THE PATENT LITIGATION LAW REVIEW

Fifth Edition

Editor
Trevor Cook

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For further information please contact Nick.Barette@thelawreviews.co.uk

Editor
Trevor Cook

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PREFACE

Although patent litigators should always be mindful that patent litigation has, with some justification, been called the 'pathology of the patent system' – not so much as a criticism but more in recognition of how remarkably little patent litigation there is – when seen in relation to the ever increasing number of patents in force at any one time, patent litigation is also the anvil on which patent law is forged. This is because the 'black letter' law of patents tends to be terse by comparison to most other areas of law, and it is only with experience of how courts and tribunals interpret such law and apply it that one can start to appreciate its true scope and effect.

This, in part, explains how such similarly expressed statutory provisions as one finds in different patent laws can sometimes result in such different outcomes in different jurisdictions – disparities that are all the more evident when they concern the same product or process, and patents that, though in different jurisdictions, are all members of the same family, and are all intended to protect the same invention. As it becomes increasingly common for patent disputes to proceed in multiple jurisdictions, these differences in outcome have become ever more apparent.

Such disparities are not only a consequence of differing substantive laws, or differences in interpretation of similarly expressed laws, they can also be a consequence of the considerable procedural differences between jurisdictions, the nature of which is outlined in this Review. However, the Review does not only summarise patent litigation procedures: the respective contributors to it, as leading practitioners in each of their jurisdictions, also focus on recent developments in substantive patent law as demonstrated by the most important recent court decisions in their respective jurisdictions, meaning that this Review also provides insight into the current controversies that affect patent law generally.

The events of the past 18 months have not left patent litigation unscathed, and it will be interesting to see how the changes that the pandemic has brought, such as remotely conducted hearings, survive the much-hoped-for return to normality. Some indication of the strength of views engendered by this issue is provided by the arguments before the European Patent Office's Enlarged Board of Appeal in Case G 1/21 regarding the legality of mandating online hearings during the pandemic. In rejecting in July 2021 the challenge to the validity of this measure, the Enlarged Board was careful not to express a more general opinion about the legality of mandating such hearings.

The pandemic has also been used as a pretext for certain interests to push for a waiver of the patent and trade secrets provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights, of which discussions are now taking place in the World Trade Organization, despite it not being intellectual property that has impeded the roll-out of

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vaccines, and the manifest need for effective patent protection to incentivise the continuing search for new and improved medical treatments.

In the European Union, the big news this summer came in June 2021 when the German Federal Constitutional Court made an order regarding the constitutional challenge mounted to German adherence to the Agreement on a Unified Patent Court (UPCA). The order has the effect of allowing Germany to participate in the UPCA and the Protocol on the Provisional Application of the UPCA. German participation in those measures is a necessary prerequisite to their entry into force.

This decision provides for the prospect of the UPCA entering into force in the second half of 2022. The UCPA will allow (but not as yet mandate) traditional European patents to be litigated in a single court covering much of the European Union.

Such entry into force will also trigger the entry into force of EU Regulations that establish a new type of European patent, the European patent with unitary effect, which will allow patentees following the European route to opt for a single patent covering all the EU Member States that participate in the UPCA, as opposed to the traditional European patent, which has effect as a bundle of national patents. Litigation over this new type of patent will only be possible in the Unified Patent Court.

However, not all is plain sailing as not only must the UPCA regain its lost momentum, but it also appears that its implementation will proceed without formal amendment of the UPCA, despite it containing provisions that assume UK involvement in it. As the United Kingdom, as a result of its withdrawal from the European Union, can no longer participate in the UPCA, this may be seen as introducing a measure of uncertainty in respect of its legal basis. We should, however, know much more by the next edition of this Review.

Trevor Cook
Wilmer Cutler Pickering Hale and Dorr LLP
New York
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Chapter 12

PORTUGAL

Marta Alves Vieira[1]

I OVERVIEW

The Portuguese patent litigation system has some particularities that make it a rather unique system.

