Spain
Espagne
Spanien

Report Q202

in the name of the Spanish Group
by Montserrat BALLESTER RODÉS, Marcel.lí CURELL AGUILÀ,
Luis–Alfonso DURÁN, Isidro José GARCÍA EGEA, Montserrat GARCÍA–MONCÓ,
Patricia KOCH, Mònica LÒPEZ, Jorge LLEVAT and Marta PONS DE VALL I ALOMAR

The impact of public health issues on exclusive patent rights

Questions

I) Analysis of current law and case law

1) *Is a research or experimental use exception recognised under your patent law? If so, under which conditions? What is the scope of the research exception? Specifically, is research or experimental use permitted for commercial purposes?*

The experimental use exception is recognised under the Spanish law. In particular, Article 52, paragraph (b) of the Patent Act (Act 11/1986, of 20 March, on Patents) excludes the *"acts carried out for experimental purposes related to the subject matter of the patented invention"* from the scope of the patents. This provision has been amended by the Second Final Provision of the Act 29/2006, of 26 July, on Guarantees and Rational Use of Medicines and Medical Devices, which implements Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 by including the so-called Bolar clause or Bolar exception within the scope of the experimental use exception.

Prior to the amendment introduced by the said Act 29/2006, it was controversial that the acts carried out for any purpose other than contributing to the progress of the scientific knowledge could be considered as included within the scope of the experimental use exception but the Act 29/2006 clarifies this issue by stating that other acts, in particular the preparatory acts for the application and obtention of regulatory approval of generic drugs, also fall within the scope of the said exception.

2) *Is a Bolar-type exception recognised under your patent law? If so, under which conditions? What is the scope of the Bolar exception? Specifically, is it limited to drugs or does it also apply to other products, including biological products, research tools, etc.? If your patent law does not provide for a Bolar exception, will using an invention without the patentee's consent for the purpose of obtaining approval of a generic product be covered by the research exception?*

The Act 29/2006 has amended Article 52, paragraph (1)(b) of the Patent Act by introducing the Bolar exception within the scope of the experimental use exception: *"The rights conferred by the patent shall not extend to: (b) acts carried out for experimental purposes related to the subject matter of the patented invention, in particular, the studies and the tests carried out to obtain regulatory approval of generic drugs, either in Spain and abroad, and the subsequent practical requirements, including preparation, obtention and use of the active principle for this purpose".*

Even though the wording of the Bolar exception refers only to medicines, as this exception is covered by the experimental use exception, it cannot be excluded that it might be also applicable to other products whose commercialisation be subject to regulatory approval. Nevertheless, for the time being, there is no case law which allows to clearly conclude that this exception extends to products other than medicines.

3) *Are parallel imports of patented medicines, medical devices or similar permitted? If so, under which conditions? Do the same principles apply if the products originate from markets where they were made available under a compulsory license?*

The Spanish law (Article 53 of the Patent Act) foresees the exhaustation of patent rights. According to Community case law and Community legislation, this possibility extends to the European Economic Area.

Accordingly, parallel imports of any kind of product, including patented medicines, are permitted within the European Economic Area. Yet, they are prohibited for products originated from those countries which do not belong to the European Economic Area.

In order to allow a parallel import the product must have been put on the market, within the European Economic Area, by the patent owner or with his express consent.

The product may not have been altered in any way (there are some exceptions established by European case law as regards alterations in trade marks, but these exceptions do not affect patents).

These principles are not applicable to products originated from markets where they are commercialised under compulsory licence; patent rights are only exhausted by the placing on the market by the owner or with his express consent. As the owner's consent is not required to obtain a compulsory licence, the *"ius prohibendi"* conferred by patents may not be considered to be exhausted.

