

Bugnion SpA

Pharmaceutical marks in Italy: overcoming weakness

While court rulings on pharmaceutical marks have been scarce over the past few years, case law does confirm such marks as potentially weak

With new opposition proceedings finally in force in Italy, it is expected that the Italian Patent and Trademark Office will also finalise its practice with regard to pharmaceutical trademarks. To this end, the latest rulings of the Italian courts on pharmaceutical trademarks should be examined.

Unfortunately, there have not been many such decisions over the past two years. The few interventions of Italian judges in pharmaceutical trademark nullity or infringement suits have not succeeded in disrupting the prevailing case law. Pharmaceutical trademarks have instead been further confirmed as potentially weak.

Such 'weakness' is due in part to their usual descriptiveness and in part to their particular consumer destination – a dispensing physician is more expert than the average consumer and less prone to confusion in dispensing, especially when compared to the position for over-the-counter drugs, which are chosen directly by a patient.

Likelihood of confusion between pharmaceutical trademarks

The likelihood of confusion between similar pharmaceutical trademarks was demonstrated by an October 28 2005 decision of the Court of Milan, in which it deemed BOTOX to be a weak or non-distinctive trademark, since its name was deemed to be strongly evocative of the *Clostridium botulinum* bacterium. The court therefore allowed the coexistence of other similar trademarks.

Other important decisions that evaluated the confusion between pharmaceutical trademarks have not been reported, with the exception of an April 2 2009 ruling of the Court of Rome. In a nullity action against the Italian designation of two international trademarks, the court

deemed RETROVIR to be similar to REBOVIR/REVOVIR. However, in the absence of an opposing party, the court had no substantive grounds and simply deemed the trademarks to be nearly identical.

The weakness of pharmaceutical and cosmetic trademarks was further confirmed by a May 13 2010 Court of Milan decision on the CLINIQUE/DERMACLINIQUE trademarks. The court ruled on the nullity of an Italian trademark and simultaneous infringement, confirming that: "the word Clinique must be originally considered as a word of common use, since its declension in French does not suffice for differentiating it from the Italian noun '*clinica*' or from the adjective '*clinico*'. It is commonly known that many commercial operators use such term for distinguishing their own activity, in various fields more or less close to the health field. Hence, the term is deprived of distinctive capacity, of originality and novelty such to be able to immediately claim an exclusive right." The trademark had acquired a certain distinctiveness with use, but was unable to prevent the registration of a subsequent mark for DERMACLINIQUE.

The last newsworthy issue in relation to Italian case law was a decision related to a three-dimensional Italian trademark (for a Listerine bottle) which was brought before the Court of Rome on December 3 2009. In this case the possible grounds for confusion between the two mouthwash bottles were excluded in accordance with the normal rules that regulate shape trademarks.

Despite a lack of case law in Italy in the pharmaceutical sector, some new rulings have been registered in the field of parallel imports and, in particular, that of repackaging.

Parallel imports – drug repackaging

While EU case law on parallel imports has developed in relation to pharmaceutical

trademark cases, the Italian courts have seen few such developments.

The Italian Industrial Property Code has regulated the industrial property aspects of parallel imports – via the so-called 'exhaustion of rights' – since 1979 in reference to patents, and since 1992 (following the adoption of EU Directive 89/104/EEC) in reference to trademarks. Now, after the entry into force of the IP code, the exhaustion of rights for parallel imports is regulated by Article 5 of the code.

The parallel import (and in particular the aspects related to re-packaging) of medicines for human use has been authorised by the Italian Medicines Agency since 1987. However, until a couple of years ago, there were no precedents relating to the repackaging of drugs imported from other EU countries.

Between September and October 2009, an Italian court issued the first decision on such a case. In two similar preliminary injunction proceedings decided on September 21 and October 23 2009 (*Roche Diagnostic v BB Farma SRL*), the industrial property specialised section of the Court of Milan ruled on the problems of re-packaging pharmaceutical devices imported into Italy from another EU country.

These orders followed a long series of cases decided by the European Court of Justice (ECJ), which inevitably inspired the Court of Milan's decision. The judges faced the difficult task of resolving the conflict between the public interest in the free circulation of products and the private interest in protecting company trademarks.

In the two cases examined by the Court of Milan, Roche opposed the sale in Italy of medical devices by BB Farma. Roche sold such devices in another EU country. The objection was based on the fact that the importer repackaged the products, altering

the original trademark. The court had to identify the line of demarcation between the legality and illegality of the wholesaler's conduct – the first verification was therefore made with regard to the relations between the wholesaler and the producer.

