Germany

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Pharmaceutical trademarks in Germany, as elsewhere in the European Union, are governed by EU laws which are applicable in all member states. These include:

- the Community Trademark Regulation (40/94) and the Community Design Regulation (6/2002), which offer protection throughout the European Union; and
- the EU Trademarks Directive (2008/95/EC) (replacing the First Trademarks Directive (89/104/EEC)). The directive has been implemented into the national legislation of all 27 member states of the European Union.

In addition, decisions of the European Court of Justice (ECJ) and the Court of First Instance on trademark issues strongly influence the development of national trademark laws. EU law is also subject to interpretation by the national courts. In many areas, this leaves room for the national legislative bodies to impose additional – and often more restrictive – conditions.

Selection, clearance and registration

Relevant national and international regulatory bodies and requirements

Clearance should include trademark searches of (at least) the German register, international registrations and Community trademarks (CTMs). Searches should be conducted not only for identical goods, but also for similar goods and even services. Depending on the search strategy, Classes 3, 5, 10 and 44 (plus the 'old' Class 42) of the Nice Classification are considered to be most relevant. In order to minimize risks, a search of pharmaceuticals-in-use databases and of the Internet is also recommended, since there is no regulatory requirement for the registration of trademarks used in conjunction with pharmaceuticals. Therefore, there could be earlier unregistered rights. Nevertheless, registration is highly advisable from a legal point of view. Earlier marks in use may constitute obstacles at the regulatory level.

Under the German Trademark Law (*MarkenG*), which to a large extent reflects the EU Trademarks Directive, signs which are capable of being represented and are distinctive may in principle be registered as trademarks. There are three ways of obtaining trademark protection through registration in Germany:

- National applications may be filed directly with the German Patent and Trademark Office.
- An international registration with the World Intellectual Property Organization may be extended to Germany if there is a basic registration in another country that is a signatory to the Madrid Protocol or the Madrid Agreement.
- Germany is also automatically included in a CTM application filed with the Office for Harmonization in the Internal Market (such application may of course be filed from within Germany).

Pharmaceuticals marketed in Germany may obtain either a European marketing

authorization, which is granted by the European Medicines Agency (EMEA), or a national marketing authorization, which is granted by the German Federal Institute for Pharmaceuticals and Medicinal Products. EMEA's (Invented) Name Review Group, which consists of representatives from all EU member states, applies strict standards to name safety issues. Consequently, there is a rejection rate of over 50% for trademarks applied for in the context of marketing authorizations for pharmaceutical products.

Confusion with INNs

A trademark application will be refused or a registered mark will be cancelled if the mark:

- is confusingly similar to the corresponding international non-proprietary name (INN) and thus lacks distinctiveness; or
- must be kept free for use by competitors in the market.

However, on October 13 2004 the highest German civil court, the *Bundesgerichtshof*, ruled that the mark ROXIMYCIN was sufficiently different from the INN roxithromycin and could thus remain on the register (Case I ZB 10/02; see also the court's October 11 2001 decision (Case ZB 5/99), which involved the trademark OMEPRAZOK and the INN omeprazol).

Non-traditional trademarks

German practice with regard to non-traditional trademarks is restrictive. The courts have held that non-traditional trademarks such as taste or touch marks were not registrable. The refusal was based on the fact that such marks are not capable of being reproduced graphically in official publications or elsewhere in such a manner that third parties may assess the risk of infringement. With regard to pharmaceuticals, the authorities and the courts will refuse registration of both standard geometric shapes and colour combinations. In addition, abstract colour marks are almost impossible to register following the decision of the ECJ in *Postkantoor* (Case C-363/99).

This strict practice also applies to the registration of the three-dimensional shape of medical and medicinal devices. However, the protection of three-dimensional shapes or patterns is not limited to trademark law. Under EU and German law, protection may also be obtained by filing an application for a registered design. While there are numerous differences between the two types of industrial property right (eg, scope of the examination and duration), both have clear advantages and can be combined in order to obtain the best possible protection for proprietary shapes. In some cases, an unregistered Community design may even be cited as an earlier right. However, due to the length of development cycles in the pharmaceutical industry and the short period of protection of unregistered designs (three years), this is rarely the case.

