

# WORLD TRADE ORGANIZATION

RESTRICTED

**IP/Q3/ESP/1**

18 November 1997

(97-5024)

**Council for Trade-Related Aspects  
of Intellectual Property Rights**

Original: English/Spanish

REVIEW OF LEGISLATION IN THE FIELDS OF PATENTS, LAYOUT-DESIGNS  
(TOPOGRAPHIES) OF INTEGRATED CIRCUITS, PROTECTION OF  
UNDISCLOSED INFORMATION AND CONTROL OF  
ANTI-COMPETITIVE PRACTICES IN  
CONTRACTUAL LICENCES

Spain<sup>1</sup>

The present document reproduces the questions put to the delegation of Spain and the responses given in the review of legislation on patents, layout-designs (topographies) of integrated circuits, protection of undisclosed information and control of anti-competitive practices in contractual licences at the Council's meeting of 26-30 May 1997.<sup>2</sup>

## **I. REPLY TO THE GENERAL QUESTION ON PRIORITY RIGHTS<sup>3</sup>**

**Does your country recognize a right of priority on the basis of an earlier patent application filed in any other WTO Member by a national of a WTO Member?**

Spain recognizes the right of priority for a patent application filed in or for Spain which invokes such a right on the basis of an earlier application filed in any WTO Member.

Justification: the Union right of priority (Article 4 of the Paris Convention) has been incorporated in the TRIPS Agreement by implication, according to Article 2.1 of the Agreement, and consequently applies to all nationals of WTO Members, who are granted the treatment provided for in Article 1.3 of the Agreement, which by implication includes the Union right of priority.

Moreover, pursuant to the most-favoured-nation clause (Article 4 of the TRIPS Agreement), nationals of WTO Members must be granted the same advantages as those granted to the nationals of any other country, in this particular case the right of priority recognized to nationals of States belonging to the Paris Union.

---

<sup>1</sup>As regards laws and regulations relevant to the areas under review as notified by Spain under Article 63.2 of the Agreement, reference is made to documents IP/N/1/ESP/1/Rev.1 and Add.1, IP/N/1/ESP/P/1-5, IP/N/1/ESP/I/1-2 and IP/N/1/ESP/L/1.

<sup>2</sup>The minutes of the meeting have been circulated in document IP/C/M/13.

<sup>3</sup>At the meeting of the TRIPS Council of 27 February 1997, Members agreed to respond to this question in the context of the present review (document IP/C/M/12, paragraph 18).

## II. REPLIES TO QUESTIONS POSED BY JAPAN

### 1. In your country, are the following subject matters protectable by patent: (1) plants and animals, and (2) plant and animal varieties?

In Spain, under Article 5 of Patent Law 11/1986:

- plant varieties covered by Law 12/1975 on plant variety protection are not patentable (Patent Law, Article 5.1(b));
- breeds of animals are not patentable (Patent Law, Article 5.1(c));
- plant varieties and, in general, plants that are not covered by Law 12/1975 on plant variety protection are patentable (Patent Law, Article 5.1(b) *a sensu contrario*);
- animals that are not breeds and animals produced by microbiological processes that are not breeds are patentable (Patent Law Article 5.1(c) *a sensu contrario* and Article 5.2). There could be exceptions to this general principle in the specific case of impediments to patentability deriving from offences against *ordre public* or morality (Patent Law, Article 5.1(a)). Offences against *ordre public* could apply to animals as a criterion for restricting patentability in the case of the higher vertebrates.

### 2. In your country, is the act of offering for sale included in the exclusive rights of patent?

Yes (Articles 50 and 51 of Patent Law 11/1986).

### 3. In your country, what kinds of acts are recognized as exceptions to the exclusive rights conferred by a patent right?

Under Article 52 of Patent Law 11/1986, rights conferred by a patent right do not extend to:

- acts undertaken privately and for non-commercial purposes;
- acts undertaken for experimental purposes relating to the subject matter of the patented invention;
- the preparation of medicines in a pharmacy individually, case by case on the basis of a medical prescription, or acts relating to the medicines thus prepared;
- use of the patented invention on board vessels entering Spanish territorial waters temporarily or accidentally;
- use of the patented invention in the construction or operation of aircraft or land vehicles temporarily or accidentally entering Spanish territory;
- acts covered by Article 27 of the Convention on International Civil Aviation of 7 December 1944 where such acts concern aircraft of a State to which the provisions of the said Article apply.

