

Agenda

Advancing economics in business

Shades of grey: arguments for and against parallel trade in pharmaceuticals

Last month the European Court of Justice announced its judgment on *Syfait v GlaxoSmithKline*, the latest case concerning parallel trading (aka grey imports). One of the most pressing competition issues facing the pharmaceutical industry, this topic was discussed during the second Oxera Economics Council meeting that took place in Brussels on September 15th

Parallel trade in pharmaceuticals in the EU was worth approximately €4.3 billion in 2006.¹ Parallel importers buy medicines under patent in Member States where wholesale prices are relatively low, and sell them at a higher price in other Member States—a form of international arbitrage. In other words, parallel traders find it profitable to re-package and export pharmaceutical products after they have been sold to a wholesaler by the manufacturer. Because a guiding principle of the EU is the single internal market, parallel traders do not require permission from the patent holders to export in this way. As parallel importing tends to reduce the revenues earned by branded pharmaceutical companies, there are incentives for these companies to attempt to limit the amount of parallel trade occurring. This raises the important question—is parallel trade good or bad from an economic point of view?

Actions taken by pharmaceutical companies to limit parallel trading are currently being investigated in a number of competition cases, most prominently where pharmaceutical companies have refused to supply to parallel importers. September's judgement of the European Court of Justice (ECJ) in the *Syfait v GlaxoSmithKline* case is one of the most recent examples (see the box below). These cases raise economic questions regarding the underlying rationale for implementing strategies designed to limit parallel imports.

This article focuses on three main questions which are important for understanding parallel importing, and where economic analysis can offer insights:

- why does parallel trade exist in the EU?

Syfait v GlaxoSmithKline A EVE, ECJ, 2008

Following a complaint by a wholesaler, Syfait, to the Greek competition authority about GSK Greece's refusal to supply Greek wholesalers with three of its patented products (Imigran, Lamictal and Serevent), the Greek competition authority initiated an investigation, and subsequently referred several questions to the ECJ. Advocate General Jacobs advised the ECJ in 2004 that the patent holder would not automatically infringe Article 82 (which prohibits abuse of dominance) by refusing to supply because the conduct might be justified in light of sector-specific factors. The Advocate General's advice motivated the Greek competition authority's decision in favour of GSK. At a more recent stage of the legal proceedings, in April 2008 Advocate General Colomer

expressed his opinion that GSK's conduct infringed Article 82 because of the company's failure to justify its actions economically. The argument that parallel trade has negative effects on R&D investments was in principle accepted, but GSK's conduct was considered to be disproportionate. The ruling of the ECJ on September 16th 2008 found that a producer of pharmaceutical products must be in a position to protect its own interest if orders from distributors are out of the ordinary. The court ruled that GSK's actions would constitute an infringement of Article 82 when orders were at 'ordinary' levels, but left it to national courts to ascertain whether the orders in this particular case would be ordinary in relation to the requirements of the market.

Sources: Judgment of the Court of Justice in Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and Others*; Advocate General's Opinion, Joined cases C-468/06, C-469/06, C-470/06, C-471/06, C-472/06, C-473/06, C-474/06, C-475/06, C-476/06, C-477/06, C-478/06, Advocate General: Ruiz-Jarabo Colomer, April 1st 2008; Advocate General's Opinion in Joined Cases C-468/06 to C-478/06 *Sot. Lélos Kai Sia EE (and Others) v GlaxoSmithKline A EVE*, press release 19/08, April 1st 2008; Judgment of the Court (Grand Chamber) (2008), 'Article 82 EC – Abuse of dominant position – Pharmaceutical products – Refusal to supply wholesalers engaging in parallel exports – Ordinary orders', in Joined Cases C-468/06 to C-478/06, September 16th.

- why are prices different across Member States?
- what are the potential welfare effects arising from parallel trade?

Why does parallel trade exist in the EU?

