Spain
Modernisation of IP law continues

In recent years various changes have been made to Spanish IP legislation, as outlined in previous chapters of *IP Value*. Developments have concerned the laws on patents (biotechnology and the Bolar clause in 2002 and 2006), industrial designs (a new act in 2003) and trademarks (a new act in 2002), as well as IP rights in general (implementation of the EU IP Rights Enforcement Directive in 2006). The result is a set of modern regulations that has brought Spanish law into line with the various EU directives and regulations concerning intellectual property.

However, the antitrust regulations were still in need of modernisation, as these provisions had drifted away from EU law and practice. Since the end of the 1990s the EU system gradually had become more economy focused, in line with the US system. However, in 2007 the Spanish legislature passed the new Antitrust Act, which brought Spanish antitrust law into line with the corresponding EU regulations. The act and its implications for IP law are discussed below.

This chapter also highlights some recent Supreme Court judgments concerning intellectual property, particularly dealing with utility models, supplementary protection certificates and the presumption of use of a patented process in relation to new product patents (this is particularly important for the chemical and pharmaceutical industries).

The chapter further considers the controversy regarding the patentability of pharmaceutical products before 1992 and the possible effects of the World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) on this issue.

New Antitrust Act
On September 1 2007 the new Antitrust Act came into force, repealing the previous act of July 17 1989. The new act reflects the major changes that have taken place in EU antitrust law over the last decade.

With regard to actions that are prohibited under antitrust law, the new act still sets out a system of exemptions to:

- improve production, marketing and/or the distribution of goods and services; and
- promote technical or economic progress.

In line with EU law, the novelty lies in eliminating the requirement for prior authorisation from the relevant authorities in order for the exemption to apply. Therefore, it is now for companies to decide whether their agreements, decisions, recommendations and practices fall under the exemptions laid down in the act, so that if an investigation is launched they can prove that their actions are exempt.

As was the case with the EU regulations passed between 1999 and 2004, this situation will affect the assessment of technology transfer, distribution, manufacturing, research and development, franchise and other agreements involving IP rights if these may have an impact on the Spanish market or contain clauses that objectively contravene the principle of free enterprise.

Previously, the power to decide on antitrust matters rested exclusively with the administrative authorities expressly established for that purpose. A key feature of the new act is that the commercial courts now have the power to hear cases arising from collusion and the abuse of a dominant position. Thus, the commercial courts may now hear cases involving, for example:

- the signing of a prohibited agreement;
- the abuse of a dominant position in a commercial agreement; or
- a claim for compensation due to prohibited conduct.

The move is designed to deal with such cases more speedily and efficiently and speed up the workings of the administrative courts. The number of court cases involving antitrust proceedings is also likely to increase, as before the new act came into force such cases could be reported only to the antitrust authorities.

The act envisages the involvement of EU and Spanish competition authorities as *amicus curiae* in proceedings...
brought before the commercial courts. The administrative authorities may be involved (without being considered a party to the case) on their own initiative or at the court’s request by providing information or presenting written observations concerning the application of Articles 81 and 82 of the EC Treaty and Articles 1 and 2 of the Antitrust Act. They may also submit verbal observations with the court’s permission.

The new act also creates a single national institution, the National Competition Commission, which is independent of the government and replaces the Antitrust Office and Court. The responsibilities of the office and court to preserve, guarantee and promote effective competition in the national market and ensure the application of the Antitrust Act will pass to the new commission.

Key Supreme Court judgments

Specific features of utility models

Common international standards exist for patents. However, this is not the case for utility models, even in the European Union. Each country has developed its own provisions for this type of protection. In Spain, certain key features distinguish utility models from patents and these should be taken into account when investing in or assessing intellectual property in Spain:

- Only inventions that “give an object a configuration, structure or constitution from which a practically appreciable benefit arises for its use or manufacture” may be the subject matter of a utility model;
- Unlike patents (where the state of the art by which novelty and inventive step must be judged comprises everything that was accessible to the public before the filing date), the Patent Act stipulates that when assessing the relevant precedents that may affect utility models, only those that have been divulged must be considered;
- Precedents will be considered part of the state of the art only if they have been divulged in Spain; and
- Insofar as inventive step is concerned, the Patent Act stipulates that in view of the state of the art, utility models are inventive if their subject matter “is not very evidently obvious from the state of the art for a person skilled in the art”.

In light of these features, various judgments have interpreted the difference between the specific terms used for utility models in relation to patents and their limits. In a judgment of February 21 2007 the Supreme Court emphasised that the difference between utility models and patents relating to inventive step may be key when determining the validity of a utility model.

The nuance employed in the Patent Act to distinguish between inventive step in utility models and that in patents, consisting of the addition of ‘very’ before the word ‘evidently’, is difficult to understand from a technical point of view. What distinguishes something that is ‘evident’ from something that is ‘very evident’? In the above-mentioned judgment the Supreme Court stated that the difference gives the inventive step criterion a degree of flexibility, as it excludes only that which is ‘very evidently’ obvious from the state of the art for a person skilled in the art, unlike the requirement for patents, in which the adverb ‘very’ does not appear. This is a key distinction for the court, since it is not so closely comparable with the state of the art for patents.

