

ES - THE NEW SPANISH PATENT ACT

On July 25, 2015, the Official Spanish Gazette published the new Patent Act, Act 24/2015, which will replace the existing Act 11/1986. Since its promulgation –motivated at the time by Spain’s adhesion to the European Economic Community and the need to adapt its obsolete patent legislation to the needs imposed, among others, by the European Patent Convention-, the 1986 Act has merely undergone certain modifications, despite the substantial changes in the national economic and business landscape. There was an urgent need to update the legislation and adapt it, once again, to the new international environment. On this occasion, given the magnitude of the required changes, the legislator considered it appropriate to draft a new law, although in view of its importance and the need of further regulatory development, the entry into force will be deferred until April 1, 2017.

Some of the aspects of the new patent regulation that could stir considerable interest are briefly explained here below.

- **Granting procedure**

The first aspect worth stressing because of its importance is the new patent granting procedure. This change could explain by itself the introduction of a new legal text, since it modifies the nature of the whole system. With the entry into force of the new Act, substantive prior examination of the novelty and inventive step requirements by the Spanish Patent Office will become compulsory. The Act of 1986 currently in force implements an optional system, whereby applicants are entitled to choose whether or not to conduct such substantive examination. The truth is that foregoing substantive examination was the preferred option for patent applicants for many years, which in practice gave rise to weak patents with a high litigation rate, unable to compete in the international market. The new procedure aims to cease this widespread practice by supporting high-quality patents and, in general, to enhance legal certainty, although it could result in a decrease of the total number of patents granted in Spain.

With regard to the procedure and for the purpose of expediency, pre-grant oppositions by third parties have been replaced with a post-grant opposition system. It will allow third parties to express their objections within six months following the publication of the grant in the IP Official Gazette. This is the most widespread system in comparative law.

- **Patentability**

The patentability of already known substances and compositions for their use as medicines or for new therapeutic applications (i.e., second medical uses) is mentioned for the first time in the Patent Act. This topic had already been covered in the revised European Patent Convention, EPC 2000, which entered into force in 2007.

- **Novelty**

When defining the state of art, the Act now explicitly refers –as encompassed within prior art- to applications of European patents where Spain is designated and also to international applications (PCT) which had entered the national phase in our country, which had been applied for before the patent's application date, and published in the Spanish language on that date or afterwards. Current legislation considers as prior art in this regard only previous Spanish patent or utility model applications still unpublished before the application date.

- **Limitations to patent rights**

On the matter of exemptions to the rights conferred to the patent owner, the new Act envisages as different exceptions the experimental use exemption and the 'Bolar-type' provision, hence echoing each one's different origin and purpose, in accordance with case-law from the Spanish Supreme Court.

Additionally, the scope of application of the 'Bolar-type' provision has been extended by deleting the reference only to generic drugs, so that the exemption will apply to the carrying out of the necessary studies and trials needed to obtain a marketing authorization for any kind of medicine, in Spain or abroad.

- **Equivalents**

Concerning the scope of the protection conferred to the patent, the Act now includes the need to take into account any elements equivalent to those used in the patent claims to establish the claims' scope, thus echoing for the first time the doctrine of equivalents developed and applied by the Courts.

- **Remedies**

With regard to damages, and for the purposes of establishing the liability of those who perform any kind of exploitation activity other than manufacturing, importing the patented product or using the patented process, such as acts performed by intermediaries, the Act eliminates the prior notification

requirement. Under the Act of 1986 currently in force, intermediaries can be deemed liable for damages only if they were previously notified of the infringement's existence by the patent owner, or if their actions were culpable or negligent. Under the new Act, however, it will be enough to show that they acted on purpose. The prior notification will be a means of evidence, but not the only one.

In order to establish the monetary amount for damages, one option is to seek compensation on the basis of a lump-sum comprising at least the amount which would have been due to the patent owner for the granting of a license that would have allowed the infringer to exploit the patent lawfully. The new wording entails an increase of the amount that can be sought under the 'hypothetical royalty' criterion.

As a benefit for the owner of the infringed patent, the new Act eliminates the period of time for claiming compensation for damages, previously limited to the five years preceding the filing date of the action.

In addition, the new Act envisages coercive daily fines to ensure compliance with Court orders for the cessation of an infringing activity, and defers quantification of damages to the enforcement stage of the Judgment in accordance with the calculation basis that shall be set therein.

As for other remedies, the Act makes it harder to obtain the publication of the judgment against the infringing party. This measure will now apply as an exception.

- **Compulsory license**

Another interesting issue is the introduction of two new cases of compulsory licenses. The first one is proposed as a measure to combat anti-competitive practices, requiring the existence of a final administrative or court decision finding an infringement of competition law. Furthermore, for this specific case, the law excludes the pre-negotiation requirement between the patent owner and the potential user, and also includes the possibility of considering the need to rectify the anti-competitive practice when setting the royalty fee.

