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Spain

Spanish practice on pharmaceutical trademarks reflects recent developments at EU level. This article examines the relationship between such marks and international non-proprietary names and the criteria for determining the relevant public

Bringing a new pharmaceutical product onto the market requires a huge investment in terms of time and money. Indeed, it is estimated that the average investment behind the development and launch of a pharmaceutical product on the international market is between $600 and $800 million and can take 12 years of work. It is therefore no wonder that the pharmaceutical industry is particularly sensitive to the protection of the industrial property rights in its products, not just as far as patents are concerned, but also with regard to the trademarks that have to be used to identify such products in the market.

This article examines two issues that specifically affect trademarks for pharmaceutical products, namely, their relationship with international non-proprietary names (INNs); and, secondly, who the relevant public is, for the purpose of determining whether there is a likelihood of confusion between two marks.

Pharmaceutical marks and INNs

INNs are names that identify pharmaceutical substances or active pharmaceutical ingredients which are responsible for the therapeutic effect of the medicinal product in question. The various national laws require that such active ingredients appear on the packaging of, and in information leaflets for, pharmaceutical products, making such active substances easily identifiable worldwide. INNs include names as familiar as ibuprofen, paracetamol or omeprazol, to name but a few.

Another feature of the INN system is that the names of pharmacologically related substances use a common stem, such as 'adol' for analgesics, 'cort' for corticoids or 'profen' for anti-inflamatories, which enables the substance to be identified as belonging to a particular group.

The INN system as it exists today was created in 1950 by the World Health Organization (WHO) under resolution WHA3.11. The first list of INNs was published in 1953; it now stands at over 7,000 names and is growing by approximately 120 to 150 new INNs a year. Many countries also have their own list of official names for active ingredients. In Spain, for example, official names are designated by the Spanish Drug Agency (*Agencia Española del Medicamento*).

Official names are obviously in the public domain and therefore cannot be used as a trademark. However, despite this, it is surprising that trademark legislation does not contain any express prohibition in this regard. It is usual for trademark laws to establish absolute prohibitions on registration which prevent, for example, the registration of trademarks that:

- include badges, emblems or escutcheons of public interest; or
- contain or consist of a designation of origin, as established, for instance, in Article 5 of the Spanish Trademark Law (17/2001) or Article 7 of the Community Trademark Regulation (207/2009).

But there are no provisions referring specifically to INNs.

In the European Union, the European Medicines Agency (EMEA) is responsible for the centralized procedure for the scientific evaluation of applications for European marketing authorizations for medicinal products. Under this procedure, which is applicable to certain types of medicinal products, such as those derived from biotechnology processes or those intended for the treatment of AIDS, cancer, diabetes or rare diseases, companies submit a single marketing authorization application to the EMEA. Pursuant to Article 6 of Regulation 726/2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use "Each application for the authorization of a medicinal product for human use shall specifically and completely include... otherwise than in exceptional cases relating to the application of the law on trademarks... the use of a single name for the medicinal product".

Therefore, the use of the centralized procedure means the allocation of a sole invented name for the product in all the member states covered by the authorization, although an exception to this general rule can be allowed in cases where the trademark has been opposed or cancelled in a particular country.

But can this name be similar to an INN or include any of its stems? The current wording of Directive 2001/83/EC on the Community code relating to medicinal products for human use, establishes that "an invented name shall not be liable to confusion with the common name". Such confusion can arise as a result of the similarity between the trademark and the INN or when the proposed invented name includes an identified INN stem. The EMEA "Guideline on the acceptability of names for human medicinal products processed through the centralized procedure" contains specific rules in this regard and indicates that one of the remits of the agency is to ensure that the proposed name cannot potentially be confused with the name of another medicinal product, but this assessment is based only on public-health or safety-risk criteria, without analyzing the potential infringement of a third party's IP rights.

