

Spain

Legal basis

Arts. 91 to 101 of the new Patents Act (Ley 24/2015, hereinafter “nLP”). This piece of legislation replaces the former Patents Act (Ley 11/1986) as amended, *inter alia* by the legislation Ley 10/2002, which implemented the Biotech Directive in Spain.

The 2015 Patents Act explicitly refers to EU Regulation 816/2006.

Grounds for applying for a licence

Pursuant to the nLP, compulsory licences may be applied for in the following situations:

- Failure to exploit or insufficient exploitation of the patented invention (for more than four years after the filing of the patent application, or three years after the publication of the mention of grant, whichever expires later). Importation may be sufficient to avoid a compulsory licence for lack of working of the invention. What is required by the Spanish law is simply that the invention is put in practice (by the patentee or with his authorisation) in any member state of the WTO, in a sufficient amount so as to satisfy the demand of the Spanish market. The Supreme Court Judgment (Contentious-Administrative Chamber) of 6 February 2003, Appeal No. 2966/1997, for example (cited below) considered that a product that was being imported from Japan to Belgium and then shipped to Spain qualified as sufficient working of the invention for the purpose of this provision of the Spanish Patents Act;
- Dependent patents (including dependency between patents and plant varieties);
- Violations of competition law (in cases where the patent holder has been declared to violate competition law, competition authorities may impose that in order to restore competition a patent must be subject to compulsory licence; if such a requirement becomes final in the administrative or judicial channel, it shall be communicated to the Spanish Patent and Trademark Office, which shall initiate the compulsory licence procedure);
- Reasons of public interest;
- Compulsory licences issued according to EU Regulation 816/2006.



General procedure

The Spanish Patent and Trademark Office (*Oficina Española de Patentes y Marcas*, hereinafter OEPM) is competent to grant a compulsory licence.

The procedure is described in Arts. 97 to 99 nLP and can be summarised as follows:

- (1) Before applying for a compulsory licence, the interested party must prove that it has tried to obtain from the patentee a licence on commercially reasonable terms, and that such agreement has not been possible after a reasonable time.
- (2) The request for the compulsory licence, together with the proof of the previous attempt to obtain the licence amicably, plus the evidence that the applicant has the necessary capacity to exploit the patent, plus the receipt of payment of the applicable taxes, must be filed before the OEPM.
- (3) The OEPM will then give the patentee one month to reply to the request.
- (4) If the patentee fails to reply, the OEPM will unilaterally grant the licence. If the patentee replies and the OEPM finds that the conditions for granting the licence are met, it will prompt both parties to agree on a mediator, or alternatively that each of them appoints an expert

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who, together with the expert appointed by the OEPM, will determine the terms of the licence. The OEPM will decide unilaterally when disagreements arise.

- (5) The decision adopted by the OEPM is appealable at an administrative level and ultimately before the contentious administrative courts, but this appeal has no suspensive effect unless so requested and justified by the licensee.

There is no provision in Spanish law that expressly provides for the possibility of obtaining a compulsory licence by way of preliminary relief. However, the provisional measures that both courts and administrative bodies may adopt under general procedural law constitute an open list, and therefore in cases of urgency it might be theoretically possible for the OEPM (or, ultimately, for the contentious-administrative courts) to provisionally grant a compulsory licence, if circumstances so justify, while proceedings are pending. Also, in an indirect manner, a similar result might be achieved if a civil court refuses a preliminary injunction (applied for by the patentee) on the grounds that a compulsory licence (or, in the context, for instance, of standard-essential patents, a FRAND commitment) should apply.

Requests for compulsory licences are very rare in practice and so far have been anecdotal. They are, however, subject to procedural regulations. Otherwise the decision will be subject to review, according to the general norms of administrative law. Any administrative decision which is believed to infringe the law can be subject to an administrative appeal by the interested party before the superior body, or before the same body if there is no superior body, within one month, and if this appeal is dismissed, the interested party may then file a judicial appeal before the contentious-administrative courts in the two months following the notification of the dismissal.

In the event of disagreement between the parties or between the experts appointed by the parties, the OEPM has discretion as to the terms of the compulsory licence.

