Our trademark practice is one of the best in the world

DLA Piper has a unique market offering for trademark matters, with a global trademark platform across multiple jurisdictions.

In Paris, we have a team of highly-skilled lawyers, formerly European intellectual property lawyers, specialized in intellectual property law, trademark management and prosecution, including filing and renewing trademarks worldwide, developing branding strategies and managing related disputes, as well as any related matters concerning designs and domain names.

The team is supported by highly advanced, state of the art technological tools enabling “best in class” effective and transparent trademark management, making our practice one of the best in the world.

DLA Piper is a global law firm operating through various separate and distinct legal entities. Further details of these entities can be found at www.dlapiper.com
Selection, clearance and registration

Like all trademarks, pharmaceutical trademarks are subject to general trademark rules regarding validity and use.

Until recently, both French and European law required a trademark to be capable of graphical representation. This requirement allowed the registration of shapes, colours and sounds (in principle), but excluded signs such as smells. The European trademark law reform package, comprising EU Directive 2015/2436/EC and the EU Trademark Regulation (2015/2424), deleted the graphical representation requirement from trademark law. This change marks a dramatic step forward in trademark law and could result in smells and other non-traditional trademarks being more easily registered.

A trademark must be capable of distinguishing the goods or services of one undertaking from those of others. It serves as a guarantee of origin for the goods or services at hand. In this regard, the shapes of products have been the subject of heated debate. For a shape to be registered as a trademark, it must not be determined solely by the nature or function of the product in question. Further, it must not give substantial value to the goods. In practice, many shape marks fall within one of the excluded categories – especially in the field of pharmaceutical products, in which no trademark application representing the shape of a product has yet been considered valid.

In any case, under Article L5121-10-3 of the Public Health Code, the holder of IP rights in the shape or texture of a pharmaceutical product cannot prohibit the use of an identical or similar shape for a generic product. EU law provides no such exception.

A pharmaceutical trademark must be distinctive. Therefore, a descriptive or generic mark will not be considered valid. The law also specifically excludes certain marks and provides that marks that are misleading or contrary to public policy cannot be considered valid.

In addition to these absolute grounds for refusal, the trademark must not infringe prior rights. The prior rights listed in Article L711-4 of the IP Code, and supplemented by case law, include:

• trademarks;
Unlike in other countries, in France the trademark owner is independent from the party exploiting the trademark and need not possess a particular quality.

- company names;
- trade names and shop signs;
- designations of origin;
- copyrights;
- designs;
- names or images or persons or personality rights;
- the names, images or reputations of territorial collectivities; and
- domain names, provided that the website in question:
  - is operational before the application; and
  - applies to the same or a similar field of activity.

The registration of a pharmaceutical trademark must not create a risk of confusion with any of the prior rights listed above. The risk of confusion must be assessed in consideration of the relevant public, usually comprising medical professionals and patients (European Court of Justice (ECJ), *Alcon v OHMI-Biofarma*, C-412/05, April 26 2007). The risk of confusion must take into account the weak distinctive character of the elements that comprise pharmaceutical trademarks (which is due to the fact that they usually refer either to the active components of the product or to the area of treatment).

For example, in the field of allergy treatments, the prefix ‘Allerg-’ is commonly used in France. Case law tends to take this reality into account, concentrating on the other elements while disregarding the identical but common use of these prefixes (Paris Court of Appeal, *Allergan v Directeur de l’INPI & Sté Santé Nature Distribution*, March 30 2011; Court of Cassation, Commercial Chamber, *Laboratoires Brothier v Ipsen Pharma*, 10-18141, April 27 2011).

After five years, a trademark may be subject to revocation for non-use. The trademark owner must therefore prove that it is exploiting the trademark for all goods and services designated in the registration. European case law considers the category of ‘pharmaceutical preparations’ to be sufficiently broad to divide into sub-categories, each of which is considered autonomously (General Court; *GlaxoSmithkline v OHIM*; T-493/07, T-26/08 and T-27/08; September 23 2009). Therefore, if a trademark owner is exploiting products in one sub-category only, it will not be deemed to have exploited products for the entire category of pharmaceutical preparations.

