

SUMMARY

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The new Spanish Defence of Competition Act

The new Spanish Act 15/2007, of 3 July, the Defence of Competition Act, came into force on 1 September 2007. The act was passed on 3 July and replaced the previous act, in force since 1989. It modifies the regulations that had previously been in force in antitrust law, adapting it to the transformation in European law in this field over the last decade, particularly with regard to regulations concerning the exemption of certain categories of agreements, and the passing of Regulation 1/2003 on the application of the competition rules laid down in articles 81 and 82 of the Treaty on European Union.

According to the act's preamble, the new regulation is intended to process cases more effectively and adapt Spanish law to the changes in Community regulations. The greater effectiveness comes from assessing cases more closely in accordance with the economic nature of the transactions carried out in the market and lightening the administrative burden the national competition authorities currently have to bear.

New regulatory bodies

The new act brings in many new aspects. The most important of these include: setting up a new body for the defence of competition called the National Competition Commission (*Comisión Nacional de la Competencia - CNC*); expanding the commercial courts' jurisdiction; and reducing the government's powers to intervene in approving company mergers or concentrations. The government's role is now reduced to public interest matters or certain actions laid down by law.

The new National Competition Commission replaces the former bodies, the Competition Defence Service and Court (they were both actually administrative bodies despite the latter being called a 'court'). These have been closed down and the Commission has taken over their roles. The CNC is thus a single organisation, which is independent of the government, and is in turn made up of two sub-organisations: the Investigative Department (which handles the investigation stage) and the Board (the decision making organism, which is made up of four board members and a chairman).

The CNC's members will be appointed by the Cabinet for non-renewable terms of six years and they will have more extensive duties than those previously responsible. Despite the fact a single organisation will be responsible for defending competition, its

separation into two sub-organisations ensures greater independence, along the same lines as before when there was the service and the court.

The courts' jurisdiction and changes regarding fines

Another of the most noteworthy new aspects that the act is bringing in is that it hands the commercial courts jurisdiction to apply the national competition regulations concerning collusive agreements and abuse of a dominant position. The previous act did not deal with this and it was one of the aspects that needed to be changed.

In practice this means higher, graduated fines. Offences are classified as minor, serious and very serious, so the penalty system has thus been restructured. The fines that can be levied on offending companies' legal representatives or directors have been doubled from €30,000 to €60,000. The so-called "clemency system" has also been introduced (in line with US regulations). This allows companies that were part of a cartel, and who report and provide proof of it, to receive a lower fine or even be exempted from a fine, provided they stop committing the offence and did not incite the rest of those involved to take part in the prohibited agreement.

Block exemption regulations, cases of non-applicability and inspection

The regulations approved by the EU and those that may be passed by the Spanish government apply to possible exemptions of certain categories of agreements.

Procedural reforms include doing away with the obligation to report restrictive agreements not covered by the category exemption regulations to the Spanish authorities in order to obtain an individual exemption. Companies should thus be ready to justify their actions if requested to do so. It will occasionally be possible to obtain a "declaration of non-applicability" whereby the CNC declares that the act does not apply to a particular agreement due to the public interest.

The CNC's inspection powers have been strengthened. It may now search the private homes of businesspeople, directors and other members of companies' staff, and question them about the matters the inspection concerns.

Finally, regulations concerning the Spanish Defence of Competition Act have not yet been passed. Until such time as they have been passed, the Royal Decrees

concerning exemptions for certain categories and control of economic concentrations that currently apply will remain in force, except insofar as they infringe that laid down in the new Defence of Competition Act.

The Spanish Supreme Court rules on SPCs for the first time

A recent judgement laid down by the Supreme Court on 4 July 2007 dealt with questions concerning the validity of so-called Supplementary Protection Certificates or SPCs for the first time. These certificates are issued to extend a patent's legal lifetime beyond 20 years, for a maximum of a further five years, provided the requirements laid down in EU Regulation (EEC) No. 1768/92 are met.

Granting of an SPC by the Spanish Patent and Trademark Office (OEPM)

The Spanish generic drug association, AESEG, launched an appeal against the OEPM's decision to grant SQUIBB an SPC. In its judgement on 17 May 2004, after rejecting the allegation that the administrative courts did not have jurisdiction to hear the appeal that AESEG had brought, the Catalan administrative court overturned the OEPM's decision. The court deemed the OEPM not to have properly applied the first substantive requirement in the regulation for granting an SPC (namely that the product that was the subject matter of the patent for which an SPC was being requested, *fosinopril + hydrochlorothiazide (hctz)*, was protected by a basic patent then in force). The court deemed that the medication fell outside the extent of protection of the SPC's basic patent since the patent's subject matter was limited to processes to produce products such as fosinopril and not the combination or association of these products with a diuretic such as hctz.