4) *Is an individual prescriptions exception recognised under your patent law? If so, under which conditions?*

Individual prescriptions or the so-called *"magistral formulae"* are recognised in Spain, in particular by Article 52, paragraph (c) of the Patent Act, which provides as follows: *"The rights conferred by the patent shall not extend to: (c) the extemporaneous preparation of medicines in pharmacies carried out singly in making up a prescription and acts related to the medicines thus prepared".*

5) *Please answer this question only if in your country methods of medical treatment are patentable subject matter: Does your patent law provide for a medical treatment defence or similar exception to the patentee's exclusive rights?*

Yes, Article 4, paragraph (4) of the Patent Act provides as follows: *"(4) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph (1), above. This provision shall not apply to products, in particular, substances or compositions, nor to inventions of apparatus or instruments for use in any of these methods".*

6) *Are compulsory licenses available under your patent law? If so, under which conditions and on which grounds (e.g. to remedy anticompetitive conduct, for cases of emergency, other public interest grounds, etc.)? Are you aware of any compulsory licenses granted in your country for the domestic manufacture and supply of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product covered.*

The Spanish Patent Act foresees the possibility to apply for compulsory licences (Title IX). A compulsory licence may be applied for in four circumstances (Article 86):

a) failure or insufficiency of working of the patented invention

b) export necessities

c) dependency of patents

d) existence of reasons of public interest

According to the information provided by the Spanish Patent and Trademark Office, since 1992 no compulsory licences have been granted for domestic manufacturing and supply of pharmaceutical products. Prior to that year, some compulsory licences based upon non-exploitation (which the Spanish law defined as lack of manufacturing within the Spanish territory) did exist.

Since the amendment of the definition of exploitation to include not only the manufacturing but also the selling within the national territory, thus covering the market needs -provided that the manufacturing be carried out in a WTO member country (Article 83 of the Patent Act)- compulsory licences for any of the purposes indicated in the question have no longer been applied for or, at least, have no longer been granted.

7) *Has new Article 31bis TRIPS been ratified in your country?*

Article 31bis TRIPS was introduced by the WTO Decision of 6 December 2005 in order to allow those countries which were not able to produce pharmaceutical products to obtain, if necessary, affordable copies elsewhere, in compliance with the provisions of the Doha Decision of 30 August 2003. On 30 November 2007 the European Union, who is a WTO member, ratified this amendment, which according to Article 300, paragraph (7) of the Treaty establishing the European Community, is legally binding in all the EU member states, including Spain. Spain is also in the process to ratify this amendment.

Be that as it may, the said amendment has not yet been formally incorporated into the TRIPS insofar as it has not yet been ratified by two thirds of its member countries, which is the required majority for incorporation.

Are you aware of any other legislative amendment in your country with a view to implementing the WTO decision of August 30, 2003?

It has not been approved in Spain any legislative amendment to implement the said Decision of 30 August 2003. Yet, the European Union has adopted 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 in order to implement the said Decision. This Regulation is directly applicable in Spain.

Are you aware of any compulsory licenses granted in your country for the importation or exportation of pharmaceutical products? If so, please provide details, including the name of the licensor, the licensee and the product, if they are publicly available.

No.

8) *Is the government allowed to make use of a patented invention without previous license and if so, on what basis (e.g. crown use) and under which conditions?*

No.

9) *Is the government allowed to expropriate a patent and, if so, under which conditions?*

Article 73 of the Patent Act 11/1986 (SPA) foresees the possibility that the government expropriate patents or patent applications by paying a fair compensation.

Art. 73 – "(1) Any patent application or patent already granted may be expropriated for reasons of public utility or public interest, subject to fair compensation.

(2) Expropriation may be for the purpose of placing the invention within the public domain so that it may be freely worked by any person without the need to apply for licenses, or it may be for the purpose of exclusive working by the State, which would then acquire ownership of the patent.

(3) Public utility or public interest shall be declared in the Act authorising the expropriation, which shall also state whether the invention shall fall within the public domain or whether the State shall acquire ownership of the patent or application. The procedure to be followed shall conform in every aspect, including fixing of fair compensation, to the general procedure laid down in the Act on Compulsory Expropriation."

