

**MADRID**

Castellana, 216  
28046 Madrid  
Tel.: (34) 91 582 91 00

**BARCELONA**

Diagonal, 640 bis  
08017 Barcelona  
Tel.: (34) 93 415 74 00

**BILBAO**

Alameda Recalde, 36  
48009 Bilbao  
Tel.: (34) 94 415 70 15

**MALAGA**

Marqués de Larios, 3  
29015 Málaga  
Tel.: (34) 952 12 00 51

**VALENCIA**

Gran Vía Marqués  
del Turia, 49  
46005 Valencia  
Tel.: (34) 96 351 38 35

**VIGO**

Colón, 36  
36201 Vigo  
Tel.: (34) 986 44 33 80

**BRUSSELS**

Avenue Louise, 267  
1050 Bruselas  
Tel.: (322) 231 12 20

**LONDON**

Five Kings House  
1 Queen Street Place  
EC 4R 1QS Londres  
Tel.: +44 (0) 20 7329 5407

**LISBON**

Avenida da Liberdade, 131  
1250-140 Lisboa  
Tel.: (351) 213 408 600

## REVISION OF EUROPEAN PATENT TRANSLATIONS TO INCLUDE CHEMICAL-PHARMACEUTICAL PRODUCT CLAIMS: A CHANGE OF DIRECTION?

**Ángel García Vidal**

*Tenured Lecturer in Commercial Law, University of Santiago de Compostela  
Academic Advisor at Gómez-Acebo & Pombo*

**The present document provides an analysis of the issue of revised European translations to add product claims, focusing on recent Order no. 130/12 of Commercial Court no. 4 of Barcelona and its implications.**

### 1. Introduction

One of the main problems in Spanish patent law in recent years has been the effects on chemical-pharmaceutical patents of the entry into force of the Agreement on the aspects of intellectual property rights related to commerce, of 15 April 1994 (ADPIC).

As is well known, in Spanish law inventions of chemical and pharmaceutical products were not patentable before 7 October 1992 [First Transitional Provision of the 1986 Patent Law; Instrument of 10 July 1986, on adhesion to the European Patent Convention (EPC) and Transitory Provision of Royal Decree 244/1986, of 27 November 1986, on EPC application in Spain]. This situation led the European Patent Office (EPO) to take into account the ban on the patentability of chemical-pharmaceutical products in Spain until 1992 and recommend applicants for European patents which included product claims to draft a specific set of claims for Spain (Communication of the President of the EPO of 13 May 1992).

Many applicants for European patents followed this recommendation, so they validated their patents in Spain with a set of

claims which included no product claims. However, many other applicants for European patents before 7 October 1992 did not follow EPO recommendations and validated the same set of claims in all designated countries, including Spain. In this way, they took the risk that these product claims might be later declared invalid by Courts of Justice.

After the entry into force of the ADPIC Agreement, holders of these European patents validated in Spain have invoked said Agreement to prevent European patents validated in Spain, with product claims, requested before 7 October 1992, to be declared invalid.

Moreover, the holders of European patents which included product claims but who drafted a specific set of claims for Spain including only process claims (following the Communication by the President of the EPO of 13 May 1992), have argued that the ADPIC Agreement allows them to add new product claims.

Against this background, the EPO Communication of 8 March 2007 established that applicants for patents pending grant could

expand their claims following the entry into force of ADPIC. This Communication was interpreted by some sectors as acknowledgement by EPO that the ADPIC Convention allowed amendment of chemical-pharmaceutical patents granted before the entry into force of ADPIC to include protection of chemical-pharmaceutical products as such. For this reason, and for clarification purposes, EPO published a new Communication specifying that the Communication of 8 March 2007 refers only to pending European patent applications.

## **2. Revision of European Patent Translations in the Jurisprudence of the Administrative Chamber of the Spanish Supreme Court**

Some holders of European patents, applications for which were made before pharmaceutical products could be patented in Spain, have tried to add product claims by amending the translation of European patent documents, regulated by article 70 of the 1973 Convention on granting of European patents, which establishes that any State requiring the translation of European patent claims must allow the patent applicant or holder to provide a revised translation of the European patent application or the European patent. (In the same sense, article 12 of RD 2424/1986, on application of EPC).

