British Journal of Pharmacy

https://doi.org/10.5920/bjpharm.1279

British Journal of Pharmacy

www.bjpharm.hud.ac.uk

*Expert Opinion*

# Trade Marks and Trade Names in the Pharmaceutical Industry

Kashif Syed* and Catherine Jewell

Beck Greener LLP, Fulwood House, 12 Fulwood Place, London WC1V 6HR, United Kingdom

ARTICLE INFO

Received: 04/01/2022
Accepted: 13/06/2023
Published: 31/12/2023

*Corresponding author.
Tel.: +44 20 7693 5600
Fax: +44 20 7693 5601
E-mail:
ksyed@beckgreener.com

KEYWORDS: trade marks; application; registration; revocation; Brexit; exhaustion; parallel imports; likelihood of confusion.

ABSTRACT

In this article, we aim to provide general guidance on some of the key trade mark issues for pharma companies to be aware of for their medicinal branding, with a particular focus on some of the issues in the maintenance and enforcement of registered trade marks, including the potential effects of Brexit on the future of "parallel imports" and the "exhaustion" of trade mark rights. First, the application process to register a trade mark in the UK is discussed, including how this differs from the approval of medicinal branding. Next is an assessment of the risks pharma companies face in having their trade mark registrations cancelled for non-use owing to what can often be a lengthy period from product conception to approval and discussion of how to overcome this. The current exhaustion regime following Brexit is outlined with discussion of what the future may hold for pharma companies grappling with parallel imports. Finally comes consideration of the issues pharma companies face when trying to enforce their trade mark registration(s) on the basis that there is a likelihood of confusion with conflicting brands, and some practical guidance to resolving such disputes.



## INTRODUCTION

For businesses, branding their products and services requires more care and due diligence than ever before and none more so than for pharmaceutical companies. The process of selecting a name, obtaining registered trade mark protection and then effectively maintaining and enforcing those rights demands that businesses understand the wide range of potential legal obstacles. Some of the particularly difficult trade mark issues that have arisen in areas such as free movement of goods are almost exclusively the domain of the pharma industry. Now that the United Kingdom has left the European Union ("Brexit") and the "Transitional Period" is over, there are more questions to be answered on those difficult issues in the post-Brexit world we face and for pharma companies in particular there is a lot riding on how the UK courts and Government decide how to approach those issues going forward.

## THE TRADE MARK APPLICATION PROCESS

In the UK, the Medicines and Healthcare products Regulatory Agency ("MHRA") approves all packaging and labelling for medicines sold, including the information that must be provided. Medicines must include a patient information leaflet ("PIL") if the label does not contain all the necessary information. The MHRA considers the safety and suitability of a name in respect of both the medicine itself and in relation to other medicines in the market and protects consumers specifically from the perspective of the medical industry. Whereas, the UK Intellectual Property Office ("UKIPO") is responsible for all registered intellectual property ("IP") in the UK and examines and grants applications for trade mark protection; the UKIPO does not examine a trade mark other than from the criteria set out under the provisions of the UK Trade Marks Act 1994 ("the Act") which are the same for all businesses and industries.

Every application has a preliminary check to ensure that it meets the formalities requirements to be given a filing date under the Act. At the examination stage, the trade mark application is assessed to ensure that the goods & services meets classification requirements under the International Nice Classification system and for what are called

https://doi.org/10.5920/bjpharm.1279

'absolute grounds' for refusal which pertain to either the distinctiveness of the mark based on the various criteria under s.3(1) or policy considerations based on the various criteria under the other subsections of s.3 of the Act (UK 1994). Examiners will also carry out an informational search on 'relative grounds' of earlier trade mark applications and registrations which they believe conflict with the mark applied for and will issue a search report with these results. The examiner will notify owners of earlier UK trade marks cited in the report but will not refuse the application based on these citations; it is up to the trade mark owner to take action at the publication stage. Once the application has been accepted by the examiner it is then published in the trade mark journal for 2 months during which time third parties have the right to oppose if they believe there is a conflict with their own earlier rights or based on absolute or other grounds. If there is no opposition to the application, the mark will then be granted and a registration certificate issued.

