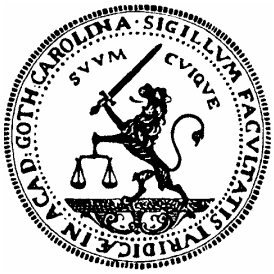

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EC competition law and parallel trade in pharmaceuticals- Time for a new approach?

Master thesis
10 points

Marcus Glader
Competition law
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Contents

Summary

Parallel trade in goods is generally viewed as a positive phenomenon within the EU as a consequence of the principle free movement of goods: When traders buy goods in one part of the common market at a low price and transfer it to a higher priced area, allowing them to undercut those prices, then this will enhance competition, drive down prices and give consumers more choice- an overall positive effect.

Traditionally, the pharmaceuticals market has not been treated any differently and the Community institutions have for many years encouraged pharmaceutical parallel trade without listening to concerns voiced by the industry that the pharmaceuticals market is characterised by special conditions setting it apart from all other markets. These include the fact that prices are not feely determined by the industry and that regulation occurs at a national level. Consequently, it is artificial to treat this sector as a single market, when the conditions of pricing, reimbursement, sale and prescription vary so dramatically between Member States. Pharmaceutical manufacturers argue that parallel trade is eroding their R&D budget, which has led to much of the new innovation industry moving abroad, particularly to the US, and that the European Union is losing competitiveness on the global scene. Not only does this have detrimental economic effects but will also impact social welfare and efficient health care provision.

This paper therefore analyses the approach taken by the Institutions toward parallel trade in the field of competition law. Article 81 EC and Article 82 EC have consistently been used as vehicles to prevent manufacturers from restricting parallel trade, but the Courts are now for the first time considering their arguments. In *Bayer*[1], the ECJ recognised that the Commission had been abusing its position as a quasi-legislator by adopting a very strict formalistic approach to Article 81 EC in order to protect parallel traders. It held that using competition provisions to introduce price harmonisation through the back door was unacceptable. The Advocate General in *Syfait*[2] reached a similar conclusion with regard to Article 82 EC, holding that the Treaty provisions did not represent a per se prohibition on restrictions to parallel trade, and that such restrictions could in certain circumstances be justified: manufacturers needed to be able to defend their economic interests in light of the divided markets across the EU.

If this line of reasoning is followed, it could represent an important shift away from the traditional approach and could pave the way for a political consensus being reached and a more acceptable solution being found. This is crucially important at this stage, after the recent eastwards enlargement, which greatly expanded the market to include areas of comparatively low GDP and pricing. Although those

[1] Joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission* [2004] January 6 2004

[2] C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and Others v GlaxoSmithKline* Opinion of Advocate General Jacobs 28 October 2004

areas are now protected by a ‘specific mechanism’, it would be helpful to have a clear policy to follow.

Preface

Although I always thought it was a bit sad to be acknowledged in legal text or even to have it dedicated to you, unfortunately this is the most romantic work that I am ever going to produce and in fact it is likely to be the only time I ever get to do anything in print so this is as good as it gets!

At this stage I would therefore like to thank my parents without whose support-both emotional and financial- I would not be here today. I appreciate their continued efforts and concern and I hope I can continue to make them proud.

Pa, you're probably going to be the only one to read this thesis, so enjoy!!

Ein besonders grosses Danke Schön an Mama, ohne deren Druckeinsatz meine Thesis um ein ganzes Stück teurer gewesen wäre!!

A special dedication goes to my two curly Proutsens. Lots of küssis for you both! Also to all the boys- Ben, Tom, and Josh and Jack the giant boys, who always make me smile.

Then of course everyone who made this year so much fun and an unforgettable experience! Too many to list, a great bunch of people from all over whom I look forward to visiting all over the world!

And a very special thanks goes to Katie, my first and bestest American friend….without whom I would probably have starved to death during the 'leprosy incident' and who was there for me no matter what! Tack så mycket och vi ses i London!

Abbreviations

AG	Advocate General
ATC	Anatomical Therapeutic Chemical
BAEPD	British Association of European Pharmaceutical Distributors
BGA	Bundesgesundheitsamt (Germany)
CADREAC	Collaborative Agreement with Drug Regulatory Authorities in EU Associated Countries
CEE	Central and Eastern European
DG	Directorate General
EAEPC	European Association of Euro-Pharmaceutical Companies
EC	European Community
ECJ	European Court of Justice
EMA	European Medicines Agency
EMEA	European Medicines Evaluation Agency
EU	European Union
GDP	Gross Domestic Product
GMP	Good Manufacturing Practice
GNP	Gross National Product
GSK	GlaxoSmithKline
GW	Glaxo Wellcome
IPRs	Intellectual property rights
MS	Member State
NICE	National Institute of Clinical Excellence (UK)
NCEs	New Chemical Entities

OTC	Over The Counter
PPRS	Pharmaceutical Price Regulation Scheme (UK)
PT	Parallel trade
R&D	Research and Development
SPC	Supplementary Protection Certificate
UK	United Kingdom
US	United States
VFA	Verband Forschender Arzneimittelhersteller (Germany)
e.g.[1], [24]	Reference to paragraph numbers in case law

1 Introduction

1.1 Objective

The purpose of this research has been to present a comprehensive overview of the European market in pharmaceuticals and to analyse the phenomenon of parallel trade within it from a competition law perspective.

This subject is of pertinent importance at this moment for two reasons:

1) The recent enlargement of the European Union to encompass 25 Member States, many of which have a GDP level well below the EU 15 average[3]. This has had important ramifications in terms of price competition and new avenues for parallel trade.
2) Two recent developments at the EC level: the conclusion of the Adalat saga on 6th January 2004 with an ECJ judgement in *Bayer*[4] that opens up many interesting questions and AG Jacobs' Opinion in *Syfait*[5] that, if followed, could represent a dramatic change of approach by the EC institutions towards parallel trade in pharmaceuticals in the EU. These two cases are significant because they bring to light considerations never previously considered at ECJ level and discuss in detail the particularities of the pharmaceuticals sector.

The objective is therefore to present the situation at this crucial crossroad, and to provide possible outcomes and solutions for the future. In order to achieve this goal this thesis presents the positions held by the different actors on the matter: the Commission, the research-based and parallel trade industries, national governments and the European Courts.

1.2 Method and Material

The method used was conventional legal research and reasoning although much data of non-legal nature is also provided to accurately describe all relevant aspects of the pharmaceuticals market. Thus, I employ econometric information as well as health policy and materials of political nature in an attempt to cover the area as comprehensively as possible.

[3] See for example T Dzitko 'Enabling access to modern medicines at reasonable prices' Business Briefing: Pharmagenerics 2003

[4] Joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission* [2004] January 6 2004

[5] C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and Others v GlaxoSmithKline* Opinion of Advocate General Jacobs 28 October 2004

Of fundamental importance for this thesis was the research published by EFPIA in various studies, which provided much of the background information presented.

In order to illustrate the positions held by the different market players official documentation and publications of the bodies themselves as well as commentaries on them were used. Their reasoning and motivations were thus analysed to determine which approach would lead to the best solution for the EU in terms of competition policy.

To determine the Commission position, official documents that accessed either online via the europa website[6] or in paper format through the Commission central library were instrumental.

1.3 Delimitations

This thesis has been written with an audience of legal professionals and students in mind; the reader is assumed to possess knowledge of basic EC law and EC competition law principles and therefore background has not been outlined.

Similarly, the substance or technicalities of the actual competition law provisions as such are not analysed. The research is instead directed at a more fundamental level of competition law, exploring its aims and objectives as well as policy considerations that influence this area of law and therefore concepts such as the meaning of 'agreement' in Article 81 EC or 'relevant market' in Article 82 EC are only examined as tangential to explain the wider picture.

This paper similarly concentrates purely on competition law. Although matters of Intellectual Property law are equally important in a discussion on the legal framework of parallel trade, a detailed analysis is beyond the scope of this work and therefore those legal principles have only been touched upon where necessary.

Also touching upon parallel trade is the question of generic medicines, which can also drive down pharmaceuticals prices. Again, a line had to be drawn and generics fell outside the limits of this thesis.

[6] www.europa.eu.int

2 Parallel trade

2.1 Introduction- What is parallel trade?

The aim of this Chapter is to provide an introduction to the phenomenon of parallel trade in general and its legal basis in the EU. The discussion will not yet refer to pharmaceuticals at this stage but more generally to parallel trade in other goods, so that a comparison can later be made to the conditions operating in the pharmaceuticals sector. This will allow a deeper understanding of the arguments upholding that the pharmaceuticals sector differs fundamentally from other markets.

'Parallel trade' is the term used to describe the situation when goods are purchased in one country at a low price and then exported into another country where the selling price is higher. The imported products are thus being sold in parallel to and in competition with domestic goods that are being distributed directly by the manufacturer.[7]

Within this category, a distinction can be made between two situations: In the first, a product is manufactured in several different Member States and sold domestically, ex factory, at significantly different prices. This enables wholesalers in the low price countries to export into a high price countries where the importer is then able to resell the product to the end consumer at a lower price than the goods supplied directly from the domestic manufacturer. The second class of parallel import covers the situation when a drug is manufactured in a high price country, and then exported into a low price country at a lower price, to reflect the customers' ability to pay. Once the product reaches the low price market, wholesalers can send it straight back to its market of origin where it can then be sold to the customer at a lower price than if it had come directly from the manufacturer.[8] Both of these categories are covered by the term 'parallel import' for the purpose of this study and in most academic literature and no specific distinction will be made during the discussion as the principles involved are essentially the same.[9]

It is important to understand that parallel importers are specialist companies whose operations occur at a wholesale level. They are professionally involved in importing and distributing goods and do not deal with private individuals. Neither is parallel importation concerned with individuals who travel abroad in order to supply themselves with goods for their own personal use.

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[7] D MacArthur 'Laying to rest the Myths of Parallel Trade in Medicines' Consumer Policy Review, Jan/Feb 2004

[8] REMIT consultants 'Impediments to parallel trade in pharmaceuticals within the European Community' Report for the European Commission. IV/90/06/01, OPOCE 1992

[9] In fact it is not even technically correct to speak of 'imports' or 'exports' within the European Union, as it is merely a movement of goods within the common market, but this is the official term used.

It is widely accepted that parallel trade will occur where price differentials exist between different national markets for the same product. The difference must be so great as to make the activity profitable for parallel importers even after considerations such as cost of transporting and adapting the products to conform to national regulation have been taken into account. Various sources have confirmed that this will only be the case when the price differential lies at a minimum of 15% - 20%.[10] However, other factors will also be significant- thus a small return on a best-selling product may well be as profitable as a larger return on a low volume product. Usually, these conditions will be met in relatively expensive ranges of branded products ranging from cars to cosmetics. A study conducted for the Commission in 1999 illustrate the importance of parallel trade in these sectors[11]:

Extent of parallel trade within the EU

Footwear and leather goods	<5%
Musical recordings	Overall 5- 10%, for some recordings up to 20%
Motor cars	Estimates up to 5%
Cosmetics and Perfumes	Around 13% for upper end of market
Clothing	5-10%
Soft Drinks	0-15%
Confectionery	<10%
Alcoholic Drinks	<5%

According to the Secretary-General of the European Association of Euro-Pharmaceutical Companies (EAEPC), parallel trade will only be possible if four conditions are present in the market:

1) there must be unrestricted free trade between the countries involved
2) there must be substantial differences between the prices of identical goods in these countries
3) the costs of transportation in relation to the cost of goods must be low
4) the distribution of goods must be entirely separate from their manufacture.[12]

The varying degrees of these conditions are reflected in the differing proportions of parallel trade in different sectors. As will be explained in Chapter 3.2, the pharmaceuticals industry presents ideal market conditions for PT to operate in.

[10] Eg Reuters 'The pharmaceutical parallel trade outlook: the challenges to pharmaceutical companies across Europe and the US' Reuters Business Insight 2004
[11] 'The economic consequences of the choice of regime of exhaustion in the area of trademarks' Report for DG XV of European Commission, London 1999
[12] D MacArthur, as referenced in FN 5

2.2 Legal Basis of parallel trade in the EU

Parallel trade is an entirely lawful channel of trade within the EU, and is in fact a result of the fundamental principle of free movement of goods enshrined in Title 1 of Part 3 of the EC Treaty (in particular Articles 28 & 30)[13]. It constitutes a central facet of the integration of European economies and is strongly encouraged by the European Institutions.[14]

Article 28 EC prohibits any quantitative restrictions on imports or any measures having equivalent effect, a concept that was elaborated by the ECJ in *Cassis de Dijon*[15] to mean that a product lawfully placed on the market of one Member State must be allowed to circulate freely throughout the EU in order to establish a true single market. Therefore, the concept of parallel trade is simply a way of taking advantage of price differences and making the most possible use of having one common market, and it has been consistently held that any impediment to this practice would fall foul of the free movement provisions. The central objective is to provide the best possible conditions for the consumer, of encouraging competition, driving down prices and ultimately enhancing welfare. Consequently, any action liable to impede wholesalers from engaging in parallel trade is seen as direct action against consumers and the Treaty rules on free movement as well as competition[16] will be used stringently.

Supplementing the Treaty provisions in this field is the Trade Marks Directive 1989[17] . Article 7 of the Directive enshrines the principle of 'exhaustion of rights' at an EEA-wide level, which means that a company marketing a product in one Member State cannot object to the product being subsequently sold in another Member State on the grounds of trade mark infringement. Effectively goods can therefore be sold and marketed within the EEA without the trade mark proprietor's consent- his rights were 'exhausted' upon release of the product into the Single Market by the owner or with his consent. This is of course also extremely important for enabling parallel trade; otherwise manufacturers could simply rely on their national IPRs to prevent the practice.

The ECJ's protection of parallel trade is apparent from early case law: in 1978 it ruled against Hoffmann-La Roche, stating that a trade mark owner may not prevent a parallel importer from repackaging a good if this is necessary for him to be able to sell it in another Member State.[18]

Since then the rulings have consistently made clear that the Treaty provisions on free movement and the single market imperative will take precedence over national

[13] Consolidated version of the Treaty establishing the European Community as amended in accordance with the Treaty of Nice consolidated version ([2002] OJ C325/1)
[14] M Farquharson and V Smith *Parallel Trade in Europe* (Sweet & Maxwell 1998)
[15] C-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649
[16] Articles 81-87 EC
[17] First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks ([1989] OJ L 40/1)
[18] Case 102/77 *Hoffmann-La Roche v Centrafarm* [1978] ECR 1139

IPR protection. In *Merck v Stephar*[19] this was strongly upheld: the fact that intellectual property protection differed in two Member States could not justify action taken by the IPR holder to prevent parallel trade. This was followed up in *Merck v Primecrown*[20] in which the ECJ held that varying degrees of price regulation could not justify such restrictive action either. In this case the patent owners of pharmaceutical products tried to prevent parallel imports from Spain and Portugal into the UK, but the ECJ stated that "although the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States, that circumstance cannot justify derogation from the principle of free movement of goods."[21]

As can be seen, parallel trade is staunchly defended and protected as being a positive occurrence in the European Union. The question is whether this position can be defended when it comes to the market in pharmaceuticals.

[19] Case C-187/80 *Merck & Co Inc v Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063
[20] Joined cases C-267/95 and C-268/95 *Merck & Co Inc and Others v Primecrown Ltd and Others* and *Beecham Group plc v Europharm of Wothing Ltd* [1996] ECR I-6285
[21] Ibid, at [47].

3 Parallel trade in pharmaceuticals

3.1 Market overview: pharmaceuticals in the EU

This Chapter will start with an outline of the structure of the pharmaceuticals market and its relative importance. It will analyse how the market is regulated at different levels and then look in more detail at the characteristics that differentiate it from other markets. This overview will pave the way for an analysis of the different positions held by various interested parties on the utility of parallel trade in pharmaceuticals.

The pharmaceuticals market in the EU is an extremely important market in terms of revenue generation as well as employment and global competitiveness as it is one of Europe's best performing high technology sectors.[22]

According to the latest EFPIA statistics, the pharmaceutical industry is a key asset to European economy. It provides about 580,000 jobs in Europe, generated a trade surplus of € 36,000 million in 2002 (up from € 7,100 million in 1990) and involved R&D investment of € 20,200 million in 2002 (up from € 7,900 million in 1990). These figures play tribute to the fact that pharmaceuticals are a large and growing market. Within the EU, France, the UK and Germany are the strongest market players as can be seen from these pharmaceutical production figures:

EFPIA 2002	**€ million**
France	30,438
UK	27,144
Germany	20,671
Total 3	78,153
Total EFPIA (EU +Norway & Switzerland)	158,647

However, drugs are not a good like any other. They form a crucial part of a country's health policy and a state has an obligation to ensure effective access to medicines for its population. Because of factors such as the ageing population, higher life expectancy, advances in biotechnology and a greater reliance on pharmaceuticals as a cure for diseases, many new demands as well as opportunities are opening up in this sector. There is great potential for innovation and consequent job creation as well as wealth maximisation, but on the other hand, the cost of providing health care is spiralling. Total percentage of elderly people, (those aged 65+) in Europe was 21% in 2002 as compared to 10.6% in 1990. The huge financial

[22] EFPIA publication 'The Pharmaceutical Industry in Figures, 2004'

constraint this is playing on national budgets is illustrated by the following EUROSTAT figures:

Expenditure on social protection in Europe (2000) [23]:

MS	Per capita expenditure in PPS	Expenditure on social protection as % of GDP	Distribution of social benefits by group of functions (%)	
			Old-age survivors	Sickness, health care
BEL	105	26.7	43.8	25.1
DEU	114	29.5	42.2	28.3
ESP	60	20.1	46.3	29.6
ITA	97	25.2	63.4	25.0
GRC	66	26.4	49.4	26.6
UK	98	26.8	47.7	25.9
EU 15	100	27.3	46.4	27.3

* PPS- Purchasing Power Standard (EUR) - Index: EU 15 = 100

It is then interesting to compare statistics from 1960 to 2001 representing total spending on health care as a percentage of GDP at market prices:
In Europe, the figures range from 3.7% in 1960, to 7.1% in 1980, 8.2% in 2000 and 8.4% in 2001. The amount for total health care expenditure in Europe was divided into three main categories: Inpatient (i.e. hospital) and outpatient care amounted to over 85% of the total amount, but pharmaceuticals made up and important third place with 14.5%.[24] There has thus been an important and steady increase of demand for and reliance on pharmaceuticals as a treatment.

These developments entail that the tension in policy between industrial and social protection aims becomes ever more marked. Many governments are trying to promote a strong national pharmaceutical industry, but this may conflict with the need for cost containment measures. This is an important background to the phenomenon of parallel trade, which of course offers products at a cheaper price.

3.2 Factors influencing pharmaceutical parallel trade

Within the EU, re-imports are estimated to represent $3.3 billion in 2001 and are forecast to rise to $7.4 billion in 2006, i.e. more than double in volume over the next few years.[25] The same source estimated that re-import penetration amounted to 7- 8% of the total prescription market in late 2001 and would rise to 10% by 2006.

[23] EUROSTAT-ESSROS, 2003 in EFPIA 2004
[24] OECD Health Data 2003, 3rd ed, EFPIA report
[25] Reuters Business Insight 2004, see FN 7

Parallel trade affects sales of approximately EUR 4.5 million per annum (value at ex factory prices in 2002) which constitutes 5% of the entire European pharmaceutical market.[26]

Price differentials

These figures illustrate the fact that pharmaceuticals are ideally suited to parallel trade. This is due to a number of reasons. It has been said that the most important precondition for parallel trade is a price differential for identical products in different markets. This is still very much the case for pharmaceuticals because prices are still regulated nationally, both from a supply as well as from a demand side: thus the prices to be charged for a product will be determined by the national government in line with its health policy, whereas the decision on which drug to prescribe will usually be taken by physicians. Thus, there is no direct control by manufacturers or consumers over the market- a very unique setting.

Prices therefore vary in different countries according to the ability and willingness of the national health system to pay for the medicines.[27] Consequently, the required margin of at least 15% price differential will often exist. Countries such as Spain, Italy and Greece tend to have the cheapest prices and are most often the source countries for parallel trade, whereas the UK, Germany and Scandinavia have been branded destination markets. This coincides with the pharmaceutical production figures above, so it seems that possibly higher prices are not only determined by a Member State's relative wealth but possibly also by a desire to protect the national industry and generate higher income. Since the advent of the monetary union, price comparison has been made a lot easier and exchange rate differentials have been reduced which translates into increased parallel trade and greater profits for the traders because although exchange rates have been fixed, national pricing controls still hinder price convergence. Similarly, any loss of parallel trade that may have arisen as a consequence of the Euro has been compensated by the re-importers through greater penetration of Denmark, Sweden and the UK, countries with high pharmaceutical prices yet separate national currencies. Reuters predicts that if or when these countries do decide to join the monetary union, the profitability of parallel trade is likely to change significantly.[28] This view is shared by the REMIT report to the Commission[29] , which states that parallel importers are

'entrepreneurs [who] have no such long term concerns for the industry and do not profess to do so. They have no R&D programmes, little capital investment, and they are aware that should pan-European pricing of pharmaceuticals arrive, parallel trade will cease to exist'.