Given the refusal to amend these claims on the part of the Spanish Patent and Trademark Office, the issue was brought before the Third Chamber of the Supreme Court, which passed several rulings on this matter [rulings of de 4 November 2010 (RJ\2010\7928 and RJ\2010\7103) of 3 March 2011, 16 September 2011, 21 November 2011 (JUR\2011\413826)]. In these decisions, the Supreme Court denies that the Spanish Patent and Trademark Office plays a merely automatic role when publis-

hing revised translations. On the contrary, it must perform a qualification and control work. In addition, the Supreme Court finds that a revised translation cannot be understood to allow only the correction of potential mistakes or inaccuracies, but it also makes it possible "to add claims included in the European patents but not included for whatever reason in the translation submitted in another State".

The Supreme Court also highlights that the possibility of submitting a revised translation is not subject to a deadline, and can be exercised at any time after publication of the original translation. (According to the SC, this can be inferred from the fact that no specific deadline is given in the EPC as well as from article 12 in Royal Decree 2424/1986, and from the aim of giving the possibility of submitting a revised translation).

## **3. Order no. 130/12 of Commercial Court no. 4 of Barcelona, of 7 May 2012**

**3.1.** Given this jurisprudential background on revised translation, Commercial Court no. 4 of Barcelona issued, on 7 May 2012, Order no. 130/12, denying precautionary measures.

The Order is part of the litigation between the holder of a complementary protection certificate for drugs and several companies, to which the claimant attributes infringement of the complementary protection certificate, as well as unfair competition. The claimant's certificate is based on a European patent applied for on 1 June 1998 and expired on 1 June 2009. What is relevant about this case is that this European patent included three different sets of claims, depending on the country for which protection was requested. Thus, the European patent granted for Spain

included process claims in English (the official language for the European Patent Office process). However, the set of claims submitted for other countries, such as Austria, Belgium, Switzerland, Germany, etc. included product claims.

The translation of the set of claims for Spain was submitted in 1995. However, in 2006 the patent holder submitted a new translation which included product claims to the Spanish Patent and Trademark Office. After the Spanish Patent and Trademark Office refused to publish the new translation, and after the Madrid High Court of Justice supported the Spanish Patent and Trademark Office's decision, the patent holder filed a cassation appeal with the Supreme Court. And it was precisely in response to that appeal that the Third Chamber of the Supreme Court passed its ruling of 16 September 2011, mentioned before, in which it accepts publication of the revised translation, including product claims (the publication took place on 7 February 2012).

Given these new products claims, the holder of the CPC granted after expiry of the patent believes that the defendants breach the right of exclusivity granted by the certificate, as they market or manufacture, or are able to market or certificate, generic drugs that contain the active substance protected by the product claims.

- 3.2.** In denying the request for precautionary measures made by the claimants, Order no. 130/12 of the Commercial Court no. 4 of Barcelona is firstly based on the close connection between a complementary protection certificate and the patent on which it is based. In this sen-

se, the Order points out that "the CPC is not an industrial property title different from the patent". To this end, it invokes the ECJ ruling of 13 July 1995 and Advocate-General Jacobs's conclusions, giving the legal basis invoked to pass the Community Regulations establishing the CPC, and which establish that the certificate is not a different industrial property title. However, it must be reminded that these statements by the ECH and the Advocate-General are absolutely reprehensible, as, Prof. BOTANA says, "beyond any doubt, this certificate constitutes a new title, as it extends the duration of a protection not granted by the patent itself" (BOTANA AGRA, "Fracaso de la impugnación por España del Reglamento sobre el certificado complementario de protección para los medicamentos", ADI 16, page. 982).

However, and regardless of the debate on whether the CPC is a distinct industrial property title, what seems to be beyond all doubt is the fact that "the certificate shall confer the same rights as the patent on which it is based, and shall be subject to the same limitations and obligations" (article 5 of the Regulations). For this reason, and as stated by the Order, "the claimant intends to extend the scope of protection of the original patent and thus the scope of protection of the CPC by means of the Revised Translation".

However, as regards extension of the protection of the patent on which the CPC is based, the Commercial Court no. 4 of Barcelona points out that the scope of protection of a European patent is determined by whatever claims have been granted for the

Member State of the EPC for which they had been requested. On this basis, it concludes that extension of the European patent as granted for Spain cannot be regarded as having taken place.