## NON-USE OF MEDICINAL BRAND TRADE MARK REGISTRATIONS AND RISK OF REVOCATION

Once granted, UK trade mark registrations are vulnerable to being cancelled for non-use (revoked) if there has been a continuous period of 5 years where they have not been put to genuine use for the goods & services registered (UK 1994). Similarly, if a trade mark proprietor opposes or applies to cancel a third party trade mark application or registration based on its earlier registered rights and it has been more than 5 years since grant of a registration, the defending party has the right to require that the proprietor proves genuine use of its mark during the course of proceedings. For pharma companies who want to obtain registered protection for their medicinal brands this on the face of it poses a dilemma as medicines will often require more than 5 years from product conception to regulatory approval and then marketing. To apply to register the mark at an early stage will leave it vulnerable to non-use cancellation before the medicine is available on the market but to delay filing a trade mark application may allow third parties to potentially beat you to the punch by filing first and thereby obtain conflicting rights in an identical or similar name.

When assessing genuine use of a mark, whether in cancellation or opposition proceedings, the UKIPO is meant to take account of all the relevant facts and circumstances surrounding its use. Among the factors to be considered are *inter alia* "*the characteristics of the market concerned, the nature of the goods or services protected by the trade mark and the territorial extent and scale of the use as well as its frequency and regularity*" (EU 2012). At its core, the test is whether the use is viewed as "*warranted in the economic sector concerned to maintain or create a share in the market for the goods or services protected by the mark*" (EU 2003a). The use made of the mark must be more than merely 'token' use (i.e. serving solely to preserve the rights conferred by the mark) or internal use by the proprietor itself but it does not always have to be quantitatively significant to be considered genuine use (EU 2003a). However, UK trade mark law also recognises situations where genuine use of a trade mark registration was not possible during the relevant 5 year period such as if there are 'proper reasons for non-use', which under the Act is an exception to the use requirement (UK 1994). Pharma companies may need to avail themselves of this where they apply to protect their medicinal brands early and are not able to get the products to market within 5 years of grant. However, case law on proper reasons for non-use indicates that the exception is narrow and stringent in nature, meaning it cannot always be relied on, particularly where the obstacles to use relate more to commercial difficulties. It would behove pharma companies to make a reasonable calculation of how long it is likely to take to get a medicine to market and then assess their branding needs accordingly.

Proper reasons for non-use must be interpreted in accordance with Art.19(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS") which defines this as "*valid reasons based on the existence of obstacles*" and provides the following criteria (World Trade Organization 2017):

*"Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other governmental requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use."*

The leading judgment on this has been the Court of Justice of the European Union's ("CJEU") decision in *Haupl v Lidl* (C-246/05) (EU 2007) where the Court held that *"only obstacles having a sufficiently direct relationship with a trade mark, making its use impossible or unreasonable, and which arise independently of the will of the proprietor of the mark, may be described as 'proper reasons for non-use' of that mark*". The CJEU has mentioned 3 conditions that must be met in order to meet this test, namely:

a) The obstacle arose independently of the will of the proprietor.

https://doi.org/10.5920/bjpharm.1279

b) There must be direct relationship between obstacle and failure to use mark.
c) The obstacle must make use impossible or unreasonable.

