United Kingdom

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Selection, clearance and registration

In the United Kingdom, pharmaceutical trademarks are governed by both trademark law and industry regulation. The relevant trademark legislation is the Trademarks Act 1994, while the relevant regulatory authority is the Medicines and Healthcare Products Regulatory Agency (MHRA). One cannot discount the role of the European Medicines Agency (EMEA), as EU-wide approval is mandatory in some therapeutic areas.

Trademarks

To avoid delays to product launch, proposed brand names should be cleared and registered approximately two years before launch.

Inherently non-distinctive marks, including pharmaceutical names that are identical (or virtually identical) to an international non-proprietary name (INN), will be refused by the Intellectual Property Office (IPO) on absolute grounds. However, if additional distinctive matter is added to an INN, the IPO is unlikely to raise objection.

The IPO will not refuse applications on the basis of conflicting registrations. Trademark owners must object where there exists a likelihood of confusion. Applicants should conduct searches of registered and unregistered trademarks, and crosscheck any conflicting marks against commercial pharmaceutical databases.

In determining oppositions, the IPO follows relevant EU case law. In *Alcon Inc v OHIM* (Case C-412/05), the European Court of Justice (ECJ) held that in relation to pharmaceutical products, the likelihood of confusion must be judged by reference to both healthcare professionals and end consumers. In *Aventis Pharma SA v OHIM* (Case T-95/07), the Court of First Instance found that the level of attention of consumers of pharmaceuticals is above average.

Non-traditional trademarks

The definition of a 'trademark' is wide enough to include unconventional trademarks such as colour, smell and sound (Section 1(1) of the Trademarks Act).

In examining applications, the IPO will apply the graphical representation requirements laid down by the ECJ in *Libertel* (Case C-104/01), *Sieckman* (Case C-273/00) and *Shield Mark* (Case C-283/01). Distinctiveness is assessed on a case-by-case basis, but it is accepted that consumers do not generally equate colour or shape with trade origin. It is usually necessary to show that the colour or shape has acquired a secondary meaning through significant use and consumer education. Given the advertising restrictions imposed on pharmaceutical products, this can be difficult. Where it is permissible, brand owners should try to educate consumers. Numerous applications for the shape of tablets have been rejected, and an application for the taste of artificial strawberry flavour as applied to pharmaceutical products met a similar fate (*Eli Lilly and Company's Application* (R120-2001/2) [2004] ETMR 4).

The novel appearance of product features and logos can also be protected by design registration. Design registrations last

for up to 25 years, giving brand owners time to acquire sufficient distinctiveness in the product feature or logo to enable trademark registration.

Regulatory approval of product names
UK marketing authorization, which includes the approval of proposed product names, is granted by the MHRA. An EU-wide authorization granted by the EMEA is effective in the United Kingdom.

Non-invented names
The MHRA (unlike the EMEA) will not approve product names comprising an INN plus the name of the manufacturer/authorization holder (eg, Boots Ibuprofen).

Invented names
The EMEA (Invented) Name Review Group pre-approves invented names prior to granting marketing authorization. The MHRA has no pre-approval procedure, but provides an advisory service to applicants.

The approaches of the EMEA and MHRA are generally the same, although the MHRA takes account only of products approved for the UK market or licensed for import into the United Kingdom under special procedures. The inclusion of an INN or 'stem' in an invented name is not fatal to authorization being granted, but factors including the therapeutic area and overall similarity of the invented name to its INN will be considered.

Parallel imports and repackaging

UK law on parallel imports is largely the same as EU law.

Goods imported from outside the EEA

Goods in transit
The Court of Appeal of England and Wales has held that goods passing through the United Kingdom under special customs procedures while being transported between non-European Economic Area (EEA) states are not being 'imported' into the United Kingdom. The goods are not in free circulation and hence, there is no UK trademark infringement.

Implied consent
Consent to importation must be clear and unequivocal, but it may be implied from facts and circumstances surrounding the transaction (see *Zino Davidoff SA* (Case C-414/99)). A wealth of UK case law demonstrates how difficult it is for an importer to establish implied consent (see, eg, *Roche Products v Kent Pharmaceuticals Limited* ([2006] EWCA Civ 1775)). However, two recent Court of Appeal decisions found implied consent on the basis that the facts were consistent only with consent having been given. The successful arguments focused on invoicing methods, high export limits, known exportation and facilitation (*Mastercigars Direct v Hunters & Frankau* ([2007] EWCA Civ 176) and *Honda Motor Co Limited v Neesam* ([2008] EWHC 338 (Ch))).