Along similar lines, Article 14.2 of the Spanish Medicinal Products Law, provides that "The name of a medicinal product, when a trade name or a trademark, may not be confused with an official Spanish name or an [INN], nor lead to error as to the therapeutic properties or nature of the medicinal product". As far as Spanish case law is concerned, in a judgment handed down on February 28 2006 in a case where the owner of a generic medicinal product used the trademark for the product in question as well as its official name in its launch of the product onto the market, the Barcelona Provincial Appellate Court held as follows: "It is precisely the professional status of the persons to whom the message is addressed which underscores the inappropriateness of indicating the trade name given that it is unnecessary. Indeed, it would suffice to provide information on the active ingredient of the generic product in order to enable such professionals, who are also familiar with the composition of the product, to prescribe the generic medicinal

product without any problem whatsoever."

Likelihood of confusion: the relevant public

However, this is not the only specific issue that arises in relation to trademarks covering medical products. Indeed, we should bear in mind, on the one hand, the health-risk factor involved in confusing these products, which could have fatal consequences, but on the other, that in the vast majority of cases, medicinal products are administered directly in a hospital and are therefore handled by qualified specialists, or are acquired by consumers on medical prescription. So who is the relevant public with a view to determining the likelihood of confusion between two conflicting marks?

The European Court of Justice (ECJ) analyzed this issue in depth in its judgment of April 26 2007, in case C-412/05 P. This decision refers to the application filed by Alcon Inc for the registration of the word sign TRAVATAN for ophthalmic pharmaceutical products in Class 5 of the Nice Classification. Biofarma SA opposed this application based on its Italian trademark TRIVASTAN. The ECJ held that "even though the choice of those products is influenced or determined by intermediaries, such a likelihood of confusion also exists for those consumers since they are likely to be faced with those products, even if that takes place during separate purchasing transactions for each of those individual products, at various times".

This decision marked an apparent change of tack when compared with previous judgments, including the decision handed down by the Court of First Instance (CFI) in the *Alcon Case* (T-237/01, March 5 2003). When referring to the relevant public, the CFI held that "In view of the intended use of the goods covered by the mark in question, the targeted public comprises medical specialists, particularly ophthalmologists and ophthalmic surgeons".

However, in the *TRAVATAN/TRIVASTAN Case* the ECJ explained the divergence of approach by stating that the CFI's decision in *Alcon* "concerned a trademark application which related not to goods sold to end users in pharmacies, but to 'ophthalmic pharmaceutical preparations; sterile solutions for ophthalmic surgery' in respect of which the [CFI] was entitled to hold without erring in law that the customary nature of the trademark at issue should be assessed from the point of view of the medical specialists for whom it was intended, namely ophthalmologists and ophthalmic surgeons practising in the European Union".

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Spanish case law appears to have evolved in step with ECJ case law. On the one hand, there are judgments such as that handed down on November 14 2001 in which the Supreme Court held that the "the likelihood of confusion on the market disappears when the two products in question are medical products prescribed by doctors and handled by pharmacists, since given the technical knowledge of those prescribing and selling them, there is no likelihood of confusion between them". The approach has since changed and so in its judgment handed down on May 25 2006 the Third Chamber of the Supreme Court held that "the general legal principle of precaution insofar as it touches upon product safety concerns, associated with preventing risks to human health and which prevents any relaxation of the assessment of the likelihood of confusion between the conflicting marks, can be cited as binding in this case... because the criterion should be stricter given that confusion could arise in the use or handling of such products by consumers". In its ruling on March 18 2009 the Supreme Court took a similar line to the ECJ's decision in *TRAVATAN/TRIVASTAN* by including within the concept of 'relevant public' not only professionals from the health care industry, but also patients, on the grounds that the fact that medicinal products are dispensed on prescription does not eliminate the likelihood of confusion as to the origin of the products.

It appears that the school of thought which considered that the involvement of clinicians avoided the likelihood of confusion has been superseded. In the author's opinion, there is no justification to relax the assessment of the likelihood of confusion in such cases, in which even the incorrect spelling of the prescription, where a brand name is involved, could have serious consequences for consumers and patients alike. WTR