

Chapter 12

Spain

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12.1 Overview of the patent system

12.1.1 Evolution and current state of the patent system

The origins of the current patent system in Spain date back to Law No. 11/1986 of March 20, 1986, on Patents (LP-1986).¹ In its day, that Law represented a complete overhaul of an obsolete patent regime based on principles established in the early 20th century. That reform took place in the context of Spain entering what was then called the European Economic Community. The negotiations for its entry included discussions on the provisions of and accession to the Convention on the Grant of European Patents, of October 5, 1973, or “European Patent Convention” (EPC).² LP-1986 incorporated provisions from that Convention and from the Luxembourg Convention on the Community Patent, of December 15, 1975.

After entering into force, LP-1986 underwent various partial revisions to adapt it to new regulatory developments within the European Union and internationally. A subsequent, more comprehensive revision resulted in Law No. 24/2015 of July 24, 2015, on Patents (LP-2015),³ which entered into force on April 1, 2017, and remains in effect today.

LP-2015 introduced some major innovations relative to LP-1986, and most significantly the following:

- The possibility of patenting previously known substances or compositions was explicitly recognized for use as medicines or new therapeutic applications.
- In addition to patents and utility models, explicit provision was made for industrial property rights in the form of supplementary protection certificates, to cover medicinal and plant protection products.
- Substantive examination (of novelty and inventive step), formerly optional for applicants, was established as the only procedure required for the granting of patents.
- A system of opposition was established for patents previously granted, under which anyone may oppose the granting of a patent within six months after publication of the grant, on the following grounds: (i) failure to meet patentability requirements; (ii) lack of sufficient clarity in the description; and (iii) patent protection beyond that specified in the application. Such proceedings are brought before the Spanish Patent and Trademark Office (SPTO), and can result in invalidation or modification of the patent.⁴
- The patent owner’s ability to obtain the amendment of their patent from the SPTO – and from courts in cases where civil litigation has been brought to invalidate a patent – was explicitly recognized.
- The regulations with regard to compulsory licenses were restructured and simplified.
- Provision was made for interested parties to settle patent disputes through mediation or arbitration.

With regard to patent-granting procedures, distinctions are drawn between three types of patents in Spain:

- patents obtained based on applications to the SPTO (after following a grant procedure established in the 2015 law);
- patents sought by means of an international application, subject to the Patent Cooperation Treaty (PCT)⁵ (in force in Spain as of November 19, 1989); and
- European patents validated in Spain (European patents are granted by the European Patent Office (EPO) in accordance with the EPC and produce effects in contracting States designated by the patent owner).

Patents granted by the SPTO based on an international application are equal, in terms of their effects and validity, to patents granted based on national applications.⁶

1 Law No. 11/1986 of March 20, 1986, on Patents (LP-1986).

2 Convention on the Grant of European Patents (European Patent Convention (EPC)), of October 5, 1973.

3 Law No. 24/2015 of July 24, 2015, on Patents (LP-2015).

4 LP-2015 provides for the same possibility allowed under LP-1986 for third parties to intervene in patent-granting proceedings (though without being recognized as “parties”) by submitting comments after publication of the patent application. Such comments must be reasoned and may refer to any aspect of an invention’s patentability.

5 Patent Cooperation Treaty (PCT), June 19, 1970, 1160 UNTS 231.

6 Article 172(1) of LP-2015.

In the same way, European patents designating Spain produce the same effects and are subject to the same regime as Spanish patents.⁷ In this case, however, the patent owners must provide Spanish translations of their European patents, as granted,⁸ within three months after their publication.

As mentioned, LP-2015 continues to provide for utility models. Legislators cited the large number of applications for that modality and the high percentage of Spanish national applicants as justification for this decision. The newer law also continues to treat utility models as a *sui generis* form of IP, not a “simplified patent”. Significant changes have been made, however, to the earlier regulations. The current regime can thus be characterized as follows:

- State of the art, which is the benchmark used to assess novelty and inventive step, is understood in the same way for utility models as for patents, as referring to everything that was available to the public, in Spain or elsewhere, prior to the patent application filing date. The essential difference is that the level of inventiveness required for utility models remains lower than that for patents.
- The scope of protection for utility models is quite broad, excluding only inventions consisting of procedures and those relating to biological materials and pharmaceutical substances and compositions – understood as those used as medicines for humans or animals.
- The grant procedure for utility models does not entail a substantive examination.
- However, for actions to be brought against infringement, a report must be obtained on the state of the art for the subject matter of the industrial model concerned.
- The protection afforded for utility models entitles their owners to the same rights as those enjoyed by patent owners. On the other hand, the duration of protection for utility models is only 10 years, without the possibility of extension, compared to 20 years for patents.

Supplementary protection certificates for medicines and plant protection products are addressed in Section 12.13.1 below.

As a final point for this Section, it should be noted that Spain has not joined yet the system of European patents with unitary effect,⁹ which entered into force on June 1, 2023.

12.1.2 Patent application trends

After LP-2015 went into force, in 2017, the number of applications for utility models decreased. One factor that may explain this decline was that infringement actions for utility models were then conditioned on owners obtaining a report on the state of the art, which had not been required before.

In the case of patents, studies showed that while fewer applications were being submitted and granted for national patents, the number of those for international patents received from Spanish applicants – as well as for European patents ultimately validated in Spain – increased.

Figure 12.1 shows the total number of patent applications (direct, PCT national phase entry and European patent ES designation) filed in Spain from 2000 to 2023.

12.2 Spanish Patent and Trademark Office and administrative review procedures

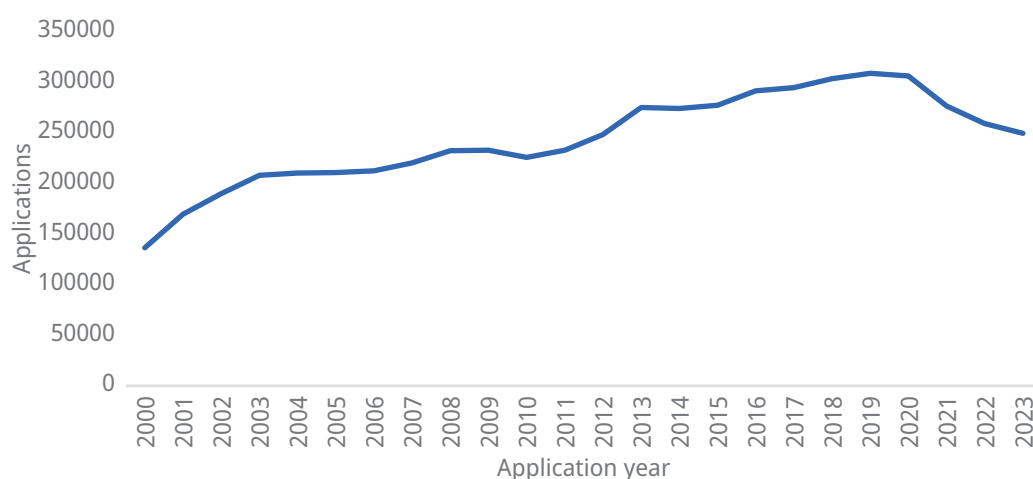
12.2.1 Spanish Patent and Trademark Office

The SPTO is responsible for the administration of industrial property. This includes administrative activities relating to recognition and registration of protection for the various forms of industrial

7 Articles 2(2) and 64(1) of the EPC and Article 153 of LP-2015.

8 Article 155 of LP-2015. The three official languages of the EPO are English, French and German.

9 The application procedure for the European unitary patent is the same as that for a “classic” European patent. The differences emerge after examination has been completed and the EPO has granted the patent. At that point, the owner can opt for what is called “unitary protection”, in which case the European patent need no longer be validated to produce effects in European Union member countries that have adhered to enhanced cooperation in the area of unitary patent protection and ratified the Agreement on a Unified Patent Court (UPC). In such event, the owner will have to submit to the jurisdiction of said court for actions against infringement and for invalidation. After the transitional period established in that Agreement, the jurisdiction of the UPC will extend to infringement and invalidation actions in respect of “classic” (i.e. non-unitary) European patents brought in EU member states having ratified the Agreement.

Figure 12.1 Patent applications filed in Spain, 2000–2023

Source: WIPO IP Statistics Data Center, available at www3.wipo.int/ipstats/index.htm?tab=patent and EPOPATSTAT, available at www.epo.org/searching-for-patents/business/patstat.html

property (with the exception of plant varieties); processing and decision-making for applications and related procedures (granting, limiting and invalidating industrial property titles, among others); record-keeping and publicity.

The SPTO is an autonomous agency attached to the Ministry of Industry and Tourism with its own legal personality and capacity to operate in pursuance of its mandate.

12.2.2 Administrative review procedures

Acts and decisions taken by SPTO bodies in proceedings of various kinds include the handling of administrative appeals, which the SPTO itself both processes and resolves. Final SPTO decisions mark the exhaustion of administrative remedies and are then subject to judicial review.

Judicial appeals against all kinds of final SPTO decisions have traditionally been handled by administrative courts. That changed in 2022, when legislation assigned jurisdiction to specialized civil courts for appeals against SPTO industrial property decisions when those decisions marked the exhaustion of administrative remedies (see Section 12.3.1).

Since the entry into force of LP-2015, the interplay between proceedings brought before the SPTO and those handled by courts, apart from that described above, has raised a point of particular interest: the possibility allowed for patent owners¹⁰ to amend their patents through recourse either to the SPTO (limitation procedure) or to the courts, in the context of civil action seeking invalidation of the patent (see Section 12.4). Since this two-track framework can result in conflicting situations, the law provides for ways to coordinate procedures. The law stipulates that courts must notify the SPTO when limitation of a patent has been sought in the context of invalidation proceedings, and the SPTO must in turn enter that fact into the Patent Registry. Once the court has made its final ruling on the limitation request it must then notify the SPTO accordingly, also for entry in the Patent Registry. It is stipulated further that when proceedings for the invalidation of a patent are pending before a court, the acceptability of requests for limitation of the patent is subject to that court's authorization. Lastly, if, during the course of invalidation proceedings before a court, the patent should be amended by the SPTO pursuant to a request made before the start of court proceedings, the owner may request that those proceedings be based on the patent as so amended.

Similar issues arise from the interplay between proceedings before the EPO and national courts concerning the validity of European patents previously validated in Spain. As mentioned earlier,

¹⁰ This possibility is subject to two limits: neither can the subject matter of the amended patent extend beyond the contents of the application as initially filed, nor can the protection it confers be expanded.

European patents are granted through centralized procedures before the EPO and then replicated as multiple national patents in countries designated by the patent owner. Opposition procedures are also centralized through the EPO, which are conducted before the Opposition Divisions, whose decisions are reviewable in the last resort by the Boards of Appeal. The European process for limiting patents works in a similar fashion.

This can result in situations where the same question is raised about the same European patent before the EPO (in the context of opposition or limitation proceedings) and before national courts (in the context of invalidation proceedings), the patent having been previously validated in the contracting State concerned. The following guidelines then apply:

- A decision by the national court to invalidate the (previously validated) patent produces effects only in the contracting State concerned.
- A decision by the EPO to revoke or amend a European patent produces effects in all of the contracting States designated, even if national courts in one or more of those States have previously validated it.
- The national court decision to invalidate the patent produces effects in the contracting State concerned even if the EPO has decided to maintain its validity, in which case it remains valid in all other contracting States having validated it.

In the event that challenges to the validity of a European patent are brought on parallel tracks, before both the EPO and a national court (in the context of infringement proceedings), it is not uncommon for the national court to find the patent valid and to have been infringed and to order legal remedies pursuant to national law – and then, on the parallel track, for the patent to be revoked by a decision of the EPO.

Since the late 1990s, in order to avoid such situations, EPO bodies have been asked to “accelerate their proceedings.” Various other remedies are also available under the national laws of contracting States. In the case of Spain, however, since national law does not specifically provide for such circumstances, the only solution at present is recourse to the instruments offered by general procedural rules. On this point, the Provincial Court of Madrid¹¹ has considered that when a ruling is to be made, if opposition proceedings are also underway before the EPO, the judicial proceedings should be suspended subject to agreement by the parties. The Provincial Court of Barcelona, on the other hand, has considered under the same circumstances that the court can suspend the proceedings *ex officio*.¹²

12.3 Judicial institutions

12.3.1 Judicial administration structure

The Spanish Constitution provides that exercise of the judicial power for all types of trials, judgments and enforcement of judgments rests exclusively with *juzgados* and *tribunales* as defined by the laws and in accordance with the rules of competence and procedure set forth therein. The term *juzgados* refers to courts composed of a single judge. The term *tribunales* refers to collegial bodies composed of at least three judges.

The judicial function is performed solely by professional judges forming part of the judicial service, which is divided into three categories: Supreme Court Justice, *Magistrado* (Senior Judge) and Judge. Courts in Spain are composed exclusively of judges with judicial training.

The Spanish Judiciary is governed by the General Council of the Judiciary. This body is recognized as having all of the powers necessary to apply the rules governing the exercise of functions performed by members of the Judiciary, particularly in matters pertaining to appointments, promotions, inspections and disciplinary measures.

The Constitution also establishes principles for the governance of judicial activities. One such principle, jurisdictional unity of the National Judiciary, underlies the organization and functioning of all Spanish courts.

¹¹ Judgment of the Provincial Court of Madrid 196/2019 of April 10, 2019, ECLI:ES:APM:2019:9686 (SAPM 196/2019).

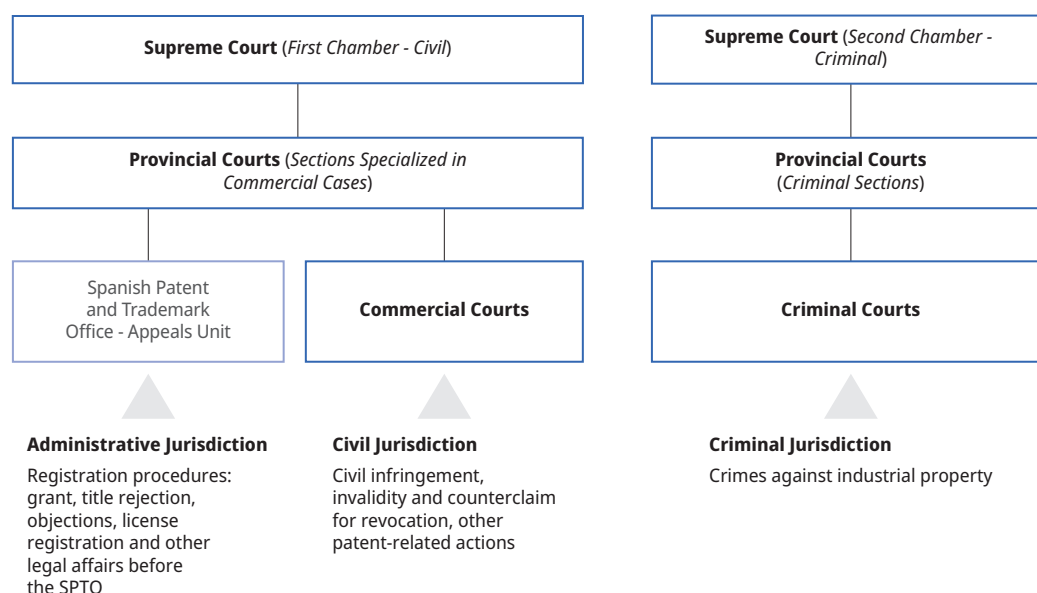
¹² Order of the Provincial Court of Barcelona of May 29, 2019, ECLI:ES:APB:2019:7520A.

The ordinary courts are classified into four jurisdictional divisions: civil, criminal, administrative and social.¹³ The Supreme Court, with jurisdiction throughout Spain, is the highest judicial body for all of these divisions, except where constitutional guarantees are concerned, for which that position is occupied by the Constitutional Court.

Within each of these jurisdictional divisions, specialized courts have been created by various legislatively authorized means to deal with specific matters. Such is the case for courts specializing in industrial property cases, which are part of the courts specializing in commercial matters and forming part of the civil jurisdictional division.

The Organic Law on the Judiciary¹⁴ provides for the establishment, operation and governance of the courts as well as rules governing the exercise of functions performed by members of the Judiciary, including judges and administrative staff. It also regulates the election, composition, powers and operations of the General Council of the Judiciary and the exercise of functions performed by General Council members.

Figure 12.2 The judicial administration structure in Spain



12.3.2 Courts specialized in industrial property

LP-1986 provided for the possibility of patent-related cases (and by extension other industrial property cases) being considered by certain first instance courts ("juzgados de primera instancia" - traditional denomination of the courts of first instance of the civil jurisdictional division). That possibility, however, never materialized in practice.

The real change took place in 2003, with an amendment to the Organic Law on the Judiciary.¹⁵ That amendment established one or more commercial courts in each province, with jurisdiction for each entire province. These new courts were assigned competence to hear cases in the first instance relating to a finite list of subject matters that included industrial property, intellectual property, fair competition and publicity. The reform also established a specialized role for the country's Provincial Courts (second-instance courts within the civil and criminal jurisdictional

¹³ In addition to the four jurisdictional orders mentioned, there is military jurisdiction. According to Article 117 of the Constitution, the law shall regulate the exercise of this jurisdiction strictly within the military sphere and when martial law is declared, in accordance with the principles of the Constitution. The organs of the military jurisdiction also form part of the Judiciary, with the Supreme Court (Fifth Chamber) functioning, here as well, as the highest judicial body.

¹⁴ Organic Law No. 6/1985, of July 1, 1985, on the Judiciary (Organic Law No. 6/1985 on the Judiciary).

