United Kingdom

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Selection, clearance and registration
Trademarks in the United Kingdom are governed by the Trademarks Act 1994. Regulation and enforcement of the rules governing the pharmaceutical industry are carried out by the Medicines and Healthcare Products Regulatory Agency. Where EU-wide approval is required, the relevant regulatory authority is the European Medicines Agency (EMA), formerly known as the EMEA.

Registration
Section 1 of the Trademarks Act establishes the main function of a trademark – namely, a mark that can be represented graphically and is capable of distinguishing the goods or services of one undertaking from those of another. A trademark must fulfil this function to be registered. An application can be rejected under absolute grounds or upon opposition by a third party.

Absolute grounds for refusal under Section 3 focus on the requirement of distinctiveness. The UK IP Office (UKIPO) will reject an application for a mark that it considers devoid of distinctive character or that has become customary or generic. Applications descriptive of the kind, quality, quantity, intended purpose, value, geographical origin or time of production of the goods or services will also be rejected.

Relative grounds for refusal under Section 5 arise where an existing registered or prior pending third-party trademark conflicts with the mark applied for.

Alcon Inc v Office for Harmonisation in the Internal Market (OHIM) (Case C-412/05) examined the likelihood of confusion in the context of pharmaceuticals. The court concluded that the relevant consumer for both prescription and non-prescription pharmaceuticals is the health professional and the end consumer. *Aventis Pharma SA v OHIM* (Case T-95/07) established that the end consumer will exercise an "above average" level of attention to pharmaceutical products, given the potential medical implications if products are confused.

A trademark search should be carried out to minimise the risk of third-party oppositions on relative grounds. Specialist pharmaceutical databases exist for pharmaceutical trademark searches.

Non-traditional trademarks
The definition of a 'trademark' extends to shapes, colours and sounds, provided that the mark does not fall under the absolute or relative grounds for refusal. The UKIPO examines applications taking into account the graphical representation requirements set out by the European Court of Justice (ECJ) in *Libertel* (Case C-104/01), *Sieckman* (Case C-273/00) and *Shield Mark* (Case C-283/01). It has proved difficult to show trade origin in a colour or shape and many applications, such as a tablet shape, have been refused. An application to register a strawberry taste for pharmaceutical products was refused in *Eli Lilly and Co's Application* ((R120-2001/2) [2004] ETMR 4).

Marketing approval
An application for a pharmaceutical

trademark must satisfy the requirements of the Medicines and Healthcare Products Regulatory Agency. A marketing authorisation (previously known as a product licence) must be obtained for every pharmaceutical product. Centralised European marketing authorisation, which is effective in the United Kingdom, can also be granted by the EMA.

International non-proprietary names

Each international non-proprietary name (INN) is a unique name that is globally recognised for a particular pharmaceutical product. An INN is public property and cannot be registered as a trademark.

The Medicines and Healthcare Products Regulatory Agency has issued policy guidance for applications for proposed product names. This guidance includes the construction of pharmaceutical trademarks and the similarity of invented names to existing INNs.

The EMA assesses proposed pharmaceutical names through the Name Review Group and by reference to criteria set out in the Guidelines on the Acceptability of Names for Human Medicinal Products Processed Through the Centralised Procedure. The guidelines address whether the proposed invented name could cause confusion with the name of another product, convey misleading pharmaceutical connotations or be misleading with respect to the composition of the product. An invented name should not be derived from its own INN.

Parallel imports and repackaging

The rules regarding parallel trading reflect those of the European Union. Regulated by the Medicines and Healthcare Products Regulatory Agency, the UK Parallel Import Licensing Scheme enables a parallel import licence to be obtained. This allows medicinal products authorised in other EU member states to be marketed in the United Kingdom, subject to various requirements. This will depend on the nature of the parallel licence obtained (simple, standard or complex). A basic requirement is that the imported products have no therapeutic difference from the UK equivalent products.

Pharmaceutical repackaging

Parallel importers of pharmaceutical products into the United Kingdom that are already on the market in other parts of the European Economic Area (EEA) rely on Article 7(1) of the First Trademarks Directive (2008/95/EC), which provides for the exhaustion of the rights conferred by a trademark. A rights holder cannot use its rights to prevent resale of its branded goods within the European Union when these goods were first put on the market in the European Union by the rights holder or with its consent. To meet local requirements for marketing authorisation for pharmaceutical products, importers are usually required to repackage products before they are imported into another member state. Product manufacturers/rights holders rely on Article 7(2) of the directive, which states that Article 7(1) will not apply where there is a legitimate reason for the rights holder to oppose the further commercialisation of the goods, especially where the condition of the goods has been altered or impaired.

