COMMENTS FROM SPAIN IN REPLY TO CIRCULAR C. 8261 FROM THE SECRETARIAT OF WIPO'S STANDING COMMITTEE ON THE LAW OF PATENTS (SCP)

EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS

In Circular C. 8261 Member States are requested to submit information on the application of the following five exceptions:
(i) private and/or non-commercial use;
(ii) experimental use and/or scientific research;
(iii) preparation of medicines;
(iv) prior use; and
(v) use of articles on foreign vessels, aircraft and land vehicles.

In view of the fact that, since the reply was sent to the "Questionnaire on exceptions and limitations to patent rights", the only new developments have concerned the exception relating to experimental use and/or scientific research, additional information will only be provided on this exception.

Experimental use and/or scientific research

Legal background

Article 52.1(b) of Law No. 11/1986 of March 20, 1986, on Patents (hereinafter: Law on Patents) included as an exception or limitation to patent rights:

> (b) acts carried out for experimental purposes in relation to the subject matter of the patented invention.

The immediate precedent for the abovementioned provision is the Community Patent Convention signed at Luxembourg on 15 December 1975, Article 31 of which provided that rights conferred by the Community patent shall not extend to acts carried out for experimental purposes with regard to the object of the patented invention.

Legislative amendments

Article 52.1(b) of the Law on Patents was amended by Law No. 29/2006, of July 26, 2006, concerning guarantees and rational use relating to medicinal and health products, which in turn transposed in Spain Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Further to the abovementioned amendment, the wording of Article 52.1(b) was unchanged, as follows:

> 1. The rights conferred by the patent shall not extend to:
> (b) acts carried out for experimental purposes in relation to the subject matter of the patented invention, in particular studies and trials for obtaining authorization of generic medicines, in Spain

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or elsewhere, and the resulting practical requirements, including preparing, obtaining and using the active substance for such purposes.

With this amendment, the "Bolar clause" was introduced into Spanish law. According to the explanatory memorandum to Law No. 29/2006, the inclusion of this exception means that the performance of the studies and trials needed for obtaining authorization of generic medicines is not considered a violation of patent law. The incorporation of the Bolar exception is also understood to have the purpose of providing clarification, via the amendment of the Law on Patents.

Grounds for the exception

According to Spanish legal doctrine[1] and case law,[2] the purpose of the exception relating to "acts carried out for experimental purposes" is to establish rules that strike a balance between conflicting interests, limiting or restricting subjective law (patent law) and therefore to be interpreted in a restrictive way. Consequently, their content must be understood as imposing two requirements, namely:

- the acts must be carried out for the purpose of experimentation or trial and must be of an exclusively technical or scientific nature; and
- they must relate to the object of the patented invention, i.e. they must be carried out on, and not just with, the invention itself.

Accordingly, experimental acts that do not have the exclusive purpose of improving or consolidating technical rules relating to inventions per se must be considered excluded from this scenario.

As stated above, the purpose of the Bolar exception is to facilitate the preparation of generic medicines. Accordingly, this exception covers the experimental studies and trials carried out to obtain regulatory approval for the marketing of generic medicines, and the resulting practical requirements, including preparing, obtaining and using the active substance for these purposes.

Issues relating to the practical application of the exception in Spain

The incorporation of the Bolar clause into the Law on Patents, by means of Law No. 29/2006, posed a problem of interpretation in terms of determining whether permitting acts aimed at obtaining authorization for the marketing of generic medicines extended to acts that preceded the entry into force of Law No. 29/2006 or only applied to acts that occurred following its entry into force. The subject gave rise to lively debate, especially regarding the words "in particular" in the added provision and the reference to the clarification purpose of the reform in the explanatory memorandum to Law No. 29/2006.

This argument was settled once and for all by Supreme Court Ruling No. 39/2012 (Civil Chamber, Division No. 1) of 10 February 2012, which upholds a previous Supreme Court ruling of 30 June 2010. According to the above rulings, the Bolar clause does not apply retroactively, on the following grounds:

[1] Fernández-Nóvoa, C.,; Otero Lastres, O.L.; and Botana Agra, M.: *Manual de la Propiedad Industrial* [Industrial property handbook], Marcial Pons, 2009, p. 168.
[2] *Passim*: Supreme Court Ruling No. 39/2012 (Civil Chamber, Division No. 1) of 10 February 2012.

