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Romania

Raluca Vasilescu
Cabinet M Oproiu

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A Global Guide

PROTECTING IP IN ROMANIA

CABINET M. OPROIU

EUROPEAN PATENT AND TRADEMARK ATTORNEYS

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- Acquiring IP rights in Patents
- Trademarks
- Designs including oppositions, appeals
- Court proceedings for cancellation and for enforcement of the IP rights

IN EUROPE:

- Filing and prosecuting European Patents including related oppositions and appeals
- Filing and prosecuting Community Trademarks including related oppositions and appeals

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www.oproiu.ro

ADDRESS:
42 Popa Savu St., Suite 1, 1st District, P.O.Box 2-229, Bucharest, Romania

CONTACT PERSONS:
Mrs. **Margareta OPROIU**, Senior Partner
Mrs. **Raluca VASILESCU**, Partner
Tel.: **(40-21) 260 2833, (40-21) 260 2834**
Fax: **(40-21) 260 2835, (40-21) 260 2836**
E-mail: office@oproiu.ro, raluca@oproiu.ro

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Author
Raluca Vasilescu

Selection, clearance and registration

In Romania, pharmaceutical trademarks are governed by the same national legislation and relevant EU directives and regulations as other trademarks. However, when selecting trademarks to register, and in contentious matters, some specific elements must be taken into account.

Pharmaceutical trademarks can be registered through various channels:

- as national trademarks, by filing directly with the Romanian Patent and Trademark Office (OSIM);
- as international registrations designating Romania through the Madrid Protocol and Agreement (Romania is a member of both); and
- since January 1 2007, as Community trademarks. Community trademarks with an earlier filing date shall be valid in Romania only from that date, which is when Romania acceded to European Union.

OSIM is the body responsible for granting trademark protection in Romania. The Trademark Law (84) was most recently amended in May 2010 in order to harmonise it fully with the EU directives and bring it into line with the EU Community Trademark Regulation with regard to examination criteria.

According to the Trademark Law, OSIM does not carry out examinations on relative grounds, just as in the case of Community trademarks. However, in recent practice OSIM has sent reports to the holder of the earlier right if a similar junior mark is filed.

The examining division carries out examinations on absolute grounds, such as descriptive character or a misleading mark in respect of the origin or the product. Some manufacturers, in particular newer companies, tend to select names that are quite close to the international common denomination in the hope that consumers will retain such names as trademarks. In most cases, OSIM correctly denies the registration of such marks.

Relative grounds are used as a reason for rejection in opposition, appeal and cancellation proceedings. On the merits of the case, relative grounds are similar to those mentioned in the Community Trademark

Regulation – namely, the later mark shall not be registered if:

- it is identical to the earlier mark and the goods or services for which registration is sought are identical to the goods or services of the earlier mark; or
- it is identical or similar to the earlier mark for identical or similar goods and services and a likelihood of confusion exists on the part of the public that includes the likelihood of association with the earlier trademark.

According to the case law of the OSIM Board of Appeal, when examining the risk of confusion for pharmaceutical trademarks, certain key factors must be taken into account:

- the definition of 'the public' and the level of attention of the average consumer; and
- the thin line between pharmaceuticals and food supplements.

Definition of 'the public' and level of attention of average consumer

The definition of 'the public' is affected by other laws, such as those governing the list of medicines and their use. In particular, the following provisions affect the notion of 'the public':

- the regulations in respect of prescription medicines and over-the-counter (OTC) medicines, and how much they are respected in practice; and
- the regulations in respect of the lists of drugs that are subsidised totally or partially by the state.

The first kind of provision has a significant influence on the definition of 'the public', as in the case of prescription drugs, the patient theoretically has little input in the choice of medicine; thus, the risk of confusion remains for pharmacists and doctors. However, in practice, the situation is different, as most pharmacists will give a patient some prescription drugs without a prescription (mainly antibiotics) if the patient is known to the pharmacist as a regular customer. This aspect has been invoked in cases of oppositions and extensively debated during OSIM Board of Appeal hearings. At present, there is no coherent approach; some decisions take into account the impact of differentiation between OTC and prescription drugs on the overall risk of confusion, while others simply ignore it.

