CASE ASSOCIATES

Parallel Trade in Pharmaceuticals

An economic assessment

Report prepared for the

European Association of Euro-Pharmaceutical Companies (EAEPC)

About Case

Case Associates is an economics and regulatory consulting firm. It undertakes assignments across a wide range of regulatory, competition law, and economic issues.

Case was established in 1996 and has been consistently listed as one of the top 20 economics competition practices worldwide by *Global Competition Review*. It has established a reputation with regulators, the private sector and legal advisers as undertaking high-level economic and regulatory work. Case has assisted many companies on regulatory matters, with economic and data analyses supporting filings in regulatory, antitrust, merger, State aid and litigation involving anticompetitive practices, market power abuses, mergers, and damage claims.

Further information on Case can be found on our website www.casecon.com.

© 2008 Case Associates. All rights reserved.

Contents

Summary

- The European courts have thrown the competition rules on parallel imports of patented medicines into disarray, and the current position is unclear and unsettled.
- The impact of parallel imports on competition and efficiency are matters which are to be resolved by empirical analysis and not theory or abstract legal analysis.
- The prices of patent medicines are not immune from commercial and market forces despite the presence of state intervention.
- Parallel trade lowers the costs of medicines to consumers and taxpayers.
- There is no evidence that parallel imports of patented medicines have reduced global pharmaceutical R&D.
- A rule of reason approach must properly balance competition concerns with efficiency gains based on factual evidence.

1. Introduction

This report has been commissioned by the European Association of Euro-Pharmaceutical Companies (EAEPC) to critically assess the legal and economic arguments put forward to justify restrictions on parallel trade in patented pharmaceuticals. This takes place against the backdrop of recent challenges by the pharmaceutical industry to the established legal position that restrictions on parallel trade are anticompetitive and contrary to the single market provisions of the EU Treaty. There is also heightened concern over the lack of competition in the pharmaceuticals sector generally as indicated by the launch of a major European Commission sector inquiry into the industry.[1]

1.1 Issues

Freedom to engage in parallel trade within the European Union is one of the lynchpins of the single market. The European Commission's policy of promoting parallel trade in all products, including pharmaceuticals, on the principle of the free movement of goods within the Internal Market is enshrined in Articles 28 to 30 of the EU Treaty. The European Court of Justice (ECJ) has held that medicinal products are not exempted from the rules of the Internal Market and has condemned state measures which restrict, without appropriate justification, parallel imports of medicines.

Until recently EU competition law has also treated restrictions on the free movement of goods and services as an infringement.

Recent cases before the European Courts have challenged this position. The Court of First Instance (CFI) in *GlaxoSmithKline*[2] and the Advocate General's Opinion (AG Jacobs) in *Syfait I*[3] (although the latter was not followed by the Court and therefore is

[1] Case No COMP/D2/39.514 *Pharmaceutical Sector Inquiry*, 15 January, 2008. http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/decision_en.pdf

[2] Case T-168/01 *GlaxoSmithKline Services limited v Commission*, 27 September 2006, Judgment of CFI ("*GlaxoSmithKline*"), now subject to appeal to the European Court of Justice.

[3] Case C-53/03 *Synetairimos Farmakopoion Aitolias & Akarnanias (Syfait) and Others, Panellinios syllogos farmakapothikarion, Interfarm – A. Agelakos & Sia OE and Others, K.P. Marinopoulos Anonymos Etairia emporias kai dianomis farmakeftikon proionton and Others, v GlaxoSmithKline plc, GlaxoSmithKline AEVE*, 31 May 2005 Judgment of the CFI *("Syfait I")*. The case was dismissed by the

not 'law') offered a different analysis, suggesting that restrictions on parallel imports are not necessarily incompatible with the internal market and competition law. However, this approach has been challenged in *Sot. Lelos Kai Sia (Syfait II),* which revisited the issues of *Syfait I.* In that case, AG Ruiz-Jarabo Colomer[4] contradicted AG Jacobs' analysis and conclusions. Considering the same facts, he concluded that a dominant pharmaceuticals company's refusal to supply patented medicines to wholesalers with a view to reducing parallel trade constituted abusive conduct which could not be objectively justified by legitimate commercial interests or efficiency considerations. The Grand Chamber of ECJ brushed efficiency considerations aside but left open the possibility that the pharmaceutical manufacturer might be able to justify a refusal to supply where the orders are out of the ordinary, having regard to size of the order and its impact in the market of the first Member State and the previous course of dealing between the pharmaceuticals manufacturer and the wholesaler concerned.

There appears to be a judicial shift from treating restrictions on parallel trade as *per se* offences to a 'rule of reason' test. There is no objection to this move as long as it is based on a factual inquiry which looks at the effects of any restrictions and where the burden of proof for establishing the efficiency of any restriction if competition placed on the pharmaceuticals companies. To date the pharmaceuticals companies have not provided evidence on this central matter.

1.2 Our Findings

Assessing the economic impact of parallel trade in patented medicines is complex.

It has been claimed that parallel imports do not benefit consumers, subvert Member States' schemes for regulating patented medicine prices, and reduce the incentives for research-based pharmaceuticals companies to invest in research and development (R&D).

Our review shows that these claims rest more on assumptions than facts. The facts which we have seen show:

First, that there is evidence that parallel trade lowers the costs of medicines to consumers and taxpayers, although there are differences as to the magnitudes of the benefits in individual Member States.

Second, the prices of patented medicines are not immune from commercial and market forces despite the presence of state intervention. In many Member States, drug prices are the outcome of negotiations between governments and related

ECJ on procedural grounds that the Greek Competition Authority was deemed not to be a "tribunal" as required by Article 234 of the EC Treaty.

[4] Joined Cases C-468/06 to C-478/06 *Sot. Lelos Kai Sia EE (and others) v. GlaxoSmithKline AEVE*. (*Syfait II*)

authorities and the pharmaceuticals companies where commercial and market forces are taken into account and influence the outcome.

Third, far from making price controls more difficult, parallel imports are often a significant part of the process of setting and negotiating prices with the pharmaceuticals companies.

Finally, and critically, there is no evidence that parallel imports of patented medicines have reduced global pharmaceutical R&D.

These facts now seem accepted by the Courts.

This report does not take a position one way or another but seeks to balance the arguments based on the dual requirements of sound economics and hard evidence. Using these standards the case against parallel imports lacks hard empirical support. The basic claims – that parallel trade generates no benefits for consumers and taxpayers, subverts price regulation in Member States, and reduces global R&D – which were relied on by AG Jacobs and the pharmaceuticals companies' allegations have simply not been substantiated despite three decades of parallel trade in pharmaceuticals. The onus is squarely on the pharmaceutical companies to establish efficiency gains from restrictions on parallel imports, which to our knowledge they have not done to date. As a recent survey by the American Enterprise and Cato Institutes, who acknowledge financial support from the Pharmaceutical Research Manufacturers Association of America (PhRMA), has observed:

> *"The economics of parallel trade present some of the most complicated challenges to the international trading system, and much work remains to be done in this area. There is very little empirical research published, and most of the benefits and costs related to parallel imports have yet to be quantified. To be sure, quantification of parallel trade, which by definition occurs outside authorized distribution channels, is inherently difficult."*[5]

[5] C. E. Barfield and M. A. Groombridge, 'Parallel distribution in the Pharmaceutical Industry: Implications for innovation, consumer welfare, and health policy', *Fordham Intellectual Property, Media and Entertainment Law Journal*, 2006, Vol. 10, pp. 185-204, at p. 186.

1.3 Structure of Report

The remainder of this report is organised as follows:

- Section 2 provides the background to recent developments in EC law.
- Section 3 critically assesses the consumer welfare effects of parallel trade.
- Section 4 looks at the relationship between parallel trade and investment in R&D.
- Section 5 concludes.

2. Background

In this section we provide essential legal and economic background to the position of the European Commission and the courts.

2.1 What is Parallel Trade?

Parallel trade arises when products are purchased in a low-price country and exported for resale to a high-price country. The margin between the low price and high price provides an arbitrage opportunity for a parallel trader to import the drugs from the country were the medicines can be purchased more cheaply. That is, if the price differential is sufficiently large for a parallel distributor to cover its costs and a reasonable margin it will purchase the drug in the low priced country and re-sell it in the high priced country.

Thus parallel trade is the consequence of significant price differences for the same product between two or more geographical markets.

Parallel trade may occur for one or more of the following reasons:

- differing regulations affecting end user prices;
- differing inflation rates and currency fluctuations;
- differing taxation policies;
- differences in income per capita which lead to differences in the ability to pay;
- differences in the willingness to pay;
- differences in marketing and sales strategies resulting in price differences.

2.2 Extent of Parallel Trade

The volume of parallel trade in pharmaceuticals across Europe is not large as a proportion of total sales – estimated at about 2-3%. However, it varies considerably between Member States, influenced by the differences in prices and the regulatory framework in the importing country. Using data for 2004 the UK, Denmark, Sweden and Norway have the highest level of imports.

2.3 The Commission's View of Parallel Trade

The European Commission's view of parallel trade is simple to state. Parallel trade is pro-competitive as it is the main source of intra-brand competition across Europe. Enterprising individuals and firms see a profit from shipping and distributing a product from an area where it is cheap to one where it has a higher price. The influx of cheaper products puts pressure on the prices in the more expensive regions, and competition between domestic and parallel importers will lead to reduction in prices and/or costs to consumers, health services and taxpayer in the importing country.

In the pharmaceuticals industry drug companies have market power arising from their patents. They can use these to restrict the sale of patented drugs to unauthorised wholesalers and traders in the absence of European law which makes it legal to engage in parallel trade. Further, all Member States require pharmacies to supply the branded product as prescribed by the physician. The effect of this requirement is to enhance the market power of the patent owner since it prevents an alternative therapeutically equivalent from being prescribed.

In industries where firms have market power patents can be used to refuse to supply and engage in regional price discrimination designed to maximise profits possibly considerably above the competitive level. If a monopolist is prevented from creating separate geographical markets through its distribution and contractual practices, then prices generally will be lower.

This view is only part of the story. There are also efficiency considerations surrounding the impact of parallel trade on R&D which we consider in Section 4 below.

2.4 EC Commission's Legal Position

The preceding analysis of parallel trade has formed the basis for the EU law enforced by the European Commission and the courts for the last three decades.

