

AMAT I VIDAL-QUADRAS

advocats

REPORT ON IP-RELATED MATTERS IN SPAIN

Issue 6 Autumn 2005

Patent Rights and Marketing Authorisation for Medicines

CONTENTS:

1. Patent Rights and Marketing Authorisations for Medicines.

2. Trade mark genericisation. The ‘Ganchitos’ case.

3. Court rules against Autocontrol for having issued a decision against a non-member company.

The Interlocutory Order of 21 July 2005 of the Provincial High Court of Barcelona laid down that providing the Spanish health authorities with samples of a medicinal product for approval purposes cannot be considered an infringement.

A mere application for marketing authorisation cannot be considered an infringement

The same court ruled on 30 September 2002 that gathering data to submit it to the Spanish health authorities for approval purposes should not be considered an infringement according to article 50(1) of the Spanish Patent Act if no samples of the medicinal product had been delivered to the Spanish health authorities. The court stated that: “*We have no evidence of the authorisation application having been accompanied with samples of the active ingredient, so [...] there is no reason worthy of consideration to class the action of applying as an infringement in itself, but rather, at most, as a serious and unequivocal preparation for a potential infringement, not yet put into practice, if the declared process infringes the priority patent rights literally or by equivalence*”.

Following this line of argument, the Interlocutory Order of 21 of July 2005 laid down the following: “*We thus*

have no evidence that by obtaining authorisation [the defendant] has committed any act of introducing into trade or use the four products for which authorisation was applied, which would be obtained through the process that is the subject matter of the patent within Spanish territory, the area covered by the scope of protection of ES 520.389, as stipulated in article 50.1 of the Spanish Patent Act. We reached the same conclusion in our ruling on 30 September 2002 (RA 126/2002), denying that an application for authorisation to market the product, without providing samples, infringes the patent right per se, even though it may be a serious and unequivocal preparation for a potential infringement, provided the process infringes the priority patent rights by equivalence”.

Providing the health authorities with the product for regulatory reasons is not a prohibited use under the Patent Act

These decisions therefore make clear that applying for marketing authorisation can never be considered an infringement.

In addition, the Interlocutory Order stated that offering a medicinal product in order to obtain marketing authorisation cannot be considered an

Should you require any further information, please contact Luis Torrents or Miguel Vidal-Quadras at ltf@avqadvocats.com mvq@avqadvocats.com or at our offices in Barcelona.

infringement since consumers would not be able to buy the medicinal product that is being evaluated. These products are not actually being offered in order to introduce them onto the market. The Provincial High Court thus stated that “*Such an offer would not appear to be the activity prohibited by article 50.1 of the Spanish Patent Act, which is an initial or preparatory act to distribute or introduce the product. It seems reasonable to interpret the term ‘offer’, in article 50.1 of the Spanish Patent Act [...] as the equivalent of inciting people to buy products protected by the patent, so it is necessary for it to be presented to possible buyers, whatever the advertising or publicity technique used. All in all, article 50(1) of the Spanish Patent Act authorises patentees to prevent any attempt at sale. So SANDOZ’s offer to provide the Spanish Drug Agency with samples within the framework of two applications for authorisation*

to sell pharmaceutical products, does not improve the right of the patentee affected by such product per se”.

It has therefore clarified the legal requirements for activities to be regarded as patent infringements. Since activities carried out with the health authorities are not themselves trading activities, they clearly cannot entail patent infringement. This was the reasoning given by the European Parliament and the Council in Common Position (EC) no. 61/2003 of 29 September 2003.

Providing the health authorities with samples

This line of argument concerning offering samples could also be used to conclude that neither offering samples of the medicinal product nor providing such samples for regulatory reasons can be considered an infringement since, as laid down by the Provincial High Court of

Barcelona, the products were not provided in order to be sold on the market.

Article 50.1 of the Spanish Patent Act, which states which acts are subject to exclusivity and therefore cannot be carried out by an authorised third party, is also relevant. This article states that acts of manufacturing, offering, marketing or using the product that is the subject matter of the patent or directly obtained by the process that is the subject matter of the patent as well as importing or possessing said product for any of the purposes mentioned are considered infringements if they are carried out by someone not authorised by the patentee. Article 50(1) of the Spanish Patent Act does not state that provision of samples of a product for the purpose of being examined by the authorities, is a patent infringement.

Trade mark genericisation. The ‘Ganchitos’ case

On 21 December 2004, the High Court of Barcelona (Division 15) laid down a judgement stipulating that the “Ganchitos” trade mark had expired due to loss of the distinctiveness of the sign, a phenomenon known in trade mark law as *trade mark genericisation*.

In this case the plaintiffs, Crecs Aperitivos Españoles, SA and Naturin, SA brought trade mark infringement action against a company that had been using the name

to distinguish extruded corn products identical to the plaintiffs’.

The defendant brought action for revocation of the “Ganchitos” trade mark and, in a subsidiary manner, expiry of it by virtue of article 53 of the Trade Mark Act 32/1988.