The second newly-introduced case of a compulsory license concerns the manufacturing of pharmaceutical products intended to be exported to countries with public health concerns, in accordance with Regulation (EC) No. 816/2006.

On the other hand, in the particular case of a compulsory license for lack of exploitation, a new rule comes into play for assessing whether or not the patent is being exploited, in such a way that preparations preceding the exploitation shall not be taken into consideration. The moment when the exploitation becomes effective is therefore relevant. In addition, the period for interrupting the

patent's exploitation has been reduced from three years to one, in order to request this type of license.

- **Patent nullity**

The new Act eliminates requirements for bringing a Court action for patent invalidity, declaring that such an action is of a public nature. Current legislation limits legal standing to sue for patent nullity to those who consider themselves affected negatively by the patent, a grievance which must be duly substantiated. This will no longer be a condition after the new Act's entry into force.

In addition, in proceedings where the patent validity is challenged, the Act introduces the possibility of the Judge's requesting from the Spanish Patent Office or from a third institution, chosen at the Judge's discretion, the issuance of a report addressing the various controversial matters contained in the parties' expert reports.

- **Limitation of the patent**

The new Act also introduces the possibility that the patent owner could voluntarily limit the same by modifying the claims at any time during the patent's lifetime, including the enforceability period of supplementary protection certificates, if any. This includes the possibility of amending the patent claims prior to engaging in litigation, before the Spanish Patent Office, and in the course and context of Court proceedings where the patent's validity is challenged, on the occasion of either a nullity action, counterclaim, or defensive plea; the patent as limited would underlie the procedure thereafter. Currently, these options are available only for European patents under Art. 138(3) EPC; with the new legislation they will be admissible for national patents as well.

- **New procedural rules**

Objective jurisdiction for handling patent matters will be assigned and limited to the Commercial Courts specifically designated by the General Council of the Judiciary to hear patent cases. At present, only Commercial Courts nos. 1, 3 and 4 of Barcelona have the status which will be required under the new Act to hear patent litigation, but in March 2015 Commercial Courts in Madrid also reached an agreement to assign patent competence to certain Courts (nos. 7, 8, 9 and 10), though this still needs to be endorsed by the General Council of the Judiciary.

Due to patent disputes' inherent complexity and the importance of expert opinions during the process, the general deadline of 20 working days for filing a statement of defense, settled by the Civil Procedure Act, has been expanded to two months, as well as for the filing of a counterclaim and the related reply, if applicable.

The new Act also clarifies that the phase of written statements (a reply to a nullity claim, counterclaim, or defensive plea) will be the appropriate procedural stage for the patentee to limit the patent's scope by amending the claims. The proposal for limitation shall then be served upon the party challenging the patent validity to file any counter-arguments within a two-month term. Neither the current Patent Act nor the Civil Procedure Act had envisaged any provisions to explain the procedural treatment that should be conferred to the possibility of limiting the patent claims –so far only under Art. 138(3) EPC- to make it effective.

The legislator has inserted as a new procedural instrument a certain type of protective letter, a tool that the Commercial Courts of Barcelona had already accepted. It allows a potential defendant facing infringement claims to defend himself against any future *ex parte* preliminary injunctions, allowing him a chance to appear in Court and justify his position in advance. Unlike other countries, in Spain the protective letter will be notified to the opposing party. Also, its validity has been restricted to three months and solely before the Court of record. In any case, it will not be binding, so the filing of a protective letter will not necessarily prevent the Judge from issuing a decision granting *ex parte* preliminary injunctions.

Concerning alternative dispute resolution in the field of employee inventions, the law eliminates the obligation of submitting these issues to conciliation before the Spanish Patent Office prior to filing suit. It now becomes a voluntary submission, left to the parties' discretion.

- **Utility models**

Likewise, the new Act's substantial changes provide a new legal framework for utility models .

Firstly, their scope has been enhanced: where in the Act of 1986 it was restricted basically to the field of mechanics, under the new Act utility models will be admissible for any product or compound, including chemical products, except those relating to biological material and pharmaceutical substances, due to the special features of these industries.

Another key change relates to the determination of the relevant state of art. The novelty required for the concession of utility models will be exactly the same as that required for patents, i.e., absolute novelty will be required, whereas under the 1986 Act currently in force relative novelty is enough and is limited to the Spanish territory. This change will avoid uncertainty under the concept of disclosure.

With regard to the granting procedure, third-party oppositions will continue to take place prior to the concession, since substantive examination will not be applicable. For this reason, before enforcing a utility model against any third parties in Court, the owner shall obtain, or at least request, a State of

the Art Report to be issued by the Spanish Patent Office, which will be joined to the public records of the utility model at stake.

It is interesting to emphasize the legislator's silence concerning the Unitary Patent, which is now closer to becoming a reality despite the difficulties it entails. Without any doubt, this position reflects the persistent reluctance of the Spanish government to get involved, a position we hope will change in time.