The administrative courts have jurisdiction to hear appeals against the granting of SPCs by the OEPM

When the Supreme Court heard SQUIBB's appeal for annulment against the judgement on 17 May 2004, it confirmed that the Spanish administrative courts do have jurisdiction to confirm whether the legal requirements for granting an SPC have been met and, if they have not, to revoke it.

The Supreme Court stated that article 17 of the regulation refers to national patent legislation regarding the hearing of appeals against decisions to grant SPCs and that due to this reference one must refer to the Spanish Patent Act to find out whether the civil or administrative courts have jurisdiction to hear an appeal against a decision to grant an SPC.

In the court's view, under Spanish legislation the civil and administrative courts share jurisdiction over patent matters. In the case of patents granted after a prior examination (which is optional in Spain), the administrative courts may also hear appeals concerning the revocation of the patent due to lack of novelty or an inventive step.

In the specific case of the SPC this appeal for annulment concerned, the SPC was granted on the basis of the process set out in article 3 of the regulation. The Supreme Court considers this process for granting SPCs to be more similar to the Patent Act's process for granting patents with a prior examination than the process for granting them without a prior examination, since despite the fact that the patentability conditions are not analysed, the SPC's underlying conditions are examined.

In the Supreme Court's view, the reference made in article 17 of the regulation to appeals under national law against analogous decisions regarding patents "specifically refers to the administrative-contentious appeal envisaged in article 47 of Act 11/1986 for granting patents processed with a prior examination (according to the interpretation examined above). The scope of the administrative-contentious courts to hear cases may and should extend to this, since in this case (...) it was verifying whether the administrative decision was in accordance with the law with regard to the question of law, i.e. it was judging whether the Spanish Patent and Trademark Office's decision to issue the SPC requested was in accordance with the applicable regulations by meeting the conditions laid down in Regulation 1768/92".

After rejecting the rest of the grounds for annulment, the Supreme Court upheld the appealed judgement and thus overturned the OEPM's decision to grant the SPC.

Conclusions

Recognising the administrative courts' jurisdiction to

confirm or overturn an OEPM decision concerning the granting of SPCs provides legal certainty in a field that the Spanish courts had not ruled on up until now. In addition, this specific case has confirmed that in order to extend a patent's legal lifetime through an SPC application one must strictly comply with the requirements for its granting in order to prevent the abuse of such rights.

The ECJ on jurisdiction regarding IP law and TRIPs. Judgement of 11 September 2007

In a recent judgement, on 11 September 2007 (case *Merck Genéricos v Merck & Co. Inc., Merck Sharp & Dohme L^{da}*), the European Court of Justice (ECJ) stated that "The WTO Agreement, of which the TRIPs Agreement forms part, has been signed by the Community and subsequently approved by Decision 94/800. Therefore, according to settled case-law, the provisions of that convention now form an integral part of the Community legal order". Therefore, "Within the framework of that legal order the Court has jurisdiction to give preliminary rulings concerning the interpretation of that agreement".

The judgement asserts that the legal framework for determining the jurisdiction of Community bodies over a particular matter depends on the competences taken on by the European Union. Hence, "as the Court has previously held, when the field is one in which the Community has not yet legislated and which consequently falls within the competence of the Member States, the protection of intellectual property rights and measures taken for that purpose by the judicial authorities do not fall within the scope of Community law, so that the latter neither requires nor forbids the legal order of a Member State to accord to individuals the right to rely directly on a rule laid down in the TRIPs Agreement or to oblige the courts to apply that rule of their own motion". If it has not legislated on a particular matter, one must take into account whether there is Community legislation regarding the specific question raised: "On the other hand, if it should be found that there are Community rules in the sphere in question, Community law will apply, which will mean that it is necessary, as far as may be possible, to supply an interpretation in keeping with the TRIPs Agreement (see, to that effect, *Dior and Others*, paragraph 47), although no direct effect may be given to the provision of that agreement at issue (*Dior and Others*, paragraph 44)".

In the specific case the court dealt with in its judgement, the ECJ found there to be no regulations concerning patents (the subject matter) and none concerning the specific question of the patent's term (specific question), which the TRIPS Agreement deals with. It would be another matter if it concerned biotech patents or others concerning which there are Community regulations. Then the court's case law concerning TRIPs not being directly applicable would apply, as stated in the Judgement in Dior and Others, which stated "*the provisions of TRIPs, an annex to the WTO Agreement, are not such as to create rights upon which individuals may rely directly before the courts by virtue of Community law*".

The court said that if it is not a Community matter it has no jurisdiction, and stated in its judgement that "*the Member States remain principally competent, they may choose whether or not to give direct effect to that provision*".

The ECJ did not mention the amendment made by the Treaty of Nice to article 133 of the Treaty of Rome, which could qualify that decision. It will be interesting to see whether a preliminary ruling concerning this is requested in the future.



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