Edwards Angell Palmer & Dodge LLP

Looking at the bigger picture

The EU regime casts a heavy shadow over the UK pharmaceutical practice

The pharmaceutical sector is extensively regulated at EU level in order to ensure that the medicinal products manufactured and distributed are safe, effective and of the highest quality. As part of the European Union, UK pharmaceutical companies have to be mindful of European law.

Given the extensive regulation of the pharmaceutical industry, there is more to branding a new pharmaceutical product than simply choosing a marketable new name. In addition to the regulatory criteria which must be satisfied, manufacturers of new medicines seeking trademark protection across the European Union must satisfy the requirements of the Office for Harmonisation in the Internal Market (OHIM). Some accuse OHIM of allowing public policy concerns to affect its decisions when dealing with trademarks in the pharmaceutical sector. Whether OHIM treats trademarks for pharmaceuticals differently from those trademarks in other sectors is a hotly debated issue.

The European Medicines Agency is tasked with the protection and promotion of public health, and is responsible for evaluating and supervising medicines for use. It is also the regulatory body responsible for authorising the names of new pharmaceutical products. According to guidelines adopted by the agency, no pharmaceutical name should:

- express misleading therapeutic or pharmaceutical connotations;
- misinform with respect to the composition of the product;
- have the potential to be confused in speech, handwriting or print with the name of another product;
- have the potential to be confused with generic names; or
- convey promotional messages or appear to have an offensive connotation in any of the official European languages.

The agency will reject any name which conflicts with an international non-proprietary name (INN), the unique name selected by the World Health Organisation for each active substance to be marketed as a pharmaceutical. The basis of the INN system is patient protection: the selection of a single name of worldwide acceptability is designed to assist in the clear identification, safe prescription and dispensing of medicines to patients.

According to the latest figures made available by the agency, in 2008 43% of names reviewed by the agency's Name Review Group were rejected. The most common reasons for rejection are:

- similarity with an existing, invented name;
- similarity with the drug's INN; and
- the conveyance of promotional or misleading messages about the product.

However, the agency's assessment is independent of the assessments carried out by OHIM for trademark registration. Even if a proposed name is accepted by the agency, it must still satisfy the criteria set out by OHIM before it can be registered as a Community trademark (CTM).

Registration with OHIM

A new application for a CTM is first examined by OHIM on absolute grounds. In order to qualify for registration, a trademark must, most significantly, be distinctive and capable of being represented graphically. Therefore, proposed trademarks which comprise or incorporate, for example, the drug's active ingredient, Latin elements describing an illness or an ingredient, or a play on dosing instructions will be rejected by OHIM on absolute grounds.

However, examples of inconsistencies to this approach can be found on the OHIM register. For example, OSTEOCARE in Class 5 has been registered for "Pharmaceutical preparations, vitamin and mineral and nutrient preparations; all for the prevention of bone deficiency", despite the seemingly obvious relationship of the word 'osteo' with bones and 'care', a common English word with an ordinary meaning. In another interesting decision OHIM ruled that the mark PARAZEET, for anti-parasitic products in Class 5, was not descriptive.

As for all other CTM applications, once the application has been accepted by OHIM as registrable on absolute grounds, it will be published for opposition purposes. The opposition period is three months and the CTM application may be opposed by the owner of a prior CTM or national right in an EU member state where the new application is confusingly similar to the existing mark or, if the prior mark has a reputation, where the new mark takes unfair advantage of or is detrimental to the distinctive character or repute of the earlier mark.

