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Selection, clearance and registration

According to Article 1(20) of EU Directive 2001/83/EC on medicinal products for human use, the name of a pharmaceutical may be either an invented name not liable to be confused with the common name, or a common or scientific name accompanied by either a trademark or the name of the marketing authorisation holder. The directive further defines 'common name' as the international non-proprietary name (INN) recommended by the World Health Organisation, or, if no INN exists, as the usual common name.

In evaluating the safety of pharmaceuticals in the authorisation procedure, the German Federal Institute for Drugs and Medical Devices will, on the basis of Article 8 of the German Medicines Act, consider whether the invented name proposed for a pharmaceutical could create a public health concern or safety risk. In particular, the invented name of a pharmaceutical should not convey misleading therapeutic and/or pharmaceutical connotations or be misleading with respect to the composition of the product.

Thus, from the outset the options for naming a pharmaceutical are legally restricted for public health reasons, and the name must be selected carefully. Not only prior trademarks and other designation rights, but also INNs and safety reasons must be taken into account before filing and registering a trademark.

Confusion between trademarks derived from INNs

It is common practice in the pharmaceutical sector to register trademarks that comprise invented names which are derived, more or less obviously, from the INNs of their active ingredients. Against this background, it is unsurprising that the question of whether a likelihood of confusion exists between two trademarks derived from the same INN is often part of opposition proceedings.

In a recent case (25 W [Pat] 516/10), the Federal Patent Court had to decide whether a likelihood of confusion existed between the earlier sign PANTOZOL and the junior mark PANPRAZOL. Both were registered or applied for in relation to pharmaceuticals to treat gastro-intestinal diseases and both contained the active ingredient Pantoprazol.

In its decision of March 17 2011 the court denied any likelihood of confusion. It found that the distinctive character of the earlier sign PANTOZOL was considerably below average, since it was clearly derived from the INN Pantoprazol. Accordingly, the court held that the junior mark PANPRAZOL was suffiently dissimilar to exclude any likelihood of confusion, despite the identity of the goods to which the marks applied. The court took the view that recognising a likelihood of confusion in such a case would preclude the registration of any sign derived from an INN after the registration of the first sign derived from that INN, thus granting an unacceptable monopoly on names derived from a certain INN to the first party to file. Nevertheless, the court also

noted that it would have found a likelihood of confusion between PANTOZOL and PANPRAZOL had the earlier sign enjoyed a higher degree of distinctivess.

This decision seems reasonable from a general legal point of view. However, it is questionable whether it is in line with EU case law, in particular the decision of the European Court of Justice (ECJ) in *adidas AG v Marca Mode* (Case C-102/07, April 10 2008). In that case the ECJ held that the requirement of availability cannot in any circumstances constitute an independent restriction of the effects of the trademark in addition to those defined in Article 6(1)(b) of the EU First Trademarks Directive (89/104/EEC). That provision states that the trademark shall not entitle the proprietor to prohibit a third party from using, in the course of trade, indications concerning the kind, quality, quantity, intended purpose, value, geographical origin, time of production of goods or of rendering of the service, or other characteristics of the goods or services.

Thus, it seems clear that the question of whether there is a public interest in the availability of a certain term, such as in the availabilty of INNs, cannot result *per se* in the limitation of the scope of the earlier trademark derived from an INN. Moreover, the requirement of availability cannot be taken into account in opposition proceedings (see Case C-3/03, *Matrazen Concord*, Paragraph 35, regarding the Trademarks Regulation (40/94)).

Since the Federal Patent Court has admitted the appeal against its decision, among other things to ensure a uniform application of the law, the Federal Supreme Court will have the opportunity to decide on this matter as well. That decision will most probably be of great significance for the future trademark strategies of pharmaceutical companies and should therefore be carefully monitored.

Admissibility of umbrella trademarks

Another key issue is the admissibility of so-called 'umbrella trademarks' in the pharmaceutical sector. An umbrella trademark can be described as a single brand name for a group of non-prescription and/or prescription products, intended to increase the familiarity of consumers with the products as a group (eg, pharmaceuticals, cosmetics, medicinal products, food supplements). These products may differ in their composition with regard to their active ingredients, their pharmaceutical form, their therapeutic indications – even their legal character (eg, food supplement, pharmaceutical product).