A reason of public interest or public utility must exist in order to expropriate a patent or a patent application. The government must compensate the patent owner with a fair compensation. The public utility or social interest must be declared by the Act ordering the expropriation.

According to Article 73, expropriation is possible in two circumstances: (i) expropriation for reasons of public interest carried out for the purpose of placing the invention within the public domain so that it may be freely worked by any person, without the need to apply for a licence, or (iii) expropriation for the purpose that the government may exclusively work the invention.

10) *If your patent law recognises other means of facilitating access to medicines, medical devices, diagnostics and the like, notably in the context of public health crises (including, among others, information tools such as the Orange Book providing timely consumer information on generic drug approvals), which have not been discussed above, please explain.*

The Spanish patent law does not set forth other means to facilitate access to medicines, except for those already cited in this paper (compulsory licences, Bolar clause and so on).

The Act 29/2006, of 26 July, on Guarantees and Rational Use of Medicines and Medical Devices, establishes some mechanisms to facilitate access to medicines. For example, Article 24, paragraph (3) provides the possibility of "comparative use" of medicines, which means an authorisation to use a medicine for clinical situations of specific patients before such a medicine be approved in Spain.

Equally, the Act 29/2006 provides that the Spanish Agency of Medicines and Sanitary Products may authorise the importation of medicines which have not been approved in Spain -but are being lawfully commercialised in other States- when the importation is absolutely necessary for the prevention, diagnostics and treatment of specific pathologies, either because no appropriate approved alternative for such a specific indication exists or there is a situation of shortage which justifies so.

The Spanish Agency of Medicines and Medical Devices may also temporally authorise the distribution of non-approved medicines to prevent potential or actual propagation of a pathogen or chemical agent, toxin or nuclear radiation which may cause damages.

The above-mentioned mechanisms do not affect the legal patent system.

II) Proposals for adoption of uniform rules

1) *Should patent law provide for*

- *research and experimental use exception;*
- *Bolar exception;*

- *parallel import of patented medicines;*
- *individual prescriptions exception;*
- *medical treatment defence;*
- *compulsory licensing;*
- *expropriation;*
- *any other limitations of the exclusive patent rights to facilitate access to medicines, diagnostics, medical devices and the like?*

If so, under what circumstances? If not, why not?

The Spanish Patent Act foresees all the above-mentioned limitations of the exclusive patent rights. In our opinion, this is appropriate. We have only a comment to make in this respect as regards the Bolar exception, which is presently foreseen in the framework of the experimental use exception: we think that it should be contained in a specific paragraph.

Furthermore, a possible limitation of the exclusive rights derived from the patent system in order to facilitate access to medicines and the like could be envisaged. For example, such limitation could consist in allowing the government to use the patented invention during a limited period of time, without the need to request a previous licence but with the need to pay compensation to the patent owner. In any event, such a limitation should be applicable only in exceptional cases for reasons of urgency or public interest.

2) *Do you see other ways than by limitations of patent rights in which patent law might facilitate access to medicines, diagnostics, medical devices and the like?*

No.

3) *Should any of the limitations of patent rights, specifically the research and experimental use exception, Bolar exception, and individual prescriptions exception be harmonised? If so, how? If not, why not?*

Yes, in Europe by Directive or Regulation, and in other countries through the WTO or the SPLT.

Summary

The Spanish Patent Act recognises an exception for experimental purposes of patents by establishing that the rights conferred by the patent shall not extend to the acts carried out for experimental purposes related to the subject matter of the patented invention, in particular, the studies and tests carried out to obtain regulatory approval of generic drugs, either in Spain or abroad, and the subsequent practical requirements including preparation, obtention and use of the active principle for this purpose.

In applying the regulations of the European Economic Community, Spain foresees an exhaustion of patent rights in the field of the European Economical Area (EEA), but the international exhaustion is not applied. Thus, parallel imports of products from the EEA are allowed, but imports of products originated from third countries are prohibited. The exhaustion is not applied to products produced in the EEA under a compulsory license.

