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# Generic drugs and comparative advertising

A recent case found that a generic pharmaceutical company can use the name of a branded drug in comparative advertising in France. **Philippe Lods** of **Lavoix** examines how branded pharmaceutical companies can defend themselves

In a ruling handed down on March 26 2008, the French Supreme Court held that the fact that an advertisement for a generic drug referred to the brand of the reference drug constituted lawful comparative advertising without any trade mark infringement. What is the impact of this ruling in legal and practical terms, and what can be done by the manufacturers of the reference drugs to protect their distinctive signs?

## The ruling of the French Supreme Court

The ruling concerned a dispute involving the Deroxat trade mark. The Paris Court of Appeal, in a ruling dated May 3 2006, held that a company that had presented its drug as a generic version of the drug Deroxat in an advertisement had committed trade mark infringement on the grounds that the advertisement did not constitute comparative advertising as it was limited to citing the Deroxat trade mark and did not feature “any element of comparison between the generic drug and the reference drug sold under that trade mark” as per article L 121-8 of the French Consumer Code transposing Directive 84/450, which was subsequently modified by Directive 97/55.

In order to justify its ruling, the Court stated that the reference to the international non-proprietary name, which refers to the active ingredient of the drug and the therapeutic indications featured in the advertisement, would have provided comprehensive and complete information to healthcare professionals as to the purpose of the paroxétine G Gam generic drug, according to the meaning of this term in article L 713-6-b of the French IP Code without it being necessary to refer to the Deroxat trade mark.

In its ruling, the Supreme Court overruled the Court of Appeal, holding “that by presenting the drug known as paroxétine G Gam as a generic version of Deroxat, G Gam was merely informing members of the public that its drug had the same qualitative and

quantitative composition in terms of the active ingredient used, the same pharmaceutical form as the reference drug, and that its bioequivalence with that drug had been demonstrated, as a result of which it was in fact implicitly performing a comparison of the essential, pertinent, verifiable and representative characteristics of these products”.

The Supreme Court’s ruling complies with the principles laid down by the European Directive and the case law of the European Court of Justice.

According to the fourteenth preliminary consideration of Directive 97/55 amending Directive 84/450, “it may, however, be indispensable, in order to make comparative advertising effective, to identify the goods or services of a competitor, making reference to a trade mark or trade name of which the latter is the proprietor” provided that, according to the fifteenth preliminary consideration, this “complies with the conditions laid down by this Directive, the intended target being solely to distinguish between them and thus to highlight differences objectively”. The rules that determine the lawfulness of comparative advertising are stipulated in section 1 of article 3 bis of the Directive.

The European Court of Justice (ECJ) considers that the definition of comparative advertising as laid down by the Directive is broad, covering all forms of comparative advertising. It is sufficient for a representation that it refers even implicitly to a competitor or to the goods or services that it offers in order to constitute comparative advertising (see points 30 and 31 of the ruling of October 25 2001 in *Toshiba Europe GmbH v Katun Germany GmbH*).

On this basis, the ECJ has recently upheld as comparative advertising (advertising that objectively compares one or more essential, pertinent, verifiable and representative characteristics of goods), (1) the mention in a supplier’s catalogue of spare parts with the item numbers of the devices for which they were destined,

(see the *Toshiba v Katun* ruling); (2) the fact that a competing supplier reproduces the key component of a distinctive sign (see the ruling of February 23 2006 in *Siemens AG v VIPA*); and (3) the fact that a competing supplier uses a sign or device that is similar to the trade mark of a competitor (see the ruling of June 17 2008 in *O2 Holdings Limited v Hutchinson 3g Limited*).

## The scope of this decision

### Legal implications

The Supreme Court ruling only applies to a generic drug which is registered in the Register of Generic Drugs, which has obtained a notice of compliance and which is not launched on the market until after the expiry of the IP rights of the holder of the notice of compliance of the reference drug. However it does have limits:

#### Limitations stipulated by law and case law

According to article L 121-9 of the French Consumer Code, comparative advertising cannot be designed in such a way as to derive undue benefit from the reputation of a trade mark, to discredit or to denigrate a brand belonging to a competitor, to generate confusion between the advertiser and a competitor or between their trade marks, or finally to present goods or services as being an imitation or a reproduction of

goods or services that are covered by a protected trade mark.