In a decision of April 12 2011 (Case 7 K 4284/09), the Administrative Court of Cologne held that pharmaceuticals containing different active ingredients to treat different diseases must not be marketed under the same umbrella trademark.

The main line of reasoning of the court was that consumers expect that pharmaceuticals marketed under an umbrella trademark contain the same active ingredient. Thus, the use of the umbrella trademark is misleading as consumers might use the new pharmaceutical to treat the disease targeted by the earlier, better-known pharmaceutical bearing the same umbrella mark. This confusion resulting from the use of the same umbrella mark could not be ruled out by displaying the different active ingredient and indication. According to the court, the name of a pharmaceutical is not a marketing instrument; rather, it constitutes a separate legal category in the interest of drug safety.

This first instance decision is somewhat controversial since it considerably limits the use of umbrella trademarks in the pharmaceutical sector. It seems in particular questionable whether the relevant public might in fact be misled in a case where not only the different active ingredients, but also the different indications are clearly displayed. One reason for using an umbrella trademark is to transfer some of the reputation of an existing product to a new product marketed under the same umbrella trademark. This is inadmissible only if the use of the umbrella trademark is misleading, not *per se*. Strict standards have to be applied, since patient safety is at stake. However, since the relevant consumers are in many cases used to the fact that companies market different products under one umbrella trademark, the court seems to have applied too strict a standard in assessing the risk of confusion among the target public.

Although the issues surrounding umbrella trademarks are yet to be settled, there is a strong tendency among the regulatory bodies and courts to allow umbrella marks only for products with identical active ingredients and indications. New detailed guidelines were drafted by the Federal Institute in November 2011. The relevant industry and consumer groups had the opportunity to comment on the draft.

Parallel imports and repackaging

Trademark rights are exhausted EU-wide if the trademark owner puts its pharmaceutical on the market in one of the EU member states. Thus, parallel imports of pharmaceuticals from one member state to another are generally permissible and do not infringe the trademark rights of the owner, even in case of repackaging and/or relabelling, provided that the importer has fulfilled the five obligations and conditions set out by the ECJ in, among others, the well-known *Paranova Case* (C-276-05). These obligations include the prior notification of the trademark owner of the importer's intention to put the imported pharmaceutical on the market. Failure to do so constitutes trademark infringement resulting in, among other things, claims to cease and desist from further import and claims for damages. The German courts strictly apply these rules and regularly decide on further details as regards repackaging and relabelling. Recently the Düsseldorf Higher Regional Court held that the same rules apply to the parallel importation of food products (I-20 U 135/1, April 5 2011).

Anti-counterfeiting and enforcement

The fight against counterfeit pharmaceuticals has become a priority issue in Germany. In 2010 the overwhelming majority of counterfeit pharmaceuticals confiscated by the German customs authorities were imported from India (67.7%). Counterfeit pharmaceuticals range from products containing no active ingredients to those containing highly toxic substances. They can harm patients by failing to treat serious conditions, provoking drug resistance and even, in some cases, causing death.

The legal framework for anti-counterfeiting measures such as cross-border seizures consists of the EU Customs Regulation (1383/2003), the German Trademark Act and the German Medicines Act. Trademark owners should work closely together with the German custom authorities to prevent effectively the distribution of counterfeit pharmaceuticals.

Advertising

The two central pieces of legislation governing the advertising of pharmaceuticals in Germany are the Advertising of Medicinal Products Act and the Act against Unfair Competition, both of which prohibit misleading advertising. The Advertising of Medicinal Products Act in particular prohibits promotional measures to the general public for prescription-only drugs; the act implements the rules on advertising contained in the Human

Medicines Directive.

Comparative advertising

In its landmark decision in *L'Oréal v Bellure* (Case C 487/07), the ECJ held on June 18 2009 that riding on the coattails of a trademark with a reputation in order to benefit from its power of attraction, its reputation and its prestige, and to exploit the marketing effort expended by the proprietor of that mark, is unfair within the meaning of Article 5(2) of the First Trademarks Directive. Thus, confusion with, or damage to, the owner of the trademark is not necessary to make a finding of infringement.

Furthermore, the ECJ held that the concept of 'unfair advantage' outlined in the First Trademarks Directive must be interpreted consistently with that term in the Misleading and Comparative Advertising Directive (84/540/EEC).