In *Haupl v Lidl*, bureaucratic obstacles in gaining building permits for supermarkets did not have a sufficiently direct relationship with use of the mark in question. In the context of pharmaceuticals, it has been held that unavoidable regulatory requirements for approval of a medicine can be a justifiable delay for putting a mark to use. In the EU Intellectual Property Office ("EUIPO") opposition case of VIADUR/DIADUR (Decision No. 1507/2001) it was held by the Opposition Division that the opponent had proper reasons for non-use of its mark as it had not been granted final approval from the 'Ministry of Health and Consumer Affairs' in Spain for marketing a pharmaceutical under the name DIADUR (EU 2001). This was later upheld on appeal before the Boards of Appeal (EU 2003b). The UK has taken a similar approach to medicinal regulation. In non-use revocation proceedings of INVERMONT Trade Mark (UK 1997) before the UKIPO, the hearing officer gave some guidance on the correct application of 'proper' reasons for non-use, holding *inter alia* that 'proper' does not cover routine or normal situations that prevent use of a mark but highlighted an exception with 'normal' delays that occur from unavoidable regulatory requirement for medicinal approval:

"*I do not think the term 'proper' was intended to cover normal situations or routine difficulties. I think it much more likely that it is intended to cover abnormal situations in the industry or the market, or even perhaps some temporary but serious disruption affecting the registered proprietor's business.* ***Normal delays occasioned by some unavoidable regulatory requirement, such as the approval of a medicine, might be acceptable but not, I think, the normal delays found in the marketing function****. These are matters within the businessman's own control and I think he should plan accordingly.*"

While there may be some favourable case law supporting the justification of medicinal regulatory approval, each case is fact specific and pharma companies should appreciate that to show proper reasons for non-use the 3 conditions mentioned above must still be demonstrated; the mere fact that regulatory approval has not been granted is not an all encompassing excuse for non-use in the absence of suitable evidence in support of the conditions. In this regard, not every matter that may delay bringing a medicine to market will be considered acceptable. For instance, in the non-use revocation case of *Viridis Pharmaceutical v EUIPO (C-668/17 P)* the CJEU held that while the performance of clinical trials could be considered a proper reason for non-use this will depend on the individual circumstance of the case and here Viridis was considered to have applied to register its BOSWELAN trade mark too early which was its own choice even though it knew "*there was great uncertainty as to both the date and the possibility of the marketing of the product covered by that mark since that product was at the clinical trial stage*". Additionally, the CJEU held that "*the completion date of which moreover remained uncertain, related back to the insufficient investment committed by Viridis in the light of the specific characteristics of the industry concerned*". This case highlights the importance for pharma companies to cover all bases and exhaust all efforts 'within their control' in getting their products to market if they want to benefit from the non-use exclusion and that there can also be a risk in applying to register a mark too early as previously highlighted.

## EXHAUSTION OF IP RIGHTS

Now that the UK has left the EU, the UK Government must decide how it will approach the whole concept of exhaustion of IP rights. This is a concept that has built up over many years, and which underpins the system of parallel trade (secondary sales of legitimate goods). While the UK was part of the EU, it was also part of the EU's exhaustion regime.

Under this regime, the IP rights in goods legitimately first placed on the market anywhere in the European Economic Area ("EEA") would be considered exhausted in the rest of the EEA. Thus, prior to the UK's exit from the EU, goods could be parallel imported into the UK from the EEA and parallel exported from the UK into the EEA.

"Parallel imports" or "parallel exports" refer to goods that have been legitimately manufactured and first placed on the market, by the IP rights holder or under licence, prior to movement across territorial borders.

At present, the UK continues to apply the EEA regional exhaustion regime, but this is not reciprocated. This means that the IP rights in goods which are first placed on the market in the EEA are

https://doi.org/10.5920/bjpharm.1279

considered exhausted in the UK, i.e. can be parallel imported into the UK without permission from the rights holder. However, the IP rights in goods which are first placed on the market in the UK are not considered exhausted in the EEA. The rights holder therefore can block parallel export of these goods from the UK into the EEA.

The EU now cannot reciprocate with the UK on exhaustion of rights because case law from the CJEU (EU 1998) rules out the possibility of an international exhaustion regime and requires that EU member states can only apply a regional (EEA) exhaustion regime. In other words, so that, in principle, there has not been an exhaustion of rights for goods placed on the market in a non-EEA country if those goods are subsequently imported into the EEA.