In Portugal, patent litigation generally takes place before the Intellectual Property Court (the Court). This specialised state court, with jurisdiction at a national level, has been operating in Portugal since 30 March 2012 and is competent to handle all actions concerning industrial property in all forms as provided in law, including both patent enforcement and invalidation proceedings.

However, in the field of pharmaceutical patents, special attention must be given to the patent enforcement system put in place by Law No. 62/2011 of 12 December 2011 (Law 62/2011).

Law 62/2011, which came into force on 19 December 2011, originally established a mandatory arbitration regime for the settlement of disputes arising from industrial property rights whenever reference medicinal products (covered by patent rights) and generic medicinal products were at stake; however, after seven years in force, significant changes to Law 62/2011 were approved by Decree-Law No. 110/2018 of 10 December 2018 (Decree-Law 110/2018) and came into force on 9 January 2019.

A special pharmaceutical patent enforcement system was maintained, but the nature of the arbitration changed from mandatory to voluntary. If the parties do not agree to submit the dispute to arbitration (which is generally the case), the enforcement action shall be brought before the Court. This unique pharmaceutical patent enforcement system has been playing a decisive role in the patent litigation landscape in Portugal, as it has been providing a stage for the most relevant patent case law in Portugal.

Criminal proceedings and voluntary alternative dispute resolution means are also available to interested parties to deal with patent disputes but are rarely used in Portugal.

II TYPES OF PATENT

Inventions can be protected by two types of industrial property rights: patent and utility models. Patents can be granted to any type of invention in any field of technology, whether it is a product or a process, as well as for new processes for obtaining products, substances or compounds that already exist.

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1 Marta Alves Vieira is of counsel at Vieira de Almeida. The first few editions of this chapter were co-authored by António Andrade, who has left the firm. His contribution is acknowledged with appreciation.

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Apart from applying for a national patent through a national route in accordance with the Portuguese Industrial Property Code (IPC),[2] it is also possible to apply for protection at both the European and international levels under the European Patent Convention and under the Patent Cooperation Treaty, respectively.

The duration of a patent is 20 years from the date of application, and the invention must have novelty, inventiveness and industrial applicability. At the European level, an extension may be granted to specific pharmaceutical and plant protection products that have been authorised by regulatory authorities by means of a supplementary protection certificate (SPC). An SPC can extend a patent right for a maximum of five years.[3] Furthermore, an additional six-month extension is also available in Portugal if the SPC relates to a medicinal product for children for which data has been submitted according to a paediatric investigation plan.[4]

Applications for patents must always be examined. The examination is a crucial part of the patent grant. New inventions involving an inventive step can also be protected as utility models if they have an industrial application.

Apart from applying for a utility model through a national route in accordance with the IPC, it is also possible to apply for protection at the international level under the Patent Cooperation Treaty. The duration of a utility model is six years from the date of application, and it can be renewed for up to 10 years.

Although the requirements for protection are similar for both types of protection of inventions, utility models are not available for inventions dealing with biological material or chemical and pharmaceutical substances or processes. The main difference between a patent and a utility model is that in the latter, a mere technical advantage will suffice for the respective protection, provided that it has novelty, inventiveness and industrial applicability.

III PROCEDURE IN PATENT ENFORCEMENT AND INVALIDITY ACTIONS

As a rule, patent rights shall be enforced and invalidated before the Court. Furthermore, according to Article 34 of the IPC, the declaration of nullity or annulment may only result from a judicial decision (i.e., one rendered by the Court).[5]

Law 62/2011 provides for a special legal system of enforcement of industrial property rights that is applicable to all disputes, including preliminary injunctions, related to reference medicines and generic medicines, regardless of whether they involved process, product or utilisation patents, or SPCs.