These trends are reflected in the statistics below:

[26] EFPIA Publication 'The Pharmaceutical Industry in Figures, 2004'
[27] A detailed analysis of why prices differ follows below
[28] Reuters Business Insight 2004, see FN 7
[29] REMIT consultants 'Impediments to parallel trade in pharmaceuticals within the European Community' IV/90/06/01, OPOCE 1992

Approximate share (%) of parallel imports in total pharmaceutical market

Country	**1997**	**1999**	**2002**
Denmark	11	10	10.2
Germany	2	2	7.1
Netherlands	14	15	13.3
Sweden[30]	2	8	9.3 (2001 figure)
UK	7	7	16.5

Source: IHE Source: LIF,SFK, IMS[31]

Physical attributes

The physical constitution of drugs also plays an important role: According to the Reuters Business Insight, tablets are a more popular product in terms of parallel trade than liquid formulations as they require less specialised transport facilities, are relatively insensitive to variations in temperature and light and have a high product to packaging ratio. This is important because the major cost that accrues to a parallel importer is transport and repackaging. Since repackaging is treated as a qualified part of the manufacturing process of pharmaceuticals, a parallel importer is considered a pharmaceutical manufacturer and will therefore have to meet all relevant requirements set by national authorities.[32] Also important in determining where and how to parallel import are the patient population, formulation, and storage requirements.[33]

Parallel trade most often occurs in best selling prescription medicines that are branded under patent protection. Since governments usually do not control the prices of non-prescription drugs, parallel trade is unlikely to continue for a substantial period of time as it can easily be made unprofitable by price adjustments.[34] There are of course products that lend themselves to PT more readily than others, thus traders prefer drugs for diseases with large patient populations, especially where the condition is chronic so that there exists a constant demand for drugs, examples include for example diabetes, depression or asthma.

Acceptance by market players

However, price is not the only determinant. Parallel trade will only thrive if healthcare stakeholders, that is to say governments, physicians, pharmacists, wholesalers and ultimately patients, accept the re-imported goods.[35] Physicians have the power to choose between re-imported and original medicines when

[30] The dramatic increase in parallel trade in Sweden can be explained by the fact that it was considered an illegal practice before accession to the EU, but had to be accepted and embraced as part of the *acquis communautaire*. Parallel trade in Sweden therefore only started in 1995.
[31] LIF= Laegemedel Industri Foreingen, SFK= Stichting Farmaceutische Kengetallen,
[32] DG Enterprise publication 'Parallel trade in pharmaceuticals' 2000
[33] J Arfwedson 'Parallel trade in pharmaceuticals' Institute for Policy Innovation, Quick Study 27.07.2004
[34] J Darba and J Rovira 'Parallel imports of pharmaceuticals in the European Union' Pharmacoeconomics, 14(1), 129-136
[35] Reuters Business Insight 2004, see FN 7

making their prescriptions, pharmacists may have financial incentives one way or the other, and consumers may have personal reasons of distrust for discriminating against foreign imported products. The opinions of these various stakeholders will be analysed in greater detail in Chapter 4 below.

A comprehensive study by Gudmundsson[36]sums up the relevant factors that distinguish pharmaceuticals from traditional sectors:

- *An industry protected by patents*: patents are necessary to avoid molecules being copied and are a fundamental condition for development of new drugs, because the temporary monopoly allows manufacturers to recoup their sunk R&D costs by excluding any shape of competition for example through generics
- *A research-intensive industry:* it takes about 10-12 years to develop a new product from the development of a newly-synthesised active substance into a marketable medicine[37] and R&D costs have risen dramatically over the last three decades
- *A highly regulated industry:* both nationally as well as at EU level strict rules are in force to control drugs before they are approved for sale. This results in delays as well as increased R&D. However, because of healthcare policies this regulation also means that patients do not always contribute to the final price so that cost-efficiency may not be a factor they take into account
- *A competitive industry:* once patents expire, manufacturers are faced with competition by generic producers. This may in some cases reduce the prices of branded drugs by at least 50%

The Commission has recognised the particularities of the market in its Communication outlining an industrial policy for the pharmaceutical sector in the European Community[38]:

'The pharmaceutical market is not a normal market. Companies channel competitive efforts into therapeutic innovation and continued improvements to existing products. Competition between companies focuses on therapeutic innovation and promotion activities with health professionals play a key role. Enterprises are therefore often less concerned about competing on prices, and rather concentrate on their costs, finances and sales volumes.'

Thus, pharmaceutical companies promote their products on the basis of quality rather than price because considerations of price are usually not at the core of a physician's choice of product. All of these factors have an impact on the structure of the market and the occurrence of PT.

[36] R Gudmundsson 'La justification économique des droits de propriété intellectuelle' PhD dissertation, Institut d' Études Politiques, Paris 1998

[37] C Vicien, 'Why parallel imports of pharmaceutical products should be forbidden' ECLR 1996, 17(4), 219-225

[38] Commission Communication outlining an industrial policy for the pharmaceutical sector in the European Community COM (93) 718 final at p. 17

To sum up, the main factors that encourage parallel trade in pharmaceuticals are:

- important price differentials
- patent protection, that excludes any other form of competition, for example in the shape of generics
- light and easy transportation
- different customer and patient preferences across Europe
- the system of EU-wide IPR exhaustion

Further influential factors discussed in Chapters 3.3 and 4 below are:

- acceptance and even encouragement by national health services and pharmacies
- the encouraging attitude of the European institutions

3.3 EU regulatory framework

Since it has now been established that parallel trade is a legal phenomenon, this Chapter will illustrate how it works in practice in the pharmaceuticals sector.

The pharmaceuticals sector is extensively regulated both at a centralised EU level as well as at a national level. This regulation occurs in the interests of consumer protection, as medicines are toxic substances that require stringent standards on marketing, packaging and distribution in order to avoid any health or safety risks to consumers. Particularly the thalidomide incident of the 1960s made the Community realise that there should be clinical tests and a prior authorisation system before any products could be lawfully marketed.[39] The first initiative was therefore Directive 65/65/EEC[40], which harmonised the information required and the criteria applied by national bodies in charge of marketing authorisations. This was followed by Directives 75/318/EEC[41] and 75/319/EEC[42] that introduced a procedure for the mutual recognition of national marketing authorisations in the different Member States. These Directives were followed up and made more comprehensive over the years and pursued a two-fold aim: protecting public health as well as establishing a single European market in pharmaceuticals. However, the fact that mutual recognition applied illustrates the fact that all marketing authorisations were still issued on a national basis. In fact, Farquharson and Smith[43] claim that the mutual

[39] DG Enterprise publication 'Pharmaceuticals in the EU' 2000

[40] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ 022, 09/02/1965, p 0369 – 0373)

[41] Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products ([1975] OJ L 147/1)

[42] Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products ([1975] OJ L 147/13)

[43] M Farquharson and V Smith *Parallel trade in Europe* (Sweet & Maxwell 1998)

recognition procedure was in fact not used very much in practice, which effectively meant that pharmaceutical marketing occurred on purely national markets.

Since 1998, marketing authorisation of all medicinal products can now occur in one of two ways:

1) An application can be made for the centralised marketing authorisation: Council Regulation 2309/93[44], effective from January 1995, established a new centralised system of marketing authorisation. It operates on a compulsory basis for all 'high tech or biotech' products and voluntarily for other products. Authorisation is applied for through the European Medicines Evaluation Agency (EMEA) whose main responsibilities are the coordination of scientific evaluation of the safety, efficacy and quality of medicinal products.[45] The Agency can then grant marketing authorisation that is valid throughout the entire EU market, so that authorised products may be purchased in one Member State for sale in another. The new Regulation 726/2004/EC[46] will enter into force in November 2005. It lays down Community procedures for the authorisation and supervision of medicinal products and will also simplify the name of EMEA to EMA, the European Medicines Agency. Interestingly, the preamble states that the centralised procedure will be made compulsory also for orphan medicinal products and any medicinal product for human use containing an entirely new active substance that is used as a treatment for acquired immune deficiency syndrome, cancer, neurodegenerative disorder or diabetes. This is said to be with a view to harmonising the internal market for new medicinal products. Progressively the compulsory nature of central authorisation will apply to all new products using a new active substance.

   According to DG Enterprise statistics, the central procedure has proven very popular with manufacturers, and the number of such central marketing authorisations has risen steadily since 1995. At the time of publication of 'Pharmaceuticals in the EU' in 2000, 122 medical products had been authorised, and clearly this number will rise significantly following the implementation of Regulation 726/2004.

2) Alternatively, the system of mutual recognition may be relied on. A marketing authorisation may be applied for at the national regulatory authorities. Once a Member State decides to evaluate the medicinal product it becomes the 'Reference Member State' and can decide whether to grant authorisation. This then only permits the product to be marketed in that Member State, but the authorisation must be sent to all other Member States

[44] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([1993]OJ L 214/1)
[45] See FN 37
[46] 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 ([2004] OJ L 136/1)

authorities who then have 90 days to recognise the original national authorisation. This procedure is provided for in Council Directive 93/39/EEC[47] and has been compulsory for all medicinal products to be marketed in a Member State other than that in which they were first authorised since 1 January 1998.

Also important in this respect is Directive 89/105/EEC[48], more commonly known as the Transparency Directive, which states in its preamble that distortions on pharmaceutical exchanges between Member states may result from the different price control and reimbursement mechanisms for medicines operating in the different Member States. The Directive proposes transparency as the only effective and available solution at present to eliminate such possible distortions of competition. It does not, however, limit national price-fixing or harmonise the national systems.

It is therefore clear that parallel trade is compatible with the mechanisms in force.[49]

3.3.1 Parallel import of centrally authorised products

According to its Communication on the Community marketing authorization for medicinal products[50], the Commission takes the view that parallel importers are not required to obtain any additional marketing authorisation for centrally authorised products to be placed on a different national market. Any medicines that are distributed in parallel to those that have central authorisation are covered by the same marketing authorisation. The parallel distributor is therefore allowed to directly place the product on the market and distribute it to another Member State[51].

Centrally authorised products are uniform and automatically approved in all Member States, whereas there may be differences between the national authorisations of the country of import and the country of export, and therefore parallel trade is easier under the central mechanism. However, the Commission reiterates that the original product must not be significantly altered by any repackaging or re-labelling that may be undertaken: any such changes can only be tolerated where they are strictly necessary to market the parallel import in the same

[47] Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products ([1993] OJ L 214/22)

[48] Council Directive 89/105/EEC relating to transparency of measures regulating the pricing of medicinal products for human use ([1989] OJ L 40/8)

[49] However, in practice some obstacles may exist in terms of extra costs incurred through repackaging and labelling. Directive 92/27/EEC[49] was introduced to protect the consumer by requiring all the relevant product information to be stated clearly on the outside of the packet in the language of the country where the product is placed on the market.

[50] Commission Communication on the Community marketing authorization for medicinal products ([1998] OJ C 229/4)

[51] Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted. COM/2003/0839 final

way as the original product. The suggested procedure is that parallel importers report their proposed distribution to the EMEA three months in advance, in which time it will check conformity of the proposed repackaging. This will also allow the authorities to carry out post marketing surveillance. The information required to be submitted by the parallel importer can be found in the Commission Communication on marketing authorisation and includes all basic details on the product and the parallel trader's proposed activity as well as justification for the repackaging. However, the EMEA has no powers of enforcement and even under the provisions that will be introduced by Regulation 726/2004/EC it will have no power to sanction non-compliance.

3.3.2 Parallel import of nationally authorised products

It seems that a parallel importer may find it extremely difficult if not impossible to access the detailed manufacturing and safety data required to obtain a national marketing authorisation.[52] Since Directive 65/65/EC, which prohibits any product to be placed on the market without a marketing authorisation, still forms the basis of the regulatory framework in this area; it would have put parallel trade in pharmaceuticals to an end practically in its entirety. The effect of the rules was therefore subsequently mitigated, particularly through the judgment in *De Peijper*[53], as well as two following Commission Communications.[54] The effect of these provisions is that parallel importers may not have to comply with the stringent requirements on information provision where certain conditions are met, i.e. where the authorities in the Member State of importation already possess all the pharmaceutical particulars relating to the product in question as a result of an existing authorisation or from some alternative source. In such circumstances a parallel importer may then apply for a special form of licence under the general provisions of free movement of goods. Member States are thus still able to rely on Article 30 EC as a justification for national safety licensing regimes, as long as they comply with the general principles of EC law such as proportionality and transparency[55]. To then be able to import a medical product, the parallel importer will have to prove to the regulatory authority that:

- The product will be imported from within the EU or EEA territory
- The product to be imported has a marketing authorisation granted under EC law in the exporting Member State

[52] A Wearing, I Kirby, M Van Kerckhoeve and W Vodra 'Parallel trade in the EU and US pharmaceutical markets' Life Sciences 2004/05

[53] Case 104/75 *De Peijper* [1976] ECR 613

[54] Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted COM/2003/0839 final, updating the 1982 Commission Communication on the same subject

[55] L Hancher 'The European pharmaceutical market: problems of partial harmonisation' ELRev 1990. 15(1), 9-33

- The local product and the imported product have the same therapeutical effects, although they no longer need to be identical. The most recent test was coined in *Kohlpharma GmbH v Bundesrepublik Deutschland*[56] that the two products must be 'substantially identical'. In this context it is however of utmost importance that the differences, should they exist, do not represent a safety concern. Similarly, this case abolished the requirement of proving a link between the original manufacturer and the imported product. The ECJ held that a link between the two marketing authorisation holders might suggest that the products were substantially identical, but was in no way necessary.

The most recent legislative measure taken in this field is Directive 2004/27/EC[57] amending Directive 2001/83/EEC, which will have to be implemented in Member States by 1 November 2005. It requires the parallel importer to give advance notice to the marketing authorisation holder and regulatory authority in the country of import before undertaking any imports.

3.3.3 Public service obligation

Another facet of the pharmaceuticals market that has been regulated centrally is the so-called public service obligation, which is intended to ensure effective health care provision so that the population as a whole can be guaranteed an adequate supply of medicines at all times.[58] It requires wholesalers to keep sufficient stocks to be able to meet domestic demand in the event of an emergency. Article 81 of Directive 2001/83 on the Community code relating to medicinal products for human use[59] reads:

'the holder of a marketing authorisation for a medicinal product and the distributors of the said medicinal product actually placed on the market in that Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of the patients in the Member State in question are covered.'

Pharmaceutical wholesalers must hold an adequate range of products to meet the requirements of a specific area and must also be able to deliver requested supplies within a short time. This of course limits their freedom to act on the market in an unrestricted way, but is warranted in grounds of public health protection as long as it is proportionate to this objective in line with general principles of EC law.[60]

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[56] *C-112/02 Kohlpharma* GmbH v Bundesrepublik Deutschland 1 April 2004

[57] 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 (Text with EEA relevance) ([2004] OJ L 136/34)

[58] Case C-53/00 *Ferring* [2001] ECR-I-9067, at para 24

[59] Council Directive 2001/83 on the Community code relating to medicinal products for human use ([2001] OJ L 311/67) as amended by Directive 2004/27 of the European Parliament and of the Council ([2004] OJ L 136/34)

[60] Recital 18, Directive 2001/83

3.4 National regulatory framework

Although these centralised rules do operate at an EU level, they concern only the marketing authorisation and safety standards, and as discussed, are not even compulsorily regulated in all instances. The actual structure of the pharmaceuticals market, however, is still very divided along national borders: different Member States have different health care systems, price regulation mechanism and attitudes towards pharmaceutical production and parallel trade. Significant differences exist in the terms and conditions under which prescription products are reimbursed by relevant national health funds or social security institutions as well as the number of products accepted for reimbursement.[61] Such differences reflect the different national health policies as well as budgetary aims and constraints, areas in which the Community has no central competence. This was reaffirmed by the ECJ in *Duphar*[62]. The Community has, however, made efforts to ensure a high level of health coverage: in its Recommendation 92/422/EEC on the convergence of social policy objectives[63] the Council recommends that each Member State should make available to all persons lawfully residing on its territory the benefits of its human health protection system, whatever their levels of income. This Recommendation is of course not legally binding and in any case still leaves open the organisational and financing aspects of health care.

Differences exist even at the fundamental level of whether to classify a drug as prescription medicine or Over-The-Counter (OTC) or allowed retail outlets: some countries restrict the sale of all medicinal products to pharmacies; Sweden for example operates on a State monopoly basis, whereby all products must be sold at an 'Apotek'. These divergences are reflections of cultural traditions and perceptions that are often deeply embedded in society.

Most commentators therefore agree that it is not possible to speak of a single market. In fact, Farquharson and Smith even claim that this will not change in the foreseeable future: they regard pharmaceuticals as 'a sector where the creation of a single European market is highly unlikely to occur even in the medium to long term due to the interest of national governments in controlling spending on pharmaceuticals'[64]. They claim that this is due to the fact that neither the pharmaceutical industry nor the Member States share the Commission's market integration aims. On the other hand, they point to a gradual harmonisation of prices through the back door because Member States' mechanisms for determining pharmaceutical prices are increasingly based upon a comparison with prevailing prices in other Member States. This is confirmed by a Reuters study[65], which argues that reference pricing as well as increasing price transparency will likely lead to greater price convergence between the EMU countries, partly because they will facilitate comparison and therefore lead to public relations disasters if a company is seen to obviously market drugs at a higher price in certain markets.

[61] L Hancher, see FN 53
[62] Case 232/82 *Duphar* [1984] ECR 523
[63] 92/442/EEC: Council Recommendation of 27 July 1992 on the convergence of social protection objectives and policies ([1992] OJ L 245/49)
[64] M Farquharson and V Smith *Parallel trade in Europe* at p. 68
[65] Reuters 'The pharmaceutical parallel trade outlook' Reuters Business Insight 2004

External reference pricing is now common practice in Denmark, the Netherlands, Ireland, Norway, Italy, Greece and Portugal.

The current absence of price competition has caused most Member States to impose some form of price or profit control and/or to restrict the number of products which qualify for reimbursement from public funds. This can be explained by the fact that the public or social insurance funds bear a considerable part of the cost of pharmaceuticals and health authorities therefore have a legitimate interest in containing spending in this area as well as obtaining good value for money.[66] It seems that a pattern is discernible: countries that have a research-based industry to protect have either chosen not to impose direct price controls (Germany), or have operated flexible, indirect methods of profit control (UK); whereas countries that are not concerned about protecting a home- industry impose strict price controls (e.g. Belgium, Spain, Portugal, Greece, and to a lesser extent Italy).[67]

However, more recent research suggests that some of the traditional patterns are changing: Donald MacArthur, the Secretary General of EAEPC, illustrates that some of the tougher recent cost-containment measures have been imposed in the traditional free markets of Denmark, Germany, the Netherlands and the UK, while some former low-price countries are introducing higher prices. This pays tribute to the theory expounded above that reference pricing is having a significant impact on European pricing strategy. His conclusion is that it is no longer possible to speak of traditional low-price and high-price countries, as the prices for specific products may be the exact opposite in certain cases. Parallel trade seems no longer to be a simple south-north process, or even a one-way process, but instead many countries act as a supplier and an importer at the same time albeit for different products.[68]

This is neatly summed up in the following table:

Manufacturer's price for a given tablet in 11 EC countries, October 1990

[66] Vicien 'Why parallel imports of pharmaceutical products should be forbidden' ECLR 1996, 17(4)
[67] L Hancher, see FN 53
[68] D MacArthur 'Laying to rest the myths of parallel trade in medicines' Consumer Policy Review Jan/Feb 2004

Country	Price (ECU)
Belgium	0.60
Denmark	0.63
France	0.45
Germany	0.95
Greece	0.22
Netherlands	0.49
Ireland	0.38
Italy	0.46
Portugal	0.49
Spain	0.31
UK	0.41
EC average	0.47

Source: a major manufacturer, in REMIT report to the Commission 1992

This illustrates that the drug is nearly one quarter the price in the cheapest country, Greece, as compared to the most expensive country, the Netherlands. Secondly, for this particular product, the UK, normally a high price country, is considerably cheaper than France, Belgium, Italy and Portugal, normally low price markets. Also remarkable is that there is a significant difference in price between Spain and Portugal, both traditionally low price markets.

So although patterns may be changing what is still very clear is that significant price differences do exist, partly due to the national health policy reasons examined above, but also significantly due to the active policy of price discrimination undertaken by many international pharmaceuticals companies. The companies will price their products differently according to variations in the ability to pay, aiming got obtain the highest price each national market can bear.[69] Price discrimination, its motivation and effects on the market are clearly outlined by Morris et al[70]. The study argues that price discrimination makes economic sense: where a firm is obliged to set one uniform price that price will have to be an average taking into account all the different markets and it is therefore likely to be higher than the price many consumers would be willing to pay. Price discrimination seems to be profitable where marginal production costs are very low (as in pharmaceuticals) or close to zero (as in the provision of a service such as the ability to cross a river on an already existing bridge). It entails welfare benefits as well as pure profit maximisation for the manufacturer in that it enables the firm to service people who otherwise could not afford to purchase its products. This in turn means that it can expand its output beyond the level it might be restricted to at a uniform price and allows the firm to enter into R&D projects, which it might otherwise not be able to consider. The ability to practice price discrimination depends of course on there being distinct markets and a limited amount of interplay or leakage between them.

[69] idem

[70] J Morris (ed) *ADPIC et Services Medicaux: Repenser le débat*, Centre for the New Europe (September 2001)

It is helpful at this stage to look at the various different systems of price and drug regulation that exist in a selection of Member States in order better to understand the dynamics of European parallel trade.

Overview of health care systems

Characteristic properties	Tax financed system	Premium financed system	Private insurance system
Type	National Health Service	Social insurance	Pluralistic (Medicare/Medicaid-Managed Care)
General definition	Government regulated care with health services	Health care as guaranteed basic right	Health goods are largely consumer goods
Finances	Taxes. Every taxpayer contributes	Contributions from employers/employees	Largely private finance
Service organisation	Public	Private/Public	Largely private
State intervention	Strong/direct	Mostly indirect	Weak/indirect
Service package	More supply orientated	More demand orientated	Demand orientated
Role of professional associations	Not very strong	Strong	Very strong
Examples	Scandinavia, UK, Italy, Spain, Greece	Germany, France, Belgium, Netherlands, Austria, Japan	USA, Switzerland

Source: F Schmidt, M Egler and R Geursen, Aventis Pharma AG, Drugs made in Germany 44, no 3 (2001)

The table depicts the variety of systems in place in different countries and illustrates different factors that will have an influence on those given national markets, which will lead to differing pricing strategies. This paper will analyse in more detail the examples of Germany and the UK.