The UK Government has conducted a consultation on exhaustion of IP rights, which was intended to assist in it deciding on its own regime. The regimes under consideration include:

(i) Unilateral application of the EEA regional exhaustion regime ("UK+" as at present);
(ii) National exhaustion;
(iii) International exhaustion;
(iv) Mixed regime.

For all of these, parallel export of goods from the UK to other countries would not be permitted automatically unless the receiving country itself applies an international exhaustion regime.

For (i) parallel imports into the UK would only be permitted automatically from EEA countries. For (ii) no parallel imports would be permitted automatically, whereas for (iii) all imports would be permitted, and for (iv) the ability to parallel import would depend on the decision for specific IP rights, goods or sector.

For each of these regimes, the import of regulated goods such as medicines would require there to be separate authorisation in the UK.

National exhaustion was only included in the consultation for completeness, as the UK Government believes that is it irreconcilable with the Northern Ireland Protocol. This requires that parallel goods may move from EU member states (including the Republic of Ireland) into Northern Ireland without restriction.

International exhaustion has the possible drawback that goods originally intended for "Least Developed Countries" may be parallel imported into the UK where they could be sold for a higher price. There is a concern that international exhaustion in the UK would lead to decreased access to key goods such as pharmaceuticals in LDC countries.

A mixed regime is used in countries such as Switzerland, which allows parallel import of most goods, but has a national regime for medicines. However, a mixed regime is likely to be complex for businesses and consumers, and would also have to be compatible with the Northern Ireland Protocol.

The UK Government has completed an initial analysis of this consultation, but considers that there is not sufficient data available to understand the economic impact of any of the alternatives to the current "UK+" regime. Whichever regime is eventually chosen, there will also be implications for licensing, territorial rights, contracts, products made from component parts and transformed goods, transit goods, consumer choice and potential consumer confusion, as well as the potential effect on innovation.

It is likely that any new regime would have an implementation period of at least one year, and possibly longer (the implementation period is also part of the UK Government's consultation). Some have suggested that an implementation period of up to five years might be needed. Thus, it seems likely that the current regime will be in place until at least the end of 2024.

## LIKELIHOOD OF CONFUSION

When enforcing trade mark registrations, the most common ground relied on in opposition and cancellation proceedings before the UKIPO and in infringement proceedings before the courts is that there exists a likelihood of confusion with a third party mark among the notional 'relevant public' or 'average consumer'. This is on the basis that the marks and the goods and services at issue are in each case at least similar to each other. A high degree of attention among the relevant public results in a higher threshold for proving likelihood of confusion. Importantly, defining the relevant public (which can include the general public at large and a specialised professional public) for the purposes of likelihood of confusion is determined by the goods and services at issue. The degree of attention of the relevant public will vary and is not based solely on whether the relevant public consists of the general public or a professional public, although the latter tends to have a higher degree of attention particularly when

https://doi.org/10.5920/bjpharm.1279

purchasing a specialised product or service as it involves business to business trading.

Insofar as pharmaceutical products are concerned, it is apparent from UK and EU case law that the relevant public is considered to have a high degree of attentiveness, particularly medical professionals who prescribe pharmaceuticals. The upshot for pharma companies is that establishing a likelihood of confusion with another pharmaceutical trade mark and thus successfully enforcing their trade mark rights can often be more difficult than for other businesses in other industries. Therefore, while settling trade mark disputes out of court is often desirable notwithstanding the business sector, it can sometimes be a pragmatic approach for pharma trade mark owners to find suitable ways to do so. In this regard, a unique consideration when applying to register pharmaceutical trade marks is that because drugs will only have specific fields and purposes and are unlikely to be confused with other types of medicines, drafting broad and extensive specifications of goods & services is not as advantageous as for brand owners in other business sectors. Rather, the main practical concern for pharma companies when enforcing their rights should be to ensure that their specific field of interest for the drug is not impinged by third parties that may be using or applying to register similar marks. An apt way to deal with potential conflicts can be to require the said trade mark user/owner to restrict its use and/or registration of the mark away from the drug's specific field of relevance. This is particularly useful not only when settling disputes with third parties but also when determining what the scope of goods & services should be when applying to register a trade mark where it can often be beneficial to carve out the nature or field of the drug being protected to put other businesses on notice of your intended use of the mark.

