Zacco

Denmark

As with all EU member states, Denmark tightly regulates the use of pharmaceutical trademarks. This analysis examines how Denmark has aligned itself with the EU model

The Danish market for pharmaceutical products is heavily regulated in accordance with EU law. Also the law relating to pharmaceutical trademarks is largely harmonized in the European Union. The following analysis looks at some of the general issues relevant to owners of pharmaceutical marks and their advisers under Danish law and practice.

Pharmaceutical products

Pharmaceuticals include all products which are either presented as a preparation for the treatment or prevention of a disease or which can be used for humans or animals to restore, change or affect a physiological function or to make a medical diagnosis. Once a product has been categorized as a pharmaceutical by the Danish Medicines Agency (*Lægemiddelstyrelsen*) its status cannot be altered, irrespective of whether there is a change in the marketing of the product. It is vital to determine whether the product is in fact a pharmaceutical and, if not, make sure that the product is not presented as such in the marketing thereof.

Regulatory approval

Pharmaceutical products can legally be distributed in Denmark only if a marketing authorization has been issued either by the Danish Medicines Agency or by the European Medicines Agency. When examining an application for marketing authorization the Medicines Agency considers not only the preparation itself but also the proposed trade name(s).

The Medicines Agency performs a search for confusingly similar trade names in its own register and applies a test of similarity which shares traits with, but is totally independent of, the test applied under trademark law. If the proposed trade name is neither confusingly similar to earlier trade names nor misleading, the trade name is approved for the preparation for which the marketing authorization is granted. Not only is the test of similarity applied by the Medicines Agency independently of the test under trademark law but the Medicines Agency also generally disregards trademark rights during its examination process.

When planning the launch of a pharmaceutical product it is thus important to clear the potential trademarks against prior marks as well as prior trade names approved by the Medicines Agency. Moreover, applicants must secure a priority date with the Medicines Agency and the Patent and Trademark Office (PTO) by filing an approval for marketing authorization and trademark registration, respectively.

The grant of a marketing authorization alone does not mean that the trade name can be used, as it may still infringe prior trademark rights. Similarly, owning a trademark registration does not guarantee that the mark can be used, as it may not be possible to obtain marketing authorization due to a prior application proposing a similar trade name. It is important to note that the Danish Medicines Agency will not accept a trade name that is confusingly similar to a trade name approved within the past 10 years irrespective of whether the earlier name is actually in use.

Marketing of pharmaceutical products

The marketing of pharmaceutical products and thus the use of pharmaceutical trademarks must comply with the Medicines Act as well as with the general provisions of the Marketing Act.

Infringement

Both the PTO and the courts assess the risk of confusion between pharmaceutical trademarks on the basis of a global appreciation of the marks. In principle, no special test is applied in relation to pharmaceutical trademarks compared to other marks; nevertheless, particular attention is given to the nature of the products and the likely purchasers.

Prescription-only medicines are prescribed and distributed by professionals who are expected to pay attention even to small differences between trademarks. However, the same medicines are later stored and used by ordinary consumers who are not expected to pay attention to such differences and for whom confusion may have severe consequences on their health and safety.

Some jurisprudence has built up in Denmark which suggests that, in the case of pharmaceutical marks, the relevant public for an assessment of the likelihood of confusion is the healthcare professional. Such decisions tend to allow for the coexistence of trademarks which would not have been allowed to coexist if the definition of 'relevant public' had included end consumers. However, Danish case law is still far from settled, as highlighted by the following cases.

In *AstraZeneca v GEA* (Case V-82-00, May 27 2002) METOZOC was found to infringe the well-known trademark SELO-ZOK. Both marks were used and registered for preparations for the treatment of cardiovascular diseases, and were prescribed for similar indications. When comparing the marks the court referred to the fact that healthcare professionals supply prescriptions to pharmacies by telephone and that prescriptions are often renewed following a telephone conversation between a patient and the healthcare professional's secretary. The court noted that, in the latter case, it was likely that the patient would remember only the distinctive suffix 'zok'.