### 4. In your country, in which case is use without the authorization of the right holder permitted, including use by the Government or by third parties authorized by the Government?

The compulsory licence regime is regulated by Articles 83-107 of the Patent Law. The cases to which it applies are: lack or insufficiency of exploitation of the patented invention; the need to export; interdependence of patents; and public interest. This regime has practically fallen into disuse. Moreover, the direct applicability of the TRIPS Agreement and the Judgement of the Court of Justice of the European Communities of 14 February 1992 (*Commission vs. Italy*, *Commission vs. United Kingdom*) has reduced its potential effectiveness.

**5. In your country, how is the obligation under Articles 34.1 and 34.2 of the TRIPS Agreement regarding the shift of the burden of proof in civil proceedings for patent infringement related to a process patent implemented?**

Article 61.2 of the Patent Law stipulates that if the subject matter of the patent is a process for the manufacture of new products or substances it is presumed, unless proved otherwise, that any product or substance with the same characteristics was obtained by the patented process.

**III. REPLIES TO QUESTIONS POSED BY THE UNITED STATES**

**1. Article 133 of the Spanish Patent Law appears to require that the patent owner adequately work the invention in Spain in order to give the patent owner the ability to obtain injunctive relief against infringing parties. Please explain how this provision complies with:**

- (a) Article 27.1 of the TRIPS Agreement, which prohibits discrimination in the enjoyment of patent rights based on whether products are produced locally or imported; and**
- (b) Article 28 of the TRIPS Agreement, which requires that the patent owner be given exclusive rights which are not conditioned in any form.**

In Spain's view, Article 133 of the Patent Law is perfectly consistent with the provisions of the TRIPS Agreement mentioned by the United States, i.e. Articles 27.1 and 28, for the following reasons:

Firstly, owing to the broad interpretation given to the concept of "industrial exploitation in Spain".

Secondly, owing to the automatic application in Spain of certain of the obligations laid down in the TRIPS Agreement arising from the principle of national treatment which, as is well known, is one of the cornerstones of the Agreement.

Thirdly, because in Spain the legislator, concerned with legal certainty in the jurisprudential interpretation of substantive law, felt that it was appropriate to include in the legislative reform currently under way in respect of industrial property a formal amendment in this regard involving the deletion, for the sake of clarity, of the geographical reference "in Spain".

Going back to the first of the reasons cited above, it should be pointed out that the concept of exploitation in Spain is made up of two elements: firstly, satisfaction of the domestic market, and secondly, supply of the market through domestic production or import of the product from another State included in the framework of an international convention to which Spain is a party and from which the said obligation to recognize the import for the purposes mentioned derives.

Moreover, it must be stressed that Article 133 of the Patent Law does not refer to "work", but to "exploitation". It is known that the responsibility for exploiting a patent (i.e. the responsibility for

keeping the reference market supplied) is considered by the TRIPS Agreement as an intrinsic and traditional element of patent law. Thus, Article 31(f) of the TRIPS Agreement does in fact permit other use without authorization from the patent holder where necessary to supply the domestic market of the Member authorizing such use.

[Follow-up question from the US]

**In its answer to questions 1(a) and (b), the Government of Spain has identified several grounds upon which it asserts that the obligation not to discriminate in the enjoyment of patent rights required by Article 27.1, and the obligations in respect of the nature of the exclusive rights to be provided through a patent in Article 28, are being respected in Spain. The original question focused on a provision of Spanish law that seemed to condition the enjoyment of the exclusive rights of a Spanish patent on the "local working" of the patented invention in Spain. Could the Spanish Government please:**

- (a) confirm that the judicial authorities in Spain would be obligated to interpret Article 133 in a manner consistent with the conclusions offered in the answers of the Spanish Government (i.e., that a failure to practice the patented invention in Spain or in another European Community member State will not affect the enjoyment of the exclusive rights of a patent in Spain); and**
- (b) indicate whether this or other provisions of the Spanish patent law are proposed to be modified in the near future.**

(a) We can confirm that the judicial authorities in Spain are obligated to interpret Article 133 of Patent Law 11/1986 in the broad manner described by Spain in the reply to question No. 1 posed by the United States.

