United Kingdom

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Selection, clearance and registration

The principal legislation governing trademarks in the United Kingdom is 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 (MHRA). In instances where EU-wide approval is required, the relevant regulatory authority is the European Medicines Agency (EMEA).

Registration

Section 1 of the act establishes the main function of a trademark, as a mark which can be represented graphically and is capable of distinguishing the goods or services of one undertaking from those of another. To proceed to registration, a trademark application must fulfil this function. The application can also be rejected under absolute grounds or opposed based on relative grounds.

The absolute grounds for refusal under Section 3 are based mainly upon the requirement of distinctiveness. The UK IP Office (UKIPO) will reject a mark if it considers the mark to be devoid of distinctive character or that it has become customary in the current language (ie, if the mark has become the generic term for that product). Applications will also be rejected for marks that are descriptive of the kind, quality, quantity, intended purpose, value, geographical origin or time of production of the goods or services.

The relative grounds for refusal under Section 5 arise where an existing registered or prior pending trademark belonging to another party conflicts with the mark for which registration is sought.

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

To avoid falling within the relative grounds, a trademark search should be carried out to investigate any problematic prior rights. Specialist pharmaceutical databases exist for pharmaceutical trademark searches, reflecting the unique and complex criteria for confusingly similar product and drug names.

Non-traditional trademarks

The broad definition of a 'trademark' in the United Kingdom extends to shapes, colours and sounds, provided that the mark does not fall under the absolute or relative grounds for refusal. The UKIPO will examine applications taking into account the graphical representation requirements set out by the Court of Justice of the European

Union (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 shape or colour, and consequently many applications for the shape of a tablet have been rejected. An application to register a strawberry taste for pharmaceutical products was also rejected in E*li Lilly and Company's Application* ((R120-2001/2) [2004] ETMR 4).

Marketing approval

An application for a pharmaceutical trademark must also satisfy the requirements of the MHRA, the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. A licence, referred to as a marketing authorisation, must be obtained for every pharmaceutical product. European marketing approval, which is effective in the United Kingdom, can also be granted by the EMEA.

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 EMEA is responsible for assessing proposals for the names of new pharmaceutical products, relying on the criteria set out in the EMEA Guidelines on the Acceptability of Names for Human Medicinal Products. The guidelines consider, among other things, whether the proposed invented name could cause confusion with the name of another product, convey misleading pharmaceutical connotations or convey promotional messages.

The approaches to proposed names are generally consistent between the EMEA and the MHRA. However, the MHRA will not provide authorisation for names consisting of an INN alongside the name of a manufacturer, while in some circumstances the EMEA will allow this.

Parallel imports and repackaging

The UK rules regarding parallel trading largely reflect those of the European Union.

Pharmaceutical repackaging

The most important legislation regarding repackaging is Article 7 of the EU First Trademarks Directive (89/104/EEC). Parallel importers into the United Kingdom of pharmaceutical products that are on the market in other parts of the EEA rely on Article 7(1) of the directive, which provides for the exhaustion of the rights conferred by a trademark. This effectively means that 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. However, to meet the local requirements for marketing authorisation for pharmaceutical products, importers are usually required to repackage products before they are imported into another member state. Consequently, the product manufacturers 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.

The interpretation of this legislation has been subject to voluminous case law. Following the ECJ's decision in *Wellcome v Paranova* (Case C-276-05), 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. Therefore, 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 will apply when the goods were first placed on the market by the rights holder or with its consent. However, consent 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)). However, in *Mastercigars Direct v Hunters & Frankau* ([2007] ECWA Civ 196) and *Honda Motor Co Ltd v Neesam* ([2008] EWHC 338 (Ch)), implied consent was found even though there was no express consent by the rights holder to the marketing of the goods within the European Union. The particular facts of the case, 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.

However, more recently, in *Sun Microsystems Inc v M-Tech Data Ltd* ([2009] EWCH 2992 (Pat)), it was held that parallel importation into the European Union of genuine branded goods bearing Sun's trademarks by M-Tech nonetheless infringed Sun's rights. There was no positive evidence that Sun had consented to the sale of the products within the EEA, so there could be no exhaustion of its trademark rights, which followed the principles outlined in *Davidoff*.

Goods in transit

Potentially infringing goods which are 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. The recent decision in *Eli Lily and Co v 8PM Chemists Ltd* ([2008] FSR 12) concerned a large consignment of pharmaceutical products imported into the United Kingdom from Turkey, to be repackaged and processed in the United Kingdom before being sent on to the target market in the United States. Pharmaceutical companies including AstraZeneca, Eli Lilly and Pfizer claimed trademark infringement as a result of the repackaging. The Court of Appeal upheld the decision in *Class International v Colgate-Palmolive* ([2006] 1 CMLR 14), and held that the goods were never classified as legally imported because they were never in free circulation and used in the course of trade. The English 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.

Anti-counterfeiting and enforcement

The United Kingdom is seldom used as a base for the manufacture of counterfeit medicine, although it is a popular transit point and potential end-user market. 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.