Parallel trade is legal within the European Union. Its legal basis derives from the European policy on freedom of movement of goods under Articles 28-30 of the EC

Treaty with the aim of bringing about greater economic convergence within the EU. The European Commission has recently stated:

> *'Parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations provided by article 30 of the EC Treaty.'*[6]

It also draws on the principle of '*regional exhaustion*' of intellectual property rights. Once a patented product is placed onto the market within the European Economic Area (EEA) by the manufacturer, it cannot hinder any further sale of the product except in exceptional circumstances where, for example, public health is at risk[7].

This is also the position in a number of ECJ decisions confirming that medicinal products are not exempted from the rules of the internal market. During the past 30 years the European Courts have criticised various state measures which restrict, without appropriate justification, parallel imports of patented medicines[8]. The ECJ has also condemned the use by manufacturers of national trademark and patent rights as a means to restrict parallel trade where the product has been lawfully put on the market in another EU State. The ECJ has also noted that national price control systems, although not in themselves contrary to the principle of free movement of goods, may nevertheless be challenged when prices are fixed at such levels that the sale of imported products becomes either impossible or more difficult than the sale of domestic products[9].

2.5 Recent Judicial Developments

In several recent cases the European courts appear to be altering their stance on parallel imports to what appears a more permissive albeit confusing stance.

---

[6] *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted*, COM (2003) 839, p. 6.

[7] See the landmark case C-78/70 *Deutsche Grammophon GmbH v. Metro-SB-Groomarkte GmbH &Co. KG*., followed by ECJ, 3 July 1974, C-192/73, *Van Zuylen frères v. Hag AG*, and confirmed by ECJ, 31 October 1974, in case C-16/74, *Centrafarm BV et Adriaan de Peijper v Winthrop BV* and ECJ, 31 October 1974, in case C-15/74, *Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.* On patents, the European Court of Justice held that '*the exercise, by a patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the Common Market.'*

[8] Case 15/74, *Centrafarm v Sterling* (1974) ECR 1147; Case 16/74 *Centrafarm v Winthrop* (1974) ECR 1183; Joined Cases C-267/95 and C-268/95 *Merck v Primecrown* (1996) ECR I-6285, para 47; Case C-436/93 *Bristol-Myers Squibb v Paranova* (1996) ECR I-3457.

[9] Case 181/82 *Roussel Laboratoria* (1983) ECR 3849.

GlaxoSmithKline (2001) - Article 81

In 2001 the European Commission's decision *GlaxoWellcome*[10] found that GlaxoWellcome's (now GSK) dual pricing scheme in Spain infringed Article 81(1) EC and refused exemption under Article 81(3) EC[11].

Dual pricing schemes charge one price for medicines for domestic consumption and a higher price for those supplied to distributors and others for export. A dual pricing scheme has the object and effect of deterring parallel imports.

The European Commission's position that such a dual pricing scheme was anticompetitive rested on two claims:

- the single market in pharmaceuticals requires the unhindered free movement of products - companies cannot erect barriers to undermine this without distorting intra-brand competition; and

- the efficiency claims advanced by the pharmaceuticals industry were unsubstantiated, i.e. there was no evidence that partitioning the common market would spur global investment in drug innovation. [12]

In 2006 the CFI in *GlaxoSmithKline* partly annulled the European Commission's decision. The Court affirmed that such an agreement was not contrary to Article 81(1) EC in its *object* but only in its *effect* insofar as it impeded consumers from enjoying savings brought about by parallel trade. The CFI acknowledged that parallel trade is the only source of price competition in the pharmaceuticals market. However, the Court considered that it was doubtful whether there were concrete benefits to consumers and national health care systems from parallel trade, due to the presence of price controls.

The court stated that for a dual pricing scheme to be an infringement proof was required of its anticompetitive effects. The CFI stated that, while the Commission examined evidence on whether there had been a loss in efficiency due to parallel trade; it erred by not considering GSK's arguments and evidence that there were efficiency gains from the GSK's dual price scheme. [13]

GSK contended that its dual pricing scheme should be exempt under Article 81(3) EC because it encouraged innovation. [14]

[10] Case IV/36.957 *Glaxo Wellcome* (2001).
[11] Cases: IV/36.957/F3 *Glaxo Wellcome* (notification), IV/36.997/F3 *Aseprofar and Fedifar* (complaint), IV/37.121/F3 *Spain Pharma* (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPC (complaint), 8 May 2001, OJ [2001] L302/1.
[12] N. de Souza, 'Competition in Pharmaceuticals - The challenges ahead post AstraZeneca', *Competition Policy Newsletter,* No. 1, Spring 2007.
[13] *GlaxoSmithKline*, para 261 and 269.
[14] *GlaxoSmithKline*, para 251.

Article 81(3)) EC provides that an agreement which infringes Article 81(1) may be exempted if it '*contributes to improving the production or distribution of goods or to promoting technical or economic progress and allows consumers a fair share of the resulting benefit'* as long as it does not impose restrictions which are not indispensable achieving these or eliminate competition*'.* [15] GSK claimed that parallel trade would reduce pharmaceuticals companies' returns in the export country; and displace the pharmaceuticals companies' sales in the higher priced importing country[16].

The Commission's view was that GSK had failed to substantiate this claim other than in broad generalities. Both parties are appealing the CFI's decision.

Syfait I (2004) – Article 82

In *Syfait I* the ECJ was asked by the Greek Competition Authority (Epitropi Antagonismou) whether GlaxoSmithKline's (GSK) refusal to supply three drugs for six months, and further supply limitations designed to prevent parallel trade, infringed Article 82 EC. Article 82 EC controls the abuse of a dominant position.[17]

Syfait I is somewhat of a legal non-evident since the ECJ declared the case inadmissible on jurisdictional grounds. It has gained notoriety nonetheless due to AG Jacobs' opinion[18] which provided a controversial assessment of the competition law issues.

AG Jacobs reasoned that due to the peculiarities of the pharmaceuticals sector a dominant undertaking's refusal to supply patented medicines with the intention of preventing parallel trade was not an abuse of a dominant position. The industry, he concluded, had special features which justified his suggested change in the legal position. These were:

- the existence of pervasive and diverse regulation by Member States within the EU and by the EU;

[15] The European Commission has issued a number of guidelines on the application of Article 81 - *Guidelines on Vertical Restraints*, 2000/C 291/01; and EC *Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements*, 2001/C 3/02.
[15] EC *Guidelines on the application of Article 81(3) of the Treaty*, 2004/C 101/08.
[16] *GlaxoSmithKline,* para 259.
[17] The earlier *Bayer/Adalat* case should also be mentioned which effectively set in train doubts about the legality of parallel distribution. This case concerned a quota system implemented by Bayer to limit the supply of Adalat to certain wholesalers in France and Spain. However, the Court did not rule on whether supply restrictions where an abuse of Bayer's dominant position (under Article 82) as this was not part of the appealed of the Commission decision. Joined Cases C-2/01P and C-3/01, *Bundesverband der Arzneimittelimporteure v Bayer AG*, (2004) ECR I-23.
[18] *Opinion of Advocate General Jacobs in Syfait I,* 28 October 2004 ("AG Jacobs").

- a pharmaceutical manufacturer's refusal to supply and thereby limit or stop parallel trade was not done to preserve price differentials across Member States but to avoid the consequences of having a very low price across the EU;[19] and

- the possibility that parallel trade would make negotiations over medicine prices between Member States and the pharmaceuticals companies more difficult.[20]

Further, AG Jacobs concluded that parallel trade would not lead to lower medicine prices/costs for two reasons:

1. In many Member States the patient only makes a small flat-rate contribution to the actual cost of the medicines and so price has little or no impact on demand from the patient's perspective.

2. Government health services determined prices within their national regulatory framework and it must be assumed that they are willing to accept the price so set. Thus, any price competition due to parallel trade may not sit well with the public body.[21]

Accordingly neither the public nor the taxpayers would benefit from parallel trade.[22]

AG Jacobs argued that if a low price set by an individual Member State spreads across the EU due to parallel trade then pharmaceuticals companies might not be able to recoup their R&D costs. In response a pharmaceuticals company will want to limit parallel distribution by withdrawing from the originator Member States but is prevented from doing so for regulatory reasons. Pharmaceuticals companies may resort to alternative strategies such as delaying the launch of their products. This, AG Jacobs argued, would lead to lower output and consumer welfare in some countries.[23]

It should, however, be noted that the AG Jacobs was careful not to generalise his assessment beyond the particular facts of the case at hand. It is also important to note that he did not consider whether there was any evidence that the negative effects identified had resulted from parallel trade.

[19] AG Jacobs, para 84.
[20] AG Jacobs, para 92.
[21] AG Jacobs, para 99.
[22] AG Jacobs, para 98.
[23] AG Jacobs, para 91.

Syfait II (2008) – *Article 82*

In *Sot. Lelos Kai Sia (Syfait II)* the Greek Competition Authority again referred the same questions as *Syfait I* to the ECJ for determination. In April 2008 AG Ruiz-Jarabo Colomer's opinion contradicted AG Jacobs' analysis on nearly every key point. He did not accept the economic arguments put forward by GSK, and in particular did not consider the claim of efficiency gains arising from restricting parallel trade as sufficiently proved.

The Court handed down its decision in September 2008 taking somewhat of a middle road. On the one hand, the ECJ rejected GSK's premise that consumers did not benefit from parallel trade; and did not see state intervention over prices as sufficient to negate the operation of commercial and market forces. On the other hand, the Court held that GSK did not have an open-ended duty to supply Greek wholesalers with all the drugs they demanded. The duty of a dominant pharmaceuticals manufacturer was limited to supply *'ordinary orders'* as a proportionate and reasonable response to protecting its commercial interests from parallel trade. The decision is disappointing since it side-steps the central legal and factual issues, by providing an ad hoc resolution.

2.6 Summary

AG Jacobs' Opinion in *Syfait I* and the CFI ruling in *GlaxoSmithKline* provide an alternative analysis of the impact of parallel trade in patented medicines in the EU. This does not correspond to the view expressed by the European Commission, by Community Courts in previous judgments , by a number of national competition authorities, and by AG Ruiz-Jarabo Colomer.[24]

These claims rest on several key factual claims that parallel trade:

1. does not benefit the final consumer because regulation constrains normal market forces.

2. does not benefit the public bodies or taxpayers which purchase/pay for medicines.

[24] The Governments of several Member States have intervened in support of the Commission in appeals before the ECJ - the Swedish government in *Syfait I;* the Polish government in *GlaxoSmithKline*; the Polish and Italian governments in the *Syfait II* case recently referred to the ECJ by the Efetio Athinon, the Athens Tribunal. The Italian Antitrust Authority (comments on pharmaceutical expenditures provided for in Article 5 of Decree No. 159 of 1 October 2007 annexed to the new Financial Law) expressly declared that it would be in the public's best interests to encourage the distribution of parallel pharmaceutical imports in Italy.

