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Patent Litigation 2023

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Portugal: Trends & Developments

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Trends and Developments

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Introduction

The year 2022 was a challenging one regarding patent litigation, despite the fact that, as in 2021, the number of judicial and arbitration cases was not that high. In fact, contrary to 2012-2017 – where hundreds of arbitral actions were filed and judged – and since Law 62/2011 of 12 December was amended by the current Industrial Property Code (2018), the number of patent cases has significantly decreased.

The reason is quite simple: there was a mandatory arbitration system in place, which established that in disputes between pharmaceutical patents and generic drugs, the publication of a marketing authorisation application for a generic medicine triggered a legal term of 30 days for the patent holder to file an arbitration proceeding. Of course this caused a massive surge in patent litigation in Portugal until the end of 2017.

The amendment of Law 62/2011 saw the establishment of voluntary arbitration instead of mandatory arbitration. Since January 2018, the triggering of the 30-day legal term to file a voluntary arbitration proceeding implies the agreement of the parties to submit the dispute before an arbitral tribunal – or in a case where there is no agreement on that question, the patent holder must file a legal action before the Intellectual Property (IP) Court. Considering that usually there is no agreement between the parties to follow the arbitration route, patent litigation cases are filed in the Estate Court and this means a decrease in patent litigation cases in Portugal in pharma and biotech patents and generic medicines.

It is also noted that the law change has meant a considerable number of agreements between pharma originator companies (patent holders) and generic companies, with a view to avoiding the costs and slowness of legal proceedings.

In relation to other patents – eg, mechanical patents or utility models – the number of cases in Portugal during 2022 was also not significant.

What follows is an analysis of (i) patent litigation cases, (ii) Supplementary Protection Certificates (SPCs) and (iii) the trends in Information Technology (IT) and trade secrets litigation.

Patent Cases

Although, as mentioned previously, the number of patent litigation cases was not high in 2022, there were a couple of interesting proceedings regarding the enforcement of pharma and biotech patents, as well as cases related to patented medical devices.

Specifically, Abreu Advogados represented pharma companies in legal proceedings where the discussion of classical matters like literal infringement, infringement by equivalence, novelty, inventiveness and sufficiency took place.

There is a tendency of the IP Court to assess sufficiency in a much more in-depth way than it did in previous years.

The judgments on infringement by equivalence are also increasingly addressed with a much better technical approach.

In addition, the IP Court is increasing the assessment of infringement and validity within expert evidence, which is normally requested by the parties or ordered by the court on an ex officio basis.

Abreu Advogados has also been involved in very interesting cases dealing with patented medical devices, one of which is still pending.

In these cases, the discussions on the inventiveness of the enforced patents are concentrated on the problem/solution approach following the European Patent Office's (EPO's) Boards of Appeal case law.

Appeals before the Court of Appeal of Lisbon regarding decisions of the IP Court are also being argued, and some of them are still pending.

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. This is because the new combined product defined under Articles 1(b) and (c), resulting from the association of two active principles, is protected in the basic patent and has not yet per se benefitted from an SPC.

As for the rest, the IP Court still usually dismisses legal actions based on the view that a marketing authorisation application, and even the grant of a marketing authorisation to a generic company for a product whose origin is patent-protected, does not represent patent infringement.

In preliminary injunctions, if there is no actual launch onto the market of a generic product that infringes a patent, the patent holder must evidence irreparable harm within the legal concept of periculum in mora.

On the contrary, if the generic is launched onto the market, the patent holder should only evidence the existence of the patent right and the infringement, which is what the Enforcement Directive expressly states.

As for the mandatory legal action before the IP Court under Law 62/2011 – if no voluntary arbitration is agreed by the parties – the jurisprudence of the Court of Appeal of Lisbon remains stable regarding the legal standing and procedural interest of a patent holder in filing such action. In other words, there is an explicit procedural interest of the patent holder in filing this specific legal action to legitimately enforce its patent rights.

