European Union

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Selection, clearance and registration
The selection of a pharmaceutical trademark is increasingly complex given the size of the pharmaceutical market, the burgeoning number of pharmaceutical trademarks and the increasing number of languages in which those trademarks are registered. This is exacerbated by the potential for harm that may arise from the inadvertent use of different medicines with confusingly similar names.

In order to sell a pharmaceutical product in Europe, one requires approval from the European Medicines Agency (EMEA) or a national authority, taking advantage of mutual recognition or decentralized procedures. This is in addition to any registration from the relevant trademark registry that the company may obtain. Most pharmaceutical companies register marks at the Office for Harmonization in the Internal Market (OHIM), as it confers protection throughout the European Union.

Registration with OHIM
A trademark application may be rejected or opposed on either absolute or relative grounds.

Absolute grounds
The fundamental requirement of any trademark is that it must be distinctive – whether inherently or acquired through use. The mark must not be merely descriptive or laudatory. The mark must also be capable of being represented graphically. Finally, the mark must not be deceptive, or contrary to public policy or to accepted principles of morality.

Relative grounds
OHIM will publish the applications that it has accepted for registration. Third parties may then oppose the marks' registration. The most common basis of challenge is that the mark is confusingly similar to a pre-existing mark registered (or with an existing reputation) in any EU member state in respect of identical or similar goods. It is also possible to challenge a registration on the basis of any of the absolute grounds, or on the basis that the mark is detrimental to the distinctive character or repute of the earlier trademark.

In a leading case (Case C-251/95), the European Court of Justice (ECJ) held that the likelihood of confusion must be assessed as a whole. Factors that might be relevant in any given case are:

- phonetic, visual and conceptual similarities of the conflicting marks;
- the nature of the relevant goods and services;
- their intended purpose; and
- their method of use and distribution, taking into account all factors relevant to the circumstances of the case.

Likelihood of confusion is assessed through the eyes of the average consumer.

Identifying the relevant consumer has proved challenging in the case of pharmaceuticals – especially prescription

drugs. Is the relevant public the medical practitioners who prescribe the drugs, the pharmacists who dispense them (these healthcare professionals are considered to be highly attentive and knowledgeable) or the patients who take the drugs (who are considered to have less attention to detail)?

The ECJ has recently ruled that in the case of prescription products, end users should be taken into account as well as healthcare professionals. The trademark TRAVATAN, applied for in respect of "ophthalmic pharmaceutical products" was refused registration because of an earlier trademark registration for TRIVASTAN in respect of "peripheral vasodilator intended to treat peripheral and cerebral vascular disturbance and vascular disorders of the eye and ear". Of particular importance to the ECJ was that end users of such products were able to make the medical professionals take into account their perception of the trademarks through their personal requirements or preferences (C-412/05).

Marketing approval from the EMEA

In order to sell a pharmaceutical product in the European Union, one must obtain market approval from either a national body in a member state (taking advantage of the mutual recognition or decentralized procedures) or the EMEA. The EMEA assesses the proposed name against the criteria laid out in the EMEA Guidelines on the Acceptability of Names for Human Medicinal Products processed through a centralized procedure. This is further complicated by the 'single trademark' requirement (see below).

The EMEA rejects as many as 35% to 40% of the applications for names that it receives – mostly because of conflicts with international non-proprietary names (INNs) for pharmaceutical substances or because the mark contains promotional elements. Up to four names can be submitted to the Invented Name Review Group (NRG), a group set up by the EMEA, to review them for acceptability. This can be done up to 18 months prior to the planned submission date of the application for a marketing authorization.

EMEA guidelines

According to its guidelines, the EMEA will consider whether the name may be confused with INNs, which are globally recognized and public property. INNs cannot be registered as trademarks. The EMEA expressly provides that proposed trademarks should not be derivatives of INNs or their stems.

If the name is invented, the EMEA will take into account whether the name will:

- convey misleading therapeutic or pharmaceutical connotations;
- be misleading with respect to the composition of the product; or
- cause confusion in print, handwriting or speech with an existing medical product.

As regards safety, the EMEA will assess:

- whether the name will cause the product to be confused with another by looking at what medical problem each of the products will be used to treat;
- how the drug is administered;
- how the product will be supplied (ie, over the counter or by prescription); and
- the potential harm that would be caused in the event of a mix-up.

The EMEA will also consider, among other things:

- whether the name aids selection of the product by the patient – thereby minimizing the risk of inappropriate use; and
- whether the name is a single name. The EMEA will usually authorize only single-name brands, unless the mark relates to a non-prescription product and the additional word is required to help the patient make the right choice.

Single trademark requirement

The mark must be applied throughout the European Union. In practice, this requires finding and registering a trademark available for use throughout the European Union. Derogations can be made from this rule if it can be shown that a trademark has been refused registration in some member states, but this is rare.

No coordination

It should be noted that the EMEA and OHIM do not liaise in their decision-making, which may often lead to inconsistency in their decisions. Further, while the decision of one body may be relevant to the other, each body addresses different issues: the EMEA is primarily concerned with safety, while OHIM is mainly concerned with confusion as to origin. A successful application for a registered trademark does not necessitate a successful application for marketing authorization of a product under that name.

Best practice

In light of the above, multiple names should be proposed for any pharmaceutical trademark. These should all be screened comprehensively in each member state as early as possible for potential conflict with existing registered marks or products, or linguistic problems (eg, an unfortunate meaning in a relevant language). They should also be compared with the relevant INNs. It is common to file applications to register a number of alternate names at OHIM before submission to the NRG/EMEA. While the NRG meets every month, best practice is to apply 12 months before launch.