3. makes price negotiations between public bodies and pharmaceuticals companies more difficult.

4. reduces the level of global investment in R&D with adverse long-term effects on drug development.

In section 3 below we examine the first three of these claims, leaving the fourth – the impact of parallel trade on R&D - for separate assessment in Section 4.

3. Impact on Consumers

The prices and conditions of supply of patented drugs are subject to considerable regulatory intervention. This is not surprising, since governments, either directly or indirectly, are often the pharmaceuticals industry's biggest customer. However, from this it does not follow that parallel trade subverts the way prices of patented medicines are set and/or that consumers and taxpayers do not benefit from parallel trade.

As will be shown, the view that the prices for patented medicines are somehow fixed in isolation from market and commercial forces is incorrect. They are often the outcome of direct negotiation between governments and pharmaceuticals manufacturers. Moreover, the price in other countries often plays a significant role in arriving of maximum prices or other controls.

The view that consumers or taxpayers do not benefit from parallel imports is also a questionable. While the research to date has been meagre it nonetheless does suggest that parallel trade has lowered prices, although the magnitudes of the price and cost reductions have been disputed.

3.1 Nature of Regulation

In order to understand the issues it is necessary to step back to explain the rationale for intervention, and the way medicine prices are set.

The primary reason for price controls of patented medicines is the view that unrestrained prices would be excessive. This flows from the existence of patent protection, the fact that patented medicines often have few substitutes, and other demand-side factors that cause market failure. Regulation seeks to achieve more 'reasonable' prices that balance the need for the cost effective availability of medicines with the pharmaceutical companies' right to earn a reasonable rate of return on their investment in R&D. While Europe's national regulatory regimes may not be consistent and/or pursue a singular (economic) objective, they nonetheless

seek to moderate the prices of patented medicines (which remain the main cost-drivers in the public budget).

There are two characteristics of the price determination in the EU:

First, the prices of patented medicines in different EU Member States are determined by much the same factors as in other markets. Although approaches to the control of drug prices in Member States differ, most prices are the outcome of negotiations between government and related organisations and the pharmaceuticals manufacturers. These negotiations are influenced by willingness to pay; the bargaining and market power of buyers and sellers; and price comparisons of the same medicine in other countries and the prices of parallel imports. That is, government intervention is not oblivious to market and commercial forces; or to the existence of parallel trade.

Second, despite state intervention and parallel trade, the prices for the same patented medicines vary considerably across the EU. Thus regulated prices reflect, perhaps imperfectly, the discriminatory structure of prices which would have existed in the absence of regulation (see below).

AG Jacobs stated that the existence of pervasive regulation provided an objective justification to conduct that was *prima facie* anticompetitive. This, however, does not follow. Regulation on its own cannot justify otherwise anti-competitive conduct. Many other products and services are heavily regulated but subject to both sectoral regulation and competition law. This applies to nearly all utility industries, such as energy, telecommunications, and postal and banking services. Despite regulation of these industries they continue to be subject to competition law and dominant firms prosecuted for abuses/infringements under EC and national competition rules.

The second claim is that parallel imports do not benefit consumers but are driven by distorted regulated prices. That is, instead of reacting to underlying economic factors, parallel imports respond to artificial price differences created by state intervention. This claim that the prices negotiated between manufacturers and individual Member States are "artificial" is not based on any analysis of the extent to which regulated prices differ from efficient prices (see section 4.1 below). We know that negotiated prices are lower than the pharmaceutical companies would ideally like, and that these negotiated prices for the same patented medicine differ considerably across the EU. We also know that there are significant regional price differences that do not appear to have been significantly reduced by parallel trade.[25] We are therefore left with very little objective support for the views expressed by AG Jacobs that parallel trade has or will result in patent medicine prices being forced down to the lowest price in Europe.

[25] However see P. M. Danzon and L-W. Chao, 'Does Regulation Drive out Competition in Pharmaceutical Markets?' *Journal of Law and Economics*, Vol. 43, 2000, pp. 311-357.

3.2 Mechanics of Price Regulation

AG Jacobs Opinion does not, in our view, accurately describe the nature of price and profits controls of patented medicines in the EU. The impression given is that Governments control prices unilaterally, and that these prices take no account of 'market' prices, the pharmaceuticals companies' interests and/or market factors. This view does not reflect the reality of how patented medicines prices are set within the EU.

There is a wide range of pharmaceutical price controls and reimbursement schemes within the EU. These include:

- Price negotiations between the health authority and the pharmaceuticals company
- Price proposals by the company subject to approval of an authority
- Free pricing but restrictions on reimbursement levels
- Profit control (only present in UK)
- Unilateral price fixing by the approving public health authority.

In a number of Member States final prices of patented medicine are not regulated. In other countries prices are negotiated between health authorities and government ministries and the pharmaceutical companies. These negotiations are influenced by the bargaining power of the parties against the backdrop of prices charged elsewhere and by cost-effectiveness assessments. The European Commission found that in 14 out of 25 EU Member States pharmaceuticals companies are either completely free to set their final end-consumer prices or negotiate these with the authorities.[26] In many cases prices for pharmaceuticals are capped at a maximum level, which provides scope for price competition below the maximum price with no regulation of the minimum prices.

In these cases the price setting process is one of bilateral negotiations, often between monopoly seller and buyer. Given the extensive state intervention across Europe the prices of major patented medicines would be heavily restrained by the purchasing power of the health service and the state as large buyers/funders. Thus the dichotomy between the present regulatory system and the realistic alternatives fails to take account of the structural features of pharmaceutical markets.

[26] European Commission, *Submission to the European Court of Justice of the European Communities to appeal the decision of the CFI in the European Commission v Glaxo Wellcome*, 11 December 2006, para 48(d).

In some countries there is 'buyer power' because a governmental agency purchases all drugs for that country and re-sells it to pharmacies who in turn dispense these direct to consumers[27]. For example, in Sweden the state owned entity Apoteket AB owns all the pharmacies.[28] In Norway, a monopoly buyer of drugs called the Apokjeden was created (with clearance from the Norwegian competition authority)[29].

In many Member States reference pricing and parallel import prices play a direct role in setting maximum reimbursement prices or through schemes that claw back (part) of price reductions obtained by pharmacists from parallel imports.

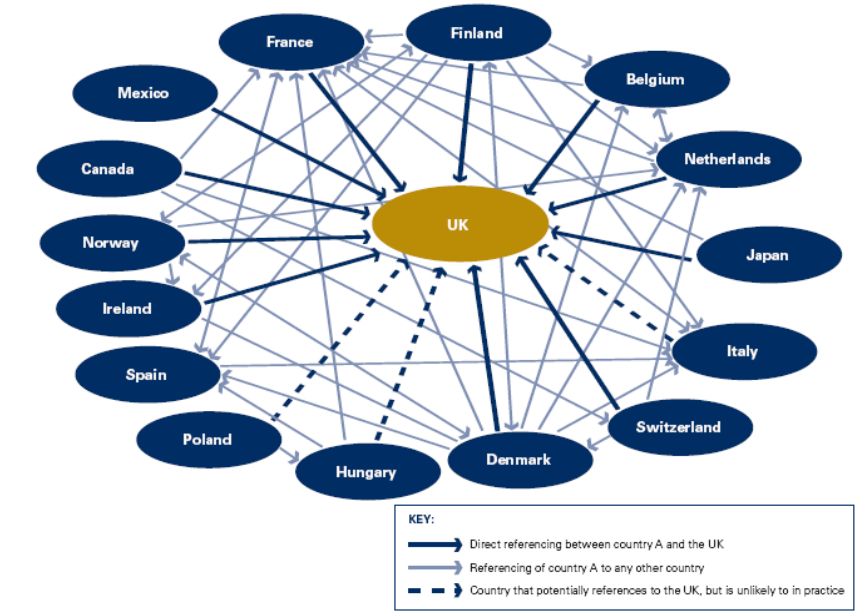
Health authorities in almost all Member States use national and international benchmark prices to establish regulated (maximum) prices. They either benchmark against prices of products that are considered similar in therapeutic terms (so called International Reference Pricing or "IRP"), or to the prices of the same product in another Member State (cross-country comparison pricing).

For example, fourteen countries set their prices for patented medicines with reference to the UK; of these 10 are EEA Member States (Finland, Belgium, Netherlands, Italy, Denmark, Hungary, Poland, Ireland, Norway, and France). In addition, other countries which do not reference their prices to those in the UK, reference them against the prices of other countries which do e.g. Spain uses Italy to reference some of its prices which uses the UK (Figure 3.1).

[27] M. Bohlund, 'The Price Effects of Differential Pricing and Parallel Distribution in Pharmaceuticals', Department of Economics, University of Uppsala, Master's Thesis, Spring 2005, p. 21.
[28] http://www.progressive-economics.ca/2007/08/08/bulk-purchasing-pharmaceutical-drugs/
http://www.perhamre.com/Lectures/Brussel30111999/tsld013.htm
[29] http://www.perhamre.com/Lectures/Brussel30111999/tsld013.htm

Figure 3.1

Figure 3.4: Overview of countries that reference to the UK



Source: Internal OFT Analysis

In other countries there are direct pass-through arrangements (Table 3.1). In Denmark, Netherlands and Sweden the patient is charged a lower price if s/he purchases a drug that is parallel imported and the pharmacist is required to inform the patient of the availability of parallel imported drugs. The price charged to patients for parallel imported drugs in these countries is not the full price but a capped contribution. Further, in Netherlands and Sweden financial incentives are provided to pharmacies to purchase parallel traded medicines.

In Germany pharmacists must by law dispense parallel imports up to a quota of 5% of sales (so called import quota), Prescribing doctors must indicate on the prescription if and when only the originator product may be dispensed (the *aut-idem* rule). Pharmacies have the right/obligation to substitute either the generic or a parallel imported product, and a parallel imported product can substitute for the originator medicine. There are penalties for pharmacies if they do not reach the 5% quota. As a corollary, parallel importers must by law offer products 15 percent, or €15 (for products of more than €100 per pack) cheaper than the branded product. This means that patients, or health insurers, benefit directly from lower prices for parallel-distributed drugs.

