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REPORT ON IP-RELATED MATTERS IN SPAIN

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FIRST COURT CASE ON SPCs IN SPAIN

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It has been possible to obtain SPCs in Spain since 2 January, 1998. Since then, the Spanish Patent and Trademark Office (OEPM) has issued such certificates to patentees who meet the requirements stipulated in Regulation (EEC) No. 1768/92 concerning the creation of a supplementary protection certificate for medicinal products.

On 17 May 2004, the High Court of Justice of Catalonia granted the first court decision to Supplementary Protection Certificates (SPCs) in Spain (Section Five of the Court, Judgment no. 692/2004). This decision makes certain statements regarding how to determine the scope of application of Regulation (EEC) No. 1768/92 to the OEPM.

The facts of the case

On 16 November 1999, the OEPM granted an SPC to E.R. Squibb and Sons, Inc. based on its Spanish patent ES 507 672 (“*process for preparing derivates of proline*”) for the product “*fosinopril sodium / hydrochlorothiazide*”.

The Spanish Generic Drug Association, the AESEG, appealed the decision since it considered that the

granting of the SPC did not meet the requirements of article 3 of Regulation (EEC) No. 1768/92.

The OEPM dismissed the appeal filed by AESEG, since the competent authority for granting SPCs in each country (the OEPM in Spain) may grant such certificates “*without examining the conditions stipulated in paragraphs c) and d) of Art. 3, which specifically refer to whether the product covered by the basic patent was previously covered by another certificate (c), and whether or not the authorisation used as the basis for applying for the SPC is the first time the product has been marketed as a medicinal product (d), and this latter point is what the challenging parties are calling into question*”. The OEPM deemed that under no circumstances could the decision be appealed by alleging that the authorisation was not the first or had been the object of a previous certificate “*since these questions were not dealt with by the Authority during the SPC granting procedure*”.

The second allegation made by AESEG was that the first Market Authorisation (MA) in the EU was not the one

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declared by Squibb in its Spanish MA (Denmark, 22 July 1994) but a previous one, such as the MA declared in France on 4 May 1992 or another on 3 July, 1990. This was also dismissed since the OEPM deemed that the fact that the MA declared by the applicant was not the first in the EU would merely affect its duration and not its validity. In any case, the OEPM considered that “*the Authority is not competent to examine and, therefore, not competent to rule on whether or not it is the first authorisation to market the product as a medicine; these are matters for the civil courts*”.

The AESEG appealed the OEPM's decision in the Spanish administrative courts, seeking to have the decision granting the SPC to E.R. Squibb and Sons, Inc. revoked. The court asked for the appointment of an expert witness and accepted the evidence provided by the parties.

The Spanish patent office has jurisdiction to rule on any grounds for the nullity of SPCs

The court rejected the OEPM's conclusion that it could not deal with questions that had not been examined during the process for granting the SPC. Citing the Judgement of the European Court of Justice (ECJ) on 11 December 2003 in a preliminary ruling about the interpretation of articles 15 and 19 of Regulation (EEC) No. 1768/92 (*Hässle*

vs Ratiopharm), the court considered that “*Article 19 of Regulation No 1768/92 cannot be interpreted independently but must be interpreted in conjunction with Article 3 thereof. However, as the Commission rightly pointed out, infringement of Article 19 is comparable to the case of the certificate being issued contrary to the requirements of Article 3*” (art. 90). In the same way, the Spanish court pointed out that article 15(1) states that “*The certificate shall be invalid if: (a) it was granted contrary to the provisions of Article 3*”.

The judgement accepted the plaintiff's claim that the Spanish patent office should have taken into account the arguments for nullity invoked in the proceedings even if the condition required in article 3(d) was involved. So, the court decided that “*the possibility of granting the certificate without examining the condition stipulated in paragraphs (c) and (d) of article 3 of the Regulation in question, as alleged by the defendant Authority, on the one hand, does not apply to paragraph (a) and, on the other hand, they are matters that the Authority could have resolved during the granting procedure. The option granted to the Authority by article 10(5) should be understood as not being compulsory in an ex officio examination of such conditions, but it is when requested by an interested party, since according to article 15(1), if the granting of a certificate infringes that set forth in article 3 of the*

Regulation then it is null and void”.

The nullity of the SPC granted by the OEPM

In considering the revocation of the certificate granted by the OEPM, the court only considered one of the arguments developed by AESEG since it was enough for the court to declare the certificate invalid. Initial legal grounds of the judgement include preliminary remarks and citations that are of interest in order to ultimately conclude that the certificate is invalid. Thus, the High Court of Justice decided that “*according to the philosophy behind the judgement of the Court of Justice of the European Communities, Division Five, of 16 September 1999, in a preliminary ruling on the interpretation of various articles in Regulation (EEC) No. 1768/1992, one should deem that this Regulation concerning the creation of a supplementary protection certificate for medicinal products and, in particular, article 3, must be interpreted in the sense that whenever a product, in the form mentioned in the market authorisation, is protected by a basic patent in force, the supplementary protection certificate can cover the product, as a medicine, in all the forms included in the basic patent's scope of protection*”. The court also declared that “*we should make clear that the SPC requested is not fosiopril sodium, but fosiopril sodium / hydrochlorothiazide*”.

