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Friedrich Graf von Westphalen & Partners



Authors

Norbert Hebeis and **Morton Douglas**

Selection, clearance and registration

Federal Institute for Drugs and Medical Devices

Pharmaceutical trademarks must be selected carefully, as patient safety is at stake. Prescription errors due to similarities between trademarks must be minimised. In Germany, the Federal Institute for Drugs and Medical Devices is the competent authority within the Federal Ministry of Health to authorise medicinal products on the basis of the Medicines Act. In the course of the authorisation procedure it examines the drug name, which comprises either an invented name or the international non-proprietary name (INN) combined with the name of the (generic) manufacturer.

Article 8 of the Medicines Act prohibits misleading names. According to this provision, a drug name is deceptive if:

- it alludes to a therapeutic effect that

the pharmaceutical does not have;

- it gives the impression that the effectiveness of the pharmaceutical is guaranteed; or
- it is misleading as to the quality and properties of the medication.

The institute also applies EU law, such as Article 1, paragraph 20 of EU Directive 2001/83/EC, which states that the name given to a medicinal product may be either an invented name or a common or scientific name, together with a trademark or the name of the manufacturer. From the wording of this provision, the institute has concluded that the INN must precede the company name and not *vice versa*. The second part of this provision states that the invented name must not be liable to confusion with a common name.

With regard to the risk of confusion with other pharmaceutical names already on the market, the institute has nothing comparable to the European Medicines Agency's Invented Name Review Group in place. As one of the final steps in the

marketing authorisation procedure, the institute examines the selected invented name and compares it to the names of existing medicinal products in its database. In this respect, the institute applies an internal publication dating back to August 1991, which provides that the name of a new pharmaceutical must be clearly different from the names of other pharmaceuticals. The greater the differences between the individual drugs and the greater the health risk in case of confusion between them, the more distinct the differences between their names must be. This is a rather ambiguous clause, which makes it difficult to predict how the institute will decide in an individual case. In fact, there is a lack of consistency in this regard. In the authors' experience, however, the institute is always open to discussion and in most cases it is possible to find a satisfactory solution where a chosen name is rejected.

Registration of trademarks deriving from INNs

As INNs cannot be registered as trademarks,

pharmaceutical companies often choose marks that comprise a term which derives from an INN, to which they sometimes add the company name. Such trademarks often cause difficulties when assessing similarity with other signs. The question is usually whether the modification of the INN dominates the sign or has, in the words of the Court of Justice of the European Union (ECJ), at least an “independent distinctive role within the composite sign”. Two recent judgments of the Patent Court provide guidance on this question.

In its decision of January 28 2010 (30 W [pat] 65/09), the Patent Court reversed a decision of the Patent and Trademark Office regarding the likelihood of confusion between the prior trademark LEVOCARB and LEVOCARB TAD. The term ‘LevoCarb’ was derived from the INNs ‘levodopa’ and ‘carbidopa’. As healthcare professionals would understand the reference to the INNs, the office held that there was no risk of confusion. However, the Patent Court reversed this decision. It found that although the common element ‘LevoCarb’ was derived from the INNs, it was sufficiently distinctive, given that neither ‘levo’ nor ‘carb’ is a common abbreviation of the respective INN. However, even though the trademarks LEVOCARB and LEVOCARB TAD as a whole were not particularly similar – due to the additional element ‘TAD’ in the later mark – it had to be taken into account that ‘TAD’ was an abbreviation of the applicant’s company name. As ‘TAD’ was visually separate from the term ‘LevoCarb’, the public would recognise ‘TAD’ as the manufacturer’s name. Therefore, the trademark element ‘LevoCarb’ had an independent distinctive role within the composite sign LEVOCARB TAD, so that a likelihood of confusion existed.

In its *Pamedro* decision of October 13 2009 (25 W [pat] 29/08), the Patent Court upheld another appeal against a decision of the office. The owner of the prior trademark PAMIDRO-CELL filed an opposition against the later trademark PAMEDRO. The Patent Court explained that even though the term ‘Pamidro’ referred to the INN ‘pamidron acid’, this trademark element had an average degree of distinctiveness. As a result, PAMIDRO was the dominant trademark element; whereas the term ‘cell’ is commonly used in relation to pharmaceuticals. As PAMIDRO and PAMEDRO were highly similar, the Patent Court concluded that a likelihood of confusion existed.

Importantly, in this regard the relevant public consists not only of healthcare

professionals, but also of end users, to whom trademarks containing modifications of INNs appear to be invented names. For this sector of the public, merely adding the company name (eg, ‘TAD’) or a descriptive term (eg, ‘cell’) is insufficient to prevent confusion.

