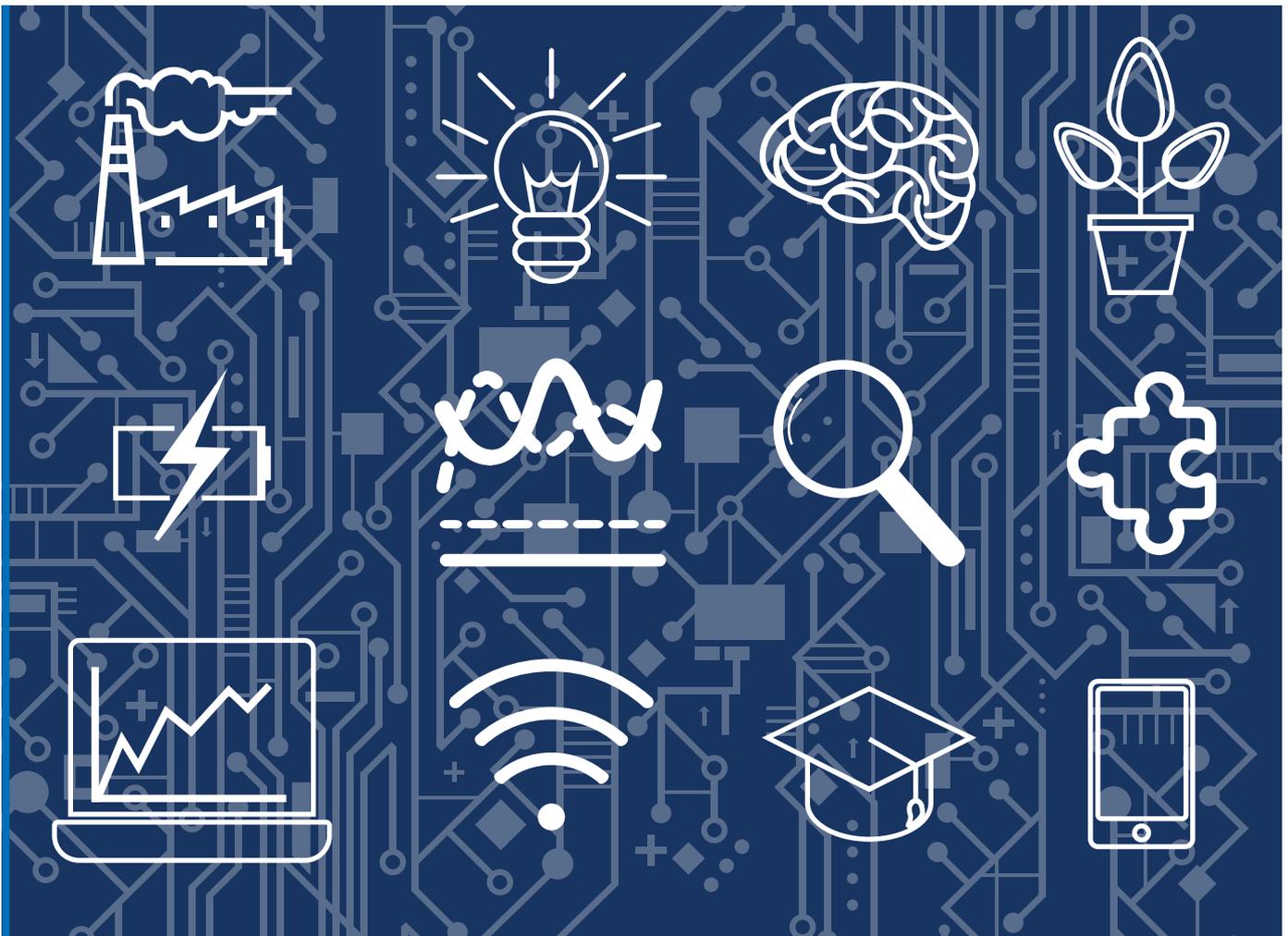




Exhaustion of Intellectual Property Rights



This is an independent feasibility study commissioned by the Intellectual Property Office (IPO) and carried out by EY. Findings and opinions are those of the researchers, not necessarily the views of the IPO or the Government.

Disclaimer

This report (Report) has been prepared by Ernst & Young LLP, a limited liability partnership registered in England and Wales with registered number OC300001, in accordance with an engagement agreement for professional services with the Intellectual Property Office (IPO). Ernst & Young LLP's obligations to the IPO are governed by that engagement agreement. This disclaimer applies to all parties, including the Department for Business, Energy & Industrial Strategy, of whom the IPO is an executive agency.

The report has been prepared for general informational purposes only and is not intended to be relied upon as accounting, tax, or other professional advice. Refer to your advisors for specific advice.

Ernst & Young LLP accepts no responsibility to update this report in light of subsequent events or any other reason.

This report does not constitute a recommendation or endorsement by Ernst & Young LLP to invest in, sell, or otherwise use any of the markets or companies referred to in it.

To the fullest extent permitted by law, Ernst & Young LLP and its members, employees and agents do not accept or assume any responsibility or liability in respect of this report, or decisions based on it, to any reader of the report. Should such readers choose to rely on this report, then they do so at their own risk.

Ernst & Young LLP reserves all rights in the Report.

Contents

1. Executive Summary	1
2. Introduction	4
2.1 Context	4
2.2 Scope	5
2.3 Approach	6
3. Literature review	7
3.1 Overview of the literature	7
3.2 Key drivers of parallel trade	8
3.3 Evaluation of different exhaustion regimes	10
3.4 Quantification	16
3.5 Summary	19
4. Quantitative survey	20
4.1 Overview of the approach	20
4.2 Response rate	21
4.3 Reasons cited and revisions to the survey approach	22
4.4 Implications of the survey	23
4.5 Prospects for further survey work	23

5. Stakeholder interviews	25
5.1 Overview of findings.....	25
5.2 Exhaustion and parallel trade by sector	26
5.3 Responses to national and international regimes	27
5.4 Summary	29
6. Options for further research	31
6.1 Quantifying the scale of parallel trade	31
6.2 Measuring the opportunity for parallel trade	34
6.3 Modelling the impacts of different regimes.....	36
6.4 Practicalities for further work	40
6.5 Conclusions for further work.....	42
Appendix A: Literature review	44
Appendix B: Survey questionnaire	62

1. Executive Summary

EY were commissioned by the UK Intellectual Property Office to conduct a feasibility study to determine whether it would be possible to estimate the scale of parallel trade across the economy, and to suggest potential research methodologies for the future. This was commissioned to inform the Government's assessment and analysis of the options for the Intellectual Property Rights (IPR) exhaustion regime when the UK leaves the EU.

The study builds understanding of the existing data to estimate parallel trade, what could be collected, its quality, and whether the data could be used to infer quantities of parallel trade. It also establishes the views of a sample of stakeholders on different potential regimes and their assessment of the consequences of a change of the IPR exhaustion regime.

In terms of scope, this feasibility study does not suggest or recommend a future exhaustion regime but establishes the current data on parallel trade and what, if any, future work could improve from this baseline.

1.1 Review covered economic literature, stakeholder interviews and a telephone survey

There were three elements to the feasibility study: a review of economic data and literature on parallel trade, stakeholder interviews across a number of sectors, and a telephone survey. The results of this study are set out in this report.

Full details of the literature review, covering over 30 economic studies is contained at Appendix A. The central finding of the literature review was that, apart from the pharmaceutical sector, there is very little data on parallel trade, which in turn explains the limited quantitative academic work. Only one study (NERA, 1999) attempts to perform a quantitative analysis across several sectors within the European Economic Area (EEA). The few existing quantitative studies consider the drivers of parallel trade, analyse motivations for arbitrage, and explain the level of trade between markets. There are also many qualitative studies that concentrate on price discrimination, the welfare implications of parallel trade, the implications on vertical integration of firms, and the opportunity to free-ride on others' investments in marketing. The lack of empirical quantification across the range of academic work suggests that quantifying parallel trade is likely to be challenging.

EY partnered with Kantar to design and pilot a quantitative telephone survey, details of which are contained at Appendix B. This included asking businesses across a range of sectors a series of questions to gather data on the current extent of parallel trade, assess what data could be available, and gauge views on different possible future IPR exhaustion regimes. The target was to achieve 30 completed surveys during the pilot phase to inform the full-scale survey design, in order to estimate the quantity of parallel trade across the whole economy.

The survey fieldwork was carried out between the 9th and 30th November 2018. However, despite contacting over 900 businesses it was not possible to generate any successful interviews. Section 4.2 of the main report covers the breakdown of response rate and reasons for refusal.

During the fieldwork, in an attempt to increase the response rate, alternative approaches were adopted including changing the term “parallel trade” to “grey trade”, repositioning and changing the focus of the questions, and broadening the screening question. However, these alternative approaches did not yield improved completion rates. The lack of responses to the pilot suggests businesses have low awareness of the issue, may be unconsciously participating in parallel trade and/or are unwilling to cooperate. This demonstrates both the complexity and low awareness of parallel trade within the business community, and is a key lesson for future research.

EY also conducted stakeholder interviews with companies from a number of sectors including trade bodies, rights holders and manufacturers. The principal aim of these interviews was to establish the extent of current parallel trade within specific sectors. They confirmed that there is limited data on the scale of parallel trade (except for pharmaceuticals), firms are not actively tracking it, and were unable to provide data on its current extent or possible changes from moving to a different IPR exhaustion regime. From the limited sample of stakeholder discussions, business favours maintaining the current regional (i.e. EEA-wide) regime. Concerns were raised over a move to an international regime, with representatives from the publishing sector seeing it as a very significant threat to their industry. Common issues flagged on an international regime were the scope for consumer harm and issues in conformity to quality standards, which would require increased monitoring at the border.

The findings of the feasibility study suggest that there is limited data available on the extent and scale of parallel trade. The lack of widespread quantitative analysis in the academic literature, absence of business monitoring of parallel trade, and the lack of response to the pilot survey is indicative of it being a fundamentally difficult area to quantify.

1.2 Scope for future research and analysis

Given the feasibility study has suggested that there is limited data available on the scale and range of parallel trade, Section 6 of this report identifies options for future research, including an evaluation of their strengths and weaknesses.

The first approach looks at data gaps – i.e. comparing estimates from two independent sources that should produce the same answer to identify a gap. For example, a measure of imports excluding parallel trade could be compared to an independent measure of consumption less domestic production for the domestic market and recorded imports. This could potentially provide an upper bound for parallel trade; but any observed gap could also reflect sources of measurement error within and between datasets, data missing below reporting thresholds, counterfeit and other illicit trade, so is likely to be highly imprecise.

The second approach matches and blends different datasets together, including company accounts data, trade data and intellectual property data to create a new dataset. The challenges in matching data on trade in generic products to specific company accounts data seem to be very significant, and it is not clear how approved trade on behalf of the rights holders would be taken into account in the calculation. The steps involved seem challenging, would take a lot of resource input, and may not be feasible given data constraints with unregistered rights such as copyright and unregistered designs.

The third approach estimates the opportunity or motive for parallel trade by comparing the price differentials for the same good in different markets. This involves measuring the opportunity for parallel trade by comparing the price differentials between the UK and other markets, then making some assessment of transaction costs, distribution costs and other factors that affect the scope for arbitrage. This would provide an upper estimate of the potential size of parallel trade at those prices, assuming that opportunities are fully exploited by the market. It would be a very labour intensive process to compile price data across enough sectors at disaggregated product level across different national markets, to make the analysis precise and representative. Even with detailed product-level data, there would need to be assumptions about tradability (transportation costs), the extent of price cutting by rights holders, pass through and price elasticity.

Another option would be to consider running a large scale quantitative survey. However, the high cost of such a survey would not appear to be justified given the response rates and challenges faced in the pilot phase. To improve the likelihood of reaching the relevant firms the survey would need to find a better form of words for explaining parallel trade to avoid confusion with illicit or counterfeit goods.

One potential area for future research is to continue targeted stakeholder interviews. In the feasibility study these provided useful insights into the key drivers of parallel trade. However, the stakeholder feedback solely represents the views of those with a good awareness of parallel trade who were willing to discuss the topic. To ensure that the views are representative across all of those affected by policy changes, the interviews would need to be expanded to include distributors (such as parallel traders), consumer advocacy groups, and other types of stakeholders. It would be especially useful if distributors were willing to be open about methods for identifying opportunities for parallel trade, and details of their volumes.

In summary, no research option that has a strong likelihood of successfully measuring parallel trade and its impact, has been identified. Although this feasibility study identifies potential avenues for future research, these are not without complications and there is not a clear and conclusive research methodology that can reliably estimate the scale and impacts of potential changes to the parallel trade regime in the United Kingdom.

2. Introduction

2.1 Context

The IPO is undertaking analysis to evaluate different possible Intellectual Property Rights (IPR) exhaustion frameworks that could apply in the UK following exit from the EU. To aid with this, EY have been engaged by the IPO to conduct an initial feasibility study for potential research methodologies.

IPR exhaustion refers to the limits on the rights to control distribution and resale of a good after it has been legitimately put on the market by the rights holder(s) in a specific territory. Once a good has been marketed, depending on the territory, the IPRs (or certain aspects of it) are said to be exhausted, and the good may be re-exported (known as parallel trade).

Through its membership of the European Economic Area (EEA), the UK is currently part of a regional-level IPR exhaustion regime, which means that goods marketed in the EEA cannot be barred from being resold/distributed across the Member States on the basis of IPRs, and rights holders have the ability to control imports from outside the EEA.

If the UK were to leave the Single Market, it could potentially be able to alter the current regime to either a national or international regime. Continuation of a regional IPR regime may also be an option, subject to negotiation with the EU as part of the UK's future trading relationship. Other customised or bespoke approaches to IPR exhaustion may also be available. The UK's no-deal preparation papers cite an unreciprocated IPR exhaustion regime as a potential default, whereby parallel imports into the UK from EEA could continue, but the EU may not grant reciprocal rights for parallel exports from the UK.

With national exhaustion, once a product is first sold in the UK with approval from the IPR holder, the rights holder cannot stop the products being resold within the UK. However, IPR holders are able to prevent resale within the UK of any goods that were not first placed on the market in the UK, thereby restricting parallel imports of products from another country.

Contrastingly, under international exhaustion, once the IPR owner (or another with approval from the IPR holder) puts the goods on the market outside of the UK, the rights holder loses their exclusive right after the first distribution of the product, meaning they cannot prevent parallel imports from abroad.

2.2 Scope

This report summarises the work undertaken for the initial feasibility study. Dependent on the suggestions provided in this report, there may be a second phase of work in order to fully quantify parallel trade and to subsequently model the potential impacts of different policy options.

A key focus of the review has been to estimate the scale of the UK's parallel trade, both within the EU and, if applicable (i.e. under any potential future international exhaustion regime), outside the EU. The review therefore tries to find data to estimate the current scale of parallel trade in the existing regional exhaustion regime, and looks at possible methods for estimating parallel trade in an alternative international exhaustion regime.

In terms of sector coverage, the IPO have previously received data and evidence on the pharmaceuticals sector, and thus steered EY to concentrate on gathering data and evidence from other sectors.

This report does not cover digital rights, because the exhaustion principle limits the right to control distribution, but not the owner's other rights such as the reproduction right. So a trader may be free to sell on an item without the rights-owner's consent but not to make further copies of it. Moreover, most digital products are licensed, so the end-user does not obtain a physical copy but is granted permission to access certain content online.

Further, the review aimed to understand the types of data collected that track and record parallel trade, what data potentially could be collected, the quality of any data that is or could be available, and what datasets could be used indirectly to quantify parallel trade if businesses did not track this directly.

A final objective of this study was to establish stakeholder views across a sample of UK sectors on different IPR exhaustion regimes and on the consequences of a change in IPR exhaustion regime.

