Vilau & Mitel

Romania

The EU courts have wrestled with the likelihood of confusion test for pharmaceutical marks over the years, often coming to seemingly conflicting conclusions. The Romanian courts, on the other hand, have preferred to keep things simple and have taken a more consistent line

The pharmaceutical industry in Romania is – as with all EU member states – highly and strictly regulated. Medicines are sold to consumers only through pharmacies under the supervision of a pharmacist. As in most countries medicines fall into two types: without prescription (over the counter (OTC)) and prescription only.

Neither the Trademark Law (84/1998) nor its Governing Rules (833/1998) contain specific provisions in respect of pharmaceutical trademarks despite:

- the general importance of the pharmaceutical industry;
- the fact that such IP rights are often very valuable; and
- the fact that misuse or confusion in this field can pose significant risks to consumers.

Thus, the Romanian Patent and Trademark Office (PTO) applies the same criteria to determine whether a pharmaceutical trademark should enjoy protection as it applies to other marks, namely whether the sign is:

- devoid of any distinctive character;
- consists exclusively of generic/descriptive signs or indications; or
- is identical or confusingly similar to other marks registered for identical or similar products.

Advertising

Advertising of medicines is governed by the Romanian Advertising Law (148/2000), as subsequently amended, and the Law on Health Reform (95/2006) according to which advertising is permitted only for OTC medicines. All pharmaceutical advertising is subject to prior approval by the National Medicine Agency and must observe strict labelling requirements, which state that pharmaceutical trademarks must always be accompanied by information on the active substance (in the form of its international non-proprietary name (INN)) and its concentration. In addition, television commercials must include a notice that the medicine is issued by pharmacists without prescription.

The Romanian Ministry of Health has also established a detailed set of rules, harmonized with Directive 2001/83/EC on the Community code relating to medicinal products for human use, governing the market authorization regime, labelling and advertising (including guidelines on acceptable differences between advertising aimed at the general public and qualified professionals).

Selection

Identifying and selecting a proper name for a pharmaceutical product should begin during the research and testing phase and represents a serious challenge for the pharmaceutical industry due to:

- the large number of existing products;
- the small number of available combinations;
- the need to avoid any confusion; and
- the lengthy process of obtaining market authorization (up to 18 months).

The need to avoid confusion with existing products is by far the most important of those factors both from a producer's perspective and from a consumer's perspective. The consequences of prescribing the wrong medicine or the wrong dose due to confusion with a soundalike/lookalike pharmaceutical product can be severe.

Parallel imports and counterfeits

Despite Romania's accession to the European Union and implementation of the exhaustion of rights doctrine for goods moving within the European Union, parallel imports of medicines have had no real impact on the Romanian market. There are two main reasons for this. First, the Romanian market is highly regulated and medicines are subject to price controls. Second, Romania has a strong history of manufacturing generics. Thus, in a bid to protect the interests of both consumers and local producers Romania has adopted specific market rules requiring doctors/pharmacists to prescribe/recommend products based on the INN rather than the brand name.

As prices are much higher in other EU member states, some international distributors now resell medicines destined for the Romanian market in other EU territories. By the end of February 2009 the National Medicine Agency had received notices for parallel trade in respect of approximately 83 medicines.

Strict control of supply chains and distribution networks, together with assistance provided by pharmacies, have helped to keep down the levels of counterfeit product on the market. Nevertheless, the Romanian Customs Office recently reported that since 2008 it has seized a total of 17,790 counterfeit Viagra and Cialis products.

Similarity and risk of confusion

The Romanian courts apply the same criteria used for any other type of trademark when dealing with marks for pharmaceutical products. Thus, the courts assess:

- the identity/similarity of the marks and products at issue; and
- whether there exists a likelihood of confusion, including a likelihood of association.

The courts have issued a number of rulings on pharmaceutical marks in the past few years, most of which coincide with the entry at the end of 2004 of a new player on the Romanian pharmaceuticals market. Three cases involving Sicomed (Zentiva) and Ozone Laboratories are currently pending before the High Court of Justice following appeals filed by the defendant (Ozone Laboratories) against rulings finding that it had infringed the trademark rights of Sicomed (Zentiva). The cases relate to the following marks:

- ALGOZONE/ALGOCALMIN (Case 17404/3/2005 (2613/2005));
- DICARBOCALM/DICARB (Case 17404/3/2005 (2613/2005)); and

- ANTINEVRIN/ANTINEVRALGIC (Case 23807/3/2007).