Anti-competitive practices
The courts have accepted that a defence based on the brand owner's alleged anti-competitive practices is arguable (see *Sportswear Co SpA v Stonestyle Limited* ([2006] EWCA Civ 380)), but it is unclear how closely connected those practices must be to the exercise of the trademark owner's rights. This issue was raised in *Bolton Pharmaceutical Company v Doncaster Pharmaceuticals* ([2006] EWCA Civ 661).

Goods imported within the EEA

Repackaging is permissible provided that the conditions set forth in *Bristol Myers Squibb v Paranova* (Case C-427/93) are met. In *Boehringer Ingelheim v Swingward* ([2004] EWCA Civ 129), it was found that re-boxing by parallel importers is necessary to gain effective market access in the United Kingdom. Following a second reference to the ECJ in *Boehringer Ingelheim v Swingward* ([2008] EWCA Civ 881), the Court of Appeal has indicated that co-branding and de-branding *per se* are permissible, but postponed its final ruling on the manner of such co-branding and de-branding pending the ECJ's decision in *Wellcome v Paranova* (Case C 276/05). This latter judgment has now been issued.

The ECJ confirmed that, once repackaging is proven to be necessary, the presentation of the repackaging should be assessed only against the condition that it should not harm the reputation of the trademark or its proprietor; there is no requirement that the repackaging should interfere as little as possible with the trademark proprietor's rights. Accordingly, the Court of Appeal is now likely to decide that the specific form of the co-branding and de-branding in issue in *Boehringer Ingelheim v Swingward* is acceptable.

Anti-counterfeiting and enforcement

Precautionary measures
Pharmaceutical companies can seek to make their products more complex and expensive to copy. They can also use covert markings on packs and/or products to aid in the detection of counterfeit products, and seek the assistance of Customs to prevent goods from entering the country.

If an EU-wide monitoring application is not already in place under the EU Customs Regulation (1383/2003), a UK monitoring application should be filed with the IP rights team of HM Revenue & Customs. The application must include a local contact who should have speedy access to experts who can confirm whether a product is genuine.

The United Kingdom operates a slightly different simplified procedure from that suggested in Article 11 of the regulation. Where the trademark owner signs a statement that suspect samples are counterfeit, Customs will seize the entire consignment. Customs will not target or detain suspect counterfeit goods which are in transit between non-EEA states, unless there is evidence of likely diversion into the United Kingdom or the European Union.

Criminal enforcement
Those dealing in counterfeit pharmaceuticals are liable for offences under the following legislation:

- the Medicines Act 1968 – maximum of two years' imprisonment and/or an unlimited fine;
- the Trademarks Act – maximum of 10 years' imprisonment and/or an unlimited fine; and
- the Proceeds of Crime Act 2002 – maximum of 14 years' imprisonment and/or an unlimited fine.

Additional offences under the Medical Devices Regulations exist in relation to faulty or substandard counterfeit medical devices, carrying a maximum sentence of six months' imprisonment or a £5,000 fine.

Although Trading Standards, the enforcement agency with a statutory duty to enforce the criminal provisions of the Trademarks Act, has limited resources, it can be relied upon to act in pharmaceutical anti-counterfeiting cases due to the health and safety implications. There is also a network of support and information exchange between the MHRA, Trading Standards and the police. Initial contact should be made with the MHRA.

Civil enforcement
Civil actions for trademark infringement are usually heard by the High Court in London, but the Patents County Court and some regional courts also have jurisdiction to hear such cases.

Discretionary interim measures include the following:

- The most powerful is a search order (previously an *Anton Piller* order), which is made without notice to the defendant. The order requires that the defendant permit a search of its premises for material listed in the schedule. Search orders are not made lightly and, in addition to evidence that the offending material is likely to be destroyed or concealed, evidence of a strong case and serious potential of damage is necessary.
- A freezing injunction may be granted where there is evidence that the defendant is likely to dissipate its assets or put them beyond the reach of the claimant.
- Interim injunctions can also be granted, with or without notice to the defendant, where there is an arguable claim and damages would not be an adequate remedy.

In each case, the claimant will be required to compensate the defendant for any damage caused if it is later decided that the order was wrongly granted.