Table 3.1 Examples of policies to promote parallel imports, 2004

Policy to promote use of parallel imported (PI) drugs	Denmark	Germany	Netherlands	Norway	Sweden	United Kingdom
Pharmacy required to inform patient of availability of PI product	X				X	
Pharmacy quota on PI dispensing rates		X				
Financial incentives for pharmacy to dispense PI drugs			X	X		X
Financial incentives for dispensing lower-price drugs in general, including PI drugs				X	X	
Lower consumer out-of-pocket contribution for PI drugs than for the domestically sourced products (either from price differential or from lower cost sharing for PI drugs)	X		X		X	

Source: P. Kanavos, D. Gross and D. Taylor, *Parallel Trading in Medicines: Europe's experiences and its implications for commercial drug importation in the US*, AARP Public Policy Institute, June 2005.

Norwegian pharmacists face financial incentives to purchase parallel imported drugs but pharmacists do not have to inform patients of the availability of such drugs nor do patients face a lower price for purchasing parallel traded products. In Denmark the new reimbursement rule in force as from 2007, established that the reimbursement level of a given drug must amount to the price of the cheapest equivalent, which under patent is likely to be the parallel imported product.[30]

In such situations, parallel trade or, the threat of parallel trade, gives hospitals and social security institutions greater bargaining power in negotiations, and an incentive to manufacturers to moderate prices in a given country – i.e. it exerts a competitive constraint on prices which can be passed on to either retailers and/or final consumers. This general effect has been noted by the Swedish Competition Authority in its review of parallel trade:

> "*Apart from the direct impact on prices noted above, there are instances of potential parallel imports having an indirect impact on prices. Faced with the prospect of competition from an incipient parallel import trade, some original suppliers of drugs have on occasion voluntarily chosen to cut prices by over*

[30] See the *Danish Health Act 2005* entered into force the 1st January 2007 in http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=11548.

10%, which had the effect of eliminating the conditions necessary for parallel imports."[31]

Other Member States do not operate such claw-back schemes. The reimbursement by the public body to the pharmacist is at the rate at which the medicine is sold by the pharmaceuticals company. Thus a pharmacist purchasing from the parallel trade is reimbursed at a higher price than the price he pays. As a result the pharmacist pockets the gain (profit) from purchasing from a parallel distributor. Thus potential price reductions are absorbed as profits in the distribution chain by the pharmacist.

The evidence indicates that, far from undermining Member States' price regulation[32], parallel trade often plays an important part in the price determination process.

3.3 Consumer Benefits

It is frequently claimed that parallel trade does not lead to lower prices to consumers but high profits for parallel importers and others. The Courts in *GlaxoSmithKline* and *Syfait II* did not endorse this position accepted as fact that there had been real reductions in the price and the costs of medicines due to parallel trade.[33] However, in *GlaxoSmithKline* the court stated that it could not be assumed that parallel trade would lower prices.

As to the presumption or otherwise of consumer gains several comments can be made.

The first is that competition authorities have not usually required an assessment of whether competition has result in significant price reductions to consumers. The focus has not been on price levels but effective competition, with a presumption that effective competition leads to consumer benefits. Even in the few competition cases where excessive prices have been alleged and found, both the European Commission and the courts have not sought to identify whether prices have actually been excessive, but only that effective competition has been restricted. For example, cartel prosecutions by the European Commission to date (under Article 81 EC) contain little evidence that the alleged agreements actually raised prices above non-cartel levels, and the courts have not questioned this. The law is based on a presumption that competition benefits end-consumers; and that a restriction on competition harms consumers.

Second, the claim that parallel traders benefit and earn excess profits relies on a number of assumptions. It assumes that there are barriers to entry to parallel trading, and that the buyers of imported drugs are oblivious to their source and the sellers'

[31] Swedish Competition Authority, *Parallel Imports - Effects of the Silhouette Ruling*, 1999, p. 39.
[32] As argued by P. Rey and J.S. Venit, 'Parallel distribution and Pharmaceuticals: A policy in search of itself', *European Law Review*, 2004, Vol. 29, pp.153-177.
[33] *European Commission submission to the Court of Justice of the European Communities to appeal the decision of the CFI in the European Commission v Glaxo Wellcome*, 11 December 2006.

margins. Economic theory suggests that where parallel trade is significant, the parallel traders' margins and prices would fall. This view is reinforced by the fact that the parallel importer has to persuade pharmacies and health authorities to accept the imported drug that by regulation must be clearly labelled and re-packaged as an import. Given this product differentiation and the need to give potential purchasers a financial incentive to purchase an imported drug it is unlikely that excessive margins would persist for any significant period.

Whether parallel traders' pocket most of the price difference is a factual matter on which, surprisingly, there is little evidence. There is, however, some research on whether consumers and taxpayers benefit from parallel trade.

3.4 Empirical Evidence

The limited research to date suggests that parallel trade does reduce the costs and prices of patented medicines, although the magnitude of these reductions is disputed.[34]

Several studies have investigated the effects of parallel trade in patented medicines on health budgets and end-user prices within the EU.[35] Three main studies are frequently cited, although it should be noted that these were commissioned by the pharmaceuticals industry and EAEPC:

- **York study (2003)**[36] The York study was sponsored by EAEPC. It examined pharmaceuticals prices in five European countries (UK, Germany, Sweden, Netherlands and Denmark) for 2002. For each country the top selling products plus a random sample of 150 products was used. In Denmark, Germany and Sweden the savings on parallel-distributed products were estimated by multiplying the volume of each medicine sold by the price differential between the parallel import price and the originator price using actual fortnightly prices. For the UK and the Netherlands the average price difference between parallel and originator products were used. The York study found that in 2002 the savings from parallel trade to the respective national health services totalled €635 million

[34] The OECD review of research studies carried out between 1985 and 2001 on the impact of parallel distribution in a number of goods found that the repeal of bans parallel imports lowered prices to consumers in Sweden, Australia, New Zealand and the EU.
OECD Directorate for Financial, Fiscal and Enterprise Affairs Trade Directorate Joint group on Trade and Competition, *Synthesis Report on Parallel Imports*, 26 June 2002, COM/DAFFE/COMP/TD(2002)18/FINAL.

[35] OECD reviewed studies of the impact of parallel distribution undertaken between 1985 and 2001 covering the US, Denmark, France, Australia, New Zealand, Sweden and the EU for a range of products including pharmaceuticals. These showed that for Sweden and the EU repealing bans on parallel distribution lead to lower prices for consumers. For Australia and New Zealand repealing bans on parallel distribution showed positive effects albeit on a smaller scale than proponents of parallel distribution had predicted. OECD, *Synthesis Report on Parallel Imports*, COM/DAFFE/COMP/TD(2002)18/FINAL, 26 June 2002.

[36] P. West and J. Mahon, *Benefits to Payers and Patients from Parallel distribution*, York Health Consortium, May 2003, ("York study").

which consists of €342 million in the UK,[37] €194 million in Germany, €47 million in Sweden, and €32 million in Denmark in 2001. The prices of parallel-distributed medicines were between 1.6% and 23% lower than list prices of the same drug in the countries in which they were imported.

- **LSE study (2004)**[38] The LSE study was commissioned by Johnson and Johnson a major pharmaceuticals company. Its object was to assess whether parallel trade generated price convergence, and the scale of the profits made by parallel traders. It used data for the period 1997 to 2002 for six European countries (UK, Germany, Sweden, Netherlands, Denmark and Norway) and prices for 19 drugs. It found significantly lower direct savings of €43 million compared to the York study despite both studies examining the same year, 2002, and the same countries. In contrast to the York findings, and the LSE study it found that most of the benefits went to parallel traders.

- **Denmark study (2006)**[39] As a response to the findings of the LSE study the EAEPC commissioned the Centre for Applied Health Services Research and Technology (CAST) at the University of Southern Denmark to update the York Study using 2004 data to estimate the direct financial benefits to national health services from parallel imports. It estimated that in 2004 the direct savings from parallel trade to national health services was €441.5 million which comprised €237 million in the UK, €145 million in Germany, €45.3 million in Sweden, and €14.2 million in Denmark.[40] This indicated that the direct savings to national health authorities from parallel trade had fallen for each country between 2002 and 2004.[41] Some of these declines in savings were attributed to regulatory changes during this period.[42] The study also sought to estimate the effect of parallel trade on the medicine prices (the "competitive effect") and found that in 2004 for Denmark and Sweden these indirect saving were €8.3 million and €16.4 million respectively.

[37] Note that the direct savings for the UK includes €134 million collected through clawback and estimated savings to pharmacists from discounts.
[38] P. Kanavos, J. Costa-i-Font, S. Merkur and M. Gemmill, *The Economic Impact of Pharmaceutical Parallel distribution in the European Union Member Studies: A stakeholder analysis*, LSE Health and Social Care, 2004, ("LSE study").
[39] U. Enemark, K. M. Pederson and J. Sorensen, *The Economic Impact of Parallel Import of Pharmaceuticals*, University of Southern Denmark Centre for Applied Health Services Research and Technology Assessment, June 2006 ("University of Denmark study").
[40] The Denmark study omitted the Netherlands from its update of the York study.
[41] For example, in Germany direct savings fell by 32% between 2003 and 2004 (Denmark study, pp. 42 and 48.
[42] Strict price controls were imposed in Sweden and there were changes in parallel import quotas and mandatory discounts imposed in Germany.

Table 3.2: Studies of savings and competitive effects of parallel trade

Study/(Year published)	Period	Countries	Direct savings (€ million)	Indirect savings/price effects	Medicines covered
York study	2002 (DK 2001)	UK Germany Sweden Netherlands Denmark	342 194 47 32 16 **635**	parallel traded drugs 1.6% to 23% lower than list prices of the same drugs in originator countries	Top selling products and random sample of 150 products
LSE study	1997-2002	UK Germany Sweden Netherlands Denmark Norway	7 18 4 13 3 1 **45**	none found	6 product categories, 19 products covering 21% of brand market
Denmark Study	2004	Denmark Germany Sweden UK	14 145 45 237 **442**	€8.3 million n/a €16.4 million n/a **25**	Top selling 50 products in 2004. Other savings identified
Persson *et al*	1998-2000	Sweden	**13**	€13 million plus pharmacy costs of 2%-133% of realised savings	6 selected products with 2-3 sub-categories.
Riksforakringsverket	1999	Sweden	**5** plus pharmacist price margin	n/a	
Ganslandt & Maskus	1994-99	Sweden	n/a	4% up to 19%	50 highest selling products in 164 forms. For a subset detailed prices for exporting countries
Linnosmaa *et al*	2001	Finland	**4.9** (incl. indirect savings)	None found	

These studies give a wide range of estimated annual savings – from a low of €43 million (LSE) to a high of €635 million (York). These differences arise from different methodologies, data samples, and approaches (as discussed in the Denmark Study).

