The IP Media Group

France

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A Global Guide

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Pharmaceutical products, and consequently pharmaceutical trademarks, are highly regulated in France. Both national and EU laws and regulations govern various aspects of the development and commercialisation of pharmaceuticals, including the intellectual property deriving therefrom.

As far as trademarks are concerned, the main regulations are as follows:

- the EU Community Trademark Regulation (40/94) (now EU Regulation 207/2009);
- the EU First Trademarks Directive (89/104/EEC) (now the EU Trademarks Directive (2008/95/EC)); and
- Articles L711-1 and following and R711-1 and following of the IP Code.

In addition to the EU and national provisions relating to trademarks, the following regulations have an impact on the registration and use of pharmaceutical trademarks:

- EU Regulation 726/2004 on procedures for the authorisation and supervision of medicinal products for human and veterinary use;
- EU Directive 2001/83/EC on medicinal products for human use, modified by EU Directive 2004/27/EC (implemented in France by Law 2007-248); and
- Articles L5111-1 and following and R5111-1 and following of the Code of Public Health.

In addition to trademark law, the general rules prohibiting unfair competition set out in Article 1382 of the Civil Code are applicable to pharmaceuticals, notably where presentation and packaging of products are concerned. National and EU antitrust regulations have an important effect on the organisation of the market for these products.

Selection, clearance and registration

Trademarks for pharmaceuticals must obey the general rules for validity that apply to all trademarks.

Absolute grounds for refusal

The sign for which registration is sought must be capable of graphical representation and used to distinguish the products concerned.

Most often, signs in the pharmaceutical field are complex signs including both graphical and denominative elements.

Colours, sounds and shapes can be registered as trademarks, as long as they can be represented graphically. Smells are currently not registrable as trademarks.

A sign's capacity to identify the origin

of the goods to which it applies may be challenged in some cases. If the mark consists of the shape of a product, the shape must not be determined solely by the nature or function of the product and must not give the product its substantive value.

So far, the French courts have not ruled on whether shape of a pharmaceutical can be registered as a trademark; but as they take a strict approach to the protection of three-dimensional trademarks, it seems likely that the shape of a drug (a 'galenic' shape) will be accepted for trademark registration only rarely. This is in line with the EU position, Therefore, an applicant should add other elements (eg, letters) to the shape in order to obtain protection.

However, a 2011 law provides that the owner of the right to a galenic shape cannot prohibit the use of a shape and texture for generics that are the same as the original pharmaceutical (Article L5121-10-3 of the Code of Public Health).

Another absolute requirement for trademark registration is that the sign be distinctive: it must not be descriptive, usual, generic, misleading, excluded by law or contrary to public order.

In addition, international non-proprietary names (INNs) used to designate pharmaceutical substances belong to the public domain and cannot be registered as trademarks.

Further, Article R5121-2 of the Code of Public Health provides that the name of a pharmaceutical (which is usually filed as a trademark) must not be confusingly similar to an INN. As part of its examination process, the Trademark Office will check whether a proposed trademark registration is likely to cause confusion with existing INNs; if this is the case, it will reject the application.

Moreover, Article R5121-3 specifically provides that the invented name chosen to designate a pharmaceutical must avoid any confusion with other pharmaceuticals and may not mislead as to the quality or properties of the product.

The Trademark Office will check that a trademark application is not misleading during the examination of a pharmaceutical mark.

Relative grounds for refusal

The Trademark Office undertakes no examination of prior rights. It is the applicant's responsibility to check that the mark does not infringe prior rights.

Pharmaceutical companies must obtain a marketing authorisation before commercialising their products. Drug producers often seek this authorisation concurrently with the prosecution of their trademark application. An application for an EU marketing authorisation involves clearing the mark and checking its validity in all EU member states, which is a lengthy and difficult process.

In addition, the administrative authority granting the marketing authorisation sometimes reaches a different conclusion from the other relevant bodies.

The general rules applicable to trademarks provide that a trademark must not cause prejudice to the prior rights listed in Article L711-4 of the IP Code. These prior rights are mainly:

- trademarks;
- company names;
- trade names and signboards (when they are known in the entire French territory and used in the same or a similar field of activity);
- appellations of origin;
- copyrights;
- designs;
- personality rights;
- image rights; and
- the image or repute of a local authority.

According to case law, domain names can now also constitute prior rights opposable to a trademark under certain conditions (the domain name must relate to a website launched and active before the trademark application for an identical or similar activity, and the trademark should be confusingly similar to the domain name).