¹⁵ Organic Law No. 8/2003, of July 9, 2003, for the Reform of Insolvency Proceedings, amending Organic Law No. 6/1985, of July 1, 1985, on the Judiciary (Organic Law No. 8/2003).

divisions); that of hearing appeals against decisions by these new commercial courts. These courts began operating in January 2004.

Current patent law in Spain, LP-2015, after entering into force in 2017, carried this specialization process a step further, assigning competence for civil patent cases to specific commercial courts – those located in the autonomous community seats of the country's High Courts of Justice – the highest courts in each of the country's autonomous communities (except for cases subject to Supreme Court jurisdiction). The General Council of the Judiciary would previously have conferred exclusive jurisdiction for such matters to the High Courts themselves.

As a consequence of the resolutions adopted by the General Council of the Judiciary, six commercial courts in Madrid, three in Barcelona and one in Valencia have been assigned jurisdiction for civil proceedings concerning patents. There are also commercial courts for Granada, Las Palmas de Gran Canaria, La Coruña and Bilbao.

The “super-specialization” process continued in 2022 for second-instance courts, with another reform of the Organic Law on the Judiciary.¹⁶ Under this latest reform, where a Provincial Court has more than one section specialized in commercial cases, the General Council of the Judiciary must distribute competence for specific matters among the sections. Explicit provision was also made for the possibility of creating specialized sections to deal exclusively with intellectual and industrial property, fair competition and publicity.

Only the Provincial Court of Madrid has more than one section specialized in commercial cases. Under the reformed provisions, Section 32 of the Provincial Court of Madrid was assigned sole and exclusive jurisdiction for intellectual and industrial property, fair competition and publicity, the only section so specialized in Spain.

There is no such structured specialization at the Supreme Court level (First Chamber).

Another important change made by the 2022 reform was to assign jurisdiction to Provincial Court sections specialized in commercial cases for appeals against final SPTO rulings on industrial property cases, hitherto subject to administrative jurisdiction.

Courts specializing in commercial cases are composed exclusively of judges with legal rather than technical training.

To ensure that the judges selected for these specialized courts have the necessary knowledge, a selection procedure has been established to qualify successful candidates as “commercial law specialists”. Those so qualified are then given preference when judges are appointed to the specialized commercial courts. Only when there are no commercial law specialists may a non-specialized judge be appointed to these courts.

The selection process consists of exercises to test theoretical knowledge and skill in drafting opinions. Successful candidates are then offered a theoretical-practical training course conducted by the Judicial School of Spain. As an eligibility requirement for participation in this process, judges must have effectively served for at least two years.

Members of the judicial service who are not specialists but do obtain an appointment to a commercial court must participate in specific training activities as determined by the General Council of the Judiciary (an online theoretical course and a theoretical-practical internship with a commercial court).

12.3.3 Relationship between invalidity and infringement proceedings

Within the country's unitary judicial system, courts competent to hear invalidation cases are the same as those competent for infringement cases, so that a single court can deal with both issues as part of the same proceedings.

16 Organic Law No. 7/2022, of July 27, 2022, amending Organic Law No. 6/1985, of July 1, 1985, on the Judiciary, with respect to the Commercial Courts (Organic Law No. 7/2022).

It is thus not uncommon for defendants in infringement cases to seek invalidation of an allegedly infringed patent by way of either a defense or counterclaim. In such cases, without prejudice to procedural particularities triggered by invalidation requests (see Section 12.4), the proceedings continue before the same court, which will then rule on both invalidation and infringement as part of the same decision on the merits.

In the event of parallel judicial proceedings, the risk of contradictory rulings is avoided by means of a consolidated process, as provided for in the procedural rules. If such consolidation is not possible, the court hearing infringement proceedings can suspend them until the invalidation proceedings have been concluded.

12.3.4 Judicial training on industrial property

As one of its key functions, the General Council of the Judiciary is responsible for the continuous, in-service training of members of the judicial service, which is provided by the Judicial School. The Continuing Training Service of the Judicial School is charged with ensuring that all members of the judicial service receive high-quality, continuous, individualized and specialized training throughout their careers.

The State Training Plan, developed annually, constitutes the fundamental core of the training activities overseen by the General Council of the Judiciary. It encompasses a wide range of activities, in various formats, covering legal but also related subjects, such as economics and foreign languages. Participation by judges in these activities is voluntary. The Plan includes specific training activities on the subject of industrial property.

The Plan also includes joint training activities with other agencies and entities, including the SPTO.

The Judicial School is part of the European Judicial Training Network, which each year organizes international seminars as well as exchange and study visits to courts in other European Union countries. This includes activities related to industrial property.

12.4 Patent invalidity

The validity of a patent can be impugned on the grounds indicated in Article 102(1) of LP-2015, which reads as follows:

A patent shall be invalidated:

- (a) when it is demonstrated that the subject matter of the patent does not meet one of the requirements contained in Title II of this Law;
- (b) when it does not describe the invention in a sufficiently clear and complete manner for it to be executed by an expert in the subject matter;
- (c) when its subject matter exceeds that contained in the patent application as submitted, or if granted in response to a divisional application or an application based on Article 11, when the subject matter exceeds that contained in the initial application as submitted;
- (d) when the protection conferred by the patent has been expanded after the patent was granted; and
- (e) when, according to Article 10, the owner of the patent did not have the right to obtain it.

12.4.1 Grounds for invalidation

12.4.1.1 The requirements for patentability

The first ground for invalidation is failure to meet any of the requirements for patentability. According to Article 4 of LP-2015 “Inventions that are novel, that involve an inventive step and that are capable of industrial application are patentable in all fields of technology.” Thus, the requirements of patentability are novelty, inventive step and industrial applicability.

Article 5 of LP-2015 also provides for exceptions to patentability, such that a patent can also be impugned, and its subject matter considered unpatentable, for falling under those exceptions.

Patents are most frequently challenged, however, for lacking novelty or an inventive step.

12.4.1.1.1 Novelty

Article 6 of LP-2015, in terms similar to those of Article 54 of the EPC, reads as follows:

An invention shall be considered to be new if it does not form part of the state of the art.

State of the art is defined in Article 6(2) as:

everything made available to the public, in Spain or abroad, by means of a written or oral description, by use, or by any other way, before the date of filing of the patent application.

Article 6(3) goes on to specify the following:

Additionally, the content of Spanish patent or utility model applications, of European patent applications designating Spain, and of international PCT patent applications that have entered the national phase in Spain, as filed, with an earlier filing date than that indicated in the preceding subparagraph and published in Spanish on or after that date, shall be considered as comprised in the state of the art.

The relevant date will be the submission date of the application, unless priority has been claimed for “an original application for a patent, a utility model or a utility certificate in or for any of the States parties to the Paris Convention for the Protection of Industrial Property, done in Paris on March 20, 1883, or of the Agreement establishing the World Trade Organization,” if filed within the previous 12 months. “As a result of the exercise of the right of priority, for the purposes of the provisions set out in Sections 6, 10(3) and 139, the filing date of the patent application shall be deemed to be the filing date of the earlier application whose priority has been rightfully claimed.”¹⁷

Assessing the novelty of a patent means comparing each patent claim, interpreted according to the description and drawings provided, against a single state-of-the-art disclosure (document).

A claim is considered to lack novelty when a document or other form of state-of-the-art disclosure, directly and unambiguously (that is, undoubtedly) anticipates each and every element of the claim at issue.

In practice, national courts apply the criteria set out in the Case Law of the EPO Boards of Appeal, summarized in the method described in the Guidelines for Examination and in the Spanish Patent Office Guidelines. The method for assessing novelty consists of three steps:

1. identify the technical elements of the invention claimed, with reference to the expert opinions provided by the parties, for comparison with one or more state-of-the-art documents;
2. determine whether the document cited by the party challenging the patent forms part of the state of the art; and
3. assess whether, at the time of its publication, the document said to anticipate the challenged claim explicitly or implicitly disclosed all of that claim's elements or steps for a person skilled in the art.

In making this last comparison, the first fundamental rule in assessing novelty is not to combine disclosures from different state-of-the-art documents for comparison with the elements of the challenged claim. Doing so would misrepresent the state of the art: the novelty of the claimed invention may in fact lie in combining different state-of-the-art solutions. These comparisons must therefore be made document by document¹⁸ (anticipation by anticipation). Not even different processes covered in the same document should be combined unless that combination is suggested therein. An exception to this first rule is when a document (the main document)

¹⁷ Article 30 of LP-2015.

¹⁸ Judgment of the Supreme Court 389/2019 of July 3, 2019, ECLI:ES:TS:2019:2244 (STS 389/2019): “Prior rights derived from the state of the art and potentially negating the novelty of an impugned invention must be assessed one by one and compared with the invention based solely on their content. This comparative judgment must be made individually for each prior right, so that an invention cannot legitimately be found to lack novelty based on a combination of several pre-existing elements.”

refers explicitly to other documents that have also been published to provide more details on a given characteristic.

The technical teachings provided in the document must be considered as a whole, as a person skilled in the art would do. Separate parts of a given document must not be taken arbitrarily out of context to extract technical information that differs from or contradicts, the document's overall disclosure, considered as a whole. In challenging the novelty of a claim, it is acceptable to combine separate passages (teachings) from a single document, but reasons must be given for concluding that a person skilled in the art would do so.

The third step of this method, in making comparisons between prior disclosures and more recent claims, involves this concept of "a person skilled in the art", with reference to the subject matter of an invention. This concept is generally understood to refer to the notion of a skilled practitioner in the relevant field of technology aware of what was "common general knowledge" in the art at the relevant date and of the means normally used to perform relevant routine work and experimentation in that field. The special characteristic of this archetypical skilled practitioner (or team of practitioners) is access to all the knowledge that defined the state of the art, and in particular the documents that need to be compared with the invention claimed.

Thus, differences between the invention claimed and what is disclosed in a prior document are assessed by considering what a person skilled in the art, after reading the document, would consider to have been disclosed. Logically, according to Article 335 of Law No. 1/2000 of January 7, 2000, on Civil Procedure (LEC),¹⁹ such knowledge must be brought to the court by experts witnesses. The concept of a "person skilled in the art" must not, however, be confused with such witnesses but rather be invoked by the judge, a layperson in this context, after considering the insights provided by expert witnesses to justify the comparison. The function of the expert witness is thus to assist the judge by identifying, reading and correctly assessing documents forming part of the state of the art that are being cited as the basis for challenging the novelty of a claimed invention.

The elements of a patent claim may have been disclosed by an earlier document either explicitly or implicitly.²⁰

Express disclosures: A document which forms part of the state of the art deprives the claimed invention of novelty, if a reading thereof reveals that the claimed elements are obvious, straightforward and unambiguous to a person skilled in the art. It should be noted that the implicit characteristics of all the elements explicitly mentioned in the document are also understood to have been disclosed to the person skilled in the art. One thing that cannot be done, when assessing novelty, is to include well-known equivalents, as such document interpretation is characteristic of the analysis of inventive step.

Subject matter described in a document can only be regarded as having been made available to the public if the information given therein is sufficient to enable the skilled person, at the relevant date of the document and with the general knowledge assumed to be available at that time, to practice that technical teaching. Similarly, a chemical compound, whose name or formula is mentioned in a state-of-the-art document, is not thereby considered as known, unless the information in the document, together with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, in the case of a product of nature, only to be separated.

19 Article 335 of Law No. 1/2000 of January 7, 2000, on Civil Procedure (LEC): "Aim and purpose of experts' opinions. Swearing or promising to act objectively. 1. Where scientific, artistic, technical or practical knowledge may be necessary to ascertain any facts or circumstances that are relevant to the matter or to acquire certainty about them, the parties may bring to the proceedings the opinions of experts having the relevant knowledge or seek that court-appointed experts should issue opinions in the cases set forth herein."

20 STS 389/2019: "Article 54 of the EPC (as well as Article 6 of LP-2015) provides that an invention shall be considered to be new if it does not form part of the state of the art, and that the state of the art comprises everything made available to the public by means of a written or oral description, by use, or in any other way. Lack of novelty may result from a written description, derived from what is explicitly indicated in the prior document [...] or implicitly disclosed, which together, would have inevitably led a skilled practitioner in the art, when putting the prior document's teachings into practice, to obtain the same results as described in the claim. Legal certainty requires that the inference be clear, direct and unequivocal, equating the term inevitable with the terms ineluctable, inescapable, or unavoidable, such that the impugned decision should not in the least be faulted for applying a criterion followed by decisions of the EPO Boards of Appeal that 'the word inevitable means unfailing, certain to occur, something that must happen or arise, so true as to preclude valid alternative solutions; it is equivalent in other words to 100% probability' (T 396/89, T 793/93)."

Implicit disclosures: The lack of novelty is considered implicit if, in carrying out the teaching of the state-of-the-art document, the skilled person would inevitably arrive at a result falling within the terms of the claim.

A general teaching or disclosure does not as a rule deprive a more specific invention of its novelty. Specific disclosures, on the other hand, do deprive more general inventions of novelty.

In the same vein, when an independent claim is novel, all of the dependent claims it incorporates by reference are also novel. Conversely, the invalidation of an independent claim for lack of novelty does not affect its dependent claims, since they incorporate features that may not be disclosed in the state of the art.²¹ This rule is also applicable to inventive step.

What is known as the “two-lists principle” is also important in this context. In determining the novelty of a selection of elements, it has to be decided whether the elements are disclosed individually (concretely) in what is alleged to be anticipatory. A claim consisting of a selection from a single list of previously disclosed elements must not be considered novel. But if the specific combination of features claimed must be selected from two or more lists of a certain length, then that combination not specifically disclosed in the state of the art, must be considered novel.

12.4.1.1.2 Inventive step

Article 81 of LP-2015 provides that “an invention is considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.” In determining the state of the art, however, patent applications not published before the relevant date, as referred to in Article 6(3) of LP-2015, are not taken into account.

The Supreme Court has clarified the following:

The criterion for this requisite inventive step is whether the skilled person, working from earlier (state-of-the-art) descriptions and their own knowledge, finds it obvious to obtain the same result, without applying their ingenuity, which indicates that there is no inventive step.²²

In practice, Spanish courts follow the problem-solution approach adopted by the EPO Boards of Appeal to assess inventive step as well as novelty. While recognizing that other methods could be used to assess inventive step and avoid an *ex post facto* analysis, the Supreme Court has explicitly admitted the validity of this approach to inventive step for use in civil proceedings.²³

As defined in the Guidelines for Examination in the EPO, this approach consists of three main stages:²⁴

1. determining the “closest prior art”
2. establishing the “objective technical problem” to be solved, and
3. considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

The point bears repeating, using the Supreme Court’s succinct description of this method:

First identify the state of the closest prior art; then identify the objective technical problem to be solved; and finally, consider whether the claimed invention would have been obvious to a person skilled in the art given the closest prior art and the objective technical problem.²⁵

21 Judgment of the Supreme Court 124/2022 of February 16, 2022, ECLI:ES:TS:2022:531 (STS 124/2022), citing Judgment of the Supreme Court 263/2017 of May 3, 2017, ECLI:ES:TS:2017:1653 (STS 263/2017): “while the invalidity of the first independent claim does not prejudice the validity of the dependent claims, however, the validity of the main claim prevents the invalidity of the dependent claims from being questioned.”

22 STS 124/2022, referring in turn to Judgment of the Supreme Court 182/2015 of April 14, 2015, ECLI:ES:TS:2015:1703 (STS 182/2015); Judgment of the Supreme Court 325/2015 of June 18, 2015, ECLI:ES:TS:2015:3194325/2015 (STS 325/2015) and STS 263/2017.

23 STS 124/2022: “It is the established case law of this chamber that ‘there is no single method for the judicial assessment of inventive step, yet the method followed must ensure that such assessments take decisive factors into account (STS 182/2015)’”.

24 Guidelines for Examination in the EPO, Part G, Chapter VII, 4. Problem-solution approach.

25 STS 124/2022.

12.4.1.1.2.1 *The closest prior art document*

The closest prior art document is that which, in one single reference, discloses the combination of features that constitutes the most promising starting point for a development leading to the invention. In selecting the closest prior art, the first consideration is that it must be directed to a similar purpose or effect as the invention, or at least belong to the same or a closely related technical field as (the technical field of) the claimed invention. In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention.

When judges hear civil invalidation proceedings, the principle of coherence obliges them to respond to an invalidation request, as argued by the party filing it, in accordance with Article 218.1 of the LEC, which provides that “The judgments must be clear, precise and coherent with the claims and with the other pleas of the parties, as deduced in due time during the proceedings.”

But unlike what happens in a patent office, where the document representing the most promising starting point is selected by the examiner, in a court it is the parties who select such documents.

What often happens is that parties propose several documents for examination. In that case, the court can meet the coherence obligation by assuming that the skilled person would reject documents if no more promising than others as starting points. The court can then analyze the starting point as argued by the parties without analyzing every document they propose, rejecting as many as the patent owner can demonstrate are not as promising as what he has proposed.

The Guidelines for Examination in the EPO²⁶ state the following on this point:

In some cases, there are several equally valid starting points for the assessment of inventive step, e.g. if the skilled person has a choice of several workable solutions, i.e. solutions starting from different documents, which might lead to the invention. If a patent is to be granted, it may be necessary to apply the problem-solution approach to each of these starting points in turn, i.e. in respect of all these workable solutions.

But the Guidelines also qualify this statement, as follows:

However, applying the problem-solution approach from different starting points, e.g. from different state-of-the-art documents, is only required if it has been convincingly shown that these documents are equally valid springboards.²⁷

12.4.1.1.2.2 *The objective technical problem*

The objective technical problem needs to be formulated by first comparing the invention with the closest prior art and then identifying the changes necessary to achieve the technical differences offered by the claimed invention. This means first identifying the differences between the prior disclosure and the claim, and then deriving the technical effect of those differences.