There is other evidence. Szymanski estimates that parallel traded pharmaceuticals account for around 20 per cent of the UK market and that some sell at 15 per cent less than non-parallel distributed medicines.[43] A more specific example are the actions of Merck Sharp and Dohme (MSD) which reduced its UK price of Cozaar (UK's sixth most prescribed drugs in the UK) by one-third when faced with parallel importers who had gained 75% of sales. The estimated savings to the NHS was £30.2m per annum (assuming the same sales volumes and a Government claw back of 10%).

There have also been a number of studies on the impact of parallel trade in Sweden and Finland:

[43] S. Szymanski, 'Intellectual Property Rights: Trading in pharmaceuticals', London: Economic and Social Research Council, 2004.

- **Persson *at el* (2001)**[44] This study examined the impact of the introduction of parallel trade on Sweden's healthcare expenditure. The study examined prices of 7 drugs; 5 of which made up 46% of all parallel trade sales in Sweden. The effect of parallel distribution in Sweden was based on strong assumptions - that a) in the absence of parallel trade prices would remain constant; b) any price reduction occurring after parallel distribution was introduced was fully attributable to parallel distribution; c) any percentage reduction in the price of specific drug pack sizes could be generalised to all drug pack sizes; and d) an assumed price elasticity of 0.2 (i.e. a 10% price reduction leads to a 2% increase in the volume of the drug consumed). Persson estimated direct savings by multiplying the difference between the originator price before parallel distribution and the parallel trader's price, by the quantity of the parallel-distributed medicine sold adjusted for increased consumption due to the price elasticity. The indirect savings are estimated by multiplying the difference between the pre parallel distribution and the post parallel distribution originator price, by the volume of originator drugs sold which was adjusted for increased consumption due to price elasticity. One defect of Persson's approach is that savings are underestimated if the originator price is on an upward trend and overestimated if the originator price is falling. Persson estimate direct savings were SEK 100 million (€13 million) and indirect savings were SEK 218 million (€13 million). Further, for the two drugs, which did not have a significant share of parallel trade, Persson found that the estimated benefits of parallel distribution were outweighed by the increased costs to pharmacists of handling more drugs (although the latter is of no concern to the final buyer).

- **Ganslandt and Maskus (2004)**[45] This study examined the impact of parallel distribution on drug prices in Sweden. Sweden experienced a policy change on parallel trade when it joined the European Union in 1995. Prior to January 1995 Sweden did not permit parallel distribution. From a position of no parallel distribution in 1995, parallel imports into Sweden grew to about 6% (SEK 1.0 billion) of Swedish pharmaceuticals sales by 1998. Ganslandt and Maskus found that prices of those medicines subject to import competition fell 4 per cent relative to those not subject to import competition. The study also found that original producers in Sweden cut their prices by between 12% and 19% when faced with competition from parallel traders relative to the prices charged by firms who faced no such competition. The authors conclude that parallel imports represent a significant form of competition in Sweden.

- **Linnosmaa *et al* (2002)** This study estimated the effect of the introduction of parallel distribution in Finland for 169 drugs during 1998 to 2001. However, not all

[44] U. Persson, A. Anell and M. Persson, *Parallelhandel med lakemedel I Sverigie – en ekonomisk analys*, Lund: Instituet for Halso-och sjukvardsekonomi, 2001.
[45] M. Ganslandt and K. E. Maskus, *Parallel Imports and the Pricing of Pharmaceutical Products: Evidence from the European Union*, Research Institute of Industrial Economics, Working Paper No. 622, February 2004. published as 'Parallel imports of Pharmaceutical Products in the European Union', *Journal of Health Economics*, Vol. 23, 2004, pp. 1035-1057.

the drugs were available for the entire period studied. Linnosmaa found that there was no significant relationship between originator prices and parallel import prices.

3.5 Continuing Impediments to Parallel Trade

Another claim is that parallel imports will result in a uniformly low price across the EU. This has not occurred. The claim is based on a simple model which does not reflect reality.

If parallel trade were costless and demand and supply conditions in each Member State identical, then the unrestrained parallel imports of patented drugs would work to equalize both wholesale and retail prices. But this is not the case. The harmonisation of medicine prices across the EU is unlikely because of major differences in the demand and supply conditions, health care systems, the costs of parallel trading, and tax structures of Member States.[46] It is also unlikely because of the profit maximising strategies of pharmaceutical manufacturers designed to limit the extent of parallel distribution.

Therefore it is no surprise that despite over three decades of parallel distribution (and significant price regulation) across the EU that the prices of patented medicines are not uniformly low. Indeed, the evidence shows '*that parallel trade has not yet led to a large reduction in aggregate price dispersion across EU countries*'.[47] The reason for this must be that despite the law there remain significant impediments and costs to parallel trade of patented medicines within Europe. These include the practices of the pharmaceuticals companies. A statistical study by Margaret Kyle found evidence that pharmaceuticals companies manipulated a range of non-price variables to reduce the potential gains from parallel trade.[48] This included reduced availability of medicines, selectively price reductions, and the introduction of fighting brands.[49]

Further, the costs of trade to the parallel traders are not insignificant. Parallel importers incur high costs to obtain marketing authorisations and to keep their inventory; they are required to re-label and repackage their medicines in compliance with the law and good manufacturing practices; and their stock is dependent on manufacturers' willingness to supply. Moreover, the medicine may be regarded as inferior by pharmacists or consumers, because of the need to over-sticker or to use a

[46] Spyridonidis interviewed 22 individuals related to the pharmaceutical industry including parallel traders, pharmacist and wholesalers, as well as academics and consultants from across Europe. It found that price harmonisation of medicine prices across the EU was not possible due to the different structure of health care systems, margins and tax structures. D. Spyridonidis, *An Overview of Policies Related to Parallel Trade of Medicines In EU and Analysis of the Greek Pharmaceutical Market*, MSc dissertation, Imperial College London, 2005.
[47] M. Kyle, 'Strategic Responses to Parallel distribution', National Bureau of Economic Research Working Paper No. W12968, 2007, p. 4.
[48] M. Kyle, *Strategic Responses to Parallel distribution*, NBER Working Paper No. W12968, March 2007.
[49] T. Valletti and S. Szymanski, 'Parallel distribution, International Exhaustion and Intellectual Property Rights: A welfare analysis', *Journal of Industrial Economics*, 2006, Vol. 54 pp. 499-526 available http://ssrn.com/abstract=934536

box different from the form supplied in the domestic market. Thus the parallel traders may face increased costs and unsure supply and demand, which may impede their market penetration and the prices they can charge.

The demand for imported medicines may also be dampened by institutional impediments and financial disincentives faced by dispensing pharmacists. In a number of countries regulations reduce pharmacists' incentives to seek out the lowest cost distributor (see above). For example, in Denmark, Sweden and Germany pharmacists' profit margins are fixed to the final price of the medicine, so there is no incentive to search for the lowest cost product, with the effect that this reduces the demand for parallel imported medicines.

3.6 Summary

The limited evidence to date shows that parallel trade in patented medicines:

- reduces the cost to the national health services to the immediate benefit of both tax payers and patients;
- plays a direct and indirect role in facilitating price control schemes in Member States;
- has not led to uniformity of medicine prices suggesting that there are significant impediments to parallel imports; and
- remain the only source of intra-brand competition for patented medicines.

Finally, the debate over parallel trade is highly charged and partisan. A recent study for the European Commission concluded on alleged negative effects of price regulation on R&D or generally were 'unsubstantiated by any compelling evidence'; and that because most studies had been commissioned by 'stakeholders' they were possibly biased.[50]

[50] Escuela Andaluza de Salud Publica, *Analysis of Differences and Commonalities in Pricing and Reimbursement Systems in Europe*, Report for DG Enterprise and Industry of the European Commission, June 2007.

4. Impact on R&D

The conflicting claims over the relationship between parallel trade and R&D can be resolved easily. If it could be shown that parallel trade reduced global R&D then this would be an important consideration in evaluating the economics of and objective justification in law of restricting parallel imports. But no evidence supporting this statement is available in the literature to date, and pharmaceutical companies have not been able to substantiate it in recent cases before the Community courts.

It is accepted that R&D is important to the pharmaceuticals industry. It is the largest global investor in R&D. In 2004 the ratio of R&D investment to sales by the pharmaceuticals and biotechnology industry was 15.3% larger than any other of the top 700 EU companies ranked by R&D investment. Research-based pharmaceutical companies devote 17% of their total sales on research and investment compared to the computer software and services industry where it is 10.5%. Further, due to stringent testing requirements, much R&D is "wasted" in the sense that it does not result in commercial applications. However, to put these figures in context, the pharmaceutical industry spends nearly twice as much on marketing and advertising that it does on R&D.[51]

Given the importance of R&D, and the claim that parallel imports reduce manufacturers' incentive to undertake research, it is surprising that pharmaceuticals manufacturers have not set about collecting evidence and undertaking the research to establish this claim. As a result there is no empirical evidence of a positive or negative link between parallel imports and pharmaceutical R&D.

This is not entirely surprising since the level of global R&D is the outcome of many factors - the interaction between regulations, the costs of drug research, patent law, the degree of competition faced by the pharmaceuticals' companies in addition to the expected profitability of R&D. The role played by revenue losses due to parallel

[51] See M-A Gagnon and J. Lexchin, 'The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States', *PLos Medicines*, 2008, Vol. 5. (available at http://ts-si.org/files/10.1371_journal.pmed.0050001-L.pdf). This independent study by the authors examined the 2004 reports of two international market research companies (IMS and CAM) to show that the U.S. pharmaceuticals industry spent 24.4% of the US domestic sales dollar on promotion and 3.4% on R&D (on total sales of US$235.4 billion).

distribution in this mix of often conflicting factors is uncertain and very hard to determine.

4.1 The Theory

The claim that parallel trade reduces global R&D is based on a simple theory that fails to take account of the legal and economic context of parallel trade in the EU. Indeed, economic models of parallel trade that adopt more realistic assumptions find that parallel trade has more equivocal effects on industry gross profits and R&D.[52]

The Simple Case

Let us first consider some basic theory.

R&D involves large fixed costs which dwarf the variable costs of producing, distributing and marketing drugs that are successful. This means that if the drug companies sell their newly developed medicines at their marginal costs of production and distribution they would make significant losses. Pharmaceutical manufacturers therefore need pricing structures that enable the fixed costs of successful and unsuccessful R&D to be recovered by prices that exceed marginal costs.

The efficient way to do this is through discriminatory pricing schemes where different prices are charged in different regions and/or to different customer groups. This system of discriminatory pricing means that those who have less choice pay more, all things equal. In simple terms, prices will also be higher, the higher per capita income since this reflects a greater willingness to pay.

