

Exhausted? You're not alone...!

What next for parallel imports after Brexit?

Background

1 January 2021 marked the start of a new era for the United Kingdom and European Union. On that date, some four and a half years after the UK voted to terminate its membership of the EU, EU rules finally ceased to have effect in the UK.

Whilst trade mark practitioners across the world were busy grappling with the 1.5 million new cloned registrations that had crept onto the UK register overnight, eyes glazing over at the endless strings of 8s, 9s and 0s, many other key issues were still to be discussed and agreed on between the leadership of the UK and EU.

One particularly sticky issue was, and remains, the movement of goods between the UK and EU, which for the first time in decades would be subject to comprehensive checks, tariffs and duties. The UK would also need to decide what approach it would take to the exhaustion of IP holders' rights in this new landscape.

With the UK government having recently closed its public consultation on the issue of exhaustion of rights, we explore in this article the options under consideration and the potential consequences, particularly for the pharma sector. The pharma sector is acutely affected by this issue, with parallel imports accounting for potentially 5-10% of total imports of pharma goods.

The position prior to Brexit

Exhaustion is a restriction on an IP right holder's ability to control the distribution of goods protected by those rights. The basic principle is that once goods are put on the market by or with the consent of the IP rights holder in a certain country, the holder cannot generally rely on its rights to prevent the further distribution or resale of those goods in the same country (under a national exhaustion regime), in the same region (under a regional exhaustion regime), or anywhere in the world (under an international exhaustion regime).

Countries are generally free to choose which exhaustion regime they will apply to incoming goods. Members of the European Economic Area ("EEA" – consisting of EU member states plus certain other European countries), however, must apply rules of regional exhaustion, meaning first sale of a product anywhere in the EEA precludes the IP owner from taking action against parallel imports into any other EEA member state (except for under certain circumstances). With the UK no longer being a member of the EEA after Brexit, the rules now need to be redefined. Or do they?

The current options

At present, the UK is voluntarily continuing to participate in the EEA regional exhaustion regime. This means that the IP rights in goods first placed on the market anywhere in the EEA are considered exhausted in the UK. Therefore, these goods can be parallel imported into the UK without the rights holder's permission. However, the arrangement is not reciprocal; IP rights in goods first placed on the market in the UK are not considered exhausted in the EEA. As a result, the rights holder may stop the parallel export of these goods from the UK into the EEA.

The UK government recently launched a consultation on the issue of exhaustion, inviting stakeholders to submit their views on which regime would be preferable, going forwards. The consultation identified four options as follows:

1. “UK+”

Under this option, the UK would carry on automatically permitting parallel imports from EEA countries, but not from any others. There would need to be separate authorisation for regulated goods such as medicines.

The UK government indicates that this is the least costly option for businesses reliant on the EEA for supply of goods and raw materials. In particular, the UK's National Health Service is a major purchaser of medicines from EEA countries and makes significant savings from parallel imports. Distributors have tended to be in favour of this option.

2. National

A national exhaustion regime would mean that the UK would not automatically permit parallel imports from any country.

It appears that the UK government has effectively ruled out this option. The government believes that it would be necessary for goods to be checked at the border between the Republic of Ireland (a member of the EEA and EU) and Northern Ireland (which is part of the UK). However, it has made a separate commitment under the Northern Ireland Protocol to keep an open border between the two countries, meaning no checks.

Some in the pharma sector have also expressed concerns about a national regime. It is thought that trade in parallel imports of pharmaceutical goods amounts to as much as £1bn in the UK, and a minimum of 5% of the total UK pharmaceutical market by volume. Distributors are concerned about medicine shortages, and wastage of products near expiry due to lost opportunities for re-sale. However, others believe that it would provide greater incentive for innovation as IPR holders could maximise profits and investment.

3. International

Under an international regime, the UK would automatically permit parallel imports from any country (again, provided there is separate authorisation for regulated goods such as medicines).

Opening up the UK market to international exhaustion could in theory provide consumers with greater choice and lower prices. It is thought that parallel trade helped to reduce the prices of pharmaceutical products in Sweden by 12-19% after it switched from a national to a regional exhaustion regime back in the 90s (per Ganslandt and Maskus (2004)). However, industry stakeholders have expressed concerns about domestic shortages arising from a wider market for UK exports, and about a potential need for increased regulatory approvals.

4. Mixed

Permission for parallel imports would vary depending on the type of IP right, product or sector concerned. This could allow the government to balance out the varying needs of different stakeholders; however, it may be more logistically difficult and bureaucratic to administer, depending on how nuanced the differences are.

What next?

The UK government does not appear to be prepared to accept a national or mixed regime as it considers these to be incompatible with the Northern Ireland Protocol. The lack of data regarding the impact of an international regime, and opposition to such a regime from many industry groups, makes it seem that the continuation of UK+ would be an easy choice.

However, perhaps there is scope for more thought to be given as to the compatibility of a national regime with the Northern Ireland Protocol. As most parallel imports are identified and challenged at the point of sale, would border checks even be necessary under such a regime? The UK government also does not seem to have fully explored the option of granting

parallel trading rights as part of bilateral treaties – i.e. agreeing two-way exhaustion on a country-by-country basis.

As the government now starts to review the responses to its public consultation, one question looms – who will it choose to protect with its new regime?

Acknowledgments: statistics and industry views taken from “Exhaustion of Intellectual Property Rights”, a 2019 study commissioned by the UK Intellectual Property Office and carried out by Ernst & Young LLP. Downloadable from:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/808871/Exhaustion-of-intellectual-property-rights.pdf