> "What used to be a clear interpretation has been obscured through the amendment of Law No. 29/2009, of July 26, 2009, specifically by the expression "in particular" used in the new text and the reference to "purposes of clarification" in the explanatory memorandum. For a legal provision to provide clarification, its content would have to be understood as already being part of the provision and it would then have retroactive effect (as in cases involving legal provisions providing interpretation or clarification – see rulings of: October 22, 1990 and March 6, 1991 (RJ 1991, 3072); April 9, 1992 (RJ 1992, 3188); November 24, 2006 (RJ 2006, 8136); and April 6 and November 18, 2009 (RJ 2009, 5562)). However, the objections expressed do not constitute sufficient grounds for maintaining a different interpretation from the one stated above, not only because of the lack of normative value of the explanatory memorandum and the ambiguity of the expression "in particular" which is under discussion here but also, especially, because the two exceptions are based on different reasoning. Furthermore, what the Law of 2006 does is to incorporate, as stated by the explanatory memorandum itself, the "Bolar clause", which did not exist at the time of the drafting of the provision – Article 27 CPC of 1975 (LCEur 1976, 19) – on which the original 1986 Law on Patents was based. This shows the internal incoherence of the explanatory memorandum, which is even more acute if account is taken of the fact that, firstly, the aforementioned incorporation is fundamentally a response to the need to transpose (something which should have occurred months earlier) Directive 2004/27/EC, which has only been effective in relations between individuals since its transposition on account of the demand that the judicial bodies should follow a "consistent interpretation" in the application of domestic legislation, which does not have retroactive effect (ruling of November 24, 2006 (RJ 2006, 9261)), and, secondly, that it would be paradoxical, and hence absurd, for Spain to have maintained in the international context (complaint against Canadian law) a legal position contrary to that of its own domestic legislation." (underlining added).

Consequently, acts aimed at obtaining authorization for the marketing of generic medicines undertaken prior to the incorporation of the Bolar exception into the Law on Patents do constitute an infringement of patent law.

QUALITY OF PATENTS

Since the subject of the quality of patents was placed on the agenda of the Standing Committee on the Law of Patents at its sixteenth session, **Spain** has repeatedly expressed its support for the initial proposal from the delegations of **Canada** and the **United Kingdom** (SCP/16/5) and for the subsequent proposals from **Denmark** (SCP/17/7) and the **United States of America** (SCP/17/10 and SCP/19/4), examining various aspects of the subject of the quality of patents. Evidence of our interest in this matter is found in the previous comments already presented (SCP/18/INF/2) in which **Spain** replied to the questionnaire on these matters proposed by the delegations of **Canada** and the **United Kingdom** (SCP/18/9) but not approved by the Committee.

Further evidence of our commitment to the quality of patents can be found in the proposal put forward by the delegation of **Spain** during the nineteenth session of the Committee (SCP/19/5) aimed at improving understanding of the inventive step requirement. As stated in that document, the Spanish proposal comes within the framework of point 17 of the revised proposal from **Canada** and the **United Kingdom** (SCP/17/8) concerning process improvement. In view of the statements made by many Member States during recent sessions of the Committee, it may be

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deduced that there is consensus regarding the quality of patents; a patent would imply quality if the invention to which it applies meets the requirements – particularly the requirements of patentability and sufficiency of disclosure – established in countries' patent legislation, so that patents would only be granted to inventions that deserve it. During the last session of the Committee, Spain sought to enhance understanding of the patentability requirement that is most complicated to evaluate, namely inventive step. Despite the fact that it was explicitly stated in the abovementioned proposal that the aim was not to have any kind of international harmonization but to improve knowledge of the requirement through studies concerning the definition of experts in this field, inventive step evaluation methods and different levels of inventive step, the proposal did not receive unanimous support.

During the last session of the Committee, a number of Member States said that they would prefer instead to improve knowledge of the requirement of sufficiency of disclosure. This delegation would have no objection to further consideration of that requirement prior to study of the patentability criteria referred to above, and so it does not rule out the submission of a proposal to that effect. In our opinion, the important thing is to ensure further consideration of all aspects of the quality of patents.