2.3 Approach

The approach to research consisted of three main areas detailed below:

1. Baseline review of available literature – this involved an extensive search of the publicly available literature on parallel trade and exhaustion regimes to gather insights on the drivers of parallel trade, the merits of different regimes and the methods employed to quantify parallel trade.
2. Market research – EY partnered with Kantar to design and pilot survey research. This was conducted by Kantar’s fieldwork team via a telephone questionnaire for businesses across all sectors.
3. Stakeholder interviews – a number of stakeholder interviews were held with trade bodies and businesses identified by the IPO or through EY’s network of business contacts. These interviews focused on trying to establish the value of parallel trade in different sectors.

Section 3 explores the findings from the literature review, analysing the drivers of parallel trade and the pros and cons of different regimes. Full details of the literature review are set out in Appendix A.

Section 4 details the process and results of the pilot telephone survey, including an analysis of why businesses did not participate.

Section 5 summarises the insights from thirteen stakeholder interviews. Findings are anonymised due to the confidential nature of these interviews.

Finally, in Section 6 the options for further work in a potential second phase of research are considered, in particular options to estimate the extent of parallel trade through data techniques, and the potential for modelling to determine the impacts of a change to the exhaustion regime.

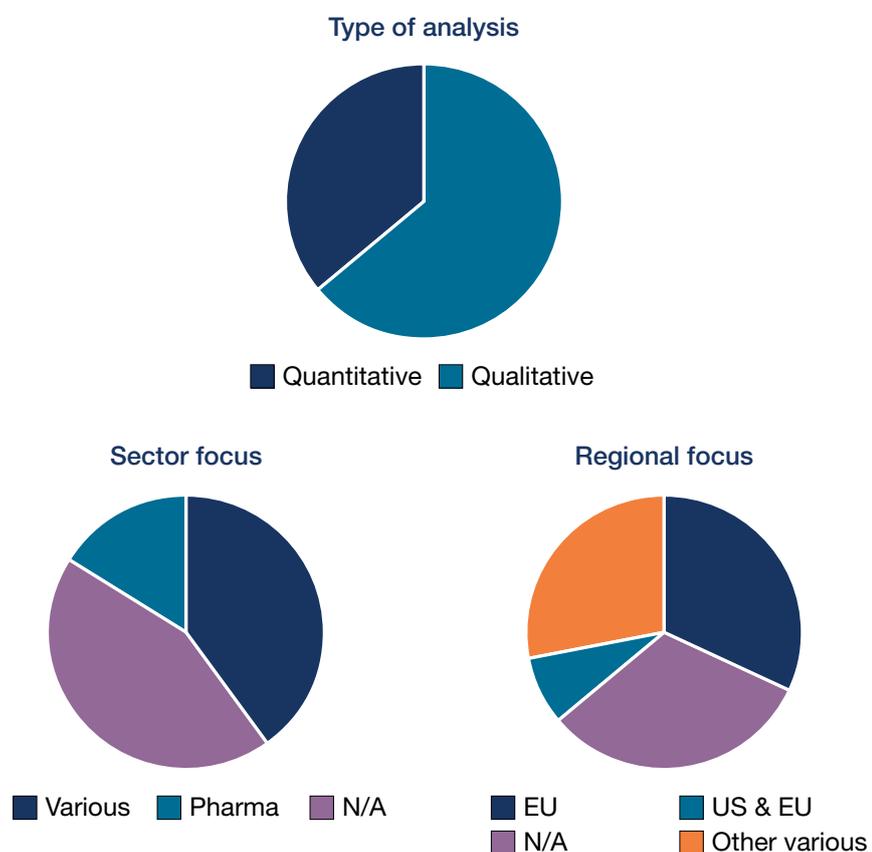
3. Literature review

An extensive search of literature has been conducted to build an understanding of the factors driving parallel trade, the arguments for different regimes as well as to further explore the availability of data to quantify levels of parallel trade. Full details of the literature reviewed are in Appendix A.

3.1 Overview of the literature

Over 30 economic journal articles have been reviewed, in particular from a survey article of research on IPR Exhaustion¹, literature identified from the REPEC Ideas economic journals database², and articles passed on by the IPO. In order to identify relevant literature a variety of search terms were used, such as “parallel trade”, “parallel imports/exports”, “grey imports” and “IPR exhaustion”.

From this review, 24 relevant papers were identified that focused on parallel trade. The majority of papers (over 80%) considered parallel trade in the context of IPR exhaustion, with around a third considering the implications of parallel trade on innovation.



1 Intellectual Property and Development, Lessons from Recent Economic research, by Maskus and Fink, The World Bank, 2005

2 <http://repec.org/>

Some general themes that emerged across the literature review are summarised below:

- Most papers reviewed considered parallel trade on a purely qualitative basis, noting the paucity of robust data on parallel trade.
- A large proportion of papers did not have a specific regional focus, although just over 30% of the literature was based on the EU or the US.
- Nearly half of the key papers identified did not focus on particular sectors, although five papers were identified with a pharmaceutical industry focus.

A principal finding from the literature review is that there is a scarcity of data on parallel trade, and that this has limited the quantification of parallel trade in academic work. Although a number of papers use some quantitative analysis, only one paper reviewed (NERA, 1999) attempts to quantify the scale of parallel trade across different sectors in the EEA.³ The few other studies which include quantification focus on measuring the drivers of parallel trade. This includes analysis of arbitrage opportunities (based on the price disparities between markets), and the level of trade barriers between markets.

The qualitative analysis provided by most papers focused broadly on price discrimination, the welfare implications of parallel trade, the implications of parallel trade on vertical integration, and the opportunity to exploit others' investments in marketing.

3.2 Key drivers of parallel trade

The literature review identified several factors that may motivate parallel trade in a particular sector or region. In particular price differentials between different markets are the most commonly identified motivation, and these give rise to the potential to profit from redistributing goods between different markets (i.e. arbitrage).

- Price differentials are considered the primary driver of parallel trade as they provide arbitrage opportunities for parallel traders (NERA, 1999).
- In exploring the scale of price differentials that can motivate parallel trade, Ganslandt, Maskus & Wong (2005) report that in 2001, the drug Viramune cost US\$3,508 in the US, US\$2,565 in Sweden, and US\$483 in South Africa. However, this is likely to be an extreme case caused by the difference in health systems between countries (see below).
- Differences in retail prices (adjusting for transport costs) between source country (i.e. where IPR is held), and the target market where it is sold, can provide parallel traders the opportunity to purchase the products in low-price countries, and then resell them in countries where the IPR holder charges a higher price (Bonadio, 2011). This study does not provide any example price differentials across countries.

³ The findings from the NERA study are explored in more detail in section 3.4.

- Wholesale price differences along the distribution chain can also contribute to arbitrage opportunities for parallel trades despite retail prices in different countries being equal. Wholesale price differences across markets were suggested in survey responses as a major factor in driving parallel trade within the EU (NERA, 1999), although no direct comparison is made with retail price differences. It was noted that, compared to the EU, countries such as the US have lower wholesale prices, and this could drive parallel trade in an international exhaustion regime.

Government price controls can also cause price differentials that foster parallel trade. In this case, the control of prices is by government rather than market forces, and this creates a persistent pricing differential across markets and therefore sustained arbitrage opportunities for parallel traders.

- Ganslandt and Maskus, 2007, note that this is a key factor in driving parallel trade in the pharmaceutical sector as national governments choose different policies, with some adopting stricter price caps that lower prices substantially compared to prices in other countries.

Another frequently cited indirect driver is exchange rate differences. Variation in exchange rates over time can contribute to the price differentials explained above, and thus facilitate parallel trade.

- Fink (2005) cites empirical evidence from the US in the 1980's (Parallel Imports, Demand Dispersion, and International Price Discrimination, Malueg and Schwartz, 1994)⁴. This finds that parallel trade was estimated to be at 2-3% of US exports, and disproportionately concentrated in particular products, typically brand-named consumer such as cosmetics and fragrances, luxury automobiles and cameras. The authors suggest that incomplete pass through of exchange rate changes into prices is a cause of parallel trade. This is due to parallel imports increasing consistently with the appreciation of the US dollar until the mid-1980s then subsequently subsiding rapidly.

High promotional expenditure by authorised channels in a target market can create opportunities for parallel traders to sell products in target markets without incurring these marketing costs.

- Prices charged in these markets may be higher due to promotional expenditure creating the perception of a higher quality product (NERA, 1999), although the study does not provide data analysis to support this.

The literature also notes that product quality differences can also provide arbitrage opportunities to facilitate parallel trade. Rights holders may be deliberately targeting different quality products at perceived differences in consumer preferences across markets. Distributors might then see opportunities to move products across markets, e.g. to target low income consumers in an otherwise high priced market, or vice-versa to target high income consumers in an otherwise low-priced market.

4 In turn, Malueg and Schwartz cite the source of the data as Chard and Mellor, "Intellectual property rights and parallel imports", 1989. No methodology is given, and the Chard and Mellor paper is unavailable without a subscription / payment for access.

- High end consumer goods and premium brands are more likely to experience parallel trade (Maskus and Chen, 2005), although this is not quantified, other literature such as NERA (1999) supports this. It noted that premium products across cosmetics and clothing are more susceptible to parallel trade.

The above reasons lead to lower profits for IPR holders, although there appears to be no data analysis on these factors in the papers reviewed.

- NERA (1999) discusses some factors that drive parallel trade that are theoretically beneficial to IPR holders. One such driver is overproduction in one market which can lead to discounting and opportunities to redistribute produce to another market creating price differentials which can be exploited. This excess supply can result from demand mis-forecasting or by deliberate over-ordering by distributors to trigger volume discounts and other supplier benefits. Other reasons that create opportunities for parallel trade include loose contractual terms created by manufacturers and failure to enforce contracts.

3.3 Evaluation of different exhaustion regimes

Based on the literature review, this section outlines the theoretical benefits of national or international exhaustion regimes. In general, the benefits of the national exhaustion regime tend to be the downsides of having an international exhaustion regime and vice versa.

The literature finds that several drivers of parallel trade give rise to lower profits for IPR holders, whilst others have implications on consumer choice and information. A national exhaustion regime is expected to create a stronger incentive for risk-taking and innovation as it gives IPR holders the ability to maximise profits in each market they sell their products. Other research looks at the incentive to invest and innovate:

- Ganslandt, Maskus & Wong (2005) note that parallel trade erodes IPR holder's price setting power in industrialised countries where most returns to investment are realised. In the context of pharmaceuticals they note that this would hamper incentives to develop new treatments.
- In particular, Muller-Langer (2010) note that increased parallel trade would reduce incentives for pharmaceuticals to invest in R&D. Reducing parallel trade through a national exhaustion regime would provide IPR holders the incentive to invest in innovation and product development.
- Mantovani & Naghavi (2010) model the impact of parallel trade on R&D in countries at different stages of development, and conclude an adverse impact is more likely to be present in emerging industries in developing countries than in established industries in already developed countries. They also provide details of other studies which have looked into this topic further, e.g., Li & Maskus (2006) built a theoretical two-country model of endogenous investment in process innovation focused on the impact on cost-reducing R&D, which concludes that parallel imports always inhibit R&D.

- However, in a dynamic context, competition can also stimulate further innovation. Li (2006) models competition between firms and finds ambiguous results on innovation dependent on transportation cost, suggesting that competition does not necessarily reduce innovation.

3.3.1 National exhaustion

Some authors argue that a national exhaustion regime would allow for positive distributional effects across countries.

- Due to differences in average incomes across markets, parallel trade reduces the incentives for IPR holders to serve low-income markets by making it unprofitable (Ganslandt, Maskus & Wong, 2005). As noted above in section 3.2, the authors show these price differentials can be very large.
- National exhaustion regimes help preclude parallel imports which increases the degree of price discrimination and provides IPR holders with incentives to supply products at a lower cost in low-income countries, as they can be assured that these low price items will not flood back onto the domestic market (Bonadio, 2011).

National exhaustion regimes extend IPR holders' control over the international distribution of their products.

- This would help protect investments in marketing as well as after-sales services. It also helps to control the quality of products being provided to consumers (Fink & Maskus, 2005).

Further, a national exhaustion regime would reduce the opportunity for parallel traders to “free ride” on promotional and market development investment made by authorised distributors or IPR holders themselves.

- Palangkaraya and Yong (2006) found through use of a theoretical economic model, that both parallel imports, and the threat of such imports, reduced the domestic distributor's incentive to invest in market development.

The papers that considered national exhaustion regimes did not focus on consumer impacts, although a contrast could easily be drawn with the consumer benefits identified for international exhaustion regimes (see sections 3.3.2 and 3.3.3 below).

- Deloitte (2012) use a supply and demand model to show that domestic consumers will tend to be worse off as a result of parallel import restrictions. The Deloitte study also found that restrictions on parallel imports on books in Australia have led to consumers paying an approximate 10% price premium.

3.3.2 International exhaustion

Conversely, an international exhaustion regime provides opportunity for parallel trade and reduces the power of IPR holders to control such behaviour.

Supporters of international exhaustion regimes stress that parallel trade facilitates competition in the distribution of products, and that national exhaustion regimes can be seen as a non-tariff barrier to trade. An international exhaustion regime would create more competition and help to reduce prices, compared to the prices that would be set if IPR holders had a monopoly over both production and distribution of their products.

- It is argued that parallel importers are able to secure lower prices for goods (Dobrin & Chochia, 2016), and that differences in the quality of parallel imports would also increase choice for consumers (Fink & Maskus, 2005).
- Fink (2005) quotes anecdotal evidence from Australia which cited that retailers dropped the prices of top-selling CDs by one third after the removal of parallel import restrictions.
- Deloitte (2012) found that since parallel import restrictions on CDs were relaxed in both Australia and New Zealand, real CD prices fell considerably (e.g. falls of 30-40% in wholesale prices and 20-26% in retail prices between 2002 and 2011). The Deloitte study also found that, whilst parallel import restrictions in Australia kept the price of books high (see section 3.3.1 above), the number of New Zealand book titles published annually remained fairly steady between 2005 and 2008 despite the removal of parallel import restrictions.
- Muller-Langer (2008) noted a study by Ganslandt and Maskus (2004) that found that between 1994 and 1999 parallel trade helped to reduce the prices of pharmaceutical products in Sweden by 12-19%. They attributed this to parallel trade as Sweden provided a natural experiment due to its switch from a national to regional regime after it joined the EU in 1995.
- Ganslandt and Maskus (2007) note this was the only statistical analysis employing data on parallel imports and prices of original manufacturer's goods relating to the pharmaceutical industry.
- Bonadio (2011) notes that parallel trade can encourage IPR holders to reduce prices due to competition by parallel traders, which can act as a solution to potential anti-competitive behaviours by IPR holders.
- An international exhaustion regime is in alignment with a move towards free trade which ultimately increases productivity and efficiency for countries as they focus on their comparative advantage (Heath, 1997).
- Muller and Langer (2007) note that policymakers in developing countries support an open regime to parallel trade as they place more emphasis on affordability.

- Dobrin & Chochia (2016) argue that parallel traders benefit from rights holders' promotional investment, and do not provide consumers with the pre-sales or after-sales service that authorised distributors provide.
- Further, Bonadio (2011) argues that parallel importers do not consider target market quality, and sell low quality products in countries with higher quality standards which could harm consumers.
- Contrastingly, Sauer (2008) concluded there was insufficient support for the claim that parallel imports reduces the quality of products. By using Finland and Sweden as examples, she used changes in prices in goods exposed to parallel import competition between the two nations' accessions into the EU to 2004. She found that for both countries, there was an increase in quality⁵ immediately after their entry into the EU (a change from national to regional regimes thus a move to increased parallel trade). However, the paper also noted some weak evidence of a reduction in quality after a lag – e.g. between 1997-1998 it was found that Finland experienced a 0.3% decrease in quality, although Sweden had a 2.4% increase, and then by the end of 2004, the quality of imports increased for Finland but decreased for Sweden.

3.3.3 Regional exhaustion

Switzerland can be considered to be a case study of a change to a regional exhaustion regime. In 2000 a court ruling determined that national exhaustion rights apply, which prompted research into the potential impacts of alternative international or regional exhaustion regimes.