In Spain, the rights conferred by a patent shall not extend to the extemporaneous preparation of medicines in pharmacies carried out singly in making up a prescription and acts related to the medicines thus prepared.

In Spain, methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall be regarded as inventions, which are not susceptible of industrial application and thus not patentable. Spain, as a country adhered to the European Patent Convention follows the criteria of the European Patent Office in this sense.

The Spanish Patent Act also foresees the possibility to apply for compulsory licenses for:

a) Failure or insufficiency of working of the patented invention

b) Export necessities

c) Dependency of patents

d) Existence of reasons of public interest.

In applying TRIPS, it is assumed that an invention is worked in Spain if the object is manufactured or sold in Spain.

Spain has not modified its legislation in order to adapt it to article 31 bis of TRIPS, although the European Union has done so by adopting Regulation (EC) No. 816/2006 which is directly applicable to Spain.

The Spanish legislation does not allow the Government to use a patented invention without a previous license. Nevertheless, the Law allows the Government to expropriate a patent for reasons of public utility or public interest, by means of a fair compensation. The public utility or public interest must be declared by Law.

The Spanish Group considers that the Bolar exception should be included as a specific exception, instead of being regulated within the scope of the experimental use exception.

Furthermore, it is considered that it would be advisable to harmonise the limitations to the right of patents in the framework of the International Substantive Patent Law Treaty (SPLT) which is being discussed in the WIPO.

Résumé

La Loi sur les Brevets espagnole reconnaît une exception pour l'utilisation expérimentale des brevets, en établissant que les droits conférés par les brevets ne s'étendent pas aux actes qui sont réalisés à des fins expérimentales et qui se réfèrent à l'objet de l'invention brevetée, en particulier les études et les essais réalisés pour l'autorisation de médicaments génériques, en Espagne et en dehors de l'Espagne, ainsi que les pratiques requises correspondantes, ce qui inclut la préparation, l'obtention et l'utilisation du principe actif à ces fins.

En application de la réglementation de la Communauté Économique Européenne, il existe en Espagne un épuisement du droit du breveté dans le cadre de l'Espace Economique Européen (EEE); cependant, un épuisement international n'est pas applicable. En conséquence, les importations parallèles de produits en provenance de l'EEE sont autorisées, mais pas les importations en provenance de pays tiers. L'épuisement ne s'applique pas aux produits qui ont été produits dans l'EEE sous une licence obligatoire.

En Espagne, les droits conférés par un brevet ne s'étendent pas à la préparation de médicaments réalisée dans les pharmacies extemporanément et par unité en exécutant une ordonnance médicale, ni aux actes relatifs aux médicaments ainsi préparés.

En Espagne, sont considérées comme des inventions non susceptibles d'application industrielle, et donc non brevetables, les méthodes de traitement chirurgical ou thérapeutique du corps humain ou animal ainsi que les méthodes de diagnostic appliquées au corps humain ou animal. L'Espagne, en tant que pays membre de la Convention sur le Brevet Européen, suit les critères de l'Office Européen des Brevets en cette matière.

La loi Espagnole établit également la possibilité de demander des licences obligatoires pour:

a) Absence ou insuffisance d'utilisation de l'invention brevetée

b) Besoin pour l'exportation

c) Dépendance entre brevets

d) Existence de raisons d'intérêt public pour l'octroi.

En application de l'Accord sur les ADPIC, on entend qu'une invention s'exploite en Espagne si l'objet est fabriqué ou vendu en Espagne.

L'Espagne n'a pas modifié sa législation de façon à l'adapter à l'article 31 bis de l'Accord sur les ADPIC, mais une telle adaptation a été réalisée par l'Union Européenne à travers le Règlement (CCE) n° 816/2006, qui est directement applicable en Espagne.

La législation espagnole ne permet pas au gouvernement d'utiliser une invention brevetée sans licence préalable. Cependant, la loi permet au gouvernement d'exproprier un brevet pour cause d'utilité publique ou d'intérêt social, moyennant une indemnité appropriée. L'utilité publique ou l'intérêt social doivent êtres déclarés par la loi.