2 Approved by Decree-Law No. 110/2018 of 10 December.

3 See Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, amended by Regulation (EU) 2019/933 of the European Parliament and of the Council of May 2019. See also Regulation (EC) No. 1610/96 of 23 July 1996 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products.

4 In accordance with Regulation (EC) 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004, amended by Regulation (EC) 1902/2006 of the European Parliament and of the Council of 20 December 2006 and by Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018.

5 Following the entry into force of the new IPC in 2019, the Portuguese Patent Office is now entitled to declare, *ex officio*, the nullity of an SPC if the basic patent lapsed before its expiry date or if it was annulled (see Article 118(11) of the IPC).

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Until January 2019, mandatory arbitration proceedings should be initiated within 30 days of publication by the Portuguese Authority of Medicines and Health Products (INFARMED), on its official website, of the marketing authorisation application or of the date of the registration application, in the case of centralised marketing authorisation.

Decree-Law 110/2018, which amended Law 62/2011, maintained the same enforcement system for pharmaceutical patents and generic medicines but revoked the mandatory arbitration route (although there are still some pending cases). Since 9 January 2019, an interested party who seeks to enforce an industrial property right, in light of the publication of a marketing authorisation application for generic medicines, must still do so within a 30-day deadline, but the nature of the arbitration is now voluntary rather than mandatory. If the parties do not agree to submit the dispute to arbitration (which has been the rule), the enforcement action shall be brought before the Court.

In light of the recent changes in Law 62/2011, the Court is now being faced with a growing number of patent cases, and it has been questioning the patentee's procedural interest to bring an action against the generic companies where no acts of infringement have yet been committed. Owing to discussions on several procedural matters, the expertise of the Court in the field of pharmaceutical patent cases is not sufficiently developed yet.

Because patent infringement is considered a criminal offence, punishable with imprisonment for up to three years or a penalty up to a maximum of 360 days, the injured parties may also resort to criminal courts; however, the resort to criminal proceedings in Portugal is mainly reserved for the most blatant cases of trademark infringement – counterfeiting – and is not common for patent enforcement cases.

Where the cases demand specific technical skills and expertise that the judges and arbitrators do not possess, the court or tribunal may be assisted by an expert (a technical adviser).

Industrial property has guarantees established by law for property in general and enjoys special protection under the IPC and other legislation and conventions in force; therefore, a patent holder or a licensee or sub-licensee (if this is contemplated in the respective licence or sub-licence contract) has standing to sue.

The enforcement of patent rights can be made through actions aiming at preventing or putting an end to the infringement of those patent rights. In relation to invalidity claims, the Public Prosecutor's Office or any interested party are entitled to bring a suit to annul or declare the nullity of a patent against any holder of registered patent rights. Nullity can be invoked at any time by any interested party. Annulment actions, following the enactment of the new IPC, must now be filed within five years of the decision of the respective grant.

Patent infringement and invalidation proceedings before the Court follow the procedural rules set out in the Civil Procedural Code. Patent infringement proceedings under Law 62/2011 follow the mandatory provisions of that Law.

Voluntary arbitration proceedings also follow the Law on Voluntary Arbitration,[6] as well as the procedural rules of the arbitration adopted in each case. Patent infringement proceedings before the criminal courts follow the procedural rules set out in the Criminal Procedural Code.

In any case, as a rule, the parties submit their pleadings with evidence, which gives them the opportunity to present their case in writing and to file their requests in relation

6 Approved by Law 63/2011 of 14 December 2011.

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to further evidence to be presented. The evidence generally includes documentary evidence and testimonial evidence, but it may also include written depositions, legal opinions and expert opinions.

The IPC contemplates measures and procedures to ensure the enforcement of the industrial property rights, including specific rules for obtaining relevant evidence of infringement and discovery, as well as for interim measures or preliminary injunctions. In this context, whenever evidence is in the possession of, held by or under the control of the opposing or a third party, the interested party may request to the Court that it be presented, provided that, to justify its intentions, it presents sufficient indication of a violation of industrial property rights.

