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Key issues of pharmaceutical trademarks

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Key issues of pharmaceutical trademarks

Due to their importance to public health, pharmaceutical trademarks are affected not only by IP law, but also by regulatory law. Trademark owners must thus be prepared to tackle questions which are often rooted in the political, financial or technical context

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Unlike marks in most other business fields, and due to the dichotomy between rights ownership and public safety, pharmaceutical trademarks are affected by regulatory law. This influence accompanies the trademark throughout its existence. Pharmaceutical trademark owners therefore face a number of specific questions which often have their background in political, financial or technical conditions and circumstances – be it ongoing reforms of social security systems, changes in ethical rules or the challenges of the Internet. Within this context, key issues of pharmaceutical trademarks arise in relation to trademark protection as well as trademark defence.

The different purposes of trademark and pharmaceutical law

Both trademark law and pharmaceutical law seek to prevent potential confusion in the relevant business circles (patients and medical professionals) due to similarities between conflicting trademarks. However, the respective perspectives are very different.

Trademark law is not intended to protect the public against medication errors. It rather aims to protect the business interests of the trademark owner in securing the identification of its products, thereby informing the patient's or doctor's decision as to which product to buy or prescribe, and securing the commercial success of the product. Otherwise, it would not be possible for the owners of conflicting trademarks to resolve their disputes by restricting the use and coverage of their marks in such a way as allows them to coexist. In entering into a coexistence agreement, the owners of conflicting trademarks often commit to use their marks in different therapeutic areas, in order to ensure that the trademarked products of one rights owner cannot accidentally be confused with the other's.

Under pharmaceutical law, the key issue is the danger that the accidental use of a trademarked product in a different therapeutic area could result in serious health risks. In its Guideline on the Acceptability of Names for Human Medicinal Products Processed through the Centralised Procedure, issued on 11th December 2007, the European Medicines Agency (EMEA) explicitly stated that its primary concern is the public health issues arising from the names of medicinal products and any conflicts with existing names, rather than any potential trademark infringement issues.

These differing perspectives can sometimes lead to conflicting results. Where similar trademarks are used for the same medical indication, the matter becomes a trademark issue; where similar trademarks are used for different medical indications, the matter becomes a health safety issue.

Even with considerable search efforts, it is increasingly difficult to come up with new pharmaceutical trademarks, due to the distance which must be maintained from

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existing third-party marks and the multitude of trademarks already on the market. Each change in examination practice is a double-edged sword for trademark owners: while they may benefit from a stricter practice when defending their trademarks against later marks, they will suffer when applying for registration of a new trademark and faced with existing third-party trademarks.

Assessment of the relevant public

It is thus unsurprising that a key issue in balancing the various interests is the proper assessment of the relevant public. This assessment centres on two sets of criteria: end users versus health professionals and prescription-only preparations versus over-the-counter preparations. The likelihood of confusion between two trademarks can depend significantly on the levels of knowledge and attentiveness that characterise the relevant business circles. In general, the courts regard patients as the end users where over-the-counter pharmaceuticals are concerned, and tend to focus on doctors and pharmacists as skilled health professionals where prescription-only pharmaceuticals are concerned. However, some uncertainty arose after it was admitted that consideration should also be given to the end user, who is generally regarded to be particularly attentive and circumspect in choosing products relating to health and medical care, in the case of prescription-only products also – a finding that raises more questions than it answers. The European Court of Justice (ECJ) has since pointed out, in *TRAVATAN/TRIVASTAN* (Case C-412/05, 26th April 2007), that the involvement of skilled professionals in the distribution of prescription-only pharmaceuticals does not exclude the possibility that end users can influence the actual prescription of the pharmaceutical (eg, when preferences are expressed by the patient). This should lead to a consideration of the end user in all cases. Any reduced likelihood of confusion can then no longer relate to the special skills of professionals, but only to the special interest and attentiveness of end users in health matters. It remains to be seen whether the European courts will thus refrain from making any reference to health professionals in future – with a stricter approach regarding conflicting trademarks.

Similarity of trademarks and international non-proprietary names

In addition to distinctive trademarks that identify each individual product, 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. Pharmacologically related substances have an INN with a common stem to allow for recognition of similar pharmacological effects in different products.

As an INN is generic, an application to register a trademark that is similar to an INN may be rejected as being descriptive of a quality of the product and therefore a term that cannot be monopolised. In this regard, the trademark is compared with the INN in its entirety, not only with regard to the stem. 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 is therefore barred from protection. The key criterion is not whether the trademark may mislead the relevant public as to the product's pharmacological effect, but rather whether the trademark, if registered, would monopolise a term that needs to be kept free for general use. The trademark examination practice of, for example, Germany – as the

third largest pharmaceutical market in the world and the largest in Europe – shows that there must be more than just minimal differences between the mark and an INN, but that there can nonetheless be quite a close correlation.

The EMEA and the national health authorities which grant marketing authorisations for medicinal products have another approach to INNs. As the names of medicinal products must not be liable to confusion with an INN, and as pharmacologically related substances have INNs with a common stem, the EMEA will examine the closeness of a suggested trademark with its own or a different INN – taking into consideration in particular any similarity in the medical indication of the product and its supply and administration – to ensure that any similarity of a trademark component with an INN stem is not misleading as to the pharmacological effect of the medicinal product.