In the case at hand the Supreme Court found the differences between two devices to be sufficient to consider that the invention could be protected by a utility model. It overturned the judgments of the lower courts, which had considered the differences to be irrelevant and concluded that there was no clear inventive step. This feature of the Spanish patent system may affect decisions on the use or development of technologies that can be protected by utility models.

Cases concerning a grant of supplementary protection certificates

On July 4 2007 the Supreme Court ruled in a case concerning the first grant of a supplementary protection certificate in Spain. AESEG, the Spanish generic drug association, had sought judicial review of the grant of a supplementary protection certificate by the Spanish Office of Patents and Trademarks (OEPM). AESEG argued that the decision had breached the EU requirements for granting a supplementary protection certificate because the product for which the supplementary protection certificate was sought fell outside the scope of the patent on which it was based.

On judicial review, the Administrative High Court found for AESEG. The pharmaceutical company affected by the revocation of the supplementary protection certificate appealed to the Supreme Court, claiming that supplementary protection certificates can be challenged only in the civil courts and thus the administrative courts have no jurisdiction to hear such an appeal.

The Supreme Court held that the OEPM has jurisdiction to hear matters that affect the requirements for granting a supplementary protection certificate. It regarded the procedure for granting supplementary protection certificates (as regulated by EU Regulation 1768/92) as comparable to the patent-granting procedure. In the court’s opinion, the EU rules require
the national authorities to analyse whether the conditions for granting supplementary protection certificates have been met. Therefore, the scope of cases that the OEPM and the administrative courts can hear concerning the granting of supplementary protection certificates extends to verifying whether administrative decisions to grant such certificates accord with the law.

**Presumption of use of a patented process for a new substance**

Spanish law stipulates that if a patent concerns a process to manufacture new products or substances, there is a rebuttable presumption that any product or substance with the same characteristics has been obtained through the patented process. Since it came into force, there has been debate as to whether this provision involves a reversal of the burden of proof or a legal presumption. In its judgment of February 2 2007 in the *Enalapril Case*, the Supreme Court ruled that the Patent Act refers to a legal presumption and not a reversal of the burden of proof.

If the rule were considered to reverse the burden of proof, the defendant would have to provide proof that the process used to obtain the product did not infringe the patented process. This interpretation would modify the general legal principle that the burden of proof is on the party making the allegation – in this case, the patentee alleging that its patent rights have been infringed.

According to the Supreme Court’s interpretation, patent law stipulates that the product is presumed to have been obtained using the patented process and the defendant must prove that it has not used that process. Nevertheless, proof against these allegations is evidence not that the processes are not equivalent, but merely that they are not identical.

**Pharmaceutical product patents filed before 1992**

In recent years the issue of the patentability of pharmaceutical products has arisen in Spain and other countries around the world. Until October 7 1992 such products could not be patented in Spain. Therefore, patents that are due to expire before October 7 2012 are affected by this prohibition.

In the last two decades most countries around the world have lifted the ban on patenting pharmaceutical products. In Europe, this took place in Greece, Norway and Eastern European countries between 1991 and 1993, and in Finland and Portugal in 1995. It would be a major development for patentees of pharmaceutical products if the lifting of the prohibition had retroactive effect.

Claims that the lifting of the prohibition has retroactive effect are based on the TRIP’s Agreement. In particular, it is argued that this would imply accepting the possibility of considering the protection of pharmaceutical products valid even if the patents were filed before 1992. This proposal is not without its legal problems, as has been observed in various court judgments. However, pharmaceutical companies have grasped at this chance and have put pressure on the Spanish government to change the law in their interests. So far, the government has resisted this pressure as it is aware of the impact that a modification of this kind would have on pharmaceutical expenditure over the coming years.

The legal arguments employed in the debate are complex and sophisticated. The matter has even gone as far as the European Patent Office, which in the first half of 2007 published two rather contradictory communications. The first, issued in March 2007, stated that Spain accepted that the patentability of pharmaceutical products was retroactive. However, a second communication in June 2007 corrected the first, since the office had taken into account only the interpretation of one court in a controversial action where judgments had gone both ways. In the second communication the office stressed that it is not possible to vary the contents of European patents that have already been granted in order to extend protection to pharmaceutical products. This cut off the route by which companies were attempting to modify patents that had already been granted.

The issue affects patents that were filed with the European Patent Office and granted protection in Spain prior to 1992. Several cases are ongoing in the Spanish courts and it is likely that the main appeal courts in Barcelona and Madrid will lay down a clear doctrine on this issue in early 2008.
Miguel Vidal-Quadras Trías de Bes is head of the firm’s industrial property, IP and pharmaceutical law department. He graduated in 1993 from the University of Barcelona with a PhD in law and has been a member of the Barcelona Bar Association since 1997. He is the author of various IP publications and a professor of patent law at Universitat Ramon Llull and Universidad de Barcelona. His areas of expertise include litigation, IP, technology transfer and pharmaceutical law.

Oriol Ramon Sauri graduated in law in 2002 from Universitat Autònoma de Barcelona and holds an LLM in industrial property, IP and competition law from ESADE, Universitat Ramon Llull. He joined the Barcelona Bar Association in 2004 and joined the firm in the same year. He is a member of the AIPPI. His main areas of expertise are litigation, intellectual property, competition, advertising and pharmaceutical law. He speaks Spanish, Catalan and English.