

# AMAT I VIDAL-QUADRAS

## advocats

### REPORT ON IP-RELATED MATTERS IN SPAIN

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#### DOCTRINE OF PATENT EQUIVALENCE IN SPAIN

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In three very recent decisions, Spain's most famous court dealing with patent cases, Division 15 of Barcelona Provincial Court, has ruled on the scope of the doctrine of equivalents in a very similar way to the doctrine laid down in the United Kingdom and Germany in recent decades.

#### **Principles used to analyse equivalence**

In the first judgement, on 20 April 2005, in a mechanical patent case, the Barcelona appeal court clearly stated the following, in view of its examination of the doctrine of equivalents as developed to date:

*"It seems clear that the formulation of the doctrine of equivalents, which allows the protection of a patent to be extended to cover embodiments in which a claimed medium is replaced with another medium that is structurally different but carries out the same function in the invention, starts from the basis of considering whether the two media are equivalents, and whether they substantially perform the same function to bring about substantially the same result (the double identity test)".* This double identity test was previously developed in a judgement by the same court on 18 September 2000. In the second decision, the

Barcelona appeal court had the opportunity, five years later, to reformulate that doctrine. Thus, the court added: *"However, this configuration of equivalence must ordinarily be corrected [...] since simply applying it unhesitatingly and unthinkingly could protect the result and block technological progress. Hence the corrective criteria such as the triple identity test in comparative law, which requires the same function, in the same way, with the same result, which has traditionally been followed by the US courts and been found acceptable for relatively simple mechanical patents, but also involves the risk of protecting the result and, at the same time, failing to protect the patent holder against replacements that, as they are evident or obvious, do not perform the same function in essentially the same way".*

This judgement on 20 April 2005 was also a landmark decision in Spain, since it also includes the principle of the non-obviousness of the challenged embodiment. Thus, the inventiveness of a certain solution leads to the conclusion that the new solution can never be considered an equivalent to the patented solution.

The court is explicit regarding the connection between inventiveness and equiva-

Should you require any further information, please contact Luis Torrents or Miguel Vidal-Quadrás at [ltf@avqadvocats.com](mailto:ltf@avqadvocats.com) [mvq@avqadvocats.com](mailto:mvq@avqadvocats.com) or at our offices in Barcelona.

lence by obviousness: *“The inventive step test is linked to the so-called principle of obvious equivalence, which concerns whether a person skilled in the art would have regarded the equivalent element to be an obvious alternative to the claimed element, in order to obtain substantially the same result for the same technical problem, according to the patent’s teaching, his/her knowledge and his/her interpretation of the claims in the manner stated, so one cannot exclude the possibility that obviousness, or even an inventive step, may be shown through other forms of evidence”*. As the court explains, this is the interpretation adopted by other jurisdictions: *“This view has been accepted by the German Federal Court since the famous Formstein Judgement (29 April 1986), which includes practically the same principles as followed by the English courts in the Catnic (1982) and Improver (1989) judgements, which have brought together a doctrine that raises three questions for determining equivalence. The first is whether the variant alters the way the invention works; the second, whether the modification would have been obvious for a person skilled in the art who read the patent on its publication date; and the third, whether a person skilled in the art who read the patent would have deemed, in view of the terms of the claim, that the holder intended that following the strict meaning of the claims was an essential requirement of the invention”*.

### **Equivalence in patents for chemicals and pharmaceuticals**

As stated in the judgement of the Barcelona appeal court on 7 June 2005, the doctrine of equivalents as applied to chemical cases is different to simple mechanical patent cases: *“In Spain, there is no clear doctrine of equivalents that provides rules pursuant to which a judgement on equivalence can be made. On certain occasions, the test of substantial differences has been used, according to which any variants in shape, size, layout of elements, and even any replacement of these elements for others, are equivalents, when they do not alter the fundamental principle of the invention described, claimed and protected by the patent or the utility model (Judgement of Division 3 of the Supreme Court, 10 June 1968). This doctrine can be used more as a scheduling principle of protection of the patent rights against infringements by equivalents than as practical criteria to settle specific disputes [...] we should warn that this criterion, as well as the one invoked by the appellant party, the substantial triple identity (function-way-result: when substantially the same function is performed and substantially the same result is achieved), responds more suitably to a judgement on a mechanical patent, in which the judgement of the overall process is more relevant, and the substantial identity of the function takes over more importance than the*

*variations in a certain specific sequence of the process that allows the same result to be achieved. This criterion is not sufficient to determine the equivalence of a pharmaceutical patent, where the variations take place in the manner, and specifically in the sequences of the proceedings, which as such are important for a skilled person in the art although in an overall examination the importance of its contribution could be diminished. This would mean that greater attention must be placed on the stages or sequences of the process and more importance should be placed on the opinion of the skilled person, but never losing sight of the target sought with this doctrine of equivalents: avoiding infringement of an invention when there are variations that are intended to eliminate the scope of protection of such patent, or when there are irrelevant changes to the extent that they could be deemed encompassed within the claims of the patent”*. This judgement makes a thorough study of the doctrine of equivalents in Spain in the preceding years and seeks to explain how to align the principles traditionally followed by the Spanish courts with common European standards.