3.4.1 Case study: Germany[71]

Germany is the largest pharmaceutical market in the European Union both by volume and by value, and ranks third on the global scene. Since it is also traditionally a high priced country, it is a prime target for parallel trade. This trend

[71] The following country overview sections are based on J Arfwedson, 'Parallel trade in pharmaceuticals' 2003 and the REMIT report to the Commission 1992, see FN 29

has been strengthened by recent government policy initiatives to substitute re-imported products and generics for brand names in order to keep costs as low as possible.

The German health care system operates at two different levels: patients are either privately insured or insured by the public regime. They receive different treatment and pay accordingly. In 2002 the government decided to increase the minimum income required to enable access to private insurance in an effort to increase reliance on public healthcare.

Price regulation of medicines in countries like Germany happens in an indirect manner: prices of drugs are not fixed, but instead the health authorities will reimburse only a certain amount. The difference will then have to be paid by the patient. Consequently manufacturers tend to set prices at a level close to the reimbursement price, especially where comparable drugs exist that are fully reimbursed. Physicians will be inclined to prescribe the product for which the patient will be charged the least if he knows them to have the same therapeutic effects.[72] This type of price setting was endorsed by the ECJ in *Roussel Laboratoria BV and Others v État Néerlandais*[73] provided it does not violate any provisions of Community law, in particular the principle of non-discrimination.

Parallel trade has grown dramatically since 2000, when a new law was enacted that required pharmacists to replace brand names with re-imported drugs when the latter are at least 10% cheaper. According to VFA statistics, parallel trade more than trebled between 1998 and 2001 (see also table on p. 14) to more than € 800 million[74]. A subsequent law of 2001 further strengthens support of parallel trade: it requires pharmacists to sell low-priced alternatives, i.e. re-imported products or generics, whenever possible and forces pharmacists to have a minimum sales quota of re-imports of 5.5% in 2002, increasing to 7% in 2003. If the pharmacist does not reach the set target in any specific month, his reimbursement bill for that month will be accordingly reduced. Thus parallel trade is forecast to increase, accounting for a predicted $3.6 bn or 9% total penetration by 2006.

The fact that these policy measures are effective to achieve a reduction in prices can be illustrated by specific examples: in the early 90s, government decisions led to an 11% drop in prescription drug sales while two major generic producers (Ratiopharm and Hexal) doubled their market share to 20% of the total.[75]

However, recent data also shows that the price differential between original drugs and parallel traded drugs has shrunk considerably, and that price increases in parallel imports far exceed those of original products. Thus, a study of eight products that amount to about 17% of all imports shows that the target of 10%,

[72] R Nazzini 'Parallel trade in the pharmaceuticals market: current trends and future solutions' World Competition 2003, 2691), 53-74
[73] Case 181/82, *Roussel Laboratoria BV and Others v État Néerlandais* [1983] 3849
[74] Verband Forschender Arzneimittelhersteller 'Parallel- und Reimporte im Arzneimittelmarkt: Gesundeitspolitik auf dem Irrweg', May 2002
[75] R Gudmundsson 'La justification économique des droits de propriété intéllectuelle' PhD dissertation, Institut d'Études Politiques, Paris 1998

which would guarantee automatic prescription above the original product, was not reached in a single case. The largest difference was 6% and for half of the products studies it was less than 3%.[76]

Similarly it seems that some regulatory impediments do exist to parallel trade, namely in the form of parallel licensing procedure. REMIT concluded in its study[77] that in importers' eyes the procedure of the federal health ministry (BGA) is seen as excessively cumbersome and time-consuming. The time officially laid down by the BGA itself is 4 months, already substantially higher than the period of 45 days given by the Commission in its Communication on parallel imports in 1982.[78] However, in practice, this period is often even extended up until delays of a year accrue. In 1992, the study estimated the value of parallel imports excluded from the German market as a result of the BGA's procedures at DM 1132m.

3.4.2 Case study: the UK

The UK has the largest proportion of parallel trade of any country within Europe- it is estimated that 90% of UK pharmacists source products through parallel trade. The exact penetration of parallel trade within the pharmaceuticals market is not entirely clear; one source estimates it at 20% of all pharmaceutical prescriptions[79] while another differentiates between branded sales, of which 19.8% would be parallel imports, and 16.5% of the total UK retail market.[80]

ABPI concludes that these high figures are due to three main reasons:

1. Higher prices on selected products
2. One of the easiest licensing procedures for parallel imported products in the EU
3. A reimbursement system in the NHS that gives incentive to parallel trade

The reimbursement system and price setting mechanism operating in the national health service deserves closer attention. In the UK, the general price-setting is based on negotiations under the Pharmaceutical Price Regulation Scheme (PPRS). Under this scheme, the Department of Health enters into agreements with the ABPI about levels of profitability and allowances for R&D. These agreements set a profit ceiling for new products. Prices can thus be freely determined by the manufacturers as long as they do not surpass the given ceiling. This imposes a maximum price requirement, albeit indirectly. As Nazzini puts it 'The example of the UK clearly shows that a free negotiation system with specific allowances for R&D and profit

[76] VFA study 2002, see FN 74
[77] Of 1992, more recent data on this issue was not obtainable
[78] As amended by Commission Communication on parallel imports COM/2003/0839 final
[79] Pharmafocus, 30 Nov 2002
[80] Reuters Business Insight 2004

levels is in fact a maximum price setting system with elements of democratic participation in it.'[81]

This is part of a general government policy aimed at cutting prices. Another is the so-called pharmacist 'claw-back' system: when the government sets the remuneration of retail pharmacists, account is taken of discounts which they receive from wholesalers and parallel importers compared with official lists. The level of these discounts obtained is reviewed every two years and a discount scale is established, which is taken into account in the final amount reimbursed. Thus the NHS claims back 9% of pharmacists revenues, whether parallel imported products are sold or not. This means that the cheaper the price, the greater the profit for the pharmacist,[82] and that most of the savings that are being made by these measures accrue to the pharmacist. The total amount of savings was estimated at being in excess of € 164 million between 2001 and 2002.[83] However, the flip side of this is that ABPI puts the loss of income for the national pharmaceuticals industry at GBP 1 billion per year.

As in Germany, there seems still to exist an impediment to parallel trade because of the delay in obtaining import licences. The Medicines Control Agency (MCA) in charge of licensing parallel imports took an average of 19 months in 1992 to approve an application, and this figure rose to nearly 4 years in some cases.[84] Yet at that time the agency had recently reorganised its activities to become more efficient and was aiming at achieving average lengths of no more than 6 months. Similarly, in 1992 a common complaint was that the cost of obtaining parallel licences was prohibitive, rising up to GBP 12,000 in certain cases. However, these concerns seem to have been taken into account in the interest of promoting parallel trade and the licensing fee for parallel imports as of 1 April 2004 stands at GBP 1,483.[85]

[81] R Nazzini at p. 58 (see FN 72)
[82] J Arfwedson 'Parallel trade in pharmaceuticals' Institute for Policy Innovation, 2004 and REMIT report to the Commission IV/90/06/01, OPOCE 1992
[83] Reuters 'The pharmaceutical parallel trade outlook' Reuters Business Insight 2004
[84] REMIT Report, see FN 82
[85] Available at http://www.mca.gov.uk/

4 Different perceptions on parallel trade in pharmaceuticals

4.1 Introduction

The previous Chapters have illustrated that parallel trade is a strong reality in the pharmaceuticals market in the European Union and looked at some of the reasons why. It is now necessary to determine whether parallel trade is looked upon favourably and the arguments on either side. This will allow a determination of a future approach for the European Union.

As an independent report to the Commission on the review and reform of Community pharmaceutical regulation stated:

'there are relatively few areas where the different participants in the regulatory process agree on the extent of the shortcomings in these systems, let alone the solutions. Decisions on what changes to make to the systems will, as ever, involve the Commission and the legislature in balancing different considerations, all of which are important but often conflicting.' [86]

Manufacturers' wishes naturally collide with those of parallel importers in terms of profit maximisation whereas Member State governments have their own agendas of providing adequate medical care for their population while increasingly being pressured by financial constraints. They are, however, very staunchly in favour of retaining the provision of health care as a national competence so that mechanisms of control for pricing and reimbursement, key aspects of the regulation of the pharmaceuticals sector, are set to remain national.[87] The Commission then has the difficult role of trying to compromise between these positions as well as reconciling its internal conflicting aims of establishing an effective industrial policy with the single market prerogative as well as to a more limited extent also health and social policy.

EFPIA has summed up what it perceives to be the three most important policy dilemmas in this area:

1. National intervention in the market for medicines *vs* free movement of goods principle

2. Health policy *vs* industrial policy

3. Collective provision of healthcare *vs* individual responsibility

[86] CMS Cameron McKenna and Andersen Consulting (2001), at paragraph 1.7
[87] J Attridge 'A single European market for pharmaceuticals: could less regulation and more negotiation be the answer?' European Business Journal 2003, v. 15, n. 3, 122-143

Within these broad categories, many different considerations come into play, as is illustrated by a table by Permanand[88]:

Competing pharmaceutical policy interests

Health care policy	**Industrial policy**	**Public health policy**
Cost containment and improving efficiency	Promoting local R&D capacity	Safe medicines
Cost-effective medication	IPR protection	High-quality preparations
Regulating doctor and consumer behaviour vis-à-vis medicines	Supporting local scientific community	Efficacious treatments
Generic promotion and/or substitution	Generating and protecting employment	Innovative cures
Improving prescribing	Promoting SME policies	
Ensuring access to medicines	Contributing to positive trade balance	
	Sustaining the university research base	

Despite this plethora of concerns, there is a clear- cut division between supporters and opponents of parallel trade, no party occupies a middle ground. On the pro side, there are the parallel traders themselves, the Commission as well as governments and healthcare payers in export countries; on the con side are branded pharmaceutical manufacturers in destination markets and certain governments (e.g. France) in source markets.[89]

The next sub-chapters will therefore determine precisely each market player's position and the reasons influencing them, particularly as regards the issues identified as most important in their argumentation: parallel trade's influence on a) R&D and competitiveness, b) social welfare and c) miscellaneous other factors.

4.2 Pro: parallel traders

This section is based mainly on information published by EAEPC, the Association of Euro-Pharmaceutical Companies that represents pharmaceutical parallel trade in Europe.[90] Its primary aim is to safeguard the free movement of medicines as laid down in the EC Treaty, i.e. to protect parallel traders in their activities. The main justifications for parallel trade used by the Association are that free trade will:

[88] G permanand and C Altenstetter 'The politics of pharmaceuticals in the European Union' in E Mossialos, M Mrazek and T Walley *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* European Observatory on Health Care Systems (2004)
[89] Reuters Business Insight. See FN 80
[90] It has a membership of over 70 firms from 16 countries in the EEA. Website: www.eaepc.org

- lead to improvements in health standards through the provision of innovative medicine at lower cost
- benefit statutory healthcare systems, other third party payers and the public as both patients and taxpayers
- assist the EU to achieve its objective of a single European market

Most of the arguments therefore boil down to the idea that parallel trade is a positive driver for social welfare, because it brings savings, competition and generates wealth.

4.2.1 R & D

Parallel traders reject the allegations by the pharmaceutical industry that parallel trade erodes R&D. They argue that the profits of the biggest pharmaceutical companies continue to grow, with most of the big companies achieving double-digit growth rates in 2003, so that a lack of competitiveness cannot be proven. At the same time spending on sales and marketing in Europe is growing: between 2002 and 2003, spending in Germany increased by 25%, in Spain by 26% and in Italy by 20%- according to EAEPC evidence that there is enough cash flow for companies to invest in marketing rather than R&D without losing out on profitability. A diversion of sales from one European country to another has therefore not led the research-based industry cutting back on R&D. In fact, they argue the opposite is true: according to the manufacturer's body, EFPIA, spending on pharmaceutical R&D grew more than threefold from 1985 to 1999. In Europe's largest destination market, the UK, R&D spending increased by 108% between 1990 and 1998.

With parallel trade in pharmaceuticals amounting to a market share of an estimated 5% EU-wide in 2002, Donald MacArthur, the Secretary General of EAEPC, argues that this level is too small to have any effect on R&D investment. He further relies on evidence by an independent consultant[91] that values total direct losses to manufacturers from parallel trade at about € 500 million per year, which is an amount roughly equivalent to a company's cost in discovering, developing and launching only a single new active ingredient, so not that much relative to total costs of pharmaceutical companies. Manufacturers also incur financial losses not due directly to parallel trade but rather due to their attempts to prevent the practice, for example through lower sales volumes, loss of customer goodwill, or legal costs.

4.2.2 Social welfare

According to parallel importers, parallel trade results in the payer and/or consumer in the product's country of destination paying less than would otherwise be the case. This means an increased and improved access to medicines for European citizens, and both direct and indirect savings to social health care insurance systems

[91] I Senior, speaking at an open forum 'Parallel trade in European Pharmaceuticals', 6 September 2000, Vision in Business Conference, London

and consumers in the countries of supply. EAEPC relies on figures released by the York Health Economics Consortium[92] that show the levels of direct savings to patients and social health care as a consequence of parallel trade. The total amount was estimated at over € 630 million in 2002:

Country	**2002 savings (€ m)**
UK	342m
Sweden	47m
Germany	194m
Netherlands	32m
Denmark	16m (2001)
Total 5 countries	631m

As well as these direct savings, indirect savings are said to accrue through the competition that parallel trade provides that results in a general price erosion. EAEPC explains that parallel trade is the only form of competition to any specific medicine during the life of its patent and it therefore provides consumers with a choice they would otherwise simply not have. This is because generics are no viable substitute during the life of a patent. If no parallel trade occurred, innovative medicines that have high or even dominant market share would have no incentive to offer low prices. The availability or even the mere threat of parallel trade, however, can result in lower prices, greater discounts or improved terms. These indirect savings were also quantified:

In Denmark, for example, an independent market researcher 'Media Consult' calculated in 1997 that the downward spiral of prices through alternating price reductions by manufacturers and parallel traders led to annual savings of more than € 50 million. The York study found that in 2002 parallel trade led to direct savings of € 15.7 million, a much lower yet still significant amount. Importantly, the savings were split roughly 60/40 between the government (i.e. taxpayers) and patients respectively.

In Sweden, a study by Ganslandt and Maskus[93] found that prices of Swedish brands subject to competition from parallel trade increased less than other products during the period 1995-1998.

In the UK, direct savings from parallel trade amounted to an estimated € 342 million, or 17% of total medicines expenditure. Much of the savings passed to the government in the shape of lower hospital medicine prices but significant savings remained with the pharmacies.

The York study therefore concluded that 'these direct and indirect savings from the parallel trade of pharmaceuticals have played a major role in holding down the spiralling healthcare bill in many European countries'.

[92] York Health Economics Consortium 'Benefits to payers and patients from parallel trade' May 2003

[93] M Ganslandt and K Maskus 'Parallel imports of pharmaceutical products in the European Union' The Research Institute of Industrial Economics, Working Paper No.546, 2001

Similarly, EAEPC argues that not only the social health care providers benefit, but that savings accrue directly to the patient in several ways. First, because a patient may avoid paying excess payment that might otherwise be due in cases of reference pricing, i.e. where the amount to be reimbursed is fixed at a set cap. Second, because patients are increasingly resorting to 'lifestyle drugs' as well as oral contraceptives which are often not reimbursed at all. Therefore, the consumer makes a direct saving from the purchase. Finally, because parallel trade offers the exact same product, not copies or substitutes, doctors and patients need not be reluctant to switch brands for fear of different physiological reactions or simply mistrust of an unknown brand. As Donald MacArthur, Secretary General of EAEPC, explains, parallel trade can only take place if there is demand and demand would not exist unless traders passed on significant cost savings.

4.2.3 Other issues

Other fears that the EAEPC rejects as unfounded are that parallel trade is likely to lead to counterfeit, substandard or pirated products, as well as parallel trade leading to shortages of supply in exporting countries.

Donald MacArthur points out that the link between PT and counterfeit goods has never been proven, and that all parallel importers are subject to stringent regulation so that any leaks in the system are highly unlikely. A survey published in 1999 found that the proportion of counterfeit drugs in the EU was the second lowest in the world after the US, and the German Federal Health Ministry has confirmed that not a single case of counterfeit medicine has ever entered through the parallel trade chain.

As regards shortages of supply, all European countries operate on a 'public service obligation' that is protected both by EC law (see Chapter 3.3.3 above) and also by either national law or through customary codes of practice that require wholesalers to supply local markets before being allowed to export. An example of such national legislation is Article R.5515-13 of the French Public Health Code, which requires wholesalers to keep a permanent emergency stock that consists of 90% of all forms of medicines currently sold in France, which the wholesaler must be able to deliver within 24 hours of receipt of an order. Additionally, the Order regarding 'best practices of wholesale distribution of medicines for human use'[94] must be complied with in order to avoid a fine. This requires pharmaceutical manufacturers and wholesalers to manage their inventories in a way that ensures a normal and regular supply to all recipients. Similar legislation exists in Spain: Article 79(2) of the Spanish Medicines Law also requires wholesalers to maintain minimum stocks to guarantee continuity of supply[95]. The AG in *Syfait* at [86] also mentions 'moral' obligations alongside legal duties, and it seems that the bad publicity that would ensue a shortage due to exportation scandal is as strong a factor as actual legislation. Therefore, Donald MacArthur argues that any shortages that do occur,

[94] Order 2000/9 of June 30, 2000

[95] Although no concrete evidence was found of similar provisions in other countries, most commentators seem to assume that the situation is the same throughout the EU Member States.

as for example in Greece, are due to the manufacturers themselves, through their practice of introducing supply quota systems.

These views are shared by the API (now BAEPD), representing parallel importers into the UK, which has stated that 'parallel importers introduce an additional element of competition into the UK pharmaceuticals market place and therefore help to control cost and ensure that the national health service gets value for money'.

Thus, to summarise, the benefits in the eyes of parallel importers are that parallel import:

- Is able to stimulate price competition among otherwise monopolistic manufacturers
- Brings significant savings to payers and patient
- Has no impact on the ability of the pharmaceutical industry to invest in R&D
- Uses only genuine, regulatory-approved products from original brand manufacturers
- Is totally free of counterfeit, pirated and substandard products

It is therefore necessary to examine the information put forward by the opponents to parallel trade and try to create the true overall picture of the pharmaceuticals market.

4.3 Con: the pharmaceutical industry

The view of those against parallel trade is mainly defended by EFPIA, the European Federation of Pharmaceutical Industries and Associations, as well as ABPI, the Association of British Pharmaceutical Industries. Clearly, the economic interests of manufacturers are undermined by parallel trade and they will do anything within their power, often testing the boundaries of legality, to try and prevent parallel trade from occurring. The industry is a significant lobbyist to the European Community as it is a very strong factor in terms of European competitiveness as well as employment so the arguments put forward are not to be treated lightly.

The main arguments on this side of the line that directly challenge the findings presented by parallel importers can be summarised as follows:

- As regards R&D, the industry claims that R&D *is* adversely affected, that this has an impact on the innovative medicines development and therefore on long-term health costs.

- As regards savings, the main argument is that these savings accrue for the most part to the parallel importers themselves and not to the patient or social healthcare system at all.

4.3.1 R & D

Drug manufacturers face a very costly process in developing a new drug, both in terms of time and money. After many years of trials, only a very small proportion of all tested substances will ever pass to the approval process, let alone to the stage of human testing and final marketing authorisation. Out of a total of about 10,000 substances synthesised by a research laboratory, only a few hundred will be worth applying for a patent and out of those only one or two will then receive marketing authorisation, thereby reaching the consumer.[96] This has led the Commission to recognise that:

'The huge risks [in pharmaceutical research] make individual companies very vulnerable, not least because 90% of R&D spending is financed by the industry itself. It is therefore the long-term capacity to generate the resources needed to bring new products onto the market- a capacity that depends on the success of those already on the market- that determines the ability to compete of the principal multinational companies.' [97]

These findings are supported by figures published by EFPIA: the latest study, in November 2001, estimated the average cost of researching and developing a new chemical or biological entity at € 870 million. EFPIA affirms that these ever increasing costs are almost entirely financed by the industry's own resources. It is in this regard important for a manufacturer to recoup his investment before the patent period runs out and he becomes subject to competition from generic alternatives. Thus the increased amounts of investment that are used by parallel importers as a sign to disprove any negative effect on R&D are in fact being spent on clinical trials and the procedure of getting approval by regulatory authorities. High failure rates mean that these costs have risen exponentially, yet this investment does not necessarily represent greater innovation.

Although about € 20,200 million was invested in R&D by the pharmaceutical industry in 2002 in Europe, Europe's research and development basis has gradually been eroded over the last ten years. Whereas R&D investments in Europe grew by 2.6 times between 1990 and 2003, the corresponding increase in the US is more than fourfold.[98] In terms of GDP expenditure, R&D represented 1.99% of the EU's total GDP, compared to 2.80% in the US and 2.98% in Japan.