Regarding acts carried out on a commercial scale, the applicant may ask the Court to allow the presentation of banking, financial, accounting or commercial documents that are in the possession of, accessible to or under the control of the opposing or third party.

Whenever industrial property rights are violated, or there are grounds to believe a third party may cause serious, difficult-to-repair harm to those rights, the interested party may request urgent and effective provisional measures aimed at preserving evidence of the alleged violation. This legal provision gives rise to a great amount of discussion in doctrine and case law in relation to the interpretation of 'damage to an industrial property right that is serious and difficult to repair' – in other words, irreparable harm.

The interested party may also request the submission of detailed information (from the alleged violator or from third parties) on the origin and distribution networks of the goods or services it suspects infringe industrial property rights.

In invalidation proceedings before the Court, a patentee may limit the scope of protection of an invention by altering the claims both via the administrative route (before the Patent Office) and the judicial route (before the Court).

Separately or within the scope of a counterclaim in infringement proceedings, it is common for the defendant to request the declaration of nullity of the patent, usually claiming that the patent did not meet, at the time of its grant, the patentability requirements.

This was a hot topic in the context of mandatory arbitration under Law 62/2011 as the case law of the arbitral tribunals has been very torn concerning the arbitral tribunals' own competence to assess the validity of patents (or SPCs), even if raised as a defence with mere *inter partes* effects. The courts of appeal have been strongly divided about this topic, despite the fact that none of the decisions rendered had a general binding force.

Decree-Law 110/2018 inserted a new provision in Law 62/2011, allowing the invalidity objection to be assessed and declared with mere effects *inter partes* in the context of voluntary arbitration proceedings.

However, this new provision does not at all settle the previous discussions on this topic, and discussions are being held in relation to the legal nature of this new provision (in particular, whether it has an interpretative nature); therefore, and until the case law is settled, this controversy is still pertinent, not only in pending mandatory arbitrations but now in the context of voluntary arbitration, as well as in the context of judicial proceedings. The Court has also been questioning the possibility of filing an invalidity counterclaim under Law 62/2011 special proceedings.

A typical patent infringement or invalidation case in the Court may take a couple of years or more, depending on the complexity of the matters involved therein. A preliminary injunction may take between three and eight months.

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In respect of voluntary arbitration proceedings under Law 62/2011, as amended by Decree-Law 110/2018, the Law establishes that the final hearing must take place 60 days after the filing of the defence, although this deadline was already provided for in the context of mandatory arbitration, and it was rarely complied with.

In the context of potential voluntary arbitration, the applicable Law on Voluntary Arbitration establishes a 12-month period for the arbitration award, which may be extended by agreement of the parties. This deadline to give a final award was often extended in the context of mandatory arbitration, particularly in more complex cases.

Regarding the costs of the proceedings, court fees are calculated based on the value of the dispute, as fixed by the court on the basis of the worth of the interest of the parties in dispute. Arbitration costs include the arbitrators' fees (in the context of mandatory arbitrations, usually around €60,000 for the arbitral panel, in cases where the arbitration reached its end with a final merit award) and the administrative costs (secretary and other administrative expenses).The parties must also consider the attorney's fees and possibly the experts' fees.

It is possible to apply for an interim injunction seeking a provisional decision that prevents or puts an end to the infringement of an industrial property right, including the seizure of the infringing products.

With regard to preliminary injunctions, Article 345 of the IPC provides that whenever there is violation of, or justified fear that, another party may cause serious and difficult-to-repair harm to an industrial property right, the court may, if the interested party so requests: (1) order appropriate measures to rule out any imminent violation; or (2) prohibit continuation of the violation.

The injunction can be effective against the infringer's suppliers or customers if these are also parties in the injunction proceedings and, therefore, specifically covered by the court's injunction decision.