It should be stressed in this connection that the TRIPS Agreement, as an international normative instrument, prevails over domestic law. Under Article 96.1 of the Spanish Constitution and Article 1.5 of the Civil Code, the provisions of international treaties are binding for Spain as soon as they enter into force and, as treaty provisions, they form part of the country's internal legal order and are fully effective within that order.

The case history of the Constitutional Court and the Supreme Court shows that in case of contradiction or conflict between international agreements and domestic legislation applicable in the same area, the former prevail, provided they (the international agreements) are clear and unconditional in their direct application (Constitutional Court Judgement 28/1991, BOE 13.3.1991; Constitutional Court Judgement 180/1993, BOE 5.7.1993; Supreme Court Judgement of 22 May 1989 and Supreme Court Judgement of 26 March 1991).

However, should a Spanish court not take account of Articles 27.1 and 28 of the TRIPS Agreement in a given case and fail to adopt the requested precautionary measures, it would be up to the party requesting such measures to make an appeal against the denial of the measures under Article 1428 of the Civil Procedure Law (of 1881, amended in 1984 and 1992).

(b) Article 133 of the Patent Law is indeed to be modified to the extent of deleting, for the sake of clarity and of legal certainty, the geographical reference "in Spain".

The Spanish Patent Law is currently undergoing thorough revision.

**2. Could the Spanish Government please explain whether inventions within the categories specified below are eligible to be patented in Spain, if the invention is novel, involves an inventive step, and is useful:**

- (a) process inventions which, in whole or in part, consist of steps that are performed by a computer and are directed by a computer program; and**
- (b) product inventions consisting of elements of a computer-implemented invention, including in particular:**
  - (i) machine-readable computer program code stored on a tangible medium such as floppy disk, computer hard drive or computer memory; and**
  - (ii) a general purpose computer whose novelty over the prior art arises primarily due to its combination with a specific computer program.**

(a) Patent Law 11/1986 does not consider computer programs to be patentable inventions where the subject matter of the patent covers only that category (Article 4.2(c) and Article 4.3 of the Patent Law). This provision was taken from the Munich Convention on the Grant of European Patents of 5 October 1973 (Article 52.2 and 3).

In other words, inventions that pertain to, use, or can be implemented by a computer program are considered patentable. When the computer program is part of a device and provides the solution to a technical problem it is possible, in principle, to protect it by patent provided the invention complies with the other legal protection requirements.

The Spanish Patents and Trademarks Office must ex officio check that the invention does not consist exclusively of a computer program (ex Article 31.2 of the Patent Law).

In solving this type of case, the Spanish Patents and Trademarks Office takes account of the precedents established by the Boards of Appeal of the European Patent Office (EPO). The EPO has made a highly restrictive interpretation of Article 52.2(c) of the Munich Convention and has taken a favourable stance with respect to the granting of patents claiming computer programs (Decisions T-26/86, T-208/84, T-209/91, T-158/88, T-769/92, T-59/93, T-6/83, etc.).

(b) The above reply applies, *mutatis mutandis*, to part (b) of the question as well. However, a few clarifications are needed:

- (i) When a product invention contains an electronic device for reading computer program codes it is, in principle, patentable, in conformity with the precedents established by the Boards of Appeal of the EPO - see in this connection Decision T-26/86 (OJ EPO 1988, 19), according to which a computer-driven X-ray device was patentable in spite of the fact that the device itself (without the computer program) was based on existing technology. In this case, the novelty lay in the computer program.
- (ii) When a product invention consists of a computer whose novelty over the prior art arises primarily due to its combination with a specific computer program, that invention, is also, in principle, patentable - see in this connection Decision T-6/83 (OJ EPO 1990, 5) of the Board of Appeals of the EPO, according to which an invention consisting of the coordination of internal communications between programs within a data processing system was patentable.

