F PATENT LITIGATION LAW REVIEW

Editor Trevor Cook

ELAWREVIEWS

PATENTLITIGATIONLAW REVIEW

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Enquiries concerning editorial content should be directed to the Publisher – gideon.roberton@lbresearch.com

ISBN 978-1-912228-02-7

Printed in Great Britain by Encompass Print Solutions, Derbyshire Tel: 0844 2480 112

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ACKNOWLEDGEMENTS

The publisher acknowledges and thanks the following law firms for their learned assistance throughout the preparation of this book:

ALLEN & OVERY LLP

ANAND AND ANAND

ANDERSON MŌRI & TOMOTSUNE

BAKER MCKENZIE

BIRD & BIRD SZEPIETOWSKI I WSPÓŁNICY SP.K.

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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 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.

Such disparities 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.

For those of us in Europe, the main development in patent litigation had been expected to be the entry into force of the Unified Patent Court Agreement, which had been foreseen for early in 2018, even though the UK, a necessary party to the establishment of the new Court, has initiated the procedure under Article 50 TFEU by which it will leave the EU in 2019, and the basis on which it can remain part of the new Court once it leaves the EU is unclear. However, these plans have now been thrown into doubt by the pending challenge before the Federal German Constitutional Court to the consistency of the Agreement with the Federal German Constitution – a challenge that is not expected to be resolved soon. It is to be hoped that by the next edition of this *Review* this particular source of uncertainty will have been resolved and the chapter devoted to this new jurisdiction will by then have practical application.

Trevor Cook

Wilmer Cutler Pickering Hale and Dorr LLP New York October 2017

Chapter 19

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 62/2011 of 12 December 2011, which came into force on 19 December 2011, establishing 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 are at stake.

This mandatory arbitration system played – and still plays – a decisive role in the patent litigation landscape in Portugal, as it has provided a stage for the most relevant patent case law in Portugal in the past years.

Nevertheless, the Court is still the competent forum to invalidation actions and infringement actions out of the scope of said mandatory arbitration system.

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.

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 European and international levels – under the European Patent Convention and under the Patent Cooperation Treaty, respectively.

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² Approved by Decree-Law 36/2003 of 5 March and amended by Decree-Law 318/2007 of 26 September, Decree-Law 360/2007 of 2 November, Decree-Law 143/2008 of 25 July and Law 16/2008 of 1 April.

The duration of a patent is 20 years from the date of application, and the invention must have novelty, inventiveness and industrial applicability. 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.^{3,4} 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.⁵

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 very similar for both types of protection of invention, 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 general rule, patent rights shall be enforced and invalidated before the Court, as mentioned above. Furthermore, according to Article 35 of the IPC, the declaration of nullity or annulment may only result from a judicial decision – that is to say, one rendered by the Court. However, as also mentioned above, there is an exception for actions related to pharmaceutical patents and generic medicines that are subject to mandatory arbitration under Law 62/2011.

Litigations arising from the claiming of industrial property rights, including preliminary injunctions, related to reference medicines (patent rights) and generic medicines, regardless of whether they involve process, product or utilisation patents, or complementary protection certificates, will be subject to necessary arbitration, either institutionalised or not.

Taking into account the broad scope of the definition of mandatory arbitration set out in the law, one may conclude that it covers all disputes that are related to pharmaceutical patent rights and generics, and are intended to enforce such industrial patents or to claim for damages for the infringement of the same rights. As a result, in Portugal there is a double jurisdiction system, where patents related to medicinal products follow a separate special regime.

On the one hand, 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

³ See Council Regulation (EEC) No. 1768/92, concerning the creation of a supplementary protection certificate for medicinal products (codified as 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).

⁴ 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.

⁵ In accordance with Regulation (EC) 1901/2006.

law. However, given the relatively recent establishment of this Court and also the competence of arbitration tribunals to handle pharmaceutical patents arbitration cases, there is not yet sufficient expertise in this field.

On the other hand, the possibility of constituting *ad hoc* arbitral tribunals to handle pharmaceutical patent cases could lead to the conclusion that parties would be able to appoint as arbitrators individuals with a strong knowledge and expertise in patent law. It happens that, given the restricted number of individuals with such kind of expertise in Portugal, and also the fact that the courts of appeal are applying strict criteria as to the number of appointments of the same individual as arbitrator, the parties are now being faced with difficulties in such appointments.

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/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 should be filed in a 10-year period after the occurrence of the facts that motivate the actions.

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 before an arbitral tribunal shall follow the mandatory provisions of Law 62/2011 and of 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 general 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 (for pharmaceutical patents the competence to assess and decide on injunctions relies on the arbitral tribunals, according to the mandatory arbitration system). In this context, whenever

⁶ Approved by Law 63/2011 of 14 December.

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 said 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 provision of detailed information (from the alleged violator or from third parties) on the origin and distribution networks of the goods or services it suspects violate 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, also usually claiming that the patent did not meet, at the time of its grant, the patentability requirements. This has been a hot topic in the context of mandatory arbitrations under Law 62/2011.