Parallel imports and repackaging

The European Union has adopted the EU-wide exhaustion regime. Pharmaceuticals which have been put on the market by the manufacturer in the European Union can be exported to any other EU member state by a parallel importer without infringing the manufacturer’s trademarks; its trademark rights are ‘exhausted’. However, this exhaustion is subject to certain legal requirements stipulated by the ECJ (see Joint Cases ECJ C-427/93, C-429/93 and C-436/93, *Bristol-Myers Squibb v Paranova*, July 11 1996, and C-348/04, *Boehringer Ingelheim v Swingward and Dowelhurst*, April 26 2007).

One formal requirement is the importer’s obligation to notify the manufacturer before putting the imported pharmaceuticals on the market. If it fails to do so, putting the product on the market in the country of import will constitute trademark infringement. In this case the infringer will have to pay damages to the trademark owner. Three methods of determining the damages are available. First, the trademark owner may demand that the infringer pay a ‘fictitious licence fee’. Second, it can demand payment of the profits earned from the infringing trademark use (recovery of profits). Third, the manufacturer can calculate its damages based on lost profits. This last method is seldom used in parallel import cases because of difficulties in proving lost profits.

ZOLADEX: parallel imports and damages

In its *ZOLADEX* decision of July 29 2009 (I ZR 87/07), the Federal Court of Justice upheld a judgment of the Hamburg Appeal Court regarding the calculation of damages based on a fictitious licence fee and on the recovery of profits. At first sight, it may seem surprising that the Federal Court of Justice granted the trademark owner a licence fee of only 2% of the sales – the plaintiff had claimed 10% – even though it confirmed that a trademark owner can demand full recovery of profits.

Regarding the fictitious licence fee, the Federal Court of Justice argued that a licence fee in excess of 2% of the total sales would not be justified. Reasonable parties to a licence agreement would have taken into consideration that a parallel import is an

import of original goods which the trademark owner has previously already sold and generated earnings with. The court also found that the failure to notify the trademark owner did not constitute a severe impairment of the trademark owner’s interests, compared, for instance, to defective product packaging that might harm its reputation.

However, these considerations do not play a role if the trademark owner chooses the second method of calculating damages – the recovery of profits. According to the Federal Court of Justice, profits must be surrendered insofar as they result from the trademark infringement. The crucial point here is that the trademark is an integral part of the marketing authorisation granted to the pharmaceutical manufacturer; without the trademark, the imported pharmaceutical would not be marketable in Germany. Thus, all profits generated are attributable to the trademark infringement and must therefore be paid over to the trademark owner. As a result of this decision, when suing a parallel importer for damages, it is highly advisable to choose recovery of profits as the remedy for trademark infringement.

IVADAL: bad-faith applications relating to pharmaceutical trademarks

The *IVADAL* decision is another important judgment rendered by the Federal Court of Justice in 2009. Pharmaceutical manufacturers have often registered and used different trademarks for the same preparation in different EU member states. In the case at hand, the appellant used the *IVADAL* trademark in Austria; the designation of the same product in Germany was *STILNOX*. The respondent, a trademark agency, applied to register the *IVADAL* trademark in Germany. The Federal Court of Justice considered whether this application by the trademark agency was filed in bad faith.

The court noted that, due to the principle of territoriality of trademark rights, it is possible to apply for a trademark in Germany in the knowledge that an identical sign has been registered and is being used for identical goods in a neighbouring country. Special circumstances in Germany would be required in order to give rise to an assumption that an application had been made in bad faith. The court held that where the applicant is a trademark agency, which cannot use the mark itself, it will be considered to be acting in bad faith if the factual circumstances justify an assumption

that it is trying to induce third parties to buy the mark in a legally abusive manner. This could be the case if trademarks were applied for in the knowledge that only a small and pre-determinable number of third parties could possibly be interested in acquiring them.

In the present case, only the manufacturer of the pharmaceutical product and parallel importers could possibly have been interested in acquiring the German IVADAL trademark. These parties might be concerned that the respondent could intend to use the mark in order to prevent them from using the IVADAL sign in Germany and might therefore feel compelled to acquire the mark. These circumstances justified a conclusion that the respondent had acted in bad faith.

Nevertheless, it is strongly recommended that pharmaceutical companies close the gaps in their trademark protection within the European Union – in particular, by filing Community trademarks.

Anti-counterfeiting and enforcement

Counterfeit pharmaceuticals are becoming an increasingly troublesome issue in Germany, especially because of the possibility to obtain pharmaceuticals by mail order. In 2009 about 5.3 million counterfeit pharmaceutical items were seized by German Customs, compared to just 350,000 in 2008.

However, the increasing numbers of counterfeit products seized prove that the German anti-counterfeiting laws are quite effective. EU Regulation 1383/2003, the trademark law, which includes provisions on cross-border seizure, and the German pharmaceutical legislation provide effective options to deal with this problem. In addition, German Customs cooperates closely with trademark owners. It is nonetheless of paramount importance that pharmaceutical companies utilise the tools provided by law, including seizure of counterfeit goods by Customs.