It is established case law that where the goods or services are intended for both professionals and end consumers, the relevant public must be deemed to be composed of both categories. This is the case for pharmaceutical products where the relevant public is composed of healthcare professionals and patients, despite the fact that the end users (ie, the patients) are either influenced or have no choice in the selection of the product (European Court of Justice, Alcon/OHIM-Biofarma, C-412/05 P, paragraphs 56-61, April 26 2007). However, OHIM has made clear that it is concerned only with the potential for confusion regarding the commercial origin of the goods. Consideration of the harmful consequences linked to the incorrect use of a pharmaceutical product as a result of confusion regarding the identity or

characteristics of the goods are not relevant from a trademark perspective. Even an above-average level of attention is insufficient to exclude a likelihood of confusion where the goods at issue:

- are of the same nature;
- have the same purpose (ie, to treat human health problems);
- are aimed at the same public (ie, healthcare professionals and patients); and
- use the same distribution channels.

For example, the EU General Court upheld a decision of the Fourth Board of Appeal of OHIM to refuse registration of the mark E-PLEX for goods in Class 5, due to the likelihood of confusion with the earlier registered mark EPILEX for "anti-epileptics" in Class 5, even when the applicant subsequently restricted its specification of the goods to exclude anti-epileptic medicines (*Longevity Health Products Inc v OHIM* (Case T-161/10, May 24 2011). This is particularly true where the marks are highly similar visually and phonetically, as in the case of KREMEZIN and KRENOSIN, where the EU General Court upheld an OHIM Board of Appeal decision of a likelihood of confusion (*Kureha Corp v OHIM*, Case T-487/08, June 16 2010).

Despite claims that OHIM's approach to assessment differs between pharmaceutical and non-pharmaceutical trademarks, the recent EU General Court decision concerning SEROSTIM and SEROSLIM indicates the contrary (*Market Watch Franchise & Consulting, Inc v OHIM,* Case T-201/08, September 28 2010).

The court rejected the argument that in the case of pharmaceutical names with a chemical basis, minute deviations can have decisive importance. The court concluded that the relevant public would view the marks as "coined terms which do not have any particular meaning", and that the marks were so similar visually and phonetically that the one difference between them, the sixth letter, could "even be overlooked or misheard". The court held that there was likelihood of confusion where the goods were identical and even where there was a low degree of similarity in respect of "soaps, hair lotions and dentifrices" in Class 3.

It is the overall impression created by the whole mark which is relevant, rather than its various elements, and OHIM has shown a tendency to give prevalence to prefixes when assessing the likelihood of confusion. In the case of the marks RNAiFect and RNActive, the Court of First Instance held that although the prefixes of the two marks were identical, attention would be drawn to the more distinctive endings of the words and the clear difference in pronunciation (*CureVac GmbH v OHIM*, Case T-80/08, October 28 2009). Even marks which have identical components can be distinguishable where the other components offset the similarity of the marks. This approach was used to reach a more surprising decision of no similarity or likelihood of confusion in the case involving CIDINE and HELICIDINE (*Ajinomoto Omnichem v Almirall-Prodesfarma SA*, Case R-1645/2007-2, May 27 2009).

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Anti-counterfeiting

The European Commission has introduced new legislation concerning falsified medicines which must be implemented by EU member states by January 2013. While the new legislation deals with "falsified" rather than "counterfeit" medicines, the introduction of harmonised, pan-European measures to ensure the safety of medicines and rigorous control of trade in medicines will inevitably affect the ongoing battle against counterfeiting. The key elements of the new measures are as follows:

- Importers, manufacturers and distributors must all register as brokers of medicinal products with the competent authority of the EU member state in which they are established.
- All active substances intended for use in medicinal products, whether manufactured in the European Union or imported, must be manufactured in accordance with good manufacturing practice and distributed in accordance with good distribution practice.
- Internet sellers must be registered and the website must display a common logo with a link to official national registers to make it easier to identify legal online pharmacies.
- Manufacturers must inform competent authorities about products that they suspect of being falsified, so that they may take measures aimed at preventing such products from entering into circulation.
- The packaging of prescription medicinal products must display certain safety information to demonstrate the authenticity of the products and display evidence of tampering, even if the products are legally repackaged.

The guidelines also include the development of a pan-European early warning system, which sends alerts to all member countries and distribution chains when falsified products are discovered. WTR