Brian Ager, Director General of EFPIA, acknowledges that this erosion of innovation is caused by a multitude of reasons, including the economic and regulatory framework, the science base and societal attitudes towards new technologies that are less favourable than the conditions in the US. He does, however, lay a significant amount of blame on parallel trade. He argues that it deprives the industry from valuable resources that could be invested in new

[96] S Kon and F Schaeffer 'Parallel imports of pharmaceutical products: a new realism or back to basics' ECLR 1997, 18(3), 123-144

[97] Commission Communication outlining an industrial policy for the pharmaceutical sector in the European Community COM (93) 718 final

[98] A Gambardella, L Orsenigo and F Pammolli 'Global competitiveness in pharmaceuticals' Report prepared for DG Enterprise, November 2001

products. He also states that the fact that parallel trade hardly exists in the US is a major factor in the recent trend. Particularly worrying is that 70% of sales of new medicines marketed since 1998 are generated on the US market compared with only 18% on the European market, whereas in the 1960s European companies invented 65% of new chemical entities (NCEs). Of the top 10 worldwide pharmaceutical products by sales, 8 originate from the US as against 2 from the EU[99]. Similarly, when looking more closely at the type of product placed on the market, it seems that the US has a competitive advantage in the newer biotech fields relative to more traditional pharmaceutical research. This trend clearly highlights that R&D is more attractive in the US and that Europe is losing its competitive edge. As the report by Gambardella, Orsenigo and Pammolli puts it, 'innovation constitutes one of the key sources of competitiveness in this industry and it is a major determinant of market structure'. [100]

These views are shared by the ABPI in the UK, where parallel trade is particularly wide spread. (See chapter 3.4.2 above). ABPI feels that parallel trading has now grown to such an extent that it has a significant impact on the distribution of medicines in the UK and in fact represents a major drain on NHS resources overseas. The UK-based industry currently spends GBP 7million a day on research, while parallel trade is seen to deprive the pharmaceutical industry of much needed income to find more efficient medicines. In fact the latest figures, released on April 5th 2005, confirm this trend for the UK: Investment in R&D in 2003 was GBP 3.2 billion, slightly down from 2002 when the rate was GBP 3.3 billion. It must also be borne in mind that at the same time other high-tech businesses have registered an increase. Capital expenditure was also down from an average of GBP 925 million over the last five years to GBP 753 million in 2003.[101]

Although ABPI recognises that the prices of modern medicines dropped by five percent, and that 2.2 per cent fewer were prescribed, which amounted to a GBP 50 million saving for the NHS on branded medicine, it still does not see this as a factor outweighing the negative impact of parallel trade on the British industry. It emphasises that savings though parallel trade do not accrue to the patients and that the decline of R&D is a most worrying trend that is largely caused by parallel imports.

These findings are also supported in the academic literature. Rey and Venit provide a comprehensive overview of the effect of parallel trade on the pharmaceutical industry's resources. They claim that parallel trade reduces pharmaceutical companies' revenues in two ways:

(i) the manufacturers lose revenues on the amount of product exported from lower price countries and sold in higher price countries

(ii) if pharmaceutical companies attempt to reduce PT by delaying the introduction of products in lower-price markets, they lose revenues during the period of delay

[99] Determined with reference to the parent company

[100] Gambardella et al report, see FN 98

[101] ABPI publication 'Facts and statistics from the pharmaceutical industry' 2005

Thus, parallel imports negatively impact R&D because they reduce both current revenues and thereby reducing the funds available for current projects, as well as expected revenues and thereby a firm's incentive to invest in R&D. The fact that governments directly set prices and thus determine their countries' contributions to the R&D effort means that because there are European countries that have no interest in keeping a national pharmaceuticals industry thriving because it simply does not exist, they will have no desire to keep prices at a competitive level but instead will push for the lowest possible prices. Because of parallel trade, this will eventually push prices down to overall lower levels and negatively affect the overall available R&D budget[102].

4.3.2 Social welfare

This threat of lowering prices is also recognised by Vicien[103] in the context of social welfare provision. She argues that the forced lowering of prices to the lowest regulated price on the European market means that manufacturers may instead opt for a policy of refusing to sell their products in the cheapest markets, or even locking manufacturing plants out which of course has knock-on effects on employment, regional balance and health care. This is due to the fact that manufacturers cannot simply react to this lowering of prices by raising the overall prices in cheaper countries because they are not free to set prices themselves. In Greece, for example, 16% of medicines originally intended for Greece are re-routed to higher priced markets such as the UK, which may lead to severe shortages.[104]

Rey and Venit argue that the most efficient outcome for governments would be a free choice of how to price medicines in order to be able to balance the competing national interests of encouraging R&D on the one hand and curbing healthcare expenditure on the other. Where a Member State chooses to impose a low price regime on suppliers, it has intervened in the market to favour itself as purchaser and has simultaneously created an artificial advantage for resellers established in that Member State. The resulting ability to parallel import into higher priced countries and thereby make a profit does not therefore reflect any superior efficiency on their part but simply a market distortion attributable to government intervention. The parallel trader is not only gaining an unfair advantage but is also undermining the pricing policy of other Member States that have opted for higher prices in order to encourage R&D.[105]

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[102] P Rey and J Venit 'Parallel trade and pharmaceuticals: a policy in search of itself'. ELRev 2004. It must be borne in mind, however, that although the authors are expressing their personal views, their opinion was formed in connection with work undertaken for GlaxoSmithKline in a case involving parallel trade. Thus there might be need for a slight caveat as to the objectivity of this work.

[103] F Vicien 'Why parallel imports of pharmaceuticals should be forbidden' ECLR 1996, 17(4), 219-225

[104] EFPIA 'The Pharmaceutical Industry in Figures, 2004'

[105] P Rey and J Venit see FN 102

Contrary to what is claimed by parallel importers, a recent study by Kavanos of LSE[106], seems to contradict the findings presented in the York Health study, and demonstrate that the vast majority of the benefits from parallel trade directly benefit the parallel importers rather than the payers or the patients. The main conclusions drawn in the LSE special research paper are that:

- the benefits accruing to health insurance organisations are, at best, modest. This is true both in absolute value terms or as a proportion of total national expenditure on branded medicines
- patients do not benefit directly from parallel trade
- pharmacists realise modest financial benefits where there are financial incentives for them to dispense parallel imports. In all other countries they do not benefit at all
- parallel importers are the ones reaping significant benefits compared to all other stakeholders
- manufacturers incur a significant loss of business in destination countries from the conduct of parallel trade, which reduces manufacturers' overall profitability without necessarily increasing societal welfare

The study illustrates how these effects work in practice in all the different Member States. In Germany, the reimbursement system is based on a policy of co-payment between State and consumer that is fixed at a set fee per pack, whereby the larger the pack the smaller the fee becomes in relative terms. This policy does not therefore give patients any indication of the real value of the drugs they are buying and does not allow them to benefit financially from available parallel imported equivalents. In the UK, a similar situation exists, whereby patients do not know the real price of medicines nor would benefit from any reduction is price as the prices are fixed by the government. Over 80% of all prescriptions are co-payment free, and therefore the entire cost is footed by the State. For the remaining products, patients pay a fixed fee per prescription[107] or buy pre-paid certificates in cases of chronic disease and therefore constant need of medication. Either of these methods of payment will not allow patients to realise any direct benefits of lower actual pricing.

Thus, although lower prices can in theory be presented as an advantage to the patient, this will only be true if the patients pay a significant proportion of their medication themselves. In practice, however, as seen by the examined examples, there is no reduction of the actual cost of medication and therefore no improved access to healthcare[108].

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[106] P Kavanos et al 'The economic impact of pharmaceutical parallel trade in European Union Member States: a stakeholder analysis' Special Research Paper January 2004

[107] GBP 6.20 from 1 April 2002, and GBP 6.30 from 1 April 2003

[108] Much emphasis is continually placed in recent academic literature on the findings presented in this study. However, EAEPC claims that the results are fundamentally flawed and biased because the research was sponsored by Johnson & Johnson. It's main criticisms are that the analysis was based on false assumptions. See http://www.eaepc.org/news_and_press/press_releases.php?n=3&start=5&id=28 for a detailed discussion.

4.3.3 Other issues

Some commentators argue that the drive towards lower uniform prices as brought about by parallel trade is detrimental to the European consumer in several ways. As Danzon argues:

'for a company to consider launching a product at a lower price, the expected net revenue from that country, after covering all country-specific incremental costs, must exceed the revenue loss that its low price would cause through parallel trade or international price comparison in other markets'[109].

If not, the company simply would not supply in that market or would wait until better conditions would be negotiated. EFPIA provides evidence that this leads to unacceptable delays: Glaxo's refusal to accept a relatively low reimbursement price for its migraine medicine, Imigran, delayed its launch in France for several years even though it had already been approved and there was large potential demand. It seems that the same is true in other low price countries in the EU, where companies are withholding or delaying releasing new products because they do not want to erode the prices they can earn in other markets.[110] These worries are exacerbated by the accession of new Member States to form a much-enlarged common market.

In summary, the main arguments used to prove that pharmaceuticals parallel trade within the EU is detrimental are that it:

- forces prices down to an artificially and unacceptably low level that reduces companies' profitability and investment budget
- brings no savings to patients, only to parallel traders themselves
- erodes Europe's R&D base with subsequent detriment on its economic performance
- May lead manufacturers to adopt measures detrimental to consumers, such as delaying launch of a product

[109] PM Danzon 'The economics of parallel trade' Pharmacoeconomics 1998, Mar 13(3), 293-304

[110] EFPIA 'Art 82: can it be applied to control sales by pharmaceutical manufacturers to wholsalers?' EFPIA study, November 2004

5 Pharmaceutical parallel trade in an enlarged European Union

5.1 Introduction

On May 1, 2004, ten new Member States joined the European Union.[111] This entails that they have accepted the *acquis communautaire*, that their national laws therefore reflect EC law rights and obligations that are contained both in the founding Treaties and secondary law. This is specifically expressed in the Act of Accession: by virtue of Articles 2 and 10 of the Act of Accession, Community law applies completely and *ab initio* in all the acceding countries and allows for derogations only where specifically provided. Thus, all the rules on parallel trade that have so far been discussed would apply also in the accession States. The great challenge this would represent was recognised by the Pharmaceuticals unit of DG Enterprise[112], so one of its key tasks was to help pharmaceutical registration authorities in CEE States to prepare for EU membership- not only in terms of incorporating the *acquis* but also in terms of adapting their administrative machinery and societies to make the *acquis* work in practice. One specific measure that was adopted was the introduction by CEE country regulatory drug authorities of a common simplified procedure for authorising the use of Community-authorised medicines on their territory,[113] effective from 1 January 1999. To this effect the new Member States formed a Collaborative Agreement with Drug Regulatory Authorities in EU-associated Countries (CADREAC). This simplified procedure then allowed marketing authorisation to be granted to medicinal products that had already been authorised within the EU using the centralised procedure. Work was also undertaken on the authorisation procedure of drugs subject to the mutual recognition procedure: Once accession countries had harmonised their national procedures to EU standards, authorisations granted in accession States would be mutually recognised by existing Members.[114]

However, there is still significant divergence in economic and health conditions between 'old' and 'new' Member States as well as important differences in the level of patent or supplementary protection in the new CEE States[115], which opens up new avenues for increased parallel trade

According to the latest EFPIA data[116], the average income per capita of acceding States is about one third of the average income per capita in the EU-15, the health status is significantly lower than in the EU-15, threats to health are increasing, and

[111] The ten new Member States are: Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia and Slovenia.
[112] The Pharmaceutical Unit website http://pharmacos.eudra.org
[113] DG Enterprise publication 'Pharmaceuticals in the European Union', 2000
[114] Reuters Business Insight
[115] O Lemaire 'Parallel trade of pharmaceutical products within the enlarged European Union' [2005] EIPR 43
[116] EFPIA 'The Pharmaceutical Industry in Figures 2004'

the share of GDP devoted to the health sector is about half (4.5%) of the share devoted by the EU (8.4%). At the same time, acceding countries' markets are characterised by a strong presence of local generic manufacturers as well as a lack of transparency of pricing and reimbursement of pharmaceuticals compared to the European standard. In comparison with the EU-15 life expectancy is still low (as low as 65.2 years for males in Estonia, in 2002[117]), and mortality rates are high (highest in Latvia: 13.9 per 1,000 population, in 2000[118]), so great efforts are likely to be made to raise standards in the acceding countries to levels comparable to the old Member States. All of these factors represent ideal conditions for the exploitation of parallel trade.

As discussed, according to the rule in *Merck v Stephar*[119], the principle of Community exhaustion will apply even if the product was placed on the market of a Member States where it was not patentable. In the eight new CEE Member States[120], pharmaceutical products were not patentable until the 1990s. Therefore, the patentee in the country of importation would not be able to object to the parallel importation and goods would be able to flow freely from the new into the old Member States.

5.2 The 'Specific Mechanism'

Following intense lobbying by the pharmaceuticals industry, a provision in the Accession treaty was agreed upon to suspend the application of this rule temporarily. The 'specific mechanism' can be found in Chapter 2 (Company Law) of Annex IV of the Act of Accession.[121] It reads as follows:

"With regard to the Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland, Slovenia or Slovakia, the holder, or his beneficiary, of a patent or supplementary protection certificate for a pharmaceutical product filed in a Member State at a time when such protection could not be obtained in one of the abovementioned new Member States for that product, may rely on the rights granted by that patent or supplementary protection certificate in order to prevent the import and marketing of that product in the Member State or Member States where the product in question enjoys patent or supplementary protection, even if the product was put on the market in that new Member State for the first time by him or with his consent.

Any person intending to import or market a pharmaceutical product covered by the above paragraph in a Member State where the product enjoys patent or supplementary protection shall demonstrate to the competent authorities in the application regarding that import that one month's prior notification has been given to the holder of the beneficiary of such protection."

[117] Eurostat, Statistics in Focus, 20/2003
[118] Idem
[119] Case 187/80 *Merck & Co Inc v Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063
[120] All acceding States excluding Cyprus and Malta
[121] [2003] OJ L 236/33

Although legal commentators are very unhappy about the wording of this provision[122], it is clear that the objective of inserting it was to avoid a huge amount of parallel trade occurring. It allows producers that marketed products in an acceding country before pharmaceuticals could be protected by patents to prevent parallel trade even after May 1, 2004.[123] It is therefore a limitation on parallel trade from the low price acceding countries into the existing Member States. As Lemaire[124] summarises:

'In a nutshell, the specific mechanism provides that the holder of a patent or SPC (Supplementary Protection Certificate) covering a pharmaceutical product in a Member State can block the parallel trade of that product in any of the new CEE Member States by or with its consent, provided the product was not afforded the same level of patent protection in the CEE state of export.'

Since the first paragraph of the Specific Mechanism provides a clear and precise right, which is not subject, in its implementation or effects, to the adoption of any subsequent measure, it is directly effective and must therefore be applied unconditionally by national courts and authorities.[125] However, it is not a substantive guarantee. As Heath clarifies,[126] the specific mechanism only means that the parallel importers cannot invoke provisions of the free movement of goods to overrule domestic patent law. It is not a provision to determine which rights a patentee should enjoy under domestic patent law, because it already takes those rights as a starting point.

The operation of the specific mechanism can be compared to similar measures taken at the time of accession of the southern European States. The Act of Accession of Spain and Portugal (as well as the Agreement on the EEA for Finland and Iceland) also contained a temporary exception to the free movement of goods principle.

Lemaire has compiled a list of questions to be asked that will determine the applicability of the specific mechanism to individual products:

1. Is the product being exported from one of the eight CEE Member States?
2. If so, is the product protected by a valid patent and/or SPC in the importing country?
3. If so, is the product protected by a parallel valid patent and/or SPC in the exporting country?

[122] Commentators such as Lemaire, Feddersen and Heath recognise that the provision is riddled with ambiguity, not least because the different language version use different legal terms. Disputes are therefore envisaged on matters such as the term of protection offered, the territorial scope and the notification period, to mention but a selection.
[123] T Feddersen ' Parallel trade in pharmaceuticals in a Europe of 25: What the 'specific mechanism' achieves and what it does not' [2003] EIPR, v.25, n.12, 545-555
[124] O Lemaire, see FN 115
[125] Idem
[126] C Heath 'Parallel imports of patented pharmaceuticals from new EU accession States' 2004 ICC, International Review of Industrial Property and Competition Law 2004, v.35, n.7, 776-787

(a) If so, the product can move freely from that Member State into the country of import.
(b) If not, it will be necessary to determine why the level of patent or supplementary protection in the country of export differs from that available the country of import. Import may then be prohibited.

5.3 Case study: Poland

Dzitko provides the perspective of an acceding Member State on the effect of the specific mechanism in practice[127].

Poland is the largest of the acceding States and in fact now ranks sixth in terms of population in the EU-25. At the same time, however, Poland has a GDP rate way below the European average: $ 9,000 compared to $ 23,000- it is ranked 21st out of the 25 countries on an economic scale, and although forecasts vary, it is clear that it will take many years before the European GDP average will be reached.[128]

Dzitko argues that the pharmaceuticals market will play a key role in this integration process because it will enable all Europeans a better standard of living through access to effective and affordable medicines. Pre-accession this was not the case in Poland. This was due to certain characteristics of the Polish pharmaceuticals market:

Although the sector had shown remarkable growth throughout the 1990s, increasing from € 970 million in 1992 to € 2.9 billion in 2002, per capita pharmaceutical expenditure in Poland was still only € 73 in 2002. This is way below even the traditionally low price EU 15 Member States. Greece, for example, has a per capita spending of approximately € 180, whereas Spain spends about € 200. At the same time a study by IMS shows that prices for 'typical products' in Poland are at the same level or in certain cases even higher as in Germany, a well-established high price pharmaceutical market in Europe[129]. In addition, Poland's national health system is based to a much more significant extent on patient co-payment than other countries, a fact that translates into a bill of nearly €1 billion per year that patients themselves are footing. This clearly results in poor access to medicines for Poles, as many will choose not to buy medicines faced with the unaffordable prices.

Dzitko therefore argues for parallel trade as the solution to this problem: patients and hospitals would be paying less because there would be increased competition from parallel imports and therefore pressure to cut down prices of directly distributed pharmaceuticals. He refers to figures illustrating that price competition from parallel trade does have a direct influence on the price of brand-name products: Between 1995 and 1998 those products that faced such competition

[127] T Dzitko 'Enabling access to modern medicines at reasonable prices' Business Briefing: Pharmagenerics 2003
[128] One study suggested that Poland would need as long as 24 years. Socio-Economic Indicators Center (SICENTER), Slovenia, www.sicenter.si
[129] IMS Health, "Parallel trade 2003- a concise guide', PPR Communications Ltd

underwent a price increase of only 0.73% while prices of products not subject to parallel trade competition increased by 4.74%. (A similar finding to that reached in Ganslandt and Maskus' study in Sweden, see Chapter 4.2.2). He is therefore opposed to the specific mechanism, arguing that it will slow down the integration process. He is in favour of as much parallel trade as possible, to truly achieve a single market in pharmaceuticals so that prices can fall, Poland can turn into a main source market for parallel trade products, and access to medicines and efficient health care will become a reality. The pharmaceutical industry, however, clearly does not agree, seeing all the negative effects simply increasing exponentially upon enlargement.

5.4 Parallel trade after enlargement

EU enlargement offers access to a wider market both for branded as well as generic products, CEE countries have large populations and publicly funded healthcare systems whose development will be sped up by accession so that expenditure on pharmaceuticals will increase. However, the financial constraints of such dramatic growth will soon be felt and recourse to parallel imports is likely to ensue. It is therefore not clear whether enlargement will benefit mainly patent holders or parallel importers. The specific mechanism will of course ease fears in the short to medium term, yet as Nazzini points out it is not a solution to the overall threat of parallel trade. It seems that in the long term parallel trade will experience significant growth, once the specific mechanism's temporary protection expires and CEE markets have had a chance to adapt: it will take some time before manufacturers from new Member States can increase production in such significant amounts to be able to flood the market. They will also have to spend time and capital investment in upgrading their facilities to comply with EU Good Manufacturing Practice (GMP)[130]. Not enough research has yet been undertaken or published to be able to conclude on the effects of enlargement, but the preliminary findings can be interpreted in either direction to support arguments both in favour and against parallel trade. The EAEPC, for example, claims that the special mechanism is not justified in terms of health or economics. It believes that the mechanism has the effect of barring old Member States from benefiting from saving associated with parallel trade while granting new Member States an unfair advantage because they will be able to enjoy the savings immediately upon entry into the EU. It furthermore claims that around 60% of products by volume produced in accession countries are locally produced copies and therefore ineligible for parallel trade in any case. Furthermore, since patent protection started in 1990 in the CEE States, i.e. nearly 15 years pre-accession, the transitional period in which to comply with EU standards is redundant. Donald MacArthur, the EAEPC Secretary General voiced his concerns in April 2003 that:

'the special mechanism is nothing more than an export ban designed to benefit western multinational pharmaceutical companies by protecting them from free and fair competition – the European consumer is the loser from this derogation'.

[130] R Nazzini 'Parallel trade of pharmaceuticals- a prescription for success or a free market overdose' ECLR 1998, 19(6), 332-342

On the other hand, the pharmaceuticals industry, the main advocate of the specific mechanism, sees it as its rightful protection against the disproportionately large influx of parallel trade from the much cheaper new Member States.

6 The Commission's approach

6.1 Introduction

The Commission then has the difficult task of finding a solution that is acceptable to all the different actors and that provides the best conditions for consumers in the EU. However, the main considerations that shape central EC policy do not necessarily coincide with the worries that are considered most significant by the other concerned parties, there are even marked differences between the Member State governments' views and the Commission's view. The funding of health care, for example, is not a central EC responsibility and therefore controlling levels of expenditure will not rank as highly in the Commission's list of concerns.

