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IMPLEMENTING THE BOLAR PROVISION IN THE EU

Article 10(6) of Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use contains a provision that has come to be referred to as the *Bolar provision*. This concerns the interpretation of certain pharmaceutical activities as regards patent law and clarifies that "*conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products*".

A way of ensuring certainty

The European institutions have stated that they want the generic industry to rest assured that carrying out all the necessary steps to obtain marketing authorisations for their products will not be viewed as infringements. Failure to make such a clear statement had created uncertainty in the European generic industry, since among EU countries there were different situations regarding experimental use (the most restrictive law in the EU, Dutch law, led to some controversial decisions with European implications through the ECJ judgement on 9 July 1997, in which the court, based on article 36 of the EC Treaty, confirmed that domestic law had exclusive jurisdiction over such actions).

The Commission's first Proposal for a Directive included a provision stating that the work needed to develop a generic medicament "*shall not be regarded as contrary to patent rights or to complementary protection certificates for those medicinal products*". The proposal was debated in the European Parliament, which proposed an amendment to the text aimed at strengthening and clarifying what should be considered to be development of generic medication. This was rejected by the European Commission, which kept the text put forward in its initial proposal.

The Council supports the Parliament's proposal

The Council of the European Union of 12 June 2003 agreed to adopt a proposal for modification of Directive 2001/83/EC in line with the Parliament's proposal for an

amendment rejected by the Commission.

On 29 September 2003, the Council and the Commission adopted a common position, which was published in the Official Journal of 9 December 2003. The Council's reasoning for adopting the formulation proposed to the Commission was as follows: "*In relation to submission of applications and granting of an authorisation, the Council believes that these activities, being of an administrative nature, will not infringe patent protection. The Council and the Commission have underlined this in a joint statement (5). Thus, it is neither necessary nor appropriate to include those activities in a provision on exemptions from patent protection. As concerns the submission of samples, this will be covered by the addition agreed by the Council: "and the consequential practical requirements"*. The common position adopted by the Council and the Parliament stated the following: "*(5) The Council and the Commission consider that the submission and subsequent evaluation of an application for a marketing authorisation as well as the granting of an authorisation are considered as administrative acts and as such do not infringe patent protection*". The text was finally passed through Directive 2004/27/EC of the European Parliament and Council.

Article 10(6) of the Directive should be seen as clarification that certain pharmaceutical activities do not constitute infringement of patent law and unification of EU law. As stated by the European Council, "*it is neither necessary nor appropriate to include those activities in a provision on exemptions from patent protection*". No change to patent law is therefore necessary in the majority of EU countries including Spain.

A proposal consistent with the approach taken by the administrative courts in Spain

The European Council's declaration is consistent with prior decisions adopted by Spanish administrative courts in cases in which patentees opposed the granting of marketing authorisations for generic medicines on the basis of their patent rights. The High Court of Justice of Madrid stated in its decision on 8 January 2003 (in the case *MSD v. Spanish Medicines Agency et al.*): *"the authorities' actions in the procedure we are dealing with here is limited to ensuring that if the product comes to be marketed it poses no risk to the health of users and does not involve any fraud concerning its effectiveness as a treatment, and in no way does it prejudge third parties' industrial property rights nor does it imply granting a right to produce and/or market the product in question.(...) nor does the procedure in question or the decision to authorise the marketing of the generic medication affect the industrial property rights adduced"*.

In its decision on 29 October 2003 (Appeal no. 95/2003), the National High Court stated: *"Although pharmaceutical products must be authorised by the authorities and registered in a public health registry as a prerequisite for marketing them, this is independent of the decision that the manufacturer makes concerning it. In other words, the damage that exercising the authorising power could cause the owner of the medication in question is determined by the private legal effects that derive from the marketing of the generic medication, which is outside of the scope of these proceedings*". This decision confirmed previous statements by the court (appeals nos. 408/2001, 397/2001 and 45/2003).

Article 10(6) of Directive 2004/27/EC envisages what the Spanish courts had already decided in several cases: applying for a medication is not an infringement.

COMPENSATION FOR LOSSES AND DAMAGES IN INDUSTRIAL PROPERTY CASES

A recent Supreme Court judgement, on 3 March 2004, concerning industrial property proceedings (Appeal 122/2002) rejected a claim for losses and

damages, despite declaring the infringement of exclusive rights to be proven. The judgement thus confirms that the court does not share the strand of case law according to which it is not necessary to prove that damage was actually caused, but that it is simply enough to prove that the exclusive rights were infringed.