In another case against Ozone Laboratories, this time with regard to the marks CLARITINE and CLAROZONE, the Court of Appeal overturned a decision of the Bucharest Tribunal in favour of Ozone Laboratories (*Schering-Plough v Ozone Laboratories* (Case 32351/3/2005 (4739/2005)). The lower court had ruled that Ozone Laboratories' CLAROZONE mark was not confusingly similar to Schering-Plough's CLARITINE mark. On appeal, the court held that there was a likelihood of confusion due to the similar intended use for the medicines (ie, they were both types of anti-histamine), notwithstanding the fact that Clarozone is an OTC product whereas Claritine is available on prescription only.

Other prominent cases include the following:

- In *Pharmacia Corporation v PTO* (Case 2344/2/2004 (470/2004)) the Bucharest Court of Appeal established that there was a high degree of similarity between the marks ENERION and ETURION and thus a likelihood of confusion existed. The court made a detailed phonetic analysis of the marks and determined that the likelihood of confusion should be analyzed from the perspective of the average consumer. The decision is final.
- In *Ranbaxy v Antibiotice Iasi* (Case 449/3/2008) the Bucharest Court of Appeal confirmed the decision of the Bucharest Tribunal in which the latter rejected Ranbaxy's claims that the marks SIMVOR and SIMCOR were so similar as to cause a likelihood of confusion. The decision is still subject to a second appeal at the High Court of Justice.
- In a case involving the marks AMOXICLAV and MOXICLAV the court was asked to rule on a settlement between the parties. Despite concluding that there was a high degree of similarity between the marks, the High Court of Justice finally ruled in favour of the defendant (*Lek Pharmaceuticals v Medochemie* (Case 1518/3/2004)).
- In *Sanofi-Synthélabo v Biofarm* (Case 3707/2000) the Bucharest Tribunal upheld an injunction request and ordered the defendant to cease all sales and advertising under the mark MAGNEZIU VITAMINA B6. The court held that the name, packaging and colours used for the Magneziu Vitamina B6 product were similar to those used by the plaintiff for its Magne B6 product. The court also ordered the seizure of any products bearing the infringing packaging and labels.

Dragos M Vilau
Partner
dragos.vilau@vilaumitel.ro

Dragos M Vilau is one of the founders of Vilau & Mitel. His practice focuses primarily on corporate and commercial law, intellectual property, mergers and acquisitions, and banking/finance. Mr Vilau has significant experience in advising clients on investing and growing their business in Romania. He has authored various articles on intellectual property, among other topics.

Ionut Lupsa
Senior associate
ionut.lupsa@vilaumitel.ro

Ionut Lupsa coordinates the IP, IT and copyright practice group at Vilau & Mitel. He is a member of the Bucharest Bar Association and is qualified as a trademark attorney. Over the past 11 years his practice has focused mainly on intellectual property, information technology, e-commerce, dispute resolution and litigation. He has been involved in numerous cases before Romanian courts.

In each of the above cases the courts employed the same test as they would use in any case involving conflicting trademarks. They assessed whether the marks were visually, phonetically and conceptually similar, and looked at whether they covered identical products. In only one of the cases cited above (*Sanofi-Synthélabo v Biofarm*) did the court examine whether the defendant had obtained the relevant market authorization from the National Medicine Agency.

Romanian and EU approaches compared

At EU level, the test for establishing a likelihood of confusion has lacked uniformity over the years. In some decisions courts have suggested that the likelihood of confusion is reduced where the trademark covers prescription-only medicine. They reason that healthcare professionals and consumers being advised by such professionals are less likely to be confused. In other cases the courts have stated that the test for a likelihood of confusion must be even stricter than for other marks because of the serious consequences that could result from any confusion. For their part, Romanian courts have preferred to keep things simple and have not placed added importance on some elements over others. In Romania, the relevant public is the average consumer and likelihood of confusion is determined in the same way as in any other case. WTR