Such a discriminatory pricing scheme will be efficient if, in aggregate, global prices result in zero expected excess profits to the pharmaceutical companies. This structure of prices is known as 'Ramsey pricing' after the mathematical economist who developed the principle in the 1920s.[53] Under a Ramsey pricing scheme different customer groups are charged prices in inverse relationship to their (price) elasticity of demand. This appeals to economists as an efficient way of recovering fixed costs with the minimum distortion of consumption.[54]

Ramsey pricing is about recovering the past costs of R&D, not about stimulating future investment. The final limb of the pharmaceutical companies' claim is the

[52] See P. Pecorino, 'Should the US Allow Prescription Drug Reimports from Canada?', Department of Economics, Finance and Legal Studies, University of Alabama, 2002; G.M. Grossman and E. Lai, 'Parallel Imports and Price Controls', 2006; R. Ahmadi and B. Yang, 'Parallel Imports: Challenges from Unauthorized Distribution Channels', *Marketing Science*, 2000, Vol. 19, pp. 279-294; H. Raff and N. Schmitt, 'Why Parallel Distribution may Raise Producers' Profits', CESIFO Working Paper No. 1503, July 2005.
[53] F. P. Ramsey, 'A Contribution to the Theory of Taxation', *Economic Journal,* Vol. 37, 1927, pp. 47–61.
[54] P. M. Danzon, 'The Economics of Parallel distribution', *PharmacoEconomics*. Vol. 13, 1998, pp. 293-304.

existence of a direct link between their gross profitability and the level of global R&D.[55] That is the proposition that any action that reduces gross profits reduces R&D. This argument is not based on any evidence of a direct link between parallel trade and less R&D. Rather it is general assertion drawn from some studies, which have shown a positive correlation (not causation) between gross profits and R&D in the pharmaceutical industry. [56]

There are number of caveats to applying this theory to the legal and policy analysis of parallel trade.

The first is that economic theory justifies efficient differential pricing not unfettered discriminatory prices set by manufacturers.[57] Ramsey pricing assumes market power, but unrestrained market power can lead to mark-ups in excess of those required to achieve efficient cost recovery i.e. subject to a earning only a risk-adjusted normal rate of return. Thus the theory does not support unfettered pricing by the pharmaceuticals manufacturers. For example, Poland is currently a 'high-price country', at least for certain newer medicines, which is not what one would expect.

Second, the adverse impact on prices and profits implicitly assumes *unrestrained and costless* parallel trading in an otherwise unregulated marketplace. This in theory will unravel even an efficient Ramsey pricing scheme. However, as we have discussed above, in practice parallel trading is neither unrestrained nor costless. Patented medicine prices in the EU have remained highly discriminatory despite direct government price controls and 30 years of parallel importing. Thus the claim that in general or in a particular case, parallel imports have significantly undermined the (efficient) pricing of patented medicines in Europe has not been substantiated.

From Simple to the Complex

A number of recent papers, in an area of economic research desperately short of serious analysis, sound a cautionary note on the claim that parallel imports necessarily reduce pharmaceutical profits and/or R&D expenditure.

Impact on Profits

Consider first the alleged link between parallel imports and gross profits. Two recent models developed by academic economists suggest that parallel trade can increase manufacturers' profits.

---

[55] The OFT states that parallel trade leads to static and dynamic inefficiencies. However, it undertook no research nor cited any evidence to support these claims. Office of Fair Trading, *The Pharmaceutical Price Regulation Scheme – An OFT market study*, 2007, para 5.93 – 5.96

[56] F. M Scherer, 'The Link between Gross Profitability and Pharmaceutical R&D Spending', *Health Affairs*, 2001, Vol. 20, pp. 216-220.

[57] D. A. Malueg, and M. Schwartz, 'Parallel Imports, Demand Dispersion, and International Price Discrimination', *Journal of International Economics,* Vol. 37, 1994, pp. 167–195.

- **Ahmadi and Yang (2000)**[58] show that parallel trade may extend the global reach of patented products and increase global profits. This is because parallel trade enables a manufacturer to further segment consumer groups. Without going into the mechanics of the model (a three-stage Stackelberg game) the authors show that the market can be segmented into three groups when parallel trade occurs – a) those customers who continue to purchase the product from authorised dealers because they value the warranty and service levels; b) customers who previously purchased the product from authorised dealers but switch to the parallel trader due to the lower prices; and c) new customers who purchase from the parallel trader attracted by lower prices. Parallel trade increases sales but its effect on profits depends on the relative sizes and profitability of these three groups. If the profits from group c) exceed the loss from group b) then aggregate profits will increase.

- **Raff and Schmitt (2005)**[59] develop a model in a provocatively titled article 'Why Parallel Trade may Raise Producers' Profits'. This shows that letting retailers trade unsold inventories may result in larger orders being placed with the manufacturers and higher profits and consumer gains. Raff and Schmitt show that this will be the case where:

  1. distributors must place orders for the good before they know actual demand;

  2. the products have little value at the end of the demand period or inventories are costly to maintain;

  3. demand differs across countries

  4. the differing demand affects the quantity of the good demanded rather than the consumer's willingness to pay.

  If, under these conditions, the manufacturer were to ban parallel trade then distributors could become saddled with large inventories, which would depress prices. Distributors foresee such a loss and reduce their orders, which in turn reduces the manufacturer's profits. If the manufacturer allows parallel trade then this stops the retail price falling dramatically since the distributors are able to sell to parallel traders if demand is unexpectedly lower. Thus, the distributor will place a larger order with the manufacturer with than without parallel trade. The manufacturer's incentive to allow parallel trade is stronger when the price elasticity of demand is similar across countries but country demand uncertain. Conversely, when the price elasticity of demand differs across countries then the

[58] R. Ahmadi and B. Yang, 'Parallel Imports: Challenges from unauthorized distribution channels', *Marketing Science*, 2000, Vol. 19, pp. 279-294.
[59] H. Raff and N. Schmitt, 'Why Parallel Distribution may Raise Producers' Profits', CESIFO Working Paper No. 1503, July 2005.

manufacturer's inclination is toward banning parallel distribution so as to practice third degree price discrimination.

Impact on R&D

Two recent papers directly model the relationship between parallel trade and R&D. [60] These again show that even in theory the outcome of parallel trade depends very much on the specific facts (assumptions).

- **Li and Robles (2007)**[61] challenge the claim that parallel trade necessarily decreases the incentive to innovate by reducing profits. This, they argue is based on a focus on assessing post-innovation profits to the neglect of pre-innovation profits i.e. the increase in profits due to a new innovation. The authors' model a research-based firm that already has sales of a product (the pre-innovative product) and is conducting research on a second post-innovative product. The firm sells its products in its home country whilst distributors sell them in the foreign country. The distributor is able to re-import the manufacturer's products back into the home country causing the distributor and the pharmaceutical firm to compete (Cournot style). The impact of parallel trade depends on the relationship between the two products manufactured by the pharmaceutical firm i.e. whether they are independent or dependent (i.e. complements or substitutes respectively). If the two products are independent of each other (i.e. the demand for one product is not related to the demand of the other), then parallel trade will reduce the post-innovation profits of the two products. If the two products are complements, then parallel trade will reduce the profits on the new product as sales are siphoned away by the distributor, whilst at the same time increasing the demand for the existing product. Thus, there is additional profit on the existing product. However, this additional profit is diminished by parallel traders. Thus, when the pre-innovation and innovative products are complements parallel trade reduces the incentive to innovate by reducing profits on the innovative product and reducing the additional profits on the pre-innovative product. If the two products are substitutes then the introduction of the innovative product reduces the profits on the first product, resulting in reduced incentives for the pharmaceutical firm to innovate. Allowing parallel trade reduces the size of the disincentive to innovate.

- **Grossman and Lai (2006)**[62] also challenge the view that parallel trade necessarily reduces investment in R&D. Unlike other studies that treat the

[60] Parallel trade may indirectly stimulate R&D. In the absence of parallel distribution there would be no intra-brand competition during the patent life of a drug. There would thus be intra-brand competitive constraints acting on pharmaceuticals companies, and hence no pressure to divert profits into R&D, rather than to return them to shareholders in the form of dividends. This was the position of the Commission in *Microsoft* (2004).
[61] C. Li and J. Robles, 'Product Innovation and Parallel Trade', *International Journal of Industrial Organization*, 2007, Vol. 25, pp. 417-429.
[62] G. Grossman and E. Lai, *Parallel Imports and Price Controls*, July 2006.

government as an exogenous actor, the authors incorporate government price controls in their analysis. Gross and Lai assume differentiated products, investment in new products by one monopoly company, and two countries - North (which undertakes all the innovation) and South (which does not do any innovation). They show that in the presence of parallel trade the government regulated price is endogenous and higher in the presence of parallel imports into the North for two reasons:

1. The Northern monopolist may not sell in the low price country (South) in order to prevent re-importation into the high-priced North. In response, government of the South will increase its regulated price to prevent denial of the drug.

2. A government in the South who sets a low price will not be able to free ride on the research incentives in the high priced country. The Government in the South will raise its price to increase incentives to innovate.[63]

Even models that suggest that parallel imports reduce innovation are sensitive to their assumptions. Often extensions to the basic model lead to cases where parallel imports can increase the level of R&D.[64]

There are two further points that can be made with regard to this literature.

In more complex models, such as those discussed above, where the level of prices are set in negotiations with health authorities/governments is endogenous, it is not self evident that the pharmaceuticals companies' profits would necessarily fall. There may be a harder bargaining over price levels in the knowledge that prices set in different countries will encourage some re-importation of drugs from lower to higher priced countries.[65]

[63] They state that this assumption is supported by Kanavos' and Cost-i-Font's observation '*that the growth in parallel distribution in Europe has been accompanied by a relaxation of price controls in low-price countries such as Portugal, Italy and France, which now tolerate prices closer to European averages than they did before*', Grossman and Lai, p.25.

[64] Valletti (T. Valletti, 'Differential Pricing, Parallel distribution and the Incentive to Invest', *Journal of International Economics*, Vol. 70, 2006, pp. 314-324) finds that if price discrimination is based on different willingness to pay then parallel distribution reduces investment. However, if it is based on the different costs of supplying markets which only the monopolist faces, then parallel distribution increases investment. Valletti and Szymanski ('Parallel distribution, International Exhaustion and Intellectual Property Rights: A welfare analysis', 2005) find that parallel distribution cause a reduction in investment in product R&D and quality. Consequently, consumers are supplied an inferior product which lowers their consumers' surplus *ex ante*. However, *ex post* there is a gain in consumer surplus since consumers who did not previously purchase the good now buy. The overall effect of parallel trade depends on whether the *ex ante* loss dominates the *ex post* gain in welfare. Valletti and Szymanski show that when the monopolist can price discriminate based on differences in demand (willingness to pay) allowing parallel distribution will reduce their investment in R&D. However, if consumers in the low priced market have different valuations depending on whether there has been investment in R&D which they value more after the investment has been made, then the marginal return on investment will be greater when parallel distribution is allowed.