- Plaut Economics (2004), which updates an earlier study of international exhaustion by analysing trade patterns to provide expected results for regional exhaustion applied to patent law under Switzerland's new anti-trust laws (introduced in 2003):
- The analysis takes into account the effective arbitrage potential (i.e. considering costs of transport, market entry barriers, co-existence of high and low price markets) to define the potential market size subject to arbitrage opportunities. Two sectors are considered – pharmaceuticals and consumer goods.
- The study assumes that between 10 and 30 per cent of the international price difference is sufficient to cover transport costs and the profit margin of the parallel importer, and notes that these numbers are relatively small compared to e.g. the NERA study. The availability of data on transport costs for parallel import of consumption goods is considered to be relatively poor. In the NERA study qualitative estimates are used, where it is assumed that the smaller the value/weight ratio is, the higher the transport costs that are incurred. Plaut take relatively low costs so to ensure that the effects of a system change are not underestimated.

5 Sauer (2008) employs the Aw and Roberts (1986) index number methodology to examine the quality of parallel imports "This method proposes that changes in an aggregate unit value index can be decomposed into the changes attributable to quality and pure (quality adjusted) prices. The change in an aggregate unit value index is a biased measure of the true change in prices. Observed prices may be increasing due to an increase in quality. This bias can be removed by using a Tornqvist price index, which will reflect the quality-adjusted import price."

- The study finds that the potential for arbitrage under a regional exhaustion regime is defined by estimated price differentials of between 6.8% and 14.4%, compared with price differentials of between 9.7% and 20.5% under an international exhaustion regime.
- Taking into account trade patterns, the value of products where there is potential for parallel trade under regional exhaustion is estimated to be between CHF 1,477 and 2,594 million (£1,182 - £2,075 million), and under international exhaustion between CHF 1,806 and CHF 2,781 million (£1,445 - £2,224 million).
- Applying the estimated price differentials to this leads to forecast arbitrage savings of between CHF 100 and 374 million (£80 – £300 million) per annum in a regional exhaustion regime, compared to arbitrage savings of between CHF 176 and 570 million (£140 - £455 million) per annum in an international exhaustion regime.
- The arbitrage savings from a regional exhaustion regime are between two-thirds and three-quarters the potential gain previously estimated under a fully international exhaustion regime with Switzerland's previous anti-trust laws.

In a second study, Frontier Economics and Plaut⁶ use both microeconomic and macroeconomic models to assess the expected impacts of a change to regional exhaustion applied to patent law:

- Specifically they identify the sectors most significantly impacted by filtering through three stages - patent-intensity by sector (quantified through a detailed study of patent protection in force conducted specifically to inform this work⁷), tradability (which is evaluated by assessing product characteristics and discussion with experts - e.g. capital goods are cited as have an accompanying service or consulting component, which cannot easily be parallel traded), and estimated price differentials.
- Once the opportunity for parallel trade is identified, the price differential can be applied to identify the potential arbitrage saving. As in the previous Plaut study, sectors are aggregated into pharmaceuticals and consumer goods, and price differentials are quantified for these two broad sectors. Price differentials of 40% for pharmaceutical products and between 12% and 30% for consumer goods are reported. The impact of regional exhaustion is expected to be a reduction in 14-32% in pharmaceutical prices and reduction of 4-8% in consumer goods prices.

⁶ Date unknown.

⁷ An aggregate measure is presented on a sliding scale from 0 to 5, although it is unclear how this is derived.

- In a further step, price elasticities are used to estimate the corresponding volumes of parallel trade. These price elasticities are sourced from a literature review, with 16 papers cited in an appendix (see section 6.2 for a discussion of price elasticities that could be used in an equivalent methodology applied to the UK).
- To determine which sectors to model the macroeconomic impacts, they then make an assessment of the importance to the Swiss economy, based on consumption, production and R&D location.
- In macroeconomic terms, there is a small increase in household disposable income, which also increases consumption of domestic manufactures, and up to a 0.1% increase in Swiss GDP. Although some reduction in local sales of patented products is anticipated, overall it is expected that the impact on Switzerland as a research location will be negligible.

The Frontier Economics study also references earlier studies of the impact of regional exhaustion:

- Ganslandt and Maskus examine the transition of the Swedish economy from national to regional exhaustion, noting that the market share of pharmaceuticals for parallel imports reached 6% and led to a 4.5% price reduction.
- The Danish Ministry of Industry find that parallel imports reach a market share of 10% in pharmaceuticals and 3-15% across individual consumer goods groups.⁸

⁸ EY hasn't been able to locate the original Danish Ministry of Industry report in an Internet search, and therefore cannot examine the methods used and consider whether they could be replicated for the UK.

3.4 Quantification

NERA (1999) is a widely cited report in the literature on parallel trade and IPR exhaustion regimes. It is the only study that has been reviewed that attempts to quantify the scale of parallel trade across a range of sectors.

3.4.1 Scale of parallel trade

The main objective of the NERA study, which was commissioned by the EC, was to examine the economic consequences for the EU of alternative regimes for the exhaustion of IPRs for trademarks. NERA provide quantitative analysis on 10 sectors and the effect of exhaustion regimes using a survey (see below), as well as desk research from the OECD on price differentials between the US, EU and Japan, and simplified market assumptions around factors such as trade barriers, technical barriers and transaction costs.

The study includes survey results based on a telephone interview with trademark holders, consumer organisations, importer/exporter associations and SME associations across 10 sectors including footwear, musical recordings, automotive, clothing and alcohol. The aim of the survey was to provide quantitative information and questions were tailored to different respondent groups, with each question having multiple choice answers.

NERA notes that the survey had a lower than planned response rate. Over 5,500 organisations across all EU countries were contacted, with a target of achieving 176 responses. Out of these, 160 respondents were successfully screened although only 137 interviews were completed in full, and these survey responses were supplemented with information provided in submissions and position papers and collected through further interviews with interested parties (an additional 33 responses in total).

The study does not detail the questionnaire, but the reported responses cover the level of parallel trade in a particular sector within the EEA, and implications of a change in exhaustion regime.

Some findings include:

- The highest prevalence of parallel trade within the EU was estimated to be in the following sectors: cosmetics and perfumes (parallel imports accounting for up to 13% of the total market); clothing (5-10%), soft drinks (0-15%) and musical recordings (5-20%). The lowest parallel trade estimates were for alcoholic drinks, domestic appliances and footwear with estimates of less than 5% parallel trade in the industry.
- From the sector analysis, musical recordings and cosmetics and perfumes were found to be the most likely to see increases in parallel trade with an international exhaustion regime.

- The study noted that for musical recordings, although consumers may gain some benefit from discounting, producers would suffer a reduction in profitability, and incentives to invest in new acts would be reduced.
- For cosmetic goods, the increase in parallel trade was expected in premium products rather than non-premium products, which could affect the luxury image of these goods.
- Alcoholic drinks were highly unlikely to be affected as EU prices were found to be relatively low.
- Footwear was found to be moderately susceptible to parallel trade due to trademarks playing a crucial role in developing and advertising brands. Retailers would be disadvantaged but consumers would benefit from lower prices. This is different to clothing which was found to be susceptible only for premium brands.
- The study found moderate decreases in prices, on average less than 5%, from changing to an international exhaustion regime. This is estimated “based on survey data, knowledge of existing price differentials and a number of approximate judgements and estimates”. The impact on profits then depends on the existing profit margin in each sector; the lower the existing profit margin, the greater the impact on profitability of a given price change. In some cases, small price changes are expected to lead to a large reduction of profits e.g. in consumer electronics (about 35%) and domestic appliances (about 25%), with both industries expected to face medium parallel import penetration. In comparison, cosmetics and perfumes would be likely to have a moderate parallel import penetration and thus see a small price reduction of 3%.
- The survey responses from manufacturers identified that the main beneficiaries of an international exhaustion regime are expected to be parallel importers, the transport sector and consumers. However, NERA’s modelling results show the price effects are generally small or negligible, and the only medium to large effects are the reductions in profitability for rights holders. Thus, the NERA study has been characterised, e.g. in the Plaut/Frontier Economics work on Switzerland, as concluding that parallel trade benefits mainly parallel importers and less so consumers.

Since the study was published in 1999 the EU has continued to expand in terms of the number of countries included, and also in terms of the depth of integration. The introduction of the Euro covering the majority of the EU trading block is also likely to have led to significant changes in parallel trade. On the one hand, for the countries in the Euro area, the single currency removes any opportunities for arbitrage that had been due purely to currency fluctuations. On the other hand, the single currency makes price differentials more transparent and easier to exploit without fear of currency movement undermining expected profits. It is not possible to say what the net impact of these changes will have been on the scale of parallel trade, but the fundamental nature of the changes means that NERA’s estimates from 1999 cannot simply be adopted as viable estimates of the current scale of parallel trade.

3.4.2 Quantification using price differentials

A number of papers have sought to quantify other aspects of parallel trade. These are again largely focused on the pharmaceutical industry, and many cover the US market rather than the EEA. Some of this quantification is noted above (e.g. see Fink, 2005, citing evidence from the US in the 1980's published by Malueg and Schwartz). Other key points relevant to the EU are highlighted below:

- Suppliet, Duso and Herr (2014) note interesting data around the pharmaceutical industry. They highlight findings by Murray and Weissenfeldt (2013) who estimated parallel trade in pharmaceuticals in 2012 totalled €5.3bn in the EU and €2.9bn in Germany (based on ex-factory prices).⁹ These are similar to the latest estimates provided by the trade body for pharmaceutical distributors (€5.5bn in parallel trade across the EU)¹⁰.
- The European Federation of Pharmaceutical Industries and Associations (EFPIA, 2013) approximate the total market share of parallel trade in the sector in 2010 for four countries - Denmark (24%), Germany (11%), Netherlands (10%) and UK (7%).
- Deloitte (2012) used price differentials between books and music CDs in New Zealand and Australia to estimate the price impacts of parallel import restrictions. They found that parallel import restrictions on books in Australia result in a 10% price premium for customers compared to what they would otherwise be without the restrictions.

9 EY does not have access to the original paper by Murray and Weissenfeldt, and so have been unable to ascertain their methodology.

10 Estimate based on the IMS/IQVIA prescription drug database.

3.5 Summary

To conclude, the literature review provided notable insights into the key drivers of parallel trade. The most significant of these factors are price differentials, which provide the arbitrage opportunities. In markets such as pharmaceuticals where governments set prices, parallel trade will be persistent due to the inability of market forces to equilibrate prices in response to arbitrage opportunities.

Based on the literature review, national exhaustion regimes are beneficial to IPR holders and are generally favoured by producers as they provide the incentive to innovate, whilst also removing the ability of parallel traders to easily benefit from investment by producers and authorised distributors. In contrast, international exhaustion regimes support increased competition and provide consumers with increased choice and potential benefits in the form of more competitive pricing. However, international regimes also risk causing consumer harm due to the potential to reduce the quality of products or cause consumer confusion. Some of the literature argues that an international exhaustion regime would stifle innovation, but this argument is contested, and absent empirical work it is not possible to draw any firm conclusion. None of the literature comprehensively quantifies all the impacts on consumers and producers in a model of the macro-economy, making it hard to draw inferences for the overall merits of national, regional or international exhaustion regimes.

One key conclusion from reviewing the literature is that data on parallel trade in sectors other than pharmaceuticals is scarce. Price differentials have been used to show opportunities for parallel trade, whilst theoretical models have been produced to explain the issues. The lack of empirical quantification across a raft of academic work indicates that there are challenges to quantifying parallel trade. The options for further work and potential quantification methods are outlined in section 6.

4. Quantitative survey

Working with Kantar Millward Brown (“Kantar”), a pilot quantitative survey was conducted through telephone interviews with businesses, aiming to gather data on the current extent of parallel trade, assess what data could be available, and gauge views on different possible future IPR exhaustion regimes.

The intention was that the pilot stage would inform the feasibility and design of a full survey, which could be large enough to be scaled up to an estimate of the quantity of parallel trade across the whole economy

The output of the survey could be grossed-up to measure the current extent of parallel trade and, by deduction, the impact of a change from a regional to a national exhaustion regime. Estimates of the impact of a change to an international exhaustion regime could be either qualitative responses or quantitative estimates.

4.1 Overview of the approach

The questionnaire for the telephone interviews covered the following areas:

- Business demographics;
- Establishing awareness of parallel trade;
- Whether the company was able to identify the parallel traded goods;
- Where the data / estimates was sourced from and how reliable it would be;
- The scale of parallel trade;
- A breakdown of parallel trade activities by product origin/destination/group;
- What countries they exported and imported parallel-traded goods to and from;
- Whether any historical data was available;
- How the quantity of parallel trade has changed over time;
- Information around parallel trade in their supply chain; and
- The implications of a change in exhaustion regime on businesses and the pricing of their products.

The survey was split into two separate sets of questions, one for rights holders

(manufacturers) and one for distributors, to enable targeted questions to each of them.

The survey fieldwork was carried out between the 9th and 30th November 2018. The survey aimed to cover businesses from all sectors and across manufacturers, distributors and retailers. The target was to achieve 30 completed surveys, which could be considered to give an overview of the range of response likely in a full-scale telephone survey, and would then be used to inform the design of the second stage of the survey.

4.2 Response rate

Kantar's fieldwork team contacted 926 businesses, including 403 manufacturers, 332 distributors and 191 retailers.

Multiple attempts were made to reach most of the 926 contacts with the following outcomes:

- 826 contacted by phone and followed up by phone or email depending on the status of the call.
- 159 were sent emails, along with a letter from the IPO attached in order to provide verification that the interviewers were genuinely working on behalf of the IPO.
- The email was sent to 100 additional contacts and 59 that had already been contacted by phone but hadn't responded to calls.

Of the 926 relevant individuals identified, Kantar's fieldwork team were able to make contact with 208 respondents. Although 38 of these contacts immediately declined to have any conversation at all, the team were able to talk to 170 about taking part in the survey.

Whilst 26 (of the 170) did want to take part in this exercise, they did not pass through the initial screening question. The majority (23) being unaware of Parallel Trade whilst a small number (3) were aware of the concept although not actively practicing it.

The remaining 144 were interested in hearing more about the focus of the project, however, after having Parallel Trade explained, they declined the opportunity to have any involvement with the survey being unwilling or unable to discuss the topic of parallel trade.

Of the 144, the majority (120) gave no reason for this whilst the remaining 24 gave a range of reasons for declining; including that they were not willing to speak on the topic or that it was against company policy to participate (see Table 1 below).

Table 1: Survey refusal type

Refusal Type	Count
Parallel Trade – not willing to speak on this topic	7
UK Government sponsored	3
Not relevant	1
Company policy against survey	13
Refused with no reason specified	120
Total	144

26 contacts were willing to take part in the survey, however, they did not pass through the initial screening question, with the majority (23) unaware about parallel trade and a small number (3) who were aware but said that they did not participate in it.

The remaining 38 initially successful contacts requested a call-back. However, these call-back attempts were all unsuccessful, resulting in zero completed interviews.

4.3 Reasons cited and revisions to the survey approach

With some of the potential participants the fieldwork team had the opportunity to explore further the main reasons for non-participation, as outlined in Table 1 above. The detailed reasons cited included:

- Survey targets not being interested in engaging on the topic.
- Respondents have already spoken with government on this issue.
- Businesses said they purchase directly from the manufacturer, and not from any other source or have a licensed agreement with manufacturers.
- Others questioned the intent/credibility of the survey, and were not prepared to cooperate even after the fieldwork team provided information to verify the survey and its source (e.g. Kantar, with EY for the IPO).

Part way through the survey the fieldwork team explored alternative approaches, including re-positioning and changing the focus of the interview questions, and using the term grey trade in place of parallel trade. The fieldwork team also included a new screener question which identified parallel trade amongst a number of options within the questionnaire. However, response rates did not improve.