Le Groupe Espagnol considère que l'exception « Bolar » devrait être inclue comme une exception spécifique, au lieu d'être régulée dans le domaine de l'exception pour utilisation expérimentale.

Il considère également qu'il conviendrait d'harmoniser les limitations au droit du brevet dans le cadre du Traité International sur le Droit Matériel des Brevets (SPLT) qui est en discussion à la OMPI.

Zusammenfassung

Das Spanische Patentgesetz kennt die Ausnahme zur Forschungs- und Versuchszwecken und hat festgelegt, dass die Wirkung eines Patents erstreckt sich nicht auf Handlungen zu Versuchszwecken, die sich auf den Gegenstand der patentierten Erfindung beziehen, insbesondere Studien und Versuche, die für die Erlangung einer Generika Zulassung für das Inverkehrbringen in Spanien und ausserhalb Spaniens erforderlich sind; und die sich daraus ergebenden praktischen Anforderungen, einschliesslich der Vorbereitung, Erhalt und Benutzung des aktiven Elements für diese Zwecke.

Die Umsetzung in Spanien der EG-Vorschriften sieht die Erschöpfung eines Patentrechts im Bereich Europäischer Wirtschaftsraum (EWR) vor, nicht aber die internationale Erschöpfung. Damit ist das Parallelimport aller Produkte von der EWR erlaubt, während das Parallelimport von Produkte aus Drittstaaten verboten ist. Die Erschöpfung wird nicht auf innerhalb des EWR mit einer Zwangslizenz hergestellten Produkten angewandt.

In Spanien, die Wirkung eines Patents erstreckt sich nicht auf die unmittelbare Einzelzubereitung von Arzneimitteln in Apotheken auf Grund ärztlicher Verordnung sowie auf Handlungen, welche die auf diese Weise zubereiteten Arzneimittel betreffen

In Spanien gelten Verfahren zur chirurgischen oder therapeutischen Behandlung des menschlichen oder tierischen Körpers und Diagnostizierverfahren, die am menschlichen oder tierischen Körper vorgenommen werden, nicht als gewerblich anwendware Erfindungen und werden deswegen keine Patente dafür erteilt. Spanien, als Mitgliedstaat des Europäisches Patentsübereinkommens, folgt demnach die Kriterien des Europäischen Patentamtes.

Das spanische Patentgesetz sieht auch die Erteilung von Zwangslizenzen vor, wegen:

a) Fehlende oder ungenügende Übung der patentierten Erfindung

b) Notwendigkeit für den Export

c) Abhängigkeit zwischen Patenten

d) Offentliche Interesse für die Erteilung.

TRIPS-Abkommen zufolge, gilt eine Erfindung in Spanien als benutzt solange das Produkt in Spanien hergestellt oder verkauft wird.

Spanien hat keine legislative Änderung durchgeführt um das Gesetz an Artikel 31 bis vom TRIPS-Abkommen anzupassen, obwohl dieses im EU Rahmen durch die Verordnung 816/2006 umgesetzt worden ist, die in Spanien direkt anwendbar ist.

Das spanische Gesetz erlaubt der Regierung nicht, eine patentierte Erfindung ohne Lizenz zu benutzen. Das Gesetz erlaubt jedoch der Regierung, aus Gründen öffentlicher Nützlichkeit oder sozialen Interesses, ein Patent gegen eine gerechte Vergütung zu enteignen. Das öffentliche Nutzen oder soziale Interesse muss gesetztlich geregelt werden.

Die Spanische Gruppe ist der Meinung, dass die Bolarausnahme als spezifische Ausnahme im Gesetz aufgenommen werden sollte, anstatt sie als Ausnahme zur Forschungs- und Versuchszwecken zu regeln.

Die Gruppe ist auch der Meinung, dass die Beschränkungen auf das Patentrecht im Abkommen über das materielle Patentrecht (SPLT), die zurzeit an der WIPO diskutiert werden, auch zu harmonisieren wären.