Parallel imports and repackaging

Key issues

In principle, parallel imports, relabelling and repackaging within the European Union and the European Economic Area (EEA) (including the European Free Trade Association) are permitted. Parallel imports originating from states which are not members of either of these organizations are not permitted. To a large degree, parallel importation and repackaging are governed by EU law, as interpreted by the ECJ. The ECJ has clearly stated that both parallel imports and repackaging are permitted under EU law, since the invocation of trademark rights to prohibit such cross-border trade would represent an artificial barrier to the free movement of goods under Articles 28 to 30 of the EC Treaty. Nevertheless, the ECJ recently indicated in the *GSK-AEVE* decision (Case C-53/03, confirmed on September 18 2008 in Joint Cases C-468/06 and C-478/06) that while the refusal to supply pharmaceutical products in order to prevent parallel trade to other member states constitutes an abuse of a dominant position, this is not so in every case. Pharmaceutical companies are allowed to defend their economic interests and thus refuse to supply those that make orders which are out of the ordinary in terms of quantity.

A notable number of German decisions have dealt with this issue and defined the conditions under which parallel imports and repackaging may take place in Germany. The importer must notify the proprietor of the trademark in advance of its intention to import the goods and must provide the latter with samples upon request. Such advance notice must give the proprietor sufficient time to take action. Generally, a notice given 15 days prior to entering the market is deemed to be sufficient. If no advance notice is given, damages for trademark infringement may arise for the period between the date of entry of the goods into the market and the date on which the belated notice was given. However, it is not necessary to obtain the consent of the trademark proprietor in order to import the goods, as parallel imports are permitted by law if all the rules governing relabelling and repackaging have been complied with.

Repackaging is permitted only if it is legally required at the time of the sale of the product in order to gain entry to the market. Repackaging is not permitted if it is carried out only for the commercial benefit of the parallel importer. If repackaging, relabelling or bundling are necessary, the importer may use both the brand name and the trade dress of the original product in order to ensure that consumers do not reject the imported product. However, the importer must meet numerous conditions, the most important of which being the following:

- the pharmaceutical product must be in its original condition; and
- the packaging must clearly establish which entity is responsible for the repackaging, relabelling or bundling, as well as identify the manufacturer of the product.

Enforcement

In the event that the importer fails to notify the trademark owner or to comply with the requirements for parallel importation, injunctive relief in the form of an interim injunction is available. It is also possible to file an ordinary action before the civil courts. However, while the cost of litigation in Germany is reasonable compared with many other jurisdictions, damages are traditionally low. If an action is successful, the costs of legal representation may be recovered from the losing party only within strictly defined limits.

Anti-counterfeiting and enforcement

Prevention

In addition to employing prevention measures (eg, markers and other safety features), trademark owners may also file criminal actions and obtain damages against counterfeiters. While German Customs may be contacted directly, the limitation of border controls to the external borders of the European Union and the lack of internal EU border controls mean that Customs seizures and border control measures are far more effective at EU level. Applications for Customs actions may be filed for particular goods within member states. The authorities will then notify the proprietor of the trademark that suspected counterfeit goods have been seized. The proprietor will check whether the goods are genuine or counterfeit and the authorities will take action accordingly.

Enforcement
Following the entry into force of the IP Rights Enforcement Directive (2004/48/EC), which was implemented into the German national legislation on September 1 2008, the situation of trademark proprietors has changed considerably. Among other things, the directive has extended mark owners' rights to:

- secure evidence prior to taking legal action;
- obtain information from parties not directly involved in the counterfeiting activities;
- demand the recall of infringing goods;
- demand the disclosure of banking, accounting and trade documents in order to secure the payment of damages; and
- demand the publication of the court decision.

The directive also introduced a simplified procedure for the destruction of counterfeit goods, which does not require a binding judgment from a court of law.

Advertising
Pharmaceutical advertising in Germany is governed by:

- the legislation on unfair competition;
- the law governing the advertising of medicinal products; and
- to some extent, the self-imposed codices of the pharmaceutical industry (ie, the European Federation of Pharmaceutical Industries and Associations Codex and the German FSA Codex and BPI Codex).

The codices have been accepted as self-regulatory instruments by the German antitrust authorities. For example, cases involving infringements of the FSA Codex are adjudicated by the FSA Adjudication Board, which may impose financial penalties on infringing companies. The codices are also recognized by the majority of German courts as defining good commercial practice.

As far as advertising is concerned, there is a clear difference between prescription medicines and those sold over the counter (OTC). For prescription medicines, consumer (ie, patient) advertising is prohibited; for OTC products, advertising is possible only within closely defined limits. Advertising directed at healthcare professionals is allowed both for prescription and OTC drugs, but is also strictly regulated.