General

UK litigants benefit from the remedies set out in the IP Rights Enforcement Directive (2004/48/EC). These include, for the first time in the United Kingdom, the availability of final orders forcing the recall of infringing stock from distribution channels and public dissemination of the judgment at the defendant's expense.

Despite the high quality of the UK court system and IP judiciary, the cost of litigation has attracted criticism. However, successful parties can recover a good proportion of their costs from the losing side.

IP infringement cases are usually heard within 12 to 18 months of the commencement of proceedings, but they can be resolved more quickly by means of summary judgment or speedy trial. UK courts favour alternative dispute resolution.

Before commencing actions against generic manufacturers or parallel importers, consideration should be given to any competition law implications. The IP departments of several pharmaceutical companies were raided by the competition authorities in 2008 following a probe into out-of-court settlements in patent infringement cases against generics.

Advertising

The Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994 regulate the advertisement and promotion of medicines. These have been variously amended, principally by Directives 2001/83/EC and 2004/27/EC.

The regulations are enforced by the MHRA, but the pharmaceutical industry is principally self-regulated by its two trade associations, each with its own code of practice. These codes reflect the legislation, but aim to go beyond it to maintain standards in the industry. In addition, the MHRA publishes "The Blue Guide", which aims to explain the provisions of the Medicines (Advertising) Regulations and provide additional guidance:

- Advertising of prescription-only medicines (POMs) to the general public is forbidden, the only exception being approved immunization campaigns. Advertising and promotion of POMs to healthcare professionals is permissible, but strictly regulated on behalf of the Association of the British Pharmaceutical Industry by the Prescription Medicines Code of Practice Authority, which publishes the Code of Practice for the Pharmaceutical Industry.
- The advertisement and promotion of over-the-counter medicines and food supplements is regulated by the Proprietary Association of Great Britain, which publishes a Consumer Code (governing advertisements aimed at consumers) and a Professional Code (governing advertisements aimed at practitioners). Different rules exist for pharmacy products (medicines sold under the supervision of a pharmacist) and general sales list products (which can be sold by any retailer).

For serious breaches of the codes, the trade associations may apply sanctions that include:

- an audit of the advertiser's internal procedures;
- the issuance of a corrective statement;
- a public reprimand; or
- suspension or expulsion from that association.

In addition, the Medicines (Advertising) Regulations create an offence, which on conviction carries a fine and/or imprisonment for up to two years. The MHRA has the power to prosecute in such cases.

Generic substitution

Generic substitution by pharmacists is not currently permitted. Section 10(a) of the Medicines Act 1968 requires that the dispensing of medicines be "in accordance with a prescription given by a practitioner". Pharmacists are bound by the code of ethics of the Royal Pharmaceutical Society of Great Britain to ensure that "except in an emergency, a specifically named product is not substituted for any product without the approval of the patient or carer and the prescriber, a hospital drug and therapeutics committee, or other similar locally agreed protocols." The exemption permits the practice in the internal dispensaries of certain hospitals where the decision to dispense the generic is made at policy level by a committee of clinicians.

The minister for health recently announced an agreement with the Association of the British Pharmaceutical Industry on the 2009 Pharmaceutical Price Regulation Scheme, setting the price of POMs and allowing generic substitution from early 2010. The arrangements, which are currently under consultation, will allow practitioners to indicate where only the brand name drug should be dispensed. There will be exclusions in relation to certain medicines.

Online issues

Domain names

Disputes regarding '.uk' domain names are adjudicated by Nominet. The Nominet Dispute Resolution Service, while based on the Uniform Dispute Resolution Policy, is simpler and less restrictive. Importantly, even though a registration is obtained in good faith, it may be considered 'abusive' if the name has been used in an abusive fashion.

A complaint against a domain name which is an INN is unlikely to succeed because no single party can have rights in an INN.

Many disputes are resolved at the mediation stage.

E-pharmacies

The rise of online pharmacies, including those advertising the illegal supply of POMs without prescription, has created problems for the MHRA. The MHRA has led raids against unlicensed e-pharmacies selling POMS and penalized e-pharmacies for breaches of the codes of practice in relation to the sale of POMs, and pharmacy and general sales list medicines.

Despite these difficulties, online dispensing has been endorsed to an extent by medical practitioners.

In 2007 the Royal Pharmaceutical Society of Great Britain launched its internet pharmacy logo, which aims to help consumers identify legitimate online pharmacies. WTR

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