Once the closest prior art has been identified, the second step, taking the problem-solution approach, is to identify the objective technical problem, which means starting with the document representing the prior art closest to the claim at issue and identifying the structural and functional technical differences between what is disclosed in that document and the claim at issue. Once those distinguishing features have been identified, their technical effect is determined and used as the basis for formulating the objective technical problem.

As a general rule the objective technical problem is formulated based on the problem that the patent claim at issue, according to its description, has solved. But if the examination reveals that the problem described has not been solved, or properly framed in the prior art, then the objective technical problem solved by the patent claim must be identified.²⁸ This situation can arise when the challenging party proposes a closest prior art document different than the one on which the patent-granting decision was based.

²⁶ Guidelines for Examination in the EPO, Part G, Chapter VII, 5.1 Determination of the closest prior art.

²⁷ Judgment of the Provincial Court of Barcelona 1610/2021, July 27, 2021, ECLI:ES:APB:2021:8276 (SAPB 1610/2021).

²⁸ SAPB 1610/2021.

If the court considers that the closest prior art document or objective technical problem cannot be applied as proposed by the challenging party, the logical course is to dismiss the petition for invalidation, since what is up to the court in a civil case is merely to assess the claim's validity based on the allegations of the parties, not to re-examine the requirements for patentability.

12.4.1.1.2.3 *The obviousness test*

Once the closest prior art and objective technical problem claimed to be solved by the invention have been determined, the next step is to assess whether or not the solution offered by the invention is obvious to the person skilled in the art.

This assessment entails a test referred to as the “could-would approach”. According to the Guidelines for Examination in the EPO,²⁹ the question to be answered in this third stage is whether there is any teaching in the prior art as a whole that would (not simply could, but would) have prompted the skilled person, faced with the same objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims and thus achieving what the invention achieves.³⁰

The Supreme Court has stated that:

in assessing whether an invention is obvious, the skilled person does not consider documents or prior rights in an isolated manner, as must be done in assessing novelty, but rather combines them to determine whether the prior information available is sufficient to enable them to reach the same conclusions without need for the information disclosed by the inventor.³¹

In Judgment No. 334/2016, of May 20, 2026, however, the Supreme Court states that:

The origin of a particular combination is contingent upon an assessment of what was suggested or obvious for the average skilled person, bearing in mind that assessing obviousness often means determining what specific prior rights must be combined to show that the invention would be obvious for an average skilled person with the knowledge available as of the priority date.³²

12.4.1.2 **Insufficiency of the description**

Article 27(1) of LP-2015 provides that “The invention shall be described in the patent application in a sufficiently clear and comprehensive manner to enable a person skilled in the art to carry it out”, failing which, per the patent is invalid.³³

The Supreme Court, without calling them binding, has cited three types of considerations by the EPO Boards of Appeal in this area:

- i) First, the occasional failure of a procedure to deliver the results claimed does not affect its reproducibility if only a few attempts are necessary to turn the failure into a success, provided those attempts remain within reasonable limits and do not require an inventive step (T 931/91).
- ii) Second, reproducibility is not affected if the selection of inputs for different parameters is a routine exercise and/or if additional information is provided using examples in the description (T 107/91). In case T 764/14, the Chamber concluded that the skilled person was capable, based on common general knowledge and in the corresponding routine variation of experimental conditions, of supplementing the information contained in paragraph 0031 of the patent at issue and therefore of determining the input concerned, possibly with some uncertainty but without an undue burden [...].
- iii) And in addition, “the EPC does not require that it be possible for the claimed invention to be executed with a few additional undisclosed steps. The only essential requirement is that each of those additional steps be so obvious to the

²⁹ Guidelines for Examination in the EPO, Part G, Chapter VII, 5.3 Could-would approach.

³⁰ Judgment of the Provincial Court of Barcelona 513/2023 of December 14, 2023, ECLI:ES:APB:2023:15254 (SAPB 513/2023).

³¹ STS 182/2015, and STS 325/2015.

³² STS 124/2022.

³³ Article 102(1) of LP-2015.

skilled person that, in the light of their common general knowledge, a detailed description of those steps would be superfluous (T 721/89).³⁴

In the application of this cause of invalidity,

The skilled person is the same as the one we would have to use to assess inventive step. In Judgments No. 334/2016, of May 20, 2016 and No. 532/2017, of October 2, 2017, we [the Supreme Court] clarified that “the skilled person” is a hypothetical specialist in the technical field corresponding to the invention at issue, possessed of common general knowledge in that subject matter and having access at the relevant date to related, state-of-the-art information – and in particular to the documents in the “prior art search report”. This person has more expert knowledge about the technical problem area than about any particular solution. They are not a creative, lack special ingenuity (they are not an inventor) and are influenced by prejudices common to the time in the state of the art concerned.³⁵

12.4.1.3 The addition of subject matter

Article 102(1)(c) of LP-2015 mentions as a cause of invalidation cases where the subject matter of a patent “goes beyond the content of the patent application as filed [...]”.

This cause of invalidity flows from the prohibition in Article 48(1) of LP-2015, similar to that contained in Article 123 of the EPC, which establishes the following general rule:

With the exception of those cases involving rectification of obvious errors, the applicant may amend the claims in their application at any stage of the grant procedure where it is specifically permitted under the present Law, and subject to what is regularly established.

Article 48(5) of LP-2015 limits the possibility of amending claims where their “subject matter goes beyond the content of the patent application as initially filed.”

The Supreme Court cited another criterion applied by the EPO Boards of Appeal in this area, again without binding effect:

‘The content of the application as filed’ refers to information disclosed by the entire application, understood as including the claims, description and drawings.³⁶

Assessing this cause of invalidation logically requires a comparison between the claims in the patent application and those in the patent as granted. The claim is invalid if new protected subject matter has been added – if it incorporates new technical features that the skilled person would not consider to be clearly and directly derived from the application.³⁷

12.4.1.4 The expansion of protection

With reference to the patent granted, as in the previous instance, Article 48(6) of LP-2015 prohibits amending the granted patent during the opposition or, as the case may be, the limitation procedure, so as to extend the protection conferred by the patent. Article 102(1)(d) of LP-2015 provides for the invalidation of a claim “when the protection conferred by the patent has been expanded after being granted”. Just as in the case of added content above, the patent originally granted must be compared with the amendment made after an opposition or limitation procedure conducted subsequent to its grant.

The Supreme Court explained that:

Limitation is an amendment made to claims as provided for in Article 105 of LP-2015 and Article 105a of the EPC. Limitation can therefore neither add new subject matter

³⁴ Judgment of the Supreme Court 505/2021 of July 7, 2021, ECLI:ES:TS:2021:2713 (STS 505/2021).

³⁵ STS 505/2021.

³⁶ SAPM 196/2019.

³⁷ SAPB 513/2023: “incorporates new technical characteristics that the skilled person would not consider to be clearly and directly derived from the application, as we explained in our Judgment No. 14/2022, of January 13, 2022 (ECLI:ES:APB:2022:1), which in turn cites two other judgments by the same court: Judgments No. 593/2019, of March 29, 2019 (ECLI:ES:APB:2019:2939) and No. 2752/2020, of December 15, 2020 (ECLI:ES:APB:2020:12688).”

for protection (Article 48(5) of LP-2015 and Article 123(2) of the EPC), nor expand the scope of protection (Article 48(6) of LP-2015 and Article 123(3) of the EPC).³⁸

12.4.1.5 Patent registered by a person not entitled to obtain it

Article 10(1) of LP-2015 begins as follows: “The right to a patent shall belong to the inventor or to their successors in title, and it shall be transferable by any of the means recognized in the Law.” This means that the inventor can apply for registration or transfer of their patent rights, but if the patent is granted to a person not entitled to obtain it, then such person who is so entitled may claim transfer of ownership, per Article 12(1) of LP-2015, or seek invalidation of the patent per Article 102(1)(e) of LP-2015.

12.4.2 The effects of invalidity

12.4.2.1 Partial invalidity of a patent

A claim is either invalid or valid in its entirety. If the invalidity affects only part of a claim, the claim can be limited in accordance with Article 102(2) of LP-2015, but only the owner can propose such limitation (Article 103(4) of LP-2015). The court cannot limit a claim through partial invalidation. It can only invalidate the claim in its entirety. In referring to total or partial invalidity of a patent, Article 104(5) of LP-2015 speaks of invalidating all or some of its claims, but not of partially invalidating a single claim. This was better explained in Article 112(2) of LP-1986:

Where the causes of invalidation only affect part of the patent, partial invalidation shall be declared through annulment of the claim or claims affected by those causes. Partial invalidation of a claim may not be declared.

Now, while the earlier explicit provision has been rescinded, the rule preventing partial invalidation of a claim still applies. If a cause of invalidity partially affects a claim, it is up to the owner to limit it. If the owner does not do so, the judge will have to declare the entire claim invalid.³⁹

12.4.2.2 The *ex tunc* effects of invalidation

Article 104(1) of LP-2015 provides that:

A declaration of invalidation shall imply that the patent has never been valid and that neither the patent nor its original application have had any of the effects provided for in Title VI of the present Law, to the extent that invalidation has been declared.

Without prejudice to compensation for damage and prejudice that may be due when the owner of the invalidated patent has acted in bad faith, according to Article 104(3) of LP-2015,

The retroactive effect of invalidation shall not affect the following:

- a) Decisions on infringement of the patent that have become *res judicata* and have taken place prior to the declaration of invalidation.
- b) Contracts concluded before the declaration of invalidation, to the extent that they were executed prior to the declaration. However, for reasons of equity and to the extent justified by the circumstances, restitution of the amounts paid under the contract may be claimed.

Once it has become final, the declaration of invalidation of a patent shall become *res judicata* in respect of all persons.⁴⁰

12.4.3 Standing to bring invalidation proceedings

Since invalidation proceedings can be exercised by anyone with a legitimate interest in doing so, such proceedings are termed public by law,⁴¹ unless brought by a person not authorized to do so, in which case such standing is reserved for persons able to claim ownership.⁴²

³⁸ SAPB 513/2023.

³⁹ SAPB 513/2023.

⁴⁰ Article 104(4) of LP-2015.

⁴¹ Article 103(1) of LP-2015: “Actions impugning the validity of a patent shall be made public.”

⁴² Article 10(1) of LP-2015: “The right to a patent shall belong to the inventor or to their successors in title and it shall be transferable by any of the means recognized in the Law.”

An action for invalidation may be brought during the entire validity period of a patent and during the five years after the expiry of the rights.⁴³

12.4.4 Passive standing

An action for patent invalidation must be brought against its registered owner and communicated to all persons owning equitable rights in the patent registered in the Patent Registry, so that they may take part in the proceedings.⁴⁴

12.4.5 Limitation of the patent during invalidation proceedings

During the invalidation proceedings, Article 103(4) of LP-2015 permits the patent owner to “limit the scope of the patent by amending the claims” in order to defeat any alleged grounds for invalidation. “The proceedings will then be based on the patent as so limited.”

It must be recalled that limitation can result neither in the addition of subject matter, as explained earlier, nor expansion of the scope of protection for the claim limited. As a first condition for a limitation to be ultimately effective, the limits must not be exceeded, and as a second, the amended text of the claim must overcome the alleged cause of invalidity.

12.4.6 Jurisdiction for invalidation proceedings

Civil courts will in all cases have jurisdiction for invalidation proceedings based on the causes mentioned.

12.4.6.1 Appeals against SPTO patent decisions

SPTO decisions with respect to national patents are administrative decisions that may be appealed before national courts. If the ground for challenging a patent is a violation of the administrative rules governing the granting process, the Administrative Courts have jurisdiction for the dispute.⁴⁵ However, since the enactment of Organic Law No. 7/2022, the civil sections specialized in commercial cases in the Provincial Courts have jurisdiction for actions against violations of substantive provisions of patent law.⁴⁶

12.4.6.2 Invalidation proceedings before civil courts specialized in commercial matters

If an SPTO decision granting a patent is not challenged by any interested party, through the opposition procedure, within a period of six months,⁴⁷ the administrative decision will become final and the interested parties may only bring an action for invalidity of the patent before the specialized commercial courts.⁴⁸ This claim may be asserted by way of action or by way of defense. If obtained by way of judicial action, a declaration of invalidity produces effects in respect of all persons, as provided in Article 104(4) of LP-2015, and the patent registration is canceled. If obtained only by way of defense, it produces effects only between the parties.

12.4.7 The burden of proof in invalidation proceedings

Once a patent has been granted by a final administrative decision, it is not the owner who must prove that the requirements for patentability have been met. It is rather up to a plaintiff bringing action for invalidation to prove that the challenged claim is flawed on grounds for invalidation. According to Article 102(1)(a) of LP-2015,

A patent shall be declared invalid in the following cases: (a) when it is proved that, in respect of the subject matter of the patent, one of the conditions of patentability contained in Title II of the present Law, has not been met.

43 Article 103(2) of LP-2015: “An action for invalidation may be brought during the legal term of a patent and during the five years after its expiry.”

44 Article 103(3) of LP-2015.

45 Article 54(2) of LP-2015.

46 Article 82(2)(3) of Organic Law No. 6/1985 on the Judiciary.

47 Article 43.1 of LP-2015.

48 Article 116 *Jurisdiction* of LP-2015: “Cases arising from actions of any class or nature relating to the application of the present Law will be subject to the jurisdiction of civil, criminal or administrative courts according to the delineation of their respective fields of competence.”

If it must be proved that one of the conditions of patentability has not been met, that burden logically falls on the challenger, not the patent owner.⁴⁹

12.5 Patent infringement

The patent system offers legal certainty to inventors operating in a given technology sector. Those who register their inventions enjoy the exclusive right to exploit them for a determined period of time. Patents are also a way to make public an innovation that might otherwise remain unknown. A patent title determines what constitutes an invention protected by exclusive rights while also enriching the corpus of human knowledge and contributing to social progress. A patent delineates what must be respected during its period of duration so that actors in the market can avoid infringing the protected rights of others. Those interested in using protected technology can seek authorization to do so from its inventor, in exchange, as the case may be, for the price of licensing it. Or alternatively, they can opt to solve the same technical problem using means already available in the public domain or attempt through their own research and using their own resources to devise a different creative solution. Conversely, using a patented solution without permission from the patent owner constitutes infringement, subject to legal prosecution.

If a patent right holder or legitimate licensee detects the presence in a market of competing products or services they consider to be infringing their exclusive rights, they can deploy legal mechanisms in defense of their legitimate interests. Disputes not resolved by alternative means can then lead to litigation in the courts.

12.5.1 Claim construction

The subject matter of a patent is a crucial starting point in understanding the scope of protection provided by public authorities for an exclusive right to the invention concerned. This is part of what makes the claims made in a patent so important.

The protected content of a patent consists of one or more claims, which define the subject matter of the patent for which exclusive rights are sought. These claims take concrete form in an invention's technical features (structural and functional). They consist of one or more elements, the interrelationship between them and the technical effect they produce as the purpose of the invention.

There are various kinds of claims. They may relate to a physical entity (a product, substance or mixture), a device (an apparatus or machine) or even a system (a series of devices working together). A claim can also consist of an activity (procedures or methods for the manufacture of a product or even new uses for a product, such as previously known substances or compositions used as a medicine or for new therapeutic applications) (see Articles 6(4) and 6(5) of LP-2015). Claims relating to a physical entity protect the product or device in its entirety, and therefore convey the right for their owners to prevent third parties from exploiting them without the owner's consent. The owners can thus prohibit others from manufacturing, offering, commercializing (using, importing or possessing for those purposes) the patented product (mechanical, electrical, nutritional, chemical, pharmaceutical, phytosanitary, microbiological, biological, genetic) irrespective of the procedure used to obtain it (since the claims relate to a physical object). Claims made for a procedure protect the operations used to transform one or more initial substances into one or more final products, enabling their holders to prevent only use of the patented procedure and offers thereof for use. Also, a claim for a procedure to obtain a product protects only the product obtained directly from that procedure – not manufacture of the product using a different procedure.

49 SAPB 513/2023: "11. It is true, as in this case, that an administrative procedure can be assessed indirectly, but it is not the central focus of the court's proceedings. Now, unlike the administrative procedure, where the burden of convincing the examiner fell on the applicant, in our case, the burden of convincing the court that the patent has not met one of its requirements, and specifically inventive step, falls on the party bringing action for invalidation, whether by way of defense or counterclaim. It must be left clear that it is not up to the plaintiff to prove again that their patent meets all the requirements; nor is it up to the judge to reassess the patent as if he were an examiner. It is up to the judge, according to Article 218 of the LEC, to render a decision coherent with the claims and pleas of the parties without deviating from the factual grounds or fundamental points of law argued by the parties. 12. The party opposing invalidation must prove that the patent, or more specifically the claim at issue, lacks novelty or an inventive step. That party does not have to prove that the examiner was mistaken in granting the patent, since, as we have said, invalidation proceedings are not about reviewing the patent granting procedure. The proof required must be sufficient to overcome the doubts of the court, because if the court has doubts, the case must be decided in favor of validity, by virtue of Article 217 of the LEC."

A claim is expressed as an explanation of positive features. Exceptionally, however, the scope of a claim may be limited in a negative manner by means of a disclaimer, so that one element is explicitly excluded from the claimed protection.

All patents must contain at least one independent claim – the claim that defines the entity or activity that constitutes a solution to a technical problem as identified in the application. The independent claim must clearly specify each and every one of the features necessary to define the invention – unless such features are implicit in the generic terms used.

The patent may include more than one independent claim in the same category (product, procedure, device or use), but must comply with the requirement of “unity of invention”. That means that the claims must have subject matter in common forming a single general inventive concept. It must otherwise be divided among different patents.

The independent claim can (optionally) then be followed by one or more dependent claims, structured so as to add one or more technical features. This results in a scope more limited than the claim on which they depend but without altering the essential nature of the invention. Dependent claims can embody different, more specific versions of the invention.