In *Ferring v Patent and Trademark Appeal Board* (Case V-112-02, May 2 2003) PERTANZA was found to infringe the mark PENTASA. PENTASA was used for a prescription-only preparation for gastro-intestinal diseases whereas the PERTANZA mark applied to, and was used for, an anti-depressant available only on prescription. As both products were prescription preparations, the court held that the relevant public for assessing the risk of confusion included healthcare professionals, their secretaries, pharmacists and patients, all of whom often communicate by telephone, which in practice could lead to confusion between the trademarks.

In *ScanVet v Pharma Nord* (Case V-8-04, January 30 2006) use of the generic term 'glucosamine' in connection with the

established trade name Pharma Nord (to create the mark GLUCOSAMIN PHARMA NORD) was found not to infringe the registered trademarks GLUCOSAMIN PHARMA and GLUCOSAMIN NORD. Both of the registered trademarks were found to be distinctive for glucosamine and pharmaceutical preparations including glucosamine.

In *Novartis v Patent and Trademark Appeal Board* (Case V-16-07, October 16 2007) MITIZAX was found not to infringe MINIMAX. MINIMAX was registered for, among other things, "pharmaceutical, veterinary and sanitary preparations and substances" and used for a nutritional beverage for children, whereas the mark MITIZAX covered "pharmaceutical and veterinary preparations for the diagnosis, prevention and treatment of allergies" and was intended to be used for a preparation for the treatment of allergies to house dust mites.

Parallel imports

Over the years, the courts have issued a number of decisions on repackaging and co-branding of parallel-imported products. Recent cases are in accordance with the jurisprudence of the European Court of Justice (ECJ). For example, following the ECJ's decision in *Boehringer II* (Case C-348/04, April 26 2007), the Danish Supreme Court ignored established case law and overturned the decision of the Maritime and Commercial Court so as to harmonize Danish practice with the prevailing approach in the European Union (*AstraZeneca v Paranova* (Case 72/2005, December 3 2007)).

The matter concerned Paranova's parallel importation of AstraZeneca's preparation for the treatment of asthma with the active component bambuterol, which was marketed in Denmark under the trademark BAMBEC. The product was repackaged, de-branded and marketed by Paranova under the trademark BAMBUTEROL PARANOVA. Further, it was stated that the preparation corresponded to Bambec.

The Supreme Court referred to the decision of the ECJ and applied the latter's test to determine whether the form of the repackaging (AstraZeneca had consented to repackaging but had not accepted the specific form of repackaging employed) would cause damage to the trademark owner. The court concluded that no damage would occur to AstraZeneca or the reputation of the trademark BAMBEC.

Enforcement

As with other trademarks, pharmaceutical marks can be enforced by instigating infringement proceedings or by requesting a preliminary injunction.

An injunction is an effective remedy to block the use of an infringing trademark but is rarely used in the case of pharmaceutical marks. Most disputes between such marks are resolved before the product bearing the conflicting mark comes onto the market. The majority of cases heard by the courts stem from decisions of the Patent and Trademark Appeal Board. The very few infringement disputes involving pharmaceutical marks that are heard by the courts tend to relate to generics or trademarks for borderline pharmaceutical products.

Counterfeits

The importation of counterfeit pharmaceutical products is increasing and now covers a variety of drugs. If a customs surveillance of the relevant trademark is in place and Customs uncovers a shipment of counterfeit pharmaceuticals, the shipment is suspended under the EU Customs Regulation (1383/2003) and Customs informs the Medicines Agency (since importation of medicines also requires authorization). Where the products are found to be counterfeit or lacking appropriate authorization they are destroyed either by the trademark owner with the consent of the receiving party or by the Medicines Agency. WTR

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Zacco is one of Europe's largest IP consultancies with more than 600 employees in Denmark, Germany, the Netherlands, Norway and Sweden. Together with its associated law firms, Zacco provides a full range of IP services, including IP management, filing and prosecution, litigation, licensing and portfolio management services.