4.4 Implications of the survey

Despite the lack of success in responses, the comments provided in declining the survey do offer some insights:

- General low awareness of the term parallel trade. Even when the term was thoroughly explained, it was still not clear to respondents.
- Where there was claimed understanding of the term, respondents believed that their organisation did not participate in parallel trade (even after listening to the definition again).
- Where a letter from the IPO was sent out in advance it was noted that, although a few individuals became curious about the study, the letter did little to increase participation rates.
- In a handful of cases, asking about parallel trade in a less complicated way (in a way that respondents could understand) helped with clarity around the term but did not improve participation rates.
- Parallel trading activity may have a degree of stigma surrounding it leading to individuals in organisations that were involved in parallel trade, feeling unwilling to admit to the activity in case they are doing something wrong.
- Parallel trading activity may have been going on for so long that it has become normalised in daily activities leading to individuals genuinely not recognising that their organisation conducts parallel trade, or regarding the activity as 'business as usual' and may call it something else.

4.5 Prospects for further survey work

In theory the survey approach is flexible to answer a wide variety of questions, covering not just current practice, but also responses to potential future changes in the exhaustion regime, rights holders appetites to block parallel trade (e.g. in a national exhaustion regime), and distributors attitudes to exploiting new parallel trade opportunities. However, the experience has shown that it will be challenging to collect data on parallel trade via a survey. A further large scale survey could be costly, and with a high probability of limited success.

The lack of responses to the pilot suggests that respondents are either unaware of the issue, or unwilling to cooperate. This highlights significant challenges to producing a robust sample that is representative of the market. There are also other practical challenges to aggregating data from different links in the distribution chain and collecting accurate data across the different stakeholders involved:

- Manufacturers will have limited visibility over their downstream supply chains unless it is short and closely monitored, which is more likely for low volume, high price items where price discrimination is possible.

- Distributors are likely to be the best source of data on parallel trade. They are likely to differ across industries and over time. However, distributors may not be willing to be open about parallel trade practices, or may not be aware if their stock is parallel trade. Moreover parallel trade could be generated from any layer of the distribution chain, and there is a risk of double counting if different layers of the distribution chain are surveyed (e.g. the same item could be surveyed as parallel trade in one distributor and then it could be counted again when it is moved onto another distributor, regardless of whether it is re-exported).
- Retailers may be unaware of whether the stock they hold is from parallel trade, and may find it difficult to estimate the value or volume of stock from parallel trade. Hence any estimates would be subject to error. Additionally, it is likely that stock held from parallel trade may change over time, e.g. it could be opportunistic purchases that are not representative.

A very large sample size would be required to reduce the effect of the multiple possible sources of measurement error.

Kantar have suggested that, to make a further survey work, it would be necessary for participants to 'opt in' to the discussion, rather than having an agency "cold-call" companies. For example, this might be achieved through initial contacts made by trade representative bodies, or through advertising on a relevant trade body website (distribution, manufacturing, procurement etc.). Take-up could be further improved through incentivising responses (e.g. a payment to a nominated charity).

However, based on the experience thus far, take-up might still be insufficient to make quantitative estimates for the wider population. The opt-in process moves away from a random sample and introduces potential sample-selection bias. This makes grossing up an economy-wide estimate less reliable. On balance, with the challenges to achieving response rates and the difficulties in grossing-up to an economy-wide estimate, this is not a recommended option for further research.

5. Stakeholder interviews

Stakeholder interviews have been held with companies in a number of sectors discussed with IPO. The stakeholders were identified from EY's existing business relationships. A mix of trade bodies and manufacturers (IPR holders) were interviewed to understand the data they hold on parallel trade, the scale of parallel trade, the reasons for parallel trade, and the impact of a change in exhaustion regime on their respective businesses or sector.

The stakeholder interviews were conducted largely with rights holders and trade bodies, and, apart from pharmaceuticals, did not cover distributors (i.e. parallel traders), consumer advocacy groups, and other types of stakeholders. This reflects the mix of accessible stakeholders and the constraints on time available for the interviews in the feasibility stage. It is likely that those not covered may have different views, and distributors in particular may be better placed to quantify parallel trade. It is recommended that any further stakeholder interviews should target these types of stakeholders.

5.1 Overview of findings

The stakeholder interviews provided informative insight into the views of businesses and trade bodies on parallel trade and exhaustion regimes.

A common finding from the interviews was that there is limited data on the scale of parallel trade and, other than pharmaceutical sector representatives, those interviewed do not track the extent of parallel trade. Stakeholders were not able to provide data on either the current extent of parallel trade within the EU or estimates of the potential extent of parallel trade outside the EU if an international exhaustion regime were to be adopted.

Many stakeholders do not see parallel trade as a material issue, and accept a small amount of parallel trade within the current EU system as business as usual. Automotive sector stakeholders thought there may be significant parallel trade in their supply chains, although no other sectors mentioned supply chains.

Stakeholders highlighted that they are more concerned with IPR breaches. Premium brands are the most concerned with parallel trade; however, these businesses have the most visibility and control over distribution chains.

Regarding a change in exhaustion regimes, stakeholders favour maintaining the current EU regional exhaustion regime, which is universally accepted. Particular concerns were raised over a change to an international exhaustion regime, and the publishing sector in particular saw an international exhaustion regime as a very significant threat.¹¹

¹¹ No consumer groups were interviewed, thus the findings reflect producer views.

5.2 Exhaustion and parallel trade by sector

A principal aim of the stakeholder interviews was to establish further information on the extent of current parallel trade within specific sectors. Although the interviews provided further understanding and estimates of parallel trade, other than the pharmaceutical sector, none were able to provide monetary estimates.

The main findings for each sector are noted below.

- Pharmaceuticals - stakeholders from this sector were the only respondents interviewed who were able to provide an estimate on the size of the parallel trade market. Comments from stakeholders indicated that parallel trade in the EEA could be in excess of £5bn (at 2012 ex-factory prices). Within the UK, they expect parallel imports to amount to £1bn, a minimum of 5% of the total UK pharmaceutical market by volume (30 million packs out of an estimated 5-10 billion dispensed per annum), and are estimated to directly save the NHS almost £100mn per annum through the reimbursement of pharmacies. In addition to direct savings, the presence of parallel importers in the market could be expected to put downward pressure on prices for products sourced directly from rights holders, leading to further indirect savings to the NHS. Parallel exports were estimated to be £400-500mn. The reliability of this data is debated – with a difference in opinion between trade bodies representing distributors and those representing manufacturers. Estimates are based on survey data collected from pharmacies, which would require further investigation in any further stage of research.
- Pharmaceutical distributors argue that, as well as savings to the NHS, parallel imports offer security and diversity of supply. However, manufacturers argue that parallel trade complicates and confuses the true UK market demand expected to be supplied by the brand owner, and that there is no continuity of supply of parallel imports, which leaves the brand owner having to hold additional stocks to cover for parallel exports or the supply of parallel imports drying up.
- Alcohol – from the interviews with two leading drinks industry trade bodies and two drinks manufacturers, it is possible that parallel trade in the alcohols sector is a significant proportion of UK imports, and a smaller fraction of UK exports. There is some proscribed parallel trade outside of the EEA in this sector. One respondent suggested that an accurate estimate of parallel trade in this sector might potentially be derived with access to customs warehouse data, which creates tracking data for products for excise purposes. Responses on enforcement varied, with one rights holder tightly controlling distribution, and another suggesting that some in the industry may be relaxed about parallel trade because it grows their total market penetration.
- Food – interviews with stakeholders from the food industry highlighted a lack of existing data and no obvious source of data that could be used to derive an estimate on the size of the parallel trade market. One manufacturer responded that many of its products are low unit cost and low margin as well as being market specific, which reduces the motivation for parallel trade.

- Fast Moving Consumer Goods (FMCG) – the extent of parallel trade is believed to be a small proportion of the total UK market. One respondent reported occasional spikes in parallel trade in specific products, e.g. up to 30% of their market being accounted for parallel imports at one point in time.
- Publishing – publishers believe that the current level of parallel imports into the UK is very small in this sector, because the market for English language books elsewhere in the EEA is not large. Publishing rights negotiated with authors tend to follow the IPR exhaustion model, i.e. the EEA is the relevant market for UK copyright, and publishers try to acquire exclusive copyrights for EEA area distribution. There is greater risk of parallel trade where only one global edition of a product is available, rather than different editions in different markets (e.g. different editions for the US and the UK/EEA markets).
- Automotive – the level of parallel trade for finished goods is estimated to be small because manufacturers exert control over distribution chains. There is believed to be a small amount of parallel trade in certain specialist markets. Parallel trade is believed to be a significant proportion of the supply chain for automotive components, and possibly also of the after-care market in parts.

5.3 Responses to national and international regimes

The interviews sought views on the implications of a change to a national or international IPR exhaustion regime for imports, exports, pricing and distribution chains. Discussion also asked for views on an unreciprocated exhaustion regime as set out in the UK government's no deal papers – this would permit parallel imports but not allow equivalent parallel exports with the EEA. This section compares the implications under each regime raised under each topic for all sector stakeholders.

5.3.1 Imports

Under a national exhaustion regime, most stakeholders responded that parallel imports would be reduced and consumer choice would be narrowed. Pharmaceutical distributors suggested there would be significant shortages of medicines, although another trade body noted that the removal of parallel trade could improve market signals for UK manufacturers to meet a more stable demand. Automotive stakeholders indicated that there could be a significant adverse impact on manufacturers' supply chains.

With a change to an international regime, stakeholders raised concerns over the products coming from parallel trade not being suitable for UK consumers (e.g. text books containing inappropriate materials), as well as issues with packaging and labelling within the food sector, and potentially the need for increased regulatory approvals particularly with pharmaceutical products.

Publishers are particularly concerned that an international exhaustion regime would make it difficult for UK publishers to compete with US rights holders, and also that cheaper editions intended for developing markets would flood back into the UK market. They

warn that this would undermine the UK publishing sector (an estimate of 25-30% loss of revenue is cited, based on the number of deals that currently have exclusive Europe rights and the share of revenues they represent), and curtail the cultural influence and soft power it provides to the UK.

An unreciprocated exhaustion regime would, on the face of it, preserve the protection of the EEA publishing market from parallel imports, and therefore be unlikely to have a materially adverse effect on the UK industry. However, the publishing industry would want reassurances that the legal framework of copyright would be equally as robust as the Single Market has been, and that unreciprocated exhaustion should never be offered or negotiated in future trade agreements with third parties.

5.3.2 Exports

In relation to exports, pharmaceutical stakeholders responded that a national exhaustion regime would lead to greater wastage of products near expiry or out-of-date because there would be reduced opportunity for re-sale of any surplus products. One pharmaceutical trade body suggested that lost exports to Germany and Nordic countries would amount to £500mn per annum. The automotive sector raised concerns that there could be disruption to manufacturers' supply chains, which could make the UK an uncompetitive place to both produce and export product from, which in turn could damage the industry.

Some stakeholders, e.g. in alcohols sector, suggested that an international exhaustion regime would instead lead to loss of control and margins. Pharmaceutical industry stakeholders raised concerns over domestic shortages due to a wider market for UK exports.

In pharmaceuticals there were differing views on restrictions on parallel exports and an unreciprocated exhaustion regime. The trade body representing distributors were concerned about the loss of influence politically for the UK industry across the EU. The trade body representing pharmaceutical manufacturers supported restrictions on parallel exports. Parallel export was described as a common cause of local and national shortages leading to a constant threat in the continuity of patient care. However, it was noted that it would be necessary for adequate notice to be given of such a change, to ensure that other EU markets could prepare and ensure they have adequate domestic stock for their patients.

5.3.3 Pricing

The majority of stakeholders across sectors responded that prices in the UK market would increase under a national exhaustion regime. A range of factors were cited for this across sectors, including high cost in the after-care market within the automotive sector, and a reduction in the low-end market for FMCG.

Most respondents agreed that an international exhaustion regime would put downward pressure on UK prices and reduce producers' ability to price discriminate. Publishing in particular emphasised the threat this would pose to the UK domestic industry, potentially being unable to invest in supporting new authors.

5.3.4 Distribution chains

Some alcohol industry stakeholders noted there would be a narrowing of competition between suppliers under a national regime. However, FMCG stakeholders said this regime would provide UK manufacturers with more control over distribution of their products and also potentially reduce informal retail channels such as market traders. The pharmaceutical sector raised concerns over costs to the NHS and an expected closure of pharmacies.

With an international exhaustion regime, alcohol industry stakeholders suggested that IPR holders will attempt to control distribution through authorised distributors and retailers.

5.4 Summary

From the stakeholders covered it is not possible to make a narrow estimate of the existing scale of parallel trade within the EU, and it would be speculative to say anything about the potential scale of parallel trade in an international regime.

- Parallel trade is significant in pharmaceuticals (5-10% of total pharmaceutical imports), where there is data to quantify with some reliability. It is likely that parallel trade is also significant in alcohols (particularly high end) and in parts of the automotive sector (e.g. the component supply chain and the after-care market). In other sectors covered by the stakeholder interviews (FMCG, food manufacturers, publishers) the scale of parallel trade appears to be small.
- Benchmarking off the estimated 5-10% of imports in pharmaceuticals, this might be regarded as an upper-end of the scale of parallel trade (as a share of imports) in other sectors. Based on this, parallel trade could be up to 5% of imports in some sectors, e.g. alcohols and automotive, and is likely to be a small proportion (e.g. 1-2% of imports) in FMCG, food and publishing.

- Only publishing ventured an opinion on the likely scale of parallel trade in an international regime, not explicitly quantifying this but expecting very significant competition from US editions or editions originally put on the market for less developed countries.

Generally the stakeholders interviewed do not favour a change in exhaustion regime from the current regional exhaustion regime.

- A national regime was explicitly favoured by publishers and luxury drinks producers. Pharmaceutical stakeholders were divided, with manufacturers preferring a transition to a stricter regime, whilst distributors prefer to retain a regional exhaustion regime (whereas an international regime has some attractions, they expect higher regulatory costs in such a regime).
- The majority of stakeholders interviewed resist a move to an international exhaustion regime. Common issues were the scope for consumer harm and issues in conformity to safety and quality standards, which would require increased monitoring at borders.
- Stakeholders from alcohols, pharmaceutical and publishing sectors commented on unreciprocated exhaustion regime. None of them favoured an unreciprocated exhaustion regime, except perhaps as a temporary measure.

6. Options for further research

The preceding sections strongly suggest that there is limited data available on the extent and scale of parallel trade. The lack of quantitative analysis of the scale of parallel trade in the academic literature is indicative of it being a fundamentally difficult area to quantify. The formal survey approach has clearly been challenging, and even if participation could be improved there would be significant difficulties in aggregating. Stakeholder interviews have been informative in terms of understanding particular sectors, and further interviews targeted at distributors could add to that understanding. However, none so far (except pharmaceuticals) have been able to give quantitative estimates of the current scale of parallel trade in a regional exhaustion regime, let alone estimates of what it might be in alternative national, international, unreciprocated or bespoke exhaustion regime.

This section therefore explores potential further research to create and use data, and evaluates its strengths and limitations.

6.1 Quantifying the scale of parallel trade

The underlying source of trade data – customs declarations, and Intrastat returns within the EU – do not capture any information on whether the product is being exported/imported by its rights holder or by a third party distributor – i.e. potentially a parallel trader. Parallel trade is expected to be included in total trade statistics, but cannot be separately identified.

It is likely that a proportion of parallel trade within the EU is not captured in Intrastat returns due to traders falling below the threshold for engaging in the Intrastat survey. These thresholds are set to cover 97% of exports and 93% of imports by value, resulting in high thresholds for completing the Intrastat survey – over £250,000 for exports and £1.5mn for imports. It is therefore possible that this might cover a disproportionate level of parallel trade relative to the overall trade levels. However, this Intrastat data is also likely to miss smaller traders exporting/importing by or on behalf of rights holders, and so it may not necessarily help to distinguish parallel trade. Intrastat do attempt to estimate trade below the reporting thresholds, although this might not be accurate. (Potential further analysis of the composition of trade below the Intrastat threshold is discussed in section 6.1.1 below.)

ComExt data, which is the global compilation of data from customs returns, does show goods re-imported and re-exported at the detailed product category level of disaggregation¹². This is likely to include some parallel trade. However, it will certainly not include all parallel trade, and neither will it necessarily all be parallel trade.

¹² E.g. re-imports to the US were modelled in the Maskus and Chen research paper.