The claims must be clear, concise and based on the description.⁵⁰ They provide the basis for determining whether the patentability requirements (novelty, inventive step and industrial applicability) have been met. The content and form of claims is regulated precisely (see Article 7 of the Implementing Regulations for the Law on Patents, approved by Royal Decree No. 316/2017, of March 31, 2017 (Implementing Regulations for the Law on Patents)⁵¹, regarding the national patents and the Implementing Regulations to the Convention on the Grant of European Patents, with reference to national patents). Under these regulations, claims must include, first of all, a preamble indicating the subject matter of the invention and the precise technical features used to define the elements claimed, which combine to constitute the state of the art. Claims must then include a section explaining the technical features (characterization section), which combined with the content of the preamble represents what the patent is intended to protect. Whereas the preamble provides the context and characterizes the invention, it is the characterization section that contains the actual inventive elements.⁵² That is where the technical features to be protected, presented as novel, are explained.

Patents are not the only industrial property instruments for protecting inventions under Spanish law. LP-2015 provides for two others. The first, utility models, require novelty, inventive step and industrial applicability but are considered “minor” inventions. They offer a configuration, structure or composition to give an object or product some practically appreciable advantage for use or manufacture (Articles 2 and 137 of LP-2015). The second, supplementary protection certificates, are for medicines and plant protection products. For a maximum duration of five years they provide the same protection as a patent for the active ingredients or combinations of active ingredients of medicines or plant protection products after patent protection expires, to compensate for the time required to complete the formalities entailed in obtaining marketing approval (Articles 2 to 6 of Regulation (EC) 469/2009 of the European Parliament and of the Council of 6 May 2009,⁵³ in conjunction with Articles 45 to 47 of LP-2015). The general analysis of what constitutes an infringement of exclusive rights also applies to these titles, albeit with certain particularities in each case.

12.5.2 Patent infringement disputes

Patent owners considering legal action to defend their rights must first clearly identify which of their claims may have been infringed. An error sometimes committed in this regard is losing sight of what the plaintiff's patent actually protects and what rights it actually confers. A strategy to avoid is focusing on the properties of the object, product or substance the plaintiff is commercializing, as it should not be assumed that they all correspond to the features of the invention as registered. It is important to bear in mind that in patent litigation, the latter and not

50 Articles 28 and 68 of LP-2015.

51 Royal Decree No. 316/2017, of March 31, 2017, approving the Regulations for the Implementation of Law on Patents.

52 Article 7 of the Regulations for the Implementation of Law on Patents.

53 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, 2009 OJ (L 152) 1.

the former is what matters. what needs to be perfectly clear in the complaint is what the plaintiff has registered specifically and how it has been unduly affected by the activities of a third party. Cases are lost when this basic point is forgotten.

A second important point in filing these complaints is to identify the features of what the defendant has been manufacturing or commercializing. This is precisely what should be compared with what is claimed in the patent. What the defendant may have subsequently registered is not relevant in this context, as infringement disputes are not about comparing titles according to legal priority. What matters is to verify whether the actions of the defendant constitute an infringement of the priority right registered by the plaintiff.

The best approach to these disputes is to accompany the complaint with an expert opinion⁵⁴ on related technical issues, with which the judge – however specialized the court may be in the subject matter concerned – may well be unfamiliar.⁵⁵ The opinion should focus first on the scope of the claims allegedly infringed, and then on how the defendant's activities infringed them.

To clearly assess whether the conduct of the defendant constitutes an infringement of the plaintiff's patent, the protected subject matter of the patent must be determined according to the patent's definition of the exclusive right.⁵⁶ This means delving into a legal analysis that must be based on properly structured technical information. The plaintiff's legal position will not otherwise be sufficiently robust.

Precise specification of what constitutes the patent's subject matter will be of fundamental importance in deciding whether infringement has occurred. It must be remembered here that protected subject matter is defined by a patent's claims as informed by the description and drawings accompanying them. In bringing action against an infringement, the first step is to determine the scope of patent protection.⁵⁷ This is because, as stressed by the Spanish Supreme Court, patent claims perform two functions. First, they define the subject matter to be protected by indicating the technical features of the invention necessary to execute the procedure or define the product concerned and thereby solve the technical problem identified in the specifications. And second, they determine the extent of protection conferred by the patent or patent application, taking into account the accompanying description and drawings.

The subject matter of the invention must be determined based on an analysis of the technical features in the characterization section, which must relate to the content of the preamble that introduces and contextualizes the invention. That permits what is novel about the invention to be identified, and thus for the extent and limits of the patent protection to be outlined. But to delineate more precisely where that protection is relevant to the case, it must be determined where the patent is exclusive and interpret the claims infringed to ascertain their technical and legal meaning in the context of the case. It is important to maintain the right legal balance in performing this analysis. The interpretation of claims should be neither too exorbitant nor too literal. The key is to find the right balance between equitable protection for the applicant and a reasonable degree of certainty for third parties (as described in the Protocol on the Interpretation of Article 69 EPC). Spanish case law in this area⁵⁸ admits no need for a strictly literal interpretation, allowing for a more intuitive approach, to find the true meaning behind the content of a claim. In determining the scope of patent protection, Spanish rulings have also tended to admit and factor in arguments based on the history behind patent applications and grants, including disclaimers, limitations and other steps taken by applicants in their interactions with patent offices.

12.5.3 Opposition by defendants

It is obviously not infrequent for patent owners bringing actions against infringement of their rights to encounter defendants mounting an offensive strategy against those rights. They may for instance file counterclaims for the patent to be declared invalid or subject to exceptions.⁵⁹ This shifts the argument to an issue prior to the alleged infringement: whether the requirements

54 Article 335 of LEC.

55 Article 118 of LP-2015.

56 Article 68 of LP-2015.

57 Judgment of the Supreme Court 223/2015 of April 29, 2015, and STS 389/2019.

58 Judgment of the Supreme Court (First Chamber) 598/2014 of November 7, 2014 (STS 598/2014), and STS 389/2019.

59 Article 120 of LP-2015.

for patentability of the invention were initially met or there are any other legal causes of invalidity that may be alleged.⁶⁰ The decision process for handling those kinds of disputes has been covered above, so we turn next to the alleged infringement.

An argument the defendant may raise in that connection is that of having been authorized to use the patent, which calls for an analysis of the origin and scope of such authorization to determine whether the defendant's conduct was in fact justified. The defendant might also argue that their conduct was not an infringement because it did not encroach on the scope of the exclusive right conferred by the patent.

12.5.4 Literal infringement

The defendant's conduct can be considered infringement if the technical solution addressed by the products and services they offer is precisely the same as what has been included in the characterization section of the patent owner's claims. Only if that can be demonstrated can the defendant's conduct be considered a literal infringement of the plaintiff's exclusive rights. If the patent includes multiple claims, such encroachment on any constitutes infringement, since each claim represents a legally protected invention (which must nonetheless comply with the principle of inventive unity). If the claims are structured more broadly, with various dependent claims, encroachment on any of those can also be successfully impugned as infringement.

For the court to rule that infringement has occurred, a wealth of carefully structured technical information must be provided to the judge to demonstrate that each and every one of the technical features registered in the patent are present in the defendant's product or service. It is up to the plaintiff to provide that information and meet a burden of proof appropriate for the circumstances with sufficient supporting evidence. That effort may well fail, however, if the expert opinion provided to the court does not meticulously compare the registered claims with the specific characteristics of the object manufactured, commercialized or used by the defendant. The same is true if the opinion neglects to cite the text of the patent and concentrates instead on comparing the objects, materials or products manufactured or commercialized by each party, rather than the content registered for the invention. That is not the right approach to analyzing potential patent infringement. It does not provide the judge with the technical criteria needed to determine whether exclusive rights have been infringed. Mere intuition does not suffice.

A finding that an exclusive patent right has been infringed can be obtained only by means of a legal effort to rigorously compare registered claims with the object manufactured, commercialized or used by the defendant, and only if the defendant's actions fit within the scope of protection for any of the claims.⁶¹ It will be concluded that the defendant has infringed the plaintiff's exclusive rights if the defendant's products or services simultaneously embody all of the elements contained in one of the patent's claims and each and every one of the technical features protected by the registered claims under the patent. The manufacture, sale or use of objects considered to be a reproduction of technical features registered by the plaintiff will permit the protection legally afforded by patents to be invoked.⁶²

A finding of patent infringement requires more than a general comparison between the invention claimed and a competing version of that invention. A much more rigorous element-by-element comparison must be made between the two. Only when all the technical features of the patented invention have been reproduced by the impugned activities can it be considered that the rights conferred by the patent have been infringed (the rule of the simultaneity of all elements must have been satisfied). Courts in Spain may not invoke the "essentiality" doctrine, now considered obsolete, to rule that a patent has been infringed. Dating back to LP-1986, the relevant comparison has not been between the "essence" of the patent and the product or service at issue, but between each element, one by one, to demonstrate that each and every one of the technical features of the object protected by the patent have been reproduced identically or equivalently by the allegedly infringing object.

The mere fact that someone has acted in the light of another person's patent does not constitute infringement, unless the technical features claimed in the patent have been reproduced element

60 Article 102 of LP-2015.

61 STS 389/2019 and STS 598/2014.

62 Articles 59, 60, 71 *et seq.* of LP-2015.

by element. If a different solution is offered for the problem the patent is intended to solve, such that any of the elements of the invention claimed has not been reproduced, either because use has been made of an innovative method – or an alternative method within the state of the art but not protected by patent – then no exclusive right has been infringed and the infringement action must fail.

12.5.5 Infringement by equivalence

In following the approach described above, it is important to prevent infringement from going unpenalized through a subterfuge: that of introducing irrelevant variations in a product or process to avoid the appearance that patent claims have been duplicated.⁶³ It is therefore important to bear in mind what was mentioned earlier about the interpretation and scope of claims. Infringement by equivalence is where an opposing party avoids identically reproducing every element of a patent claim by replacing one of its characterizing elements with another that is clearly equivalent. Spanish legislation makes it explicitly clear that patents also protect inventions where apparent discrepancies in an element are found in reality to be equivalent.⁶⁴ Such equivalence means that infringement has in fact occurred, carrying the same legal consequences as literal infringement.

When the comparison of elements is performed as described earlier, attention must be paid to whether a variation in an element that initially appears not to reproduce an element in a patent claim is not in reality a substantial variation from the perspective of a person skilled in the art. It is infringement – not literally but by equivalence (although the legal effect is the same) – if a function, the way it is performed, and the results obtained in solving a problem targeted by a patented claim are essentially replicated. Hence the crucial importance of patent descriptions. The proviso in all of this is that it must be obvious to the skilled person that the variation observed in the element concerned falls within the patent's scope of protection, based on its claims as interpreted in the overall context of the patent, including its accompanying description and drawings.

As a general rule, an element must be considered equivalent to an element of a claim if in its context it performs the same function to produce the same results from the perspective of a person skilled in the art. However, some additional factors must be considered in reaching that judgment. These include whether the skilled person – from the perspective of the priority date (if earlier, so as to avoid *ex post facto* judgments) – would have considered the element as falling outside the patent's scope of protection based on its description, drawings and claims. Consideration must also be given to whether the element would correspond to the prior art or be obvious from the perspective of the prior art. And yet another point to consider is whether the patent owner expressly and unequivocally excluded the element from the claim during the application process to avoid an objection from the examiner based on the prior art.

An approach frequently used to determine this issue of equivalence is the so-called triple identity test, which consists of analyzing whether the element performs the same function, uses the same *modus operandi* and produces the same result. While particularly useful for mechanical patents, this method may prove inadequate for other types of patents (for chemicals, medicines, etc.) which must be assessed based on a concrete case and an objective application of the rules described above – and from the perspective of a person skilled in the art. It is especially important in this context not to confuse this hypothetical “person” with an expert trial witness, the former being a legal concept and a function of the technical sector concerned, such that the point of reference must be determined according to the particularities of the case.

Another method used in assessing equivalence or non-equivalence comes from British case law (the “Catnic” and “Improver” cases) and is now also used in Spanish forensic practice. It consists of asking and answering up to three questions in sequential order until the situation is clarified. First, does the variant used by the defendant substantially alter the functioning of the invention described in the plaintiff's patent? If it does, there is no equivalence. If it does not, the process continues with the second question: would the proposed alternative have appeared obvious to the skilled person reading the patent at the time of its publication? If it entails inventive step,

63 Judgment of the Supreme Court 309/2011 of May 10, 2011, and STS 389/2019.

64 Article 68(3) of LP-2015.

there is no equivalence. If it would have appeared obvious, the third question is asked: in the opinion of the skilled person, having read the text of the claims and the patent description, did the patent owner intend to adhere strictly to the terms of the claim, as essential to the invention?

In any case – and this cannot be stressed too often – it is indispensable to methodically analyze, through element-by-element comparison between the patent and the good or service at issue, whether infringement by equivalence has been committed. To be rigorous, it is not acceptable to settle for general considerations about the overall invention. It is necessary to determine precisely what specific element is being substituted by equivalence for an element specified in the patent claim.

On the other hand, an element cannot be considered equivalent if the patent owner made the corresponding element in the patent claim subject to a disclaimer or limitation during the application process.

12.5.6 Indirect infringement

Patent protection can extend even beyond the areas discussed above. Patent owners also have the right to prevent third parties from delivering or offering to deliver to persons not authorized to exploit it, without the owner's consent, means of exploiting a patented invention relating to an essential element thereof, knowing, or under circumstances making it obvious, that those means can effectively serve, and are intended to serve, that purpose. This is what is known as indirect or contributory infringement.⁶⁵

Three requirements must be met for an act to be considered indirect infringement:

1. the alleged infringer must have provided means necessary to put an essential element of the patent into practice;
2. the person acquiring those means must not be legally authorized to exploit the patent; and
3. the infringer must have known, or circumstances must have made it obvious, that the means provided would permit, and were intended to permit, the invention to be put into practice by someone not authorized to do so.

The circumstances prevailing in the case can be assessed by analyzing various factors. Such an analysis might reveal, for example, that the means offered had no other use than for infringement; that a given volume of sales could be generated using the means offered to work the invention; or that information or instructions were provided to the defendant on how to operate the invention and any other data that may prove relevant in practice.

Such means need not be intended for use in the same country from which they are offered for their provision to constitute indirect infringement.

In some cases, the provision of such means may not provide a sufficient basis for a finding that indirect infringement has been committed. One such case is where the means provided consist of products purchasable for purposes other than patent infringement – unless the party providing them induces the receiving party to use them for such infringement.⁶⁶ Where such products are currently available on the market it will be necessary to show that the indirect infringer has induced direct patent infringement for their conduct to be considered unlawful. This line of argument is an example of how a patent can be defended without expanding its scope of protection. It should not, however, have the effect of preventing such products from being supplied for legal uses, unrelated to patent infringement.

12.6 Judicial patent proceedings and case management

12.6.1 Key features in patent proceedings

Judicial proceedings relating to patents are handled in Spain within the civil jurisdictional division, and more specifically by specialized commercial courts.

⁶⁵ Article 60(1) of LP-2015.

⁶⁶ Article 60(2) of LP-2015.

The basic rules governing such proceedings are contained in LP-2015, which dedicates Title XII to "Jurisdiction and Procedural Regulations".⁶⁷ Also applicable, for matters not covered in LP-2015, are procedural rules contained in the LEC.

One of the more noteworthy characteristics of patent-related litigation in Spain is that the cases are adjudicated by specialized civil courts.

Beyond patent infringement, invalidation and declaration of non-infringement actions,⁶⁸ specialized commercial courts have recently been assigned jurisdiction for appeals against SPTO decisions that mark the exhaustion of available administrative remedies for industrial property disputes. Among others, such decisions include patent refusals, oppositions, limitations and the validation of European patents. Jurisdiction for reviewing such SPTO decisions was reassigned from the country's administrative courts⁶⁹ to civil courts by Organic Law No. 7/2022. The type of judicial proceedings and the court competent to conduct them varies according to the matter in dispute, whether it be patent infringement, invalidation, declaration of non-infringement actions or appeals against SPTO decisions.

As discussed in greater detail below, patent invalidation, patent infringement and declaration of non-infringement actions are adjudicated in the first instance by ordinary commercial courts,⁷⁰ as regulated by the LEC, with significant particularities introduced by Title XII of LP-2015.

Unlike the approach taken by other legal systems, patent infringement and invalidation cases can be handled in Spain as parts of the same proceeding by a single commercial court, which is a common approach in forensic practice.

Patent cases typically start with a patent owner filing an infringement complaint and the defendant denying the infringement and filing a counterclaim for invalidation of the patent allegedly infringed, or invalidation of one or more of the patent's claims. The judge then analyzes the validity of the patent, and if the invalidation counterclaim is denied, turns to the alleged infringement.

It is also common for the party seeking invalidation and/or a declaration of non-infringement, to initiate the proceedings, with the defendant then filing a counterclaim for patent infringement (seeking a declaratory judgment, injunction, removal and damages).

The process works differently for the judicial review of SPTO patent decisions marking the exhaustion of administrative remedies, as mentioned earlier. In those cases, SPTO decisions are appealed directly and in a single instance to the commercial sections of specific Provincial Courts.

The process for substantiating these appeal proceedings does not go through *juicio ordinario*, but *juicio oral* (characterized by greater simplicity of proceedings), subject to the special procedures introduced in Article 447*bis* of the LEC (see Section 12.6.9.2).

12.6.2 Pre-action and pre-trial

Before filing an infringement action, the patent owner and other parties with standing derived from the patent can petition the competent commercial court judge to authorize urgent measures (inquiries or investigations) to take evidence substantiating whether exclusive rights granted under the patent are being infringed.

