Italy

Contributing firm
Studio Legale Caneva e Associati

Author
Daniele Caneva

Selection, clearance and registration

Pharmaceutical trademarks are governed by the general trademark law set out in the Intellectual Property Code (30/2005), rather than by specific legislation.

According to Article 7 of the code, registration may be granted to any new sign capable of being graphically represented and of distinguishing a product. The prevailing approach excludes the registrability of a smell, taste or sound that cannot be represented on paper.

The same applies to denominations. In addition, shapes and chromatic tonalities may be registered as trademarks, provided that the public perceives them as different from the actual products. Such shapes and tonalities must not:

- be imposed by the nature of the product itself;
- be necessary to obtain a technical result; and
- confer substantial value on the product (Articles 7 and 9 of the code).

All signs – including denominations, shapes and colours – that are to be used as trademarks must be capable of distinction.

A sign is capable of distinction when the public considers the trademarked products or services to have an element indicating the origin of the product or service, and when that mark distinguishes the product or service from those belonging to competitors. Thus, signs that have no distinctive characteristics (ie, those that are generic or descriptive, indicating the nature or the characteristics of the product) cannot lead to exclusive trademark rights (Article 13 of the code).

Furthermore, the trademark must be new – that is, it cannot be:

- identical to signs used in current language or in trade; or
- identical or confusingly similar to other distinctive signs owned by other parties (Article 12 of the code).

By requiring a sign to be distinctive and by considering the likelihood of confusion, the Italian legal system emphasizes the difference between weak and strong trademarks.

'Strong trademarks' are those characterized by a high distinctive capability – that is, formed by words or signs of the common language which have no conceptual connection with the trademarked products.

'Weak trademarks' are those characterized by a low distinctive capability – that is, formed by descriptions of the products or words which specify their nature.

An initially weak trademark can strengthen its distinctive capability and become a strong trademark by acquiring secondary meaning, which arises after such widespread diffusion of a trademark (eg, broad distribution of the product and extensive advertising) that the mark becomes well known.

The category of weak trademarks has become important in regard to pharmaceutical trademarks since they generally reveal the name of the active

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ingredient or of the therapeutic effects of the drug itself. For this reason, the Italian courts has often defined pharmaceutical trademarks as ‘expressive’ – that is, they are extremely weak and show only either very slight modifications compared to the generic name of the drug, or simply evoke the characteristics of the product. In fact, the Italian courts have recognized the validity of trademarks in the pharmaceutical sector that would otherwise be recognized as void due to their lack of distinctive capability.

This does not mean that international non-proprietary names can be appropriated as trademarks for pharmaceutical substances. It is still forbidden to register as a trademark a sign that is regularly used in current language and in business.

It is clear that the weakness of pharmaceutical trademarks affects their protection: on several occasions the likelihood of confusion among trademarks that are highly descriptive of a drug has been eliminated when there are very slight differences by virtue of the qualification of clashing trademarks as weak trademarks.

If an invented mark is used for a drug, it will be protected as a strong trademark. Therefore, in court proceedings all variations and modifications shall be considered where they move away from the ‘heart’ of the trademark, in order to avoid a finding of lack of innovation or counterfeiting.

In judging the likelihood of confusion among pharmaceutical trademarks, the Italian courts have borne in mind the following qualification: although for general purpose products that are affordable to everyone it is necessary to consider end consumers as a reference point, in regard to drugs the target audience comprises physicians (ie, knowledgeable and qualified personnel) since such products are to be chosen by them.

Based on these considerations, in some decisions the courts have excluded the likelihood of confusion between similar pharmaceutical trademarks, even if they are invented signs and fall into the category of strong trademarks.

Therefore, in Italy, it is possible to use a trademark that is similar to the generic name of the drug and which differs very slightly from other trademarks that also evoke the name of the drug. However, this type of trademark, being weak, does not benefit from wide protection and the mark owner cannot prevent third parties from using trademarks similar to its own if these marks recall the generic name of the drug or its therapeutic application.