### **A rule for assessing patent infringements**

Patent infringements must be judged on an objective basis, not merely according to the contents of the claims. This is the conclusion of the Barcelona’s court’s analysis

of the provisions applicable to patent construction in its judgement on 2 May 2005: *“In this context, the subject matter being interpreted is the contents of the claims (articles 26 and 60(1) of the Spanish Patent Act) or, which amounts to the same thing, their terms (art. 69(1) EPC), because they define the subject matter of the invention and the extent of protection. However, one should follow the principle of adhering to the spirit of the claim when trying to find out its true contents, beyond the actual words used. However, the interpretation*

*(of the claims, remember) is basically objective, as it is a matter of identifying and locating an invention in the state of the art, and this should be based on the statement of science in the claims.*

According to the judgement on 7 June 2005, one must analyse “1) if the defendant’s process substantially alters that described in the plaintiff’s patent; 2) if the alternative proposed by the defendant’s process is obvious for a skilled person; and 3) if the skilled person, bearing in mind the text of

*the claims and the description of the patent, would consider the subject matter of the invention the variation (in the method of acting) by introducing the process that is reported to infringe the patent by equivalence [Judgement of Barcelona Provincial Court, Division 15, 2 May 2005 (RA 150/2003)]”.*

This could therefore be the standard to be followed in the future in assessing infringement in patent cases in Spain.

## **IMPLEMENTING PHARMACEUTICAL IP-RELATED MATTERS OF DIRECTIVE 2004/27/CE**

The draft bill for a new medicinal product act, published by the Spanish Ministry of Health in June, shows how the Spanish Government expects Directive 2004/27/EC to be implemented.

### **The Bolar provision - a particular case of use exemption**

Among other provisions, the main concern as regards pharmaceutical IP-related matters is the implementation of the so-called Bolar provision in article 10(6) of the directive. This provision will entail adding a second part to article 52(1)(b) of the current Spanish Patent Act, on the experimental use exception, which will read as follows: *“Actions carried out for experimental purposes, which concern the subject matter of the patented invention, in particular studies and trials performed*

*for the authorisation of medicinal products and the resulting practical requirements, including preparing, obtaining and using the active substance for such purposes.”* (The additional new part begins with *“in particular ...”*).

In this wording the Health Ministry has demonstrated its intention to include submission of information required by regulatory authorities as a particular use exemption for acts reasonably related to development.

### **Implementation of the Bolar provision does not modify the current law**

In addition, the preamble of the aforementioned bill stresses that the wording of the article must be viewed as a mere clarification of what experimental use is. Therefore, it cannot be interpreted as a new exemption from

patent infringement. The preamble says that acts related to the submission of information required by regulatory authorities were already implicitly included in the Spanish exemption of experimental use from patent infringement before the implementation of article 10(6) 2004/27/EC in article 52(1)(b) of the Spanish Patent Act.

### **Other IP-related matters related to the future act**

Besides the implementation of the Bolar provision, other major aspects must be taken into consideration concerning the bill’s contents.

Article 17(1) of the draft bill does not fully implement the contents of article 10(1)(II) of European Directive 2004/27/EC. The article’s current wording is as follows: *“Protection of authorisation file data.- 1. Generic medicinal*

*products authorised pursuant to this Act may not be marketed until ten years have elapsed from the date of the initial authorisation of the reference medicinal product.”* In contrast, article 10(1) of the EC Directive says that *“the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community.”*

Hence, we should add that the Spanish medicinal

product regulations should include that the reference medicinal product may have been authorised for more than 10 years not just in Spain, but also in any of the member states of the EU. This is in order to prevent an interpretation that could limit the scope of the article to a national analysis.

The draft bill for a new Spanish Medicinal Product Act does not appear to implement the last paragraph of article 11 of European Directive 2004/17/EC, also on patent-related matters. This paragraph reads as follows: *“For authorisations under Article 10, those parts of the summary of product*

*characteristics of the reference medicinal product referring to indications or dosage forms which were still covered by patent law at the time when a generic medicine was marketed need not be included.”* However, failure to implement this provision of the EC Directive does not allow for contrary interpretations due to the primacy of European law.

In spite of the fact that there are some legal aspects of the draft bill that could be clarified, the implementation of the EC Directive appears to be sufficiently accurate and in line with that laid down by EU institutions.

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The contents of this publication were written by Luis Torrents, Miguel Vidal-Quadras, Oriol Ramon and Rita Reyes.

**AMAT I VIDAL-QUADRAS**  
**advocats**

Pau Casals, 14, 5è – 08021 Barcelona – tel.+34 93 321 10 53 – fax.+34 93 419 31 47 email:avq@avqadvocats.com  
[www.avqadvocats.com](http://www.avqadvocats.com)