Another problem is that the Commission's involvement happens on two levels that are often hard to reconcile:

1. Promotion of the single market
2. Ensuring a high level of health provision across the Community[131]

Increasingly this tension is making it difficult for the Commission to decide on an approach to take with regard to pharmaceuticals since such different goals are being pursued. The question is whether the point of departure should remain rooted in the industrial policy perspective, so that the main goals are to encourage competitiveness and innovation; or whether the emphasis should instead be placed on health and consumer protection concerns, with the main focus on access to affordable medicines and the establishment of a true single market. An effort to reconcile these objectives was recently made by the Commission with the establishment of the G10 Medicines Group, which was chaired jointly by the Commissioners for DG Enterprise and DG Health and Consumer Protection, and involved representatives of Member States, different sectors of the industry, mutual health funds and a specialist in patient issues.[132] The Group's objective was to reconcile the 'twin goals of both encouraging innovation and competitiveness and ensuring satisfactory delivery of public health and social imperatives'.[133] However, both the G10 Group as well as previous discussions under Commissioner Bangemann, the so-called Bangemann Round Tables[134] failed to address the matter of parallel trade specifically, let alone provide any acceptable solution. It seems that the Commission still repeatedly ignores the specific features of the pharmaceuticals market, and is unsure what direction to take. Partly, the Commission is constrained in its approach by the legal framework it operates in:

[131] L Hancher 'The European Community dimension: coordinating divergence' in E Mossialos, M Mrazek and T Walley (eds) *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* European Observatory on Health Care Systems (2004)
[132] See webiste: http://pharmacos.eudra.org/F3/g10/g10home.htm
[133] High Level Group on Innovation and Provision of Medicines, *G10 Medicines Report*, 07.05.2002
[134] Held at Frankfurt 1996-1998

The basis for policy making in the health care sector is Article 152 EC, as amended by the Treaty of Amsterdam. It extends Commission competence only to a limited extent in relation to health policy, and thus competence is intended to be carried out at the lowest effective level in line with the principle of subsidiarity. Member States accordingly defend their right to set their own health care policies. [135]

Article 152 states that 'Community action in the field of public health shall fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care'. Thus, although the EU has a public health mandate and is bound to the objectives of a wide-ranging Community Action Programme for Public Health[136], its influence is restricted. As detailed above, the EMEA is limited to issuing recommendations and has no power of sanction, and matters of pharmaceutical pricing and reimbursement remain firmly in national competence.

Therefore, the central policy approach has been leaning increasingly towards an industry-orientated stance. Hancher argues that this translates into a situation where higher retail prices are acceptable to the extent that they reward the research-based industry and consumer protection issues such as guaranteeing medicines at a fair price are then left up to the national authorities to deal with[137]. This emphasis on industrial policy is very apparent in the Commission Communication 'A stronger European-based Pharmaceutical Industry for the Benefit of the Patient- a Call for Action', 2003. The Commission recognises that the pharmaceutical industry can make a major contribution to the Lisbon Objectives of turning the EU into the most competitive and dynamic knowledge-based economy in the world, capable of sustainable economic growth with more and better jobs and greater social cohesion. It bases much of its conclusion and therefore its policy direction on the report prepared by Gambardella et al that concludes that Europe is losing out on the innovativeness front and is lagging on the global scene in terms of competitiveness in pharmaceuticals[138]. The Commission feels that the adequate response to tackle this problem is to create a truly unified single market. It proposes to use industrial policy not only as a goal in itself to promote economic aims, but also as a vehicle to counter-act public health concerns. The Communication again reiterates that a genuine single market would achieve the twin goals of patient welfare and increased R&D investment.

This approach now seems firmly to be the one advocated, and it has been stated that 'the EU's main goal for the pharmaceutical sector has thus been the deregulation of

[135] G Permanand and C Altenstetter 'The politics of pharmaceuticals in the European Union' in E Mossialos, M Mrazek and T Walley (eds) *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* European Observatory on Health Care Systems (2004)

[136] The latest programme was adopted on 23 September 2002 and encompasses an action programme for 2003-2008 that focuses on better provision o health information, rapid reaction to health threats and tackling health determinants.

[137] L Hancher 'The European pharmaceuticals market: problems of partial harmonisation' ELRev 1990, 15(1), 9-33

[138] A Gambardella, L Orsenigo and F Pammolli 'Global Competitiveness in pharmaceuticals, a European perspective' Report prepared for DG Enterprise November 2000

national markets…..the underlying concern of the EU regime has been to liberalise the pharmaceutical market within the context of the single European market'.[139]

In line with this argumentation, parallel trade has consistently been hailed as a positive phenomenon that drives down prices so that consumers end up paying a price that reflects the costs of production and therefore forces companies to work on an efficient basis. The general conclusion is that parallel trade should not be restricted in the pharmaceutical sector any more than in other markets.

This approach is illustrated by publications issued by the Commission, speeches of Commissioners, as well as through decisions relating to the enforcement of Treaty rules.

A summary of DG Competition's position can be found in Commissioner Monti's speech 'Competition and Consumer: the case of pharmaceutical products' at the European Competition Day in Antwerp, October 2001[140]. He states that the 'merciless policy' against companies trying to prevent parallel trade makes sense also in the pharmaceuticals sector even though the industry claims otherwise. He argues that the industry is wrong in stating that parallel trade in medicines harms consumers and brings no benefits at all for consumers in the high price countries, and refers to the GlaxoSmithKline decision[141] for further elaboration. This position can also be found in the DG Enterprise publication 'Parallel trade of pharmaceuticals' of 2000, which mentions only benefits of parallel trade: the basic starting point is that parallel trade is not harmful in terms of supply patterns because it can only operate where surplus quantities to national demand exist, and that it then contributes positively to national economies in terms of ensuring competition, reducing costs of pharmaceutical spending for consumers, health care providers and governments, creating jobs, and paying various additional taxes. It refutes the arguments that parallel trade cause detrimental effects to the R&D based industry by referring to the industry's ever increasing profits. The publication also relies on a figure of total parallel trade penetration of only 1.4% (quite different from the figures discussed in the chapters above). The main conclusion then is that the interests of shareholders and investors may not be put before those of citizens and that therefore 'parallel trade must be encouraged, not risked'. Although the concern about R&D is shared with opponents to parallel trade, the Commission's approach directly contradicts their proposed solution.

The two main avenues open to the Commission to pursue its goal of a single European market and thereby translate its policy into practice are:

- Positive harmonisation through regulations and directives. As discussed above this has occurred in the limited field of marketing authorisation and the Directive on Pricing Transparency.

[139] Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the regions- A stronger European-based pharmaceutical industry for the benefit of the patient- A call for action' COM(03)383 final
[140] SPEECH/01/450 of 11/10/2001
[141] C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and Others v GlaxoSmithKline* Opinion of Advocate General Jacobs 28 October 2004 (see next chapter for further details)

- 'Negative' harmonisation through the enforcement of Treaty rules, particularly on competition and free movement. Although this occurs on an *ad hoc* basis in specific cases brought usually following a complaint or a Commission investigation, it does give guidance on the Commission's approach. It is therefore particularly useful to look at the most important and recent decisions concerning parallel trade in order to establish the Commission's point of view.[142]

6.2 Organon[143]

This case concerns Commission proceedings initiated against Organon Laboratories Limited, a British subsidiary of Akzo Nobel. They were initiated under Article 85 EC (now 81 EC) following Organon's notification to the Commission of a new pricing system for its contraceptive pills. This new system restricted a 12.5% discount given to wholesale customers within the UK to those that would sell pills only in the UK. Previously the discount had been available for all products regardless of their final destination. This was, of course, intended to prevent parallel import of these contraceptive pills (Marvelon and Mercilon) - particularly into the Netherlands- and parallel importers therefore objected. The Commission tackled the issue by using the competition rules, and more specifically found that the new price regime formed part of a continuous business relationship between Organon and its wholesalers and could therefore be treated as an agreement for the purposes of Article [81] EC. Since it differentiated prices of products according to the final geographical destination of the product, it led to a division of the single market along national borders. It would affect parallel trade in Marvelon to the Netherlands and thus the Commission made it known that is wished to adopt a decision under Regulation 17/62 withdrawing immunity from fines that would have ensued following Organon's initial notification.[144] Consequently, Organon decided to abandon its new pricing mechanism so that an official decision by the Commission was never needed. This case is however illustrative of how the Commission uses tools such as the strict interpretation of an agreement in Article 81 EC to combat any obstacles to parallel trade.

Commentators feel that Organon is one example of the blind policy adopted by the Commission that does not take market realities into account. Kon and Schaeffer[145] argue that the Commission was wrong to treat their pricing policy as action restricting competition because the distortions were created not by the activities of the individual market participants but by the system of regulation itself. Thus the initial practice of granting discounts on certain products was not in any way initiated by Organon unilaterally or even in agreement with any other undertaking, but was instead a direct result of the UK Pharmaceutical Price Regulation Scheme

[142] This paper will restrict itself to developments in competition law.
[143] IP/95/1345
[144] Article 15(6), Reg 17/62
[145] S Kon and F Schaeffer 'Parallel imports of pharmaceutical products: a new realism or back to basics' ECLR 1997, 18(3), 123-144

(PPRS) which governs the maximum amount of annual return on capital employed that is permitted for pharmaceutical companies operating in the UK. This scheme in practice allows oral contraceptives to be supplied to the consumer at no cost. In the Netherlands, Dutch-originating Marvelon is not fully reimbursable under the relevant social security scheme, and so the difference in pricing was a direct consequence of the different national reimbursement regimes. It seems that consumers in the Netherlands were not affected in any way by the new pricing scheme in the UK: they had no more difficulty obtaining and didn't pay more for supplies of parallel imported Marvelon than before, and it is hard to understand why an undertaking should be compelled to apply a discount structure which is unique to the UK reimbursement system to products that are sold in other Member States subject to different health care regimes.

Kon and Schaeffer therefore argue that the Commission's approach is inappropriate on two separate levels: firstly, it does not take into account the actual responsibility of the companies involved and ignores the realities of the structure of the pharmaceuticals market; and secondly, the Treaty competition provisions are not the most effective way to achieve greater integration and are not the appropriate method to do so because the partitioning of national pharmaceuticals markets is attributable to the failure to harmonise different regulatory regimes.

6.3 Glaxo Wellcome[146]

Another recent decision that has been subject of much academic criticism is that concerning the dual pricing regime set up by Glaxo Wellcome in Spain. Although in this decision the Commission goes into great detail about the reasons for its fine, it refutes in its entirety the argumentation and evidence put forward by the industry and again defends parallel imports with every possible tool available to it. This case was seen as particularly important by many because the Commission was confronted for the first time with an agreement that explicitly sought to restrict parallel trade but which the company sought to justify on economic grounds.[147]

Glaxo SA, the Spanish subsidiary of Glaxo plc, decided to introduce new sales conditions in an attempt to discourage parallel exports. The new pricing mechanism involved a two-tier system, whereby medicines financed by the funds of the Spanish social security or by Spanish public funds that were then sold within Spain were charged at a lower price than medicines destined for markets outside Spain. Essentially different prices were charged for the same medicine depending on final geographical destination. Glaxo notified this change of sales conditions under Articles 2 and 4 of Regulation 17/62 implementing Articles 85 and 86 of the Treaty[148] , hoping to obtain negative clearance or alternatively individual exemption

[146] 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 (compalint), EAEPC (complaint),* [2001] OJ L302/1

[147] L Hancher 'The European Community dimension: coordinating divergence' in E Mossialos, M Mrazek and T walley (eds) *Regulating pharmaceuticals in Europe: striving for efficiency, equity and equality* European Observatory on Health Care Systems (2004)

[148] OJ 13, 21.02.1963, p. 0204-0211

under Article 81(3) EC. The Commission did not, however, accept any of Glaxo's reasoning and instead held that the new sales conditions amounted to an export ban and dual pricing that had as their object to restrict competition. Therefore, the agreement entered into with the Spanish wholesalers introducing the pricing mechanism was prohibited under Article 81 EC and was consequently banned by the Commission. The decision has now been appealed to the CFI, but the Commission's staunch position as regards maintaining parallel trade is again very apparent. In particular, it is interesting to look at the reasoning of the Commission with regard to the particularities of the pharmaceuticals market. Glaxo advances many of the arguments outlined in Chapter 4.3 above, yet none of them are accepted.

As regards price regulation of the market and the argument that pharmaceutical manufacturers are no more than price takers who have to accept the prices set by national authorities, the Commission places great emphasis on the fact that pharmaceutical companies have much greater negotiating power than they make out when discussing prices for domestic sales. It argues that the negotiation on the price of medicines was 'open on the basis of price proposals made by the companies themselves. The Spanish authorities allow the companies to base their proposals on all their costs, including those related to R&D' ([121]). It concludes that 'the Spanish authorities leave room for real price bargaining and do not set the price unilaterally' ([122]).

As regards parallel trade as a threat to the EU's competitiveness in pharmaceuticals, the Commission blatantly disregards evidence suggesting that parallel trade from Spain endangers UK prices and therefore compromises the UK policy choice to foster R&D. The Commission instead argues that 'parallel trade constitutes only a very negligible percentage of pharmaceutical sales and can therefore only produce a marginal effect on the prices in the target country.' This is reinforced by the statistics that R&D costs take up only 15% of a company's turnover ([157]). In order to back up this statement, the Commission points out that the UK has always been and still continues to be a high priced market, with prices substantially higher than in other countries even after a long period of parallel trade by Spanish imports. This is used as proof that parallel imports have not affected UK prices.

Similarly, the Commission argues that there is no evidence that parallel trade has caused reductions in Glaxo Wellcome's R&D budget or that it has prevented that budget from growing ([155]). It relies on a statement made by GW itself, 'that parallel trade is not the key driver for decisions on R&D'[149] and refers to growth figures in R&D investment despite decline in total revenue. It also refutes the argument that there is a nexus between the loss of revenue resulting form parallel trade within the Community and the migration of R&D abroad, in particular to the US. It states instead that the reasons for choosing a particular research location are multiple and complex and cannot be blamed simply on parallel trade.

The policy implications are clear: companies will simply have to accept the national regulatory divergences.

[149] Frontier Economics Study II, p 7, submitted to the Commission by GW

The pharmaceutical industry was very disappointed by the Commission's approach: Brian Ager, EFPIA Director General, released a statement that 'EFPIA considers that the European Commission has taken an overly formalistic approach in applying the EC competition rules to protect parallel trade…the desire to create a single market for nationally price-controlled pharmaceuticals in Europe, through the encouragement of parallel trade, is unrealistic and damaging…'[150]

The damage can be felt both from an industrial policy perspective as well as a health policy perspective, as the two are intrinsically linked: any loss of investment in R&D resulting in innovation moving abroad may reduce prices for health care in the short run, but not only is this obviously a short-sighted economic return, it is also damaging from a long term social care perspective: past studies prove that innovative medicines have made major contributions to cost containment in healthcare.[151] In practice, this means that lack of innovation resulting in fewer new and effective drugs being placed on the market leads directly to higher national health service bills because of the lack of efficiency gains being introduced.

To sum up, the considerations to be taken into account by the Commission are many and complex, and often there is internal disagreement between different Directorate Generals on the approach to be taken, but the overall overarching concern at this stage is the promotion of the Single Market without exception. However, as discussed, there is great evidence to the extent that the market is so different from other sectors that the usual competition rules cannot be applied. It is therefore important to determine the approach adopted by the Courts.

[150] EFPIA press release 'European pharmaceutical industry disappointed by Commission's approach to parallel trade of medicines' 09.05.2001

[151] Attridge 'A single European market? Less regulation and more negotiaiton?' European Business Journal, 2003, v 15, nr 3

7 Recent developments in competition law

7.1 Introduction

The Commission is the first port of call in matters of competition law and will act against companies where it suspects a violation following a complaint or upon its own motion. If a decision is handed down, it is however legally binding only against its addressee, and often the decision will be appealed to the Courts. The Courts therefore have the vitally important task of reviewing the Commission's motivations and conclusions and handing down judgments binding on all. They are, therefore, equally as important in shaping EC policy as the Commission, although on a more ad hoc basis. However, most commentators recognise the seminal role the ECJ has played in the creation of the Single Market and realise that the bulk of the work towards true integration was done in the Courts.[152] In fact, some would even go so far as to argue that the ECJ in its activism was prepared to stretch the letter of the law to achieve the broader goals of the Treaty.[153]

It is therefore important to see how the Courts treat the matter of parallel imports within the ambit of competition law. Manufacturers are very creative in their attempts to try to discourage parallel trade, ranging from introducing differential price mechanisms to limiting the supply of medicines. EC competition law can restrict these practices in two ways: Article 81 EC prohibits any agreements between undertakings with the object or effect of restricting competition, whereas Article 82 EC targets dominant companies who abuse their position. Any measures introduced by manufacturers in an attempt to discourage parallel trade are susceptible to attack under these provisions. As the cases referred to them turn on points of law, often the main discussion and the deciding factors will be technicalities of competition law. But it is important at this stage to look beyond those technicalities and try instead to extract a general approach towards parallel trade, to determine whether the Courts have had a change of heart recently and are paying more heed to the voice of the industry.

This research is particularly pertinent at this stage because the ECJ for the first time in *Bayer* really looked into arguments regarding the nature of the market, and the AG in *Syfait* proposes a radical departure from the previous path.

[152] Through landmark cases such as Case 26/62 *Van Gend v Loos* [1963] ECR 1, Case 6/64 *Costa v Enel* [1964] ECR 585

[153] David Hull 'Parallel trade in pharmaceutical products in Europe: The Advocate General's opinion in *Syfait v GlaxoSmithKline'* Competition law insight, 09.11.2004

7.2 Article 81 EC: Bayer[154]

7.2.1 Background

The case of Bayer revolved around Bayer AG's heart medication, Adalat. In most Member States the price of Adalat is either directly or indirectly fixed by the national health authorities, in particular on the basis of internal reimbursement policies, and this resulted in a significant disparity of prices: Between 1989 and 1993, the prices fixed by the Spanish and French health care services were on average 40 per cent lower than in the UK. Similarly, the product has a strong market presence in the UK whereas the southern European Member States prefer other therapeutic alternatives to combat cardiovascular disease.[155] This fact made Adalat a prime target for parallel trade. In practice, there was, however, an obstacle to the unlimited parallel exportation of the product in the shape of national public service obligations. Due to the obligation on wholesalers to keep a sufficient stock of medicinal products to supply the monthly consumption of their regular pharmacy customers, they ordered huge quantities of the product in order to be able to supply the excess to the UK. Bayer AG estimates that sales of Adalat by its British subsidiary fell by almost half as a direct result of the exportation. This entailed a loss in turnover of DEM 230 million for the British subsidiary and represented a loss of total revenue to Bayer of DEM 100 million.[156]

In order to combat the parallel traders Bayer implemented a new supply policy aimed at making the parallel imports into the UK more difficult: it refused to supply the large quantities demanded by the wholesalers and instead introduced a quota system which was based upon previous orders and allowed a maximum ten per cent rise on the previous year's quantities so that there would be no excess available once the public service obligation had been complied with. An important factor is that Bayer at no time explicitly stated its motives behind the new policy; in fact, it even used shortages of supply as an excuse although it seems from evidence that all parties were well aware of the true motivation[157]. The wholesalers tried to find ways around the newly imposed limits by exaggerating the needs of their local markets. In order to do so they persuaded their local subsidiaries to inflate their orders by ten per cent and to then forward the excess to their head office which could, in turn, export to the UK. Other measures included being much more secretive about the final destination of deliveries and sending orders by registered

[154] Joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission* [2004] January 6 2004

[155] HH Lidgard 'Unilateral refusal to supply: an agreement in disguise' ECLR 1997, 18(6), 325-360

[156] EFPIA 'Article 82: can it be applied to control sales by pharmaceutical manufacturers to wholesalers?' EFPIA study, November 2004

[157] The Commission has a recording of a converstaion between Bayer France and a French wholsaler (CERP Boulogne) about the reasons for Bayer's refusal to fulfil the latter's supply requests: 'CERP thinks that it is deliberate Bayer policy to prevent the growth of parallel imports. I explained that we [Bayer] had very low stocks and our main concern was to supply the French market. CERP asked whether I took them for fools'. (see M Jephcot 'Commentary on case T-41/96 *Bayer AG vCommission'* ECLR 2001, 22(10), 469-476)

mail. Bayer soon realised what was happening and refused completely to provide any excess at all on the wholesalers' usual orders.

Following complaints by wholesalers, the Commission held that Bayer France and Bayer Spain had infringed Article [81] EC. Its reasoning was that Bayer had imposed an export ban on its wholesalers, who had complied with it and therefore tacitly agreed to the terms set by Bayer. Their conduct showed sufficient 'concurrence of wills' to be treated as an agreement that became an integral part of their business relationship, and was sufficient to fulfil the requirements of Article [81(1)]. Bayer was consequently ordered to cease the prohibition on exports and was fined ECU 3 million. The Commission's reasoning ran as follows: the wholesalers had implicitly agreed to the export ban in the course of their continuous business relationship with Bayer since they knew that the reason for limiting supplies was to prevent parallel exports and that they subsequently aligned their conduct to Bayer's requirements. This decision clearly shows the Commission's determination to defend parallel trade in all circumstances. It reached its conclusion based on a very wide interpretation of the meaning of 'agreement' under Article 81 EC. The Commission used the Treaty rules in a very formalistic way to come to the desired result, and greatly stretched the notion of 'agreement'.

Thus the central facet of the case turned around the definition of 'agreement' as interpreted by the different parties. The Commission took a very wide view and based its conclusions on previous case-law, drawing an analogy to *Sandoz*[158] and the *Johnson & Johnson* decision[159] in particular. In *Sandoz*, distributors were held to have tacitly agreed to an export prohibition where Sandoz systematically reduced customers' orders and stated on the invoices to wholesalers that export was prohibited. Although the export ban was printed on the invoices and distributors therefore only found out about this condition after the purchase agreement had been entered into, it was held to form part of a continuous business relationship between Sandoz and its distributors and could thus be treated as an 'agreement'. It was held that the fact that the invoices were systematically used meant that the clients implicitly agreed with its terms. In fact, the reasoning goes so far as to imply that a failure to object amounts to tacit agreement. In the Commission's words:

'an agreement within the meaning of Article 85(1) requires an interest of the two parties in concluding that agreement, without the interest necessarily being held in common. Here, the applicant's interest was to prevent, or at least reduce, parallel exports. The wholesaler's interest was to avoid a reduction in supplies of Adalat' ([39]).

Although there was therefore no community of interest, both parties had sufficient interest of some sort.