It is now established that where repackaging is deemed necessary by the importing member state, the repackaging should be assessed to ensure that it does not damage the reputation of the trademark or its proprietor. Subject to national marketing restrictions, a parallel importer has a degree of freedom to market the product in the importing member state.

Implied consent

Exhaustion of rights apply when the goods were first placed on the market by the rights holder or with its consent (which can be implied). In *Zino Davidoff SA* (Case C-414/99), the importance of a rights holder's ability to control the initial marketing of goods in the EEA was emphasised; subsequent UK case law makes it difficult for an importer to establish implied consent (see *Roche Products v Kent Pharmaceuticals Limited* ([2006] EWCA Civ 1775)). In *Mastercigars Direct v Hunters & Frankau* ([2007] ECWA Civ 196) and *Honda Motor Co Ltd v Neesam* ([2008] EWHC 338 (Ch)), implied consent by the rights holder was found.

The facts of the cases, including the behaviour of the rights holder in *Mastercigars* and previous dealings between the parties in *Honda*, were consistent with implied consent to the importation.

Goods in transit

Potentially infringing goods in transit in the United Kingdom will not give rise to trademark infringement unless the goods are used in the United Kingdom in the course of trade. *Eli Lilly and Co v 8PM Chemists Ltd* ([2008] FSR 12) concerned the importation of pharmaceutical products from Turkey into the United Kingdom in sealed boxes that were then sent on to the United States. Pharmaceutical companies including AstraZeneca, Eli Lilly and Pfizer unsuccessfully claimed trademark infringement. The court was not persuaded by the risk that consumers in the United States might incorrectly view the origin of the goods as the United Kingdom, rather than Turkey.

Goods in transit will not fall under the definition of a 'counterfeit product'. This was illustrated in *Nokia Corporation v HMRC* ([2009] EWHC 1903 (Ch)), where counterfeit telephones passed through the United Kingdom during transportation from Hong Kong to Colombia. The telephones were not deemed to be counterfeit because they had not been placed on the UK market.

Anti-counterfeiting and enforcement

The United Kingdom is a transit point and end-user market; it is seldom used as a base for the manufacture of counterfeit medicine. Counterfeit medicine in the United Kingdom initially focused on erectile dysfunction and weight loss, but is now concentrated on medicines in the cardiac and oncology fields.

Prevention

Pharmaceutical manufacturers employ various measures to prevent copying, such as a complex shape and/or markings that are difficult to reproduce. Manufacturers work closely with UK Customs through customs monitoring applications and the use of covert markings to enable identification of counterfeits. To minimise the risk of counterfeit medicines reaching consumers, the Medicines and Healthcare Products Regulatory Agency licenses all steps of the medicine distribution system, from manufacturing to distribution and storage, and monitors the supply and manufacture of medical devices.

Criminal enforcement

Criminal enforcement is the principal method of preventing the distribution of counterfeit pharmaceutical products in the United Kingdom.

Responsibility for enforcement lies with the Medicines and Healthcare Products Regulatory Agency. Through the Enforcement and Intelligence Group, and working with the police, Customs and Trading Standards, the Medicines and Healthcare Products Regulatory Agency can prosecute manufacturers and distributors of counterfeit medicines.

The primary legislation relied upon are:

- the Medicines Act 1968 (maximum of two years' imprisonment and an unlimited fine);
- the Trademarks Act (maximum of 10 years' imprisonment and an unlimited

fine); and
- the Proceeds of Crime Act 2002 (maximum of 14 years' imprisonment and an unlimited fine).

Further criminal sanctions are available under the EU Customs Regulations (1383/2003) and the Medical Devices Regulations.

Civil enforcement

Civil enforcement is rarely pursued due to disproportionate cost and is likely to be economically viable only where collective action is taken by several brand owners. A successful civil action can result in a search order without notice to the defendant, a freezing injunction or an interim injunction. However, a defendant can be compensated if an order is incorrectly granted.

Advertising

The advertisement of pharmaceutical products is primarily governed by the Medicines (Advertising) Regulations 1994 (SI 1994/1932) and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), as amended, in conjunction with the system of self-regulation supported by the Medicines and Healthcare Products Regulatory Agency.

Advertisement of pharmaceutical products is also governed by two trade associations, each with its own code of practice. The Association of the British Pharmaceutical Industry Code of Practice for the Pharmaceutical Industry, administered by the Prescription Medicines Code of Practice Authority, is the self-regulatory system covering prescription medicines. Advertisement of over-the-counter medicines to the general public is regulated by the Proprietary Association of Great Britain. The codes of practice exist to supplement, and in some instances surpass, the regulations. Self-regulation is the principal method of dealing with complaints.

