THE PATENT LITIGATION LAW REVIEW

Fourth Edition

Editor
Trevor Cook

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FOURTH EDITION

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

Editor
Trevor Cook

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CONTENTS

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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, in fact, 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 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 extraordinary events of the last several months have not left patent litigation unscathed, and it will be interesting to see how the changes that the pandemic has wrought, such as remotely conducted hearings, survive the much-hoped-for return to normality. The pandemic was also seen in its early days by some commentators as an excuse to renew pressure to expand the scope of the defences to patent infringement. Although some legislatures have succumbed to such pressure, these measures contribute nothing to the search for the new and improved treatments, which remains the real priority. Instead, this search only serves to emphasise the need for stronger and better focused incentive structures, in which patent law has a role to play.

On a global basis, courts in multiple jurisdictions continue to be involved in controversies over standard-essential patents, one emerging aspect of which is the potential challenge that these present to the territorial nature of patents, as exemplified by the judgment of the UK Supreme Court in August 2020 upholding the imposition by the English courts of a global licence, on terms that they have assessed, as the price for exploiting standard-essential patents

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in the UK. The past year has also seen such controversies expand from mobile telephony into the automotive sector. In the United States, the most prominent controversy remains the question of excluded subject matter, as to which there remains a dearth of clear judicial guidance. In Europe, one apparent trend has been towards greater flexibility as to injunctive relief, particularly in medicine – by, for example, in the UK, tailored injunctions, or, in Germany, expedients such as compulsory licences. Although, in Germany, there has also been also talk of legislation to address the issue.

Also as to Europe, previous editions of this work have, perhaps unwisely, tempted fate by including a chapter on the anticipated entry into force of the long-heralded Unified Patent Court Agreement. We have adopted a different approach in this edition, waiting for the dust to settle after two major developments earlier in 2020. The first of these was the decision of the Federal German Constitutional Court upholding, albeit on narrow procedural grounds, a challenge to the consistency of the Agreement with the German Constitution. The second was the decision of the UK, which withdrew from the EU on 31 January 2020, to withdraw its ratification of the Agreement. This raises the prospect, even if the German ruling is susceptible, as the German government currently hopes, of a legislative solution, of having to amend the Agreement before it can enter into force to take account of the UK withdrawal.

Trevor Cook
Wilmer Cutler Pickering Hale and Dorr LLP
New York
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Chapter 14

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 (that correspond to 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. In case the parties do not agree to submit the dispute to arbitration (which has been generally the case), it is established that the enforcement action shall be brought before the Court. This unique pharmaceutical patent enforcement system has been playing – and still plays – a decisive role in the patent litigation landscape in Portugal, as it has provided – and is expected to continue to provide – 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.

1 Marta Alves Vieira is a managing associate at VdA. The previous editions of this chapter were co-authored by António Andrade, who has left VdA. His participation in writing the previous versions is therefore acknowledged with appreciation.

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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.

Apart from applying for a national patent through a national route in accordance with the Portuguese Industrial Property Code (IPC), it is also possible to apply for protection at both 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.[2,3] Furthermore, a six-month additional 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, such examination being 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 international level under the Patent Cooperation Treaty. The duration of a utility model is six years from the date of application and 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 – that is, one rendered by the Court.[5]

2 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.

3 See also Regulation (EC) No. 1610/96 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.

5 Following the entry into force of the new IPC, the Portuguese Patent Office is 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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A special legal system of enforcement of industrial property rights was created by Law 62/2011 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.

Until January 2019, mandatory arbitration proceedings should be initiated within 30 days of the Portuguese Authority of Medicines and Health Products' (INFARMED) publication, on its official website, of the marketing authorisation application, or from the date of the registration application, in 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. Since 9 January 2019, the interested party who seeks to enforce an industrial property right, in light of the publication of a marketing authorisation application for generics medicines, still needs to do so within a 30-day deadline, but the nature of the arbitration for generic medicines is now voluntary rather than mandatory. If the parties do not agree to submit the dispute to arbitration (which has been the rule so far), the enforcement action shall be brought before the Court.

Given the relatively recent establishment of the Court and also the competence of arbitral tribunals to handle pharmaceutical patent cases until recently, the expertise in this field is not yet sufficiently developed. However, this first instance Court is now being faced with a growing number of patent cases, in light of the recent changes in Law 62/2011 and developments in patent litigation landscape are expected in the upcoming years.