French case law provides that the assessment of the risk of confusion between pharmaceutical trademarks follows the same rules as for trademarks in other fields. In *Pierre Fabre Médicament v Institut National de la Propriété Industrielle* (February 28 2007) the Paris Court of Appeal noted that nothing can justify a different approach to the assessment of the risk of confusion with regard to pharmaceutical trademarks. The fact that the trademarks are to be used for different therapeutic preparations is irrelevant

(see *Boehringer v Fournier*, Paris Court of First Instance, January 19 2010).

Further, case law provides that the risk of confusion must be evaluated from the point of view of the average consumer, not from a specialist's point of view (see *Organon v Sanofi Synthélabo* (Paris Court of Appeal, September 19 2001)).

However, pharmaceutical trademarks are usually made up of elements that refer to the active components of the product. This means that the weak distinctive character of such elements will be taken into consideration in the global appreciation of the similarity between signs when assessing the risk of confusion (eg, see the Paris Court of Appeal's October 2 2009 decision that ARTHRALGIC was different from ARTICALGIC).

Use of pharmaceutical trademarks

A prerequisite for the market launch of a pharmaceutical is that the product have been approved for sale. The marketing authorisation is delivered after a lengthy examination process by the European Medicines Agency for an EU-wide authorisation and the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS) for an authorisation valid only in France.

In order to remain valid, a trademark must be used within five years of registration, except where there is a legitimate excuse not to have done so. A legitimate excuse can be that the marketing authorisation procedure was not completed during this five-year timeframe (eg, *Farmaceutisk Laboratorium Ferring v EDRA* (Paris Court of First Instance, September 14 1999)). This use must be serious and contact between the product and consumers must be proven. If the packaging was manufactured in France and there is no proof of sales, this does not constitute contact between the product and consumers (*Flamant Vert v Teva* (Paris Court of First Instance, May 22 2014, 12/00880)).

Distribution

In France, pharmaceutical products are sold in pharmacies only (Article L4211-1 of the Code of Public Health). This monopoly is protected and breach thereof is a criminal offence.

Parallel imports and repackaging

Once a product bearing a trademark has been launched on the EU market by the rights holder or with its consent, the product shall circulate freely within that market.

Where pharmaceuticals are concerned, local rules on distribution may necessitate that the product be relabelled or repackaged – for instance, when a specific translation not provided on the original packaging is needed. Consumer resistance towards the relabelling of goods may also force the importer to repackage them.

Courts at national and EU levels have issued many decisions concerning the parallel import of pharmaceuticals. The courts have imposed several conditions on the repackaging or relabelling of pharmaceuticals.

A rights holder can oppose relabelling or repackaging, except when the following conditions are cumulatively fulfilled:

- The relabelling or repackaging is necessary to gain access to the market and its prohibition would contribute to the artificial partitioning of markets between member states;
- The relabelling or repackaging will not affect the original condition of the product inside the packaging;
- The name of the party that repackaged the product and the name of the manufacturer are clearly mentioned on the new packaging;
- The presentation of the product will not prejudice the reputation of the trademark or that of the rights holder; and
- The importer has given notice to the rights holder before commercialising the relabelled or repackaged product.

These conditions were set out by the European Court of Justice (ECJ) in *Boehringer Ingelheim* (C-348/04, April 6 2007) and *Bristol Myers Squibb v Paranova* (C-427/93, C-429/93 and C-436/93, July 11 1996).

The burden of proving these five conditions rests with the importer; but if the importer provides evidence that the original condition of the product is not affected, or that the presentation of the product does not prejudice the reputation of the trademark or of the rights holder, it is up to the rights holder to prove the contrary.

Following these decisions, a new question was raised in *Orifarm v Merck* (C-400/09, October 19 2009): does a parallel importer which has not repackaged the pharmaceuticals itself, but has requested a third party to do so, and which has nonetheless mentioned its own name on the new packaging infringe the rights holder's rights? The ECJ answered that the trademark holder could not oppose the commercialisation of the repackaged product simply because of the presence on the packaging of the name of the parallel importer instead of the name of the company which actually repackaged the goods (C400/09 and C207/10).

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Aurélia Marie is head of the firm's trademarks, designs, domain names and copyright department. She specialises in the law of distinctive signs (trademarks, company names, trade names, domain names), designs and copyright, as regards both acquiring and exploiting such rights. She also has wide expertise in conducting due diligence reviews of portfolios of trademarks and designs, contracts, advertising law and unfair competition.