Such urgent inquiries and investigations, regulated by Articles 123 *et seq.* of LP-2015, are intended to assist interested parties having *prima facie* evidence of infringement in seeking evidence that their exclusive rights are in fact being infringed.

The purpose is to avoid a long and costly trial over potential patent infringement when it cannot otherwise be substantiated by the prospective plaintiff.

⁶⁷ Articles 116-136 of LP-2015.

⁶⁸ In this context, *acción negatoria* (negatory action) refers to an action for a judge to declare that a particular act does not constitute patent infringement.

⁶⁹ Administrative courts are those competent for the judicial review of administrative acts.

⁷⁰ Where an action seeks compensation only, and where the amount claimed is 15,000 euros or less, the case is substantiated by a verbal proceeding (Articles 249(1)(41) and 250(2) of LEC).

Since these measures are preliminary to judicial action, their authorization is subject to requirements designed to protect the alleged infringer against unfounded petitions.

Accordingly, before deciding on such a petition, the judge may order such reports and investigations as they deem necessary.

These measures may only be authorized, moreover, when it can be presumed, under the circumstances in the case, that the substantiation of patent infringement will not be possible without them.

In authorizing such inquiries or investigations, the judge must fix a deposit to be made by the petitioner to meet any damage or prejudice they might cause.

To avoid the possible elimination of any traces of infringement, these measures are conducted without giving prior notice to the persons targeted.

To ensure protection for the trade secrets or confidential information of the prospective defendant and avoid the possibility that acts of unfair competition might subsequently be committed by the petitioner, the latter does not take part in the enforcement of these measures.

Such inquiries or investigations are ordered by the judge with the participation of one or more experts they may designate for the purpose. Having subsequently been informed of the results, and having heard the arguments of the petitioner, the judge then determines whether evidence of the alleged infringement has indeed been substantiated.

If they deem it has not, the inquiry or investigation is closed and a separate record of it is made (and kept secret: the petitioner is notified that they will not be informed of the results).

Conversely, if a presumption of patent infringement is found to be warranted, the judge, assisted by the designated expert or experts, must make a detailed inventory of the machines, equipment, products, processes, facilities or activities by means of which such infringement was presumably carried out.

A copy or certification of the findings is then provided to the petitioner solely for use in pursuing the infringement action, after which the petitioner has 30 working days to do so. If the petitioner fails to bring the infringement action within that time, the findings resulting from this process cease to have effect and may not be used for any subsequent judicial action.

If the findings are rejected, or the infringement action is not filed within the allotted time, the person targeted by these measures can request appropriate compensation for expenses and damage incurred, including loss of income, to be charged against the deposit, all without prejudice to such additional liability as the petitioner may have incurred.

12.6.3 Venue, jurisdiction and case assignment rules

12.6.3.1 Infringement and invalidation actions

Since September 1, 2004, with the entry into force of Organic Law No. 8/2003,⁷¹ jurisdiction for patent infringement, invalidation and other related civil litigation in Spain, has been assigned to the commercial courts located in the autonomous community seats of the country's High Courts of Justice.⁷²

For cases concerning industrial property, on the other hand, jurisdiction was significantly restructured after the entry into force of current patent law, LP-2015, on April 1, 2017.

According to Article 118 of LP-2015, objective jurisdiction for industrial property litigation has been assigned to commercial courts in autonomous community seats of High Courts of Justice,

71 Prior to the enactment of this reform, the judicial review of SPTO decisions on industrial property had been the responsibility of the administrative law chambers of the High Courts of Justice, which are organs of administrative litigation jurisdiction.

72 There are 17 autonomous communities in Spain, which means that commercial courts in 17 cities (the seat of each community's High Court of Justice) were assigned jurisdiction for such litigation.

but not in every autonomous community – only those which the General Council of the Judiciary has designated for such exclusive jurisdiction.

To date, the General Council of the Judiciary has exclusively assigned specialized jurisdiction for industrial property cases to commercial courts in Barcelona, Madrid, Valencia, Las Palmas, Bilbao, La Coruña and Granada.

Territorial jurisdiction for those cases is assigned to a commercial court specialized in that area according to the domicile of the defendant, as described above, or in its absence to the domicile of the defendant's authorized representative in Spain if such a specialized commercial court is located there.

Absent courts specialized in industrial property at both venues, then the plaintiff can choose any commercial court recognized as competent for industrial property cases.

For industrial property infringement cases, the court specialized in such cases in the autonomous community where the alleged infringement has either occurred or produced effects may be chosen as competent, at the plaintiff's discretion.

Absent such courts in those venues, any commercial court assigned jurisdiction for industrial property cases by the General Council of the Judiciary may be chosen as competent, also at the plaintiff's discretion.

Jurisdiction for all appeals against commercial court decisions in any province is assigned to the corresponding Provincial Court specializing in such appeals.

12.6.3.2 Appeals against SPTO decisions

The reform of Organic Law No. 7/2022, which entered into force on January 14, 2023, assigned, as a sole instance, jurisdiction for appeals against SPTO industrial property decisions marking the exhaustion of administrative remedies to the commercial sections of certain Provincial Courts.

More specifically, such competence was assigned to the commercial court located in the seat of the High Court of Justice in the autonomous community where the plaintiff is domiciled, if assigned jurisdiction for industrial property cases by the General Council of the Judiciary, or in the absence of such a court, where the plaintiff's authorized representative in Spain is domiciled.⁷³ Alternatively, the specialized sections of the Provincial Court in which the headquarters of the SPTO are located may be chosen as competent, again at the plaintiff's discretion.⁷⁴

12.6.4 Provisional measures

Patent infringement proceedings provide a classic example of how provisional measures are requested, granted and used. In Spanish law, the general rules governing provisional measures contained in the LEC are supplemented where necessary by special rules in LP-2015.⁷⁵

12.6.4.1 When provisional measures may be requested

Provisional measures may typically be requested in Spanish proceedings when an action is filed but also before or after the start of proceedings, during the substantiation phase. They may also be requested after the judgment is issued, pending appeal.

As a general rule, provisional measures are requested when the action is filed, but a prospective plaintiff may do so beforehand by invoking and substantiating urgency or necessity.

The aim in requesting a provisional measure before the action is filed is typically to put an immediate and provisional stop to suspected infringement at a time when it is still not possible or practically feasible to formalize a duly grounded complaint, accompanied by such expert reports or documents as may be necessary to support an infringement allegation.

⁷³ As noted earlier, only the specialized sections of the Provincial Courts of La Coruña, Bilbao, Barcelona, Madrid, Valencia, Granada and Las Palmas have been assigned such exclusive jurisdiction.

⁷⁴ The SPTO is based in Madrid.

⁷⁵ Articles 127-132 of LP-2015.

Provisional measures may sometimes be requested after the action is filed, when warranted by related facts or circumstances (typically, developments of which the plaintiff was not aware earlier or which may aggravate the damage being incurred).

Subject to certain conditions, provisional measures may be requested even after a judgment has been rendered in the first instance, pending the formalities required for appeal.⁷⁶

As a particularity in patent matters, provisional measures may also be requested at this stage where a sentence has been imposed, to ensure the enforcement of the decision.⁷⁷

12.6.4.2 Hearing with the defendant

As a general rule, whether requested before, simultaneously with, or after the action is filed, a hearing must be held with the defendant before a provisional measure is ordered. The parties must then appear so that the defendant can make oral arguments to defend themselves against the provisional measure.

A court may exceptionally order a provisional measure without a prior hearing with the defendant, if requested by the plaintiff on substantiated grounds of urgency, or alternatively, if the prior hearing would have the effect of compromising the effectiveness of the provisional measure.

Here, the urgency is linked to the immediate need to adopt the provisional measure as its effectiveness could be compromised by the delay required to summon the defendant.

This is particularly the case where it is demonstrated that the mere prospect of holding the hearing would enable the defendant to alter their behavior so as to defeat the provisional measure's purpose.

Provisional measures ordered without a hearing for the defendant can be opposed in writing. The parties can then be summoned to a hearing where the court can review its previous decision in the light of the defendant's arguments.

Given the potential impact of provisional measures in the field of patents, especially in the case of preliminary injunction, LP-2015 provides for a special mechanism called "protective letters", to avoid the possibility of provisional measures being ordered without a prior hearing (see Section 12.6.4.5).

12.6.4.3 Types of provisional measures and preliminary injunction

The specific types of measures a judge may order under LP-2015 include the following: cessation or prohibition of acts potentially infringing the petitioner's rights when there is *prima facie* evidence that such infringement is imminent; the detention and storage of goods presumably infringing a patent owner's rights, and of the means exclusively used for their production or for carrying out a patented process; the requirement of a security deposit to cover any damages awarded by the court; and the entry of appropriate registry notations.

Preemptive provisional measure often make the most sense in industrial property litigation and are explicitly provided for, in general terms, in Article 726(2) of the LEC, and more specifically in Article 128(1) of LP-2015. These consist in particular of cessation or prohibition of particular acts, so as to ensure the effectiveness of the rights at issue, not only in terms of the judgment to be pronounced but also by avoiding the prolongation of a situation that appears *prima facie* to be unlawful and unjust and the aggravation of its consequences for the plaintiff. These measures will also help to ensure the effectiveness of the judgment ultimately rendered by safeguarding the plaintiff's potential right to compensation (the implicit intent of Article 726(1) of the LEC). They may also be justified by the legitimate aim of not permitting the defendant to benefit from potentially infringing activity while the case is being adjudicated.

⁷⁶ Article 730(4) of LEC.

⁷⁷ Article 130(1) of LP-2015.

12.6.4.4 Requirements for the adoption of provisional measures

The requirements for adopting provisional measures in civil proceedings are clearly set out in the LEC. The measures must be aimed exclusively at guaranteeing the effectiveness of the prospective judgment – as both necessary and sufficient to protect the right at issue – and providing the least burdensome solution (proportionality) for the case concerned.⁷⁸ In addition, the petitioner must demonstrate the risk deriving from procedural delay (*periculum in mora*) and the likelihood of success on the merits (*fumus boni iuris*), and must make a security deposit to compensate for damage potentially to be caused by the provisional measure.⁷⁹ All of these requirements must be met for the provisional measures to be ordered.

12.6.4.4.1 Risk deriving from procedural delay

Periculum in mora, the risk deriving from procedural delay,⁸⁰ an essential requirement for provisional measures, must be assessed when there is a reasonably foreseeable and objective risk that the defendant may take advantage of procedural delay to render ineffective such protective measures as may eventually be ordered, or that a situation may arise in the interim preventing or hindering the effectiveness of remedies ultimately awarded. In a scenario where exclusive rights are being unlawfully infringed, the risk of procedural delay is clear. Prolonged proceedings may in that case enable the defendant to persist in the infringing conduct and aggravate the damages caused to the plaintiff, not only commercially and economically but possibly in other ways (moral or reputational damage, for instance). Such monetary compensation of whatever amount as may be awarded subsequently could then prove inadequate to remedy the detrimental consequences of infringement, if permitted to persist through conclusion of the proceedings. The final result could then prove a belated and ineffective solution. To decide otherwise could aggravate damage the plaintiff is attempting to stop.

12.6.4.4.2 Likelihood of success on the merits

Fumus boni iuris, the second essential requirement for provisional measures,⁸¹ entails a provisional but relatively in-depth analysis, according to the circumstances in the case and based solely on information available at the time (which can be expanded during the evidentiary phase of proceedings), of *prima facie* evidence supporting the plaintiff's allegations and therefore justifying protective measures. Such an analysis needs to accompany the application for provisional measure to demonstrate that the plaintiff's case is well-founded.

12.6.4.4.3 Security deposit, counter-guarantee or substitutionary guarantee

LP-2015 contains special rules⁸² on the security the plaintiff must provide to compensate for damage potentially to be caused by the provisional measure should the suspicion of infringement prove unfounded. They also allow for a counter-guarantee being required to ensure that the defendant can later resume their commercial or industrial activity – but only where the provisional measure is sufficiently restrictive to justify such an exceptional solution.⁸³

12.6.4.5 Provisional measures and protective letters

A unique situation that may arise in patent litigation is the possibility that persons apprehensive at the prospect of provisional measure without a prior hearing can preemptively submit a “protective letter” to the court stating what their arguments would be should a provisional order be requested.⁸⁴ If a provisional order is requested after the judge receives such a letter (within three months) the judge can then consider the arguments of both parties and reach a decision directly. The intent of this provision is to ensure that the judge has at their disposal as much information as possible, before taking a decision that may involve a restriction of commercial or industrial activity, so that their decision on the matter may be the most appropriate one.

12.6.4.6 Effects of provisional measures on subsequent judgments on the merits

If, after a provisional measure has been granted, a judgment in the first or second instance absolves the alleged infringer, the provisional measure is lifted *ex officio*, unless the plaintiff

⁷⁸ Article 726 of LEC.

⁷⁹ Article 728 of LEC.

⁸⁰ Article 728(1) of LEC.

⁸¹ Article 728(2) of LEC.

⁸² Articles 129(1), (3), (4) and (5) of LP-2015.

⁸³ Article 129(2) of LP-2015.

⁸⁴ Article 132 of LP-2015.

requests otherwise or requests alternative measures. The judge then considers and decides on that request after hearing from the other party.

If the judgment absolving the alleged infringer becomes final, any remaining measure is lifted *ex officio*, and the defendant may seek compensation for damage incurred.

12.6.5 Amendment of the patent

The obligation to allow owners to limit their patents, at least in the case of European patents validated in Spain, was imposed by Article 138(2) of the EPC, as revised in 2000. Under that provision, the owner of a European patent has the right to amend and limit the patent's claims during proceedings on its validity.

Given the absence of any domestic provision on this point, no such right was recognized for national patents; nor were there any procedural rules for the amendment of European patents validated in Spain. Court rulings were therefore initially left to each judge's discretion in such cases.

That omission was only partly corrected by the patent law now in force.

12.6.5.1 Patent amendments in judicial proceedings

Patents can be amended during the course of either invalidation or infringement proceedings.

In the case of invalidation proceedings, the patent owner can opt, on a principal or subsidiary basis, to limit the patent by amending its claims.

In this scenario, the owner needs to present and justify a new set of claims to serve as the basis for further proceedings. The plaintiff seeking invalidation must then adjust their arguments so as to either maintain or revise their request for invalidation in light of the limitation proposed.

As explained in Section 12.5.3 in more detail, requests for invalidation of a patent, entirely or partially, are also a typical defense against actions for patent infringement.

The defendant may question the validity of the patent by means of an exception, to have the action simply dismissed, or by filing a counterclaim to have the patent explicitly declared invalid. When such an exception is invoked, the patent owner may request that it be treated as a counterclaim.

If the defendant responds, on either a principal or subsidiary basis, by invoking invalidity, the patent owner can then opt to limit the patent by amending its claims – bringing and justifying a new set of claims in response to the counterclaim (or invalidity defense, as the case may be). The owner must also explain, and possibly prove, how the proposed limitations affect the infringement action.

In the light of a patent amendment made in response to either a counterclaim or a defense, it is then up to the petitioner for invalidation to maintain or amend their petition in light of the proposed limitation.

12.6.5.2 Effect on the proceedings of patent amendment outside the process

A patent under litigation for infringement or invalidity can also be amended outside the process. This may happen when the patent owner applies to the SPTO for an amendment; when an opposition or limitation procedure or an appeal is filed, in the case of national patents; or when procedures are filed before the EPO, in the case of European patents. Amendments may also be made in proceedings before another court.

When a patent is amended outside the process in response to changed circumstances, the patent owner may request that the amended version serve as the basis for court proceedings, which can significantly alter the course of those proceedings.

Spanish procedural rules on this point remain limited, with article 120(4) of LP-2015 providing simply that the judge or court must entertain allegations from the other parties, which can create

a range of problems, in particular, the need for both the plaintiff and the defendant to provide new expert evidence analyzing the amendments to the patent, as well as the possibility for the parties to dispute such new evidence. The problem is exacerbated by the fact that this amendment is not limited in time to the initial phase of the proceeding, and may therefore occur at a late stage of the process.

12.6.6 Gathering of information

Without prejudice to the information provided in Section 12.6.8 on confidentiality below, the LEC expressly and extensively deals with parties' ability to collect information from each other and from third parties in support of their rights.

12.6.6.1 Preliminary proceedings

In the framework of preliminary proceedings,⁸⁵ prior to and in preparation for court proceedings, a party intending to bring legal action for the infringement of an industrial property right can apply for the exhibition of banking, financial, commercial or customs documents issued within a specific period of time and assumed to be in possession of whom may be sued as liable.

This application must be accompanied by *prima facie* evidence of the existence of the infringement, which may consist of the presentation of a sample of the specimens, goods or products in which the infringement has occurred.

The applicant may request that the Clerk issue a testimony of the exhibited documents if the served party is unwilling to hand them over for incorporation to the proceedings.

12.6.6.2 Exhibition and production of documents during the proceedings

Once the trial has begun, the plaintiff may seek exhibition of the same documentation described for preliminary proceedings above.

In addition, the LEC establishes a duty of exhibiting documents amongst the parties. Each party may thus seek that the other parties exhibit any documents that are not in their possession and which refer to the matter at issue in the proceedings or the value of the evidence.

There are strict consequences for unjustified failure to comply with this duty, up to the point where a court may, taking into consideration other evidence, attribute probative value to the version such document's contents may have given, or to a non-certified copy of such document if filed by the applicant for exhibition.

The exhibition of documents by third parties may also be allowed, but subject to greater restrictions.

The exhibition of documents in the possession of non-litigant third parties may only be sought where the court deems that knowledge of such documents is important for the purposes of issuing judgment. The judge must also hold a prior hearing with the third party concerned.