Preliminary injunctions related to pharmaceutical patents may also be filed before the arbitral tribunals, currently in the context of voluntary arbitration.

Ex parte decisions are not common in patent matters in Portugal. Likewise, there is neither regulation nor tradition in Portugal on protective letters used as means of reducing risk in *ex parte* preliminary relief. In this sense, a protective letter would not reduce the risk of *ex parte* preliminary relief, notably because of the lack of regulation on those protective letters.

Article 343 of the IPC foresees the applicant's liability in provisional and precautionary measures, and it was recently amended to include, as a ground for possible damages, the measure of being 'abusively applied for or in bad faith'. It also provides that the damages can be claimed by the defendant as well as by 'any injured third party'.

IV SUBSTANTIVE LAW

i Infringement

Articles 101(1) and 101(2) of the previous IPC already provided that the patent confers upon the holder the exclusive right to use the invention anywhere in the Portuguese territory, which translates into the right to prevent others from manufacturing, offering, storing, marketing or using the patented product, or importing or possessing it for any of the mentioned purposes without his or her consent.

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Article 102 of the current IPC further lists the following specific prohibited conduct:

a the use of a protected process (or the offer to use the process, if the third party knew or should know that the unauthorised use is prohibited);

b the offer, stockpiling, marketing, use and the importation for any of the previous conducts of the products directly obtained by the process that is the subject of the patent; and

c indirect infringement.[7]

Proceedings can be brought for preparatory acts, although difficulties may occur in relation to the evidence of those acts.

In civil proceedings – before the judicial courts and arbitral tribunals – liability for infringement lies with the civil liability of the infringer, namely the company that performed the infringement. The liability of foreign suppliers is difficult to discuss and prove in civil proceedings and is not usually a topic in those actions.

In criminal proceedings – before the criminal courts – criminal liability lies with the company that infringed IP rights but can also lie with the directors of infringing companies.

In accordance with Article 98 of the IPC,[8] 'the scope of protection conferred by the patent shall be determined by the contents of the claims and the description and drawings shall serve for the interpretation thereof'. This means that patent claims are commonly interpreted under this legal criterion.

Neither this provision nor other provisions of the Portuguese law foresee equivalents for determining the extent of protection by a patent; however, the doctrine of equivalents is regularly invoked in patent litigation cases and is also regularly considered and applied by the courts and arbitral tribunals.[9]

Furthermore, considering the fact that Portugal is a member of the European Patent Convention (EPC), although the Protocol on the Interpretation of Article 69 European Patent Convention of 5 October 1973, as revised on 29 November 2000, has no equivalent under Portuguese Law, it should be applied by the Portuguese courts and tribunals as legal framework for the interpretation of the patent claims and determination of their scope of protection, regardless of the patents being European or Portuguese, for reasons of equality and legal certainty.

The prosecution history may also play an important role in determining the scope of patent protection, notably whenever the doctrine of equivalents is argued before a Portuguese court.

The contents of an opposition, a reply, an amendment or any submitted document filed by the parties, subject to the previous analysis of the Patent Office, will also play an important role in determining the scope of a patent. There is no estoppel defence or estoppel effect under the Portuguese civil procedural rules, and there is no precedent rule.

7 Very similar to Article 26 of the Agreement on a Unified Patent Court.

8 Clearly based on Article 69 of the European Patent Convention, which states that 'the extent of the protection conferred by a European patent or a European patent application shall be determined by the claims. Nevertheless, the description and drawings shall be used to interpret the claims'.

9 The doctrine of equivalents was first introduced by the Portuguese courts with two judgments rendered by the Appeal Court of Lisbon in 1974 in the framework of the IPC of 1940.

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ii Invalidity and other defences

Under Article 32 of the IPC, patents, utility models and registrations shall be totally or partially null if:

a their object cannot be protected;
b when granted, procedures or formalities essential to the grant of the right have been omitted; or
c public rules have been violated.

