France

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 pharmaceuticals' development and commercialization, including the intellectual property derived from them.

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

- the Community Trademark Regulation (40/94), amended by Regulation 422/2004, and the Community Trademark Implementation Regulation (2868/95), amended by Regulation 1041/2005;
- 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 also have an impact on the registration and use of pharmaceutical trademarks:

- Regulation 726/2004 on the EU procedures for the authorization 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 provided by 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 organization 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.

Nevertheless, 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*

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(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 the law or contrary to public order. When the mark consists of the shape of a product, the shape must not be determined solely by the nature or the function of the product.

This may cause difficulties for 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 non-functional and thus protectable as a trademark.

In addition, international non-proprietary names (INNs) used for designating 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 and, where this is the case, will reject the application.

Moreover, Article R5121-3 specifically provides that the invented name chosen for designating a pharmaceutical:

- shall avoid any confusion with other pharmaceuticals; and
- shall 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 provides 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 authorization before commercializing their products. Drugs producers often seek this authorization concurrently with the prosecution of their trademark application. An application for a marketing authorization 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 authorization sometimes reaches a conclusion different 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.

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.

The criteria applied by the Office for Harmonization 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 final users too.

Use of pharmaceutical trademarks

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

To remain valid, a trademark must be used within five years of its registration, except when there is a legitimate excuse not to have done so. A legitimate excuse can be that the marketing authorization procedure was not completed during the 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 its breach is a criminal offence.

Parallel imports and repackaging

Once a product bearing a trademark has been launched on the EU market by the trademark owner 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 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 trademark owner 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 artificial partitioning of markets between member states;
- The relabelling or repackaging shall 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 shall be clearly mentioned on the new presentation of the product;
- The presentation of the product shall not prejudice the reputation of the trademark or that of its owner; and
- The importer shall give notice to the owner of the trademark before commercializing 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 is on the importer, but when 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 its owner, it is up to the trademark owner to prove the contrary.

It is worth noting that there may exist discrepancies between the situation deriving from ECJ case law and the French regulations derived from the Code of Public Health (see eg, 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.

Trademark owners 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 authorized 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 authorization of its owner. Otherwise, such reference is considered an infringement (Article L121-8 of the French 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 authorization, is allowed only when this reference is necessary for indicating 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 courts tackle references to an original product's trademark in advertisements for generics. Previously, some courts were of the opinion that reference only to the INN was appropriate.

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 organization representing pharmaceutical companies) and 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. WTR

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CONSEILS EN PROPRIÉTÉ INDUSTRIELLE

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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 post-graduate professional degree (*Diplôme d'études supérieures spécialisées*) 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 (*Certificat d'aptitude à la profession d'avocat*) in 1987 and her post-graduate 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 specializes 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.