Non-traditional trademarks

While it is theoretically possible to register non-traditional trademarks (eg, shape, taste and smell) in respect of pharmaceuticals, in practice this has proved difficult. The first challenge is ensuring that the mark can be represented graphically: this is a particular problem for smell and taste marks. The second challenge is that it will be difficult to establish the distinctiveness of elements of the medicine that are not visible at the point of purchase. A good example of these challenges is shown by Eli Lily's refused application (1452853) for the artificial taste of strawberries in respect of certain pharmaceuticals.

Parallel imports and repackaging

The principle of the free movement of goods within the internal market is the basis of parallel trade. Parallel imports of a pharmaceutical product and the conditions on which they can be allowed are governed by Articles 28 and 30 of the EC Treaty. Prohibitions or restrictions on imports within the internal market will be permitted only under certain conditions on grounds of the protection of industrial and commercial property.

The legal framework of parallel imports and repackaging further involves Article 7 of the First Trademarks Directive (89/104/EEC, codified as Directive 2008/95/EC).

Article 7(1) of the directive states that "the trademark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trademark by the proprietor or with [its] consent".

Article 7(2) provides that Article 7(1) "shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialization of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market".

The ECJ, in its judgments of July 11 1996 (Cases C-427/93, C-429/93, C-436/93, C-71/94, C-72/94, C-73/94 and C-232/94), established the main conditions which govern the repackaging of a pharmaceutical product for

parallel import (some of them already announced in Case 102/77). The conditions established in the July 1996 rulings are still the basis of current case law (see the opinion of Advocate General Sharpston delivered on October 9 2008 in Case C-276/05). It is for the parallel importers to prove that these conditions are met (Case C-348/04).

The ECJ considers that Article 7(2) of the directive must be interpreted as meaning that the trademark owner may legitimately oppose the further marketing of a pharmaceutical product which has been put on the market in another member state by the owner or with its consent, where the importer has repackaged the product and reaffixed the trademark thereto without the owner's authorization, unless the following five conditions are satisfied.

Condition 1 – It is established that reliance on trademark rights by the owner in order to oppose the marketing of repackaged products under that trademark would contribute to the artificial partitioning of the markets between member states.

Such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several member states in various forms of packaging (whether or not the trademark owner deliberately sought to partition the markets between member states), and the repackaging carried out by the importer is necessary in order to market the product in the member state of importation.

This condition of necessity (which needs to be reviewed by the national court in accordance with Case C-443/99) is satisfied if the prohibition imposed on the importer against replacing the trademark hinders effective access to the markets of the importing member state. In contrast, that condition will not be satisfied if replacement of the trademark can be explained solely as an attempt by the parallel importer to secure a commercial advantage.

Replacing the packaging of pharmaceutical products – rather than simply sticking labels on those packages – is objectively necessary if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as a result of strong resistance from a significant proportion of consumers to relabelled pharmaceutical products (Case C-443/99).

Condition 2 – It is shown that the repackaging cannot affect the original condition of the product inside the packaging.

Such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as:

- the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their placement in new external packaging;
- the fixing of self-stick labels on the inner packaging of the product;
- the addition to the packaging of new user instructions or information; or
- the insertion of an extra article.

It is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by:

- the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information; or
- the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer.

Condition 3 – The new packaging clearly states who repackaged the product and the name of the manufacturer.

This information must be printed in such a way that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand. Similarly, the origin of an extra article from a source other than the trademark owner must be indicated in such a way as to dispel any impression that the trademark owner is responsible for it.

Condition 4 – The presentation of the repackaged product is not liable to damage the reputation of the trademark and of its owner; thus, the packaging must not be defective, of poor quality or untidy.

According to the ECJ, it is for the national court to ascertain whether the insertion into single external packaging of both original external packaging and loose blister packs constitutes an untidy form of packaging liable to damage the reputation of the trademark; as for the cutting of blister packs, it is for that court to assess in each particular case whether it has been carried out in such a manner that the reputation of the trademark might suffer.

A repackaged pharmaceutical product could be presented inappropriately and, therefore, damage the trademark's reputation – in particular where the carton or label, while not being defective, of poor quality or untidy, is such as to affect the trademark's value by detracting from the image of reliability and quality attached to such a product and the confidence that it is capable of inspiring in the public concerned.

Condition 5 – The importer gives notice to the trademark owner before the repackaged product is put on sale, and, on demand, supplies it with a specimen of the repackaged product.

The ECJ has pointed out that where a parallel importer has failed to give prior notice to the trademark proprietor concerning a repackaged pharmaceutical product, it infringes that proprietor's rights on the occasion of any subsequent importation of that product, so long as it has not given the proprietor such notice. The sanction for that infringement must be not only proportionate, but also sufficiently efficient and enough of a deterrent to ensure that the directive is fully effective. A national measure under which, in the case of such an infringement, the trademark proprietor is entitled to claim financial remedies – on the same basis as if the goods had been spurious – is not in itself contrary to the principle of proportionality (Case C-348/04). WTR

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Alexander Denoon is a member of the IP group with more than 13 years' experience. He has both a law degree and a science degree (human genetics). Mr Denoon has spent more than five years in-house with technology companies including Biotech Australia, Redfern Broadband Networks and Silverbrook Research. As general counsel and company secretary, he managed and implemented IP strategies.

Mr Denoon advises clients in relation to the protection and exploitation of IP rights. This ranges from representing clients in respect of the IP aspects of merger and acquisition transactions to licensing, joint ventures, development agreements and sponsorship agreements. He co-wrote the chapter on intellectual property in *The Law and Regulation of Medicines* (edited by Dr Peter Feldschreiber) published by Oxford University Press in 2008.