[65] Pecorino uses a partial equilibrium model of trade where a monopolist sells in both the home and foreign countries. Prices in the foreign country are modeled as a Nash bargaining game between the monopolist and the foreign government, whilst in the home country the monopolist sets a profit maximising price. Pecorino examines the effects of re-importation of the medicine from the foreign country to the home country and finds that negotiated foreign price becomes the home price. This causes the monopolist to bargain 'harder' in the Nash bargaining game in the foreign country to obtain a

Second, the operation of price regulation makes any categorical statements difficult. Price regulation has an immediate and direct effect on gross profits. Thus this, and not parallel imports, is going to have the major impact on the profitability of pharmaceuticals companies. It also has an effect on the level of parallel imports because the lower the regulated price, the lower the level of parallel imports (and exports). In other words, the net impact on profits in countries with parallel imports is likely to be somewhat less than calculated by multiplying estimated price difference by the estimated quantity imported. For example, the OFT has attributed the relative decline in parallel imports of patented medicines into the UK to lower prices due to regulation[66].

There is no reason to uncritically accept the conclusions of any of these models, as models can always be developed on the basis of different assumptions and lead to different outcomes. The litmus test is whether a model provides a workable basis for predicting economic outcomes. However, what they do show, and which is common sense, is that parallel imports, patent medicine prices, price regulation, industry profits and R&D are all interconnected, affect one another, and can lead to unexpected offsetting factors. .

higher price than would otherwise prevail in the absence of re-importation. Consequently, the monopolist's profits may not fall if re-importation is allowed. This result is valid for a linear and constant elasticity of demand. P. Pecorino, 'Should the US Allow Prescription Drug Reimports from Canada?' *Journal of Health Economics,* 2002, Vol. 21, pp. 699-708.

[66] Office of Fair Trading, *The Pharmaceutical Price Regulation Scheme – An OFT market study*, 2007.

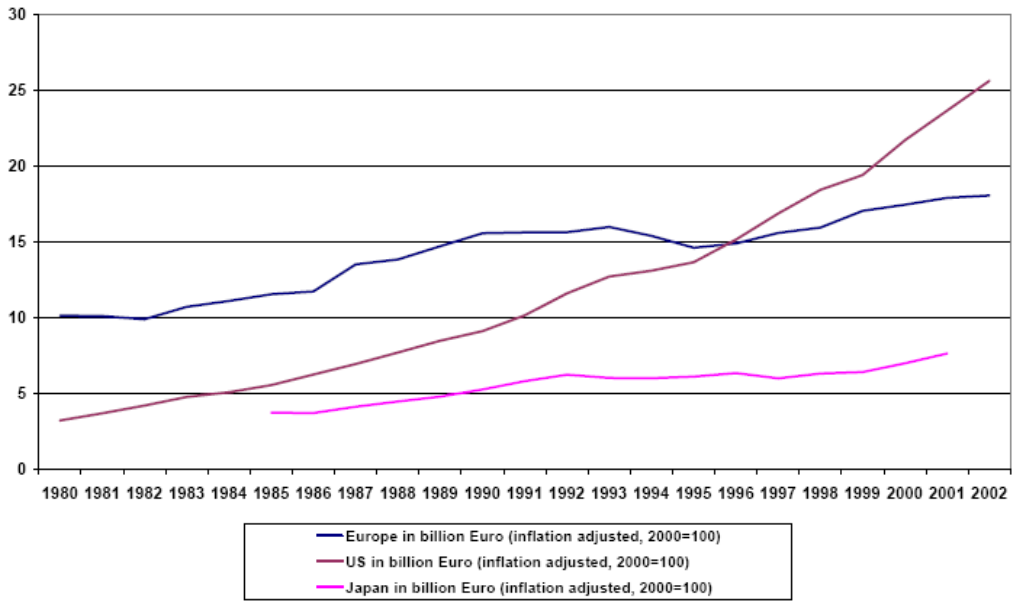
4.2 The Evidence

As already stated there is no factual evidence of a direct or indirect link between parallel trade and global and/or European pharmaceutical R&D.

Further, the issue is not one likely to be resolved by establishing a simple correlation between drug companies' revenues or profitability and the level of investment in R&D since this would beg the question of causation as to whether any revenues lost due to parallel imports will cause a reduction in R&D.

Figure 4.1

Figure 4: Pharmaceutical R&D expenditure 1980 to 2003 in billion Euro (adjusted for inflation, 2000=100)



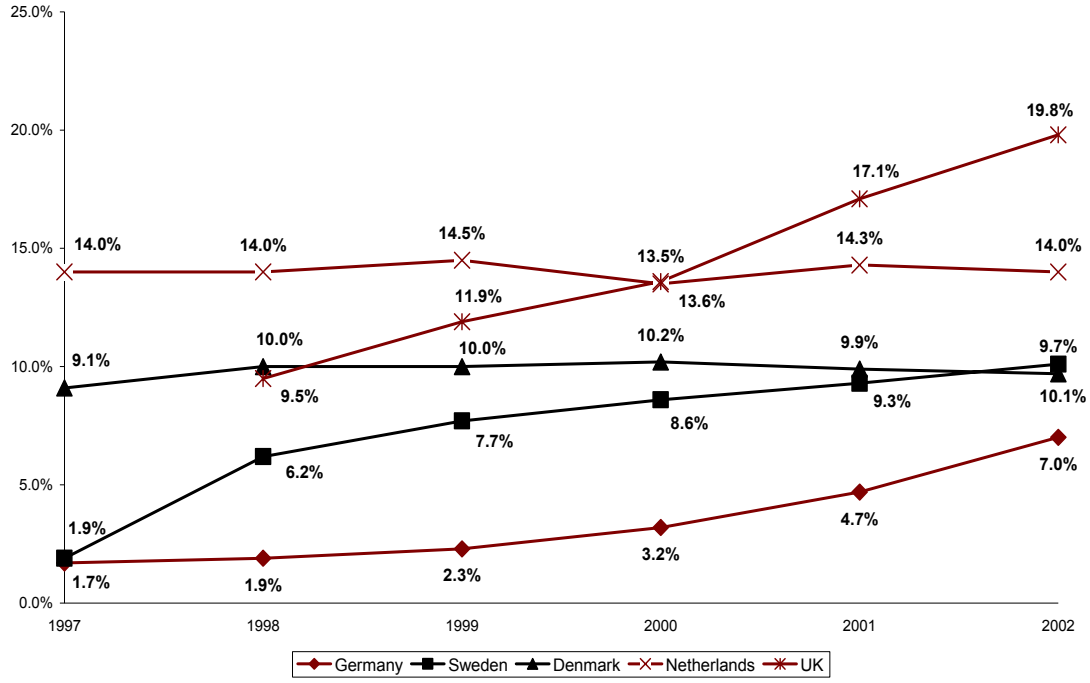
Source: Parexel's Pharmaceutical R&D Statistical Sourcebook 2003/2004, pages 1, 289, and 296. European data based on official figures provided by EFPIA member associations. It covers all R&D spending within EFPIA countries (EU-15, excl. Lux, plus Switzerland and Norway) by national and foreign companies. The 2002 figure is an estimate. Japanese data from the JPMA Data Book 2003. US pharmaceutical spending is based on the PhRMA Annual Survey, 2003. Inflation adjustment and conversion to Euro using CPI data and exchange rates from Datastream.

Source: CRA, *Innovation in the Pharmaceutical Sector - Study for the European Commission*, 2004.

This is the conclusion of a number of studies reviewing the evidence by authors that have at times been retained by pharmaceuticals companies. For example, the LSE study, commissioned by a pharmaceutical company, states:

> *It is difficult to determine how lower manufacturer revenues associated with PI* [parallel imports] *affect pharmaceutical R&D spending and even more difficult to predict how any changes in spending might affect the development of innovative drug treatments'* [67]

Figure 4.2: Parallel imports by value, 1997-2002 (%)



Source: Kanavos *et al*.

Another assessment concludes:

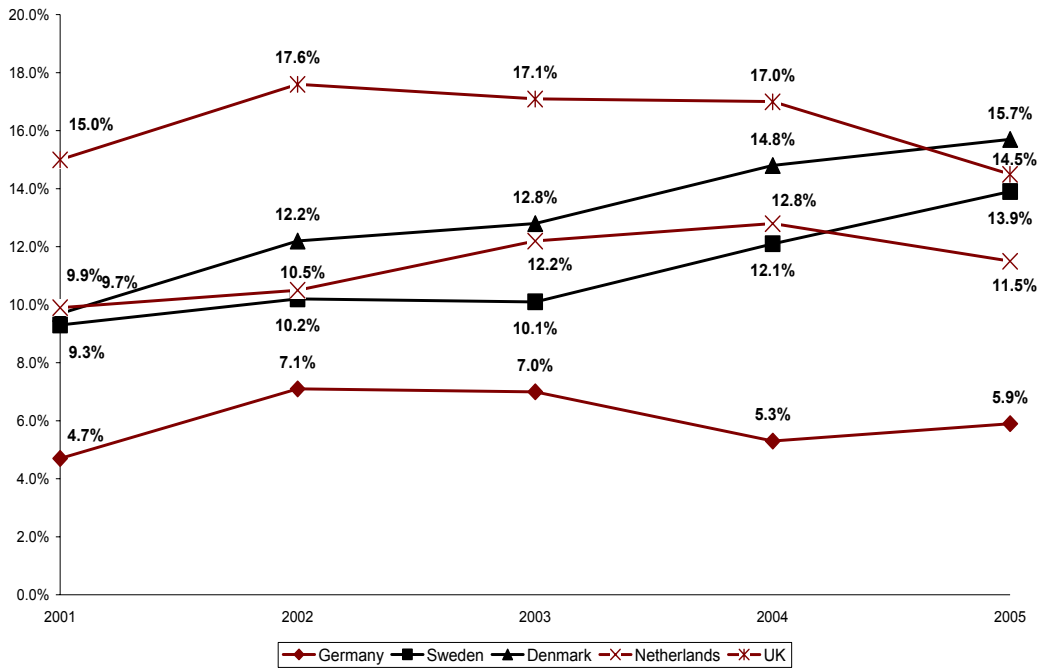
> *'.. there are no studies that show how lower manufacturers revenues from PI affects pharmaceutical R&D and new drug development, either in the countries with PI or the EU overall. Specifically, it is not known whether PI leads to lower R&D spending by manufacturers'. … some PI countries that engage in PI – notably the UK and Sweden – are home to some of the world's most successful pharmaceutical companies.'* [68]

[67] LSE Study, p. v

[68] P. Kanavos, D. Gross, and D. Taylor, *Parallel Trading in Medicines: Europe's Experience and its Implications for Commercial Drug Importation in the United States*, Washington: The AARP Public Policy Institute, 2005.