The court set the case of loss of the trade mark’s distinctive ability within a national, Community and international legal framework: “*Signs may lack distinctiveness per*

se or through the use made of them, so one must contemplate the possibility of a sign intrinsically apt for playing its role of identifying the company ceasing to do so with use. One must remember that this is what shows consumers the features of the product or service to which they apply. This is the case referred to in the aforementioned article 5(1) of the Trade Mark act in force, the remote precedent of which in article 6 quinquies of the Paris Convention, article 11(1)(b)

of the Trade Mark Act 32/1988 of 10 November, and article 3(1)(d) of the First Community Trade Mark Directive. It should be noted that the difference between Community regulations and our national legislation lies in the fact that, in the latter, habitual use of the trade mark refers to specific services for which registration is being applied, which is not the case in the directive. One should also remember that in order for the absolute prohibition on registration to be effective, the trade mark must be made up exclusively [as highlighted by article 7(1)(d) of the Community Trade Mark Regulations] of genericised signs, otherwise one would have to look at whether or not the whole has a differentiating effect”.

On this basis the court declared the ‘Ganchitos’ trade mark, registered in classes 29 and 30 of the International Nomenclature, expired.

Loss of distinctive ability of the trade mark *ab initio*: on the trade mark’s Registration date

According to the judgement “The sign’s loss of distinctive ability may have taken place on its filing date or afterwards (forced upon it) and, in both cases, the negative consequences are the same”.

If the loss of the sign’s distinctive ability took place on the trade mark’s Registration date, action could be taken to revoke the sign in question due to it infringing the absolute prohibition on

generic marks in article 5(1) of the Spanish Trade Mark Act (formerly 11(1)(a) of the 1988 Trade Mark Act). In the case mentioned, it was not revoked since, as stated above, the Provincial High court of Barcelona stated that it order for it to be revoked it would have been necessary to prove that the trade mark was already a generic or usual sign on the date it was registered (no such evidence was provided).

A *posteriori* expiry due to genericisation of the trade mark

Expiry due to genericisation of the trade mark is stipulated in article 55(1)(d) of the Trade Mark Act 17/2001 (in the sense of the former article 53(b) of Act 32/1988). A trade mark may expire “when in trade, due to the activity or inactivity of its patentee, it has become the usual name for a product or service for which it is registered”.

Although a trade mark may originally have had distinctive ability for the products or services to which it applies, it could lose such distinctiveness through the way in which the patentee uses it: “These are cases in which it tries to give the consumer the idea of certain features, through the trade mark, that belong to the product marketed or service provided, or the kind to which one or the other belongs. In these cases the product or service becomes the vehicle for generalisation of the subject matter being identified by the trade

mark, which the legal regulations cannot cover. It is the conversion of a sign into the usual name for the product”.

The Barcelona court thus declared the “Ganchitos” sign expired. It had been Registered to distinguish food products (classes 29 and 30 of the International Nomenclature of Nice).

Forced loss of a trade mark’s distinctive ability: including it in a dictionary

In this particular case, the Barcelona appeal court considered that “In these proceedings it has been proven that the initial distinctive nature of the Ganchitos word mark was lost with use. Proof of this point was echoed, with the necessary length and accuracy, in the disputed judgement (since no infringement was detected in the practice and assessment of it, this relieves the court from going into an analysis of it again, although it does deserve inclusion in a dictionary as a term which in very widespread use - which is sufficient for these purposes and unanimity is not required - among competitors in the relevant market sector). This is due to the usage made by the aforementioned appellants to a monopoly not over the product made, but over a kind of snack defined thereby to which it belongs due to its features. All the foregoing is due to the sign having lost its identifying ability. However, the evidence does not show the specific date within this period when it started, so we cannot state

it for the purposes set out in article 55.2 of the Trade

Mark Act in force”.

Court rules against Autocontrol for having issued a decision against a non-member company

In its judgement on 24 May 2004, the Provincial High Court of Madrid ratified the judgment of Madrid Court of First Instance number 42 on 24 March 2003, partially accepting the claim brought by Laboratorios Lesvi, S.L. and revoking the decision issued by the Commercial Communication Self-regulation Association (Autocontrol), ordering the latter to publish the decision in its monthly magazine and on its website.

The judgement stated that Autocontrol acted unlawfully in issuing a decision accepting the complaint

made by Abbott Laboratories, S.A. against an advertising message for the promotion of a pharmaceutical product for which Laboratorios Lesvi, S.L. was responsible. This company is not a member of Autocontrol and had previously expressly refused to submit to the mediation proceedings proposed by the association.

In spite of this, on 3 June 2002, Autocontrol issued a decision against Laboratorios Lesvi's will, accepting the complaint made by Abbott Laboratories, S.A. After the relevant ordinary proceedings, the judge laid down a

judgement declaring the decision invalid due to the decision issued by Autocontrol's jury on 3 June 2002 being null and void. It had acted unlawfully in issuing it. The court ordered Autocontrol to publish the judgement in its monthly magazine and on its website for three months.

The judgement is final and has already been enforced with the publication of the judgement in the Association's monthly magazine and for three months on its website.

© AMAT I VIDAL-QUADRAS

The contents of this publication were written by Miguel Vidal-Quadrás, Oriol Ramon, Miriam Johansson 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