Price-setting mechanisms in the pharmaceutical sector are different from those in many industries. New drugs brought to the market are afforded patent protection, which confers a temporary monopoly on its holder (historically, this was often for 20 years, although this may differ across jurisdictions and products). Patent holders are thus not constrained by competition when setting prices during this period (they may still be constrained by national regulations—see below). The rationale behind patent protection is that there are sufficient incentives to invest in pharmaceutical research, that the costs of R&D and drug testing are recovered, and that returns from ‘successful’ drugs are sufficient to

compensate for the costs of unsuccessful drug developments. After patent expiry, ‘generic’ entry can occur and place a competitive constraint on pricing (this can raise competition issues in itself, although these are not the focus here since parallel trade more frequently takes place in patented drugs).

Once a drug is sold, the patent holder can no longer restrict the circulation of the product within the EU. A buyer of a patent-protected drug is thus entitled to use and dispose of it without further restrictions. In the terminology of intellectual property law, patent rights are ‘exhausted’ within the EU territory. This principle is consistent with the creation of a single European market. Parallel trade within the EU would thus appear to be legal by virtue of this rule.²

Wholesale prices for pharmaceutical products have traditionally differed within the EU. For example, pharmacy purchase prices are on average higher in

Third-degree price discrimination explaining parallel trade

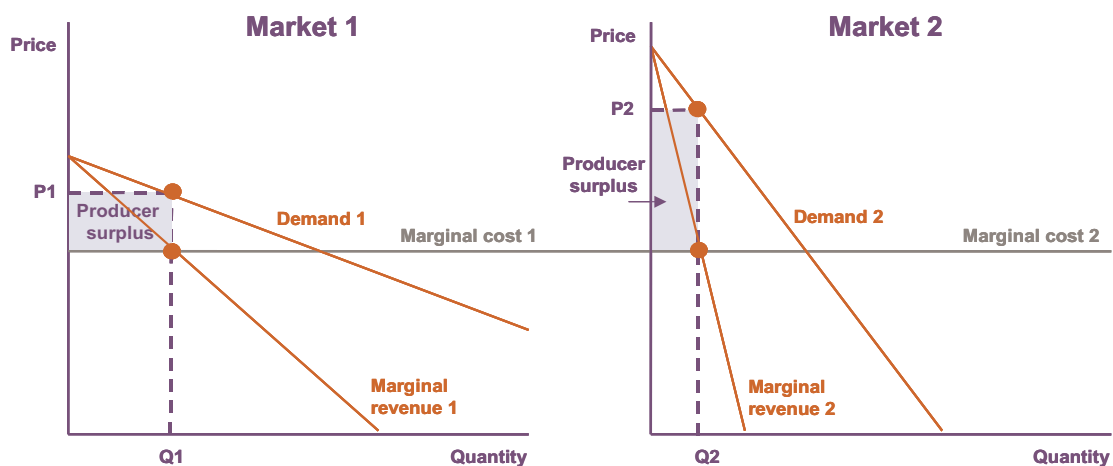
Standard economic theory describes third-degree price discrimination as a situation where customers are charged different prices for the same product for reasons that are unrelated to costs of production or the quantity sold. The market is usually separated by time or location.

The stylised figure below shows two markets. In market 1, demand is relatively sensitive to price. Market 2 shows a market with inelastic demand. With price discrimination, monopolists would set prices equal to P1 in market 1 and P2 in market 2. Prices are thus higher in markets with inelastic demand, despite the marginal costs of production being the same. The shaded areas show the respective producer surpluses (profits) in both markets.

Without price discrimination—or where such discrimination is undermined by parallel trade—a monopolist would charge the same price in both markets. The price level would thus be between P1 and P2, implying

that consumers in market 1 would pay more and consumers in market 2 less. On balance, the welfare implications of this type of price discrimination cannot be determined at the outset. There is clearly a redistribution of income between buyers in the two markets (eg, is it desirable that Greek consumers pay less for their medicines than German ones?). Price discrimination also raises producer surplus at the expense of consumers. However, the overall welfare effect of this form of discrimination from an economic perspective usually depends on the following rule of thumb: if total output under price discrimination is higher than under uniform pricing—ie, if it allows products to reach consumers that would otherwise not be served—then price discrimination raises welfare and parallel trade reduces it (eg, in the extreme, some national markets may not be served if uniform pricing across all countries were required). This is ultimately an empirical question.