Consequently, the owner of a trademark can prevent the use of its mark in comparative advertising if the ad does not satisfy all of the conditions laid down in Article 3(a)(1) of the Misleading and Comparative Advertising Directive.

In two recent decisions dealing with comparative advertising of pharmaceuticals, the Hamburg courts applied the principles of the ECJ outlined above (Higher Regional Court, Case 3 W 30/10 and District Court, Case 416 O 103/10). Both cases concerned ads aimed solely at professionals in the healthcare sector. In each ad the prior trademark (P) of the originator of a certain pharmaceutical product containing the active ingredient T had been integrated into the logo of a manufacturer offering a generic also containing the active ingredient T. The logo appeared as follows: T + NAME® of generic company, with the taglines "Originator: P" and "Bioequivalent to P®". This logo was used as a prominent heading displayed on each page of the ads.

The courts held that the use of the prior trademark by integration into the logo of the generic company was unfair, as the reference to the trademark was objectively unnecessary in this particular context. They emphasised that generic companies may have a legitimate interest in informing doctors and patients of which original preparation the advertised generic drug substitutes. However, the constantly recurring naming of the original drug as a tagline to the logo was not necessary for this legitimate purpose. It served only to position the generic drug in the market, thus unfairly riding on the reputation of the original.

The key questions of whether, and to what extent, a generic competitor is allowed to use a trademark in advertising have thus not yet been settled.

Generic substitution

According to Article 129 of the Social Security Code (V), pharmacists must substitute an original preparation with a cheaper generic product if the doctor mentions only the active ingedient on his or her prescription, or prescribes a certain original product without explicitly excluding substitution. According to new legislation, as of January 2011 substitution is possible even if the generic product is not entirely identical to the original preparation as regards all indications, the exact size and the dosage form. However, German civil courts are still very critical of the alleged identity of generics and original preparations. In addition, the stronger the trademark and its reputation, the less doctors and patients will support or accept generic substitution.

Online issues

In its judgment of May 5 2011 (Case C-316/09), the ECJ ruled, by way of a preliminary ruling initiated by the German Federal Supreme Court, on the interpretation of the Medicines Directive with regard to the restrictions on advertising of pharmaceutical products over the Internet.

The ECJ confirmed that the concept of advertising of pharmaceuticals is very broad and may include the dissemination over the Internet of information relating to pharmaceutical products. However, material that is purely informative and without promotional intent is not covered by the provisions of that directive.

The ECJ therefore concluded that the dissemination on a manufacturer's website of information relating to prescription-only pharmaceuticals which consists solely of the faithful reproduction of the packaging of the pharmaceutical, or of a literal and complete reproduction of the package leaflet or the summary of product characteristics, is not prohibited by Article 88(1)(a) of the Medicines Directive, provided that this information is not accompanied by any additional element that supports its classification as advertising. The ECJ explicitly took into account the fact that the information provided in this case was accessible on the website only by someone who sought to obtain it, and that a person who was not interested in the pharmaceutical concerned would not have unwillingly been confronted with that information. However, the ECJ held that a different classification must be adopted where the information relating to the pharmaceuticals is selected or rewritten by the manufacturer, since such manipulation of information can be explained only by an advertising purpose.

The factual background of the case at hand must now be analysed and decided by the German Federal Supreme Court based on the preliminary ruling of the ECJ. Many further cases concerning the line between advertising and pure information in the sense of the ECJ decision are still pending. WTR

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Rainer Kaase is a partner of Harmsen Utescher, a partnership of lawyers and patent attorneys. Mr Kaase's IP and life sciences practice covers contentious and non-contentious trademark issues, as well as patent, unfair competition and contractual issues such as licence, distribution, manufacturing and co-marketing agreements, in particular in the pharmaceutical sector. Mr Kaase's clients include small and medium-sized companies, as well as global players, in various industries, including the pharmaceutical, food, fashion and retail sectors. Mr Kaase's expertise encompasses national and international trademark strategies, representation before the European and all German courts and advice on labelling – especially in the pharmaceutical and food sectors. Mr Kaase holds a law degree from the University of Marburg/Lahn and an LLM from the University of Cambridge, England. He is a member of, among others, the Pharmaceutical Trademarks Group, the Federal Association of Pharmaceutical Manufacturers and the Association of Food Law and Food Science. Mr Kaase frequently speaks on IP-related issues.

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