Parallel imports and repackaging

In Italy, the trademark owner cannot oppose the further circulation of a product that it has marked and put on the market in the European Union (known as the exhaustion of trademark rights).

Pursuant to Article 7 of the EU First Trademarks Directive (89/104/EEC), Article 5 of the code provides that “the exclusive powers given by this code to the owner of an industrial property right expire once the products protected by an industrial property right are put in commerce by the owner itself or through its consent in the territory of the state or in the territory of a member state of the European [Union] or of the European Economic Area. Said limitation of the owner’s power does not apply, with reference to the trademark, should legitimate reasons exist so that the owner itself opposes the further commercialization of the products, in particular when their condition is modified or altered after their introduction into commerce”.

Thus, a trademark owner can always oppose the commercialization of its marked product if, for example, it has been repackaged. However, this principle does not apply in the pharmaceutical sector; the repackaging of imported drugs is imposed by law.

In Italy, according to the EU Medicinal Products for Human Use Directive (2001/83/EC) (as amended), the following requirements apply:

- The external packaging and the package insert must be approved by AIFA (the Italian drug agency, part of the Ministry of Health); and
- The description given in the product packaging must be in Italian (Article 73 and following of Legislative Decree 219/2003).

In addition, the European Court of Justice (ECJ) has stated that “the change brought about by any new carton or relabelling of a trademarked medicinal product [...] may thus be prohibited by the trademark proprietor unless the new carton or relabelling is necessary in order to enable the marketing of the products imported in parallel and the legitimate interests of the proprietor are also safeguarded” (Case C-348/04, *Boehringer Ingelheim*, April 26 2007).

In that decision the ECJ further declared that “Article 7(2) of [the] First [Trademarks] Directive [(89/104)] ... must be construed as meaning that the proprietor may legitimately oppose further commercialization of a pharmaceutical product imported from another member state in its original internal and external packaging with an additional external label applied by the importer”, unless the following conditions have been fulfilled:

- It is established that reliance on trademark rights by the proprietor in order to oppose the marketing of the overstickered product under that trademark would contribute to the

artificial partitioning of the markets between member states;
- It is shown that the new label cannot affect the original condition of the product inside the packaging;
- The packaging clearly states who overstickered the product and the name of the manufacturer;
- The presentation of the overstickered product is not such as to be liable to damage the reputation of the trademark and of its proprietor; thus, the label must not be defective, of poor quality, or untidy; and
- The importer gives notice to the trademark proprietor before the overstickered product is put on sale, and, on demand, supplies the rights holder with a specimen of that product.

Anti-counterfeiting and enforcement

Pharmaceutical trademarks can be protected against counterfeiting by using the general IP enforcement tools:
- preliminary injunction – it is possible to pursue an action for a preliminary injunction in the event of any infringement;
- ordinary trial – it is possible to pursue an action for a permanent injunction in the event of any infringement;
- seizure at Customs – it is possible to ask the Customs authorities to intervene under the Customs Regulation (1383/2003); and
- protection under the criminal law – it is possible to ask for protection under Articles 473 and 474 of the Criminal Code and Article 127 of the IP Code.

Advertising

Italy has specific legislation governing drug advertising – Title VIII of Legislative Decree 119 (April 24 2006).

It is prohibited to advertise drugs that require a prescription or that must be administered by skilled health personnel. This means that it is possible to advertise only over-the-counter drugs, and drugs that do not require a prescription and are non-refundable by the National Health Service.

Thus, the Italian legislature has implemented the power conferred by the EU Medicinal Products for Human Use Directive, which prohibits the advertisement of refundable drugs in the European Union (Article 88).

In general, "the advertisement of a drug shall encourage the rational usage of the drug by showing in an objective manner and without exaggerating its properties, and cannot be misleading" (Article 114(3), Legislative Decree 119/2006). In order to encourage the sensible use of drugs, it is prohibited to distribute drugs to consumers for promotional purposes (Article 115(3)).