Thus, a trademark accepted by the trademark authorities may still be rejected by the health authorities.

Over-the-counter products and the definition of "pharmaceuticals"

In the first instance, the definition of "pharmaceuticals" is an issue of pharmaceutical law with relevance in court cases mainly to over-the-counter products – in particular, nutritional supplements, vitamins and mineral preparations. It determines whether a certain product is a pharmaceutical product and is therefore subject to an expensive and time-consuming proceeding to obtain a marketing authorisation, or rather a food product which can be sold without permission from the authorities. However, the definition can also become a trademark issue, as a trademark registration usually covers entire groups of products, such as "pharmaceutical preparations and substances, dietetic products for medical purposes", even though the trademark is then used for one particular preparation only. The trademark must be used for the registered goods within a certain period following registration in order to maintain its protection. The question may then arise as to whether the trademark has in fact been used for the registered goods – "pharmaceutical preparations and substances" – if the relevant product might actually be a food product. The same issue can arise if the manufacturer has undertaken (eg, through a trademark coexistence agreement) to use its trademark for certain pharmaceuticals only; or if the product might be a cosmetic or medicinal product rather than a pharmaceutical. In such cases it is common trademark practice to refer to definitions of the regulatory law.

The definition of a "pharmaceutical", however, is unclear, 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 is applied with a focus on pharmacological action – is less clear than it may seem. Judicial attempts to shed light on the definition often turn out to be unhelpful, as they raise new questions and make arriving at a clear definition an ongoing project.

Consequently, trademarks for borderline products should be registered for both possible categories in a sufficiently detailed way as ensures that the product is covered by the trademark registration regardless of how it is defined.

Parallel imports

Parallel imports remain a key issue, particularly in Germany and the United Kingdom, where pharmaceuticals are more expensive than elsewhere in the European Union. The ECJ has established the relevant criteria for a justified prohibition against parallel imports, but certain issues remain to be clarified. In particular, as a result of questionable statements by the ECJ, there are still questions in relation to the rebranding and repackaging of imported pharmaceuticals. Unfortunately, national courts have repeated and thereby corroborated these statements, instead of challenging them.

In *Bristol-Myers Squibb* and *Boehringer* the ECJ stated that a trademark owner must tolerate the rebranding of imported pharmaceuticals if, among other things, the rebranding "is necessary in order to market the product in the member state of importation" (Case C-427/93, 11th July 1996 – *Bristol-Myers Squibb v Paranova*; C-348/04, 24th April 2007 – *Boehringer v Swingward*) – however, not only "if necessary", but also "only in so far as necessary". Nevertheless, the ECJ did not consider the use of the product's INN combined with the importer's name as an option for the rebranding – something which is quite common for generic products

and will become even more so as a result of the private labels of pharmacy cooperations and franchise systems. An obligation imposed by the health insurance or social security systems for the pharmacist to replace a prescribed preparation with a cheaper one (the imported product), except where expressly prohibited in the prescription, may avoid a predicament that is a condition for rebranding of an imported pharmaceutical. The parallel importer thus has an option to market the product in the EU member state of importation without using the manufacturer's trademark – something which is less harmful to the trademark and avoids a *de facto* compulsory licence to the manufacturer's trademark.

In its *Aventis* decision (C-433/00, 19th September 2002 – *Aventis v Kohlpharma*), the ECJ allowed for an imported pharmaceutical to be repackaged to create a unit of bigger size, instead of being bundled in original packs, where the pharmaceutical was subject to a central marketing authorisation granted by the EMEA. However, the ECJ's argument that bundled packs of preparations with central marketing authorisation would form a new pack size that was not covered by the marketing authorisation is questionable, as each of the bundled packs would retain its character as a pack in itself, with its own marketing authorisation. In this case also, bundling would thus be the less harmful alternative to repackaging.

It remains to be seen whether parallel importers will still be able to exploit such gaps in trademark protection if the proposed new EU directive regarding the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source (Doc No KOM (2008) 688) of 10th December 2008 becomes a reality. The European Commission stopped short of imposing a ban on repackaging: the proposal now provides for the use of safety features, such as seals, which make it possible to identify, authenticate and trace medicinal products, but which would allow for resealing in the event of repackaging.

Counterfeits and the Internet

The sale of counterfeit or otherwise unauthorised pharmaceutical products is another key issue. Online pharmacies range from legitimate outlets to murky operations selling illegally. The dramatic increase in counterfeit pharmaceuticals is not only a trademark issue, but also a health issue, as counterfeit products at best are often of poor quality and at worse can cause serious damage to health.

Although the law is on the side of the trademark owner, the identification of counterfeits, the individuals who sell them and the jurisdictions in which they are sold is often difficult and requires significant effort. Even then, it may be difficult to enforce the law. It is thus important to cooperate closely with the authorities, beginning with an application to the customs authorities for the seizure of products which are likely to be counterfeit. *iam*

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