The OEPM issues a decision and has discretion to determine the terms of the licence, including its scope, royalties, duration and guarantees that must be offered by the licensee, and any other relevant clauses. The following rules apply (Arts.100 and 101 nLP):

- Compulsory licences are non-exclusive.
- The remuneration (royalties) is determined based on the economic importance of the invention.
- The parties must act in good faith. For the patentee this means *inter alia* that it must disclose to the licensee the know-how in its possession that is necessary for an adequate exploitation of the invention.
- The compulsory licence will also be extended to the supplementary protection certificates that may be granted for the patent.
- The compulsory licence cannot be assigned to the licensee unless with the whole business or business unit in charge of its exploitation. In the case of dependent patents, it is also necessary that the dependent patent is assigned together with the compulsory licence over the previous patent.
- Sub-licensing is prohibited and will be deemed null and void.
- The OEPM, through the procedure explained above, will determine the remaining conditions regarding the scope of the licence, its duration, the guarantees that may be requested from the licensee, and any other relevant clauses. General rules on licensing apply to fill in any possible gaps.
- Any of the parties may submit a request to the OEPM for the amendment of the terms of the compulsory licence when there are new circumstances that justify so. In particular, the licensee can request the amendment of the terms of the compulsory licence if the patentee has granted voluntary licences to other third parties in more favourable terms.
- The OEPM, ex officio or at the request of the interested party, may declare the termination of the licence, after hearing the licensee, if the licensee incurs a material or repeated breach of the terms of the compulsory licence.

Appeal/review

The decision reached by the OEPM is appealable at an administrative level (i.e. to be resolved within the OEPM) and subsequently before the contentious-administrative courts, first to the *Tribunal Superior de Justicia*, then to the Contentious-Administrative Chamber of the *Tribunal Supremo*. The appeal will be heard by the *Tribunal Supremo* only if it deems the case to have a cassational interest for the formation of case law.

Statistics and jurisprudence

The OEPM has published statistics for compulsory licences between 1986 and 2010 only. Six applications for compulsory licences were reported by the OEPM during that period: one

application (denied) related to a national patent, two applications (denied) related to European patents, and three applications (one denied, and two archived for reasons not reported – presumably settled or deemed to be withdrawn) related to utility models.

As for court precedents on compulsory licences, these include:

Supreme Court Judgment (Contentious-Administrative Chamber) of 6 February 2003, Appeal No. 2966/1997

A pharmaceutical company had requested a compulsory licence over a patent that was considered to be unexploited in Spain. The OEPM refused to grant the licence and Madrid's High Court of Justice revoked the OEPM decision based on formal reasons, namely the fact that the OEPM had not respected the established procedure for granting compulsory licences. However, the patentee appealed before the Supreme Court, which reinstated the original OEPM decision, denying the compulsory licence on the grounds that a compulsory licence cannot be granted in a situation when the substantive requirements are not met. In this case it was concluded that the patent was being exploited in Belgium, and therefore this exploitation in an EU member state was considered sufficient in view of the rulings of the Court of Justice of the European Union in the cases C-60/1990 and C-235/1989.

Supreme Court Judgment (Criminal Chamber) of 29 April 2015, appeal No. 20119/2015

This decision deals with a social problem that was widely reported in the Spanish media, namely a criminal complaint (among other collective actions such as demonstrations and protests) filed by a group of patients suffering from hepatitis C. This complaint was filed against the Minister of Health for, *inter alia*, refusing to grant a compulsory licence that would enable these patients to have access to a life-saving patented medicine that, due to budgetary constraints, at that time was accessible only to 10% of the patients within the context of the public health system. The complaint was dismissed by the Supreme Court on the grounds that the possibility of granting compulsory licences in cases of public interest is at the discretion of the government, and not an obligation imposed by the law.

Supreme Court Judgments (Contentious-Administrative Chamber) of 25 May 2001 and 26 May 1994, Appeals No. 4083/1994 and 545/1992

The OEPM closed the compulsory licence proceedings because the parties settled. The patentee appealed the OEPM's decision but the Court of Appeals and later the Supreme Court dismissed the appeal and confirmed the OEPM's decision. Since a licence agreement between the parties was reached, it was no longer a compulsory licence (subject to the contentious administrative courts) but a contractual licence (subject to the civil courts) and therefore the contentious administrative jurisdiction could not rule in relation to its validity.