Figure 1 Stylised illustration of third-degree price discrimination with monopoly pricing



Germany, the Netherlands and the UK than in Greece and Spain.³ The national pricing that creates opportunities for parallel trade in the European market for pharmaceutical products therefore exhibits the characteristics of third-degree price discrimination, the economic welfare effects of which can be either positive or negative depending on the circumstances (see the box above).

Why are prices different in EU Member States?

An important question is why manufacturers are able to charge higher prices in some Member States than in others. Is it due to differences in price elasticity of demand or willingness to pay, as in the standard theory of price discrimination? Or is it the result of other factors? In the case of pharmaceuticals, wholesale price differentials for patented drugs mainly reflect differences in the way countries regulate their pharmaceutical markets and how prices are determined in negotiations between governments and the industry.

- **Price controls.** Member States apply different rules for fixing wholesale pharmaceutical prices. For example, in 2003, unrestrained wholesale pricing of patented drugs was permitted only in Germany and the UK. Other countries imposed price caps in a variety of forms. In Portugal, for example, minimum prices were set at the level of identical products in France, Italy and Spain.⁴
- **Reimbursement systems.** Insurers have incentives to reduce overall expenditures on pharmaceutical products by limiting reimbursed services. The design of reimbursement systems differs across Member States. For example, under the German reference pricing system, the patient has to pay any amount in excess of the maximum reimbursement price set by the government.⁵ A co-payment mechanism requires the patient to make some of the payments regardless of the list price.
- **Negotiations.** National health and social insurance programmes are often ultimately controlled by the government. As a sole purchaser of pharmaceutical products, governments have a strong bargaining position to negotiate prices with patent holders. Wholesale price differentials may therefore also reflect country-specific policy objectives towards pricing of pharmaceuticals and profitability of pharmaceutical companies.

The importance of regulatory restrictions on pricing increasing opportunities for parallel trade has also been acknowledged in the recent judgment of the ECJ in relation to the GSK Greece case:

it cannot be ignored that such State intervention [price regulation] is one of the factors liable to create opportunities for parallel trade.⁶

Parallel imports thus create a tension between the principle of autonomy of Member States in setting pharmaceutical prices and the creation of a single European market. Price differentials in the EU are due to the Member States each regulating their own pharmaceutical prices, while the principle of free movement of goods within the EU allows traders to arbitrage those differences.

What are the potential welfare effects arising from parallel trade?

Price reductions for consumers

Are wholesale price reductions resulting from parallel trade passed on to end-consumers? Who are the main beneficiaries of those wholesale price reductions? Answers to these questions require a better understanding of the different distribution channels in the pharmaceutical sector.

Parallel traders purchase pharmaceutical products from manufacturers in low-cost countries and sell them to pharmacists in countries that offer higher margins. Pharmacists sell those parallel imported drugs to end-consumers, who are then fully or partly reimbursed by health insurance. Health insurances are either publicly or privately financed, implying that the end-consumer and tax payer indirectly benefit from cost savings of health insurances.

A study by the London School of Economics (LSE) examines the effect of parallel trade in the Netherlands, Germany, the UK, Norway, Sweden and Denmark, the main destination countries for parallel trade in the EU. The study shows the extent of benefits arising due to parallel trade for parallel traders, pharmacies and health insurances.

- **Parallel traders.** As shown in Table 1 below, the extra profits made by parallel traders are considerably larger than the cost savings made by health insurance organisations and pharmacies.⁷ Parallel trade therefore causes a redistribution of profits from manufacturers to intermediaries. A change in the profitability of the different parties in the upstream segment of the value chain could alter the incentives faced by the different parties. As a result, there may be a positive effect on investments in distribution systems but a marginal reduction in R&D spending by manufacturers in the longer term.