This is of course a very broad interpretation and the Commission in *Bayer* was trying to build upon this reasoning and further extend it to the situation at issue where there was no explicit export ban, but where this was the understood hidden

[158] Case C-227/87 *Sandoz v Commission* [1990] ECR I-45
[159] 80/1283/EEC: Commission Decision of 25 November 1980 relating to a proceeding under Article 85 of the EEC Treaty (IV/29.702: *Johnson & Johnson*) [1980] OJ L377/16

motive. Similarly in *Johnson*, distributors accepted an unwritten export prohibition imposed by the manufacturer, which applied a monitoring system and threatened to suspend or delay supplies that would ultimately reach parallel exporters.

Effectively, the Commission in Bayer was arguing that the Treaty imposes a general, per se prohibition on hindrances to parallel trade.

However, signs that the Commission was pushing its policy too far can be seen already from the Order of the President of the Court of First Instance.[160] Interestingly, the President of the CFI granted Bayer's application for suspension of the operative part of the Commission's decision until final judgment. He did not accept the analogy to *Sandoz* or the *Johnson & Johnson* decision because Bayer did not make use of an express export prohibition, and accepted that given the economic harm Bayer had incurred, it had a legitimate interest in taking unilateral measures to limit parallel trade in Adalat. This is important because it is the first indication that the Commission's assessment may be faulty because it did not take into account the economic realities of the pharmaceuticals market, and that the industry's concerns may finally stand a chance of success.

7.2.2 The CFI judgment

7.2.2.1 Meaning of 'agreement' in Article 81 EC

On appeal, the CFI had to deal with Bayer's main argument that the Commission's analysis would remove a central element from the concept of agreement within the meaning of Article [81], namely the existence of a joint intention. It argued that its policy was entirely unilateral and should therefore escape attack under Article [81] EC.

Faced with these two views, the CFI came to the conclusion that here no agreement had been entered into. In coming to this conclusion the CFI referred to established case law to the effect that Article [81(1)] concerns only conduct that is co-ordinated bilaterally or multilaterally; any 'decision on the part of a manufacturer which constitutes unilateral conduct escapes the Article [81(1)] prohibition.'[161] It then continued:

'it is also clear that, in order for there to be an agreement, it is sufficient that undertakings have expressed their joint intention to conduct themselves on the market in a specific way[162]. As regards the form in which that common intention is expressed, it is sufficient for a stipulation to be the expression of the parties'

[160] ECR 1996, page II-00381
[161] Cases 107/82 *AEG Telefunken AG v Commission*[1983] ECR 3151, Case C-25/84 *Ford and Ford Europe v Commission* [1985] ECR 2725,Case 43/92 *Dunlop Slazenger v Commission* [1994] ECR II-441
[162] Case 41/69 *ACF Chemiefarma v Commission* [1970] ECR 661, Case 209/78 *Van Landewyck v Commission* [1980] ECR 3125, Case T-7/89 *Hercules Chemicals v Commission* [1991] ECR II-1711

intention to behave on the market in accordance with its terms,[163] without its having to constitute a valid and binding contract under national law.[164]' ([67] and [68])

The CFI then concluded at [69]:

'the concept of an agreement within the meaning of Article [81(1)] of the Treaty, as interpreted by the case law, centres around the existence of a concurrence of wills between at least two parties, the form in which it is manifested being unimportant so long as it constitutes the faithful expression of the parties' intentions.'

However, it also made clear that:

'a distinction should be drawn between cases in which an undertaking has adopted a genuinely unilateral measure, and thus without the express or implied participation of another undertaking, and those in which the unilateral character of the measure is merely apparent'. ([71])

It went on to state that tacit acquiescence may be enough to establish agreement but that the Commission had not proved its case on this point, that in fact evidence was lacking to prove both the export ban and the alleged agreement. The CFI felt that the reduction of supplies could not amount to an export ban because Bayer did not implement any policy of systematic monitoring of the actual destination of the products supplied. It was important in this respect that no intention to monitor the conduct of each wholesaler could be proved, and that no system of penalties was implemented in case of exports.[165] Similarly, the CFI felt that not sufficient evidence had been provided to show that Bayer had attempted to get the acquiescence of the wholesalers to the implementation of its policy. A factor that was important in reaching that conclusion was that the wholesalers actually openly resisted the new policy and tried to find ways to circumvent the rules.

This is also why the case law relied on by the Commission could be distinguished. In *Sandoz,* for example, the conclusion that the export ban formed part of the general framework of commercial relations was only reached after a very careful examination of the detailed authorisation procedure implemented by Sandoz. The fact that Sandoz carefully examined every new customer before allowing it to market its products and the fact that the conditions of supply were used repeatedly and uniformly for each sales operation were instrumental. Additionally, Sandoz actually used an explicit clause prohibiting export and wholesalers complied with it without complaining. This more than anything indicated their tacit acquiescence to that clause. The CFI felt that those circumstances were in stark contrast to the situation in Bayer, where no cooperation was necessary on behalf of the wholesalers ([163]).

[163] *Chemiefarma* and *Van Landewyck,* see FN 162
[164] *Sandoz,* see FN 158
[165] M Jephcot 'Commentary on case T-41/96 *Bayer AG v Commission*' ECLR 2001, 22(10), 469-476

This clarifies that the CFI placed the burden of proof in a number of important respects on the Commission and as Jakobsen and Broberg[166] have pointed out,

'the burden of proof plays a prominent role in the clarification of whether a given conduct falls within the concept of agreement….in the Bayer case the CFI found that on a number of central issues the burden of proof lay with the Commission. This was most certainly the main reason why Bayer won the case.'

The CFI, therefore, most definitely did not accept the Commission's arguments to the effect that the Treaty rules establish a per se prohibition on restrictions on parallel trade. The CFI considered that 'the reasoning in *Merck and Beecham*[167], contrary to what the Commission claims, does not in any way presume a general prohibition on preventing parallel exports, applying not only to member States but also, and in all cases, to undertakings.'[168] This conclusion, taken together with the CFI's acceptance of a non-dominant supplier's attempts to restrict parallel imports as well as its conclusion that the existence of an intent to restrict parallel trade by the supplier is not sufficient to give rise to an agreement suggests, according to Rey and Venit[169], that the CFI does not consider the protection of parallel trade as an overarching goal of Community law. Thus, the CFI expressly recognised that pharmaceutical companies have a legitimate right to restrict parallel trade- provided the supplier's actions do not infringe the Treaty competition provisions.

This outcome seems to be in conformity both with the provisions of the Treaty as well as sound industrial policy and has been praised by many commentators[170]. From an industrial policy perspective it makes economic sense to allow non-dominant companies to design their strategies in what they perceive to be the most effective manner, as long is it does not endanger the competitive climate in the European Union.

In this respect, the ECJ agreed fully with the CFI's reasoning and reached the same conclusions, making them authoritative and binding.

To sum up, it seems that a non-dominant undertaking is able to limit parallel trade in its products as long as its conducts is truly unilateral, that is to say there should be

- no reference, either direct or indirect, to the quota system in any distribution agreement. Distributors should not in any way be given incentives to comply with the policy be it positive or negative incentives, e.g. in the form of penalties;

[166] PS Jakobsen and M Broberg 'The concept of agreement in Article 81 EC: on the manufacturer's right to prevent parallel trade within the European Community' ECLR 2002,, 23(3), 127-141
[167] Joined cases C 267/95 & 268/95 *Merck and Beecham* [1996] ECR I-6285
[168] 96/478/CE Commission decision of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3- ADALAT) at [178]
[169] P Rey and J Venit 'Parallel trade and pharmaceuticals: a policy in search of itself' ELRev 2004, 29(2), 153-177
[170] See specifically on this point HH Lidgard 'Unilateral refusal to supply: an agreement in disguise' ECLR 1997, 18(6), 325-360

- no explicit or tacit agreement. The manufacturer should avoid discussions with wholesalers that imply mutual awareness of the quota system.[171]

7.2.2.2 Constitutional issues

The second aspect of the CFI judgment was its express rejection of the Commission's policy of relying on parallel trade to achieve price uniformity. It stated that the Commission's belief that parallel trade would ultimately lead to price harmonisation was not proven (that it was 'devoid of all foundation' [181]) and went on to raise constitutional concerns regarding the use of the competition provisions as a means of achieving the single market:

'it is not open to the Commission to attempt to achieve a result, such as the harmonisation of prices in the medicinal products market, by enlarging or straining the scope of Section 1 (Rules applying to undertakings) of Chapter 1, Title IV of the Treaty, especially since that Treaty gives the Commission the specific means of seeking such harmonisation where it is undisputed that large disparities in the prices of medicinal products in the Member States are engendered by the differences existing between the state mechanisms for fixing prices and the rules for reimbursement as is the case here' ([179]).

This paragraph highlights two important aspects: a) that the CFI is taking into account the realities and economics of the pharmaceuticals sector and b) that the CFI is questioning the approach taken by the Commission, criticising the Commission for straining beyond credibility the notion of an agreement when the root of the problem lay with the Commission's failure to properly harmonise the market. In other words, the Commission should not abuse its quasi-judicial power in competition law cases by stretching the Treaty rules in order to attain the ideological objective of a Single Market. However, the CFI also notes that such distortions should not be remedied by the Courts either, but should be tackled systematically by the Community legislature. This is in line with previous ECJ statements, such as in *Centrafarm v Winthrop*[172] or *Bristol-Myers Squibb and Others*[173] and is reassuring in terms of legal certainty.[174] It is also in line with the provisions and division of competencies that can be found in the Treaty. It is important therefore at this stage to determine what mechanisms the Treaty sets out to achieve harmonisation and the single market objective.

Article 2 EC lists the Community's goals as including the establishment of a common market. According to Article 3(g) EC, it must also try to establish 'a system ensuring that competition in the common market is not distorted'. The

[171] Howrey Client Alert 2004 'Is it possible to limit parallel imports by restricting sales to whloesalers?'
[172] Case 16/74 *Centrafarm v Winthrop* [1974] ECR 1183, para 17
[173] Joined Cases C-427/93, C-429/93 and C-463/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457, para 46
[174] O Lemaire and M Meulenbelt 'Adalat and Kohlpharma- where now for parallel trade in the European Union?' RAJ Pharma July 2004, 499-505

reconciliation of these different aims can be difficult and a sensitive issue, as can be seen from the CFI's comments. For our purposes, Article 14 then states that 'the Community shall adopt measures with the aim of progressively establishing the internal market' and refers to Article 95 EC. Article 95 EC in turn provides that the Council will adopt these measures that are expressly referred to as 'harmonisation measures' (Article 95(3)) in accordance with the procedure set out in Article 251 EC, which means that they should be based on a Commission proposal, be subject to the opinion of the Parliament and be approved by a qualified majority in the Council.

Importantly, the European Community functions on the basis of the principle of conferred powers as embodied by Article 5 EC, which provides that the 'Community shall act within the limits of the powers conferred upon it by this Treaty and of the objectives assigned to it therein'.

Thus, as a result of these provisions it is clear that any harmonisation with regard to the internal market should be a legislative act that embodies important political elements in the shape of both Parliament and Council involvement. It is therefore not surprising that the CFI objected to the use of competition rules as a means of harmonisation.

7.2.2.3 Competition law as a means of furthering integration

Surveying past case law, it becomes obvious that EC competition law has always been used as a vehicle for promoting secondary aims, yet it seems that now a fine line has been crossed. Already in 1964, the ECJ in the *Consten-Grundig* case[175] made clear that Community rules on competition also serve the purpose of 'integration', whereby the establishment of a common market is a particular form of integration. In fact, some commentators go so far as to argue that 'what glues all the provisions of the EEC Treaty together into a coherent whole, is named 'integration'[176].

Integration has in this context been defined as the interdependency of Member States as carried out with the assistance of the Community, whereby Member States are subject to a common decision-making structure and an increasing assimilation of both their countries and societies,[177] and more particularly economic integration has been defined by Pelkmans as 'the elimination of economic frontiers between two or more economies'.[178] In *ICI*[179] the Court defined this concept by referring to

[175] Joined cases 56 and 58/64 *Établissements Consten SARL and Grundig-Verkaufs-GmbH v Commission* (1996) ECR 299
[176] RB Bouterse *Competition and Integration- What goals count?* Kluwer Law and Taxation 1994
[177] M Zuleeg in H von der Groeben, H Von Boeckh, J Thiesing and C Ehlermann *Kommentar zum EWG-Vertrag* (Baden- Baden 1983)
[178] J Pelkmans in M Cappellatti, M Seccommbe and J Weiler (eds) *Integration through law: Europe and the American federal experience, Forces and Potential for a European Identity* (New York 1986)
[179] Case 48/69 *ICI v Commission* (1972) ECR 619

three basic features: elimination of obstacles to trade, fair conditions of competition and unity of market.

This aim is of course expressed most apparently in the four freedoms, all of which are aimed at breaking down trade barriers. Thus, already early case law implies that the spirit of free trade also underlies the competition provisions, and that any action taken by virtue of the Treaty should have as its background aim the furthering of integration.

Ehlermann has recognised that competition law plays a hugely important part in the overriding goal of achieving single market integration.[180] It can do so in two different ways: firstly, competition law can be moulded in such a way as to encourage trade between Member States, both by 'levelling the playing fields of Europe' and by facilitating cross-border transactions and integration; secondly, it can prevent measures which attempt to maintain the separation of national markets, such as national cartels, export bans or market sharing measures.[181] The fact that this is such an important concern has meant that the Community authorities have often taken decisions that prohibit behaviour that other competition authorities that are not concerned with single market considerations would not have reached. However, there is a legitimate concern that it is being taken too far. The difficult question to answer is how far the integration goal can be pushed and when the fine line is crossed to make the Commission approach unconstitutional, as held by the CFI in *Bayer*.

The CFI aimed its criticisms at the incorrect exercise of Commission power, when instead the other more political institutions of Council and Parliament should have been involved. According to Schockweiler[182] an institution can misuse its powers in one of two ways:

1) by acting *ultra vires*, i.e. encroaching into an area of competency of another institution, or
2) by disregarding or deviating from the goal for which the discretion has been given

It is therefore possible to argue that in *Bayer* the Commission was guilty of both of these misuses: It took away competency from the Council and Parliament and also overly emphasised the integration objective to the detriment of competition policy. Although preventing parallel trade is in this case restricting one type of competition, competition policy often recognises that in certain circumstances restrictions of competition can have positively beneficial results. This is the justification for allowing exemptions under Article 81(3) for particular sectors for example. Therefore, the mere fact that parallel trade is prevented will not be enough to argue that competition concerns are being disregarded. But although integration underpins competition policy, it will not be allowed to overtake those objectives.

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[180] Ehlermann 'The contribution of EC competition policy to the single market' (1992) 29, CMLRev 257, and also the Commission's XXIXth *Report on Competition Policy* (1999), point 3.
[181] R Whish *Competition law* 5th ed, 2003 (LexisNexis Butterworths)
[182] F Schockweiler 'Le détournement de pouvoir en droit communautaire' *L'actualité Juridique Droit Administratif* 1990

The fact that Member states have for so long held onto their national health care systems and the repeated political discussions in this field have always been unsuccessful shows that great national interests are at stake that should not simply be circumvented by using inappropriate methods. Attempts by the Community institutions to harmonise pricing can consequently only be realised and also attain legitimacy once a broad political consensus has been reached by the Member States which can then be expressed though the legislative process provided for by the Treaty.[183] This would also shift away the burden of harmonising the Community pharmaceuticals market away from the shoulders of the individual manufacturers, which clearly should not be their role. The CFI's attempt to restore the balance of power and to force the Commission to reconsider its approach is therefore commendable.

7.2.2.4 Freedom of action

At the same time, the CFI recognised at a more concrete level that Bayer's unilateral conduct stemmed from expertise it had acquired in the pharmaceuticals market that it used to maximally exploit the nationally divided market. It was the division of the market that forced Bayer to adapt its market strategy in the way it did: if price regulation of pharmaceuticals were harmonised across the EU, Bayer's policy would not have been necessary. The CFI therefore acknowledged the importance of respecting individuals' freedom of action in their commercial conduct[184]:

'The case law of the Court of Justice indirectly recognises the importance of safeguarding free enterprise when applying the competition rules of the treaty where it expressly acknowledges that even an undertaking in a dominant position may, in certain cases, refuse to sell or change its supply or delivery policy without falling under the prohibition laid down in Article [82].' ([180]).

Companies need to be able to act freely in line with their business policy as far as possible and to adapt to the conditions prevailing on their market for which they are not responsible.

7.2.3 The ECJ judgment

The ECJ judgment concurred in all important aspects with the CFI without going into as much detail on the specifics analysed in this last chapter, which is why the CFI reasoning was referred to. The ECJ judgment is, however, the binding precedent that will be used.

[183] P Rey and J Venit 'Parallel trade and pharmaceuticals: a policy in search of itself' ELRev 2004, 29(2), 153-177
[184] M Jephcot 'Commentrary on case T- 41/96 *Bayer AG v Commission*' ECLR 2001, 22(10), 469-476

Although the ECJ judgment is therefore highly commendable and does resolve a number of important issues, it explicitly stated that in Bayer it restricted itself to the specific circumstances of the case and that neither the possible application of other aspects of Article 81, or Article 82 or any other possible definitions of the relevant market were at issue ([42]). Therefore many avenues are still open to the Commission to try and achieve its aim in other ways, and many commentators have predicted that it will increase its efforts to find a 'concurrence of wills' or more probably try to insist on a narrower market definition thereby increasing the chances of a finding of dominance and the possibility of attack under Article 82.[185] It is therefore important to compare Bayer with a recent development under Article 82.

7.3 Article 82 EC: Syfait[186]

7.3.1 Background

Following Bayer, this case also involves a strategy adopted by pharmaceuticals undertaking to combat parallel trade, in this case a limitation of supply.

Syfait involves proceedings brought under article 82 EC against GlaxoSmithKline in Greece: Greek pharmaceutical wholesalers complained about GSK's commercial strategy of limiting the amount of certain products supplied to its wholesalers so that they would no longer be able to export any surplus amount to higher priced Member States. Some reports suggest that the volume of exports was several times the size of the Greek market for these products. By supplying hospitals and pharmacies directly, GSK alleged to be combating shortages on the Greek market. This claim was, however, rejected by the Greek Competition Authority. Clearly, the purpose of this strategy was to prevent parallel imports into higher priced countries from occurring, and unusually GSK admitted that its intention was to partition the market. Although GSK subsequently reinstated supplies to the wholesalers, it refused to meet their orders in full.

The Greek Competition Commission initially adopted interim measures requiring the Greek subsidiary of GSK to meet in full orders that it received but then decided to suspend the proceedings and make a reference for preliminary ruling to the ECJ in order to receive clarification on points of EC law.

In making the reference the Greek Competition Authority proceeded on the basis of two assumptions:

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[185] See for example D Henry 'The Bayer judgment: to agree or not to agree' EU Focus, Issue 140, March 2004 and the Global Cousel Life Sciences Handbook 'Parallel trade in the EU and US pharmaceutical markets' Life sciences 2004/05

[186] C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and Others v GlaxoSmithKline* Opinion of Advocate General Jacobs 28 October 2004

1. That GSK was in a dominant position with regards to at least one of its products, Lamictal, an epileptic drug. Questions of market definition or dominance would not therefore be considered by the ECJ.[187]
2. That GSK's intention behind this strategy was to limit parallel trade.

With that in mind, it asked guidance on whether a dominant pharmaceutical undertaking necessarily abuses its dominant position within the meaning of Article 82 EC whenever it fails to meet in full all the orders placed with it in order to limit its customers' export activity. If not, it further asked what factors would be relevant in determining whether the conduct did in fact amount to an abuse in any particular case.

In this respect the Commission (with whom the complainants and the intervening Swedish government agreed) was of the opinion that such a restriction of supply was in itself abusive unless the dominant company could objectively justify its conduct, whereas GSK argued that the specific circumstances of the European pharmaceuticals market should be taken into account and that such a restriction constituted a proportionate protection of its legitimate business interests in that particular environment. The Commission position illustrates that it still has not moved from its support for parallel trade and is holding onto its traditional arguments even in the wake of *Bayer*.

7.3.2 Advocate General Jacobs' Opinion

Leaving aside the question of admissibility for this discussion, the AG delivered an opinion that is highly favourable to GSK and adopts many of the arguments repeatedly presented by the pharmaceuticals industry over the years as outlined in Chapter 4.3 above. His opinion is not in any way binding upon the ECJ but does hold significant weight in their decision-making. If followed, it would represent a dramatic departure of the approach previously adopted. Already as it is it represents a significant step forward simply by virtue of the fact that the actual realities of the market are analysed at all and taken into consideration in the decision making process. At the very least, his opinion will force the ECJ to also consider those factors and not to rely stubbornly on technical competition law without linking that to the economic and regulatory environment in which it operates. AG Jacobs' foresight is therefore to be praised. He took into account many of the facts and statistics presented by the pharmaceutical industry and translated them into possible effects on consumer welfare in the European Union.

The first issue considered by AG Jacobs was whether the conduct complained of amounted to an abuse per se, as argued by the Commission. He concluded that

> 'a dominant pharmaceutical undertaking which restricts the supply of its products does *not* necessarily abuse its dominant position within the meaning of

[187] This is in itself already a point of contention as the market definition employed will be highly deteminative for dominance and as mentioned, there will be strong tactical considerations involved in determining the relevant market and dominance following *Bayer*.

Article 82 EC merely because of its intention thereby to limit parallel trade' ([69]- emphasis added).

He arrived at this conclusion after a survey of all the relevant case law relating to refusal to supply both existing and new customers, ranging from *Commercial Solvents*[188] to *IMS Health*[189] and extracted three main conclusions from this body of law:

1. A dominant company may in certain circumstances be obliged to supply its products, but only where competition would otherwise be unacceptably harmed; for example where an interruption in supply would limit the ability of its customers to compete in a downstream market.