## CONCLUSION

To protect and enforce new brands effectively demands multifaceted considerations with an even more astute approach needed by pharma companies who must contend with additional challenges unique to their sector. From ensuring that a medicinal brand name meets the MHRA's criteria for approval, to determining a drug's timeline to market and the inevitable vulnerability of a trade mark registration to non-use cancellation, to grappling with parallel importers of drugs, to evaluating how and when to settle disputes with competitors and to enforce trade mark registrations before the courts and UKIPO while conscious of the higher standards required for pharma trade marks.

However, while the UK is no longer part of the EU, in many ways it is still currently business as usual at least with regard to the exhaustion of IP rights unless and until the law develops and changes. For now, the UK's approach to exhaustion remains largely unchanged from pre-Brexit as it continues to apply the unilateral exhaustion regime (UK+ regime).

Pharma companies would be wise to carefully follow developments both with UK Government policy as well as UK case law which will slowly but perhaps inevitably diverge from the rest of the EU with the new found independence British judges now have. It will be interesting to see what changes and when and how that impacts the future state of the pharma industry as a whole.

## CONFLICT OF INTEREST

KS is a trade mark attorney and an IP litigator and advocate, CJ is a patent and trade mark attorney at Beck Greener LLP, a London based firm of Chartered and European Patent and Trademark attorneys. This article does not constitute legal advice on any specific issues. For any specific matters, a personalised advice should always be sought from a licensed attorney.

## REFERENCES

EU (1998). Silhouette International Schmied GmbH & Co. KG v Hartlauer Handelsgesellschaft mbH (C-355/96). Published 16 July 1998, available at: https://curia.europa.eu/juris/liste.jsf?num=C-355/96

EU (2001). Almirall-Prodesfarma, S.A. v Alza Corporation (1507/2001). Published 27 June 2001, available at: https://euipo.europa.eu/eSearchCLW/#basic/*///name/VIADUR

EU (2003a). Ansul BV v Ajax Brandbeveiliging BV (C-40/01). Published 11 March 2003, available at: https://curia.europa.eu/juris/liste.jsf?num=C-40/01

EU (2003b). Alza Corporation v Almirall-Prodesfarma, S.A. (R 745/2001-2). Published 9 June 2003, available at: https://euipo.europa.eu/eSearchCLW/#basic/*///name/VIADUR

EU (2007). Armin Häupl v Lidl Stiftung & Co. KG. (C-246/05). Published 14 June 2007, available at: https://curia.europa.eu/juris/liste.jsf?num=C-246/05

EU (2012). Leno Merken BV v Hagelkruis Beheer BV (C-149/11). Published 19 December 2012, available at: https://curia.europa.eu/juris/liste.jsf?num=C-149/11&language=EN

EU (2019). Viridis Pharmaceutical v EUIPO (C-668/17 P). Published 3 July 2019, available at: https://curia.europa.eu/juris/liste.jsf?language=en&num=C-668/17

https://doi.org/10.5920/bjpharm.1279

UK (1994). Sections 3 & 46 Trade Marks Act 1994. Available at: https://www.legislation.gov.uk/ukpga/1994/26/part/I

UK (1997). Reports of Patent, Design and Trade Mark Cases, 114(4):125-133; https://doi.org/10.1093/rpc/1997rpc125

World Trade Organization (2017). Art.19(1) Agreement on Trade Related Aspects of Intellectual Property Rights. Available at: https://www.wto.org/english/docs_e/legal_e/31bis_trips_04_e.htm