Ms Marie is a French trademark attorney and a European trademark attorney with postgraduate degrees in the law and practice of international contracts and industrial property law from the University of Paris. She joined Cabinet Beau de Loménie in 1993 and became a partner in 2003. She works in both French and English, and also speaks Spanish.

There may be discrepancies between the situation deriving from ECJ case law and the Code of Public Health (eg, see Articles R5121-108 to 136 of the code).

Anti-counterfeiting and enforcement

Infringement can lead to civil or criminal penalties, depending on the circumstances and the procedure used.

The EU IP Rights Enforcement Directive (2004/48/EC) was implemented in France on October 29 2007. This has reinforced the means for fighting infringement. Rights holders can file requests with Customs to stop infringing goods from entering the French or European market. Customs can also act *ex officio* to stop the import of infringing goods into France or Europe.

Advertising

The advertising of pharmaceuticals is strictly regulated. However, a distinction is made between prescription-only products and over-the-counter drugs. Advertising for prescription products can be directed at health professionals, doctors and pharmacists only. In all cases (including over-the-counter drugs), pharmaceutical advertisements are controlled by the AFSSAPS and must be authorised before broadcast or publication.

With the development of generics, issues have arisen with regard to the reproduction of the trademark of the original in comparative advertising.

Comparative advertising must adhere to specific conditions and should relate to a comparison of characteristics that are essential, pertinent, representative of the products and verifiable.

Legitimate comparative advertisement can make reference to a trademark without the authorisation of the rights holder. Otherwise, such reference is considered to be an infringement (Article L121-8 of the Consumer Code).

Another issue is whether the manufacturer of a generic product can refer to the trademark of the original or should refer solely to the INN. Currently, reference to a trademark belonging to a third party without authorisation is allowed only when this reference is necessary to indicate the

destination of the product, on condition that there is no confusion as to the origin of that product (Article L713-6 of the IP Code).

In *Beecham v GlaxoSmithKline* (March 26 2008) the Supreme Court reversed a Paris Court of Appeal May 3 2006 decision and found that the presentation of a product as the generic of an original product was legitimate comparative advertising, without any comparison of other elements of the pharmaceutical product being necessary. This position was confirmed again by the Supreme Court in *Sandoz v Beecham Group PLC* (May 24 2011).

Generic substitution

Under Article L5125-33 of the Code of Public Health, pharmacists are allowed to substitute a trademarked product prescribed by a medical practitioner with a generic product, whereas substitution of a trademarked product with another is prohibited by Article L716-10 of the IP Code.

The court condemned a company which had presented its product as a generic of a pharmaceutical in order to have the product substituted for this pharmaceutical. When a pharmaceutical is prescribed by a doctor, the pharmacist cannot deliver another product without the consent of the doctor, except in case of emergency and the interests of the patient, or when a generic is available. In the present case, the two pharmaceuticals were both originals. Substitution therefore was not possible (*Mylan v Ipsen Pharma*, Supreme Court, October 9 2012).

Online issues

Online advertising

Online advertising is covered by the general rules on advertising. Domain names and websites must respect the rules governing pharmaceutical advertising. Consequently, according to an agreement concluded in December 2001 between *Les Entreprises du Médicaments* (an organisation representing pharmaceutical companies) and the AFSSAPS, a trademark may be registered as a domain name only if it designates an over-the-counter product or vaccine.

Distribution through the Internet

The development of the Internet has radically changed the distribution environment. France has now incorporated into French law EU Directive 2011/62/EC (Ordinance of December 19 2012 and Decree of December 31 2012). Thus, since January 2 2013, owners of a pharmacy can sell certain medicinal drugs online. Prescription drugs, veterinary drugs and medication not freely accessible to the consumer are excluded.

Such activity is strictly regulated and the creation of a website is conditional on the physical existence of a pharmacy (Articles L5125-34 to L5125-41 of the Public Health Code). It must be held by a pharmacist, who must obtain permission from the Regional Health Agency and inform the Order of Pharmacists of his or her intent to sell online.

The site itself must include minimum information on each page. A breach of these rules may result in penalties ranging from temporary closure of the site to an administrative fine, which may be accompanied by a maximum penalty of €1,000 a day.

The conditions imposed on the online sale of non-prescription drugs are detailed in an order of June 20 2013, and compliance is monitored by the competent authorities. In August 2014 the Paris Court of First Instance ordered Enova Santé, which acted as an intermediary between consumers and pharmacists for online drug sales and which delivered such drugs, to stop all offers for sales. The court held that Enova Santé played an active role in online drug sales even though it was not registered with the Order of Pharmacists as a pharmacist and had obtained no permission for such sales. **WTR**

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