In addition, under Article 114 of the IPC, a patent shall be null and void if:

a its object does not meet the requirements of novelty, inventive step and industrial application;
b its object cannot be protected according to the applicable provisions of the IPC;
c it is recognised that the title or heading given to the invention covers a different object; or
d its object has not been described such that anyone skilled in the art can carry it out.

Under Article 33 of the IPC, patents, utility models and registrations can be totally or partially annulled if the holders are not entitled to them, namely if:

a the right does not belong to them; or
b they were granted with disregard for the rights set forth in the procedural rules set out in the IPC.

One or more claims may be declared null and void or annulled, but partial nullity may not be declared, nor may a claim be partially annulled. The typical grounds for an invalidity action are the lack of novelty or inventiveness, or industrial applicability (industrial use). 'Insufficient disclosure' has also been raised in recent cases.

The legal and technical discussions on those grounds do not differ from those of the EU countries – and the EPC States – meaning that jurisprudence from the European Patent Office (EPO) is the most relevant basis for those discussions.

In relation to the obviousness or inventiveness test, the EPO's jurisprudence on this matter is generally followed – notably the 'could/would' approach to determine whether a patent is 'obvious' or 'inventive' in view of the prior art. In addition, consideration of the person skilled in the art in each case is defined under the EPO's case law. For the insufficient disclosure argument, the plausibility test is normally considered.

In relation to other defences, although rarely applied in practice, the interested parties can object to patent infringement by invoking:

a legal limitations of the rights conferred by a patent (e.g., acts performed in private and not for commercial purposes or only performed exclusively for trial or experimental purposes – *Bolar* exemption);
b exhaustion of rights (as the rights conferred by a patent do not allow its holder to forbid acts related to the products protected by it after its sale by the patentee or with his consent, in the European economic area);
c non-opposability (as, in general, rights conferred by a patent are not opposable in Portuguese territory before the date of the application or of priority if it is claimed against someone who, in good faith, has learned of the invention by his or her own means and used it or made effective, serious preparations to use it); or
d the existence of a licence.

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V FINAL REMEDIES FOR INFRINGEMENT

Under Article 347 of the IPC, whoever illegally violates the industrial property rights of another person, be it with criminal intent or by mere blame, must pay compensation to the injured party for the damages resulting from the violation.

First, the industrial property right holder has to prove the causality of the infringement for the damage's calculation. In determining the amount of compensation for losses and damage, the court shall take into account, in particular, the profit obtained by the violator and the resulting damage and lost profits suffered by the injured party. It shall also take into consideration the costs borne with the protection of the right in question, and the investigation and termination of the harmful conduct.

In calculating the compensation to be paid to the injured party, the revenue resulting from the violator's unlawful conduct shall be considered. Normally, the evidence in this regard is produced by means of expert evidence with the necessary inspection of the parties' commercial accounts. If the mentioned damages aspects fail to be evidenced, there is also the possibility of calculating damages based on the licence analogy criteria.

In the absence of specific evidence for the purpose of calculating the damages or regarding the total extent thereof, the decision may also determine that the damages be ascertained during the phase of execution against the infringer.

The Court may also decide on additional measures relating to:

a the fate of the goods that have violated the industrial property rights;

b the prevention of the continuation of the proven infraction; or

c the publication of the judicial decision.

VI OTHER TYPES OF PATENT PROCEEDINGS

Apart from the proceedings already mentioned, in the context of infringement proceedings, declaratory judgment suits are also available to obtain a decision of non-infringement of an industrial property right, usually in anticipation – on the part of whoever intends to use or market what is protected by that right – of enforcement actions that the owner of that right may initiate (although not very common). The Court is competent in those cases.

Patent infringement is considered a criminal offence, punishable with imprisonment for up to three years or a penalty up to a maximum of 360 days; therefore, the injured parties may also resort to criminal courts or district courts with general competence, including criminal cases, although this route is rarely used.

