Parallel trade of medicines in Europe – the trade mark issues

March 2024

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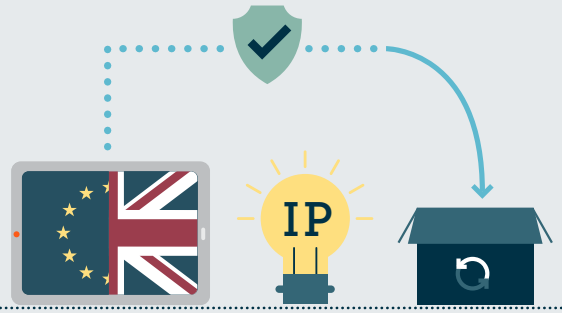
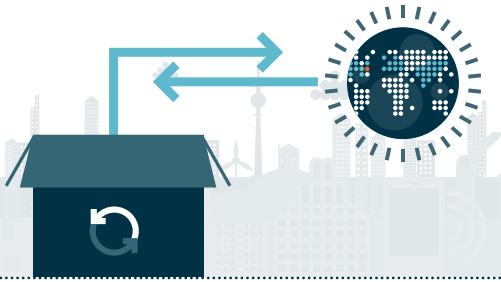
What is parallel trade?

Parallel imports are goods that have been imported into a new geographical market without the consent of the intellectual property (IP) rightsholder, provided that the goods have already been placed on the market by the owner of the intellectual property rights (IPRs) or with their consent. They are genuine goods protected by IPRs and are not counterfeits. In the medicines context, parallel imports can be originator or generic products.

Parallel trade ultimately seeks to take advantage of contrasting prices in different geographical markets – goods will be purchased at a lower price in one market and re-sold at a higher price in another. In 2020, the parallel import market for medicines accounted for 2.8% of the total medicines market in the EU, with a value of around €5.9bn.





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Free movement of goods

A central tenet of the EU is the free movement of goods, which also extends to the EEA but no longer applies to the UK post-Brexit. However, the principle is not absolute and does not preclude restrictions for a range of reasons, including the protection of industrial and commercial property.

Intellectual property rights

Trade mark proprietors have the exclusive right to place goods on the market using their trade mark. However, this right is limited by the principle of exhaustion, meaning that once the goods have been placed on the market by the trade mark proprietor or with their consent, the rightsholder cannot restrict the further distribution or sale of those goods. The trade mark right in relation those goods is "exhausted".

The principle of exhaustion is not absolute and does not apply where there are **legitimate reasons** for the trade mark proprietor to oppose further commercialisation of its goods. This is particularly the case where the condition of the goods is changed or impaired.

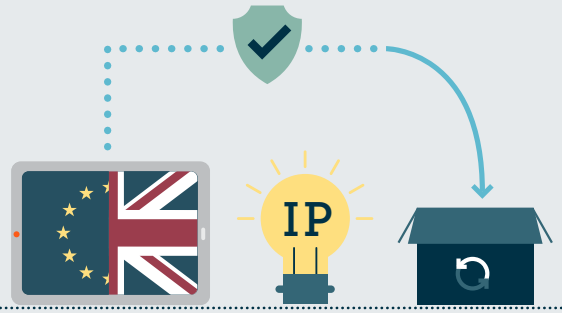
EU and EEA – once goods have been placed on the market in the EU or the EEA by the IPR owner or with their consent then the trade mark right is **considered exhausted** and those goods can be parallel traded throughout the EU or EEA.

UK – the UK currently has an asymmetric exhaustion regime. Goods placed on the market in the UK are no longer considered exhausted in the EU or EEA and therefore **exports from the UK to the EU or EEA** would require the trade mark proprietor's consent. However, goods placed on the EU or EEA market continue to be **considered exhausted** in the UK and therefore parallel imports from the EEA to the UK **can continue**.