As stated in the reply to the SCP/18/9 questionnaire and in document SCP/18/INF/2, the Spanish Patent and Trademark Office (OEPM) has implemented the ISO 9001:2008 quality management system for the processing of international patent applications under the Patent Cooperation Treaty (PCT), both in the receiving office phase and with respect to its action as international searching and preliminary examining authority. Moreover, the Technological Information Unit also has UNE-166006:2011 certification. Under the procedure for granting national patents and utility models, the OEPM is also implementing the ISO 9001:2008 quality management system. Further information on quality at the OEPM can be found on the following web site: http://oepm-calidad.es/index.html .

Programs for work sharing among patent offices and for the use of external search and examination information

Two proposals have already been put forward on this subject: one by **Denmark** (SCP/17/7) and one by the **United States of America** (SCP/19/4).

Given the territorial nature of patent law, any applicant wishing to protect his/her invention in several countries has to file an application in all of them. There is the inevitable risk of duplication of efforts and inefficiency in the resources used, since different offices may undertake parallel searches in relation to the same inventions.

With a view to reducing this inefficiency, at least in part, a number of different initiatives have been taken, all of which take due account of the sovereignty of the different States and a particular example of which is the Patent Prosecution Highway (PPH). **Spain** has signed

bilateral agreements of this type with **Japan, the United States, Canada, the Republic of Korea, Finland, Portugal, Russia** and **Mexico**. Further information on the PPH agreements signed by the OEPM can be found on the following web page: **http://www.oepm.es/cs/OEPMSite/contenidos/PPH/PPH.htm**

At the OEPM, the first step taken by the examiner when starting the search in relation to an application is to attempt to detect other applications in the same family which have already been published. The existence of searches and/or examinations already undertaken with regard to the invention directs and facilitates the subsequent work of the examiner, even though it is the latter who takes the final decision.

Spanish patent legislation makes provision for the re-use of previous search and examination results. Article 33.5 of Law on Patents No. 11/1986 provides for a reduction in the payable search fee when searches conducted in the context of the PCT are able to be re-used:

Article 33

5. Where the prior art report can be based wholly or partially on the international search report conducted under the Patent Cooperation Treaty, the applicant shall be reimbursed 25, 50, 75 or 100 per cent of the fee, depending on the extent of the latter report.

Similarly, Article 39.3 provides for a reduction in the preliminary or substantive examination fee:

Article 39

3. Where the preliminary examination can be based wholly or partially on the international preliminary examination report produced by the competent international preliminary examining authority, the applicant shall be reimbursed 25, 50, 75 or 100 per cent of the rate, depending on the extent of the aforementioned report.

Our experience in this field has shown that the main impediment to effective use of the results of searches and examinations already conducted in other national or regional offices in relation to the invention for which a patent is sought, where these are available, is the language barrier, especially where languages very different from the mother tongue of the examiners are concerned. Currently available machine translation tools do not provide the desired quality, even though rapid progress has been made in this field. Until more advanced machine translation tools are available, full use of search and examination results originating from other patent offices will not be possible.

In our opinion, efforts to facilitate the re-use of search and examination work done by other patent offices should focus on two main areas:

- Improvements in machine translation tools;
- National and regional offices should make documents from the processing history for already published patent applications publicly available in databases, so that

patent examiners have easy access to search and examination results for patent applications belonging to the same family. At the OEPM such information can be found at the following address: http://archivoenlinea.oepm.es/register/regviewer .

Technical cooperation work by WIPO relating to the re-use of results should be geared to these two aspects.

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From: Belda Soriano, Leopoldo <leopoldo.belda@oepm.es>
Sent: mercredi 6 mars 2013 16:53
To: Miyamoto, Tomoko; Dolotbaeva, Aida; Henninger, Thomas
Subject: Correction to SCP 12/3

Dear Tomoko,

I've spotted a mistake in the Information about the Spanish law in the annex on inventive step to the document SCP 12/3:

http://www.wipo.int/export/sites/www/scp/es/national_laws/inventiva.pdf

The following part should be deleted, since it only applies to novelty:

"y el contenido de las solicitudes de patente o modelo de utilidad españolas o solicitudes internacionales PCT o europeas que designen a España con una fecha de presentación anterior (fecha de prioridad) que se publiquen posteriormente."

Best regards.

Leopoldo

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