In the above-mentioned rulings, the ECJ highlighted the fact that the competitor's use of the manufacturer's trademark was only permissible provided that there was no risk of confusion in people's minds, including a risk of association between the manufacturer whose products were identified and the competing supplier, such as would result in people assigning the reputation of the manufacturer's products to the competitor's products, ie the competing supplier could not unduly benefit from the reputation of the manufacturer's products".

In a further recent ruling, the ECJ held that by marketing low-end perfumes designed to imitate perfumes from renowned brands by way of concordance tables, the competing manufacturer sought to unduly benefit from the renown of the luxury brands. The Court therefore ruled that this advertisement was unlawful (see the ruling of June 25 2009 in C-487/07, *L'Oréal v Bellure*).

By applying the law and the case law, the manufacturer of a reference drug would thus be entitled to oppose the use of its brand in a comparative advertisement for a generic drug if, in the case under consideration, this use was of such a nature as to induce a risk of confusion, including a risk of association, and/or if it might enable the generic manufacturer to unduly benefit from the renown of the trade mark of the reference drug.

This would be the case, for instance, if the generic manufacturer were to compare the two products while in the process appropriating other signs, commercial documents or methods of presenting the product which might induce people into confusing the origin of the products and associating them with one another.

#### Limitations resulting from the protection of elements accompanying the drug's trade mark

The French courts previously held that the reproduction of the distinctive shape of a pill or the decoration of the packaging of the reference drug by a generic manufacturer constitutes an infringement of IP rights or an act of unfair competition.

In a ruling dated September 27 2005, the Court of Appeal of Versailles, dealing with a case that had been referred to it by the French Supreme Court, held that Laboratoires Irex had infringed the IP rights of the three-dimensional trade mark of the reference drug Lexomil, consisting of the shape of a pill, by adopting for its own generic drug Anxyrex the same distinctive, oblong shape that was breakable in four.

This trade mark, which had been registered with the French Trade Mark Office, represented a breakable rec-

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Now a partner of Lavoix, Philippe joined the firm in 2000, after spending nine years with several other French IP firms. His practice focuses on trade mark and design prosecution and litigation with regard to IP matters and domain names. He also handles agreements relating to licensing, know-how, cooperation, research and co-ownership.

tangular pill with rounded edges.

The Court of Appeal held that this three-dimensional trade mark was valid as its form was neither necessary nor usual on the date of its registration, and that it had a unique appearance that was unrelated to any quest for a technical outcome.

Note too, in this respect, that OHIM agreed to register the Pfizer VGR 100 Community trade mark (number 000848861), consisting of the representation of a blue-coloured pill shaped like a rhombus with slightly bulging faces, well known under the name Viagra.

In the absence of protection by a trade mark or model, the French courts tend to qualify a reproduction or imitation of packaging elements as acts of unfair competition.

In a case involving Bristol Myers Squibb and UPSA Conseil on the one hand and Ivax on the other, concerning a product sold under the name Citrate de Bétaïne, the commercial court of Nanterre held, on March 11 2005, that the fact that Ivax was selling its drug in a box of a similar colour to that of the plaintiffs constituted an act of unfair competition, as the strong resemblance between the respective packaging elements was likely to induce a risk of confusion.

In France, the decoration of a packaging element can be protected by a registered three-dimensional trade mark.

The very shape of packaging and packaging elements can be protected by a trade mark and/or model. In a case involving these questions but unrelated to drugs,

the French Supreme Court held that the shape of a cylindrical box made from rigid cardboard and comprising a beading at one end constituted a valid trade mark (see the ruling of December 8 1992).

### **Practical scope**

In France, the advertising of drugs to members of the public is only authorised for drugs that may be available without prescription (so called over-the-counter drugs)

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## **The ECJ considers that the definition of comparative advertising is broad, covering all forms of comparative advertising**

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and that are not reimbursed by the mandatory health insurance schemes.

The customer base for these drugs usually pays particular attention to the brand image of the product resulting from the intrinsic quality of the product and from its presentation.

Therefore one may suppose that an original drug, whose trade mark is renowned or at the very least whose presentation is attractive, will have a greater chance of retaining its drawing power against the corresponding generic drug.

The distinctive and original elements that surround the original trade mark thus deserve to be carefully protected.