The majority of the arbitral tribunals have considered that they do not have the competence to assess the validity of patents (or SPCs), a position that has been confirmed by the large jurisprudence of the courts of appeal (in particular, the Lisbon Court of Appeal). Also the Supreme Court of Justice decided that arbitral tribunals are incompetent to appreciate the nullity or invalidity of patents and SPCs, even within the context of a defence by a procedural exception and with mere *inter partes* effects. However, the Supreme Court opened the door to the possible stay of the arbitration proceedings (to be assessed on a case-by-case basis) whenever an invalidity action was brought in the Court. In fact, some arbitral awards have already determined the stay of the proceedings in light of invalidity proceedings pending in the Court.

It should be noted that in another case, the Constitutional Court was called to assess the matter of the lack of competence of an arbitral tribunal on validity issues. Unexpectedly, the Constitutional Court considered that a legal interpretation of Law 62/2011 (mandatory arbitration system), in the sense that prevents the defendants in arbitral proceedings from incidentally arguing the invalidity of a patent with a mere *inter partes* effect, is unconstitutional. While not having a generally binding force, this decision has caused discussions in patent mandatory arbitration cases.

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 mandatory arbitration proceedings under Law 62/2011, said law establishes that the final hearing must take place 60 days following the filing of the defence, although this deadline is rarely complied with.

Furthermore, the Law on Voluntary Arbitration applicable to these mandatory arbitrations 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 is often extended, in particular in more complex cases.

In preliminary injunctions before the arbitral tribunals, the decisions may take three to five months.

As to the costs of the proceedings, court fees are calculated based on the value in 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 (usually around €60,000 for the arbitral panel, in cases where the arbitration reaches its end with a final merits award) and the administrative costs (secretary and other administrative expenses). Added to this, the parties have to consider the attorney's fees and possibly the experts' fees (usually based on an hourly rate).

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 338-I) 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 should be filed before the arbitral tribunals.⁷

Ex parte decisions are not common in international patent matters in Portugal. Likewise, there is no regulation or 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 these protective letters.

Theoretically, patentees can face liability for threatening infringement proceedings, for example under unfair competition law. Nevertheless, there are no relevant cases in Portugal on that basis, and therefore there is no case law that could help to define a legal tendency on this matter.

IV SUBSTANTIVE LAW

i Infringement

Articles 101(1) and 101(2) of the IPC provides 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.

⁷ If the dispute is within the scope of the mandatory arbitration system.

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 97 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 such provision, nor other provisions of the Portuguese law, foresees '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), 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.

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 33 of the IPC, patents, utility models and registrations shall be totally or partially null:

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

⁸ 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'.

⁹ 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.

In addition, under Article 113 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;
- it is recognised that the title or heading given to the invention covers a different object; and
- d its object has not been described in such a way that anyone skilled in the art can carry it out.

Under Article 34 of the IPC, patents, utility models and registrations shall be totally or partially annullable if the holders are not entitled to them, namely:

- *a* if the right does not belong to them; or
- *b* if 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 are able to object to patent infringement by invoking:

- 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);
- 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 338-L 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 of all, 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:

- 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. However, this route is almost never used in relation to patent disputes. 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. As a general rule, 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, Article 3(7) of said law establishes that the arbitral award may be appealed to the second-instance court. This provision has been often construed as preventing the decision of the second instance court to be appealed to the Supreme Court of Justice. In fact, in most cases, the Supreme Court has rejected ordinary appeals.

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.

VIII THE YEAR IN REVIEW

i Ruling of the Portuguese Supreme Court of Justice of 14 December 2016 – Case 1248/14.6YRLSB.S1

The Supreme Court of Justice decided that Court of Intellectual Property has exclusive jurisdiction to revoke patents. The mandatory arbitration court established by Law 62/2011 cannot declare the nullity of a pharmaceutical patent, even if the issue is raised merely as a defence and with effects limited to the parties to the proceedings.

ii Ruling No. 251/2017 of the Portuguese Constitutional Court of 24 May 2017 – Case 297/16

The Constitutional Court considered that a legal interpretation of Law 62/2011 (mandatory arbitration system), in the sense that it prevents the defendants in arbitral proceedings from incidentally arguing the invalidity of a patent with a mere *inter partes* effect, is unconstitutional.

In short, the Constitutional Court considered that the constitutional right to a defence, as a corollary of the constitutional due process right, was being limited in a non-proportional way in light of a provision of the Portuguese Industrial Property Code that limits the retroactivity effects of the revocation of a patent.

IX OUTLOOK

The IPC is currently being revised. This may imply a change of the existing legislation, namely in respect of unitary patents.

Furthermore, the Unified Patent Court (UPC) System, where the UPC will have exclusive competence in respect of European patents and European patents with unitary effect, as it is designed, may have a significant impact on patent litigation in Portugal.

The legal system governing mandatory arbitration in respect of disputes over property rights, including injunction proceedings, involving reference medicinal products (patent rights) and generic medicinal products, brought great developments in patent litigation in Portugal. However, there are still numerous uncertainties and perplexities around these arbitrations, and it is expected that some of them will be overcome with further case law.

It is also hoped that the IPC will be in a suitable position for the discussion of infringements of all intellectual property rights, including patent rights, by improving the swiftness as well as the technical and legal quality of its decisions.

It should be also noted that, 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.

Finally, it is expected that the IPC, under revision, will transpose to national legislation – notably the Directive on Trade Secrets, which may have implications on the growing enforcement of trade secrets instead of patent rights.

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SBN 978-1-912228-02-7