The second kind of provision refers to the lists of drugs that are subsidised by the state. Such lists are published annually by the House of Insurance (the social security body). The current version of the lists comprises the commercial denominations – that is, the trademark and not the international common denomination. The doctors choose from this list and the pharmacist must deliver the exact medicine prescribed, and not another drug with the same pharmaceutical formula. This reduces the risk of confusion between medicines; however, if the prescribed drug is unavailable, the patient must return to the doctor to have a different medicine prescribed.

The lists include patented drugs and generics listed in alphabetical order. In some earlier versions of the lists, there was a version comprising only the international common denomination, which made the risk of confusion among doctors and pharmacists quite high.

The evaluation of the risk of confusion for the purpose of registration of the marks does not usually take into consideration the distinction between subsidised drugs and others, as the lists are amended every year, whereas the term of protection of a trademark is much longer.

Other elements to be taken into consideration in evaluating the risk of confusion, including the risk of association, relate to the list of goods of the marks in conflict, as well as the therapeutic indications and normal channels of distribution of the drugs. The more specialised the drug and the more restricted the channels of distribution, the smaller the risk of confusion, and vice versa.

Thin line between pharmaceuticals and food supplements

Food supplements are in the same class as pharmaceutical preparations (Class 5). Their composition is usually similar to that of vitamins. The main difference between them is the chain of authorisation and the chain of distribution.

> **Prescription medicines, as well as medicines comprising substances defined as narcotic and psychotropic drugs by international conventions, cannot be advertised to the public**

Pharmaceutical preparations undergo a strict approval process at national or EU level, whereas food supplements undergo a simplified process. Pharmaceutical preparations can be sold only in authorised places such as pharmacies or distributed in hospitals and health centres, whereas food supplements can be sold in many places, including pharmacies, supermarkets and drugstores.

As the chain of distribution and the composition partially overlap, food supplements are similar to pharmaceutical products for the purpose of registering the marks.

In recent years there has been an increase in the registration of marks for food supplements at national level. There is some confusion at the level of OSIM, as the body responsible for the registration of marks, when it comes to assessing the similarity of marks when one refers to a food supplement. Most probably, this confusion will be resolved over time and with more decisions.

New national regulations for selecting brand names

A March 2012 decision of the Council of the National Drugs Agency aims to regulate the registration and use of 'umbrella-type' commercial denominations.

Specifically, according to the decision:

- a proposed umbrella-type brand name shall not be accepted for medicines for human use if such umbrella already exists in the brand name of a food supplement, cosmetic product or medical device sold by the same company; and
- it is prohibited to maintain an umbrella-type commercial denomination approved for a medicine from the moment of approval by the same company of a food supplement, cosmetic product or medical device whose denomination includes the umbrella.

Parallel imports and repackaging

The requirements relating to the manufacture and distribution (including import) of medicines are set out in Title XVII – Medicinal Products of the Health Reform Law (95/2006). Pursuant to Articles 700(1) and (2) of the law, a pharmaceutical product can be put on the market only after having obtained a marketing authorisation at national level or following the centralised procedure at EU level.

Parallel import occurs when a product placed on the market in one country is bought by a party which exports it to another country without the permission of the marketing authorisation holder. Parallel importing is permitted between EU member states based on the principle of free movement of goods. The requirements relating to parallel imports are described in the European Commission Communication on Parallel Imports (COM(2003) 839 Final).

According to the principle of exhaustion of rights, the rights holder loses its right to control the distribution of the goods once the medicinal product has been put on the market in any EU or EEA member state, so that the product can be traded freely by authorised wholesalers in any of these countries.

This principle was introduced in Article 38 of the Trademark Law: "The right conferred by the trade mark is exhausted and the holder cannot forbid other persons the use of the mark for products that were put on the market in the EU and the European Economic Area under this mark by the owner or with his consent."

National law provides for an exception to

the exhaustion of rights – namely, justified reasons for which the owner of the mark is entitled to forbid other persons from using the mark in parallel imports, "especially when the state of the products is modified or altered after having put them on the market".

Parallel imports are regulated by Decision 2/2007 of the Scientific Council of the National Drugs Agency, issued in March 2007 and amended in 2009. According to this decision, parallel imported goods can be sold under a different brand and can be repackaged and relabelled.

Any distributor that is not the holder of the marketing authorisation and wishes to import a medicinal product from an EU member state (ie, a parallel importer) must notify its intention to the authorisation holder and the National Drug Agency. The authorisation holder cannot oppose the grant of the secondary licence unless it has justified reasons, as set out above.

