 21 October 2021 corresponds to the significant trend of the decisions delivered in 2021:

“ The grant of an MA for a generic product whose original is protected by an SPC allows the generics company to use the MA without control by the SPC holder at any time. The grant of an MA may not be an actual infringement of intellectual property rights. Still, it comes from common knowledge that such a situation objectively creates the risk of infringement. This clearly means that the patent holder has an actual and genuine interest in filing a lawsuit to condemn the holder of the MA to refrain from exploring the invention protected by the SPC as long as it is in force. Even though the holder of the MA declares that it

does not intend to launch the product in the market, it is perfectly plausible, legitimate, justified and proportionate, thus licit, that the SPC holder wishes to justify its right against the simple possibility or risk that a declaration of the generics company is not accomplished in the future. This is a better solution for settling the case, but it is also better for safeguarding legal certainty. “

This type of lawsuit has been occupying the courts but usually does not correspond to an honest discussion on the validity and actual infringement or threat of infringement. The number of judgments delivered in 2021 is relevant.

Outlook for 2022

It is expected that these trends will continue in 2022.

First, and similar to foreign jurisdictions, the legal questions related to the scope and extension of protection through SPCs shall continue.

Secondly, it is not expected that the current version of Law No 62/2011 will be modified. The eventual modification of the orientation of the Court of Appeals of Lisbon’s jurisprudence is not expected either. This is likely to develop on a case-by-case basis, depending on the facts and arguments in question.

Finally, judgments on patent infringement litigation related to cases currently pending in the courts is expected.

PORTUGAL TRENDS AND DEVELOPMENTS

Contributed by: Manuel Durães Rocha, António Andrade and Ricardo Henriques, Abreu Advogados

Abreu Advogados is an independent law firm with over 28 years of experience in the Portuguese market and present in ten locations. As a full-service law firm, Abreu is one of the largest law firms in Portugal, working with the most prestigious law firms in the world in cross-border projects. Universally recognised as market leaders in IP (notably in patent and trade mark litigation), Abreu's team has a comprehensive approach to the clients' commercial requirements, including industrial property rights,

copyright protection, enforcement (ie, administrative and court litigation), arbitration, as well as drafting and revision of IP licensing and contracts. Abreu has represented world-renowned pharmaceutical companies on lawsuits related to alleged patent and SPC infringement and invalidity, as well as judicial appeals before the IP Court and Court of Appeals against the refusal of SPCs. The team is also experienced in trade mark litigation, notably for famous and well-known brands.

AUTHORS



Manuel Durães Rocha is a partner at Abreu Advogados and co-head of the IP team, working primarily in the areas of intellectual and industrial property and in the health and pharmaceutical sector. He is a qualified Portuguese Industrial Property Agent, European Patent Attorney and European Trademark Attorney before the EUIPO. He has been the leading partner in some of the most complex cross-border proceedings under the scope of trade mark protection and patents and advises a range of Portuguese companies on life sciences matters, medical devices and luxury trade mark products, holding a unique track record in these matters in Portugal.



António Andrade is a partner at Abreu Advogados and co-head of the IP team. A specialist lawyer in IP law and a patent, trade mark and design attorney, he has over 20 years' experience. He is also a member of several national and international intellectual property organisations. His work ranges across intellectual and industrial property, in addition to specific cases in the area of life sciences, and he has been particularly involved in court and arbitration litigation regarding patents (especially pharmaceutical patents), trade marks, designs, copyright and trade secrets.



Ricardo Henriques is a partner at Abreu Advogados and co-head of the IP team, working primarily on matters related to intellectual property, information technology, personal data

protection, media and advertising and telecommunications. He is also an official Industrial Property Agent and Arbitrator at ARBITRARE and has been an appointed arbitrator in several arbitration proceedings. He advises clients on preventing and/or resolving IP and IT litigation, focusing particularly on copyright and technology litigation, intellectual property and technology licensing and other regulatory issues. He has worked for a wide range of national and multinational companies in the automotive, pharmaceutical, hardware and software development, retail and online retail sectors.

Abreu Advogados

Av. Infante D. Henrique, 26
1149-096 Lisboa
Portugal

Tel: +351 21 723 18 00
Fax: +351 21 723 18 99
Email: lisboa@abreuadvogados.com
Web: www.abreuadvogados.com

Abreu:
advogados