

THE PATENT
LITIGATION
LAW REVIEW

THIRD EDITION

Editor
Trevor Cook

THE LAWREVIEWS

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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.

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 appeal, to be heard by the UK Supreme Court this autumn, against the imposition by the English courts of a global licence, on terms that they assess, as the price for exploiting standard-essential patents in the UK. Meanwhile, three appeals concerning standard-essential patents are pending before the German Federal Supreme Court, providing it with its first opportunity for a decade (since its *Orange Book Standard* decision) to revisit this area of the law. In the United States the most prominent controversy remains the question of excluded subject matter, which for want of clear judicial guidance has now attracted the interest of the legislature. In Europe, one apparent trend is 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 is also talk of legislation to address the issue. Again in Europe, the past year has seen no progress towards the entry into force of the

long-heralded Unified Patent Court Agreement. Although the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the German Constitution is the only formal impediment to its entry into force, the imminent withdrawal of the UK from the EU as from 31 October 2019 presents a further problem, because the Agreement as drafted does not envisage participation by non-EU Member States. This raises the prospect, even if the German challenge is rejected, of having to amend the Agreement before it can enter into force to take account of such withdrawal; either to exclude the UK from its scope or, as the UK government has urged, expressly to provide for its inclusion, a course that, however, it is not at all clear would be compatible with the case law of the European Court of Justice, irrespective of any treaty language.

Trevor Cook

Wilmer Cutler Pickering Hale and Dorr LLP

New York

October 2019

PORTUGAL

António Andrade and Marta Alves Vieira¹

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). Those changes 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 is likely to be the most common scenario), it is now 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.

Finally, the above-mentioned Decree-Law 110/2018 also put into force the new Industrial Property Code (IPC), which is the most significant piece of national legislation regarding the protection of industrial property.

¹ António Andrade is of counsel and Marta Alves Vieira is a managing associate at Vieira de Almeida.

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 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 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).

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, the enforcement action shall be brought before the Court.

The establishment of an Intellectual Property Court could lead to the conclusion that the judges of said Court would be highly specialised in intellectual property law. However, given the relatively recent establishment of this 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. The Court is now expected to deal with a growing number of patent cases, in light of the recent changes in Law 62/2011.

Finally, since 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.

It must be noted that, 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 advisor).

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 Law 62/2011. Voluntary arbitration proceedings shall also follow also the Portuguese 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 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 – especially as regards pharmaceutical patents – 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. It is therefore likely that this controversy will maintain pertinence, now in the context of voluntary arbitration and also in the context of judicial proceedings.

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

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 (Article 345) 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:

- a* order the appropriate measures to rule out any imminent violation; or
- b* 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 measure and it was recently amended in order 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'.

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 specifically lists the following 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 (very similar to Article 26 of the Agreement on a Unified Patent Court).

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,⁷ ‘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.⁸

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.

7 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’.

8 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.

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 annulable 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’ 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 – being 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 in order 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 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 (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 damages 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 taken into account. 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. The competent court is the Intellectual Property Court.

It must be also noted that 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 was almost never used in relation to patent disputes and it is not likely that it will be often used in the context of Law 62/2011.

Yet it must be said that often the parties manage to reach an alternative solution to litigation by executing an 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.⁹

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

⁹ 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*.

VIII THE YEAR IN REVIEW

i Arbitration award of 14 December 2018 – Novartis v. Normon (Imatinib)

In the context of mandatory arbitration proceedings under Law 62/2011 (in its original version), the Arbitral Tribunal granted several claims put forward by the claimants aiming at the enforcement of second medical use claims.

This was an interesting decision, since the Portuguese case law is not significant and gives contradictory signs about what can be understood as a conduct that infringes a second medical use claim.

The Tribunal acknowledged that a preventive award against the defendant was justified and that the generic company should take additional steps deemed appropriate and necessary to prevent or deter the use of products, once supplied, for the therapeutic purposes protected by the patent claims at stake.

In brief, the defendant was ordered (1) to refrain from importing, manufacturing, storing, marketing, selling or offering the medicinal products at stake containing the relevant active ingredient for the protected therapeutic indication; (2) to refrain from promoting or offering the medicinal products at stake for the treatment of the protected therapeutic indication; (3) to make it clear, in writing, to all prospective purchasers, in the context of private procedures for acquisition of generic medicines containing the active substance at stake, to inform and that its medicinal products are not indicated for the treatment of the protected therapeutic indication; and (4) when medicinal products containing the active substance at stake are purchased through a public procurement procedure for use in the treatment of the protected therapeutic indication, to ensure that any proposal made in the context of said procedure expressly states that the medicinal products are not for the treatment of the protected therapeutic indication and can only be used in the treatment of other therapeutic indications other until the expiry of the invoked patent.

No appeal was filed against the arbitration award.

ii Ruling of the Lisbon Court of Appeal of 19 February 2019 Case 236/16.2YHLSB-7

The Court had issued a decision on the matter of the industrial property rights' holders liability for ungrounded preliminary injunctions. The Court had held that the liability arising from former Article 338-G(3) (currently Article 343(3)) of the IPC should be considered a strict liability and had ordered the preliminary injunction applicant to pay damages to the generic company that had been ordered to stay out of the market while the industrial property rights asserted were in force.

The Lisbon Court of Appeal overturned this decision and clarified that the liability provided for in said provision of the IPC demands the allegation and demonstration of the fault or negligence of the industrial property rights' holder that applied for the preliminary injunction.

According to this ruling from the Lisbon Court of Appeal, the relevant provision of the IPC shall be read in light of the general Portuguese provisions of tort law and, notably, Article 483(2) of the Civil Code, that clearly establishes that 'strict liability only exists whenever the law so specifies'. The Appeal Court's interpretation of former Article 338-G(3) (currently Article 343(3)) of the IPC is that it does not suggest in any way whatsoever (expressly or even implicitly) a strict liability and that it would have been rather easy for the legislator to include such a reference.

In this case, where the industrial property rights' holder filed for a preliminary injunction on the basis of the public record that attested a certain expiry date of its right, which was published in the Industrial Property Office Bulletin, the Lisbon Court of Appeal concluded that the IP holder acted in good faith and with the required prudence, in view of the official elements available at the time.

An appeal against this ruling is still pending before the Supreme Court of Justice.

IX OUTLOOK

There were significant changes in the Portuguese legal framework this year, including major changes to Law 62/2011 and the approval of a new IPC.

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 by an alternative system and there are now many new and old issues to be overcome. In this new scenario, arbitration will not be an expectable way to generally enforce pharmaceutical patent rights against generic companies because it is not likely that generic companies will accept to enter into arbitration agreements (as the short life of this new system is already confirming).

It is likely that in the coming years, these changes will impact on the current patent litigation landscape and on the Intellectual Property Court's respective role.

Furthermore, the future of the Unified Patent Court (UPC) system is still uncertain. However, since 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 may have also significant impact on patent litigation in Portugal.

It should be also noted that 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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He is a member of several IP international organisations, including AIPPI (Portuguese group), ECTA, FICPI, INTA, MARQUES and Union-IP. He was the chair of the ECTA Design Committee (2010–2016) and is currently a member of the ECTA Copyright Committee. He is also a member of the Union-IP Litigation Commission.

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