

Madrid, June 6, 2017

In response to circular **C.8653** dated March 16 2017, the Spanish Patent and Trademark Office (OEPM) hereby provides updated information following the enactment on April 1 of Law No. 24/2015 to govern patents and its implementing instrument, Regulation RD316/2017, pertaining to aspects of national and regional patent laws, which can be found at http://www.wipo.int/scp/en/annex_ii.html. The OEPM further provides an update on the **opposition, limitation and withdrawal procedures** that were enacted under **Law No. 24/2015**.

PRIOR ART

1. Everything made available to the public in Spain or abroad by means of written or oral description, use, or other means of dissemination before the filing date (priority date). (This part remains the same; point 2 has been changed)
2. This has been changed: The contents of Spanish patent or utility model applications, of European patent applications that designate Spain and PCT international patent applications that have entered the national phase in Spain, as originally presented, with an earlier filing date than that mentioned in paragraph 1 above and that had been published in Spanish on or before that date.

NOVELTY

The invention does not form part of the state of the art (it remains the same). The state of the art consists of everything made accessible to the public in Spain or abroad by means of a written or oral description, use or other means of dissemination before the filing date of the patent application and the contents of Spanish patent or utility model applications, of European patent applications that designate Spain and PCT international patent applications that have entered the national phase in Spain in the form originally filed, with an earlier filing date and that had been published in Spanish on or before that date.

INVENTIVE STEP

REMAINS THE SAME

GRACE PERIOD

Disclosure should not be taken into consideration in determining the state of the art if it occurred during the six months preceding the filing date and if it was due to, or in consequence of:

1. an evident abuse in relation to the applicant or his legal predecessor;
2. Display of the invention by the applicant or his legal predecessor at an official or officially recognized exhibition, as provided for in the Convention Relating to International Exhibitions, signed at Paris on November 22, 1928 and last amended on November 30, 1972. The applicant shall state when filing the patent application that the invention has been so displayed and shall file a supporting certificate within the time limit and under the conditions laid down in the implementing regulation.

SUFFICIENCY OF DISCLOSURE

REMAINS THE SAME

EXCLUSIONS FROM PATENTABLE SUBJECT MATTER

REMAINS THE SAME

EXCEPTIONS AND LIMITATIONS OF PATENT RIGHTS

PRACTICALLY REMAINS THE SAME. The only difference is that both experimental acts and tests carried out for authorization of generic medicine were previously included in the same paragraph, but they are now in two separate paragraphs:

3. Acts carried out for experimental purposes.
4. The studies and tests carried out to obtain regulatory approval of generic medicines, either in Spain or abroad, and the subsequent practical requirements, including preparation, collection and use of the active element for these purposes.

OPPOSITION PROCEDURE

LAW NO. 24/2015

It is regulated in Article 43 of Law No. 24/2015 on patents and in articles 36-40 of the implementing regulation RD 316/2017.

1. Any person may oppose the granting of a patent within six months following its publication in the Official Bulletin of Industrial Property for any of the following reasons:

- (a) The claimed invention does not fulfil one or some of the patentability requirements set forth in Title II of the Law.
 - (b) Its description is not sufficiently clear and complete for a person skilled in the art to carry it out.
 - (c) The object of the patent exceeds the content of the patent application as filed.
2. Opposition shall be reasoned, expressed in writing and filed to the Spanish Patent and Trademark Office, together with the relevant evidentiary documents and proof of payment of the relevant fee.
 3. Once the written opposition has been accepted for consideration, the registered patent holder shall be invited to present his arguments and modify, if deemed appropriate, his claims. The Spanish Patent and Trademark Office shall transmit to all parties the claims and suggestions for their modification advanced by the other parties, affording a right of reply to each party, within the time limit and under the conditions laid down in the implementing regulation.
 4. Once the deadline mentioned above has passed, the Spanish Patent and Trademark Office shall accept the opposition in whole or in part if it agrees with one or more of the reasons for the opposition set forth in paragraph 1, or dismiss them if it does not agree. However, where reasons that wholly or partially prevent the patent from being maintained persist in spite of the modifications or arguments advanced, the title holder shall be given at least one opportunity to remedy the defect or present further arguments, before making a definitive decision on the opposition.
 5. The decision of the Spanish Patent and Trademark Office shall be published in the Official Bulletin of Industrial Property, reflecting, where appropriate, the changes that have been made to the patent. The protection given by this law shall be extended retroactively to the modified patent.
 6. Where a patent is cancelled with retroactive effect, the provisions of article 104 regarding nullity shall apply if appropriate.

REGULATION RD 316/2017

Article 36 of the Regulation stipulates formal requirements. A case in point is the content of the notice of opposition.

Article 38 of the Regulation sets a three-month time limit for the title holder to respond to the notice of opposition and a two-month time limit for opponents to reply to the arguments and/or modifications presented by the patent title holder.