12.6.7 Taking of evidence

12.6.7.1 Admissible evidence

There is nothing particular to patent proceedings in terms of the evidence parties may use to prove the facts on which their arguments are based, all of which is regulated by the LEC.

Evidence is taken by the following means: the questioning of opposing parties, the production of public or private documents, the presentation of expert testimony or reports, the taking of evidence by the court and the questioning of witnesses.

Any means to record words, sounds and images are also admitted, as well as any instruments that allow words, data and mathematical operations carried out for accounting purposes or any other purposes, which are relevant to the proceedings, to be saved, known or reproduced.

⁸⁵ Preliminary proceedings are those performed prior to trial for the preparation thereof. These proceedings are different from those discussed in Section 12.6.2, the purpose of which is limited to establishing the reality of the infringement and have a specific regime (article 123 of LP-2015).

The foregoing list of evidentiary possibilities is not closed. Other forms of evidence may also be used if they serve to substantiate facts relevant to the case.

Facts in dispute can also be established by means of judicial presumptions or rebuttable legal presumptions.

Judicial presumptions are those where a judge, based on an admitted or proven fact, can presume the certainty of another fact if there is a precise and direct link between the admitted and presumed facts according to normal human judgment.

Legal presumptions are those established in law for presumed facts that need not be proven by the party they benefit. Unless expressly indicated otherwise, legal presumptions can be rebutted by evidence to the contrary.

A typical example of a legal presumption in the field of patents, as a consequence of Article 34 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), is found in Article 69(2) of LP-2015, which provides that where a patent concerns a process for the manufacture of new products or substances, it shall be presumed, barring evidence to the contrary, that any product or substance with the same characteristics has been obtained by using the patented process.

Given the object of patent proceedings, expert testimony is essential to ascertaining the infringement or validity of a patent, as discussed in Section 12.6.7.2.

12.6.7.2 Expert opinions

In judicial proceedings relating to patents, given their technical nature, expert testimony represents an indispensable form of evidence in determining whether a patent has been infringed or meets the requirements for validity.

An expert report, while obviously no substitute for a judicial assessment, does provide critical input enabling a judge, after also considering other evidence, to reach their own conclusions.

In Spain, reports may be prepared by experts designated by the parties, or by the judge when a litigant so requests, or may be provided pro bono.⁸⁶ When designated by the judge, the expert is selected from one of the lists provided annually by various professional associations and cultural and scientific academies and institutions concerned with the study of subject matter to be covered by the expert opinion. The first designation from each list is selected by drawing lots followed in turn by those next on the list.

In patent litigation, both parties generally provide expert reports prepared by their own designated experts, but there is no impediment to either the plaintiff or defendant providing an expert report prepared by an expert of their choice, and the other party requesting a report from a court-designated expert.

The plaintiff and defendant must submit the reports prepared by their own designated experts together with their claim or defense, or counterclaim as the case may be.

As an exception, the defendant or plaintiff may respond to a claim or counterclaim but provide the expert opinion later, provided the impossibility of submitting it simultaneously with the response can satisfactorily be demonstrated.

These provisions are stricter in the case of patent litigation than in other general cases. The general regime is more flexible as it allows the subsequent submission of expert reports not only by the defendant but also by the plaintiff, and it is sufficient that it was not possible for them to provide the expert opinions with the claim or the response.

Where later submission of the expert reports is allowed, parties must submit them as soon as possible, and at least five days before the preparatory hearing discussed in Section 12.6.9.1.4.

⁸⁶ Exemption from certain costs of the process, based on the litigant's economic situation.

Parties may also submit new expert reports as necessary or useful in the light of subsequent allegations or arguments, for the defense or during the preparatory hearing. Such reports must be submitted at least five days before the start of the trial.

If the complaint is for infringement and the defense is based on the patent's invalidity, for instance, the plaintiff might then submit an expert report supporting the patent's validity.

Expert reports are submitted in writing, but parties may request an expert's presence during oral proceedings, where considerable latitude is often allowed.

Expert participation during the trial may consist of:

- explanations for the expert's opinion, or elaboration where necessary on specific points therein;
- responses to questions and objections with respect to method, premises, conclusions and other aspects of the opinion;
- a full presentation of the opinion, where written content may need to be supplemented by additional documents or materials to fully convey the expert's point of view;
- responses to requests for a wider opinion, elaborating on the feasibility and utility of providing one, on additional related points to be included and on the time needed to prepare it; or
- a critique of one expert's opinion by another for the opposing party.

The judge may also take an active part in questioning experts and requesting explanations for their opinions; the judge may not, however, order an expanded opinion *ex officio*.

As a particular aspect of cases involving an action for patent invalidation, and where the parties' expert reports are contradictory on specific points, the judge may order, either *ex officio* or at a party's request, a written expert report from the SPTO on those specific points.

The author of the SPTO report may then be called by the judge to testify on its content.

12.6.8 Confidentiality

The Spanish legal system places great importance on protecting the confidential information of parties to judicial proceedings.

The provisions generally applicable on this point are contained in Law No. 1/2019, of February 20, 2019, on Trade Secrets.⁸⁷

That Law provides for various measures to protect the confidentiality of such trade secrets where necessary, including:

- restricted access to any document, object, material, substance, electronic file or other media containing information that may partially or fully constitute a trade secret;
- restricted access to hearings, and to recordings or transcriptions thereof, potentially revealing information that may partially or fully constitute a trade secret;
- the preparation of a redacted, nonconfidential version of the judicial decision issued in such a case, concealing or removing information that may constitute a trade secret, to be made available on an unrestricted basis.

Article 122 of LP-2015 also contains a specific provision on confidentiality in connection with preliminary proceedings or measures for the seizure of evidence. In that connection, where a court has found it necessary to shed light on the facts in a case by gathering information considered by the court to be confidential in nature, the court must also take the measures necessary, if so requested by the parties, to protect the confidentiality of the information gathered and effectively supervise the use of that information by the party having requested it.

87 Law No. 1/2019, of February 20, 2019, on Trade Secrets.

12.6.9 Proceedings

12.6.9.1 Infringement and invalidity proceedings

The ordinary proceedings to substantiate patent litigation entail the submission of both written and oral evidence.

The first phase in these proceedings, focused on allegations, is dominated by written submissions and starts with the filing of a formal claim.

12.6.9.1.1 Statement of claim

Infringement or invalidation proceedings start with a written claim generally similar to those filed in ordinary trials on other matters.

The statement of claim must provide the plaintiff's and the defendant's identifying information and circumstances, domicile, residence or place where they can be located. It must then enumerate and separately present the facts and legal arguments supporting the claim and clearly state what is being asked of the court.

The claim must be accompanied by documentation supporting the claim, including the opinions of experts designated by the plaintiff, as explained in Section 12.6.7.2.

12.6.9.1.2 Statement of defense

The defendant's response to the plaintiff's claim also resembles those presented in most other ordinary trials, consisting of a written statement denying or admitting the facts as presented by the plaintiff.

The defendant must also indicate procedural exceptions and other allegations that need to be considered as part the proper adjudication of any case.

Patent litigation sets apart from other proceedings in a longer time limit for responding to the plaintiff's claim: two months,⁸⁸ compared to 20 working days for most ordinary proceedings.⁸⁹

Another particularity, where the validity of a patent is being challenged, as mentioned in Section 12.6.5, is that the plaintiff can amend their claim during the substantiation phase by opting to limit the patent and present a new set of claims. A patent can also be amended out of the proceedings owing to a change in circumstances, and the patent owner may then request that the amended patent serve as the basis for court proceedings.⁹⁰

Where proceedings have been initiated by an action for invalidity, the amendment of a patent claim to limit the patent must take place during consideration of the defendant's (the patent owner's) response to the plaintiff's claim (that of the party alleging invalidity).

12.6.9.1.3 Counterclaim

Spanish procedural rules permit defendants to respond to a plaintiff's claim not only by defending themselves but also by making their own claims against the plaintiff.⁹¹

Such counterclaims are admissible, however, only if made in connection with the initial claim.

In patent litigation, as explained earlier, that connection is clear when the claim is for infringement, the defendant denies the infringement and then files a counterclaim for invalidation of the patent.⁹² The connection can also be established when after the initial claim is for invalidity, the defendant denies the invalidity and files a counterclaim for infringement.

The patent owner can also limit the patent by amending its claims when responding to the counterclaim in which the defendant accused of infringement requests the invalidation of the patent that the initial plaintiff considers infringed. See Section 12.6.5 for more details.

⁸⁸ Article 119 of LP-2015.

⁸⁹ Article 404(1) of LEC.

⁹⁰ Article 120 of LP-2015.

⁹¹ In order for the counterclaim to be adjudicated, it may also need to be filed against a third party, in addition to the initial plaintiff.

⁹² As described in Section 12.6.9.1.2, invalidity can also be invoked as part of a defense against the initial claim, rather than as a counterclaim.

Once a response has been made to the initial claim, and to the counterclaim as the case may be, the written phase of proceedings comes to a close and subsequent proceedings are predominantly oral.

12.6.9.1.4 Preparatory hearing

Once the claim or, as the case may be, the counterclaim has been answered, the parties are summoned to appear before the court for a preparatory hearing.

This hearing is aimed essentially at reaching an agreement between the parties to deal with procedural issues, delineate the object of the proceedings and decide on what evidence will be admissible (for an immediate ruling by the judge after hearing proposals from each party).

12.6.9.1.5 Trial

Trial is where the evidence ruled admissible is presented and debated before the court.

As described in Section 12.6.7, the range of admissible forms of evidence is quite broad and may consist of statements by the parties, witness testimony, oral expert reports, dissenting expert opinions, the taking of evidence by the court, and in some cases recorded words, images and sounds.

Following this evidentiary phase, the parties present their conclusions. During this phase the attorneys for each party present oral statements on the facts in dispute and assessments of the evidence and legal arguments presented in support of their respective claims. This concludes the proceedings prior to the court's judgment.

It is not uncommon for patent litigation to be scheduled over several sessions on successive days.

12.6.9.1.6 Judgment

Following the trial, if there is no agreement to hold final proceedings,⁹³ the court has 20 days to issue its ruling, which must be in writing.

Judgments issued on patent cases generally resemble those issued in other cases, though sometimes entailing difficulties inherent in the subject matter concerned.

The judgment must include an analysis and assessment of the facts based on the evidence presented and cite legal norms and principles in support of the judgment's dispositive provisions.

The judgment's dispositive provisions must be numbered and formulated as acceptance or dismissal of the parties' respective arguments.

12.6.9.2 Proceedings against SPTO decisions

Appeals filed against SPTO decisions are substantiated by means of a verbal proceeding, subject to special provisions contained in Article 447*bis* of the LEC.

A verbal proceeding consists of a combination of written and oral proceedings.

Very briefly, following an SPTO decision marking the exhaustion of administrative remedies, these verbal proceedings are initiated by a written appeal to the Provincial Court having jurisdiction to hear it. The case file is then obtained from the SPTO, the parties are summoned and the appellant is given a deadline for the formalization of their appeal.

The SPTO and other interested parties are then invited to respond.

Following the written allegations phase, if one of the parties so requests, the parties are summoned to an oral hearing before the court to consider the appellant's allegations and hear allegations from the other parties.

Following that hearing, or in its absence, the proceedings conclude in preparation for the judgment.

93 The final proceedings are evidentiary in nature and very limited. They can only be granted at a party's request and under very specific circumstances. The judge may exceptionally order such proceedings *ex officio*.

12.6.10 Alternative dispute resolution

Generally speaking, except where prohibited by law, or limited in the general public interest or in the interests of third parties, the LEC offers parties the option of recourse to mediation or arbitration for disputes at issue.

When parties in an ordinary trial are summoned to the preparatory hearing they must be informed of the possibility of such recourse to reach a negotiated solution to the dispute. The parties indicate their decision on that point and the reasoning behind it during that same hearing.

At the start of the preparatory hearing, the court may invite the parties to pursue an agreement through mediation or other means and thus dispense with the court proceedings. The court may urge them to attend a briefing on that possibility.

Failing such an agreement the hearing will continue, and after dealing with procedural issues and delineating the facts in the case, the court may urge the parties or their representatives and their attorneys to reach a settlement of the dispute.

In addition to its general provisions, LP-2015 expressly provides for alternative resolution mechanisms for patent disputes, consisting of mediation and arbitration. It also provides for prior conciliation in cases concerning the inventions of employees.

12.6.10.1 Mediation and arbitration

Interested parties may resort to mediation or submit their patent-related disputes to arbitration for matters defined by law as subject to individual discretion.

In the context of patent grant, opposition and appeal proceedings, disputes relating to the fulfillment of requirements for patents to be granted and maintained, and to remain valid, are not matters of individual discretion and thus fall outside the scope of mediation and arbitration.

In the case of arbitration, a final arbitration award has the effect of *res judicata*, and the SPTO is bound to perform the steps necessary to execute that decision.

Similarly, in the case of mediation, an agreement signed by the mediator and the parties, once recorded as a public deed or confirmed by a court, becomes an enforceable right, and the SPTO must be notified accordingly for the enforcement of that right.

12.6.10.2 Conciliation in respect of employee inventions

As a step preliminary to judicial action based on the applicable governing provisions, disputes relating to inventions in the context of an employment or a service contract relationship may be submitted, if the parties so agree, to a conciliation process before the SPTO.

Disputes subject to such prior voluntary conciliation may relate to patent ownership or economic compensation that may, under certain circumstances, be accorded to the inventor. More specifically, in accordance with article 15(2) of LP-2015, an employee is entitled to compensation, even where the patent is legally owned by the enterprise employing them,⁹⁴ when the personal contribution made by the employee and the importance of the invention for the enterprise clearly exceed the explicit or implicit content of the employment contract or relationship.

If the employee is the legal owner of the patent,⁹⁵ but where knowledge gained while employed by the enterprise has predominantly contributed to obtaining the patent, or where means provided by the enterprise have been used to obtain it, the enterprise is entitled to assume ownership of the invention or to reserve the right to use it in exchange for fair economic compensation.⁹⁶

Public universities and public research institutes may decide to assume ownership of inventions conceived by researchers in their employment. If they do so, the researchers concerned are

94 Ownership corresponds to the enterprise where inventions have been conceived by employees or service providers while their employment or service contracts or relationships with the enterprise were in effect and have resulted from research activity explicitly or implicitly covered by their contracts (Article 15(1) of LP-2015).

95 Ownership corresponds to the employee in the absence of the circumstances indicated in the previous footnote.

96 Article 17 of LP-2015.

entitled to participate in the profits the entities earn from exploiting, transferring or assigning their rights to the inventions. If disputes in this regard are submitted for conciliation, a conciliation committee, composed of an SPTO expert serving as chairperson and two other members selected by each of the parties concerned, is assembled to facilitate an agreement and thereby avoid litigation.⁹⁷

12.7 Patent protection through civil proceedings

Patent owners enjoy powers inherent in their exclusive legal rights.⁹⁸ They have the right in particular to prevent third parties from undertaking without their consent such activities as manufacturing, offering for sale, putting on the market or using the product that is the subject matter of the patent, or importing or possessing it for one of the above-mentioned purposes. They can also prevent third parties from making use of a process that is the subject matter of a patent, or from offering such use, knowing or circumstances making it obvious, that use of the process without the patent owner's consent is prohibited. They can likewise prevent third parties from offering for sale, putting on the market or using the product directly obtained by the process that is the subject matter of the patent, or importing or possessing it for any of the above-mentioned purposes.

Patent owners who have become aware that their rights are not being respected may ensure their enforcement by means of legally sanctioned judicial action against infringements of this category of exclusive rights. In Spain, LP-2015 includes special regulations to align Spanish law with the requirements of EU Directive on the Enforcement of Intellectual Property Rights (EU Enforcement Directive)⁹⁹ and with the TRIPS Agreement.

The means of protecting patent rights explicitly catalogued in Spanish law (Article 71 of LP-2015) consist of petitions for court orders for the cessation of infringement activity and the effects thereof, including compensation for damages and prejudice incurred.

12.7.1 Actions for the prevention of patent infringement

Cessation and prohibition represent the archetypical means of defending patent rights, designed to prevent or stop intrusions into the exclusive domain reserved for patent owners. Specifically, two main types of actions of this nature can be distinguished, which are the following:

1. Actions for the cessation of patent infringement call on the court to put a stop to ongoing patent infringement and prohibit future recurrences. The factual premise for the admissibility of such an action is that acts of infringement are currently underway (manufacture, sale, importation, etc.) or about to resume or be repeated. This factual premise is purely objective, based on the actual occurrence of activity within a sphere exclusively reserved for the patent owner, irrespective of such subjective elements as culpability. Defendants need not be aware, for instance, that their conduct constitutes infringement to become passive targets of infringement lawsuits. What matters is stopping any form of infringement activity.
2. Actions for the prohibition of acts that would constitute patent infringement are intended to prohibit conduct on the part of the defendant that has been identified as potentially infringing, even when such infringement, though imminent, has not yet occurred. The premise for admitting this form of action is an existing risk of something about to occur, something objectively predictable: the initiation of infringement activity.

Spanish law admits the possibility to anticipate cessation and prohibition orders, albeit of provisional duration, in response to an application for provisional measure. In any case, whether or not this possibility of this interim protection has been pursued, these are requests that the plaintiff may submit to the court for it to rule on in its final decision on the patent litigation.

Spanish patent law, in article 72(2), consistent with the EU Enforcement Directive, permits applications for cessation and removal filed against a patent infringer to be extended to

⁹⁷ Article 21 of LP-2015.

⁹⁸ Article 59 of LP-2015.