The literature review and stakeholder discussions reinforce this. The absence of empirical research into parallel trade itself suggests there is a lack of data. Discussions with stakeholders find that rights holders do not systematically track it, and are only aware of sporadic instances. In other sectors it is likely that parallel trade happens as a matter of course.

6.1.1 A gap analysis

A gap analysis has been briefly considered. This works by comparing estimates from two independent sources that should in theory produce the same answer, e.g. consumption less domestic production should be the same as imports. Such gap analysis is used elsewhere to make statistical estimates e.g. in constructing estimates of tax gaps, the UK government compares estimates of actual VAT receipts with expected (theoretical) VAT receipts estimated from data on consumer spending.

This approach could work if a measure of imports excluding parallel trade could be compared to an independent measure of consumption less domestic production for the domestic market. Any gap between consumption less domestic production for the domestic market and recorded imports could be partly due to under-recording of imports below the Intrastat threshold, some of which will be parallel trade and some may be trade by or on behalf of rights holders. Attributing all the gap to parallel imports may therefore give an upper bound on the scale of parallel imports (although the gap could also reflect measurement errors, counterfeit and other illicit trade).

- The method could potentially be replicated over a period of years to create a time series, subject to consistency in the source of the import data (e.g. a change in the reporting threshold would create a discontinuity in the series).
- Although a detailed product level analysis may not be necessary, it could be conducted at a granular level if desired. For example, breakdowns of consumers' expenditure from the ONS Living Costs and Food Survey are available at a similarly detailed level to the HS6 codes used to identify trade data.¹³ If required, more granular measures of consumption of individual products may be available from commercial consumer spending datasets.
- Domestic production less exports could be identified at the appropriate sectoral level (e.g. from the ONS Output of the Production Industries dataset) and netted off from total consumption, leaving the remainder to be accounted for by imports.
- If import data excluded parallel trade then the gap analysis would then work. Potentially the official Intrastat import data could work, if those excluded below the threshold are predominantly parallel traders. However, provided there are some large distributors making Intrastat returns, it seems likely that the import data would include some parallel trade within the EU. It is also likely that other smaller importers and exporters are also absent from the import/export data, hence it may not be correct to infer that the gap is due to parallel trade.

¹³ HS codes refer to the Harmonized System, which is international nomenclature for the classification of traded products. It allows participating countries to classify traded goods on a common basis for customs purposes. At the international level, the Harmonized System for classifying goods is a six-digit code system, known as HS6.

- To pursue this further a discussion with the Intrastat statistical team would be needed in order to ascertain what if anything is known about trade below the Intrastat reporting threshold. If time permits further analysis could be undertaken to explore data on imports and exports of firms below the Intrastat threshold, e.g. using company accounts data available in business data registers.

Alternatively, trade bodies may be able to collect data directly from rights holders on their cross-border trade, which could then be compared either directly to official import data (the discrepancy would then be accounted for by parallel trade and any other sources of measurement error) or compared to consumption less domestic production. This, on the face of it, is a simpler comparison. However, it is likely to suffer from incomplete response rates, inconsistent reporting, and from inconsistencies in reporting between this survey and returns previously made to Intrastat.

In conclusion, a gap analysis has the potential to provide an upper-bound for parallel trade, but is also likely to reflect other sources of measurement error within and between datasets, and is therefore unlikely to be able to give a precise estimate.

6.1.2 Analysis by data matching

Another approach could be to create data on parallel trade by matching and blending different datasets together. This has been discussed with a trade data company. However, the steps seem challenging, and may not ultimately prove feasible:

- Trade data is published at a detailed 8-digit HS code level within the EU (and 6-digit level outside the EU). At this level of detail the product category is very precise – e.g. specific clothing item of a specific fabric – although each code would still include goods from many multiple brands.
- Importers and exporters operating within each HS code can be downloaded from HMRC's UKTradeInfo website.
- In theory these two could be matched to international trade reported in company accounts to try to determine how much could be attributed to each trader (aggregate datasets of company accounts data are available and could be used for this purpose¹⁴). However, for businesses importing/exporting across multiple markets there is not likely to be enough information in company accounts to disaggregate their total international trade.
- If it were possible to do this stage, the resulting trade would then need to be matched to a database of IPR holders. Whilst this exists for patents, it is not readily available for copyright, although alternatives may be possible (e.g. it may be possible to identify copyright owners through stakeholder discussions)
- Finally, for non-rights holder trade, there may still be approval from the rights holder (i.e. acting as an authorised distributor).

14 E.g. Bureau van Dyke's Orbis database.

The challenges in matching data on trade in generic products to specific company accounts data seem to be very significant, and it is not clear how approved trade on behalf of the rights holders would be allowed for in the calculations. For these reasons the data matching approach appears to have a low chance of success.

Neither a data gaps analysis nor a data matching approach could directly provide estimates of the potential scale of parallel trade in an international exhaustion regime, although they could be used as an input to further analysis to estimate this (see section 6.3).

6.2 Measuring the opportunity for parallel trade

Although it may not be possible to derive the scale of parallel trade, an alternative approach might be to estimate the opportunity/motive for parallel trade that lies in price differentials for the same goods sold in more than one market. Some of the aforementioned studies have taken a price differentials approach to quantifying potential parallel trade, e.g. the Swiss studies by Plaut and Frontier Economics detailed in section 3.3.3.

This approach would have the advantage of being able to measure potential parallel trade in an international exhaustion regime outside of the EU, which the data gaps or data matching techniques cannot directly measure.

Once price differentials are established, an estimate of volumes of parallel trade can be made using price elasticities. To do this a series of assumptions would need to be made:

- That opportunities for parallel trade would be fully exploited by distributors / parallel traders. This means that the analysis produces an upper-bound estimate.
- The ability of parallel traders to compete in the market for each specific product, which would need to be quantified (e.g. in the Plaut/Frontier Economics studies for Switzerland an estimate of “tradability” was established, taking into account for example the inclusion of after sales service in the product).
- The degree to which the potential lower price could be supplied through more competitive pricing by rights holders currently supplying the market rather than by parallel traders. This determines the degree of substitution away from existing rights holder’s sales to parallel imports.
- The degree to which the lower price is passed through to the consumer.
- An assumption for the own price elasticity of demand to determine the extent to which consumers respond to the lower prices by increasing consumption.

Since parallel traded goods are expected to be highly substitutable with the same goods sourced by alternative means, price elasticities should reflect this by taking the upper end of available estimates (i.e. more elastic than those used in the Plaut and Frontier paper on Switzerland). Estimates of price elasticities are likely to exist for many products, but

they would have to be collated from a number of sources; e.g. in 2011 DEFRA published a comprehensive study of price elasticities across many different food and drink categories. The estimates collated may not be consistent with each other or up-to-date. Alternatively, large scale models (e.g. the GTAP model – see section 6.3.1) will also embody a set of price elasticities at the sector level, although these would need to be reviewed (e.g. compared against other estimates) before they could be used.

To be a valid identification of arbitrage opportunity this would also need to allow for the costs of trade (e.g. transport and insurance costs, exchange rate risk). Costs of transit could be identified through a combination of desk research into transport and insurance charges and assumptions over the origin of parallel imports, with stakeholder inputs used to validate the estimates. Exchange rate risk could be approximated by the premium paid for currency options or hedging.

In broad terms this analysis could be done using sector-specific aggregate price indices. However, this would pick-up differences in prices due to heterogeneous preferences and consumption patterns across markets, not genuine opportunities for arbitrage of homogenous products. To be an accurate representation of arbitrage opportunities it would ideally be undertaken at a very detailed product level¹⁵ – e.g. the SKU or Global Trade Item Number for individual items¹⁶. SKU level pricing data across different markets would be available from commercial data providers¹⁷. This could provide a ready-to-use dataset of price differentials across a large number of products, although it is unclear at this stage how comprehensive the coverage would be (e.g. is it limited to FMCG or does it cover the full range of consumer goods). There may also be other obstacles to making a direct comparison of prices, e.g. it may be difficult to track the precise date the pricing information was collected and therefore the appropriate exchange rate to use.

The analysis would also need to be repeated or spread over a period of time, since pricing and exchange rates are always evolving. In particular in a period of exchange rate volatility (e.g. the recent past leading up to an uncertain Brexit) estimates of price differentials could be particularly volatile.

In theory SKU level products could be matched through to the relevant IPR, i.e. simply to establish whether any IP right applies, and if so is it patent, trademark or copyright. This would enable the analysis to filter out price differences where no IP rights apply (so there is no scope for parallel trade), and also to categorise the differentials between patent, trademark and copyright.

In summary, this approach requires very detailed data work at the product level, which may be feasible for a sample of products. How easy it is to then scale up to sector or economy-wide conclusions on the scale of parallel trade would depend on the availability and coverage of SKU-level data, and the time available to conduct detailed analysis across a large number of product categories. Given the assumption that all price differentials are exploited, this would be an upper-bound of the scope for parallel trade.

¹⁵ Although subsequent analysis of volumes would still rely on broader sector-level price elasticities.

¹⁶ Stock Keeping Unit (SKU) is a distinct type of item for sale; these attributes could include manufacturer, description, material, size, colour, packaging, and warranty terms. Global Trade Item Number (GTIN) are standard, global, tracking units.

¹⁷ E.g. Nielsen's point of sale database.

The significant advantage of this approach is the flexibility to apply it to both regional and international exhaustion regimes (and, by deduction, the cost under a national regime).

6.3 Modelling the impacts of different regimes

Subject to having at least some estimates of the scale, e.g. broad-brush estimates from the existing work, or detailed analysis as outlined in sections 6.1 and 6.2 above, modelling the impacts of different exhaustion regimes could be technically feasible. This could include analysis of a national, international, unreciprocated or other bespoke regimes, including allowing for variation in treatment across sectors. Ideally this would use a standard global trade model, such as the commonly used Global Trade Analysis Project (GTAP), which has a widely accepted framework for modelling barriers to cross border trade, and is likely to be the most appropriate modelling framework for assessing changes to international exhaustion rights. This section explores the feasibility of such a modelling approach.

6.3.1 Proposed modelling tool

The GTAP model and database is contributed to and widely used by government agencies, international institutions, the private sector and academia to model cross-border effects of trade policies. Some examples include the World Bank, the World Trade Organization (WTO), the European Commission, the Organisation for Economic Co-operation and Development (OECD), and the United Nations Commission for Trade and Development (UNCTAD).

The GTAP database represents the world economy, and consists of bilateral trade, transport, and protection matrices that link individual country/regional economic databases (in particular input-output tables, showing how intermediate goods and services are used in production of final consumption goods). The database is built up from national input-output tables, trade, macroeconomic, and protection data from several sources. The underlying input-output tables are mainly drawn from each country's national statistics. This means they are heterogeneous in base years and sectoral detail; thus for achieving consistency, the GTAP project makes substantial efforts to make the disparate sources comparable (e.g. by standardising on base years and sectoral definitions).

The behavioural relationships (e.g. the sensitivity of exports to prices) in the GTAP model are intended to represent the relationships between prices and quantities across the entire global economy, consistent with economic theory, and assuming perfectly competitive markets. These relationships have been quantified through a mixture of empirical estimation, calibration, and applied economic theory. Only the most important relationships have been econometrically estimated; e.g. these include the international trade elasticities (Hertel et al., 2005). The remaining economic relationships are based on literature reviews, applied in accordance with economic theory and intuition.

The GTAP database is updated only periodically, and tends to lag the latest available data for the most advanced economies by several years. This is because it needs to be consistent across countries, and so can only be as up-to-date as the last country to

produce trade and input-output data. The current release, the GTAP 9 database, as used in this modelling, features 2011 as the reference year, and includes 140 regions and 57 different commodities (sectors). A new release with 2014 as the reference year is expected to be available soon.

The lags in the database (i.e. starting from 2011) are a potential limitation of the approach. However, the primary focus of the modelling is to understand the impact of the change in the exhaustion regime. This is what the GTAP model simulation will show – the real world will doubtless be different, but the point is to show the impact specifically due to the policy change, not to accurately forecast trade or GDP.

6.3.2 Modelling assumptions

There are a number of steps and assumptions that would need to be made to be able to model changes to exhaustion regimes in the GTAP model:

- a. Define the regions of the world economy – the GTAP model can only run with 10-12 regions separately identified. For example, these could be: UK, rest of EEA, US, rich commonwealth, Indian sub-continent, China, Africa, rest of Asia, rest of Americas, and the rest of the world.
- b. What sector aggregation to model – again, the model requires an aggregation to a maximum of 12 sectors, from an initial 57 separately identified sectors in the GTAP database. For example, the sectors specifically modelled could include: beverages & tobacco, chemicals (which includes pharmaceuticals), motor vehicles, textiles, paper and paper products (which includes books), electronic equipment, trade (which includes retail and wholesale).
- c. Estimate the share of imports / exports that is accounted for by parallel trade in each sector. This could be by assumption based on responses to the stakeholder interviews, and benchmarking to the share in parallel trade in pharmaceuticals, by reference to the earlier NERA study, or potentially informed by a detailed study of data gaps / data matching / price differentials as outlined in sections 6.1 and 6.2 above).
- d. The sector categories available in GTAP are much broader than the products assessed as part of this review. The modelling would need to either scale down (or possibly up) the share of the broader GTAP category that is accounted for parallel trade, or make a simplifying assumption such as the same share applies across the whole sector (e.g. if we assume 5% parallel trade in books, then for modelling assume 5% parallel trade across all paper and paper products).

- e. Since IPR exhaustion is not a parameter in the GTAP model the policy change could not be modelled directly. Therefore it would need to be proxied by either a tariff equivalent (as widely used in trade modelling to simulate non-tariff barriers) or by varying one of the technical non-tariff barriers that exist in the modelling framework (e.g. the efficiency cost of cross-border trade.)
- f. To model a change to a national regime (or a unilateral national regime), the scale of the “shock” to each sector would be determined by the share of imports/ exports accounted for by parallel trade and by a scaling factor that represents the proportionate change in the efficiency of cross-border change (or an estimate of the equivalent tariff). The share estimate described above (steps c and d above) would be multiplied by the policy impact (step e). The latter might be informed by the literature; e.g. estimates of price competition impacts of parallel trade could inform the scale of the tariff equivalent. The modelling would also presume that rights holders would stop parallel trade where they have the ability to – or an alternative assumption could be applied if a survey was able to provide contrary evidence.
- g. For modelling an international regime there is no similar scale of parallel trade currently. However, the scale of the shock would still need to be estimated in accordance with an idea of how widespread parallel trade could be expected to be across each different sector. This requires a further assumption, probably a ball-park estimate informed by the research conducted for this report and any further stakeholder discussions. (This makes the modelling of a change to an international exhaustion regime more uncertain than the modelling of a change to a national exhaustion regime.)
- h. Impacts on investment and innovation in IP-rich sectors: to some extent the model will see increased returns (e.g. from a national regime) and reallocate resources in the economy to create an increased investment in response to that. A dynamic version of the model (i.e. that models a path over time) would do this better than a static version. However, this is limited to a reallocation of resources, not a response in terms of greater risk-taking and innovation. An alternative would be to model impacts on innovation outside the main model (e.g. using empirical literature on how innovation responds to returns) and then impose an innovation effect in line with the change in returns in each modelled sector.
- i. The GTAP model requires a number of key assumptions known as “closure rules” on how economies respond to disruptions and adjust to reach a new equilibrium. These include:
 - i. Economic activity: The standard approach in these type of models is to assume that changes in the demand for labour result in a change in wages and prices, rather than a change in unemployment. The modelling therefore tells us what change to the real wage is required to ensure that unemployment does not rise.

- ii. Trade balance: As the primary interest is the impact on exports and imports, the modelling could allow the current account to diverge from balance (i.e. a current account surplus or deficit can open up). Forcing the current account to return to balance (or at least to its existing level of surplus/deficit) would be more appropriate if the objective was to understand the impact on the macro-economy. However, this would lead to second round impacts on exports and imports, which would make the modelled outputs less transparent, and, the overall macroeconomic effects would then include some perhaps unrealistic offsetting changes in the non-traded goods sectors.