The regulations prohibit certain material in advertisements, including advertisement of prescription-only medicines to the public or advertisements directed (exclusively or principally) at children. The regulations also require that advertisements:
- state that the advertised product is a medicine;
- state the name of the medicine, including the common name if there is only one active ingredient; and
- include instructions for use of the product and adequately direct consumers to the instructions.

The Medicines and Healthcare Products Regulatory Agency is responsible for enforcing the regulations and deals with complaints regarding breach of the codes of practice. It publishes the outcome of investigations in order to inform the industry and the public, and also publishes *The Blue Guide* on the advertisement and promotion of medicines in the United Kingdom. The most common method of enforcement is by vetting advertisements before publication. The agency is also involved in monitoring published material, handling complaints and enforcing sanctions for advertisements that fail to comply with the regulations. Breach of the regulations is a criminal offence; the agency can pursue sanctions of a fine and/or up to two years' imprisonment.

Generic substitution

The Medicines Act 1968 does not permit automatic generic substitution, except in an emergency or under strict hospital control.

Between January 5 2010 and March 30 2010 the Department of Health undertook a consultation on the proposal to introduce automatic generic substitution following amendments to the Pharmaceutical Price Regulation Scheme in 2009. The consultation identified a number of concerns, including that:
- patients could be confused by a change in appearance of their medication and fail to take it as prescribed;
- practitioner workload would increase in counselling and reassuring patients regarding changes in medication appearance; and
- the use of similar packaging, size, shape and colour to the original by generic substitution could result in the original product not being sold.

Due to these and others concerns, it was confirmed on October 10 2010 that automatic generic substitution would not proceed. Pharmacists may dispense generic medicine if a generic prescription is received, but must prescribe the specific branded product for a branded prescription.

Online issues

E-pharmacies

The rapid growth of the Internet and e-pharmacies poses many dangers, including the purchase of incorrect or fake medicine, or the illegal sale of prescription-only medicines. The Royal Pharmaceutical Society of Great Britain was split in September 2010 into:
- the General Pharmaceutical Council – the independent regulator for pharmacists, pharmacy technicians and pharmacy premises; and
- the Royal Pharmaceutical Society – the representative body for pharmacists and pharmacies.

The council has introduced a logo that can be found on legitimate online pharmacy sites to provide a visual means to help consumers to identify registered online pharmacies. The logo provides a direct link to the council's website, enabling consumers to verify the registration details of the pharmacy and the pharmacist(s) behind the e-pharmacy's website.

All pharmacies in Great Britain, including online pharmacies, must be registered with the council. The standards for pharmacists operating an internet pharmacy service are identical to the standards for pharmacy owners and superintendent pharmacists of retail pharmacy businesses, with the additional requirements that:
- there must be systems in place to protect and maintain data integrity; and
- the council must be satisfied that patients and the public who use the internet service are readily able to identify:
- the name of the owner of the business;
- the address of the registered pharmacy premises at which the business is conducted;
- the name of the superintendent pharmacist;
- how to confirm the registration status of the pharmacy and pharmacist; and
- details of how to make a complaint.

Domain names

Domain names in the United Kingdom are allocated by Nominet on a first come, first served basis. Nominet provides a dispute resolution service that is broadly similar to the Uniform Domain Name Dispute Resolution Policy, but generally faster, cheaper and more streamlined. The use of the name of another business as a domain name may constitute passing off. WTR

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Colin Sawdy specialises in trademark, copyright, design and domain name matters. His practice focuses on international trademark prosecution and portfolio management, trademark enforcement, opposition proceedings, revocation and invalidity actions, as well as providing brand clearance advice. Mr Sawdy regularly advises clients on an array of copyright, design and domain name matters, ranging from securing the protection of such rights through to their exploitation and enforcement against infringing third parties. His clients include a wide range of industries, such as financial services, entertainment, children's merchandising, fashion, consumer electronics, household products and pharmaceuticals. Mr Sawdy continues to be a well-regarded and regular contributor to various international IP industry publications.

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James Dunne specialises in brand clearance and trademark matters, including trademark enforcement, opposition proceedings, revocation actions, trademark prosecution and portfolio management in the European Union and internationally. A dual-qualified lawyer (also admitted as a solicitor in New South Wales, Australia), Mr Dunne advises clients across a wide range of industries, including food and beverages, clothing manufacturing and retail, cosmetics and personal care, electronic software, reprographics and document management, luggage and travel goods, fruit production and transportation, television and media, and financial services.