The parties are also entitled to seek alternative means of dispute resolution, such as mediation or voluntary arbitration, provided that the parties agree to such alternative dispute resolution. Law 62/2011 expressly foresees the voluntary arbitration route to resolve pharmaceutical patent disputes related to reference medicines and generic medicines; however, this route is almost never used in relation to patent disputes, and it is not being used in the context of the current version of Law 62/2011 either.

The parties often manage to reach an alternative solution to litigation by executing a settlement agreement either before or during pending proceedings.

There are mechanisms to obtain a compulsory licence to a patent. A patent holder who, without a good reason or legal basis, does not exploit an invention, directly or under licence, or does not do so in such a way as to meet national needs, may be obliged to grant a licence for its exploitation.

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Compulsory licences must be requested from the Patent Office, and the interested parties – the applicant and the patent holder – are allowed to file their arguments on the request. If the Patent Office decides in favour of the granting of the compulsory licence, it shall give both parties one month to appoint an expert who, together with the expert appointed by the Patent Office, shall agree, within two months, on the conditions of the compulsory licence and the compensation to be paid to the patent holder.

Customs proceedings – under the relevant EU Regulations – are significantly growing as a supplementary route for preventing patent infringement.

VII APPEAL

A first instance decision can be appealed to the second instance court (the court of appeal) both on matters of fact and of law. The decision under appeal is assessed by a panel of three judges, one of whom is the reporting judge. In particular circumstances, decisions from the second instance courts can be appealed to the Supreme Court of Justice, which decides only on matters of law. Generally, new evidence is not allowed at the appeal stage, and it is not common to have hearings at this stage, the appeal process basically being proceedings in writing.

In relation to the decisions given by arbitral tribunals constituted under Law 62/2011, the arbitral award may be appealed to the second instance court.

In the previous mandatory arbitration system, this provision has often been construed as preventing the decision of the second instance court from being appealed to the Supreme Court of Justice. Although, in most cases, the Supreme Court used to reject ordinary appeals, appeals were admitted in cases where, according to the procedural law, the decision was always appealable.[10]

Usually decisions on the appeals – both at second and last instance – may take up to eight months, and the appeal court fees are not significantly high.

VIII THE YEAR IN REVIEW

i Ruling of the Supreme Court of Justice of 18 March 2021

In the context of nullity proceedings brought by a generic company against the holder of an SPC before the Court, the Supreme Court of Appeal confirmed the Rulings of both the Court and the Lisbon Court of Appeal confirming the validity of the SPC, in light of Article 3(a) and (c) of the SPC Regulation.[11]

A first SPC had been granted to an active ingredient, and a second one had been granted to a combination of the active ingredient with another active ingredient based on the same basic patent. The validity of the second SPC was challenged by a generic company.

The Supreme Court concluded the following.

a Article 3(a) of the SPC Regulation[12] shall be interpreted in the sense that a product that is composed of several active ingredients of combined effect is 'protected by a basic

10 Namely, in case of the contradiction of decisions rendered by the Lisbon Court of Appeal or based on the violation of certain rules related to court jurisdiction or *res judicata*.

11 Ruling of the Supreme Court of Justice of 18 March 2021, Case 281/17.0YHLSB.L1.S1.

12 Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

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patent in force' when the combination of the active ingredients of its composition is expressly mentioned in the basic patent claims or, even if not expressly mentioned in those claims, when it is implicitly, but necessarily, addressed in the basic patent claims.

b The combination will be implicitly, but necessarily, addressed in the claims as long as it complies with three cumulative conditions:

- the combination of active ingredients corresponds to the 'functional definition included in the claims of a patent';
- the combination active ingredients is 'encompassed, in the light of the description and the drawings . . . by the covered invention [by the patent]'; and
- each of the active ingredients is 'specifically identifiable, in the light of all the elements disclosed by the said patent'.