**Regulatory approvals**

In order for a pharmaceutical trademark to be registered, no prior authorisation is needed *per se*. Unlike in other countries, in France the trademark owner is independent from the party exploiting the trademark and need not possess a particular quality (eg, be a pharmacist or be authorised to sell the product).

However, prior authorisation is required in order to exploit a pharmaceutical trademark; in practice, this is often sought at the same time as the trademark application is filed. Authorisation can be issued by the European Medicines Agency or the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM). A delay in the issue of this authorisation may constitute a legitimate excuse for the trademark owner not exploiting the trademark in five years.
Confusion with INNs
The aim of international non-proprietary names (INNs) is to facilitate the identification of pharmaceutical substances and active pharmaceutical ingredients. Each INN is a unique name that is globally recognised and is public property. It is also known as a generic name.

Article R5121-2 of the Public Health Code provides that a pharmaceutical trademark must not create a risk of confusion with an INN. This requirement is taken into account by national and European trademark offices, which consider whether an applied-for trademark is likely to be confused with an INN during the examination process. Should this be the case, the trademark application will be rejected.

Even if the trademark application is accepted by the relevant trademark office, there remains the risk of cancellation by a court, should it identify possible confusion between the trademark and an INN (Lyon Court of Appeal, Merial v Virbac, 13/08055, May 13 2015).

Parallel imports and repackaging
Parallel imports within the European Union are governed by the rule of exhaustion of rights, which provides that once a trademarked product has been offered for sale on the European market by the trademark owner or with its consent, the product may freely circulate within the market. There is no exception to this rule for pharmaceutical products.

However, the issue of repackaging is important for pharmaceutical products. Indeed, since the sale of such products is strictly regulated, packaging requirements differ between countries (as exemplified by the issue of translation of instructions on packaging).

The courts have considered this issue and have held that, in principle, the trademark owner has a right to oppose the repackaging of its products. However, the right of opposition yields in certain circumstances. The following conditions must be met, set out in Bristol Myers Squibb (C-427/93, C-429/93 and C-436/93; July 11 1996) and further interpreted in Boehringer Ingelheim (C-348/04, April 6 2007), as follows:

- The repackaging must be necessary to permit imports;
- The repackaging must not:
  - adversely affect the original condition of the product; or
  - damage the reputation of the trademark or its owner;
- The repackaging must indicate the names of:
  - the party by which the product has been repackaged; and
  - the manufacturer of the product; and
- Prior notice must be given to the trademark owner.

The importer has the burden of proving compliance with all conditions. Should it fail to do so, the rights holder will have the right to oppose import. However, should it prove compliance, the onus will rest with the rights holder to prove otherwise.

Regarding packaging, the EU Falsified Medicines Directive (2011/62/EC) provides new control measures for preventing the distribution of falsified pharmaceutical products. Member states have transposed the directive into national law and must implement the new control measures by 2017. These include tracking measures based on the serialisation of products and cover all pharmaceutical products subject to prescription.

Anti-counterfeiting and enforcement
Trademark infringement is punishable by both civil and criminal penalties. The aim is to fight infringements more efficiently by strengthening the powers and resources of Customs.

Customs measures
In its most recent reports, Customs stated that the number of goods seized for IP infringement has increased dramatically. This is particularly relevant in the pharmaceutical sector: in 2014 Customs seized twice as many pharmaceutical products (2,580,793) as in 2013 (1,354,705). Further, while in 2013 infringing pharmaceutical products represented 17.8% of the total products seized, in 2014 they represented 29.3%.

In response to this trend, Law 2014-315 strengthened the measures available to
Customs to fight IP infringement by aligning French law with EU provisions. These measures include:

• a simplified new procedure for the destruction of illegal products;
• a longer timeframe for the rights holder to request customs intervention; and
• the extension of retention measures to IP rights other than trademarks.