The competent authorities in charge of monitoring advertising campaigns are as follows:
- the AGCM (the antitrust authority), which has the power, at the request of a consumer, a competitor or any public administrative body, to halt an illegal advertising campaign (Article 26 of Legislative Decree 206/2005);
- the *Giurì* (a private dispute settlement body) that implements the Advertising Code – Article 25 of the code provides that "the commercial communication concerning drugs and treatments shall take into account the particular significance of the matter ... Said commercial communication shall draw the attention of consumers to the need of suitable protections in the use of products by clearly and explicitly inviting them to read the general precautions on the package"; and
- the ordinary courts, in the event of an act of unfair competition under Article 2598 of the Civil Code.

Generic substitution

Article 1(3) of Law 425/1996 defines 'generic drugs' as drugs which are no longer protected by patents and which use the international non-proprietary name (INN) followed by the name of the manufacturing company instead of the trademarked name. Generic drugs have the same therapeutical indications, dosing schedule, effectiveness and safety standard as brand name drugs, but cost less.

Under Article 7(1) of Law 405/2001, the National Health Service refunds the cost of drugs not protected by patents up to the lowest price of the equivalent available generic drug.

For such drugs Article 7(1) establishes that a pharmacist can substitute the brand name drug with the generic one provided that the doctor has not expressly stated in the prescription that the drug cannot be substituted.

From a legal point of view, the substitution of a brand name drug for which the patent has expired with the generic one does not imply the common use of the trademark.

Online issues

Italy has specific rules concerning the distribution of drugs. The sale of prescription drugs can take place only at a pharmacy, whereas non-prescription drugs can be sold in supermarkets and shopping centres "in a suitable department, in the presence ...or with the assistance of one or more pharmacists" (Law 248/2006).

Therefore, based on these provisions the online or telephone sale of drugs is prohibited.

Furthermore, a clear prohibition on online sales is established by Article 25 of the Professional Pharmacists Deontological Code, which provides that "the pharmacist is not entitled to sell or transfer drugs through the Internet or any other informatics network, even those ones without the obligation of prescription, including the homeopathic ones, in conformity with the EU directives and the WHO [World Health Organization] guidelines unless otherwise established by the specific national norms."

The Italian regulation is in contrast with the principles established by the ECJ, which has declared that the online sale of drugs without prescription is legal. In *DocMorris* (Case C-322/01, December 11 2003), the ECJ declared that "a national prohibition on the sale by mail order of medicinal products the sale of which is restricted to pharmacies in the member state concerned, is a measure having an effect equivalent to a quantitative restriction for the purposes of Article 28 [of the EC Treaty]. Article 30 [of that treaty] may be relied on to justify a national prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies in the member state concerned in so far as the prohibition covers medicinal products subject to prescription. However, Article 30 ...cannot be relied on to justify an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription in the member state concerned".

The EU E-commerce Directive (2000/31/EC) does not establish any specific restrictions on the online sale of drugs; however, it does provide the option of adopting restrictions for public health purposes.

In addition, so far and contrary to World Intellectual Property Organization recommendations, the Italian domain name registration authority has not adopted any specific restriction regarding INNs when allocating domain names. WTR

Biographies

Studio Legale Caneva e Associati

Studio Legale Caneva e Associati
Corso di Porta Vittoria 18,
Milan 20122,
Italy
Tel +39 02 5412 1573
Fax +39 02 5412 1581
Web www.canevaeassociati.it

Daniele Caneva
Partner
daniele.caneva@canevaeassociati.it

Daniele Caneva graduated from the University of Milan having written a thesis on the Antitrust Law. Since 1996 he has taught on IP issues for the IP department of the University of Milan. The founder of Caneva & Associati, he deals exclusively with IP litigation before national and international courts.

Mr Caneva is a member of major associations in the IP field, including the Italian anti-counterfeiting association INDICAM, the International Association for the Protection of Intellectual Property (AIPPI), the *Società Italiana per lo Studio della Proprietà Intellettuale*, the International Trademark Association, the International League of Competition Law and the *Union des Avocats Européens*. He regularly contributes to IP magazines.