In a decision rendered by the Court of Appeal of Lisbon on 18 May 2022, the court was very clear:

"In the light of the ratio legis of Law No 62/2011, that provision must be interpreted in the sense that it does not prevent the filing of a lawsuit against a generics manufacturer based on an imminent or current violation of an industrial property right after the period set therein has elapsed, provided that the patent is in force. Otherwise, a new patent expiry date would have been created in the Portuguese legal order, which neither the Industrial Property Code nor the international conventions to which Portugal is bound in this matter to provide or consent; and which would, moreover, be of strongly questionable compatibility with the provisions of Articles 42 and 62 of the Constitution, which protect, respectively, intellectual rights and private property.

[...]

The submission of an application for authorisation to market a generic medicinal product is, therefore, sufficient for holders of intellectual property rights (eg, patents) on the active substance of the medicinal product to have an interest in acting, requesting that the applicant for authorisation is ordered to refrain from manufacturing, marketing, storing or exporting medicinal products.

And so, it is concluded that the general criterion for assessing the procedural interest – the violation of a right or the existence of a dispute – is derogated by Article 3 of Law No 62/2011, of 12 December – namely, in the wording of Decree-Law No 110/2018, of 10 September – in derogation from the general rules, the holders of [intellectual property] rights do not need to justify resorting to action based on an infringement, current or imminent, or to demonstrate an interest in acting.

It is, therefore, sufficient 'the publication, on the Infarmed website, of a request for [marketing authorisation] (or registration) for a generic medicine' so that the holders of the patents of the reference medicines can propose the action.

In addition, a recent decision from the Supreme Court of Justice on 15 September 2022, should be highlighted, which is a very comprehensive decision regarding all the issues that have been discussed in relation to the matters at stake.

"Regarding the question that matters to be considered, we have that this Supreme Court of Justice (SCJ) has taken a consistent orientation in the sense of recognising the interest in acting to the plaintiffs with recognised industrial property rights, resulting from a patent, in the face of a request for a marketing authorisation, however publicised, from which we will closely follow a recent statement that, in a clear and well-structured way, highlights the jurisprudential orientation adopted.

Thus, in the judgment of this SCJ, handed down on 21 April 2022, within the scope of Process No 40/20.3YHLSB.L1.S1, it was understood, and this Collective Court supports, that the holders of IP may propose the special action provided for in Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September, in view of the publication of a simple request for a marketing authorisation, gleaning from this paragraph: 'As for the matter of the defendants' appeal involving the assumption of procedural interest, even if this is not included in the Code of Civil Procedure, it is admitted and recognised by case law'.

[...]

This requirement of interest in acting being fulfilled when, in relation to the plaintiff, 'the situation of need, in which he finds himself, requires the intervention of the courts […] hand of the process or to make the action proceed – but no more than that' – Antunes Varela/José Miguel Bezerra/Sampaio e Nora, op. cit. p.180 and 181 – it follows from this that the claimant of a conviction action will only have a procedural interest as long as he alleges the violation of his right – cfr Manuel de Andrade, Elementary notions of civil procedure, p.80 or by Antunes Varela/José Miguel Bezerra/Sampaio e Nora, op. cit. p.182.

[...]

Law No 62/2011, of 12-12, when introducing amendments to the Medicines Statute, also added an Article 23-A, in which it is expressly stated that the request that aims to obtain inclusion of the medicine in the co-payment cannot

be rejected based on the existence of any industrial property rights, and that the decision to be taken on the inclusion or exclusion of medication in the reimbursement is not intended to assess the existence of any industrial property rights.

[...]

In tune with this understanding also the decision of the SCJ of 5-17-2018, in proc. 889/17.4YRLSB.S1 repeats that '[the] grant of [a marketing authorisation] for a generic does not constitute, in itself, a violation of the industrial property right arising from the patent of the reference medicine, not being included, for therefore, in none of the actions prohibited by the provisions of Article 101.º, No 2, of the Industrial Property Code' (text of Article 102 of the new Industrial Property Code, approved by Decree-Law No 110/2018).

[...]

As already stated – in the decision of SCJ of 8-4-2021 in proc. 219/19.0YHLSB.L1.S1 of which the here rapporteur was a subscriber and whose understanding was replicated in ac. STJ of 9 December 2021, in proc. 225/20.2YHLSB-A.S1, of which the rapporteur here was rapporteur there – being a condemnation action at stake, such as the one proposed by the plaintiffs against the defendants, the question that arises as an alternative is to know whether 'the presentation of a marketing authorisation application for a generic medicine is sufficient for the holders of intellectual property rights (eg, patents) on the active substance of the medicine to have an interest in acting, requesting that the authorisation applicant is condemned to abstain from the manufacture, marketing, storage or export of medicinal products' or if 'the presentation of an application for authorisation to market a generic medicinal product is not sufficient for holders of intellectual property rights to on the active substance of the medicine are interested in acting, making it necessary that the applicant has started or is about to start manufacturing, marketing, storage to, or the export of medicines.