Table 1 Benefits of parallel trade to parallel traders, pharmacies and health insurances, 2002

Country	Benefits to parallel traders ¹	Benefits to pharmacies ²	Savings to health insurance ³
Norway	€2,832,000	€500,000	€500,000
Germany	€97,965,000	€0	€17,720,000
Sweden	€4,707,000	€0	€3,382,000
Denmark	€6,108,000	€0	€2,980,000
UK without clawback ⁴	€518,013,000	€-positive but invisible	€6,887,000
UK with clawback	€469,450,000		€55,887,000
Netherlands without clawback	€47,688,000	€5,902,000	€11,620,000
Netherlands with clawback	€40,692,000		€18,798,000

Notes: ¹ Revenues and profits to parallel importers are calculated as the inter-price difference multiplied by the volume of parallel imports in the destination country. ² Benefits to pharmacies are estimated on the basis of the intra-country price spread between locally sourced and parallel imported drugs multiplied by the quantity of parallel imports sold. The effect on pharmacies excludes discount. ³ Savings to health insurance are calculated as the sum of direct cost savings due to the intra-country price spread and competition effects. Competition effects in destination countries describe the extent to which there is price competition and price convergence over time. ⁴ 'Clawback' refers to a situation where pharmacies have to share discounts received by suppliers with health insurances. Pharmacies are reimbursed at the list price minus the clawback, which is usually expressed as a percentage of the price.

Source: London School of Economics (2004), 'The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis', Special Research Paper.

- **Pharmacies.** Benefits to pharmacies are relatively minor according to the LSE study.
- **Health insurance schemes.** Table 1 also outlines cost savings for health insurance systems. Parallel imported drugs are sold at a lower price to the end-consumer, which reduces the costs to health insurance systems. Cost savings to health insurance systems are likely to be passed on to tax payers and/or consumers.
- **End-consumers.** Direct benefits for patients from parallel trade depend on the structure of cost-sharing systems in the respective countries. In co-payment systems, customers contribute to total healthcare expenditure by making a small payment. Parallel trade would reduce these payments.⁸

The overall finding of the LSE study is that the pass-through rate of wholesale price reductions to end-consumers is relatively low. Parallel traders are shown to maximise their profits by placing parallel imported products on the market at a slightly lower price than the locally sourced product. In the GSK Greece case, the ECJ also found that a large proportion of the price differential is taken up by intermediaries.⁹

An interesting question is whether the high proportion of benefits accruing to the traders reflects some degree of market power. A potential reason for such market power could be caps on the amounts which can be exported. An alternative explanation could be that the margin earned by the parallel importer is a normal profit, representing the set-up of the trading and distribution network. In the latter case, the size of the regulatory differences creates just enough arbitrage opportunity to generate trading opportunities, but it is sufficient to cover

only the transactions costs and extra capital expenditure for setting up the distribution network.

Efficiency gains

Efficiency gains in production are another potential source of benefits of parallel trade. Those benefits could potentially accrue in a situation of international arbitrage. However, this is less likely to arise in the pharmaceutical sector. The reason for this is that prices in exporting countries are not lower because of more efficient producers, but because of different regulatory approaches to pricing. Parallel trade therefore does not appear to promote efficiency gains in production in the usual way of placing pressure on costs. In fact, it could increase real social costs as additional transportation and administration costs accrue.¹⁰

Shortage of supply in the exporting country

Another potential effect besides possible price reductions is a shortage in supply in the source country.¹¹ Pharmaceutical companies are required to supply all EU Member States, whereas parallel importers serve only those countries offering attractive profit margins. In low-price countries, manufacturers may sell part of their goods to parallel traders which export the goods to other countries. Demand in low-price countries might therefore not be met even though manufacturers fulfil their requirements. Demand in the exporting country may not be met in full if parallel traders find it more profitable to sell drugs abroad than in the source country. That parallel imports may therefore lead to shortages in exporting countries was also found by the ECJ.¹²

Reduction in manufacturers' marginal investment incentives into R&D

An important question yet to be explored in the economic literature is to what extent a limitation of parallel trade would increase future R&D investment, if at all. Sunk

investment in R&D forms a significant part of pharmaceutical companies' overall costs. R&D is a form of joint cost incurred by pharmaceutical companies that operate globally, such that these costs cannot easily be attributed to a particular country. Parallel imports reduce the profits of manufacturers in high-cost countries, which, in turn, may limit manufacturers' marginal ability to recover R&D costs.

Conclusion

At the heart of the policy debate surrounding parallel trade in drugs lies the peculiarity that the principle of a single European Market strives towards uniform price levels, while Member States regulate prices at different

levels. This problem is not unique to the pharmaceutical sector. So is it necessary to create sector-specific competition rules for dealing with parallel trade in this sector? Can we find a solution with the help of competition policy rules alone?