Anti-counterfeiting and enforcement

Romania joined the European Union on January 1 2007. As a consequence, the responsibility of Romanian Customs to protect the external borders of the European Union increased considerably, as Romania shares major borders with non-EU countries. In 2013 the total number of goods seized by Customs was 2,548,785 pieces, with a value of around €13 million.

As of January 1 2014, the EU Customs Regulation (608/2013) replaced former EU Regulation 1383/2003. The new regulation is also directly applicable in Romania and is supplemented by national legislation, the Customs Intervention Law (344/2005), which applies to applications based on national trademarks. The national legislation goes beyond the EU legislation as Customs interprets the legal provisions rather liberally, so that when it seizes goods for another reason (eg, an issue with the documents), it checks whether there is also a rights infringement.

Advertising

The advertising of pharmaceutical products is specifically regulated in Title XVII of the Health Reform Law.

Pursuant to Article 798, advertising is prohibited for medicines that do not have valid marketing authorisation in the Romanian territory. The information contained in the advertising material must correspond to that given in the leaflet, and the advertising must encourage patients to use the medicine sensibly through an objective presentation and without exaggeration of the properties. Most importantly, the advertising must not be deceptive.

Advertising to the public is permitted only for medicines that, due to their composition and therapeutic indication, can be used without a doctor having to establish the medical condition; rather, it is sufficient to

Raluca Vasilescu
Partner
raluca@oproiu.ro

Raluca Vasilescu is a Romanian patent and trademark attorney, a European patent attorney and a European trademark attorney. She is a member of the Anti-counterfeiting Committee and the Council of the European Communities Trademark Association, and president of Romanian Chamber of Patent Attorneys. Ms Vasilescu handles patent and trademark matters from prosecution to enforcement. She is the author of numerous articles in the field of industrial property and of the Romanian chapter in *Enforcement of Intellectual Property Rights Through Border Measures* (Vrins/Schneider, Oxford University Press, 2012). Her current writing projects include contributions to commentaries on the Community Trademark Regulation and the Community Design Regulation (CH Beck Hart Nomos).

ask the pharmacist's advice. Advertising to doctors is also allowed.

Prescription medicines, as well as medicines comprising substances defined as narcotic and psychotropic drugs by international conventions, cannot be advertised to the public. Neither can medicines that are prescribed and used within the social security system, with the exception of vaccination campaigns initiated and approved by the Ministry of Health.

The direct sale or distribution of medicinal products to the population for advertising purposes is prohibited.

Online issues

EU Directive 2001/62/EC, amending EU Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use, which aims to prevent the entry into the legal supply chain of falsified medicinal products and which entered into force on January 2 2013, established a new framework for distance sales – that is, the online sale of medicinal products.

The new measures aim to tighten control of e-commerce relating to medicinal products by establishing:

- an obligation to introduce safety features that allow verification of the authenticity and identification of individual packs and provide evidence of tampering;
- a common logo with the help of the European Commission which is recognisable throughout the European Union while allowing for the identification of the member state in which the person offering medicinal products for sale at a distance is established;
- stricter norms for control and inspection of manufacturers of active substances; and
- measures and criteria for verification of the persons authorised to engage in activity as a wholesaler in medicinal products.

According to Article 85c of EU Directive 2011/62/EC, member states must ensure that medicinal products are offered for distance selling to the public by means of information society services as defined in EU Directive 98/34/EC, which lays down procedures for the provision of information in the field of technical standards and regulations and information rules.

Finally, according to the new directive, member states can impose conditions and may establish penalties justified on the grounds of public health protection for the retail supply in their territory of medicinal products sold to the public online.

To date, there has not been enough time for such provisions to be reflected in national legislation.

Other legal issues

Since 2007, supplementary protection certificates (SPCs) have been available for pharmaceutical products, under the EU Supplementary Protection Certificate for Medicinal Products Regulation (469/2009).

Several complex cases are pending before the Romanian courts. In one of these the court is to consider whether an SPC can be amended so that instead of protecting a combination of three active ingredients, as granted, protection is limited to a combination of two active ingredients. Recent European Court of Justice guidance (ie, *Medeva*) has been submitted to the national court in this case. **WTR**

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Cabinet M Oproiu
Str Popa Savu 42, Ground Floor
PO Box 2-229, Sector 1
Bucharest, 011434
Romania
Tel +40 21 260 28 33/34
Fax +40 21 260 28 35/36
Web www.oproiu.ro