In this context, the important thing is to find out whether the general criterion for assessing the procedural interest mentioned above is derogated by Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September.

[...]

In this regard, it is enunciated in decision of the SCJ of 8-4-2021 that we follow [The] text of Article 3 of Law No 62/2011, of 12 December, in the wording of Decree-Law No 110/2018, of 10 September, is compatible with two interpretations: the first in the sense that it prevents holders to invoke their IP rights after the expiry of a period of 30 days counting from the publication on the Infarmed website of the application for authorisation to market a generic medicine; the second in the sense that it does not prevent or, in any case, does not absolutely prevent holders from invoking their rights after the 30-day period has elapsed.

The preference for the first interpretation would determine one of two things – either that the procedural interest would be waived or, even if the procedural interest was not waived, that the application for a marketing authorisation would have as an automatic, immediate and necessary effect the 'need reasonable, justified, well-founded, to resort to the process'.

In any case, the first interpretation, in the absolute, rigid terms in which it is stated, would cause

insurmountable or almost insurmountable difficulties – as they concluded; eg, the judgment of the Constitutional Court No 123/2015, of 7 July 2015[11], the judgment of the SCJ of 7 December 2016, handed down in case No 554/15.7YRLSB.L1.S1 or the judgments of the Constitutional Court No 187/2018, of 10 April 2018, and No 496/2018, of 10 October 2018.

Concretising: the decision of Constitutional Court No 123/2015 deemed 'unconstitutional the normative dimension resulting from Article 3, paragraph 1, in conjunction with Article 2 of Law No 62/2011, of 12 December, according to which the holder of an industrial property right may not sue the holder of the marketing authorisation or the applicant for a marketing authorisation beyond the period of 30 days, counting from the publication by Infarmed referred to in Article 9, paragraph 3, of the same Law, for violation of Article 20, paragraphs 1 and 5, of the Constitution of the Portuguese Republic.

[...]

On the other hand, the preference for the second interpretation, which does not prevent or does not at all prevent holders from invoking their rights after the 30-day period has elapsed is compatible with two solutions: the first in the sense that the special action provided for in Article 3 of Law No 62/2011 may be proposed as long as an application for authorisation to market a generic drug is published on the Infarmed website – advocated Evaristo Mendes, 'Patents for medicines. Arbitration required. Jurisprudence commentary. Precedent of Law No 62/2011', in: Intellectual Properties, No 4-2015.

In favour of the second term of the alternative, it is argued that holders of intellectual property rights need – continue to need – to justify recourse to action based on an infringement, current or imminent, and to demonstrate an interest in taking action. The presumption of interest in bringing an action could not be fulfilled by the allegation by the plaintiff that there is, on the part of the defendant, the intention to market the drugs for which he requested marketing authorisations, above all, 'when the court is faced with the peremptory assertion of the defendant, who has not challenged the claimant's right nor has he been accused of having violated it, that he does not intend to commercialise the generic in question before the expiry or invalidation of the patent'.

Violation, or the threat of violation, of the applicant's IP rights would always be necessary because the non-existence of the legal obligation to initiate an arbitration action – whenever the application for marketing authorisation for a generic drug is publicised and because the mere formulation of such a request does not, in itself, generate any infringement or threat of infringement of the patent relating to a pharmaceutical compound used in the production of medicines – it would determine that there is no interest in acting by the holder of that patent in an action in which the abstention of infringement is petitioned of the rights arising from the same and the prohibition of alienation of the marketing authorisation to third parties, to the exclusion of other circumstances that point to the likelihood of the prediction of the violation of a right.

[...]