As decided by the ECJ in its Judgement of 16 September, 1999 “*the protection conferred by the certificate cannot exceed the scope of the protection conferred by the basic patent.*”

The answer to be given to the second question must therefore be that, in order to determine, in connection with the application of Regulation No 1768/92 and, in particular, Article 3(a) thereof, whether a product is protected by a basic patent, reference must be made to the rules which govern that patent” (art. 28 and 29). The court decided that this

doctrine was applicable to the case, especially since the expert witness showed that “*the claims of the patent in question do not mention associating the proline derivatives, which the patent covers, with hydrochlorothiazide*”, concluding that “*the certificate granted by the challenged decision exceeds the basic patent's scope of protection*” and therefore, according to article 15 of Regulation (EEC) No. 1768/92 the court decided to declare the nullity of the decision appealed before it.

Conclusion

The judgement is important not just because it is the first court decision on SPCs in Spain, but also because it has questioned the OEPM's practice of not accepting discussion of questions that could imply the nullity of a certificate but were not examined ex officio by the patent office. Another aspect of the decision worth stressing is the constant reference to the ECJ's decisions and the decisive role of their legal grounds in the court's reasoning.

CREATION OF THE COMMERCIAL COURTS: SPANISH COURTS SEMI-SPECIALISED IN IP

The Insolvency Reform General Act of Parliament 8/2003, of 9 July (referred to as LORC by its initials in Spanish) amends the Judicial Power General Act of Parliament 6/1985 and sets out the competences of the new “commercial courts”. This regulation stipulates that in addition to insolvency procedures, the Commercial courts shall hear, among others, any cases that are the competence of the civil courts concerning claims in which action is brought regarding unfair competition, industrial property, intellectual property and advertising. It also states that the Commercial Courts shall hear the proceedings to which articles 81 and 82 of the EC Treaty and the law that derives therefrom apply. The points stated in these precepts include attributing to national jurisdictional bodies (the commercial courts) the competence for

applying the Community regulations.

The reasons stated in the Act for having specialist commercial courts are as follows: (1) the complexity of the social and economic situation in our time, which makes it advisable to make determined moves towards specialisation; (2) it is expected to bring about greater legal security and quality in the decisions issued, since the judges will be experts in the cases they hear; and (3) it is also intended to speed up proceedings, relieving the civil courts of work, with gains in terms of efficiency and speed.

Creation of the new courts

The commercial courts started operating in Spain on 1 September 2004. In order to do this, the government has set up 37 new judicial bodies, 24 of which will be exclusively dedicated to

hearing commercial cases (5 in Madrid, 4 in Barcelona and 2 in Valencia, and one in the cities of Cadiz, Malaga, Seville, Oviedo, Palma de Majorca, Las Palmas de Gran Canaria, Santa Cruz de Tenerife, Alicante, Corunna, Pontevedra, Murcia, San Sebastian and Bilbao). A further 12 courts of first instance will partly deal with commercial cases (the courts of Almeria, Cordoba, Granada, Saragossa, Santander, Leon, Valladolid, Girona, Lleida, Tarragona, Logroño and Ceuta).

Alongside the setting up of commercial courts, and as a logical continuation of the reform implemented by the new regulations, the LORC has extended the practical application of the principle of specialisation to the Provincial High Courts, in which one or more divisions, depending on their particular circumstances, will accept exclusive competence for

hearing the appeals brought against the decisions of the commercial courts. This should guarantee improved resolution of appeals brought in cases entrusted to the commercial courts.

The Community Trade-mark Court in Alicante

The Commercial Court of Alicante shall have provin-

cial jurisdiction as a commercial court and national jurisdiction as a court of Community trade marks and designs. The new division eight of the provincial high court in that city has been set up as a Community trade mark court. The creation of this new division and its specialisation complies with that set forth in Council

Regulation (EC) No. 40/94, of 20 December 1993, on the Community trade mark, since this court will solely hear all appeals in Spain concerning this regulation on Community trade marks plus Council Regulation 6/2002, of 12 December 2001, on Community designs.

SPAIN'S MODIFICATIONS TO ITS CRIMINAL CODE COME INTO FORCE IN OCTOBER 2004

In 2003, the Spanish Parliament passed several modifications to the Spanish Criminal Code. They came into force on 1 October 2004 and one aspect they affect is intellectual property offences.

New general rules are applicable to offences; e.g., the liability of companies for offences committed by their directors. The company can be fined in these cases.

Changes to intellectual property offences

With regards to intellectual property offences, the new

act that has come into force has stiffened the financial penalties and adds offences committed against owners of vegetable varieties to crimes against patents, utility models, designs, semiconductor topographies, trademarks and trade names, denominations of origin and geographical indications.

Circumstances that aggravate the offences are the special economic importance of profits, the particular seriousness of the facts (due to the value of the unlawful objects or the magnitude of the damages caused), the fact that the

offender belongs to an organisation or association aimed at infringing intellectual property, and using people under 18 years old to commit the crimes.

The modification includes a new mention that importing products from the European Union is not considered a criminal offence if the goods were acquired from the rights holder in the country of origin or with its consent. This provision merely clarifies the doctrine of exhaustion of rights developed by the ECJ in Spanish criminal law.

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