⁹⁹ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the Enforcement of Intellectual Property Rights, 2004 OJ (L 157) 45.

intermediaries whose services are being used by a third party to infringe another's industrial property rights (even if the acts of such intermediaries do not in themselves constitute infringement). The Court of Justice of the European Union (Judgment of July 12, 2011, C-324/90, among others) has stressed that the measures to be imposed on intermediaries must be effective and dissuasive against future infringement, but also fair, proportionate and not excessively costly. Nor must they entail a general monitoring obligation in respect of third parties. In this regard the special regulations contained in LP-2015 must be coupled with legislation on services and electronic commerce in an information society (in Spain, Law No. 34/2002, of July 11, 2002, on information society services and electronic commerce).

Once the final judgment ordering cessation of the patent infringement activity has been issued, the law provides for a guarantee mechanism to motivate defendants to comply with the order or suffer economic consequences if they do not.

The court imposes a coercive indemnity in favor of the plaintiff, commensurate with the circumstances, consisting of an amount to be paid for each day that the infringement does not effectively cease. Neither the ultimate amount of this indemnity, which will be added to the general compensation that the plaintiff is entitled to receive, nor the date from which the obligation to compensate is reckoned, are determined until enforcement of the judgment commences. Thus, voluntary compliance with the judicial decision enables the defendant to avoid a costly penalty.

12.7.2 Compensation for damages and prejudice

Infringements of exclusive patent rights entitle the injured party to compensation for the detriment suffered as a result. Given its impact on the parties concerned, and importance in principle in the context of patent disputes, the compensation to be ordered requires especially careful consideration. Plaintiffs often find it useful to support their claims for compensation with expert opinions, the preparation and subsequent assessment of which entail the considerations described below.

12.7.2.1 Requirements for generating the obligation to compensate

In certain cases, as defined by law, the basis for compensation is purely objective. But in others, the amounts to be assessed are a function of culpability.

If the infringement consists of a person manufacturing or importing a patent-protected object or using a patented process without the patent owner's prior consent, that person must in any case be held liable for the damage and prejudice caused.¹⁰⁰ The only condition required to establish liability is an objective one: the person must have committed the conduct described to incur the obligation to compensate. According to case law on this point,¹⁰¹ the manufacturer's awareness of the invention through the public registry must be presumed.

On the other hand, if the infringement consists of any act of exploitation other than those indicated in the previous paragraph, an additional premise will determine whether compensation may be ordered: the person responsible must have acted knowingly, culpably or negligently. In this scenario, the date from which the obligation to compensate is reckoned is that on which the patent owner requests cessation of the infringing activity, such that the infringer has then been notified – of the existence and nature of the exclusive right and of its infringement – and yet has taken no heed of those facts. This represents a classic case of knowing infringement. The infringer may then avoid a compensation order by heeding the patent owner's reasonable and justified request, but not if they resist that request and persist in their conduct.

12.7.2.2 Extent of compensation

Compensation for damage and prejudice may include the actual damage suffered by the patent owner (or licensee as the case may be) and the loss of revenue resulting from the infringement of an exclusive right.¹⁰² The damage must in principle be established by the plaintiff. However, as

¹⁰⁰ Article 72(1) of LP-2015.

¹⁰¹ STS No. 263/2017.

¹⁰² Article 74 of LP-2015.

explained in STS 263/2017, courts are authorized in each particular case to assess whether the damage concerned has necessarily resulted from the unlawful conduct.

Damages can also be claimed for investigation costs incurred to provide reasonable evidence for the court that the infringement alleged has in fact been committed. Such costs may include those incurred to purchase an infringing product for analysis, to obtain registry certificates and to pay for reports by hired private detectives.

The patent owner may also require compensation for the prejudice suffered as a result of the loss of reputation of the patented invention caused in any way by the person infringing the owner's rights, in particular through defective manufacture or unsatisfactory presentation of the invention on the market.

The remuneration the patent owner has received from other persons working the same invention in any other manner must be deducted from the compensation to be paid by the person who has produced or imported the invention without the owner's consent.

12.7.2.3 Criteria for the calculation of lost profits

The party injured by the infringement can apply rules facilitating the calculation of compensation claimable from the infringer using one of the following methods, at the injured party's discretion (one or the other must be chosen; they may not be combined).

The first method consists of calculating the negative economic consequences suffered, in one of two ways: (a) based on the profits the injured party would foreseeably have earned from the patented invention without competition from the infringing version; or (b) based on the profits earned by the infringer from working that patented invention. The profits are calculated by subtracting from the revenues generated or anticipated, the costs directly connected with the manufacture and/or sale of the product subject to the exclusive right – but not fixed or structural costs unrelated to exploitation of that product, since the aim is full compensation for the injured party. The deductible expenses are those directly and exclusively dedicated to the infringing activity, that is, costs that it would have been necessary to incur directly and exclusively to earn the profits associated with the infringement of another's right. What must not be deducted are structural costs not directly attributable to exploitation of the good or service targeted by infringement but which rather contribute, on a shared basis, to sustaining the overall activity of the enterprise.

The calculation of lost profits may also take into account, to the extent deemed reasonable by the court, the profits obtained from working other objects of which the patented invention constitutes an essential part from a commercial point of view. The invention is deemed to be an essential part of goods from a commercial point of view when its incorporation constitutes a determinant factor in the demand for those goods.

The second method for calculating the compensation claimable from the infringer is based on the possibility of requiring the payment of hypothetical royalties. This is a legal fiction that provides a reasonable means of quantifying the profits lost by the plaintiff, based on the amount the person infringing the patent would have paid to the owner for a license allowing him to work the patent legally. In fixing the amount, special consideration has to be given, *inter alia*, to the economic importance of the patented invention, the remaining term of the patent at the time infringement commenced and the number and type of licenses granted at that time. A fair price for such royalties, based on a proven, market-based approach to estimating such a price, may be taken into account in determining this amount.

Both of these methods are moreover compatible, irrespective of the applicable regulatory text, with claims for compensation of moral prejudice (consistent with the interpretation of the Court of Justice of the European Union in its judgment of March 17, 2016 (C-99/15) with respect to Article 13 of the EU Enforcement Directive) which are to be admitted even where economic prejudice has not been proven. And the right to file such claims is not exclusive to natural persons, case law having found that legal persons may also claim moral damages in cases where their prestige has been affected, since the right to self respect and a good name or reputation is not exclusive to natural persons.¹⁰³

103 Judgment of the Constitutional Court 214/1991 of November 11, 1991, ECLI:ES:TC:1991:214.

12.7.3 Other actions for the enforcement of patent rights

Other actions specifically provided for in Spanish law may also be brought to address the consequences of infringement, as described below.

1. Actions designed to erase undesirable situations created by infringement, making the effects generated in commercial markets disappear to the extent possible, and at the infringer's expense. These include applications for: the detention of objects produced or imported in violation of patent rights and of means exclusively dedicated to the production of such objects; measures against the use of patented procedures;¹⁰⁴ the transformation of detained objects or means, or their destruction when necessary to prevent infringement;¹⁰⁵ and even the transfer of ownership of those objects or means (with compensation in that case for their value).¹⁰⁶
2. Actions to publicize judgments against patent infringers, at the latter's expense, in the form of announcements and notifications issued to interested parties.¹⁰⁷ The aim here is not retribution or even punishment for the infringer, but exclusively to contribute on a proportionate basis to correcting the alteration produced in commercial traffic and re-establishing, where necessary, the plaintiff's former market position.

While not explicit in the legislation, the regulatory framework also allows for other, less typical means of supporting patent owners. A simple declaration can be issued proclaiming that infringement has been committed against exclusive patent rights. This can be done on a one-off basis, following a specific dispute, if the aim is to dispel controversy and restore legal certainty. It is also often done as a prelude to other measures being taken in response to an infringement – though not indispensable where clearly implicit in the measures themselves.

12.7.4 Types of infringement actions

Infringement actions can be filed individually, limiting the specific exercise of one of them, if that is considered sufficient to protect the plaintiff's rights. But they can also be joined together, so as to bring simultaneously as many actions as considered necessary to protect patent rights most effectively. Plaintiffs are free to take either approach according to their interests and particular circumstances in each case.

12.7.5 Time limits for bringing actions

Civil actions against an infringement of patent rights are barred as from five years after the date it becomes actionable.¹⁰⁸

12.7.6 Costs

Costs generated as a consequence of judicial proceedings are categorized in the Spanish legal system (specifically in Article 241 of the LEC) as follows:

- fees for the defense and for technical representation;
- advertisements or public notices subject to mandatory publication;
- deposits required to lodge appeals;
- experts' fees;
- copies, certifications, notes, and documents that must be requested by law (except for any the court may request from public registries and records);
- duties that must be paid for procedures required during the proceedings; and
- fees arising from court proceedings (when compulsory).

These costs can add up to significant amounts, which is an economic consequence to be considered when initiating litigation and when deciding who should pay for it.

¹⁰⁴ Article 71(1)(c) of LP-2015.

¹⁰⁵ Article 71(1)(e) of LP-2015.

¹⁰⁶ Article 71(1)(d) of LP-2015.

¹⁰⁷ Article 71(1)(f) of LP-2015.

¹⁰⁸ Article 78(1) of LP-2015.

The costs incurred in patent litigation proceedings are regulated in the LEC. The overall guiding principle in apportioning those costs is that of objective victory (loser pays), which means that the prevailing party in a lawsuit has the right to have the opposing party pay the legal costs incurred in having to resort to judicial proceedings.

In certain situations, however, special rules provide that parties pay their own respective costs and that common costs are shared equally. These rules apply where:

- the court considers that the case has posed serious doubts, either *de facto* (the facts underlying the case are unclear or equivocal) or *de jure* (the applicable provisions are open to different interpretations, case law on the matter has not been consolidated or courts have ruled in different ways);
- the plaintiff's claim is partially dismissed (unless they have litigated recklessly, in the court's opinion);
- the defendant accepts the claim before responding (unless they have shown bad faith); and
- the proceedings terminate in abandonment consented by the defendant.

Judges may not decide on costs at their own sole discretion. They must apply the legal criteria described. And where they make exceptions, they need to justify them.

In the second instance, under the reforms of Royal Decree No. 6/2023,¹⁰⁹ the principle of objective victory (loser pays) continues to apply for ordinary appeals but a special rule is applied to extraordinary appeals in cassation, costs for which are imposed on neither party.

Court rulings with respect to costs are limited to determining which party must pay them. Once a judgment becomes final, if the parties have not reached an agreement on compliance with it, they may apply for appraisal of costs, for which the Clerk of Court (Letrado de la Administración de Justicia) determines the amount to be paid by the party sentenced to pay costs, based on the amount at issue or other relevant factors. Any disagreement over that amount is resolved through adversarial proceedings before the court, and an enforcement order may then be issued if necessary.

12.8 Other patent-related actions

12.8.1 Actions for declaration of non-infringement (negatory action)

Article 121 of LP-2015 makes explicit provision for a "negatory action" (*acción negatoria*), "an action against the owner of a patent so that the competent judge may declare that a particular act does not constitute infringement of the patent".

Before bringing this action, the plaintiff seeking such a declaration must ask the patent owner through notarial channels to make known their views on whether the plaintiff is infringing the owner's patent through industrial exploitation in Spain. If the patent owner does not reply within one month, or if the plaintiff does not agree with their reply, the plaintiff may then bring the negatory action.¹¹⁰

Such an action may not be brought by a person against whom a patent owner has already brought an action for infringement,¹¹¹ but may be brought if provoked by a demand from the patent owner directed to a person accused of infringement.

For the negatory action to succeed, the plaintiff must prove that their product or procedure does not infringe the defendant's patent,¹¹² which places the burden of proving non-infringement on

¹⁰⁹ Royal Decree No. 6/2023, of December 19, 2023, approving urgent measures for the implementation of the Recovery, Transformation and Resilience Plan in matters of public justice service, civil service, local government regime and patronage.

¹¹⁰ Article 121(2) of LP-2015: "Before bringing their action, the plaintiff must ask the owner of the patent through notarial channels to make known their views on whether their patent is being infringed by means of industrial exploitation by the plaintiff in Spain or in view of the serious and effective preparations the plaintiff is making for that purpose. If the owner does not reply within one month, or if the plaintiff does not agree with their reply, the plaintiff may bring the action referred to in the preceding paragraph."

¹¹¹ Article 121(3) of LP-2015: "The action mentioned in paragraph 1 may not be brought by any person against whom the patent owner has filed an action for infringement of the patent concerned."

¹¹² Article 121(4) of LP-2015: "Where the plaintiff proves that the act referred to in their request does not constitute infringement of the patent, the judge shall make the declaration requested."

the plaintiff. The plaintiff must then prove that their product or procedure does not reproduce each of the technical features of the patent claims at issue. As in infringement cases, each of those patent claims must be divided into technical elements to confirm whether the product or procedure exploited by the plaintiff simultaneously reproduces each and every one of those elements. If it does not, then the claim is not being infringed.

Lastly, the Law expressly provides for the possibility of joining the negatory action and the patent invalidation action.¹¹³

12.8.2 Action claiming ownership

As noted with respect to the causes of invalidity, Article 10(1) of LP-2015 provides that “The right to a patent shall belong to the inventor or to their successors in title and it shall be transferable by any of the means recognized in the Law.” And according to Article 12 of LP-2015, where a patent has been granted to a person not authorized to obtain it, the person authorized may claim transfer of ownership of the patent.¹¹⁴ Thus, the inventor or their assignee could opt to claim transfer of registration, or as explained earlier, seek to annul the registration.

12.8.3 Compensation for damage and prejudice caused by the owner of an invalid patent having acted in bad faith

Article 104(1) of LP-2015 provides that “a declaration of invalidation shall imply that the patent has never been valid” and thus cannot produce the effects provided for in Title VI¹¹⁵ of the Law.

Article 104(3) of LP-2015, to establish the limits of such retroactivity vis-à-vis *res judicata* decisions, begins with the phrase “without prejudice to compensation for damage and prejudice that may be due when the owner of the patent has acted in bad faith”. That implies that a party injured by an invalidated patent is entitled to compensation for the damage and prejudice caused when the patent owner acted in bad faith. Such bad faith implies that the owner was aware of the cause of their patent’s invalidity¹¹⁶ and has to be assessed based on when the damage was caused.¹¹⁷ This enables a person convicted for infringing a patent later ruled invalid to recover amounts paid as compensation for the supposed infringement, so long as the validity of the patent was not discussed in the initial litigation.

12.9 Enforcement of judgments

In Spain, failing voluntary compliance, the courts are responsible for the enforcement of judgments. The lower court, having heard the case in the first instance, is the one competent for enforcement proceedings.

Enforcement proceedings are initiated at the request of the interested party. They cannot in any case commence for 20 days after the judgment becomes final. The possibility of seeking enforcement lapses five years after the judgment becomes final.

The execution of judgments issued in patent infringement cases is in general governed by the LEC, with certain exceptions established in provisions specifically regulating patents.

In cases where convicted parties breach judgments which include orders to cease or not repeat patent infringement, or to refrain from carrying out acts that may constitute infringement, the court responsible for enforcement, if so requested by the party seeking enforcement, may order the convicted party to:

¹¹³ Article 121(6) of LP-2015: “The action referred to in the present Article may be brought jointly with an action to declare the invalidation of the patent.”

¹¹⁴ Article 12(1) of LP-2015: “Where a patent has been granted to a person not authorized to obtain it according to the provisions of Article 10, the person authorized in accordance with the said Article may claim transfer of ownership of the patent, without prejudice to any other corresponding rights or action.”

¹¹⁵ Effects of the patent and of the patent application.

¹¹⁶ Judgment of the Provincial Court of Barcelona 77/2018 of February 6, 2018, ECLI:ES:APB:2018:949 (SAPB 77/2018): “Our understanding in this context is that the owner’s bad faith depends on their knowledge at the time of the patent’s invalidity and of their noncompliance with the requirements for patentability.”

¹¹⁷ SAPB 77/2018: “Bad faith must be assessed based not on when registration was applied for but on when the owner decided to bring and persist in the infringement action, despite knowing that they had not met the novelty requirement.”

- put right the harm done;
- compensate the damages caused; and
- refrain from repeating such breach of the judgment, subject to being found in contempt of court.

Such order may be accompanied by a fine for each month that the harm done is not put right. The fine may be imposed without any need for the party seeking enforcement to request it. This provision is intended for purely dissuasive purposes and is payable not to the party seeking enforcement but to the Public Treasury.

LP-2015¹¹⁸ provides for the court to order coercive compensation in favor of the plaintiff in cases where a petition for cessation has been upheld. The aim is to compensate the patent owner for the damage resulting from noncompliance with an order for the cessation of acts infringing their rights. Such compensation is independent of that which may have been ordered in response to an action for damages filed jointly with the action for cessation. The law provides that such compensation must be commensurate with the circumstances. It is ordered in the form of an amount payable per day until such time as the infringement actually ceases. The amount and the date from which payments are reckoned are determined by the court competent for enforcement of the judgment.

If the court rules in favor of an action for damages, the amounts due are quantified and settled during the judgment enforcement phase.¹¹⁹ Provisions require, however, that the basis for quantification be decided as part of the judgment. The owner may require the infringer to produce documents for the purpose of quantifying the damages caused by unlawful exploitation of the patent, but the judge must then take into account the legitimate interests of the defendant for the protection of their trade secrets.¹²⁰

The SPTO must be notified of judgments, once final, that invalidate a patent, and those issued upon appeal that quash an SPTO decision to grant a patent, so that registration of the patent concerned may then be canceled, or amended as the case may be.¹²¹

12.9.1 Provisional enforcement

Spanish procedural rules generally permit the provisional enforcement of judgments that are not yet final in order to avoid damages being incurred during the time required for appeal. Exceptions are made for judgments of certain kinds, as well as non-final foreign judgments, unless provided otherwise by an international treaty.

Among the exceptions are judgments declaring the invalidity of a patent. On the other hand, judgments issued in patent infringement cases may be enforced provisionally.