As can be seen, the robustness of the modelling is dependent on the robustness of the estimates of the scale of parallel trade. Moreover, the layering of assumptions creates a very uncertain impact. These would be best seen as scenarios. A series of alternative assumptions could be modelled as sensitivity tests in order to arrive at a more robust range of impacts. The additional assumptions required to model a change to an international exhaustion regime would make those results more uncertain than those for a change to national exhaustion regime.

A key limitation is the absence of comparator modelling to benchmark against, so there would be very little guidance as to whether the modelled impacts are broadly correct. Some benchmarking could be done against stakeholder expectations of the different regimes, but these are generally not quantified, so it is of limited value for this purpose.

In practical terms, this is a significant and complex modelling project, which would benefit from external advice and/or peer review from individuals with very significant experience in trade modelling.

6.4 Practicalities for further work

Table 2 below considers the inputs required for each of the possible options for further data and modelling work, a rough estimate of the timeframe to complete, and notes the anticipated major challenges to each approach. For the three alternative approaches to quantification the resources required and the complexity of the analysis have also been ranked.

Table 2: Options for further work

	Data	Other inputs	Estimated Time	Resources (ranking)	Complexity (ranking)	Anticipated challenges
Data gaps analysis	National statistics sources, or potentially trade bodies	Discussion with Intrastat, or trade bodies collate data from rights holders May also need to purchase company accounts database to research trade below the threshold	1 month pilot stage 2-3 months to undertake full analysis across ONS sectors Further 2-3 months if analysis of trade below the threshold is required	Middle	Middle	Relies on trade below the Intrastat threshold being largely parallel trade Or otherwise trade bodies work with rights holders to supply data on approved trade
Data matching analysis	Trade data, IPR data, and company accounts	Access to detailed trade database and a patents database, purchase of a company accounts database Inputs from stakeholders to identify trademark and copyright holders	1 month proof of concept to establish whether it works 4-6 months to conduct full study across a range of products	Most resource	Most complexity	Likely imperfect matching from generic products in trade data to specific company accounts data on imports/exports May be difficult to compile data on trademarks and copyrights

	Data	Other inputs	Estimated Time	Resources (ranking)	Complexity (ranking)	Anticipated challenges
Price	Product level price data across countries and time	Purchase access to a SKU pricing database Transit charges to be verified by stakeholders, or database may need to be purchased Collation of price elasticity estimates	1 month pilot stage Further 2-3 months to establish price differentials for a range of products across different time periods Further 1-2 months to quantify parallel trade	Least resources	Least complex	Could be challenging to assemble costs of trade to compare with price differentials Complex assumptions (tradability, price cutting by rights holders, pass through and price elasticity) needed to convert price differentials into quantities of parallel trade
Policy modelling	Estimates of parallel trade by sector (broad brush or detailed estimates from above)	GTAP model and database, and advice from an experienced trade modeller A number of assumptions required to set model parameters	1 month to identify modelling approach 2-3 months to model a number of scenarios and sensitivity tests Expected to be sequential to undertaking work to quantify parallel trade			Identifying model variable to best proxy the exhaustion regime and scaling it appropriately Large number of assumptions need to be layered together

The estimated timeframes are indicative only. It might be possible to accelerate with more intensive resourcing (or equally could be slowed if there are delays in getting inputs or if unanticipated complexity arises). Each of the options would benefit from an initial stage of work to confirm that it is viable, and thereafter would take a further 2-3 months at a minimum to complete (and longer for the data matching and policy modelling options).

It is not possible at this stage to fully cost the options, but each could involve some cost for a commercial database (which an external research partner may or may not already have), and a significant amount of cost for the time in undertaking the work (assuming IPO wish to procure the work externally). For the alternative quantification methods the ranking of costs provides an ordering from the most to the least costly.

6.5 Conclusions for further work

As discussed in section 5 targeted stakeholder interviews could be worthwhile continuing. These have given valuable understanding and insights. Targeting distributors may be able to elicit further understanding, e.g. how they identify opportunities for parallel trade, and even quantification, if they are prepared to be open about it. If they do share data the sample size and approach would not be suitable for scaling up to the whole market, although it could be taken as an approximation.

Further data analysis may be feasible, either direct measurement through a gap analysis or through data matching, or indirect measurement of the opportunity for parallel trade through a pricing study. The pharmaceutical sector could be a test case for the methodologies described, as there exists some fairly reliable data for it. However, each of the methodologies has challenges:

- The pricing differentials study may be the most achievable to produce an upper bound estimate in a limited timescale, and could also apply to parallel trade in a potential international regime. However, to be valid it would need to be done at a very detailed level, making scaling up to aggregate measures difficult. A further step could then estimate the extent of parallel trade based on these price differentials, although this step would be more assumption based.
- A data gaps analysis might be able to provide an upper-bound estimate of existing parallel trade under the current regional exhaustion regime – although further investigation would be necessary to understand to what extent this approach would be valid even as an upper bound and to control for other potential factors that could explain the gap. The next step could be a discussion with the statistical team at Intrastat to ascertain what is known about trade below the Intrastat reporting threshold. Alternatively, or in addition, it may be possible to conduct a gap analysis through trade bodies collating data from rights holders.
- A trade data and analytics company has submitted a data matching proposal, which would also provide an estimate of existing parallel trade under the current regional exhaustion regime.

The data gaps and data matching approaches directly measure the existing quantity of parallel trade, which is an essential input into modelling the effects of a change in the exhaustion regime in a trade policy model. However, the price differentials approach can be extended to estimate the amount of parallel trade, subject to the availability of price elasticity estimates, and has advantages in that it can be applied to an international regime and the price differential itself can be used to calibrate the scale of the policy change (e.g. to inform an appropriate tariff equivalent).

- Alternatively, a simple broad-brush sizing of parallel trade in each sector could allow for the modelling of impacts of different exhaustion regimes in a trade model. However, this would add uncertainty to the analysis, and it would be preferable to undertake the work to quantify parallel trade first before proceeding to model different policy options.
- In addition to scaling parallel trade, this would also need to apply estimates to broader sectors, to approximate changes to exhaustion regimes through proxies such as tariff equivalents or a change in the efficiency of cross-border trade, and to impose separately impacts of narrowing or widening the exhaustion regime on innovation.
- Taken together, this multiple layering of assumptions and estimates would make it a very uncertain analysis. This uncertainty should be reflected in sensitivity tests (i.e. varying the assumptions) and reporting a range of outcomes. However, the lack of comparator analysis to benchmark against would make it unclear how much reliance could or should be placed on the work.
- Despite the challenges, such formal modelling has the potential to quantify economic impacts and weigh together effects on producers and consumers, in a robust theoretical framework that is widely accepted in trade modelling.

In summary, the most promising next steps are likely to be the following three types of further research:

- Continuing stakeholder interviews, focused on distributors and retailers.
- A pilot stage for the data analysis of price differentials in a small sample of markets. Compared to data gaps and data matching approaches, an analysis of price differentials is the least complex (and hence has the better chance of success). It also has the advantage of being able to compare national, regional and international exhaustion regimes, whereas data gaps would be limited to understanding parallel trade in the existing regional exhaustion regime.
- Developing the methodology for modelling different exhaustion regimes through barriers to trade in a global trade model, e.g. identifying how to approximate different exhaustion regimes through tariffs or non-tariff barriers. Once a satisfactory methodology is agreed (i.e. between IPO and the external research provider) then the policy modelling could be sequenced to follow the price differentials analysis, so that it can build on the price gaps and quantification identified in that work.

Appendix A: Literature review

Table 3 below outlines the literature reviewed.

Table 3: Summary of literature reviewed

	Topics			Parallel trade data Yes /No	Details	Region	Sector	Qualitative/ Quantitative
	Parallel Trade	IPR exhaustion	Innovation					
1	NERA, SJ Berwin & Co and IFF Research, 1999	✓	✓	✓	Trademark data by sector, Price data, technical barriers, transaction costs, trade barriers, , data on vertical relationships in the sector	EU	Various	Both
2	Dobrin & Chochia, 2016	✓	✓	×		US, Europe	All	Qual
3	Bulut & Moschini, 2005	✓	×	✓		NA	R&D	Quant
4	Kyle, 2011	✓	✓	×		NA	R&D	Qual
5	Fink, 2005	✓	✓	✓		NA	NA	Qual
6	Maskus & Chen, 2005	✓	✓	×	US export prices	NA	NA	Quant
7	Ganslandt, Maskus & Wong, 2005	✓	✓	×	Country level price comparison for a selection of drugs	Multiple	Pharmaceutical	Qual
8	Heath, 1997	✓	✓	×		Global	NA	Qual
9	Muller-Langer, 2008	✓	✓	✓	Pharmaceutical data	Global	All (focus on pharma)	Qual
10	Crampes, Encaoua & Hollander, 2007	✓	✓	×		Europe	All (e.g. music)	Qual
11	Sauer, 2008	✓	×	✓	ComExt data	Finland, Sweden	All	Quant
12	Bonadio, 2011	✓	✓	×		Global	All	Qual
13	Mantovani & Naghavi, 2010	✓	✓	✓		Emerging markets	All (pharma as example)	Quant
14	Ganslandt and Maskus (2007)	✓	✓	×		NA	NA	Qual
15	Palangkaraya and Yong, 2006	✓	✓	✓		NA	NA	Qual
16	Muller-Langer, 2010	✓	✓	×		NA	NA (Pharma as example)	Quant

	Topics				Parallel trade data		Details	Region	Sector	Qualitative/ Quantitative
	Parallel Trade	IPR exhaustion	Innovation	Yes /No						
				Yes	No					
17	Maskus & Chen, 2000	✓	✓	×	Yes		NERA, Feenstra US National Trade Databank Firm-specific sales	US & Europe	All	Quant
18	Saggi, 2013	✓	✓	×	No			Europe, US- Canada- Mexico	NA	Quant
19	Grossman & Lai, 2006	✓	✓	×	No			EU	NA	Quant
20	Kaiser, Méndez, Rønde, Ulrich, 2013	✓	×	✓	Yes		Generic & parallel imports	Denmark	Pharma	Quant
21	Suppliet, Duso, Herr, 2014	✓	×	×	Yes		IMS Health, Pharmascope National (German Health Insurance)	Germany, EU	Pharma	Quant
22	Fink & Maskus, 2005	✓	✓	✓	No			NA	NA	Qual
23	Plaut Economics, 2004	✓	✓	×	Yes		Evaluates potential arbitrage under regional exhaustion	Switzerland and EU	All	Quant
24	Frontier Economics / Plaut	✓	✓	×	Yes		Evaluates potential impacts under regional exhaustion	Switzerland and EU	All	Quant
25	Deloitte, 2012	✓	✓	×	Yes		Evaluates impacts of parallel trade restrictions in Australian market vs New Zealand	Australia and New Zealand	Books, CDs	Quant

1. **The Economic Consequence of The Choice of A Regime Of Exhaustion In The Area Of Trademarks, NERA (1999)**

See main paper, section 3.4.1.

2. **The concepts of trademark exhaustion and parallel imports, Dobrin & Chochia (2016)**

Provides an assessment of benefits & weaknesses of IPR exhaustion and parallel imports. Conducts analysis of the approach taken by EU and USA toward IPR exhaustion and parallel imports.

Notes there is a history of case law in development of the current regional exhaustion regime in the EEA and the shift from an international to national regime in the USA. Exceptions in the USA noted as round trip scenarios, where USA manufactured goods are permitted to be imported back into the USA and common control scenarios, where the same person/entity owns both the foreign and the USA based trademarks.

The study notes that the EU approach is perceived as more cautious than the USA, however neither adopt international, which is considered to be the most liberal view by both parties.

Arguments in favour of international exhaustion:

- Cheaper goods for consumers. Consumers are provided with larger selection of affordable parallel imports.

Arguments against international exhaustion:

- Consumers exposed to non-standard product (especially medicines and alcohol), decreased R&D investment from TM proprietors.
- International regime adoption would not be reciprocated by the other parties globally, leaving the adoptee on the back foot.
- After-sale services or guarantees not included.

Discussion around unified approach between EU and USA markets, unlikely at present but not impossible. Focus remains on own interests, e.g. EU goal is to further develop as a strong single market. Difficulty remains in pleasing all interested parties in an equal manner.

3. **Parallel research, multiple intellectual property right protection instruments, and the correlation among R&D projects, Bulut & Moschini (2005)**

Notes that the availability of multiple IPR protection instruments can move the path taken by firms engaged in R&D toward a 'social optimum'.

The study assesses the impact of IPR protection tools on decision making in parallel R&D contests and develops model to assess the contest between two firms in their R&D activity and their respective probabilities of success given the presence or lack of trade secrets.

In some fields, the availability of trade secret protection may be critical for the nature of competitive R&D and may affect companies' R&D innovation efforts.

Parallel research benefits: Increases the probability of success in developing new products.

Parallel research downsides: Can lead to excessive R&D, inefficient use of time and the wrong type of research.

4. **Strategic Responses to Parallel Trade, Kyle (2011)**

Provides an assessment of product market strategies and how these have changed to reflect European integration, changes in trade regulations and intellectual property rights.

The paper focuses on pharmaceuticals. There is a discussion around history of parallel trade of drugs in the EU and laws globally (incl. ability of companies to price discriminate within the EU), and court decisions by the ECJ which have usually favoured parallel traders.

Discussion on parallel trade regime in US and potential changes to policy between Canadian/Mexican imports/exports of medicines.

Explanation of parallel trade restrictions for pharmaceutical products, e.g. licenses to import products of identical composition dosage, etc. from a country with lower price. Analysis of second degree price discrimination.

It notes the entry conditions for parallel traders: the price of product in higher-price country, the price of matching product in lower-price country, the cost of transporting product between countries, the number of units that the importer supplies in the higher-price market, and the license fees.

The study uses the IMS Midas database used for drug pricing and sales across 30 countries, at the anatomical therapeutic chemical (ATC) classification system level. On average a manufacturer doesn't lose more than 10% of sales to parallel imports.

5. **Entering the Jungle of Intellectual Property Rights, Fink (2005)**

Introduction to parallel trade and types exhaustion regimes. A discussion of pros and cons of parallel trading regimes.

Discusses difficulty of evaluating the economic significance of the exhaustion doctrine and the very limited statistics available on parallel trade. It is noted that available evidence on the effect of parallel trade typically concentrates on prices in the importing countries and profits of intellectual property owners; no evidence exists with regard to the price effects in exporting countries.

Territorial restraints in licensing agreements and restrictive purchasing contracts can limit active and passive parallel imports, respectively, even though IPRs may exhaust internationally.

Current exhaustion regimes differ widely among countries and across the different forms of IPRs. Most regional trade agreements largely remain silent on the exhaustion issue. The US, on the whole, applies a system of national exhaustion for all forms of IPRs. OECD countries, outside the EU, also lean toward national exhaustion, although there are important cases in which IPRs exhaust internationally.

Discusses pros and cons of national vs international IPR exhaustion. In particular, international exhaustion is backed by the free trade argument. National exhaustion has been supported by arguments relating to welfare-enhancing price discrimination and a method to increase profits for IPR holders which can lead to further innovation, particularly in creative industries.

In the mid-1980s, it was found that in the US parallel imports were concentrated in goods with well-known brands that typically involved heavy investments in marketing and promotion. They were caused by free-riding and price discrimination.

Arguably, the scope for parallel trade in services is smaller than for trade in goods due to most services requiring close proximity between supplier and consumer, and differences in national standards or languages limiting the substitutability of foreign and domestic services.

6. **Parallel Imports in a Model of Vertical Distribution: Theory, Evidence, and Policy, Maskus & Chen (2005)**

Econometric study focusing on a variety of products in which parallel trade frequently occurs. The study finds support for the theory that parallel trade is created by firms' vertical pricing decisions. They construct a model explaining how vertically related manufacturers and wholesalers maximize profits through the joint setting of wholesale and retail prices in two countries. This process sets up profitable opportunities for arbitrage at the wholesale level.

Discusses policy issues around exhaustion regimes.

Shows the welfare consequences of permitting parallel importation under these circumstances depend on the extent of international trade costs.

More recently, U.S. negotiators have required countries to ban parallel imports when entering into a bilateral preferential trade agreement with the United States.