c In any case, it is not required that the product result 'in an individualised form, in terms of a concrete composition, from the technical specifications of the . . . patent'; it is sufficient for it to result from the combined disclosed elements, as considered by a skilled person in the art, 'based on his/her general knowledge in the domain under discussion'.

d Article 3(c) of the SPC Regulation shall be interpreted in the sense that as long as a basic patent protects several distinct products, the holder can, in principle, obtain several supplementary protection certificates, each one being related to each of those products, 'provided that namely each one of them is "protected" as such, by that "basic patent" as ruled by Article 3(a) of the SPC Regulation (EC) No 469/2009, interpreted in conjunction with its Article 1(b) and (c)'.

This decision is final.

ii Ruling of the Supreme Court of Justice of 4 August 2021

In the context of the enforcement of pharmaceutical patent rights under Law 62/2011, the first instance court has been dismissing the proceedings on the basis of the understanding that the claimants lack procedural interest to bring an action against the defendants, as the marketing authorisation applications do not correspond to acts of infringement and do not constitute a threat to the claimants' industrial property rights.

The Supreme Court of Justice confirmed in its decision that the industrial property rights' holders can bring the special action of Article 3 of Law 62/2011 (in the version of Decree-Law 110/2012 of 10 September) in light of a mere application for a marketing application.[13]

IX OUTLOOK

The legal system governing mandatory arbitration in respect of disputes over industrial property rights, including injunction proceedings, involving reference medicinal products (patent rights) and generic medicinal products, has brought great developments in patent litigation in Portugal; however, this mandatory arbitration system was replaced in 2019 by an alternative system, and there are many new and old issues that have yet to be overcome. Several procedural discussions are currently being held before the first instance and the appeal courts.

13 Ruling of the Supreme Court of Justice of 4 August 2021, Case 219/19.0YHLSB.L1.S1.

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It is clear that – as expected - arbitration is not being selected as the way to generally enforce pharmaceutical patent rights against generic companies because generic companies reject entering into arbitration agreements.

It is still too early to make a full assessment on how those changes will impact the current patent litigation landscape and the Court's respective role (as well as the competent court of appeal's role).

Furthermore, in the upcoming years the patent litigation landscape in Portugal will strongly depend on the future developments of the Unified Patent Court (UPC) system as the UPC is expected to have exclusive competence in respect of European patents and European patents with unitary effect. Following the German ratification of legislation for the UPC Agreement, a major obstacle in the process has been removed; however, prospects for the UPC are still not entirely clear. Should the UPC system become a reality, there will be a huge impact in the Portuguese current practice.

In addition to the growing problem of counterfeiting, which is common to many economies, internet infringements are increasing. Copyright, technology transfer, emerging technologies and software protection, namely in the field of computer-implemented inventions, are likely to undergo a great deal of development, which will be accompanied by corresponding litigation.

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Appendix 1

ABOUT THE AUTHORS

MARTA ALVES VIEIRA

Vieira de Almeida

Marta Alves Vieira is of counsel at VdA, and she is currently the head of the intellectual property practice. Marta obtained her law degree from the University of Lisbon, with a university extension in arbitration. She is admitted to the Portuguese Bar Association and also has a proficiency certificate as a trainer.

Marta Alves Vieira joined VdA and the intellectual property practice area in 2012. She has a strong background in litigation and arbitration, as well as solid experience as a litigator in the Portuguese courts gained over approximately 18 years.

In this capacity, she has been involved in intellectual property litigation (in particular, pharmaceutical patent litigation) and has advised companies in all intellectual property matters.

She is a member of several important international intellectual property organisations, such as MARQUES and ECTA, where she is currently a member and the secretary of the design committee.

VIEIRA DE ALMEIDA

Rua Dom Luís I, 28
1200-151 Lisbon
Portugal
Tel: +351 21 311 3400
Fax: +351 21 311 3406
mav@vda.pt
www.vda.pt

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