Transit: new solutions

Article 11 of the EU Trademark Regulation and Article 10(4) of EU Directive 2015/2436/EC provide that Customs can seize infringing products that are in transit and have not been introduced on the European market. In order to oppose the seizure, the holder of the goods must prove that the rights holder has no right to prevent their commercialisation in the country of final destination. These provisions will increase the volume of goods seized by Customs and assist trademark owners in fighting infringement.

At present, this solution applies only to EU trademarks. The directive must be transposed into French law before it can apply to French trademarks. ECJ case law will be significantly modified as a result and it is expected that similar solutions will be extended to other IP rights in the future.

Advertising

Advertising of pharmaceutical products that targets the general public is strictly regulated by the Public Health Code.

Only certain products can be advertised. Several conditions must be met:

• The product must not:
  • require a medical prescription; or
  • be reimbursed by mandatory health insurance schemes; and
• The marketing authorisation must not include any prohibition against advertising to the general public due to public health risks (eg, where the product is not suitable for use without medical intervention).

Ads for pharmaceutical products may not:

• state that:
  • medical consultation is unnecessary;
  • the product is guaranteed to have the relevant effects, can be used without side effects or is better than another treatment; or
  • good health might be improved by use or adversely affected by non-use;
• liken the product to food products or cosmetics;
• play on fear in a major sense or mislead in any way; or
• target children only.

Regarding products that are subject to medical prescription, advertising may be targeted at health professionals only.

In recent years, comparative advertising has become an issue. Comparative advertising...
is permitted under French law, provided that it objectively compares characteristics that are essential, relevant, verifiable and representative of the relevant goods or services. Comparative advertising can mention a trademark in order to identify the products with which the comparison is being made. Given the above limits imposed on the advertising of pharmaceuticals, the amount of comparative advertising in this field is minimal.

The courts recently considered whether it is possible to mention the name of a trademarked pharmaceutical product when advertising the generic version of that product. The Supreme Court held that the presentation of a product as the generic version of a trademarked product is considered legitimate comparative advertising (Sandiz v Beecham Group, 09-70.722, May 24 2011).

**Generic substitution**

Article L5125-23 of the Public Health Code provides that pharmacists can substitute a medically prescribed trademarked product with a generic version that fulfils the relevant conditions (eg, bioequivalence in accordance with Article L5121-1 of the Public Health Code). However, the substitution of a trademarked product with another trademarked product is prohibited and punishable by three years’ imprisonment and a €300,000 fine (Article L716-10 of the IP Code). This was upheld by the Supreme Court in a case in which a pharmaceutical company presented its product as generic even though it was an original trademarked product; the substitution was therefore unlawful (Mylan v IPSEN Pharma, 11-20.725, October 9 2012).

**Online issues**

**E-pharmacies**

In principle, pharmaceutical products can be sold in pharmacies only. This provision is strictly enforced and any violation is considered a criminal offence. However, in order to take into account the development of online sales of goods, the EU Falsified Medicines Directive (2011/62/EC), transposed into French law, provides that owners of pharmacies can sell certain over-the-counter products online. Prescription-only products cannot be sold online.

Online sales of pharmaceutical products are strictly regulated and are subject to the following conditions:

- There must be a physical pharmacy behind the website;
- The website must be managed by a pharmacist;
- The pharmacist must obtain authorisation from the Regional Health Agency; and
- The pharmacist must inform the Order of Pharmacists of his or her intention to sell pharmaceutical products online.

Non-compliance with these conditions will lead to penalties ranging from temporary closure of the website to an administrative fine. A list of authorised websites can be found on the Order of Pharmacists’ website.

The general rules for advertising also apply to online advertising.

**Domain names**

A pharmaceutical trademark can be registered as a domain name. However, the ANSM sets out specific conditions enforcing compliance of the corresponding website with the rules on advertising. For instance, the ANSM explicitly provides that if a website corresponds to a domain name which includes a pharmaceutical trademark designating a medicine or a medical device for which advertising to the general public is prohibited, it must have a secure home page. **WTR**