Prevention

Pharmaceutical manufacturers can take measures to prevent others from copying their products – for example, by creating a product that is particularly difficult to copy (eg, because of its shape or markings). Manufacturers should also file a UK customs monitoring application. To assist UK customs officers and to detect a larger volume of products, a manufacturer can place covert markings on products, to ensure that genuine products can be easily

identified and distinguished from counterfeits.

Criminal enforcement

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

The three main pieces of legislation providing criminal sanctions for counterfeit pharmaceutical products 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 also available under the EU Counterfeit Goods Regulation (1383/2003) and the Medical Devices Regulations.

Responsibility for enforcement generally lies with the MHRA or, in some instances, Trading Standards, which is responsible for enforcing the Trademarks Act's criminal provisions.

Civil enforcement

Civil enforcement is rarely pursued, given the disproportionate costs involved because counterfeiters often spread their activities across multiple brands. A civil action is likely to be economically viable only where collective action is taken by several brand owners. However, a successful civil action can result in a search order without notice to the defendant, a freezing injunction or an interim injunction. A claimant will be required to compensate the defendant for any damage caused if an order is incorrectly granted.

Advertising

The two central pieces of legislation governing the advertisement of pharmaceutical products are the Medicines (Advertising) Regulations 1994 (SI 1994/1932) and the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), as amended.

The regulations prohibit the advertisement of prescription-only medicines to the public and also prohibit advertisements directed 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 advertisement of pharmaceutical products is also governed by two trade associations, each with its own code of practice. The advertisement of prescription-only medicines is governed by the Association of the British Pharmaceutical Industry and regulated by the Prescription Medicines Code of Practice Authority, while the advertisement of over-the-counter medicines to the general public is governed 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 MHRA is responsible for enforcing the regulations and also deals with complaints regarding breach of the codes of practice. The MHRA has published *The Blue Guide* on the advertisement and promotion of medicines in the United Kingdom. The most common method of enforcement by the MHRA is through vetting advertisements before publication. The MHRA 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, and the MHRA can pursue sanctions of a fine and/or up to two years' imprisonment. An example of a recent complaint upheld by the MHRA is when, in March 2010, a healthcare professional complained that a magazine offering Botox (botulinum toxin) as a competition prize was effectively advertising a prescription-only medicine to the public. The MHRA upheld the complaint and the magazine was required to remove Botox as the competition prize.

Generic substitution

Currently, automatic generic substitution is not permitted by UK law under the Medicines Act 1968, except in an emergency or under strict hospital control.

However, following amendments to the Pharmaceutical Price Regulation Scheme in 2009, there are proposals to introduce automatic generic substitution in the United Kingdom. Under the current rules, pharmacists may dispense generic medicine if a generic prescription is received, but must prescribe the specific branded product for a branded prescription. If the proposals are implemented, a pharmacist will be entitled to substitute the prescribed medicine for a generic substitute for any prescription. The proposals also include the option of creating a list of exempt products or applying the scheme only to certain categories of medicine.

The Department of Health opened a full public consultation regarding these proposals on January 5 2010, which closed on March 30 2010. The outcome of the consultation is still awaited, with a large proportion of the medical industry, including the Royal Pharmaceutical Society of Great Britain (RPSGB), objecting to the proposals.

Online issues

E-pharmacies

The rapid growth of the Internet and e-pharmacies poses many dangers, such as the purchase of incorrect or fake medicine, or the illegal sale of prescription-only medicines. The MHRA is responsible for preventing illegitimate e-pharmacies.

Some medical practitioners have nonetheless endorsed the sale of pharmaceutical products online. The RPSGB has introduced a logo which can be found on legitimate online pharmacy sites, to help consumers identify registered online pharmacies. The RPSGB also has a code of ethics, requiring pharmacy websites to display:

- the business owner's name;
- the pharmacy's address;
- the name of the superintendent pharmacist (where appropriate); and
- details of how to confirm the pharmacy's registration status.

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. In *British Telecommunications plc v One In A Million* ([1999] 1 WLR 903), it was established that the use of the name of another business as a domain name can constitute passing off. WTR

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Nicholas Bolter has experience in all areas of IP law. He advises clients on all aspects of the selection, prosecution, protection and enforcement of trademarks, brands and designs. Mr Bolter also advises clients in relation to data protection and privacy issues, in particular with regard to the acquisition and use of customer data; he maintains a 100% success record in Uniform Domain Name Dispute Resolution Policy proceedings before the World Intellectual Property Office and similar proceedings before Nominet. He acts for some of the world's best-known brands, including leading luxury brands, apparel brands and the world's leading online retailer. Mr Bolter sits on INTA's Internet Committee and also assists the pro bono organisation Own-It!, which provides advice to individuals within the creative arts.

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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 a wide range 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, including 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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Richard Tyler is a trainee solicitor in the firm's IP department, assisting with all aspects of intellectual property. His focus is principally on trademark applications, opposition proceedings and invalidity actions, mainly for clients in the financial and entertainment industries. In addition, he has assisted with advising clients on disputes concerning design rights for household products. Mr Tyler is also involved in the firm's anti-counterfeiting practice for a leading international electronics company and for an international entertainment company.