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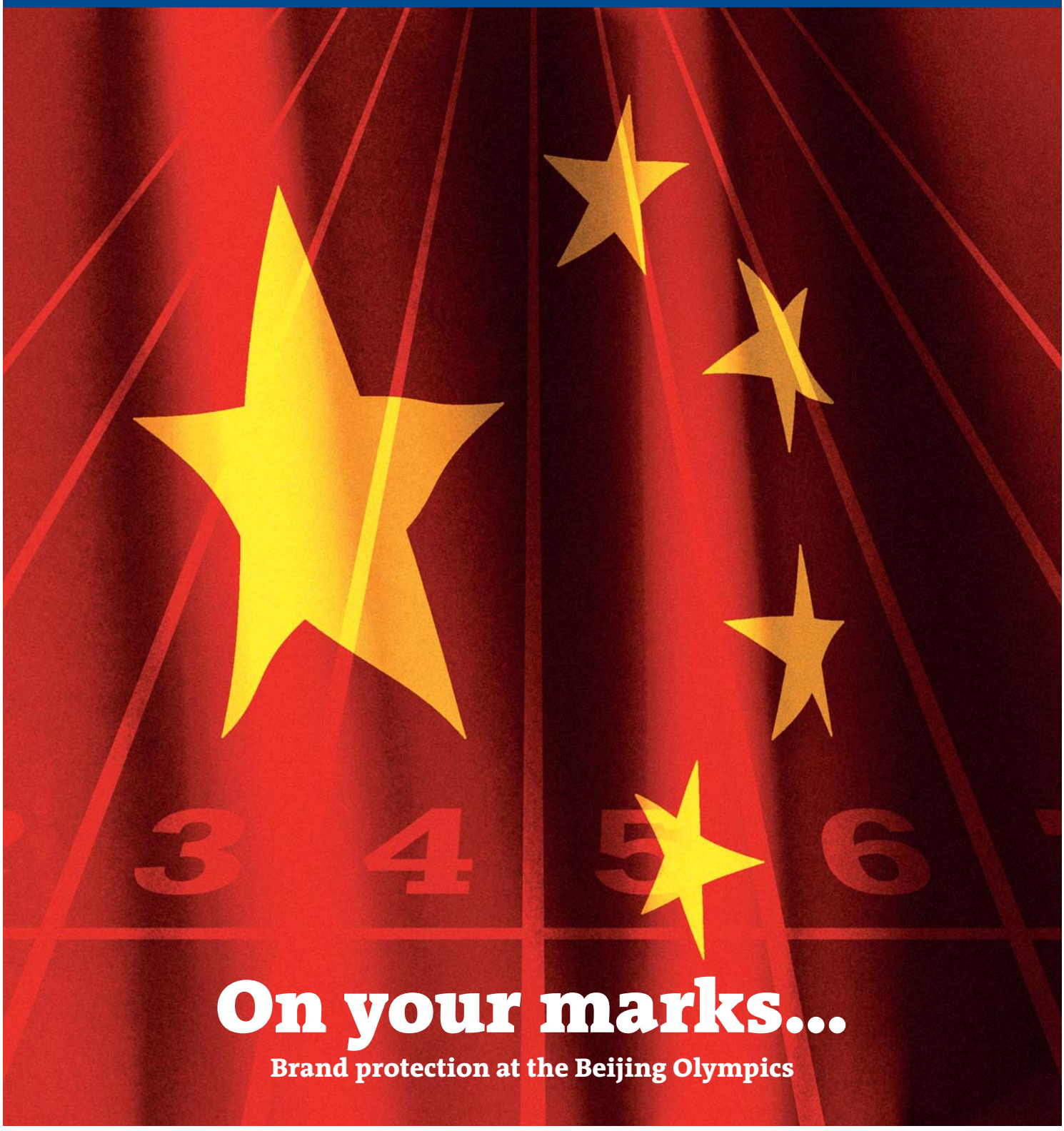

On your marks...