At a crude statistical level the increase in parallel trade does not appear to have reduced pharmaceuticals' companies' global R&D. Global R&D of pharmaceuticals companies has been rising year on year, and is now 10 times the level it was during the 1980s (Figure 4.1 above). This happened during the same period when parallel imports doubled their penetration in some EU markets, such as the United Kingdom and Denmark (Figures 4.2 and 4.3).

Figure 4.3: Parallel import by sales (%) 2003-2005



Source: EFPIA, *The Pharmaceutical Industry in Figures - Key updates 2003-2007.*

These data and the results of various studies suggest, however, that no conclusions can be drawn from the available evidence on the relationship between parallel trade and pharmaceuticals' companies R&D.

A recent study by consultants CRA on innovation in the pharmaceuticals' sector undertaken for the European Commission found that a range of factors play a part in pharmaceuticals' productivity and innovation. In particular, it found that over the past decade there has been a five-fold increase in the costs of clinical development and a 60% increase in the real costs of preclinical development[69]. These factors are likely to have a much more significant effect on innovation than parallel distribution. Other factors, such as the growing importance of generics and therapeutic reference

[69] CRA, *Innovation in the Pharmaceutical Sector: A study undertaken for the European Commission*, 2004.

pricing, also have a direct effect on pharmaceuticals companies' innovation costs. Further the CRA study dismissed the view that there had been a decline in innovation and R&D in the EU. A NERA study of the reasons for the location of pharmaceutical R&D also points to a myriad of factors with little emphasis on price regulation or parallel imports. [70]

4.3 Summary

The European Commission has made clear EU competition rules use '*an economic approach … based on the effects on the market … in their legal and economic context'*.[71] It has been shown that when parallel trade is examined in its 'legal and economic context' there is no compelling evidence that parallel trade has reduced global R&D.

Thus while one accepts that these factual matters should be fully assessed by the European Commission, it is also the case that the pharmaceutical companies in seeking exemption under Article 81(3) EC on efficiency grounds have the onus to objectively establish that these efficiencies exist[72].

There is one final consideration which although not central is relevant. Even if there were a measurable inverse relationship between parallel trade and global R&D, there would still be the question whether such R&D were efficient. Economists have tended to defend the patent system as encouraging innovation by allowing those investing in R&D to appropriate the returns. But again there is limited evidence that this is the case. The dissenting voices have even found their way into standard economics textbooks, and the law. For example, Professors Dennis W. Carlton (until recently Chief Economist at the Antitrust Division of the US Department of Justice) and Jeffrey Perloff claim that '*Patents induce research'* but qualify this later by noting that '*support for patents is not universal'*.[73] Judge Richard Posner and Professor William Landes detailed economic assessment of patent law is not based on the claim that patents encourage innovation in light of the meagre empirical support for the proposition.[74] Others have argued that the patent system actively discourages research, creates barriers to entry and raises business costs and consumer harm.[75] The European Commission's effects-based analysis under Article 82 EC in

[70] NERA, *Key Factors In Attracting Internationally Mobile Investments by The Research-Based Pharmaceutical Industry*, Report for UK Trade and Investment and the Association of the British Pharmaceutical Industry, 21 September 2007.
[71] The *Vertical Restraints Guidelines* (para 7) states in relation to 81(3) EC that: '*The onus of demonstrating that the conditions are met falls upon the parties to an agreement.'* Also UK Office of Fair Trading guidelines (OFT 401), para 4.10.
[72] The *Vertical Restraints Notice* (para 136) states that *'efficiencies have to be substantiated … speculative claims … will not be accepted.'*
[73] D.W. Carlton and J. M. Perloff, *Modern Industrial Organization*, Pearson Addison Wesley, 4th edn, 2005, p. 558.
[74] W. M. Landes and R. A. Posner, *The Economic Structure of Intellectual Property Law,* Cambridge Mass.: Harvard University Press, 2003.
[75] A. B. Jaffe and J. Lerner, *Innovation and its Discontents – How our broken patent system is endangering innovation and progress, and what to do about it*, Pinceton NJ: Princeton University Press, 2004; also F. Leveque and Y. Meniere, *Patents and Innovation: Friends or Foes?* Cerna, 2006.

Microsoft[76] established that both patents and other protections of intellectual property are not immune from competition law scrutiny, and further (as endorsed on appeal before the CFI[77]) that their existence alone did not establish that they protected an innovation and/or would stimulate future innovation.

[76] Case COMP/C-3/37.792 *Microsoft*, 24 March 2004.
[77] *Microsoft v Commission* [2007] EUECJ T-201/04.

5. Conclusions

We have shown that there are serious gaps in the so-called efficiency case favouring restriction on parallel imports and their exemption from the normal operation of EC competition law. While measuring the impact of parallel distribution is a complex undertaking, it is equally true that administering the law based on little more than simple theory extrapolated to empirical claims cannot be allowed.

Despite the contradictory analysis and conclusion from the European Courts, and the uncertain legal position, there appears some light at the end of the tunnel. If the present judicial thrust is to move the law from treating restrictions on parallel trade as a per se offence to one based on a rule of reason then there can be little objection. However, as has clearly been shown this must be based on facts and the assignment of the burden of proof on the party seeking to restrict competition to establish real efficiency gains.

Annex - Regulation of Parallel trade

A.1 Types of parallel distributors

Parallel trade is the result of commercial transactions undertaken by two types of operators: parallel importers or distributors and wholesalers.

Parallel importers or distributors who distribute imported products after repackaging them into their destination market (or market of importation). Repackaging requires the holding of a valid manufacturing authorisation from the national competent authorities. That means that a parallel importer is subject to the same regulation as a pharmaceutical manufacturer, namely good manufacturing practice (GMP) rules. In addition, however, a parallel distributor also holds a wholesalers licence and thereby is subject to good distribution practice (GDP) rules. Parallel importers are "creating" the demand on the parallel distribution market.

The other market participants are wholesalers who make excess product available for "export" within the EEA area. These partners must be authorised wholesalers according to the national and EU law.

The terminological confusion is heightened by the fact that there are, under regulatory considerations, roughly two types of medicines circulating in Europe: centrally approved ones by the European Medicine Agency (EMEA), and nationally approved ones which circulate across Europe, or certain member states, on the basis of mutual recognition. In the case of nationally approved medicines, regulators talk about "parallel imports", while in the case of EMEA approved products, the term is "parallel trade", because the EMEA rightly holds the view that within a single market there can be no importation/exportation.

A.2 Regulation of Parallel Trade

Parallel importers/distributors must face additional regulatory hurdles before they are permitted to import drugs from one Member State to another.

The EC *Wholesale Distribution Directive*[78] requires that all wholesalers of drugs obtain authorisation to purchase authorised drugs[79] from authorised manufacturers or wholesalers. Parallel distributors are required to gain specific authorisation from the national regulatory body for every drug that is imported. The number of authorisations for each drug is not restricted to one because separate authorisations must be obtained for each pack size, dosage and for every Member State from which the drug originates. The imported drug must be identical to the version of the drug already marketed in the country. Further, the drug must be repackaged, re-labelled and any instructions translated into the language of the import country.

An authorisation to import a drug is generally valid for five years. This is the case for Denmark, Germany, Greece, Italy, Spain, Sweden and UK. In Norway licences are granted for 6 years (Table A.1). Further, the EMEA requirement for centrally approved products is a five year licence.

Licences granted for parallel trade are charged at varying rates and according to different price structures by Member States. As an illustration the charges for 2004 are shown in Table A.1.

Wholesalers in a number of EU member states have a public service obligation to guarantee that they have sufficient stock to meet the demands of a specific geographical area and to deliver drugs within a very short period of time imposed upon them by the EC Directive 2001/83[80].

The public service obligation was amended by *EC Directive 2004/27* that extends the public service obligation to authorisation holders[81]. The implementation of this provision is, however, far from homogeneous across the EU.

---

[78] *Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use* ("*Wholesale Distribution Directive*").
[79] *Marketing authorisation for drugs is given by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency*, Official Journal L 136, 30/4/2004 pp 1-33.
[80] *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*, Official Journal L 311, 28/11/2001, pp. 67-128.
[81] *Amended by Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use*, Official Journal L 136, 30/4/2004, pp. 34 - 57, Article 81.

Table A.1

Table 4: Direct Costs of Obtaining a Parallel Distribution License and Duration of Marketing Authorization in Selected European Countries, 2004

Country	Cost to obtain a parallel import license and duration of marketing authorization*
Denmark	• Annual fee of DKK7,950 (about US$1,300) plus application fee of DKK15,095 (about US$2,500) or renewal fee of DKK13,975 (about US$2,300) • Application good for five years
France	• Fees not known • Application good for five years; reapplication must be filed three months before expiration to extend authorization
Germany	• €1,380 (about US$1,700) • Application good for five years; reapplication must be filed three months before expiration to extend authorization
Greece	• €180 (about US$220) • Application good for five years
Italy	• €524.20 (about US$650) per product • Application good for five years
Netherlands	• €1,465 (about US$1,800) per product • €5,672.25 (about US$7,000) per year for holding a PI license
Portugal	• No published data on fees
Spain	• No published data on fees • Application good for five years
Sweden	• SEK15,000 (about US$2,000) • Application good for five years
United Kingdom	• £1,465 (about US$2,700) • Application good for five years, but normally continues in force only as long as both UK license and EMEA marketing authorization remain in force
Norway	• NOK 70,000–80,000 (about US$11,000–US$12,500), plus control fee of 0.7% of sales volumeof the MA holder • Application good for five years, given that original product has been marketed in EMEA for six years
EMEA (for centrally approved products)	• €3,480 (about US$4,300) for each Parallel Distribution notification • Application good for five years

*Regulatory authorities do not impose fees for parallel exporting.
Source: Authors' own research from direct contacts with national regulatory authorities and the EMEA, 2004.

Source: Kanavos, Gross and Taylor, op cit.