2. However, this obligation is not absolute and a dominant company is entitled to refuse to supply in circumstances where an objective justification for the refusal exists. Thus, it is not obliged to meet orders that are out of the ordinary and may take reasonable steps to defend its commercial interests.

3. In the determination of whether such a refusal is abusive or justified, regard must be taken of the specific economic and regulatory context in which the case arises.

Based on these considerations AG Jacobs concluded that a refusal to supply was not per se illegal. He then went on to determine whether there was an objective justification for the conduct in question and decided that

'a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defence of that undertaking's commercial interests' ([100]).

This conclusion was reached by taking into account three sets of factors:

1. The pervasive regulation of price and distribution in this sector
2. The likely impact of unmoderated parallel trade upon pharmaceutical undertakings in the light of the economics of the sector
3. The effect of such trade upon consumers and purchasers of pharmaceutical products

1. <u>Regulation of price and distribution</u>

AG Jacobs recognised the heavy regulation both at a national and Community level of the pharmaceuticals market and believed that this circumstance set it apart from all other industries that produce goods that may be subject to parallel trade. He mentioned in particular (a) the price disparities caused by national regulation rather than manufacturer choice and (b) the obligations imposed on manufacturers to make sufficient stocks available domestically.

[188] Case 6/73 *Istituto Chemioterapico Italiano and Commercial Sovlents v Commission* [1974] ECR 223
[189] Case C-418/01, judgment of 29 April 2004, not yet reported

He argued that price differentials giving rise to parallel trade are created by state intervention in the Member States and took the view that pharmaceutical companies do not seek to entrench price differentials of their own making when they seek to restrict parallel trade, but try to avoid the consequences that would follow if the very low prices imposed in some countries were generalised across the EC. In short GSK was seeking to protect what it saw as its legitimate commercial interests.

Consequently, any attempts to restrict parallel trade were not aimed at protecting prices imposed by the manufacturers themselves but instead were simply a reaction to price disparities beyond their control and should therefore not be penalised. Similarly, the market partitioning in the EU is due to public service obligations imposed on manufacturers and wholesalers which require wholesalers to maintain sufficient stocks to meet domestic demand. According to the AG this duty means that manufacturers may not have the option of withdrawing a product altogether from a low-price Member State in order to limit parallel trade. At the same time it is then questionable whether this duty to supply should be upheld in cases where the wholesaler wants to export the products in question – if pharmaceutical companies cannot limit the amount of parallel trade, it becomes more difficult to manage their pan-European supply chains and they may have difficulty ensuring that sufficient supplies are available in each Member State. This outcome would run counter to the national and EU obligations aimed at ensuring continuity of supply.

2. The economics of the innovative pharmaceutical industry

The AG's main worry was that if pharmaceutical companies were unable to limit supplies as an answer to parallel trade, they would resort to other measures that would be much more harmful to the European consumer and the single market. If companies introduced higher prices in traditionally low-priced countries or, failing that, delayed the launch of products in those Member States, consumers in the low priced countries would clearly be harmed because of their inability to pay for the medicines, and the market would become more fragmented as certain medicines simply would not be marketed in 'cheaper' Member States. In the event that companies were not successful in their attempts to limit PT, he perceived parallel trade as having an adverse effect on R&D investment as pharmaceutical manufacturers may be unable to recoup their sunk costs and R&D expenditure. Similarly, he perceived a clear health policy risk if drugs are delayed or simply not available in certain markets.

3. The consequences of parallel trade for consumers and purchasers in the Member States of import

AG Jacobs pointed to the fact that the pharmaceuticals market is different from other markets because the final consumer does not actually pay for the full amount of the product and that therefore any savings do not accrue to him but to the parallel trader. Neither do the national health services nor the taxpayer benefit, because most of the profits are absorbed by those involved in the distribution chain.

Based on all of these considerations, the AG concluded that it would be contrary to the interests of efficient health care, consumer welfare, innovation and competitiveness as well as the single market objective to require a dominant company in all circumstances to supply its customers:

'a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products or the Member States, as primary purchasers of such products' ([100]).

He did, however, impose certain caveats on this conclusion. First, he emphasised that this decision was restricted solely to the pharmaceutical sector so that refusals to supply in other sectors were still susceptible to violate Article 82. Secondly, he restricted his conclusion to the economic and regulatory situation as it stands but did not propose to be offering a solution should that context change. Lastly, he warned that a dominant firm that 'more clearly and directly' partitions the common market would still be liable to scrutiny under Article 82.

An interesting part of his judgment is the way he deals with the public service obligation, a factor that is not often mentioned in the parallel trade context yet clearly has significant implications on a manufacturer's ability to steer the end destination of his products. As seen above, the advocators of parallel trade blame the actions of wholesalers for any possible shortages of medicines in a given Member State and play down the significance of this duty.

AG Jacobs, however, argued that it is the public service obligation that contributes to the initial partitioning of the market: the existence of this obligation is the only reason that low-priced countries are still supplied at all; otherwise the entire stock would simply be bought up and sold elsewhere. The whole system is based upon national segregation, aimed at ensuring sufficient supplies in each national territory. This is safeguarded by national legislation and supplemented by Regulation 2001/83. Thus, a restriction of supply by the manufacturer simply limits the amount available for export but does not section off national markets- this is achieved simply by the public service obligation itself. ([85]). But the obligation cannot be used by wholesalers to argue that a manufacturer must always and in all circumstances supply its products so that the emergency stock can be upheld. Allowing a wholesaler to require its emergency stock to be replenished even when it has been depleted for non-emergency reasons would enable the wholesaler to use the public service obligation to obtain indefinite and unlimited supplies for reasons wholly unrelated to public health protection. This would of course be a completely paradoxical result, and therefore the existence of the obligation should not render a refusal to supply abusive where otherwise it would not be.[190] Thus, the obligation cannot support a contention that GSK should be required to supply the full amounts demanded by the wholesalers.

[190] This line of reasoning is put forward by EFPIA in 'Article 82: Can it be applied to control sales by pharmaceutical manufacturers to wholesalers?' November 2004

7.4 Implications for the future

Following the discussions in both *Bayer* and *Syfait*, it is clear that change is in the making and it is to be hoped that the ECJ will follow the AG's recommendations in *Syfait* so that it will be clear once and for all that neither Article 81 EC nor Article 82 EC can be interpreted as a per se prohibition on hindrances to parallel trade. This pressure from the Courts on the Commission will surely mean that an alternative solution needs to be found to the growing problem, and hopefully political discussions can be resumed, in which the Commission will not doggedly insist on such an extreme position so that a compromise can be found. However, what could the solution be instead? The following section will look at possible alternatives and analyse them for their viability.

8 A new approach?

Following this survey of the pharmaceuticals market in the European Union and the impact of parallel trade within it, the conclusion that this paper draws is that it is indeed time for a new approach. Although much of the data presented is open to interpretation and is often used by both camps to support their argumentation, the Courts seem to have accepted that the Commission's arguments do not stand strong and that the aim of creating a single market above all other objectives is not in reality in the interest of the consumer. So the Courts at least have recognised that a new approach is called for. But what shape should it take? Given the clear delimitations contained in the EC Treaty, it is important that the central institutions take an approach that is neither *ultra vires* not out of line with the central goals of the Community. Various different solutions have been offered by commentators and this concluding chapter will look at them in turn and will present the most convincing one that takes due account of the characteristics of this sector and presents a compromise that could be accepted by all parties. It is hoped thereby to offer more than the pessimism voiced by certain commentators.[191]

8.1 Disregard competition provisions in the pharmaceuticals sector

The most obvious solution would be simply to prohibit parallel trade in its entirety. National markets would remain national and governments would be free to determine their own health care objectives, priorities and organisation. This view is strongly put forward by Concepción Fernández Vicién, Legal Secretary at the CFI, in her Article 'Why parallel imports of pharmaceutical products should be forbidden'[192]. She outlines the particularities of the market, mentioning in particular national price fixing, R&D costs, and the exhaustion of IPRs, which leads her to conclude that

'Under these circumstances it is nonsense to submit the distribution and sale of pharmaceuticals to effective competition on a European market basis, thus weakening the industry which is faced with competition from the American and Japanese industries….Competition rules, established in order to preserve effective competition in the Community market, and to avoid absolute territorial protection, should be disregarded, as it is a fact that pharmaceuticals markets are of national and not of European dimension.'

[191] L Hancher 'The pharmaceuticals market: competition and free movement actively seeking compromises' in M McKee, E Mossialos and R Baeten (eds) *The Impact of European law on Health care systems PIE 2002:* "…in so far as the cause of parallel imports is to be attributable to national divergence in price regulation, the Commission has little political or legal means, or even hope of either, to attack the problem at source."

[192] ECLR 1996, 17(4), 219-225

She argues that undertakings should consequently be allowed to respond to parallel trade, resulting simply from the conditions of the market, by imposing export bans, adopting dual pricing systems and applying mechanisms of final destination control. She points out that although such measures are considered to be classic black-list clauses that infringe EC competition law, it should be remembered that price fixing is actually the most typical black-list clause- and that this has been expressly permitted, as can be seen from the structure of the market. This is confirmed in the Commission Communication on the Single Market in Pharmaceuticals, which states that 'the existence of price control systems are not themselves contrary to the principle of free movement of goods'. In this respect it is important to be aware of the difference between the application of the competition rules at the Member State level and the individual manufacturer level. Social security does not enjoy a general exemption from the scope of the application of competition law where the activity is considered to be economic, and not purely social or sovereign or solely to cover need[193]. Thus price fixing both by manufacturers as well as Member States is covered by those statements.

However, it seems that this position is very extreme, and not viable in practice. It is unimaginable that the Commission will perform a complete U-turn in terms of policy and thereby disregard its fundamental task under Article 2 EC and Article 3 EC of establishing a common market, as well as its goal of ensuring that competition in the internal market is not distorted (also Article 3 EC). Although certain sectors do operate wholly outside the scope of the competition provisions, they are highly specific areas where social or political value judgments may lead to the conclusion that competition is inappropriate.[194] Examples would be agriculture, the labour market and to a limited extent the liberal professions. The pharmaceuticals sector, however, clearly does not form part of that category. This has also been confirmed in the Commission Communication on the Single Market in Pharmaceuticals, which states that pharmaceuticals should not be exempt from the Single Market simply because they are used in health care systems.

8.2 Find a political solution

Although the ECJ has on several occasions accepted that the root of the problem are the disparities in price fixing methods and refund arrangements operating in the different national markets, it has held that such arguments should be dealt with at the political rather than the judicial level. This is clear from *Merck v Primecrown,* which repeated what had earlier been said in *Bristol- Myers Squibb*[195] , stating that

'it is well settled that distortions caused by different price legislation in a Member State must be remedied by measures taken by the Community authorities and not by the adoption by another Member State of measures incompatible with the rules of free movement of goods' ([47]).

[193] B Karl 'Competition law and health care systems' in M McKee, E Mossialos and R Baeten (eds) *The impact of European law on health care systems* PIE 2002
[194] R Whish *Competition law* 5th ed (2003 LexisNexis Butterworths)
[195]Joined cases C-427/93 and C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457, [46]

It is clear that the ECJ was hoping that political consensus on the matter could be reached, and this optimism was shared by many commentators when the Bangemann Round Table discussions were started in 1996. However, after three such discussion rounds no compromise was reached, and it now seems slightly too optimistic to rely simply upon political negotiation. The main hurdle to finding a solution seems to be that industry and the Commission are approaching the problem from opposing starting points: the pharmaceuticals industry would ideally welcome exemption from EU competition and free movement of goods rules, whereas the Commission wants to find a solution within the existing framework to create a true single market.[196] Dr Jim Attridge, rapporteur to one Bangemann Working Group therefore stated that an important feature of the second Bangemann Round Table 'was an almost inevitable failure to agree…to the form the future EU market should take'.[197]

Another wave of hope was started with the G10 Group on Medicines, which was to discuss and try to arrive at consensus on future action. In doing so, the Group presented a package of 14 recommendations for possible measures, addressing the twin goals of encouraging innovation while ensuring satisfactory delivery of public health. However, although great progress was made and agreement reached in important areas such as the promotion of R&D, the enforcement of IP standards and the enhancement of pharmacovigilance, the G10 Group did not consider in any detail the implications of parallel trade. The only reference made to single market matters was with regard to non-reimbursed medicines that are neither purchased nor reimbursed by the State, so that all the relevant considerations and complications do not apply. Therefore, this again represented a missed chance for arriving at any purely political consensus

8.3 Block exemption under Article 81(3) EC

This proposal was first put forward by the pharmaceuticals industry at the first Bangemann Round Table, where it sought to convince the Commission to contemplate passing a Block Exemption Regulation that would exempt the agreements of the pharmaceutical industry which sought to prevent parallel trade from the ambit of Article 81 EC. However, this solution was not looked upon favourably by representatives of DG IV (now DG Comp) of the European Commission, who were members of the Bangemann Working Party One. The proposal therefore never even made it as a recommendation to be considered at the second round of discussions, and the conclusion reached was instead that exemptions would have to be at most at the individual level. However, even that approach seems not to be open any more since the *Glaxo* decision with regard to dual pricing schemes: the Commission found that the alleged beneficial effects of

[196] JS Nazerali 'Parallel imports of pharmaceuticals- a prescription for success or a free market overdose?' ECLR 1998, 19(6), 332- 342

[197] Quoted from the speech given at the conference 'The Bangemann Round Table, What Next?' held on February 6, 1998 (see JS Nazerali, FN 196)

the agreements in question did not compensate for the restriction of competition that they caused. ([147]-[188] of the decision).

In light of the recent developments, however, it might be time now for the Commission to reconsider its views on this point. Considering that domestic price regulations apply, it may seem reasonable to argue that price differentiation between products may well produce efficiencies and be beneficial for the consumers. This has led Nazzini to argue that 'the total refusal of the Commission to the very possibility of granting an exemption under the said circumstances is probably not maintainable and, ultimately, is not beneficial to the market.'[198]

However, unlike under Regulation 19/65, where block exemptions were granted for particular industrial sectors, and which was in force at the time of the Bangemann negotiations, block exemptions are since 1 January 2000 granted under Regulation 2790/99[199], which covers *all* vertical agreements that fall, prima facie, within the Article 81(1) EC prohibition. The new approach under this Regulation is a black-clause list approach, whereby any agreement containing a non-severable clause that is listed in Article 4 of the Regulation will automatically be excluded from exemption. Article 4(1)(b) lists territorial and customer restrictions as such 'black' clauses. Thus, any restriction on the territory into which or the customers to whom the buyer may sell will not be eligible for exemption. This means that an export ban or agreements to refuse to deal with know parallel traders can never be subject of a block exemption. It seems that this option is not therefore feasible in practice, although of course individual exemption would still theoretically be possible in specific cases.

8.4 Harmonisation by way of Article 96 EC

Vital to any change is the realisation that the root rather than the consequences of the problem must be tackled. As the REMIT Report put it: 'any measures aimed at stimulating parallel trade in pharmaceuticals while leaving widely diverse and regulated national price regimes intact will not create a genuine single market in the Community.' As Nazzini points out[200], the legal mechanism available to the Commission would be Article 96 EC, which could be used to remove distortions that arise from governmental regulation, i.e. the 'source' of the problem. It reads:

'Where the Commission finds that a difference between the provisions laid down by law, regulation or administrative action in Member States is distorting the conditions of competition in the common market and that the resultant distortion needs to be eliminated, it shall consult the Member States concerned.

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[198] R Nazzini 'Parallel trade in the pharmaceutical market. Current trends and future solutions' World Competition 26(1), 53-74, 2003.
[199] Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (Text with EEA relevance) ([1999] OJL 336 /21)
[200] Nazzini, FN 198

If such consultation does not result in an agreement eliminating the distortion in question, the Council shall, on a proposal from the Commission, acting by a qualified majority, issue the necessary directives. The Commission and the Council may take any other appropriate measure provided for in this Treaty'.

However, attempts by the Commission to tackle the issue at the source by seeking to harmonise national rules and regulations on pricing and profit controls are not positively viewed by either Member States or the research based industry. Member States regard this as a matter of their health policy and therefore of national competence, whereas the industry does not want convergence towards one 'European' price. As can be seen, much will depend on the classification of the matter, as discussed in Chapter 6 above. The Community's competences will vary depending on whether eliminating parallel trade in the pharmaceuticals industry is seen as a matter of health or industrial policy.

In response to the Round Table discussions, the Council for the first time considered the tensions at the heart of the Single Market in pharmaceuticals and presented its conclusions at the Internal Market Council on May 18, 1998. It considered 'that developments in Community policy should take account, in particular, of tensions regarding pharmaceutical prices and their convergence, and the divergent patterns of wealth in the Union, which are likely to increase with enlargement.' It therefore invited 'the Commission to address in its Communication how best to accommodate the requirements set out …above in ways consistent with community rules'.

The Commission Communication on the Single Market in Pharmaceuticals [201] confirmed that, on the issue of price harmonisation the Bangemann discussions also failed to reach any result. The Commission's suggested compromise was to advance a 'market segments' approach and to stimulate deregulation for over the counter (OTC) drugs as well as promoting the use of generics. As regards 'in-patent' medicines, the Communication proposed to offer adequate incentives for the research- based industry. However, the publication was strongly criticised by many different actors: both research-based and generic industry, and the pharmacy profession. No concrete action was taken following this.

8.5 A negotiation-based approach

From a more business-orientated perspective, Attridge therefore sees the solution lying in a shift towards a more negotiation-based model for the European Union.[202] This is also perceived as a possible solution by Nazzini, who argues that Member States could be encouraged to adopt negotiation procedures aimed at setting up pricing schemes in agreement with the industry that would take into account R&D

[201] Commission Communication on the Single Market in Pharmaceuticals. COM(98)588 final

[202] J Attridge 'A single market for pharmaceuticals: could less regulation and more negotiation be the answer?' European Business Journal, 2003, v 15, nr 3

costs[203]. This solution would ensure that the competitiveness of the European pharmaceutical industry is not harmed. Prices would reflect the investments made by the manufacturers as well as the efficiencies the new drug would provide rather than simply the national service's financial concerns and the government's political agenda. Attridge further elaborates that this would introduce greater flexibility which would allow purchasers, distributors and suppliers of medicines to negotiate and renegotiate agreements to suit local circumstances without having to fear disputes before national or European courts. If there is to be any chance of success, he recognises that all three of the main parties must be willing to compromise:

Member States should try to streamline the very different and complex patterns of national legislation and try to converge the principles of national price and reimbursement towards more negotiation-based systems. The long-term aim thereby would be to allow state purchasers and company suppliers to negotiate prices in their national territories but at the same time to strive towards a common, EU-wide outline framework towards which Member States would aspire to converge over a certain period of time. This could be done through incremental changes in individual national legal frameworks.

On the industry side, manufacturers should then create EU wide list prices for new products, which would reflect fully the innovative nature of the product and the need to obtain a fair reward for R&D activities. These list prices should eventually be determined according to commonly agreed principles relating to the relative value of products, which would be based upon their clinical success and cost-effectiveness. As a model for such value based pricing, much interest has been shown in the operations of the National Institute of Clinical Excellence (NICE), which was set up in 1999 in the UK to assess the clinical and cost-effectiveness of all new medical technologies. It would, however, still be up to each Member State in line with its national priorities in the health care sector, to make its own national assessment of value which would be used as a basis for negotiation with individual companies. The pharmaceutical industry thus needs to accept that if it is in practice the government buying the products, then it is the government with whom they should negotiate prices. The ideal of 'free pricing' in a consumer context would have to be given up.

As regards the Commission, it is clear that it needs to be more open towards a solution that accepts the peculiarities of the pharmaceuticals sector. It should realise what are the long-term benefits for all the parties concerned rather than 'hiding behind the formal rigidities of free market legislation'[204]. Attridge argues that if EU list prices were used that equate to the current German and UK prices (subject to slight variations), then the only sector affected by parallel trade would be those patented products in southern and eastern countries. If prices there remain low, then of course the patented product prices in the northern countries would be driven down by parallel trade and the list prices would not work. This is why he proposes that the Commission allow a limited constraint on free movement for a selected subset of products, for a select subset of countries for a limited period of time. He argues that this could take the shape of an 'EU level agreement that would constrain

[203] Nazzini, FN 198
[204] J Attridge, see FN 202

export of low price patented products from this group of countries, based upon some rational principle such as relative per capita national GNPs.' Translated into legal terms, this is precisely what the specific mechanism achieves for the CEE Member States, so that possibly a similar mechanism could be envisaged for South European Member States by virtue of a Directive adopted in accordance with Article 96.

Although this clearly is the best solution offered, it still requires a lot of willingness to compromise on behalf of all the actors involved: as discussed, already the specific mechanism was heavily criticised by the pharmaceuticals industry for unnecessarily protecting the acceding Member States so the same criticism can be levelled here. Similarly, it requires a lot of political willingness on behalf of Member State governments.

As yet, it is however the only viable solution put forward that has any prospect of succeeding and which would keep innovation within Europe, a concern shared by all of the interested parties. It may be, therefore, that this shared concern will convince them towards greater compromise and a single market for pharmaceuticals based on negotiation.

8.6 Conclusion

The main factors in reaching this conclusion are based on extensive studies carried out by independent authors and institutions. Their findings highlight that the pharmaceuticals market is indeed very different structurally from any other market of consumer goods and that they need a specifically adapted solution.

Most importantly, supply, demand and pricing are all determined nationally by Member States governments and their health care systems, whatever shape these may take. The health care service providers determine the quantities of desired products and often set prices for the medication after limited negotiation with the manufacturers. This means that pharmaceutical companies cannot set prices according to their desired profit margins but must adapt to the national circumstances. The resulting differences in price between the most and least affluent countries lend themselves to the practice of parallel trade. Because parallel trade is seen by the Commission to enhance competition, thereby reducing prices and creating the best conditions for the consumer, it is greatly encouraged. However, as detailed above, the efficiencies resulting from parallel trade seem to accrue mainly to the parallel traders themselves, and only partly to national health care systems and pharmacists and only very minimally to the consumer. So if the Commission's main concern is providing the best conditions for the consumer, both from a competition perspective in terms of lower prices, as well as from a health care perspective where lower prices translate into better access to medicines, it would seem that parallel trade does not provide the answer.