Finally, 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 usual 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 as from the decision of the respective grant.

Patent infringement and invalidation proceedings before the Court follow the procedural rules set out in the Portuguese Civil Procedural Code. Patent infringement proceedings under Law 62/2011 shall follow the mandatory provisions of said Law. Voluntary arbitration proceedings shall also follow the Portuguese Law on Voluntary Arbitration,[6] as well as the

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

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procedural rules of the arbitration adopted in each case. Patent infringement proceedings before the criminal courts will follow the procedural rules set out in the Portuguese Criminal Procedural Code.

In any case, as a rule, the parties will submit their pleadings with evidence, thus being given the opportunity to present their case in writing and to file their requests in relation to further evidence to be presented. The evidence generally includes documentary evidence and testimonial evidence, but 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 and also 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 of the Court that it be presented, provided that, to justify its intentions, it presents sufficient indication of a violation of industrial property rights.

Concerning acts carried out on a commercial scale, the applicant may also ask the Court for 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 these 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.

Finally, 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 usual 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 arbitrations 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 generally 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 settle at all the previous discussions on this topic and discussions are being held in relation to the legal nature of this new provision (in particular, if it has an interpretative nature or not). Therefore, and until the case law is settled, this controversy is still pertinent, now in the context of voluntary arbitration and also in the context of judicial proceedings.

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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.

As regards the voluntary arbitration proceedings under Law 62/2011 as amended by Decree-Law 110/2018, said law establishes that the final hearing must take place 60 days following 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 arbitrations, the applicable Law on Voluntary Arbitration establishes a 12-month period for the arbitration award, which may nevertheless be extended by agreement of the parties. This deadline to give a final award was often extended in the context of mandatory arbitrations, in particular in more complex cases.

As to 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).

Added to this, the parties must 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, the IPC provides[7] 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 the 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.

As mentioned before, 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 mentioned 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 now include, as a ground for possible damages, the measure 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'.

7 In Article 345.

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IV SUBSTANTIVE LAW

i Infringement

Former Articles 101(1) and 101(2) of the 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.

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

a the use of a protected process (or the offer to use such 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 the indirect infringement.[8]

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 – the liability for infringement relies on 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 such actions.

In criminal proceedings – before the criminal courts – the criminal liability relies on the company that infringed IP rights, but can also rely on the directors of infringing companies.

In accordance with Article 98 of the IPC,[9] '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.[10]

Furthermore, considering the fact that Portugal is a member of the European Patent Convention (EPC), even though 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 being European or Portuguese patents, for reasons of equality and legal certainty.

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

9 Clearly based on Article 69 of the European Patent Convention (EPC), 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'.

10 The doctrine of equivalents was first introduced by the Portuguese Courts with two judgments rendered by the Appeal Court of Lisbon on 1974, in the framework of the IPC of 1940.

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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 certainly 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 no precedent rule.

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 in such a way that anyone skilled in the art can carry it out.

Under Article 33 of the IPC, patents, utility models and registrations shall be totally or partially annullable 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). 'Insufficiency of disclosure' has also been raised in recent cases.

The legal and technical discussions on those grounds are not different from any of the EU countries – and the EPC States – meaning that jurisprudence from the European Patent Office (EPO) is the most relevant basis for the same 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. Also, consideration of the person skilled in the art in each case is defined under the EPO's case law. For the insufficiency of disclosure argument, the plausibility test is normally considered.

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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 (for instance, 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.

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 IP right holder has to prove the causality of the infringement for the damage's calculation.

In determining the amount of compensation for losses and damages, the court shall take into account, in particular, the profit obtained by the violator and the resulting damages 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.

Also, 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 PROCEEDING

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 competent court is the Intellectual Property Court.

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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. As already mentioned, Law 62/2011 now 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 current Law 62/2011 either.

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

Finally, there are also 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.

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 another and supplementary route for preventing patent infringement.

VII APPEAL

A first-instance decision can be appealed to the second-instance court (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 is not also usual to have hearings at this stage, the appeal process being basically a written proceeding.

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 been often construed as preventing the decision of the second instance court to be appealed to the Supreme Court of Justice. Although, in most cases, the Supreme Court rejects ordinary appeals, it has been recently admitting appeals in cases where, according to the procedural law, the decision is always appealable.[11]

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.