12.9.2 Enforcement of foreign judgments

The recognition and enforcement of judgments issued by civil and commercial courts in EU member states and by the Unified Patent Court are subject to Regulation No. 1215/2012 of the European Parliament and of the Council of December 12, 2012, on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters.¹²² Those judgments are enforceable in Spain without the need for a declaration of enforceability. The enforcement procedure for such judgments, subject to certain exceptions under Regulation No. 1215/2012, is the same as for judgments issued by Spanish courts.

The enforcement of other (final) foreign judgments in Spain is governed by the LEC, subject to contrary provisions of international treaties in force in Spain or of Spanish law on international legal cooperation in civil matters.¹²³

¹¹⁸ Article 74(4) of LP-2015.

¹¹⁹ Article 74(5) of LP-2015.

¹²⁰ Article 73 of LP-2015.

¹²¹ Article 104(5) of LP-2015.

¹²² Regulation (EU) 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters, 2012 OJ (L 351) 1.

¹²³ Law No. 29/2015, of July 30, on International Legal Cooperation in Civil Matters.

12.10 Appeals

The Provincial Courts have jurisdiction for appeals against judgments issued by the country's commercial courts. Judgments issued by the Provincial Courts are in turn subject to appeals in cassation before the First Chamber of the Supreme Court.

Judgments issued by the Provincial Courts on appeals against SPTO decisions marking the exhaustion of administrative remedies are also subject to appeals in cassation before the First Chamber of the Supreme Court.

12.10.1 Ordinary appeals

Ordinary appeals¹²⁴ are those for which the law does not specify what grounds must be invoked, only that the judgment being appealed has adversely affected the appellant.

Spain applies a "limited" appeal system that does not give rise to an entirely new trial in the second instance. Adjudication in courts of appeal is restricted to a review of proceedings and judgments in the first instance, based only on the same elements considered by the lower courts concerned.

This means that the parties may not alter their claims or arguments on appeal. Nor, with certain exceptions, may they introduce new facts or evidence.

Among the exceptions, appellants may allege new relevant facts occurring:

- after the start of the time period allowed for sentencing by the lower court; or
- before then if the appellant can prove that they only learned of the facts later.

On the other hand, the law allows the following forms of new evidence to be submitted in the second instance:

- Documents in any of the following cases, that could not be filed in the first instance:
 - when dated subsequent to the claim or the response or the preparatory hearing;
 - when dated subsequent to the claim or the response or the preparatory hearing, and the party shows that he was unaware of their existence before then;
 - when it was not possible to obtain the documents owing to reasons not attributable to the party;
- Evidence unduly rejected in the first instance;
- Evidence admitted in the first instance that could not be taken for reasons not imputable to the applicant;
- Evidence relating to facts relevant to the decision on the case as referred to in the preceding paragraph.

An ordinary appeal represents a full review in the sense that the appeals court has the authority to review everything done by the lower court judge to verify consistency with procedural rules and substantive provisions applicable to the case. The appeals court may thus review the lower court's assessment of the evidence and the factual and legal analysis underlying its decision.

Without prejudice to the foregoing, appeals courts are also subject to limits:

- they may not enter into lower court rulings not contested by the appellants (*tantum devolutum quantum appellatum*); and
- they may not worsen the appellant's situation by their judgment on their appeal (*reformatio in peius*), but may do so in response to an appeal by the opposing party.

In cases where the ordinary appeal is based on a breach of procedural rules and safeguards there are different possibilities:

¹²⁴ Regulated by Articles 455 *et seq.* of LEC.

- If the breach (inconsistency, for example) was committed by the lower court in issuing its judgment, the appeals court may quash the judgment and then resolve the questions in dispute.
- If the breach occurred prior to the judgment, so as to invalidate the proceedings, the appeals court declares the proceedings invalid as from that point and remands the case to the lower court to complete them correctly and issue a new judgment (which will also be subject to ordinary appeal).
- If the breach occurred prior to the judgment and is curable, the appeals court allows time for the flaw to be corrected and then issues a judgment on the merits of the case.

12.10.2 Appeals in cassation

Appeals in cassation¹²⁵ must be grounded on a breach of procedural or substantive provisions considered “appealable in cassation”, a concept that is central to this class of appeals.

A judgment is deemed “appealable in cassation” when it:

- is contrary to Supreme Court jurisprudence;
- concerns matters on which Provincial Court rulings have been contradictory; or
- applies provisions on which Supreme Court jurisprudence has not been established.

Judgments may also be appealable in cassation “as a matter of public interest”. This is where the challenged judgment comes in a case where the matter in dispute is one of general interest as a matter of uniform interpretation of the law. General interest is deemed to exist when the matter potentially or actually affects a great number of situations, either in itself or because it transcends the case in question.

The application initiating the appeal needs to clearly identify and demonstrate how the judgment is appealable in cassation based on one of the three premises above. The breach challenged must also have been relevant to the judgment being appealed and duly raised during the trial or considered by the Provincial Court.

When the appeal is based on a breach of procedural rules, it is essential to show that:

- objections to the breach, if possible, were raised in a lower court prior to the appeal in cassation; and
- if raised in the first instance, the objection was raised again in the second instance. If the procedural breach consisted of a curable flaw, a remedy must have been sought in the appropriate instance or instances.

The purpose of appeals in cassation is to ensure the correct application of law, not to serve as a “third instance”. The assessment of evidence and establishment of facts may not be called into question at this stage, unless a clear and immediately verifiable error has been committed based on the prior proceedings.

Appeals in cassation are decided by judgments that definitively resolve the matters in dispute. However, if an appeal argues that a challenged lower court judgment was contrary to existing jurisprudence on the matter or matters at issue, it may be resolved by an order quashing the judgment and remanding the case to the lower court for a new judgment consistent with the jurisprudence concerned.

12.11 Criminal proceedings

Patent owners may also defend their rights by bringing criminal actions. Article 70 of LP-2015 provides that the owner of a patent may bring “appropriate action of any type or nature.” This formulation encompasses criminal actions.

LP-2015 applies exclusively to civil actions, that is, only to those that may be brought before civil courts. Criminal actions are covered in the Criminal Code.¹²⁶ Procedures for patent cases do not

¹²⁵ Covered in Articles 477 *et seq.* of LEC.

¹²⁶ Organic Law No. 10/1995, of November 23, 1995, of the Criminal Code.

depart significantly from the general provisions for criminal proceedings, as set out in the Criminal Procedure Law.¹²⁷

Patent-related criminal offenses are defined in Article 273(1) and (2) of the Criminal Code. Article 273(1), referring to patented products, provides for a prison term and a fine for any person who manufactures, imports, stocks, uses, offers or brings onto the market subject matter covered by a patent or utility model, provided that they do so:

- for industrial or commercial purposes;
- without the consent of the owner; and
- knowing that the patent or utility model is registered.

Article 273(2), relating to patented processes, covers offenses committed by persons who make or offer use of such processes, or who stock, offer, bring onto the market or use products directly obtained by means of such processes. To qualify as criminal offenses, such acts must meet the same three conditions indicated in the preceding paragraph.

A significant portion of the literature on this topic criticizes the conflation of civil and criminal law protections against the same conduct, both as punishable under the Criminal Code and as a basis for civil actions under the law on patents (LP-2015).

The conflation is not total, however. Acts of indirect infringement and the importation of products directly obtained from patented processes are actionable under civil law¹²⁸ but not under criminal law.

In addition, protection under criminal law applies only where fraudulent intent is involved, which need not be found for civil actions to succeed against the manufacture or importation of patent-protected objects or the use of patented processes.

And lastly, protection by means of civil proceedings, the patent holder is entitled to claim reasonable and adequate compensation from any third party who, between the date of publication of the application and the date of publication of the grant of the patent, has carried out a use of the invention that would be prohibited under the patent.¹²⁹ The protection by criminal law is only recognized only after the patent has been granted.

In practice, therefore, the preferred option for patent protection in Spain is through the civil courts.

From a procedural standpoint, Organic Law No. 15/2003¹³⁰ introduced a series of measures still in place to strengthen protection for industrial property rights under criminal law, including:

- elimination of a condition requiring a prior complaint by the injured party as a requirement for prosecution of the offense, which can thus be initiated *ex officio*; and
- inclusion of industrial property infringements among the offenses qualifying for expedited trial proceedings.¹³¹

Article 276 of the Criminal Code provides for harsher penalties where offenses are of particular seriousness, due regard being had to the value of the unlawfully produced objects or to the particular importance of the prejudice caused, or where the perpetrator belongs to an organization or association dedicated to this type of conduct, or where minors under the age of 18 are involved in committing the offense.

Article 277 of the Criminal Code establishes a special regime for cases involving secret patents.

Article 288 of the Criminal Code provides specific forms of punishment for offenses committed by legal persons, including the temporary suspension of their activities, the temporary closure of premises and establishments and dissolution of the public entity concerned.

¹²⁷ Royal Decree No. 260/1882, of September 14, 1882, approving the Law on Criminal Procedure.

¹²⁸ Articles 60 and 59(1)(c) of LP-2015.

¹²⁹ Article 67 of LP-2015.

¹³⁰ Organic Law No. 15/2003 of November 25, 2003, on Amendments to the Organic Law No. 10/1995, of November 23, 1995, on the Criminal Code.

¹³¹ Article 795(2)(h) of the Law on Criminal Procedure.

12.12 Border measures

The preemptive measures covered here are intended to prevent entry into the Spanish market of goods suspected of infringing intellectual property rights.

Customs policy is the exclusive domain of the European Union. It is the European Commission that is therefore responsible for proposing customs legislation and providing for its enforcement, the legal framework for which is shared by all European Union member countries.

The governing regulation establishing procedures and measures applicable to border measures in Spain is Regulation (EU) 608/2013.¹³²

This Regulation applies where goods suspected of infringing an intellectual property right are, or should have been, subject to customs supervision or customs control, particularly in the following situations:

- when declared for release for free circulation, export or re-export;
- when entering or leaving the customs territory of the European Union; and
- when placed under a suspensive procedure or in a free zone or free warehouse.

It does not apply to:

- goods of a noncommercial nature contained in travelers' personal luggage;
- goods that have been manufactured with the consent of the right holder; and
- goods manufactured by a person duly authorized by a right holder to manufacture a certain quantity of goods, in excess of the quantities agreed between that person and the right holder.

The measures applicable may consist of the detention or suspension of the release of goods under the supervision or control of customs authorities, when those goods are suspected, based on *prima facie* evidence, of infringing intellectual property rights. Customs authorities may take these measures at their own initiative or upon application, so that a person or entity entitled to do so may initiate proceedings to determine if an intellectual property right has been infringed. These temporary measures are then lifted once such proceedings have been initiated.

The goods may also be destroyed, without any need to determine whether intellectual property rights have been infringed, if the owner of the goods consents or, under certain circumstances, if so requested by, and under the responsibility of, whomever has requested the intervention of customs authorities.

The Regulation consists exclusively of procedural rules for customs authorities. It does not establish criteria for determining whether intellectual property rights have been infringed.

12.13 Selected topics

12.13.1 Pharmaceutical patents and supplementary protection certificates

The granting of a patent for a pharmaceutical product does not permit its owner to start selling the patented product immediately. "Marketing approval" must first be granted by health authorities following a verification and control procedure. This requirement significantly shortens the useful life of the patent, making it difficult to amortize the investments made in developing the patented invention. The same situation applies in the case of plant protection products.

In the late 1980s, what was then called the European Economic Community began work on a legal instrument to address this lag between the patent application date for medicines and plant protection products and the date when marketing of the patented products could commence. The result of this effort was the creation of two specific industrial property titles: the "supplementary protection certificate for medicinal products" and the "supplementary protection certificate for plant protection products", regulated by two uniform texts for all member countries

¹³² Regulation (EU) No 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights, 2013 OJ (L 181), 15.

in what were then called the European Economic Community (EEC) and the European Communities (EC). Those texts were Council Regulation (EEC) No. 1768/92¹³³ and Regulation (EC) No. 1610/96 of the European Parliament and of the Council.¹³⁴

Regulation No. 1768/92 was repealed in 2009 by Regulation (EC) No. 469/2009, the regulation now in force with respect to supplementary protection certificates for medicinal products.

A supplementary protection certificate (SPC) is an industrial property title that under certain conditions extends patent protection for up to five years for the active ingredient or combination of active ingredients of a medicinal or plant protection product.

SPCs are accessory titles in the sense that they are granted to provide protection in conjunction with an existing patent. But an SPC is also a substantive title in its own right, since:

- SPC protection becomes effective after the underlying patent has expired; and
- that protection extends only to a “product” for which marketing approval has been obtained for use as medicine or for plant protection (which may be only a part of the product protected by the basic patent).¹³⁵

The SPC regime, as indicated earlier, is uniform for the entire European Union. But SPC titles themselves are not uniform (as European patents and trademarks are). They are national titles that must be obtained from national patent offices in EU member states, each of which processes the applications and grants the titles following procedures established in national legislation, without prejudice to EU regulations governing fundamental aspects of that process. Once granted, SPCs are entered into national registries, which produce effects only in the country where granted. They enter into force the day after expiration of the underlying patent.

- The conditions for obtaining an SPC are as follows:
- the product is protected by a basic patent in force;
- a valid authorization to place the product on the market as a medicinal or plant protection product has been granted;
- the authorization to place the product on the market is the first referring to the product as a medicinal or plant protection product; and
- the product has not already been the subject of a certificate.

An SPC confers the same rights as the basic patent and is subject to the same limitations and obligations. It must be noted, however, that Regulation 2019/933,¹³⁶ in amending Regulation 469/2009, introduced an exception to the protection provided by an SPC to permit companies located in the European Union to manufacture generic pharmaceutical products similar to medicinal products protected by a valid SPC, exclusively for the purpose of:

- export to third countries; or
- storage during the last six months of the SPC’s effective life and prior to the product’s entry into the European market (upon expiration of the SPC).

Lastly, the overall duration of protection that the basic patent and the SPC can provide may not exceed 15 years from the date of the product’s first marketing approval as a medicinal or plant protection product.

133 Council Regulation (EEC) No. 1768/92 of June 18, 1992, concerning the Creation of a Supplementary Protection Certificate for Medicinal Products.

134 Regulation (EC) 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the Creation of a Supplementary Protection Certificate for Plant Protection Products, 1996 OJ (L 198) 30 (for plant protection products).

135 “Product” refers to a medication’s active ingredient or combination of active ingredients. In the case of SPCs for plant protection products, “product” refers to active substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user and intended to serve purposes indicated in Article 1 of Regulation 1610/96 (protect plants or plant products against all harmful organisms or prevent the action of such organisms, influence the life processes of plants, preserve plant products, etc.).

136 Regulation (EU) No. 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products.

12.13.2 Compulsory licenses

According to applicable Spanish provisions, compulsory licenses¹³⁷ may be granted in the following situations:

- Failure or insufficiency of working the patented invention. The law provides in this regard that the owner of a patent shall be obliged to work the patented invention either themselves or through a person authorized by them, by implementing it in Spain or on the territory of a Member of the World Trade Organization in such a manner that the working is sufficient to satisfy demand on the Spanish market. Working must take place within a period of four years from the date of filing the patent application or three years from the date on which grant of the patent was published in the Official Bulletin of Industrial Property, the period which expires latest being automatically applied. Following expiration of this period, any person may request the grant of a compulsory license for the patent, provided that, at the time of the request, working of the patent has not commenced or has been suspended for more than one year. The applicant must show that they have attempted to obtain a contractual license from the patent owner but have been unable to do so on commercially reasonable terms and conditions within a reasonable period of time. A compulsory license may not be granted for this reason if objective difficulties of a legal or technical nature, independent of the will and circumstances of the owner of the patent, have made working of the patent impossible or prevented its working from being more extensive than it has been.
- Dependency between patents, or between patents and plant variety rights. Where such dependency exists, the owner of the later patent or plant variety right may apply for a compulsory license but must demonstrate that: (i) the subject matter of the later patent or plant variety right represents significant technical progress of considerable economic importance relative to the prior patent or plant variety right; and (ii) they have attempted, without success in a reasonably timely manner, to obtain a contractual license from the owner of the prior patent or plant variety right. If such a license has been granted, the owner of the prior patent or plant variety right may in turn request a license for the later patent or plant variety right on reasonable terms. This type of compulsory license is granted only where necessary to permit the working of the later patent or plant variety right.
- Need to put an end to practices that a firm administrative or judicial decision has declared contrary to legislation for the protection of fair competition. In this case, it is not necessary for the applicant for a compulsory license to demonstrate that prior negotiations have taken place with the patent owner to obtain a contractual license.
- Matters of public interest. The government may directly declare a patent or patent application subject to the compulsory license regime when: (i) the initiation, increase or generalization of working of the invention, or improvement of the conditions in which it is being worked, are of paramount importance for public health or national defense; (ii) failure to work or the insufficient quality or quantity of working leads to serious prejudice for the country's economic or technological development; and (iii) supply of the domestic market so requires.
- The manufacture of pharmaceutical products for export to countries with public health problems. These licenses are processed and regulated in accordance with Regulation No. 816/2006, of May 17, 2006.¹³⁸

Compulsory licenses are not exclusive and entail adequate compensation for the patent owner based on the circumstances in each case and economic importance of the invention. They also include supplementary certificates, upon issuance or later, applicable to the subject matter of the patent that falls within the scope of the compulsory license.

¹³⁷ Regulated by Articles 90 *et seq.* of LP-2015.

¹³⁸ Regulation (EC) No. 816/2006 of the European Parliament and of the Council, of 17 May 2006, on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. This instrument incorporated into the legal system of the European Union the WTO General Council Decision of August 30, 2003, on the interpretation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.