The principle of exhaustion is not absolute and does not apply where there are **legitimate reasons** for the trade mark proprietor to oppose further commercialisation of its goods. This is particularly the case where the condition of the goods is changed or impaired.

The future of exhaustion in the UK

The UK government carried out a consultation on the future exhaustion framework in the UK, concluding that there was not enough data to understand the potential economic impacts of the alternatives to the current asymmetric regime. The present asymmetric exhaustion regime therefore looks set to continue for some time to come.



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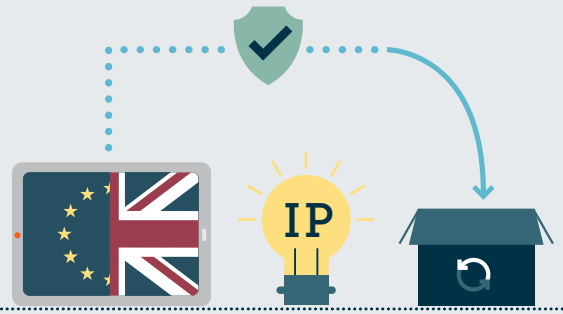
In many cases, the parallel import of medicines interferes with the rights of trade mark owners due to differing regulatory requirements for parallel imported medicines in different countries. For example, there could be requirements to increase or decrease the quantity of the product in the outer packaging or labelling requirements, such as changing the language. These differing requirements are often addressed by **repackaging the product**.

Repackaging can include:

- **Re-labelling** – this could include adding a new label or a new anti-tampering device (ATD)
- **Re-boxing** – this could include copying the original design or changing to plain packaging
- **Re-branding** – for example, a generic product being re-branded with originator branding
- **De-branding** – removing all or part of the original branding
- **Co-branding** – using the original branding and adding additional branding such as the parallel importer's branding



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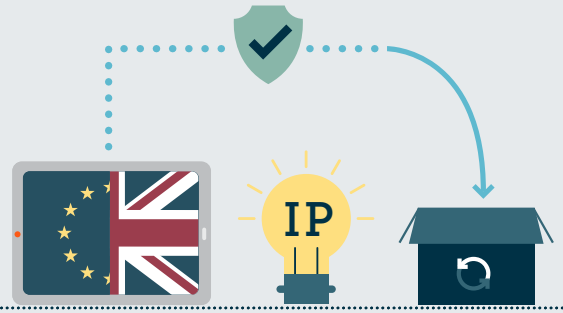
Pre-Brexit case law

In general, **parallel importers tend to prefer to re-box medicines** rather than re-label them. Unless certain conditions are met, trade mark proprietors can legitimately oppose the further commercialisation of parallel imported medicines bearing their trade marks where the products have been repackaged and their trade mark affixed to the new packaging. These conditions are known as the **BMS Conditions** and were stipulated by the CJEU prior to the end of the Brexit transition period and therefore remain applicable in the UK:

1. Modifications to the packaging must be **objectively necessar**y to market the product in the country of import.
2. The repackaging cannot affect the **original condition** of the product inside the packaging.
3. The new packaging must **clearly state** who has repackaged the product and who is the manufacturer.
4. The presentation of the product cannot be liable to **damage the reputation** of the trade mark and its owner, as such the packaging must not be defective, of poor quality or untidy.
5. The **importer must give notice** to the trade mark proprietor prior to the product being put on sale and, on demand, supply a specimen product.

Post-Brexit case law

There has been a recent spate of cases that have sought to determine the limits of the BMS Conditions and how they apply in various repackaging scenarios. Although these cases are no longer authoritative in the UK, given that they elaborate on the BMS Conditions (which are still applicable), it is likely that they would be persuasive in the English courts.