In general civil law cases, in order for compensation for losses and damages to be payable the claimant must, in all cases, prove that they have actually taken place and quantify them or establish the bases for quantifying them in the ruling. The upshot of this is that even if conduct is proven to be illegal, the affected party is not awarded the compensation sought unless the losses or damages caused were quantified during the ruling stage of ordinary proceedings.

If one applies this doctrine to industrial and intellectual property then even if it is proven that exclusive rights have been infringed, the affected party is not entitled to compensation for losses and damages except insofar as they were quantified in the ruling stage.

In order to help affected parties gain compensation for infringement of exclusive rights, case law developed the doctrine known as "*ex re ipsa*" or "*res ipsa loquitur*" (it speaks for itself). Some courts have expressed that "*the fact that damage has been caused must be proven in order for compensation to be awarded, but such proof is not necessary when "ex re ipsa" it is clear, as a logical and inevitable consequence of the infringing behaviour carried out. This is the case, as we have stated in many other judgements, in the case of trademark infringement due to the use of signs that can be confused with one another, when the affected holder opts (…) for the form of compensation stipulated in section c) of article 38 of the Trademark Act (RCL 1988, 2267), i.e. the so-called hypothetical royalty (the price that the infringer must pay the holder for the granting of a licence that would have allowed it to use it lawfully), because it is not possible to assume that a usage assignment (licence) would be granted free of charge for the marketing of a third party's services or products bearing one's own trademark. Therefore, compensation must be awarded, which shall be quantified when the ruling is laid down in accordance with that parameter, due to undue use of the sign as of the receipt of the extrajudicial order (article 37 of the Trademark Act).*" (Judgement of the Provincial Court of Barcelona, division 15, rendered on 18 February 2004 – Appeal 122/2002). In view of the foregoing case law, it would appear to be sufficient for the affected party to choose the form of compensation set out in article 43(2)(c) of the Trademark Act or article 66(2)(c) of the Patent Act *"the price that the infringing party would have had to pay the patent holder for the assignment of a licence that would have allowed it to carry out its operations lawfully"*.

In the judgement mentioned above, the Supreme Court confirmed that "*although articles 36 and 37 of the Trademark Act of 10 November 1988 entitle the holder whose trademark right has been affected to seek compensation for losses and damages, and article 38 of the same Act allows the affected holder to choose between three criteria listed to determine or set the earnings foregone (loss of profit), neither those precepts nor any other in that Act establish the legal presumption of the existence of damages and losses due to the mere fact of the trademark right being infringed, so the registered trademark holder must prove in the proceedings that such damages or losses have been caused or exist in order for it to be declared that they must be compensated; the only aspect that can be left for the ruling stage is determining or specifying the amount thereof*". The judgement goes on to say that the same court ruled along the same lines in judgements on 20 July 2000, 3 February 2003 and 29 September 2003.

In conclusion, in every case of infringement of industrial and intellectual property rights, during the court proceedings the plaintiff must try to provide the necessary evidence so that the amounts to be paid as

compensation can be sufficiently identified. The ruling will consist solely of setting the relevant amounts.

ENTRY INTO FORCE OF THE IMPLEMENTING REGULATIONS OF THE INDUSTRIAL DESIGN ACT

On 16 October 2004, Royal Decree 1937/2004 of 27 September approving the Implementing Regulations of Act 20/2003 of 7 July on the legal protection of industrial designs came into force.

These Regulations were developed pursuant to Final Provision Two of Act 20/2003 authorising the cabinet to pass the provisions required to develop and apply the Act within no more than one year. These Regulations allow the Spanish Patents and Trademarks Office to implement the Industrial Design Act insofar as it affects its powers. The Act incorporates Directive 98/71/EC of the European Parliament and of the Council of 13 October 1998 on the legal protection of designs into Spanish law.

This new regulatory instrument rounds off the process of bringing Spain's laws on the legal protection of designs up to date with the EU law in force. Through this necessary modernisation, the Spanish authorities are seeking to encourage investment in new designs and provide their creators with effective, fast protection.

One of the advantages introduced by the foregoing Regulation concerning the procedure for registering designs is that it allows publication to be deferred if the applicant so requests. Applicants may thus benefit from the system by timing the publication of the registration to coincide with the launch of the product that includes the design. Moreover, the procedure for opposing designs is regulated. This takes place after publication of the registered design (2 months) and does away with the official examination carried out by the authorities.

In addition, multiple applications for up to 50 designs in a single application are allowed. This will please the sectors most interested in this form of industrial property in Spain, which include footwear, toy and furniture companies.