Brand protection at the Beijing Olympics

Jonas Rechtsanwaltsgesellschaft mbH

Pharmaceutical trademarks in Germany

Unlike marks in most other business fields, pharmaceutical trademarks are affected by regulatory law. In Germany, this influence accompanies the trademark throughout its existence. The owners of pharmaceutical trademarks therefore face a number of specific questions – not only when registering a trademark, but also in connection with maintaining and defending it

Trademark registration

Similarity with INNs

Aside from bearing distinctive trademarks that identify each individual product to healthcare professionals and end users, pharmaceuticals have a unique but generic international non-proprietary name (INN), which identifies the active ingredient and thus assists healthcare professionals in identifying the drug's pharmacological properties.

As an INN is unique but also generic, a trademark that is similar to an INN may be rejected by the trademark authorities for being descriptive of a quality of the product. The authorities must determine:

- whether a proposed registration is a coined derivative of an INN which can coexist with it; or
- whether it is too close to the INN and therefore barred from protection.

After two changes in German trademark practice – from a rather relaxed test to a strict one and back to relaxed – the authorities must ask themselves:

- whether the trademark is capable of being directly confused with the INN;
- whether business circles that are aware of the INN will immediately recognize it in the trademark; and
- whether the trademark raises the expectation that persons not knowing the INN will immediately recognize it in the trademark once they have knowledge of the INN.

The examination practice shows that there must be more than just minimal differences between the mark and an INN, but there can be quite a close correlation. Accepted trademarks include METOPROLOC (INN: Metoprolol) and rejected trademarks include ILUPROST (INN: Iloprost).

Abbreviation of INNs

The Federal Patent Court recently held that an abbreviation of an INN (eg, 'Simva' for 'Simvastatin') can qualify for registration as a trademark since INNs – which are already simplified translations of compound chemical names – are usually not further abbreviated (30 W (pat) 40/05 of October 16 2007). The court noted that there might be an exception to this rule, in certain circumstances, if evidence exists that further abbreviation is common practice among the healthcare professionals.

Trademark maintenance

If a trademark which is registered for the class heading "pharmaceutical preparations and substances" is used only for a specific drug, the question comes up for which goods the trademark is genuinely used: the specific drug, the entire class heading or something in between? Having taken the two extreme positions in the past, the Federal Patent Court has now adopted a middle course gearing to the group of pharmaceuticals with the same therapeutic indication (ie, antibiotics, analgesics, cytostatics and so on) – a view that has been confirmed by the European Court of First Instance in *RESPICORT/RESPICUR* (Case T-256/04, December 13 2007). Since consumers are searching primarily for a product which can meet their specific needs, the purpose or intended use of the product in question is vital in directing their choices. The purpose and intended use of a therapeutic preparation, however, are expressed in its therapeutic indication, while the dosage form, the active ingredient and the obligation to obtain a doctor's prescription are, as a rule, inappropriate for defining a sub-category of goods as the application of those criteria does not fulfil the criteria of purpose and intended use of the goods.

In case of use of the trademark for pharmaceutical preparations covering several therapeutic indications, the trademark is considered used only for these indication categories (or, if it exists, a more general category covering the several indications) – not for the class heading "pharmaceutical preparations" in its entirety (Federal Supreme Court, Case I ZR 110/03 – "*Ichthyol II*", June 29 2006). Otherwise, the court reasoned, trademark owners that have registered the class heading would enjoy an unjustified advantage over trademark owners that have restricted the registration to the goods of actual use.

Marketing authorization

Drug law requires that the applicant of a marketing authorization must name the trademark under which the pharmaceutical will be sold. Even though the trademark may be changed, the applicant runs the risk that the trademark becomes subject to use requirements while the proceeding for marketing authorization is still pending. The Federal Supreme Court originally solved this dilemma by holding that the naming of a trademark in the proceeding for marketing authorization constitutes an actual use of the trademark. The court later changed its position and qualified the naming as a *justified* non-use in the meaning of Article 10(1) of the EU First Trademarks Directive (89/104/EEC) (Case I ZB 17/97 – "*IMMUNINE/IMUKIN*", November 24 1999).