According to ECJ precedent, when importing drugs sold for the first time in other countries, repackaging is considered permissible – despite being more invasive than relabelling – alongside substitution of the prescribing information sheet. If repackaging is deemed necessary to ensure normal sales of the drug in a different market from that in which it was first sold, the distributor must inform the producer, providing suitable notice of the start of commercialisation and the type of repackaging selected.

Directly referencing ECJ case law, the Court of Milan deemed it the obligation of the wholesaler or importer to prove the need to opt for repackaging over relabelling, for the purpose of ensuring market distribution.

In the reported cases the wholesaler was unable to prove such need. The court therefore ruled that the repackaging was an undue alteration of the producer's trademark rights. This decision was in line with EU case law in *Bristol Mayer Squibb* (July 11 1996) and *Boehringer Ingelheim* (April 23 2002). The court therefore ordered the seizure of the medicines.

The two 2009 cases opened the way for two further rulings on the same subject. On October 26 2010 BB Farma brought a new suit before the Court of Milan against Novartis, for the repackaging and import of a known anti-inflammatory drug sold from Spain and France into Italy.

In accordance with ECJ case law, the Court of Milan confirmed that the owner of a pharmaceutical trademark can legally oppose further sales of repackaged drugs, unless:

- the owner's exercise of its trademark right, given the sales system adopted by such owner, would contribute to the unnatural isolation of markets between member states;
- the repackaging has not altered the original condition of the product;
- the product bears the name of the repackager;
- the repackaged product is not presented in a manner that could damage the reputation of the trademark or its owner; and
- the trademark owner was informed of the repackaged product before market placement.

If any of the abovementioned requirements is not respected, the



Simone Verducci-Galletti
Associate
verducci@bugnion.it

Simone Verducci-Galletti is a registered Italian and Community trademark and design attorney. He graduated in law from the University of Perugia and specialised in EU law and economics. Before joining Bugnion's Milan office in 2004, Mr Verducci-Galletti worked as a consultant with IP firms in Rome and Alicante (Spain). His areas of practice cover trademarks, designs, copyrights and related legal issues.

trademark owner may legitimately oppose further sales of the product. The court confirmed that the importer is responsible for proving the existence of "commercial" requirements that necessitate repackaging. However, the trademark owner must prove damage to the reputation of the trademark, along with the alteration of the original product condition.

In the current case the product was packaged with three different types of "overboxing" with the following characteristics:

- The side of the original packaging on which the expiry date was reported, along with the lot number in the language of the exporting member state, was left uncovered;
- The figurative trademarks of the owner were roughly imitated;
- The NOVARTIS figurative and word marks were omitted on the new packaging; and
- The new packaging did not include any essential data (eg, the owner of the authorisation to market pharmaceutical products in Italy).

In addition, given that the Spanish

trademark differed slightly from the Italian mark due to an accent (VOLTARÉN instead of VOLTAREN), the importer had to change the trademark.

The court confirmed that "there is no proof that any regulation or procedure in effect in Italy prevents the sale of a product with the trademark that it bears in the exporting member state". Therefore, if the trademark substitution was due to a desire to obtain a commercial advantage, it must be considered censurable practice (see ECJ's decision in *Pharmacia v Paranova*, C-379/97, October 12 1999).

The court therefore ordered the seizure of the products and prohibited further sales.

The Court of Milan also ruled on trademark substitution in respect of repackaging in its order of December 4 2009 (*Shering Plough v Farma 1000*), which dealt with the parallel import from Portugal of drugs known to the public by different trademarks (GENTALIN BETA in Italy and EPIONE in Portugal).

The court reasoned as follows: "With regard to the exclusion of relabelling in place of repackaging, it should be considered that Schering's choice to give different names to the product (in Portugal the same product is called Epione, and thus the trademark owner is prevented from opposing trademark substitution, according to *Bristol-Myers Squibb* case law) would require the affixing of a high number of labels, nearly on every face of the box that constitutes its outer casing. Consequently, the box would be so heavily relabelled that it would very likely encounter consumer resistance, as consumers would not trust a product presented in such a manner." The repackaging in this case was deemed censurable, but for grounds not directly connected to the product trademark (rather, for an error in the producer's indication). [WTR](#)