Most formal economic analysis of parallel imports treats them as a channel for overcoming third-degree price discrimination across countries.

Unable to use quantity of parallel trade to test theory because no such data are collected.

Discussion of limited empirical evidence on parallel trade. Briefly notes key results from NERA study. It notes a survey of U.S. exporters to Asia in 1989 found that some distributors faced competition from U.S. suppliers, which sold products in the United States at higher retail prices than in Asia (Palia and Keown 1991).

The study finds an inverse relationship between the distribution of export prices and U.S. tariff rates. The results of the study infer that between countries where transport costs are high, attempts to deter parallel trade through setting a high wholesale price are socially inefficient. This finding suggests that a policy of regional exhaustion among free trade areas whose members are in close proximity is sensible.

7. Developing and Distributing Essential Medicines to Poor Countries: The DEFEND Proposal, Ganslandt, Maskus & Wong (2005)

Discusses a proposal to help develop and distribute medicines to poorer nations at a lower cost. Analysis of the reasons why pharmaceutical firms undersupply the medicinal needs of poor countries noting one factor is the need to restrain parallel trade.

Unauthorized parallel trade erodes price-setting power in rich countries. Because the majority of returns to R&D are realized in the industrial nations, pharmaceutical companies argue that such price spillovers would significantly hamper their incentives to develop new treatments.

Notes the threat that products may be shipped from lower-priced countries to higher-priced countries reduces the enthusiasm of rights holders to supply them at low cost.

Arbitrage between markets often referred to as parallel imports limits the scope for third-degree price discrimination. If both markets are served by the monopolist, the price in the low-income country is likely to rise as a result of parallel trade, whereas the price in the high-income country is likely to fall. Resultantly, the pharmaceutical company receives less revenue from both markets when parallel imports result in equalized prices. As there are differences in average income across developing and developed markets parallel trade makes it unprofitable to serve low-income markets. Under such circumstances, it is beneficial for all parties to restrict parallel imports and to increase the degree of price discrimination.

Parallel trade undermines the independence of health authorities in both industrial and developing countries.

The study notes that a necessary condition for an effective solution to the access development problem for pharmaceutical products in developing countries is to limit parallel exports from the developing countries as well as parallel imports into the industrial countries.

8. Parallel imports and international trade, Health (1997)

Conducts a review of the impacts on both intellectual property creators/owners and the parallel traders and consumers.

Discussion of IPR exhaustion in Europe, and the case of exhaustion when outside of the scope of the patent. e.g. Japanese patents cannot be exhausted when patented products were marketed in Germany, as that is outside the scope of the Japanese patent right.

Discussion of both legal and economic difficulties in permitting the parallel importation of patented products.

Regional regime in Europe does not support Community's function to minimise barriers world-wide, not only within Europe.

Giving notice to all re-sellers and in all languages globally is impractical and likely impossible.

Banning parallel importation would contravene the spirit of free trade advocated globally over last decade and result in undesirable economic side effects.

Push for market democracy with minimal subsidies so high-price countries are not subsidising those in low-price countries.

Harmonisation of stakeholders' interests is required. The study concludes that global adoption of the European model of IPR exhaustion at present would be impossible on world scale as it would bring economic disaster to patentees.

9. Does parallel trade freedom harm consumers in small markets?, Muller-Langer (2008)

The study notes that producers benefit from higher prices of a patented product, and readily able to cover high R&D costs, accelerating rate of R&D in the long term.

Public policy is supportive of broad access to affordable medicines in short-term.

Parallel trade limits the scope for third-degree price discrimination i.e. price in low-income countries with a high price elasticity of demand is likely to increase as a result of parallel trade, whereas the price in a high-income country with a low price elasticity of demand is likely to fall.

Reviews exhaustion regimes adopted in the EU, the US, Japan, Australia and New Zealand. Switzerland and USA preferred national exhaustion, Australia, India and New Zealand defended the principle of international exhaustion.

Discussion around development of the TRIPS Agreement and initial plans to adopt national exhaustion as a global standard to protect innovative industries. Notes that this was impossible as the views on the net benefits of parallel trade were too divergent.

Parallel trade acts as competition, with parallel trade reducing prices of pharma from 1994 to 1999 by 12-19% in Sweden (joined EU 1 Jan 1995).

Comments on effects of parallel trade on the investment in R&D - reference to Szymanski & Valletti (2005). By setting a uniform price, parallel trade freedom will be deterred.

An example of a model included the following: “If market A is sufficiently attractive (i.e. low prices) compared to market B then competition from parallel trade will be so fierce that the manufacturer has to charge such a high wholesale price in B to deter parallel trade that distribution of the goods becomes unprofitable. In this case the market in B won’t be served, therefore it is desirable for B to discourage parallel trade and encourage price discrimination.”

10. Competition and intellectual property in the European Union, Crampes, Encaoua & Hollander (2007)

This paper discusses to what extent the existence of exclusive IPRs are compatible with competition.

It conducts a comparison of US to EU IPRs, and summarises the recent history of changes in EU and US’s respective legislation.

Discusses changes in the motives for firms applying for patents, with increasing applications for technologies that have been neither developed nor licensed. Particularly in high-tech industries such as the semiconductor industry and ‘patent fences’ using blocking patents around core inventions.

Defines two forms of competition: product competition and research competition. Product competition yields allocative efficiency and gives consumers access to low cost products. Research competition produces new products and new technologies. Allows firms to escape the constraints of product competition. Market incentives may not be sufficient to produce optimal innovation. Standard models don’t account for specificities of industries R&D. Theoretical discussion of market segmentation and national, regional and international exhaustion regimes.

Examples of IPR exhaustion (music, and various cases e.g. Davidoff and Levis, Volvo and Renault etc.) and of tools used in IPR exhaustion, e.g. fractional licensing, non-exclusive licenses, direct licensing (in music). The exercise of IPR for music, automotive and others appear to conflict with competition policy objectives.

Discussion of major judgments by European courts and Parallel Trade analysis concludes that courts are more likely to “strike down agreements to segment the EU into national markets than arrangements that serve to protect the EU market from imports originating from outside the Union.”

11. The quality of parallel imports, Sauer (2008)

This paper assesses the argument of a ‘decline in quality over time with introduction of parallel imports’ through a comparison of such imports in countries which joined the EU in 1995 (Sweden and Finland) and other EU countries.

It is noted that Sweden and Finland had lower import quality in the years after their accession. Where other EU countries also had lower quality in the years after Sweden and Finland joined the union, then the reduction in quality in the accession countries is larger. The import quality of goods not subject to parallel imports competition is not lower.

It uses the “Aw and Roberts index number methodology” - a change in aggregate unit value index can be decomposed into changes attributable to quality and pure (quality adjusted) price. It also conducts a calculation of price indexes using the model. Repetition for non-parallel imports consumer goods data.

There are references to the NERA paper and likely products for parallel trade (cocoa, sugar confectionary, ice cream, alcohol, soft drinks, mineral water, clothing, footwear, CDs, soap, perfume, detergent, toiletries, consumer appliances, consumer electronics).

The study uses the Eurostat database, ComExt data for Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Netherlands, Portugal, Spain, Sweden and UK over 1995-2004 period.

The paper concludes that there is insufficient support for the claim that competition from parallel imports reduces quality.

12. Parallel Imports in a Global Market. Should a Generalized International Exhaustion be the Next Step?, Bonadio (2011)

The paper considers the definition of IPR exhaustion and its purpose. There is discussion around drivers for parallel trade - that higher profits strengthen trade between countries; injects competition into international markets; and satisfies customer demand and interest.

Puts forward the argument that parallel trades are the original product not fake goods, therefore a ban on parallel imports is a ban on circulation of original goods and an unfair duplication of the rights of IPR holder. Conversely, high technology manufacturers stress the possibility for rights owners to prevent the competition from parallel importers and that by segregating national markets they can recoup the R&D investments, re-investing in innovation to benefit the consumer in the long run.

It notes that pharmaceutical, chemical, biotechnological (high tech field) would suffer most as they invest the most in both financial and human resources in R&D. It argues that parallel trade has a cooling effect on international transfer of tech, with patentees reluctant to license in countries with international regimes and little protection.

However, it could be enough to place ad hoc clauses into the license agreements to prevent licensees invading other markets, but enforcement may be hard. Parallel importers may exploit investment in marketing, promotional campaigns and after-market services such as warranties etc. to improve the efficiency of their networks.

Allowing governments to price cap regulations is equivalent to export subsidies. The paper argues that parallel importers do not consider target market quality and sell low quality in high quality country & vice versa, which could harm consumers. Instead, it increases the chances of fake goods entering the country with original goods. Yet this is an unconvincing argument as traffickers find legitimate parallel importing attractive long term. European Commission adoption of WTO law and free trade principles in EU.

13. Parallel Imports and Innovation in an Emerging Economy, Mantovani & Naghavi (2010)

The study considers IPRs, parallel imports, innovation, trade costs and welfare. It provides an introduction to parallel imports, genuine products, the connection to IPR and the tri-issues of price discrimination, vertical price control and national price regulations.

There is an exploration of the effect of parallel imports on innovation in emerging economies with TRIPS obligations to improve their IPR regime. Do parallel imports decrease the R&D in emerging markets (e.g. Indian pharmaceuticals) and impede the development of their own innovative product?

Brief literary synopsis of Valetti & Szymanski parallel trade negatively impacts R&D. Li & Robles (2007) find conditions where parallel imports increases incentive to innovate horizontal version of the product. Li & Maskus (2006) conclude that parallel imports always inhibit R&D, and Li (2006) assesses competition between two firms and finds ambiguous results on innovation dependent on transportation cost.

Damages from parallel imports are absorbed by larger firms, but reduces R&D effort by both large and medium corporates. Trade costs transfer the burden of lower market share to the medium sized firms.

Models two competing heterogeneous firms, large and medium pharmaceutical firms in India assessing the outcome of the 'game' with parallel imports and alternatively a ban on parallel imports.

It concludes that allowing parallel imports is more likely to stimulate innovation by the more technologically advanced firm. In an emerging industry where the technology gap between firms is large, an international exhaustion system accompanied by tariffs can increase innovation and welfare in the home country. These conditions apply to the pharmaceutical

industry in India, but not in fully developed economies such as the US or EU, This is the justification for differing parallel imports policies in different regions around the world.

14. Intellectual Property Rights, Parallel Imports and Strategic Behaviour, Ganslandt and Maskus (2007)

This paper analyses how market size affects the IPR owner's decision on whether or not to allow parallel imports. It also studies the effects of parallel importing on the investment incentive of the authorised distribution channel for marketing the products.

It finds that parallel imports cannot arise if the target and the source market are too similar or too different in size. Also, both the presence of parallel imported products and the threat of parallel imports reduce the domestic distributor's market development investment.

Parallel importing arises due to price differentials that exist across countries. These price differentials may exist because of currency fluctuations, international price discrimination by manufacturers, and different marketing strategies pursued by IPR owners or authorised distributors in different countries. Parallel importers can take advantage of the investment authorised distributors make to promote products in the market by selling the same product which they obtained from a foreign source at a lower price. This creates a 'free riding' problem which reduces the incentive for the authorised distributor to invest in market development.

There are two key results of the study. It illustrates that parallel imports can arise in a vertical control setting even if the IPR owner is able to deter parallel imports. Further, legalisation of parallel imports, often has an adverse effect on the domestic distributor's incentive to invest in market development when facing competition from parallel importers even if the IPR owner can deter parallel imports. This results in a lower social welfare.

15. Parallel Imports, Market Size and Investment Incentive, Alfons Palangkaraya and Jongsay Yong (2006)

The legal principle governing whether, in fact, firms can segment markets in order to support price discrimination across countries in goods protected by IPR is the exhaustion doctrine.

Strong IPRs to stop parallel trade allows firms to segment markets and deploy price differentiation that raises profits. Without them, markets become more integrated and firms suffer a reduced ability to set discriminatory charges.

The European Court of Justice (ECJ) consistently held the view that free circulation of goods takes precedence over IPR.

A policy of national exhaustion, banning parallel imports, amounts to a government-supported segmentation of international markets.

One of the major arguments made against parallel trade is that it would diminish investments in new technologies.

It is evident that government price controls in different countries can generate parallel imports. Some countries adopt strict price caps that are substantially lower than prevailing prices in other countries. Parallel trade responds to these price differentials and products flow from countries with lower regulated prices to markets without price regulations or with higher regulated prices.

Empirical literature is quite scarce, for the simple reason that data on parallel imports largely are non-existent.

Discusses results from the NERA study. In particular that parallel imports attained their largest shares in compact disks (10-20 % of EU sales), cosmetics and perfumes (up to 13%), and soft drinks (up to 15 %). Each of these types of commodities reflects characteristics giving rise to the potential for parallel imports such as goods subject to substantial increasing returns, goods subject to heavy marketing (and goods with intensive use of trademarks).

16. An analysis of the ambiguous welfare effects of parallel trade freedom, Muller-Langer (2010)

The paper considers the regulation of parallel trade in the field of pharmaceuticals and its welfare effects.

There is discussion around the value of patent rights and its dependence on “the scope for price discrimination within the area of exhaustion”. Advocates of strong patent rights for new pharma products support a global policy of banning parallel trade. Argue that increase in parallel trade would cut profits and reduce incentives for R&D.

Creates a “double marginalisation model” between a domestic monopolistic pharmaceutical manufacturer and a foreign exclusive distributor. Double marginalisation occurs when different firms in the same industry, who both have significant market power, operate at different vertical levels of the supply chain, e.g. manufacturer and distributor, and each apply their own mark-ups to prices. The paper models the impact of parallel trade on manufacturers’ profit, consumer surplus, and national welfare. Conducts analysis of the net effect of parallel trade freedom on global welfare for low, intermediate and high trade costs.

Efficient international distribution of goods requires multinational companies to build markets via territorial dealership rights.

National governments intervene in private markets by regulating price to achieve social objectives (e.g. affordable medicines).

If wholesale price (when parallel trade is allowed) is so high then parallel trade cannot occur anyway therefore it is the same as when manufacturer holds a monopoly. There is a lower bound under an international regime, as distributors are only willing to sell as long as they can sell a quantity equal to or greater than zero if the price they can charge is equal to or greater than the manufacturer's wholesale price.

The paper concludes that "parallel trade in a double marginalisation game will never occur, as it's always beneficial for the manufacturer to monopolize in country A."

17. **Vertical Price Control and Parallel Imports, Maskus & Chen (2000)**

The paper argues that parallel trade can be viewed as an issue of vertical price control.

There is discussion of parallel trade and wholesale/manufacturer business models. It puts forward two leading theories: international price discrimination theory and the free-riding theory. A third theory takes into account the vertical relationships that exist in the marketing of a manufacturer's good internationally but doesn't rely on the presence of service externalities.

It notes that parallel trade reduces manufacturer profits by creating competition in the country receiving parallel imports, and also because the manufacturer bears additional transportation costs and is prevented from achieving efficient vertical pricing.

Transport costs involved in parallel trade diminish the returns. Trade-offs include benefiting consumers in high-price countries at expense of low-price countries. Welfare implications are ambiguous dependent on the costs of engaging in parallel trade - if the costs of engaging in parallel trade are low then there would be gains to be made from allowing it, but if costs are high, then it would be more practical to prohibit it.

Provides an explanation of exhaustion regimes and reference to the TRIPS agreement of the WTO. Reviews international policy debate on parallel imports, e.g. Australia de-regulating copyrighted goods to lower prices, and EU and USA also looking to use parallel trade to lower the price of medicines.

The authors create a theoretical model to analyse parallel imports as a response to vertical pricing arrangements between the rights holder ("manufacturer") and a foreign distributor. The study then performs an econometric test of the model relating US export prices at the wholesale level across foreign markets to the costs of shipping US exports back to the US. Maskus and Chen estimate wholesaler marginal cost using export unit-value data and Cost Insurance and Freight (CIF) rates compiled by another researcher, product sub-categories within each 10-digit HS category (US National Trade Bank), tariff rates for each HS category (World Bank), the US ad valorem tariff rate and GDP per capita data. The estimation finds that US import tariffs have the predicted U-shaped impact on export wholesale prices.