Definition of 'pharmaceuticals'

Depending on the individual product sold under the trademark and the wording of the specification of goods of the trademark, it can be questionable whether a trademark that is protected for Class 5 goods – usually including class headings such as "pharmaceutical preparations and

substances, dietetic products for medical purposes" – is actually used for these goods. The reason is that it can be difficult to distinguish properly between pharmaceuticals of Class 5 on one side and food products of Classes 29 and 30 in particular, as well as cosmetics or medicinal products of Classes 3 and 10 on the other side.

Thus, it is common trademark practice to refer to regulatory law definitions.

The definition of a 'pharmaceutical' is not clear, notwithstanding its inclusion in EU Directive 2004/27/EC relating to medicinal products for human use. In particular, the meaning of 'function pharmaceuticals' – defined as "any substance or combination of substances which may be used... either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis", which practice has applied with a focus on "pharmacological action" – is less clear than it may seem. In the past, the courts have used the 'rule of doubt' of Article 2(2) of Directive 2004/27/EC to qualify, in case of doubt, the preparation concerned as a 'pharmaceutical'. The Federal Court of Administrative Law recently made another attempt to shed some light on the definition, but in doing so, it raised new questions. An attempt by a court of appeal to leave behind all the difficulties in defining a 'pharmacological', 'immunological' or 'metabolic effect' by simply gearing to the capability of the product to fulfil a therapeutic purpose was overruled by the Federal Court. The Federal Court broadened the definition of a 'function pharmaceutical' to include not only preparations with a "therapeutic purpose", but also preparations which "re-install, correct or influence the normal activities in a human body" (Cases 3 C 21.06 – "*OPC*"; 3 C 22.06 – "*Vitamin E 400*" and 3 C 23.06 – "*Lactobact Omni FOS*", July 25 2007).

In this way, the difficulties of regulatory law can extend to trademark law in borderline cases when trying to state whether a trademark is used for the goods for which it has been registered. Consequently, trademarks for borderline preparations should be registered for both Class 5 goods and goods in Classes 29/30 or 3 and 10 goods, and in a sufficiently detailed way to ensure that no matter which definition the product concerned will be classified under, it is covered by the trademark registration.

Trademark defence

Business circles concerned

The likelihood of confusion between two trademarks can depend much on the knowledge and attentiveness of the relevant business circles. While the German courts look at the end users if non-prescription drugs are concerned, they tend to focus on the more attentive and skilled health professionals, such as doctors and pharmacists, if the preparation is a prescription-only pharmaceutical; but they also point out that the end user, who is generally regarded as particularly attentive and circumspect in the choice of all products that are related to health and medical care, should not remain unconsidered.

Insofar, the European Court of Justice (ECJ) pointed out in *TRAVATAN/TRIVASTAN* (Case C-412/05, April 26 2007) that the involvement of skilled professionals in the *distribution* of prescription-only pharmaceuticals (ie, the pharmacist delivering the pharmaceutical products) does not exclude the possibility that end users can influence (and mislead) by way of wishes and preferences the *prescription* of the pharmaceutical.

This should lead to a consideration of the end users only. Any reduced likelihood of confusion is then no longer related to special skills of professionals, but to special interest and attentiveness of end users in health matters. It remains to be seen whether the German courts will abstain from referring to health professionals in future.

Parallel imports

Pharmaceuticals are expensive in Germany – more so than in other countries of the European Union. Therefore, parallel imports play a particular role in the pharmaceutical business in Germany. The relevant criteria for the prohibition of parallel imports have been established by the ECJ. However, some details are still to be settled by the national courts. They also depend on the regulatory framework of the law on public health. For example, the use of certain sizes of packaging and potential trademark conflicts may obstruct imports of the pharmaceutical in differing package sizes from other EU countries, justifying a bundling or even re-packaging of imported pharmaceuticals. However, the possibility for pharmacists to replace the prescribed preparation by a cheaper one – unless expressively prohibited in the prescription – may avoid a predicament that is a condition for the re-branding of an imported pharmaceutical. Thus, further referrals to the ECJ can be expected. And these referrals may well continue to originate from German cases. WTR

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