Having exposed the issue in its argumentative terms and consequences, we accept, as we have already done in the transcribed judgment and in the one of 9 December 2021 – in proc. 225/20.2YHLSB-A.S1 of which the rapporteur here was rapporteur there – that Article 3 of Law No 62/2011, of 12 December, is essentially

in favour of holders of IP rights not needing to justify recourse to action based on an infringement, current or imminent, or to demonstrate an interest to act, being sufficient to publish, on the Infarmed website, a request for marketing authorisation (or registration) for a generic drug. It is not required that the interested party who intends to invoke his industrial property right under the terms of the previous article must do so before the IP Court, being able to do so there (at the IP Court) but also before an institutionalised arbitral tribunal or before a non-institutionalised arbitral tribunal.

[...]

In short, the process provided for in Article 3 of Law No 62/2011, of 12 December, sets up a special process for settling rights that is likely to be triggered by the publication of a simple application for marketing authorisation (at which time there will be no in principle, any infringement or imminent threat of infringement of industrial property rights), allows the holders of rights to establish it or not, depending on their interest in it. And can such a procedure be initiated within a period of one month from this publication, because this fits the logic of a quick process, intended to end, ideally, before there is an Infarmed decision on the application for marketing authorisation.

[...]

It was decided and an attempt was made to explain that the general criterion for assessing the procedural interest, dependent on the concrete allegation of violation of the invoked right, is derogated by Article 3 of Law No 62/2011 (in the wording of Decree-Law No 110/2018, of 10 September) which accepts the exceptional possibility that holders of IP rights do not need to justify the recourse to action based on an infringement, current or imminent, it being sufficient to publish, on the Infarmed website, an application for marketing authorisation (or registration) for a generic drug. However, this understanding, in deviation from the aforementioned general rule, is admitted because, in the absence of any concrete violation of the authors' rights, the existence/publication of the marketing authorisation application comprises, in the interpretative economy of the observed precepts, relevant objective reasons for, even in this case, grant protection of interest to the claim of the plaintiffs. Even if there is no violation of the invoked right, there is an marketing authorisation publication request and it is this existence and what it means that determines the configuration of the interest in acting."

SPC Cases

In what concerns SPC litigation, the pending cases are still focused on the fulfilment of the legal requirements established by Article 3(a) and (c) of EU Regulation No 469/2009.

In this regard, the tendency of the IP Court and Court of Appeal of Lisbon remains to follow the European Court of Justice (ECJ).

The IP Court has decided that a product protected by an SPC is protected in the basic patent (i) where the active principle is claimed in the basic patent and (ii) 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.

In addition, a very important decision from the Court of Appeal of Lisbon granted an SPC based on the following assumptions:

"If it is demonstrated that a non-active principle (excipient) – combined with an active principle – produces a pharmacologic, immunologic or metabolic effect per se covered by the therapeutic indications contained in the marketing authorisation.

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."

This is a landmark judgment not only because it overturned the refusal to grant an SPC decision from the Patent Office and the IP Court decision rendered in an appeal, but also because it is believed that it was the first grant of an SPC in the EU in the particular circumstances.

The Trend of IT and Trade Secrets Litigation

In Portugal, there has been an increase in litigation regarding patents in the field of telecommunications and IT.

Furthermore, so-called computer-implemented inventions are also subject to a large number of litigation cases, also involving copyright issues.

Software in general is not patentable in Portugal, however if the software has a technical contribution which is novel, inventive and has industrial applicability, it can be protected by a patent. The computer-implemented inventions are thus software patents and this area is being quite well developed in Portugal, notably through a large number of start-ups.

Following this notable development, it is inevitable that disputes over software patents are increasing.

Trade secrets is also an area where there are some legal disputes and it is believed that these will increase.

Outlook for 2023

It is expected that the trend of more judicial litigation regarding (i) patented medical devices, (ii) IT, TMT patents and computer-implemented inventions and (iii) trade secrets, will continue in 2023.

Legal questions related to the scope and extension of protection through SPCs shall also be ongoing.

Substantial changes to the technical and legal approach are not expected from the IP Court and Court of Appeal of Lisbon.

The impact of the Unified Patent Court is crucial to be assessed.

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Abreu Advogados is an independent law firm with over 28 years of experience in the Portuguese market, and is 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 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 and designs litigation, notably for famous and well-known brands.

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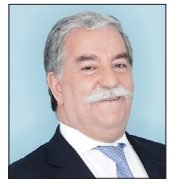

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