The vertical-pricing model provides an explanation for this pricing behaviour that is consistent with manufacturer's preferences to deter parallel trade. Using regression analysis based on the model, the data shows that tariff rates in the importing country and transport costs to move products have a significantly negative impact on US exports returning to the US.

Parallel imports can increase retail-market competition, but can also affect a manufacturer or rights owner's incentive in setting the wholesale price it charges a distributor and reduces vertical pricing efficiency.

18. **The regional exhaustion of intellectual property, Saggi (2013)**

The paper conducts analysis of the causes and consequences of regional IPR exhaustion.

Introduction to three exhaustion types: international, regional and national.

The question posed is "what are the welfare implications of regional exhaustion for the outsider (i.e. the country from which parallel imports are not permitted)?" It notes that parallel trade is more likely to occur between geographically proximate countries.

Model developed to assess three countries:

- Scenario 1: two high-income countries who jointly choose regional exhaustion.
- Scenario 2: the policy choice is set to national exhaustion or international exhaustion (non-discriminatory).

The paper finds that when free to price discriminate internationally, each firm charges its highest price in one country and lowest in another country. If price discrimination is not possible, so that a firm must charge common pricing, then its price when serving only two high price markets is higher than when serving all markets.

Common pricing is a weighted average of the optimal market specific prices for those markets. Weights are inversely proportional to the relative importance of each market.

If countries adopt non-discriminatory exhaustion policies the welfare of that country is either unaffected or worse off. Regional exhaustion makes all countries better off.

19. Parallel imports and price controls, Grossman & Lai (2006)

Describes WTO policy provisions for establishing IPR exhaustion regimes.

Discusses legal impediments to parallel imports and the differences between US and EU regimes, particularly for pharmaceutical markets.

It includes data on parallel imports of prescription drugs between US and Canada. It also includes a list of parallel importers within Europe: UK, Sweden, Germany, Netherlands and Denmark.

It provides a list of parallel exporters including Spain France, Greece, Italy and Portugal.

The paper constructs a model comparing the changes around innovation and price controls with differing IPR regimes. It looks at the change in conditions between the value of a patent between countries when parallel imports are permitted.

Innovation is at least as great in a regime with parallel trade as it is without parallel trade. The permitting of parallel imports results in retarded innovation under the orthodox view, however a switch to international exhaustion can allow the innovating country to reap lower pricing, and higher margins, along with more rapid innovation cycles and high welfare standards.

The paper provides a game theory example (using a Nash Equilibrium game) of pricing between North and South regions, where the two governments operate varying regimes. The South government adopts a price ceiling (banning parallel imports) and the North government allows international parallel imports and has no fixed costs. The North government would adopt a higher price were that price to apply to markets in two countries, compared to a price adopted in just the home country. It finds patent holders earn higher profits in both the home country and in the exporting country under international exhaustion than under national exhaustion.

20. Regulation of Pharmaceutical Prices: Evidence from a Reference Price Reform in Denmark, Kaiser, Méndez, Rønde, Ullrich (2013)

This paper focuses on the pharmaceutical markets and include a discussion of reference pricing where patients are reimbursed a fraction of the RRP when purchasing prescription drugs.

The study asks the question: To what extent do differences in the design of reference pricing systems affect market outcomes?

It focuses on Danish reference pricing reform which turned from external referenced to internal referenced pricing - statins; the best-selling drug (sales) in Denmark and globally.

Regression analysis of prices in absence of the reform is used. Prices fell for most generics followed by parallel imports and branded drugs (branded drug co-payments (the bit paid by the public consumer) increased). Demand increase for parallel imports of 28%. i.e. market-based competition induces customer switching to cheaper products. Healthcare expenditure increased by 12% for parallel imported products. (N.B. Reference prices were previously based on cross-state averages between the EU-15 member states excl. Greece, Lux, Spain and Portugal).

The paper concludes that the design of reference price systems matters for prices and demand. Switching from external to internal reference pricing reduced list prices, reference prices and consumer co-payments by approximately 22%.

21. The welfare impact of parallel imports: A structural approach applied to the German market for oral antidiabetics, Suppliet, Duso, Herr (2014)

This paper looks at the welfare effects of parallel trade in the pharmaceutical market, with a focus on the key trade-off between long-term innovation and R&D expenditure versus price reductions sufficient to benefit the consumer short-term.

Theoretical discussion around effects of parallel imports on innovation intensity and reduced investment, positive effects may result from different incentives when IPRs are nationally exhausted rather than internationally exhausted.

Parallel trade in 2012 totaled EUR5.3bn in EU and EUR2.9bn in Germany (based on ex-factory prices). Total market share in 2010 for Denmark was 24%, 11% in Germany, 10% in Netherlands, 7% in the UK. In the patent market - parallel imports accounted for 25% of sales in Germany in 2010 where Germany is largest European market for pharma and heaviest parallel importer.

The study used a model of supply and demand for oral anti-diabetic drugs between 2004 and 2010, with data taken from IMS.

It notes that challenges in making comparisons between EU and US given parallel imports are not permitted in the US and patented drugs are expensive in US. There is a discussion around diabetes and the German health insurance system. The study provides a quantification of welfare effects of parallel import policy through comparison of market with and without parallel imports of drugs.

The paper finds that the demand for antidiabetic drugs is quite elastic. Parallel imports shift the profits from firms investing in R&D to those that do not, original drugs manufacturers losses are over EUR90mn from parallel trade. The majority of this profit passes to the statutory health system.

22. Why We Study Intellectual Property Rights and What We Have Learned, Fink & Maskus (2005)

Discusses a summary of various papers (which are included in our report) which are based on intellectual property rights.

Economists have demonstrated that the desirability of allowing parallel importation depends on what causes parallel trade. Some arguments put forward for the causes include:

IPRs confer market power to firms, which allows them to set prices according to demand elasticities in national markets. The resulting price differences create incentives for arbitrage by parallel traders.

Parallel traders buy goods cheaply in the wholesale market and free ride on the promotional and sales support activities of retailers.

Incentives for arbitrage can arise if a firm sells its good to a foreign distributor cheaply in order to encourage efficient vertical pricing in the foreign market.

Discusses implications of the findings in the studies for IPR exhaustion policies. In summary:

- The welfare consequences of an exhaustion policy differ across industries and across the various types of intellectual property. For some technologies, such as pharmaceuticals, there are good reasons for restrictions on parallel trade. In others, the case for limiting parallel trade is less clear.
- A case can be made for a regional approach to parallel trade, whereby parallel trade is allowed within but not from outside a group of countries (see conclusions from literature piece no.17)

Governments need to promote competition among parallel traders by creating a certain legal framework for parallel trade and by ensuring easy market entry conditions. Otherwise, there is the risk that price reductions will be offset by real resource costs and rents to parallel traders.

23. Effects of a shift to regional exhaustion in patent law, Plaut Economics (2004)

24. Exhaustion of Ownership Rights: Impact of a System Change on the Swiss Economy, Frontier Economics and Plaut

See main paper, section 3.3.3.

25. **The Costs and Benefits of Preventing Parallel Imports into New Zealand, Deloitte (2012)**

The paper summarises previous studies of parallel imports in New Zealand, analyses the costs and benefits of parallel trade, and the impact of parallel import restrictions (PIRs) in Australia and New Zealand, and uses evidence from international price comparisons to look at this.

The paper notes there are additional sources of gains to both consumers and possibly producers, such as increases in product variety (for consumers), and improvements in inventory control (for distributors and retailers).

The study looks at empirical data for CDs, DVDs, computer software and books for factors such as employment in these industries, and growth in sales and prices, in order to analyse the impact of changes in PIRs in Australia and New Zealand. It finds that:

- Since 1998, when parallel import restrictions on CDs were relaxed in both Australia and New Zealand, real (inflation adjusted) CD prices have fallen considerably.
- There is little evidence that the PIR changes in 1998 have had significant negative consequences for the New Zealand and Australian music industries based on sales and artist data.
- The temporary ban on parallel imports of new motion picture releases in New Zealand in 2003 did not appear to have had positive impacts on the local industry.
- Data from earlier studies and from the report suggest a sizeable negative price differential for books opened up between New Zealand and Australia. This finding supports other recent evidence for books, which have shown that Australian consumers continue to pay a significant price premium as a result of remaining parallel import restrictions in Australia.

The study then conducts a comparison of international online retail prices for books, compared to music CDs in New Zealand and Australia, as Australia continues to impose PIRs on books but not on CDs. Data was collected (100 observations) from a number of sources, including Network Economics Consulting Group (NECG) and other online retail websites for the products. Deloitte then used a differences-in-differences approach to estimate the impact on prices of Australia's parallel import restrictions. They find that the parallel import restrictions that remain in Australia result in book prices 10% higher than they otherwise would be.

Appendix B: Survey questionnaire

The questionnaire for this study was developed in close collaboration with key members of the IPO project team. Questions were grouped into a number of different sections each designed to build knowledge of three distinct areas:

- The type of individual/role within an organisation most knowledgeable about the topic.
- The nature of Parallel Trade activities among the organisations targeted.
- The type of data available to explain the scope and scale of Parallel Trade activities among target organisations.

To ensure consistency, all interviews were conducted using a pre-programmed, computer-based questionnaire script to avoid any interviewer error in administering the survey. As the provided answers are entered into the system, the next relevant question was automatically displayed.

Details of each section and the intended flow of the discussion are outlined below.

Introduction

This section starts with the interviewing agent introducing Kantar Millward Brown, an international market research consultancy. They then ask to speak with someone with an oversight of the movement of the originations goods across countries.

It is then explained that, ideally, this would be an individual with a good view of both procurement and sales activities. If the interviewer is connected to this person, they then deliver a more formal introduction of the survey.

To support the interviewer at this stage, notes are provided to cover:

- A standard definition of Parallel Trade.
- An explanation of who the survey sponsor is.
- The reason why the survey sponsor is interested in the topic.
- An explanation of the fact that the study is being conducted in accordance with the ICC/ESOMAR International Code on Market and Social Research.

Screening section

This screening section ensures that only relevant individuals take part in the survey. Questions are asked to understand the nature of the contact's business and filter out those that are not relevant to the topic (these were agreed in advance with the IPO).

The screening questions focused on:

- Business type (ideally Manufacturers, Distributors and Retailers).
- Industry sector.
- Number of employees.
- Channels/sources used for importing and/or exporting non-counterfeit products from outside UK.

Once through these questions, respondent is then asked if they have come across the term 'Parallel Trade' before and if this activity formed any part of their organisation's trading operations.

If the respondents is positive about these two elements, they are then asked if they have a good knowledge of the details of their organisations parallel trading activities.

If so, the process moves to the main interview section but, if not, a request is made to find an alternative person within the organisation who could help.

Routing section

Once the individual successfully clears the screening, they are then asked a series of questions to understand what information the company collects with regards to its parallel trade activities.

The detailed routing question used in the survey is shown below:

ASK ALL RESPONDENTS					
As part of this discussion we are keen to understand what information your company collects with regards to its parallel trade activities.					
I'm going to read out some the type of data that might be collected and I'd be interested to know if:					
<ol style="list-style-type: none"> 1. You'd be able to talk about this information today 2. The information is available in the company and it could be provided at a later date 3. The information is not currently available anywhere in the company 4. You don't know if the information is available in your business 					
READ OUT AND SINGLE-CODE					
		Know this information	Could provide later	Information not available	Don't know
1	The total financial value of your business' Parallel Trade				
2	Financial breakdown of your Parallel Trade activities by product origin				
3	Financial breakdown of your Parallel Trade activities by product destination				
4	Financial breakdown of your Parallel Trade activities by product group				
5	Any other information that relates to Parallel Trade as a percentage of your overall business activities				

The information provided to this question dictates which questions they will go on to answer later in the survey.

Where respondent mentions that certain data is not immediately available, they will then be asked how long it would take to source this information. Also, they are asked for their preferred channel to provide this information with the following options offered:

- A call-back at a convenient time.
- A list of the information ideally required sent, completed and returned directly to the IPO.
- A list of the information ideally required sent, completed and returned to Kantar Millward Brown for forwarding anonymously onto the IPO.
- A list of the information ideally required sent, completed and shared in a follow up telephone discussion with Kantar Millward Brown.
- A list of the information ideally required sent, completed and shared during a scheduled face to face meeting at the respondent's premises.

Finally, if a respondent states that any data is unavailable or doesn't exist, they will be asked if they know why this was the case.

Main study section

This main section of the survey is designed to capture detailed contextual information about where information on Parallel Trade activities is located. Respondents will be asked:

- The department, system or organisation where information on parallel traded goods comes from.
- The number of years of data available for Parallel Trade activities.
- How reliable respondents feel the available data is.
- Views on changes in the amount of Parallel Trade activity the business has conducted over the last 3 years.
- The countries from which the business imports finished goods which are then Parallel Traded.
- The countries the business exports Parallel Traded goods to.
- The main product groups where Parallel Traded goods are used.

IPR exhaustion section

This section is designed to understand the potential business impact of any UK Government changes to rules relating to parallel imports. Respondents will be asked the nature of the impact if:

- The UK Government changed the rules to allow parallel imports from anywhere in the world.
- The UK Government changed the rules to prevent parallel imports from anywhere in the world.

Additional questions for manufacturers, rightsholders and distributors

Respondents identified as manufacturers or rightsholders are asked:

- If their organisation holds the Intellectual Property rights to all (or some of) the products it manufactures or distributes.
- From which countries their organisation sources components that are classed as Parallel Traded goods.

Respondents from distribution companies are asked:

- Where their organisation sourced its Parallel Traded products.
- The external factors that have the biggest influence on the amount of Parallel Traded products distributed e.g. exchange rates or shipping costs.

Data capture section

This section is intended to collect all of the detailed Parallel Trade data the respondent had earlier described as immediately available. This covers:

- The total financial value of their business' Parallel Trade.
- The total financial value of their business' parallel trade, broken down by product origin.
- The total financial value of their business' parallel trade, broken down by product destination.
- The percentage that Parallel Trade goods reduces price for their business (approximately)

For rightsholders additional questions are:

- The approximate cost of enforcing the existing regime for non-EU countries.
- The percentage impact that a change in the rules to allow parallel imports from anywhere in the world to the UK would have on international pricing.
- The percentage impact that a change in the rules to restrict parallel imports from the EEA and the rest of the world to the UK would have on international pricing.
- The percentage of the organisation's IP protected goods that are actively prevented from being parallel imported (approximately).

- Of the components used in a manufacturing process, what percentage of the total value are components sourced through parallel trade (approximately).
- The percentage of manufacturers, that the respondents organisation deals with, that are used to source products for Parallel Trade (approximately).

Classification section

The final section of the survey is intended to collect some key background information on each respondent's organisation. These details are:

- The main industry sector that the business operates in.
- Number of employees.
- The average annual turnover of the company in pound sterling.
- The average annual exports amount in pound sterling.
- The average annual imports amount in pound sterling.

At the end of the discussion, the interviewer thanks the participant for their time before closing the session.

EY | Assurance | Tax | Transactions | Advisory

Ernst & Young LLP

© Ernst & Young LLP. Published in the UK.
All Rights Reserved.

The UK firm Ernst & Young LLP is a limited liability partnership registered in England and Wales with registered number OC300001 and is a member firm of Ernst & Young Global Limited.

Ernst & Young LLP, 1 More London Place, London, SE1 2AF.

ey.com

The Intellectual Property Office
Concept House
Cardiff Road
Newport
NP10 8QQ

Tel: 0300 300 2000

Fax: 01633 817 777

Email: information@ipo.gov.uk

Web: www.gov.uk/ipo

Facebook: TheIPO.UK

Twitter: @The-PIO

YouTube: ipogovuk

LinkedIn: uk-ipo

For copies in alternative formats please contact
our Information Centre.

**When you no longer need this booklet,
please recycle it.**

@ crown copyright, 2019

This document is free for re-use under the terms
of the Open Government Licence.

Images within this document are licensed by
Ing Image.

DPS-008604