Advertising

The advertising of pharmaceuticals is regulated by the Law on Advertising in the Healthcare Sector. As this law implements EU Directive 2001/83/EC, it is similar to the corresponding provisions in other EU member states.

The Law on Advertising distinguishes between advertising to the general public and advertising to persons qualified to prescribe or supply medicinal products. Advertising to the general public of

prescription preparations is prohibited (Article 10).

If advertisements contain claims about the health benefits of a product, evidence must be provided by way of clinical studies to support these claims, failing which the advertisement is deemed to be misleading (Article 3). The German courts have extensive knowledge and expertise in dealing with such claims and interpreting clinical studies.

Interestingly, the Law on Advertising is generally enforced not by the healthcare authorities, but rather by competitors. The reason for this is the relative ease with which interim injunctions may be obtained in Germany within a couple of days, without any need for an oral hearing.

Generic substitution

Pharmacists are obliged to substitute original pharmaceutical preparations with cheaper generic products if the legal requirements in Article 129(V) of the Social Security Code are met. This is the case if the prescribing physician has not explicitly excluded the substitution or mentions only the active ingredient on the prescription. In such cases the pharmacist must dispense a cheaper generic preparation instead of the original product.

As this legal situation cannot be easily changed, especially in times when the social budgets are tight, it is recommended that pharmaceutical companies choose distinctive invented names for their original products (as opposed to modifications of the INN) and create strong brands. If physicians understand that there is a material difference between the original product and the generics, it will be easier for them to tick the box on the prescription form excluding the substitution.

Online issues

Following a 2003 decision of the ECJ, mail-order pharmacies have been allowed in Germany since January 1 2004. While the ECJ ruled that only over-the-counter (OTC) preparations could be bought by mail order, the German government also allows the mail order of prescription preparations. In order to ensure high standards, only pharmacists that run actual, physical pharmaceutical retail outlets can offer mail-order services. Foreign pharmacies can provide mail order services in Germany if they adhere to the same standards which apply to German pharmacies.

It has not yet been decided whether foreign mail-order pharmacies must also adhere to the German pricing scheme.

According to German pricing law, pharmaceuticals paid for by health insurers must have a uniform price. It is not permissible to sell them at a lower price or to promote their sale through incentives such as vouchers or other customer retention schemes. Currently, several lawsuits on this question are pending before the Federal Court of Justice against mail-order pharmacies located in other EU member states.

Mail-order pharmacies have been quite successful in their sale of OTC products, which has brought parties such as drugstore chains into play. As drugstores are prohibited from selling pharmaceuticals in Germany, they are particularly interested in the liberalisation of the regulations stipulating that OTC preparations can be sold only by pharmacies. It is reasonable to assume that the distribution of pharmaceuticals will be liberalised step by step in the coming years. [WTR](#)

Biographies

Friedrich Graf von Westphalen & Partners

Friedrich Graf von Westphalen & Partners
Partnership of attorneys, auditors and tax consultants
Kaiser-Joseph-Straße 284,
D-79098 Freiburg, Germany
Tel +49 761 21808 0 **Fax** +49 761 21808 500
Web www.fgvw.com



Norbert Hebeis
Partner
N.Hebeis@fgvw.com

Norbert Hebeis is a partner of Friedrich Graf von Westphalen & Partners, a partnership of attorneys, auditors and tax consultants. Mr Hebeis heads the firm's trademark department. Before joining Friedrich Graf von Westphalen & Partners, he was in-house trademark counsel with a large US pharmaceutical manufacturer, in charge of its European trademark department. During his years in the pharmaceutical industry, Mr Hebeis was a member of the Trademark Committee of the German Association of Research-Based Pharmaceutical Manufacturers. During this time he became acquainted with the political issues connected to pharmaceutical trademarks. Mr Hebeis holds a law degree from the University of Freiburg and a degree in political science from the *Institut d' Études Politiques* of Aix-en Provence, France. He has been a member of the Pharmaceutical Trade Marks Group, the European Communities Trademark Association and the International Trademark Association (INTA) for many years, and has given numerous presentations and written articles on trademark issues.



Morton Douglas
Partner
M.Douglas@fgvw.com

Morton Douglas is a partner of Friedrich Graf von Westphalen & Partners, a partnership of attorneys, auditors and tax consultants. Dr Douglas is a member of the firm's trademark department. Before joining Friedrich Graf von Westphalen & Partners, he was an assistant lecturer at the faculty of law at the University of Freiburg. During this time he wrote his doctorate, entitled "Trademark Exhaustion in the case of Parallel Imports of Pharmaceuticals". Dr Douglas holds a law degree from the University of Freiburg and a diploma in legal studies from Aberdeen University, Scotland. He has been a member of INTA and the German Association for the Protection of Intellectual Property, and regularly gives presentations and writes articles on trademark and other IP issues.