

Contributing firm
Cabinet Beau de Loménie



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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 First Trademarks Directive (89/104/EEC) (now the Trademarks Directive (2008/95/EC)); and
- Articles L711-1 (and following) and R711-1 (and following) of the French Intellectual Property 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:

- Regulation 726/2004 on the EU procedures for the authorisation and supervision of medicinal products for human and veterinary use;
- Directive 2001/83/EC on medicinal products for human use, modified by Directive 2004/27/EC (implemented in France by Law 2007-248 of February 26 2007); and
- Articles L5111-1 (and following) and R5111-1 (and following) of the French Code of Public Health.

Besides trademark law, the general rules prohibiting unfair competition set out in Article 1382 of the French Civil Code are also 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 pharmaceuticals 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. There has been no decision in France so far concerning the capacity for shapes to identify the origin of a pharmaceutical, but the Versailles Court of Appeal assessed in *Sandoz v Biogaran* (October 12 2006) the capacity for pictograms to identify the goods to which they apply. In that case, the pictograms were used to inform patients of the dosage and manner of administration of the

pharmaceutical. The court found that the signs were not used to identify the origin of the goods concerned. Consequently, it held that the marks were invalid.

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. 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.

This may cause difficulties when filing a trademark that consists of the shape of the drug itself (galenic shape). However, in *Laboratoires Irex v Roche* (September 27 2005), the Versailles Court of Appeal held such a shape to be non-functional and thus protectable as a trademark.

A law issued on November 27 2009 provided that the holders of IP rights for galenic shapes cannot prohibit the use of the same shape for generics, but this provision was subsequently cancelled by the Constitutional Council in Decision 2009-596DC of December 22 2009.

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 French 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 French Trademark Office will check whether a proposed trademark registration will likely 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
- must not mislead as to the quality or properties of the product.

The Trademark Office will check the compliance of the trademark application with this provision during the examination of any 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. Drugs producers often seek this authorisation

concurrently with the prosecution of their trademark application. An application for a marketing authorisation for the European Union 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 those of other relevant bodies.

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

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

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 could 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 Synthelabo* (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 decision of October 2 2009, in which it ruled that ARTHRALGIC was different from ARTICALGIC).

The criteria applied by the Office for Harmonisation in the Internal Market in the case of Community trademarks (CTMs) may appear to be slightly different.

However, it is now established CTM law that the pertinent public of reference for pharmaceuticals is not only health specialists, but also final users.

Use of pharmaceutical trademarks

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

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)).

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. Resistance from consumers towards the relabelling of goods may also force the importer to repackage them.

Courts at the national and EU levels have issued many decisions concerning the parallel importation 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 have 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 presentation of the product;
- The presentation of the product will not prejudice the reputation of the trademark or that of the rights holder; and
- The importer gives notice to the rights holder before commercialising the relabelled or repackaged product.

These conditions were set out by the Court of Justice of the European Union (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 has now been raised before the ECJ in *Orifarm v Merck*: 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 (C-400/09, October 19 2009)? The answer will determine whether the rights holder can intervene where a parallel importer requests a third company to repack the goods.

There may be discrepancies between the situation deriving from ECJ case law and the French regulations of 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 the customs authorities to stop infringing goods from entering the French or European market. Customs can also act *ex officio* to stop the importation into France or Europe of infringing goods.

Advertising

The advertising of pharmaceuticals is strictly regulated. However, there is a distinction between prescription-only products and over-the-counter (OTC) drugs. Advertising for prescription products can be directed at health professionals, doctors and pharmacists only. In all cases (including OTC 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 *princeps* (ie, original) in comparative advertising.

Comparative advertising needs to 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 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 *princeps* 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 the condition that there is no confusion as to the origin of that product (Article L713-6 of the Intellectual Property Code).

In *Beecham v GlaxoSmithKline* (March 26 2008), the Supreme Court reversed a Paris Court of Appeal decision of May 3 2006 and found that the presentation of a product as the generic of a *princeps* was legitimate comparative advertising, without any comparison of other elements of the pharmaceutical product being necessary. This should lead to a change in the way that courts tackle references to an original product's trademark in advertisements for generics. However, some courts are still of the opinion that reference only to the INN is appropriate (*Beecham v GlaxoSmithKline* (Versailles Court of Appeal, September 17 2009)).

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 Intellectual Property Code.

Online issues

Online advertising

Online advertising is covered by the general rules of advertising. Domain names and websites must respect the rules governing pharmaceutical advertising. Consequently, according to the agreement on communication of pharmaceutical companies on the Internet, 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 OTC product or a vaccine.

Distribution through the Internet

While the development of the Internet has radically changed the distribution environment, for the time being the distribution of pharmaceuticals in France remains the monopoly of brick-and-mortar pharmacies. However, discussions with the Ministry of Health to authorise distribution through the Internet are ongoing. [WTR](#)

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Aurélia Marie is a French industrial property attorney and a European trademark attorney.

She obtained a master's degree in business law in 1985 and a postgraduate professional degree in international contract law and practice in 1986 from the University of Paris X. She completed her certificate of qualification to practise as a barrister in 1987 and her postgraduate professional degree in industrial property law in 1988.

She began her career in the agreements and IP department of a large industrial business. She then practised as an attorney at law in an IP law firm before joining Cabinet Beau de Loménie in 1993. She became a partner of the firm in 2003.

Ms Marie specialises in trademarks, designs, unfair competition and copyright. She is also experienced in conducting due diligence reviews of trademarks and designs portfolios.

She speaks English and French.