Similarly, a great concern is that parallel trade erodes the R&D base in Europe in favour for the US. Because it drives down prices to the lowest common denominator in Europe, companies can no longer recoup the profits needed to make

R&D worthwhile. Options such as not providing the cheapest markets with their products so that they will not be able to influence the downwards pricing spiral are unacceptable both legally and morally, due to national and EC public service obligations. Since another major concern for the EU is to remain a strong competitive industry, and in fact to strengthen its global industrial presence, the Commission should realise that parallel trade is directly counteracting that goal. Not only that, a migration of innovation to the US also leads to detrimental conditions of competition: fewer competitors in Europe can charge higher prices, while the necessary imports are also naturally more expensive. This in turn results also in poorer health care: reliance on older and less effective drugs means that diseases are not combated as efficiently, which leads to much higher bills when they have to be treated in hospitals rather than by means of drugs only. This also has knock-on effects on the economy and competitiveness if the workforce is not operating as efficiently as it could due to illness.

Although these concerns were raised by the pharmaceuticals industry, they were not accepted by the EC institutions until recently and competition law was systematically used to eliminate any kind of behaviour that potentially restricted parallel trade. This is true both of the EC Commission, as can be seen for example from its *Organon* and *Johnson & Johnson* decisions, and also the Courts, who have also consistently struck down supply quotas, export bans, and dual pricing systems, as for example in *Sandoz*.

However, the most recent developments in the Courts seem to indicate that the arguments of opponents to parallel trade are finally falling upon more sympathetic ears. In *Bayer* the ECJ confirmed in January of 2004 that the very sweeping definition of 'agreement' for the purpose of Article 81 EC had been taken a step too far by the Commission and that the competition provisions could not be used in this way to effectively introduce price harmonisation through the back door. This was not only unacceptable; the CFI went so far as to call it unconstitutional. In *Syfait*, although judgment has not been handed down at the time of publication of this thesis, AG Jacobs makes some very important statements as to the situation under Article 82 EC. He feels that here, too, the Commission has been taking things too far by claiming that a restriction of supplies to prevent parallel trade infringes Article 82 EC. Although these cases will not entail the end of parallel trade in pharmaceuticals in Europe at once because the rulings are very fact-specific, they do point to significant reappraisals of the market circumstances being made at least by the Courts.

These developments are highly interesting and coincide, not by chance, with the latest EU enlargement, which will have a significant impact on the overall structure of the European market in pharmaceuticals. Similarly, the cases are being discussed at a time when the EMU countries have had time to adapt to the single currency and price comparisons as well as cross-border transactions are becoming ever easier- both factors that make the issue of how to tackle parallel trade all the more pressing.

At the heart of the debate lies the question on whether parallel trade really does result in a downwards spiral of prices that leads to harmonisation at the lowest

possible level, which means that R&D costs cannot be recouped, with all the consequential negative effects. Paradoxically, parallel trade is seen to drive down prices to a low uniform level, yet it is clear that if that level was ever reached, parallel trade would necessarily have to stop because there would be no more price differentials allowing it to occur. But simply allowing the situation to continue as it is in the hopes that parallel trade will eventually regulate itself or reach some kind of plateau is clearly not an acceptable solution. Based on the findings in this paper, the negotiation-based approach seems to offer a possible way forward, but whether there is sufficient willingness to achieve this result is very questionable. The ECJ judgment in Syfait is therefore eagerly awaited and hopefully it will provide some form of concrete guidance in line with the approach taken by AG Jacobs to the extent that there is no per se prohibition on restricting parallel trade. This could then pave the way for a political compromise.

Bibliography

EC primary legislation

Treaty establishing the European Community as amended in accordance with the treaty of Nice consolidated version ([2002] OJ C325/1)

EC secondary legislation

Regulations

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 (Text with EEA relevance) ([2004] OJ L 136/1)

Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines ([2003] OJ L 135/5)

Commission Regulation (EC) No 2790/1999 of 22 December 1999 on the application of Article 81(3) of the Treaty to categories of vertical agreements and concerted practices (Text with EEA relevance) ([1999] OJ L 336/21)

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([1993] OJ L 214/1)

Regulation No 19/65/EEC of 2 March of the Council on application of Article 85 (3) of the Treaty to certain categories of agreements and concerted practices (OJ 036 , 06.03.1965, p. 0533 – 0535)

Council Regulation (EEC) 17/62 First Regulation implementing Articles 85 and 86 of the Treaty (OJ 013 , 21.02.1962, p. 0204 – 0211)

Directives

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 (Text with EEA relevance) ([2004] OJ L 136 /34)

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 ([2001] OJ L 311/67)

Council Directive 93/39/EEC of 14 June 1993 amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC in respect of medicinal products ([1993] OJ L 214/22)

Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets ([1992] OJ L 113/8)

First Directive 89/104/EEC of the Council, of 21 December 1988, to Approximate the Laws of the Member States Relating to Trade Marks ([1989] OJ L 40/1)

Council Directive 89/105/EEC of 21 December 1988 relating to transparency of measures regulating the pricing of medicinal products for human use and their inculsion in the scope of national health insurance systems ([1989] OJ L 40/8)

Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products ([1975] OJ L 147/13)

Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products ([1975] OJ L 147 /1)

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ 022, 09/02/1965, p 0369 – 0373)

Accession documents

Documents concerning the accession of the Kingdom of Spain and the Portuguese Republic to the European Communities, Act concerning the conditions of accession of the Kingdom of Spain and the Portuguese Republic and the adjustments to the Treaties ([1985] OJ L 302/23)

Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the republic of Cyprus, the republic of Latvia, the republic of Lithuania, the Republic of Hungary, the republic of Malta, the Republic of Poland, the republic of Slovenia, and the Slovak Republic and the adjustments to the Treaties on which the European Union i s founded. [2003] OJ L 236/33)

Other EC publications

Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the regions- A stronger European-based pharmaceutical industry for the benefit of the patient- A call for action' COM(03)383 final

Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted. COM/2003/0839 final

Parallel Trade of Pharmaceuticals, DG Enterprise (2000)

Pharmaceuticals in the EU, (2000) DG Enterprise

The Commission's XXIXth *Report on Competition Policy* (1999)

Commission Communication on the Community marketing authorisation for medicinal products [1998] OJ C 229/4

Commission Communication on the Single Market in Pharmaceuticals. COM(98)588 final

Commission Communication outlining an industrial policy for the pharmaceutical sector in the European Community COM (93) 718 final

92/442/EEC: Council Recommendation of 27 July 1992 on the convergence of social protection objectives and policies ([1992] OJ L 245/49)

References

All websites last accessed on 16/05/2005

ABPI 'Facts and statistics from the pharmaceutical industry' 2005. Available at: www.abpi.org.uk/stastitics/section.asp?sect=1

B Ager 'Interview with B Ager, Director General of EFPIA' 2005

AIM 'Parallel trade- consumer benefit or consumer loss?' AIM position paper

J Arfwedson 'Parallel trade in pharmaceuticals' Institute for Policy Innovation, Quick Study. 27.07.2004

Arnold & Porter 'Parallel trade, update pharmaceuticals' February 2004

Arnold & Porter 'Parallel trade in pharmaceutical products following the ECJ's Bayer judgment: Can a case be made under Article 82?' The European Antitrust Review 2005, 83-86

J Attridge 'A single European market for pharmaceuticals: could less regulation and more negotiation be the answer?' European Business Journal 2003, v.15, n. 3, 122-134

T Boer 'Economic aspects of the single European market in pharmaceuticals' ECLR 1999, 18(3), 123-144

RB Bouterse *Competition and Integration- What goals count?* (Kluwer Law and Taxation 1994)

M Cappellatti, M Seccommbe and J Weiler (eds) *Integration through law: Europe and the American federal experience, Forces and Potential for a European Identity*, (New York 1986)

C Brown 'Bayer v Commission: the ECJ agrees' ECLRev 2004, Issue 7

CMS 'European pharmaceuticals parallel trade review' April 2004

T Cook 'Competition law and the techniques for preventing parallel imports' Bird & Bird publication, 31.07.2003

PM Danzon 'The economics of parallel trade' Pharmaeconomics 1998, Mar 13(3), 293- 304

J Darba and J Rovira 'Parallel imports of pharmaceuticals in the European Union' Pharmacoeconomics, 14(1), 129-136

T Dzitko ‘Enabling access to modern medicines at reasonable prices’ Business Briefing: Pharmagenerics 2003

EAEPC ‘Parallel trade- Helping to make modern medicines more affordable for Europe’ Available at www.eapc.org

EFPIA ‘The Pharmaceutical Industry in Figures, 2004’

EFPIA ‘Parallel trade of medicines’ position paper

EFPIA ‘Development of the EU single market in pharmaceuticals- the pharmaceutical industry’s agenda’ EFPIA position paper, June 1998

EFPIA ‘Article 82: can it be applied to control sales by pharmaceutical manufacturers to wholesalers?’ EFPIA study, November 2004

Ehlermann ’The contribution of EC competition policy to the single market’ (1992) 29, CMLRev 257,

M Farquharson and V Smith *Parallel trade in Europe* (Sweet & Maxwell 1998)

T Feddersen ‘Parallel trade in pharmaceuticals in a Europe of 25: what the “specific mechanism” achieves and what it does not’ [2003] EIPR, v.25, n.12, 545-555

O Freget ‘Distribution of pharmaceuticals in the EC: do the conclusions of Advocate General Tizzano in the Adalat case solve all pending issues?’ Bird & Bird publication, 31.07.2003

M Furse ‘The role of competition policy: a survey’ ECLR 1996, 17(4), 250-258

A Gambardella, L Orsenigo, F Pammolli ‘Global competitiveness in pharmaceuticals, a European perspective’ Report prepared for DG Enterprise, November 2000

M Ganslandt and K Maskus ‘Parallel imports and the pricing of pharmaceutical products: evidence from the European Union’ World Bank Research Paper February 2004

M Ganslandt and K Maskus ‘Parallel imports of pharmaceutical products in the European Union’ The Research Institute of Industrial Economics, Working Paper No. 546, 2001

Global Counsel Life Sciences Handbook 2004/2005 ‘Parallel trade in the EU and US pharmaceutical markets’ Available at: www.practicallaw.com/A41999

D Glynn ‘Article 82 and price discrimination in patented pharmaceuticals: the economics’ [2005] ECLR, Issue 3

R Gudmundsson ’La justification économique des droits de propriété intéllectuelle’ PhD dissertation, Institut d’études Politiques, Paris 1998

M Gyldmark ‘The economics of parallel trade revisited: possible implications for the social welfare in Europe’ August 2000 (reference!)

L Hancher ‘The European pharmaceuticals market: problems of partial harmonisation’ ELRev 1990, 15(1), 9-33

D Henry ‘The Bayer judgment: to agree or not to agree’ EU Focus, Issue 140, March 2004

C Heath ‘Parallel imports of patented pharmaceuticals from the new EU Accession States’ 2004 ICC: International Review of Industrial Property and Competition Law, 2004, v.35, n.7, 776-787

DW Hull ‘Parallel trade in pharmaceutical products in Europe: the Advocate General’s opinion in SYFAIT v GlaxoSmithKline’ Competition Law Insight 2004, 9.11.2004

IMS Health, “Parallel trade 2003- a concise guide’, PPR Communications Ltd

PS Jakobsen and M Broberg ‘The concept of agreement in Article 81: on the manufacturer’s right to prevent parallel trade within the European Community’ ECLR 2002, 23(3), 127-141

M Jephcot ‘Commentary on case T-41/96 *Bayer AG v Commission*’ ECLR 2001, 22(10), 469-476

A Jones and B Sufrin *EC Competition Law* (2nd edition OUP 2004)

P Kavanos et al ‘The economic impact of pharmaceutical parallel trade in European Union Member States: A stakeholder analysis’ January 2004. LSE Health and Social Care Special Research Paper

S Kon and F Schaeffer ‘Parallel imports of pharmaceutical products: a new realism or back to basics’ ECLR 1997, 18(3), 123-144

P Kotzian ‘Stuck in the middle: welfare effects of the European pharmaceutical market’ incomplete integration and a possible remedy’ MZES Working Paper Nr. 59, 2002

Law Society Gazette for Ireland ‘Bayer/Adalat- a setback for parallel trade’ May 2004

O Lemaire ‘Parallel trade of pharmaceutical products within the enlarged European Union’ [2005] EIPR 43

O Lemaire and M Meulenbelt ‘Adalat and Kholpharma- Where now for parallel trade in the EU?’ RAJ Pharma July 2004, 499-505

HH Lidgard ‘Unilateral refusal to supply: an agreement in disguise’ ECLR 1997, 18(6), 325-360

D MacArthur ‘Laying to rest the myths of parallel trade in medicines’ Consumer Policy Review Jan/Feb 2004 (UK Consumer Association publication)

M McKee, E Mossialos and Rita Baeten (eds) *The impact of EU law on health care systems* Brussels : PIE - P. Lang, 2002 (project commissioned and funded by the Belgian Presidency of the European Union)

G Morgan and S Reichenbach ‘Reasons for and implications of price differences in the EU in the automotive and pharmaceutical industries’ Thesis for Msc in Management, University of Bath

J Morris (ed) *ADPIC et Services Medicaux: Repenser le Debat* Centre for the New Europe, September 2001

E Mossialos, M Mrazek and T Walley *Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality* European Observatory on Health Care Systems series (2004)

JS Nazerali ‘Parallel imports of pharmaceuticals- a prescription for success or a free market overdose’ ECLR 1998, 19(6), 332-342

R Nazzini ‘Parallel trade in the pharmaceuticals market: current trends and future solutions’ World Competition 2003, 26(1), 53-74

NERA and SJ Berwin ’The economic consequences of the choice of regime of exhaustion in the area of trademarks’ Report for DG XV of European Commision, London 1999

OECD ‘Synthesis report on parallel imports’ 2001 COM/DAFFE/COMP/TD(2002)18/FINAL

F Ragolle ‘Restriction of parallel trade by a dominant pharmaceutical company not abusive’ Bird & Bird publication, 20.01.2005

REMIT Consultants ‘Impediments to parallel trade in pharmaceuticals within the European Community’ Final Report prepared for the European Commission. EEC Reference: IV/90/06/01, OPOCE 1992

Reuters ‘The pharmaceutical parallel trade outlook: the challenges to pharmaceutical companies across Europe and the US’ Reuters Business Insight 2004

P Rey and J Venit ‘Parallel trade and pharmaceuticals: a policy in search of itself’ ELRev 2004, 29(2), 153- 177

F Schockweiler ’Le détournement de pouvoir en droit communautaire’ *L’actualite Juridique Droit Administratif* 1990

I Senior ’Parallel trade in European Pharmaceuticals’, Vision in Business Conference, 06.09.2000

R Subiotto ‘The legal framework applicable to practices of pharmaceutical companies with respect to parallel trade’ speech given at ‘Vision in Business’ Conference, 22.01.2004

C Vicien ‘Why parallel imports of pharmaceutical products should be forbidden’ ECLR 1996, 17(4), 219-225

Verband Forschender Arzneimittelhersteller ‘Parallel- und Reimporte im Arzneimittelmarkt: Gesundeitspolitik auf dem Irrweg’, May 2002

H von der Groeben, H Von Boeckh, J Thiesing and C Ehlermann *Kommentar zum EWG-Vertrag* (Baden- Baden 1983)

R Whish *Competition law* 5th ed, (2003 LexisNexis Butterworths)

York Health Economics Consortium ‘Benefits to payers and patients from parallel trade’ May 2003

Press releases

ABPI ‘Warning from ABPI as key Pharmaceutical Industry Indicators slip’ 05.04.2005. Available at: http://www.abpi.org.uk/press/press_releases_05/050405b.asp

A&L Goodbody ‘How to protect your business against parallel imports- legally’ 17.02.2005. Available at: http://www.algoodbody.ie/news/load.asp?file=PUB:1068

A&L Goodbody ‘Syfait v GlaxoSmithKline- Article 82 and parallel trade of pharmaceuticals’17.02.2005. Available at: http://www.algoodbody.ie/news/load.asp?file=PUB:1069

Europa Rapid press release ‘Free movement of goods: Commission clarifies EU rules for parallel imports of proprietary medicines’ IP/04/65, on 19/01/2004

Europa Rapid Press release ‘Commission Communication on parallel imports of proprietary medicinal products frequently asked questions’ MEMO/04/7,on 19/01/2004

EFPIA ‘Parallel trade in medicines: EFPIA welcomes judgment from ECJ on Bayer/Adalat case’ 06.01.2004. Available at:www.efpia.org/3_press/20040106.htm

EFPIA ‘European pharmaceutical industry disappointed by Commission’s approach to parallel trade of medicines’ May 2001. Available at: http://www.efpia.org/3_press/20010509.htm

EFPIA ‘Industry welcomes the Commission response to the G10 medicines report’ 01.07.2003. Available at: http://www.efpia.org/3_press/20030701.htm

Euractiv ‘Parallel trade in medicines’ 21.05.2003. Available at http://www.euractiv.com/Article?tcmuri=tcm:29-117528-16&type=LinksDossier

Euractiv ‘Study questions benefits of parallel trade in medicines in the EU’ 28.11.2003. Available at: http://www.euractiv.com/Article?tcmuri=tcm:29-116536-16&type=News

EPHA ‘Free movement of pharmaceuticals: what defines prices?’ European Public health Alliance, July 2003. Available at: www.epha.org/a/512

Howrey ‘Is it possible to limit parallel imports by restricting sales to wholesalers?’ Howrey Client Alert January 2004. Available at: http://www.howrey.com/news/index.cfm?fuseaction=news&newsid=1834

Internet sources

www.abpi.org.uk	Association of the British Pharmaceutical Industry
www.baepd.co.uk	British Association of European Pharmaceutical Distributors (formerly API-Association of Pharmaceutical Importers)
www.eaepc.org	European Association of Euro-Pharmaceutical Companies
www.efpia.org	European Federation of Pharmaceutical Industries and Associations
www.epha.org	European Public Health Alliance
http://pharmacos.eudra.org	The Pharmaceuticals Unit, DG Enterprise
www.euractiv.com	EU News, Policy Positions and EU actors
www.europa.eu.int	The official European Union website
www.mca.gov.uk/	The Medicines and Healthcare Regulatory Agency (UK)
www.practicallaw.com	Legal articles for practitioners
www.reutersbusinessinsight.com	Data, analysis and insight by Reuters
www.sicenter.si	Socio-Economic Indicators Center

Table of Cases

C-53/03 *Synetairismos Farmakopoion & Akarnias (Syfait) and Others v GlaxoSmithKline* Opinion of Advocate General Jacobs 28 October 2004

C-112/02 *Kholpharma GmbH v Bundesrepublik Deutschland* 1 April 2004

C-418/01 *IMS Health* [2004] 29 April 2004

Joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission* [2004] January 6 2004

C-53/00 *Ferring* [2001] ECR I- 9067

Case T-41/96 *Bayer v Commission* [2000] ECR II-3383

Joined cases C-267/95 and C-268/95 *Merck & Co Inc and Others v Primecrown Ltd and Others* and *Beecham Group plc v Europharm of Wothing Ltd* [1996] ECR I-6285

Joined cases C-427/93 and C-429/93 and C-436/93 *Bristol-Myers Squibb and Others* [1996] ECR I-3457

Case 43/92 *Dunlop Slazenger v Commission* [1994] ECR II-441

Case T-7/89 *Hercules Chemicals v Commission* [1991] ECR II-1711

C-277/87 *Sandoz Prodotti Farmaceutici v Commission* [1990] ECR I-45

Case C-25/84 *Ford and Ford Europe v Commission* [1985] ECR 2725

Case 232/82 *Duphar* [1984] ECR 523

Case 181/82 *Roussel Laboratoria BV and Others v État Néerlandais* [1983] 3849

Cases 107/82 *AEG Telefunken AG v Commission*[1983] ECR 3151

Case 187/80 *Merck & Co Inc v Stephar BV and Petrus Stephanus Exler* [1981] ECR 2063

Case 209/78 *Van Landewyck v Commission* [1980] ECR 3125

C-120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649

Case 102/77 *Hoffmann-La Roche v Centrafarm* [1978] ECR 1139

C-104/75 *De Peijper* [1976] ECR 613

Case 16/74 *Centrafarm v Winthrop* [1974] ECR 1183

Case 6/73 *Istituto Chemioterapeutico Italiano and Commercial Solvents v Commission* [1974] ECR 223

Case 48/69 *ICI v Commission* [1972] ECR 619

Case 41/69 *ACF Chemiefarma v Commission* [1970] ECR 661

Joined cases 56/64 and 58/64 *Établissemsnts Consten S.à.R.L. and Grundig-Verkaufs-GmbH v Commission of the European Economic Community* [1996] ECR 299

Commission decisions

IV/36.957/F3 *Glaxo Wellcome (notification),* IV/36.997/F3 *Aseprofar and Fedifar (complaint),* IV/37.121/F3 *Spain Pharma (comlaint),* IV/37.138/F3 *BAI (complaint), EAEPC (complaint)* [2001] OJ L302/1

96/478/CE Commission decision of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3- ADALAT)

80/1283/EEC: Commission Decision of 25 November 1980 relating to a proceeding under Article 85 of the EEC Treaty (IV/29.702: *Johnson & Johnson*) [1980] OJ L377/16

Commission decision in Organon. Press release IP/95/1345 'Contraceptive pills: Commission puts an end to discriminatory pricing practices betweent he UK and the Netherlands'