The welfare effects of parallel trade are ambiguous. On the one hand, it reduces prices for drugs in high-cost countries. On the other, it may create a shortage in supply in the exporting country and reduce marginal investment incentives of manufacturers. The recent ECJ judgment tries to strike the right balance by allowing refusal to supply wholesalers/traders whose demand is out of the 'ordinary'. This debate is likely to continue.

Oxera Economics Council, September 15th 2008

These issues, along with others relating to the pharmaceutical industry, were discussed during the second Oxera Economics Council meeting in Brussels on September 15th. The Council seeks to provide economic insight into challenging issues faced by governments, regulators and business in the context of public policy in competition and regulation.

At the meeting, Oxera economists were joined by fellow Council members Mathias Dewatripont, Chairman, European Center for Advanced Research in Economics

and Statistics (ECARES), Université Libre de Bruxelles; Estelle Cantillon, Université Libre de Bruxelles; Eric van Damme, Tilburg University; Jordi Gual, Caixa d'Estalvis i Pensions de Barcelona and IESE Business School, Barcelona; Bruno Jullien, Toulouse School of Economics; Patrick Legros, ECARES, Université Libre de Bruxelles; Massimo Motta, European University Institute, Florence; and by two guest participants, Pat Treacy, Partner, Bristows, and Vincent Verouden, Chief Economist Team, DG Competition.

See www.oxera.com for more information.

¹ EFPIA (2008), 'The Pharmaceutical Industry in Figures', European Federation of Pharmaceutical Industries and Associations, p. 3.

² Ganslandt, M. and Maskus, K.E. (2004), 'Parallel imports and the Pricing of Pharmaceutical Products: Evidence from the European Union', *Journal of Health Economics*, **23**, March 17th, pp. 1035–57.

³ This was confirmed by a price comparison of 19 pharmaceutical products in 14 European countries undertaken by the London School of Economics. London School of Economics (2004), 'The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis', Special Research Paper, January, Table 3.2.

⁴ Mrazek, M. and Mossialos, E. (2004), 'Regulating Pharmaceutical Prices in the European Union', in *Regulating Pharmaceuticals in Europe: Striving for Efficiency, Equity and Quality*, Maidenhead: Open University Press, pp. 114–29.

⁵ OHE Consulting (2005), 'The Many Faces of Innovation', February 18th.

⁶ Judgment of the Court (Grand Chamber) (2008), Article 82 EC – Abuse of dominant position – Pharmaceutical products – Refusal to supply wholesalers engaging in parallel exports – Ordinary orders, In Joined Cases C-468/06 to C-478/06, September 16th, recital 67.

⁷ London School of Economics (2004), op. cit., p.15.

⁸ Ibid. p. 58.

⁹ Judgment of the Court (Grand Chamber) (2008), Article 82 EC – Abuse of dominant position – Pharmaceutical products – Refusal to supply wholesalers engaging in parallel exports – Ordinary orders, In Joined Cases C-468/06 to C-478/06, September 16th, recital 54.

¹⁰ Danzon, P. (1997), 'Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU', *International Journal of the Economics of Business*, **4**:3, pp. 301–21.

¹¹ Kanavos, P.G. and Costa-Font, J. (2005), 'Pharmaceutical Parallel Trade in Europe: Stakeholder and Competition Effects', *Economic Policy*, **20**:44, October, pp. 751–98.

¹² Judgment of the Court (Grand Chamber) (2008), Article 82 EC – Abuse of dominant position – Pharmaceutical products – Refusal to supply wholesalers engaging in parallel exports – Ordinary orders, In Joined Cases C-468/06 to C-478/06, September 16th, recital 43.

If you have any questions regarding the issues raised in this article, please contact the editor, Derek Holt: tel +44 (0) 1865 253 000 or email d_holt@oxera.com

Other articles in the October issue of *Agenda* include:

- state aid and the banking crisis
- time and timing in capital markets: implications for pensions investment
- what we talk about when we talk about consumer welfare *Phil Evans, FIPRA*

For details of how to subscribe to *Agenda*, please email agenda@oxera.com, or visit our website

www.oxera.com