**3. Article 11 of Royal Decree 767/1993 links the availability of protection for confidential test or other data submitted to a Spanish regulatory agency to the existence of a patent in force that covers the product subject to the regulatory review. Please explain how this provision of the Spanish law complies with Article 39.3 of the TRIPS Agreement, which requires protection be provided against unfair competition arising from use of confidential information submitted pursuant to the party seeking marketing approval, and which does not condition the enjoyment of this protection on the existence of patent rights.**

The United States asks if Article 11 of Royal Decree 767/1993 on the evaluation, approval, registration and conditions for dispensing proprietary medicines complies with Article 39.3 of the TRIPS Agreement, and points specifically to the fact that this Article does not condition the enjoyment of protection on the existence of patent rights.

In our view, the United States has incorrectly interpreted Article 11 for the following reasons:

Firstly, Article 11 does not deal with the obligation to protect confidential information (as mentioned below, that obligation is contained in another law), but is intended, rather, to regulate the accelerated procedure for sanitary approval. Applications for sanitary approval are transmitted in accordance with the said Article "without prejudice" (in the meaning of the provision) or independently of whether the products already approved enjoy patent rights or not.

Secondly, Article 32 ("confidentiality"), of Law 25/1990 on Medicaments (BOE 22.12.1990) contains an obligation of confidentiality: it stipulates that "the content of the applications for approval in respect of proprietary medicines shall be confidential, without prejudice to the information required for inspection purposes".

Thirdly, a subsequent applicant for approval may refer certain parts of his application to the original file only with the express consent of the holder of the previous approval. The assumption, in other words is that the holder of the previous approval has transmitted the necessary information to the subsequent applicant.

[Follow-up question from the US]

**Please explain the measures, if any, that have been implemented in Spain to protect against unfair competition those parties that have provided confidential test or other data concerning a pharmaceutical or agricultural chemical product to Spanish regulatory authorities pursuant to a request for marketing approval. Please explain how such measures, if any, are consistent with Article 39.3 of the TRIPS Agreement.**

Spain was already complying with the confidentiality obligation of Article 39.3 of the TRIPS Agreement before that Agreement was applicable in the country, i.e. before 1 January 1996.

Indeed, Article 15 of Royal Decree 767/1993 of 21 May on the evaluation, approval, registration and conditions for dispensing proprietary medicines for human use, entitled "Guarantee of Confidentiality", contains the obligation to keep the application for approval and the accompanying documentation secret.

As mentioned in the reply above, the Law on Medicaments (Law 25/1990) also contains this principle of confidentiality in Article 32.

As regards confidentiality of authorization procedures for agricultural chemical products, Article 32.1 of Royal Decree 2163/1994 of 4 November on phytosanitary products requires confidentiality when such confidentiality is requested by a party.

Finally, it should be mentioned that generally speaking, the violation of industrial and business secrets is an act of unfair competition punishable under Article 13 of Law 3/1991 of 10 January on Unfair Competition (BOE 11.11.1991). Articles 18 to 21 of that Law lay down the actions that can be taken against such acts.

**Please explain whether Spain conditions the protection for test data against use by a subsequent applicant for marketing approval for the same product on the existence of patent rights by the first applicant for marketing approval in respect of a new pharmaceutical or agricultural chemical product.**

No. In Spain, the protection of documentation submitted by an applicant for marketing approval is not conditioned on the holding of patent rights, as is clear from Article 11 (accelerated applications) of the above-cited Royal Decree 767/1993. Specifically, this Article contains two precautions with respect to the indicated procedure:

- First precaution: "Without prejudice to the right to the protection of industrial and commercial property (*sic*)". In other words, the procedure with respect to the second sanitary approval is regulated independently of whether or not there exists a patent right.
- Second precaution: "A second applicant for approval of a medicament essentially similar to another already approved medicament (...) may, with the express consent of the holder of the approval, refer certain parts of his application to the original file". In other words, the secrets of the file cannot be revealed without the express consent of the first applicant for sanitary approval.