Generic substitution

Prohibition
No generic substitution is allowed while the pharmaceuticals are subject to patent protection. Once patent protection has expired, generic substitution is permitted and encouraged by the public health system.

Key considerations
During the lifetime of a patent, patent protection is guaranteed under German law. However, once patent protection has expired, the pharmaceutical product may be manufactured and marketed by other manufacturers. The cost structure of generics is such that they are considered to be a major source of savings in pharmaceutical expenditure; the distribution and sale of generic equivalents to prescribed medicines is thus officially supported by the German Federal Health Ministry. The generics must simply be of the same strength and have the same package size as the originally prescribed pharmaceutical product, and must also have a marketing authorization for the same indication. Off-label sales of generics are thus not allowed. The prescription of generics has been expressly included in the public budgets for pharmaceuticals.

Online issues

E-pharmacies
In Germany, it is legally allowed to sell only non-prescription pharmaceuticals to end consumers on the internet. The sale of prescription medicines must be carried out by pharmacies operating with the approval of the responsible authorities (ie, with the necessary permits).

Under German law, a permit is required in order to own and operate a pharmacy and up to three subsidiaries. The pharmacies must be located on premises that are expressly listed in the permit. In order to obtain a permit, the applicant must, among other things:

- be a trained and fully qualified pharmacist; and
- be a citizen of Germany, an EU member state or an EEA member state.

The applicant must be sufficiently reliable for the operation of a pharmacy. The permit creates a personal duty and responsibility to own and operate the pharmacy.

Ownership of a pharmacy by a company or legal structure – which would make it possible for a person (or persons) not qualified as a pharmacist to participate in the profits or earnings of a pharmacy – is strictly prohibited. Therefore, it is very difficult for internationally operating online pharmacies to enter the German market.

While this peculiarity of German law is being reviewed by the ECJ, the advocate general indicated in late 2008 that the German position is compatible with EU law.

Domain names
Registered pharmaceutical trademarks are protected against infringement by later domain names consisting of the mark, confusing names or generic additions, provided that:

- there is a link between the website attached to the domain name and the pharmaceutical industry; or
- it is obvious that there could be no other good-faith use of the mark (eg, if the domain name uses the well-known name of a multinational pharmaceutical company).

If the infringer is located in Germany, relief may be sought in the ordinary courts. If the action is successful, the infringer will be ordered to bear the costs of the winning party. This applies not only to '.de' (the German country-code top-level domain) domain names, but also to any domain names held by a party located in Germany.

A plaintiff may also have recourse to the Uniform Domain Name Dispute Resolution Policy or to alternative dispute resolution proceedings, which are relatively fast and cheaper than litigation. However, such proceedings do not allow for the recovery of costs.

Actively used domain names may also cause problems for newly developed trademarks. However, it is questionable whether simply linking a domain name to a corporate internet gateway is sufficient to demonstrate such use. WTR

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Michael Best is an attorney-at-law based in Frankfurt am Main. He studied law in Mainz, Germany and in Dijon, France. He worked as a scientific assistant at the University of Mainz for three years and wrote a doctoral thesis in trademark and unfair competition law during that time. He then worked as an auditing assistant at a large German auditing firm for two years before he became in-house counsel in the trademarks department of the chemical and pharmaceutical company Hoechst AG in 1992. He became deputy head of that department in 1997. In 1998, together with Robert Freitag, he founded the law firm Freitag & Best, which specializes in IP matters, in particular trademark protection and enforcement. Mr Best is a regular speaker at IP conferences and is a member of the International Trademark Association, the European Communities Trademark Association (ECTA), the Pharmaceutical Trademark Group and other IP organizations.

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Udo Pfleghar is an attorney-at-law based in Frankfurt am Main. He trained in Melbourne, Australia, and Regensburg, Germany, before being admitted to the Bar. Having worked in Munich for a specialist IP law firm, he went to Spain in 1999 to join the Office of Harmonization for the Internal Market (OHIM) in Alicante. He worked for several years as a senior trademark examiner at OHIM, dealing with opposition and cancellation proceedings, representing OHIM before the European courts in Luxembourg and training new staff. On his return to Germany in 2004, he joined the pharmaceutical company Boehringer Ingelheim, where he was responsible for all matters related to trademarks, designs and domains as head of the trademark and domain law group. Mr Pfleghar recently joined Freitag & Best as a partner. He is a member of ECTA, the German Association for the Protection of Intellectual Property and other professional organizations.