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Re-branding

In circumstances where a **generic product is re-branded with the originator product's branding**, the CJEU has confirmed that re-branding **could be justified** under three conditions:

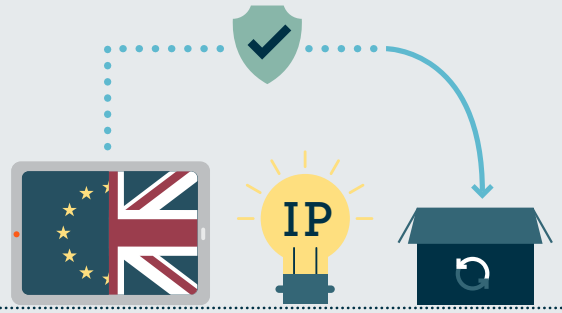
1. The generic and the original product are identical in all respects (for example, a reference and generic product manufactured by the same or economically linked undertakings, which are the same product marketed under different rules).
2. Both trade marks are controlled by the same or economically linked entities.
3. The re-branding is objectively necessary to obtain access to the import market.

The objectively necessary standard is not met if a parallel importer can obtain an **import licence** for use of the generic name. In the EU single market, this is always possible. Re-branding with the sole intention of economic gain by moving a product into a more profitable originator category will also not satisfy the objective necessity condition. Together, this effectively means that **re-branding generic products with originator brands is not possible in the EU**.

In other cases of re-branding – for example, a brand being removed and replaced with the importer's branding – the objective necessity condition will also apply, provided that the immediate packaging of the product (that is, the packaging in direct contact with the medicine) bears the original trade mark and/or the new outer packaging refers to the original trade mark.

De-branding

If a parallel importer repackages a product but only reaffixes the trade mark specific to the repackaged product and **removes other trade marks and/or distinctive signs** that appeared on the original outer packaging, then the **trade mark owner may oppose** the remarketing of that repackaged product where: i) the new outer packaging is liable to damage the reputation of the trade mark, and/or ii) it adversely affects the essential function of the trade mark in indicating origin.



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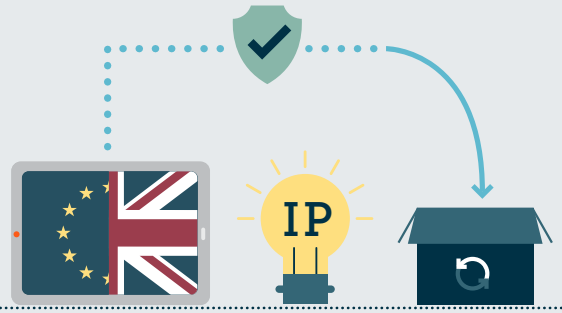
Re-boxing v re-labelling

The question of when re-boxing and re-labelling should take place has arisen in the context of the EU's Falsified Medicines Directive (FMD). The directive, which came into force in 2019, sets out two safety features that all medicines for human use in the EU must have: i) a **unique identifier** to indicate the source of the goods, and ii) an **anti-tampering device** (ATD) to indicate if the goods have been opened or altered. These safety feature aspects of the FMD ceased to apply in the UK from 31 December 2020.

Parallel importers sought to argue that the ATD requirement of the FMD justified re-boxing to avoid leaving traces of interference with the original ATD. The CJEU rejected this argument, finding that re-boxing and re-labelling are equivalent in terms of meeting the requirement of the FMD. A trade mark owner is able to **oppose re-boxing** where their trade mark is affixed where the importer is able to re-label the original packaging, provided that the importer will have access to the import market.

The importer would have to re-label the product with equivalent safety measures that can verify with the same effectiveness that the product has not been tampered. It is possible to leave tangible traces of the original packaging being opened provided that there is no doubt that the traces are attributable to the importer and the traces do not cause strong resistance from a significant proportion of consumers in the import country so as to amount to a barrier to market entry. Whether there is such resistance is to be judged on a case by case basis and importers cannot assume this to be the case.