Article 39 is entitled “Examination and resolution of opposition”

1. A Committee of three technically qualified experts from the Spanish Patent and Trademark Office, one of whom shall be the President, shall be set up to examine notices of opposition, responses and rejoinders, as the case may be. The Committee shall include a lawyer from the same Office if the decision-making so requires. In the event of a tied vote the President shall have a casting vote. The members of the Committee shall be appointed by the Director of the Department of Patents and Information Technology, taking into account experience and specialization.
2. The Spanish Patent and Trademark Office shall weigh the grounds for the opposition and the arguments from all parties, including, where applicable, the modifications proposed by the patent holder. In the event that the grounds for opposition advanced do not prevent maintaining the patent, the opposition or oppositions shall be dismissed, as appropriate. The title holder and opponents shall be notified of the decision, with grounds, to dismiss the opposition and reject the proposal to amend the patent. This decision shall be published in the Official Bulletin of Industrial Property and shall include a note related to the maintenance of the patent as granted.
3. If, in view of the arguments and the proposed modifications of the patent holder, the Spanish Patent and Trademark Office considers that the patent may be maintained in the amended form proposed by the holder, it shall approve the opposition in whole or in part, thereby maintaining the patent in modified form.
4. If there are still reasons for not maintaining the patent despite the arguments advanced and the modifications by the patent holder, the holder shall be afforded a further month as from the date of publication of his comment in the Official Bulletin of Industrial Property, to present fresh arguments or modifications of the claims, the description and, as appropriate, the drawings or biological sequences, pursuant to articles 48 and 64 of this regulation. The patent holder shall be afforded other opportunities, provided that the defects are remediable and that he has clearly attempted to correct them. Before finding a definitive solution, opponents shall be granted 10 days to present the final arguments they consider relevant.
5. The above-mentioned further opportunities afforded to the patent holder and the final arguments the opponents may submit could consist either of one or more written

submissions or a single oral hearing, where appropriate, possibly on request of the patent holder or one of the opponents. The opponents' absence shall not impede oral proceedings. In the case of the absence of the patent holder, proceedings shall be concluded and the application processed. A brief statement shall be issued regarding matters discussed at the oral hearing, together with the texts suggested by the holder. The holder shall provide the description, the claims and, as appropriate, the drawings or biological sequences as suggested, following the formal requirements prescribed in this Regulation, within 10 working days as from the day after publication of the statement in the Official Bulletin of Industrial Property.

6. If the Spanish Patent and Trademark Office approves the oppositions in whole or in part, the patent shall be cancelled or be maintained in amended form.
7. The reasoned decision cancelling the patent shall be communicated to the patent holder and the opponents and notice thereof shall be published in the Official Bulletin of Industrial Property.

Paragraphs 8-11 refer to formal aspects of the publication of the granting of the patent.

12. An appeal against a decision on an opposition to a patent may only be lodged by parties in the opposition proceedings. For this purpose, an opposition shall be considered rejected if a settlement is not reached and notification is not effected within the prescribed time limit. The time limit for appeal is one month as from the date of publication of the resolution in the Official Bulletin of Industrial Property. However, this time limit is subject to the possible re-establishment of rights under the terms and conditions laid down in article 53 of the Law.
13. In appeal proceedings the patent holder may amend the application pursuant to article 48 of the Law of Patents.
14. Resolution of the appeal shall terminate administrative proceedings.

Article 40. *Concurrence of legal and opposition proceedings*

1. If the Patent Registry contains a record of ongoing legal proceedings concerning the validity of the patent or infringement against which the opposition is filed, the Spanish Patent and Trademark Office shall so inform the Judge or the Court for the relevant purposes.
2. If the time limit for filing an opposition has elapsed, a third party may request to intervene in opposition proceedings, provided he files a notice of opposition pursuant to article 36 of this Regulation and proves that the patent holder brought action for infringement against him, or that after the patent holder has requested him to discontinue an alleged infringement, he institutes *actio negatoria*, as established in article 121 of the Law. The statement of intervention shall be filed within three months of the date on which the relevant legal action was taken. Once the

application for intervention of a third party has been approved, it shall be treated as an opposition.

LIMITATION OR CANCELLATION AT THE REQUEST OF THE PATENT HOLDER

Limitation or cancellation at the request of the patent holder is a new feature in Spanish patent law and it is regulated by articles 105-107 of Law 24/2015 and articles 41-43 of Regulation RD 316/2017

Law No. 24/2015

Art. 105

1. A patent that has been definitively granted may be cancelled or limited at the request of the patent holder by modification of the claims at any time during its period of validity, including the validity period of the complementary certificates, as appropriate.
2. The application for cancellation or limitation sent to the Spanish Patent and Trademark Office shall be submitted using the official form and shall only be entertained if accompanied by the corresponding fee.
3. The cancellation or limitation of patents bearing royalties or subject to purchase options, embargos or registered licenses in the Patent Registry shall be inadmissible without consent from the rightholders. Cancellation or limitation applications shall be equally inadmissible if legal action claiming ownership of the patent or the recognition of other property rights has been registered in the Patent Registry without the knowledge of the applicant.
4. In the event of pending legal proceedings regarding the validity of the patent and without prejudice to the stipulations of article 120, the limitation application filed to the Spanish Patent and Trademark Office shall be authorized by the Judge or Court before which the proceedings have been brought.

Article 160

1. The Spanish Patent and Trademark Office shall ascertain the validity of the documents submitted and determine whether the amended claims are in accordance with articles 28 and 48, where appropriate.
2. If the documentation is defective or if the new set of claims does not limit the object of the patent, reasoned reservations shall be communicated to the party concerned to enable him to remedy the defects or present his allegations within the deadline that is legally established. The application shall be refused if the defects are not remedied within the prescribed time limit. If there are no objections or they have been obviated, the requested cancellation or limitation shall be granted.

Article 107

1. The effects of cancellation or limitation shall be the same as that of total or partial nullity. The modified claims shall retroactively determine the scope of protection conferred by the patent.
2. The effects of cancellation or limitation on former resolutions and contracts concluded prior to the cancellation or limitation decision shall be laid down in article 104.