Indeed, according to the Order in question, the key lies in the text of the patent as it appears in the language of the proceedings. For, as stipulated by article 70.1 of the EPC, "the text of a European patent application or a European patent in the language of the proceedings shall be the authentic text in any proceedings before the European Patent Office and in any Contracting State". Even though article 70.3 of the EPC makes it possible for a State to regard as authentic a translation into an official language in that State, this is only possible "in the event of the European patent application or European patent in the language of the translation conferring protection which is narrower than that conferred by it in the language of the proceedings." (This is also specified in article 11 of Royal Decree 2424/1986).

Given this background, Commercial Court no. 4 of Barcelona finds that the Spanish translation should not be taken into account, for, after its revision, the European patent in the language of the translation (Spanish) confers a broader protection than that conferred by the language of the proceedings (English). The following statements in the Order are absolutely clear: "*The claims in the patent granted for the first group of countries, but not for Spain, have been translated, not modifying the claims specifically granted for Spain by the only competent body, the European Patent and Trademark Office. The Spanish Office (...) is competent neither to grant nor*

*to amend the European patent granted for Spain. It is merely responsible for verifying whether the translation matches the European patent as requested for our country*".

- 3.3.** This interpretation by Commercial Court no. 4 of Barcelona finally rejects the possibility for holders of chemical-pharmaceutical European patents who submitted a specific set of process claims for Spain to invoke any product claims which have been added by means of translation revision. The Order is aware of this fact, as it states that whenever patent holders attempt to do so "they will come across the unsurpassable obstacle of the discrepancy between the text providing the content of the patent (the unamended original) and the translation". Nor shall extension of the European patent granted for Spain be obtained by means of a request to the EPO, as art. 123.3 of the EPC stipulates that "the European patent may not be amended in such a way as to extend the protection it confers", and because, as was already stated, the Communication by the President of the EPO Communication of 18 June 2007 establishes that any attempt of this kind will be turned down.

Given this decision, one might wonder whether it follows the ruling previously passed by the Third Chamber of the Supreme Court. The Order of Commercial Court no. 4 of Barcelona establishes that there is no contradiction. According to the Commercial Court, the Supreme Court has analysed the effects of ADPIC on the actions of the Spanish Patent and Trademark Office, without prejudice to the effects which publication of a revised translation of the claims might have on the scope of the patent. As stated in the Order: "*The Supreme*

*Court has merely ruled on the matter in question, namely, publication of a revised translation of the European patent, and it focuses on rejecting that Spain's detachment within the EPC as regards the patentability of pharmaceutical products, after entry into force of ADPIC may constitute an argument to deny its publication. However, the Supreme Court is fully aware that, firstly, it fell to the Office and not to the Supreme Court to establish whether the translation matched the European patent as granted for Spain, that is to say, whether the original text of the European patent included the translated claims and, secondly, that, ultimately, the legal scope of publication of the translation of the patent might be controversial, among other things by contravening the original text, and that said controversy must be disregarded by courts in other jurisdictions".*

It should be taken into account that, even though the Third Chamber of the Supreme Court has expressly accepted that the revised translation may give rise to a broader protection than was conferred by the initial translation, the key lies in establishing whether that extension may exceed the text in the original language submitted at the Patent and Trademark Office. The Third Chamber of the Supreme Court does not expressly analyse this issue, but the Order discussed here does so, rejecting such a possibility.

However, Commercial Court no. 4 of Barcelona does acknowledge "the highly difficult nature of the issue".

For this reason, it remains to be seen whether the Civil Chamber of the Supreme Court supports this interpretation or not.

Indeed, some rulings in the civil domain have remarked that the fact that a specific set of claims has been submitted for Spain following the recommendation made by the President of the EPO "cannot involve self-limitation on the part of the claimant as regards legal protection of the invention" [Ruling of Commercial Court no. 6 of Madrid, of 19 October 2007 (EDJ 2007/201861)], "in such a way that said submission would in no case limit the protection conferred by a patent whose description and claims included a comprehensive technical regulation for the pharmaceutical product" [Ruling of the Provincial Court of Madrid (sec 28) of 26 October 2006].

In any case, it is clear that, if the thesis put forward by the Order of Commercial Court no. 4 of Barcelona were to be upheld, the only possibility of making the extension of the protection of a European patent effective before civil Courts by means of a revised translation would be that in which, following an application for a patent with product claims, the translation initially submitted had excluded these claims. That is, the Order thesis would not affect those patents which were not granted with a specific set of claims for Spain, and in which the product claims were removed by means of the translation.