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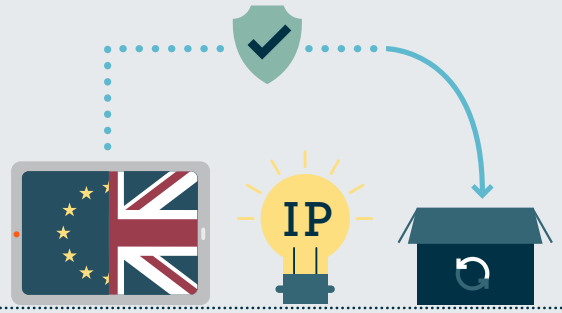
The **BMS Conditions continue to apply in the EU and the UK**. Trade mark proprietors are able to object to parallel trade where the BMS Conditions have not been satisfied.

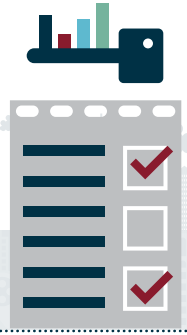
The Falsified Medicines Directive safety requirements **do not affect trade mark rights** – the BMS Conditions still apply.

In another post-Brexit decision, the CJEU also confirmed that it is **not objectively necessary** to re-brand generics with originator branding where it is possible to get an **import licence** for the generic name or if the motivation is exclusively economic to move the product into a more profitable category.

In a post-Brexit decision, the CJEU has confirmed that the **BMS Conditions apply to re-boxing, re-labelling, de-branding, re-branding and co-branding**. Using only a product trade mark without other corporate branding can still damage a trade mark's reputation and its origin function – re-boxing does not avoid the BMS Conditions.

Re-labelling and re-boxing are seen as equivalent in terms of satisfying the Falsified Medicines Directive safety requirements. **Re-boxing can be opposed** if re-labelling was possible. It is unlawful for EU Member States to require parallel importers to re-box.





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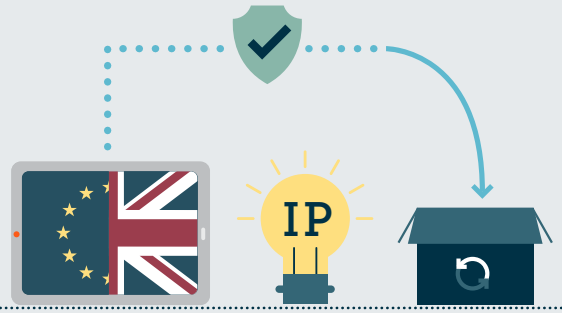

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Type of repackaging	Example	BMS Conditions apply?	Example circumstances which allow objection by rightsholder
Re-labelling	Adding a new label Adding a new anti-tampering device (ATD)	Yes	The presentation of the product is liable to damage the reputation of the trade mark and its owner, for example, the packaging is defective, of poor quality or untidy
Re-boxing	Copying the original design Changing to plain packaging	Yes	If re-labelling was possible
Re-branding	Generic product being re-branded with originator branding	Yes	Where it is possible to get an **import licence** for the generic name If the motivation is exclusively economic to move the product into a more profitable category
	Brand being removed and replaced with the importer's branding	Yes	Re-branding not objectively necessary to obtain access to import market
De-branding	Removing all or part of the original branding	Yes	If the trade mark specific to the repackaged product is reaffixed but other trade marks and/or distinctive signs from original outer packaging are removed, then the trade mark owner may oppose where: i) the new outer packaging is liable to damage the reputation of the trade mark, and/or ii) it adversely affects the essential function of the trade mark in indicating origin
Co-branding	Using the original branding and adding additional branding such as the parallel importer's branding	Yes	The presentation of the product is liable to damage the reputation of the trade mark and its owner, for example, the packaging is defective, of poor quality or untidy

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Contacts

Richard May
Partner, UK
T: +44 207 105 7857
E: richard.may@osborneclarke.com

Dr Robyn Trigg
Senior Knowledge Lawyer, UK
T: + 44 20 7105 7338
E robyn.trigg@osborneclarke.com