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

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VIII THE YEAR IN REVIEW

i Ruling of the Lisbon Court of Appeal of 23 January 2020 – Case 1002/19.0YRLSB-6

The Court confirmed an arbitral award given by the first instance Arbitral Tribunal, in the context of mandatory arbitration proceedings, in relation to an SPC dispute and its compliance with Article 3(a) and (c) of the SPC Regulation. A first SPC had been granted to an active ingredient and a second one was granted to a combination of said active ingredient with another active ingredient based on the same basic patent. The validity of this second SPC was challenged by a generic company.

In relation to this topic, the Lisbon Court of Appeal considered, in brief, that:

a In relation to Article 3(a), the recent case law of the Court of Justice of the European Union (CJEU) has been sustaining that the same basic patent, should it cover different 'products', may allow the grant of several SPCs, provided the products are protected as such (citing C-443/12 and, in particular, C-484/12). In Case C-322/10, the CJEU states that, under Article 3(a), an SPC cannot be granted to active ingredients that are not mentioned in the patent claims. In this case, it was deemed as proven that the product is covered as such within the scope of the basic patent.

b In relation to Article 3(c), this provision is intended to avoid that, based on the same patent, but on a different marketing authorisation for a medicine containing an active ingredient in combination with another active ingredient (this one protected as such in the basic patent), a second SPC is granted for that combination – which is not the case at stake. In this case, it was deemed as proven that the second SPC specifically covers, in an innovative and inventive way, the combination of active ingredients at stake. This combination, based in a synergy between the active ingredients, is the object of specific claims in the basic patent and it constitutes the essence of the research and development activities, in terms of innovation and invention.

This decision is not yet final as an appeal against this ruling was filed before the Supreme Court of Justice and its admissibility in being challenged.

In relation to the same SPC – although in the context of nullity proceedings brought by a different company against the SPC holder before the Intellectual Property Court – the Lisbon Court of Appeal confirmed once again the validity of said SPC, in light Article 3(a) and (c) of the SPC Regulation – Ruling of the Lisbon Court of Appeal of 4 April 2020 – Case 281/17.0YHLSB.L1 – PUCRS. This Ruling also cites the CJEU case law (for instance, Cases C-484/12 and C-121/17) to support its conclusions.

ii Ruling of the Lisbon Court of Appeal of 9 January 2020 – Case 2970/19.6YRLSB-6

The Lisbon Court of Appeal (with a dissenting vote from one of the judges) overturned a decision given by the Arbitral Tribunal in the context of mandatory proceedings regarding the payment of a periodic penalty by the defendant in the event of infringement of the order given to the defendant to refrain from any use of the generic medicinal products falling within the scope of a supplementary protection certificate.

This Ruling was interesting because in several patent litigation cases, the Lisbon Court of Appeal and the Supreme Court of Justice have been indicating as a requirement for the grant of such a claim the proof of an actual or imminent situation of breach of the duty to perform imposed by the decision. However, the Lisbon Court of Appeal now adopted a different approach and sustained that not only does civil law not set out this additional

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requirement, but also that the IPC provides that in decisions ordering an unlawful activity to be terminated, the court may establish a periodic penalty payment to ensure the respective enforcement (as a preventive measure). According to the Court, these rules find their purpose in the intention expressed in the EU Directives for the protection of the respect for industrial property rights and effective deterrent of non-compliance.

This decision is not yet final.

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, brought great developments in patent litigation in Portugal. However, this mandatory arbitration system was replaced in 2019 by an alternative system and there are now many new and old issues still to be overcome.

In spite of being quite recent, this new system is already confirming what was expected: arbitration is not being selected as the way to generally enforce pharmaceutical patent rights against generic companies because generic companies have not been accepting of entering into arbitration agreements.

It is still early to make a full assessment on how these changes will impact on the current patent litigation landscape and on the Court's respective role (and also on the competent Court of Appeal's role).

Furthermore, the future of the Unified Patent Court (UPC) system is not yet entirely clear. However, because the UPC is expected to have exclusive competence in respect of European patents and European patents with unitary effect, as it is designed, future developments in this field would have significant impact on patent litigation in Portugal.

In addition to the growing problem of counterfeiting, which is common to many economies, internet infringements are still 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

VdA

Marta Alves Vieira is a managing associate at VdA. 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 trainer.

Marta Alves Vieira joined Vieira de Almeida and the intellectual property practice area in 2012, and is now a managing associate, with a strong background in litigation and arbitration and a solid experience as a litigator in the Portuguese courts for approximately 17 years.

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

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

VDA

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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